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Psychosocial interventions for informal caregivers of people living with cancer

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Psychosocial interventions for informal caregivers of people living with cancer

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ABSTRACT

Background

Increasingly, cancer is recognised as a chronic condition with a growing population of informal caregivers providing care for cancer patients. Informal caregiving can negatively affect the health and well-being of caregivers. We need a synthesised account of best evidence to aid decision-making about effective ways to support caregivers for individuals 'living with cancer'.

Objectives

To assess the effectiveness of psychosocial interventions designed to improve the quality of life (QoL), physical health and well-being of informal caregivers of people living with cancer compared with usual care.

Search methods

We searched CENTRAL, MEDLINE, Embase, PsycINFO, ProQuest, Open SIGLE, Web of Science from inception up to January 2018, trial registries and citation lists of included studies.

Selection criteria

We included randomised and quasi-randomised controlled trials comparing psychosocial interventions delivered to adult informal caregivers of adults affected by cancer on a group or individual basis with usual care. Psychosocial interventions included non-pharmacological interventions that involved an interpersonal relationship between caregivers and healthcare professionals. We included interventions delivered also to caregiver-patient dyads. Interventions delivered to caregivers of individuals receiving palliative or inpatient care were excluded. Our primary outcome was caregiver QoL. Secondary outcomes included patient QoL, caregiver and patient depression, anxiety, psychological distress, physical health status and intervention satisfaction and adverse effects.

Data collection and analysis

Pairs of review authors independently screened studies for eligibility, extracted data and conducted 'Risk of bias' assessments. We synthesised findings using meta-analysis, where possible, and reported remaining results in a narrative synthesis.

Main results

Nineteen trials ($n = 3,725$) were included in the review. All trials were reported in English and were undertaken in high-income countries. Trials targeted caregivers of patients affected by a number of cancers spanning newly diagnosed patients, patients awaiting treatment, patients who were being treated currently and individuals post-treatment. Most trials delivered interventions to caregiver-patient dyads (predominantly spousal dyads) and there was variation in intervention delivery to groups or individual participants. There was much heterogeneity across interventions though the majority were defined as psycho-educational. All trials were rated as being at 'high risk of bias'.

Compared to usual care, psychosocial interventions may improve slightly caregiver QoL immediately post intervention (standardised mean difference (SMD) 0.29, 95% confidence interval (CI) 0.04 to 0.53; studies = 2, 265 participants) and may have little to no effect on caregiver QoL at 12 months (SMD 0.14, 95% CI -0.11 to 0.40; studies = 2, 239 participants) post-intervention (both low-quality evidence).

Psychosocial interventions probably have little to no effect on caregiver depression immediately to one-month post-intervention (SMD 0.01, 95% CI -0.14 to 0.15; studies = 9, 702 participants) (moderate-quality evidence). Psychosocial interventions may have little to no effect on caregiver anxiety immediately post-intervention (SMD -0.12, 95% CI -0.33 to 0.10; studies = 5, 329 participants), depression three-to-six months (SMD 0.03, 95% CI -0.33 to 0.38; studies = 5, 379 participants) post-intervention and patient QoL six to 12 months (SMD -0.05, 95% CI -0.37 to 0.26; studies = 3, 294 participants) post-intervention (all low-quality evidence). There was uncertainty whether psychosocial interventions improve patient QoL immediately (SMD -0.03, 95% CI -0.50 to 0.44; studies = 2, 292 participants) or caregiver anxiety three-to-six months (SMD -0.25, 95% CI -0.64 to 0.13; studies = 4, 272 participants) post-intervention (both very low-quality evidence). Two studies which could not be pooled in a meta-analysis for caregiver physical health status found little to no effect immediately post-intervention and a small intervention effect 12 months post-intervention. Caregiver or patient satisfaction or cost-effectiveness of interventions were not assessed in any studies. Interventions demonstrated good feasibility and acceptability.

Psychosocial interventions probably have little to no effect on patient physical health status immediately post-intervention (SMD 0.17, 95% CI -0.07 to 0.41; studies = 4, 461 participants) and patient depression three to six months post-intervention (SMD -0.11, 95% CI -0.33 to 0.12; studies = 6, 534 participants) (both moderate-quality evidence).

Psychosocial interventions may have little to no effect on caregiver psychological distress immediately to one-month (SMD -0.08, 95% CI -0.42 to 0.26; studies = 3, 134 participants), and seven to 12 months (SMD 0.08, 95% CI -0.42 to 0.58; studies = 2, 62 participants) post-intervention; patient depression immediately (SMD -0.12, 95% CI -0.31 to 0.07; studies = 9, 852 participants); anxiety immediately (SMD -0.13, 95% CI -0.41 to 0.15; studies = 4, 422 participants), and three to six months (SMD -0.22, 95% CI -0.45 to 0.02; studies = 4, 370 participants); psychological distress immediately (SMD -0.02, 95% CI -0.47 to 0.44; studies = 2, 74 participants) and seven to 12 months (SMD -0.27, 95% CI -0.78 to 0.24; studies = 2, 61 participants); and physical health status six to 12 months (SMD 0.06, 95% CI -0.18 to 0.30; studies = 2, 275 participants) post-intervention (all low-quality evidence).

Three trials reported adverse effects associated with the interventions, compared with usual care, including higher distress, sexual function-related distress and lower relationship satisfaction levels for caregivers, higher distress levels for patients, and that some content was perceived as insensitive to some participants.

Trials not able to be pooled in a meta-analysis did not tend to report effect size and it was difficult to discern intervention effectiveness. Variable intervention effects were reported for patient and caregiver outcomes.

Authors' conclusions

Heterogeneity across studies makes it difficult to draw firm conclusions regarding the effectiveness of psychosocial interventions for this population. There is an immediate need for rigorous trials with process evaluations and clearer, detailed intervention descriptions. Cost-effectiveness studies should be conducted alongside future trials.

PLAIN LANGUAGE SUMMARY

Psychosocial support for informal caregivers of people living with cancer

Background

Increasingly, people who are not health professionals provide care for a partner, family member or friend affected by cancer, which can have negative effects on their health and well-being. Psychosocial interventions that comprise psychological or social support and involve direct interaction between a healthcare professional and caregivers (or caregiver-patient pairs) may help to address the negative health effects for caregivers.

Review question

What is the effectiveness of psychosocial interventions compared to usual care for informal caregivers of people living with cancer on a range of outcomes related to health and well-being?

Results

We found 19 trials that compared psychosocial interventions with usual care, in studies that included almost four thousand participants. Studies included caregivers of people affected by different cancers across all stages of the disease. There were differences in intervention make-up. Intervention examples include providing information and/or teaching caregivers (or caregiver-patient pairs) coping, communication or problem-solving skills to manage symptoms or improve relationships. Interventions were delivered by nurses, psychologists or other professionals on an outpatient basis or at home via telephone.

There may be a minimal benefit for caregiver quality-of-life immediately after the intervention, but this may not last. Psychosocial interventions may have little to no effect on quality of life for patients six to 12 months post-intervention, but we are uncertain whether or not interventions improve quality of life for patients immediately post-intervention.

Psychosocial interventions may have little to no effect on caregiver depression, anxiety, distress and physical health and patient anxiety and distress at any time after the intervention, or on patient depression immediately and patient physical health six to 12 months post-intervention. Psychosocial interventions probably have little to no effect on patient physical health immediately post-intervention or patient depression three to six months post-intervention.

Three studies reported adverse effects including increased distress and sexual function-related distress and lower relationship satisfaction levels for carers, increased distress levels for patients, and intervention content that was seen as inappropriate for some participants. No studies looked at cost-effectiveness or intervention satisfaction for caregivers or patients. Because the quality of evidence was low generally, findings must be treated with caution.

Conclusion

Psychosocial interventions do not impact to a clinically meaningful degree outcomes for caregivers irrespective of patient cancer stage or type. Perhaps, other outcomes (e.g. relationship quality) or other psychosocial interventions (e.g. meditation) may be more helpful for caregivers. Interventions should be subjected to better conducted trials. Intervention development should involve caregivers and pay particular attention to individual personal needs.

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

Psychosocial interventions compared with usual care for informal cancer caregivers					
Patient or population: informal caregivers of people affected by cancer Settings: outpatient setting Intervention: psychosocial interventions Comparison: usual care					
Outcomes*	Illustrative comparative risks	No of Participants (studies)	Quality of the evidence (GRADE)	Comments	
	(95% CI)				
	Corresponding risk				
	Psychosocial intervention				
Global quality of life score Multiple measures used. Caregiver Strain Index (Campbell 2007)** FACT-G total score (Northouse 2007). Additional studies (reported in comments section): SF20 subscales (Blanchard 1996) SF36 social functioning subscale (Kurtz 2005) Higher scores indicate better QoL. Follow-up: immediately post-intervention	The mean score in the intervention group was 0.29 standard deviations higher (0.04 higher to 0.53 higher)	265 (2)	⊕⊕○○ low ^{a,b}	In addition, two studies which could not be pooled due to variation in outcome measure and time point of measurement. One study reported that there was no intervention effect on caregiver QoL though mean scores on subscales were in favour of the intervention group compared to the usual care group immediately post-intervention. A second study also reported higher QoL scores for the intervention compared to the usual care group but no overall difference between groups	
Global quality of life score Multiple measures used. WHO-Five-Wellbeing Index (Ledderer 2013) FACT-G total score (Northouse 2007). Additional study (reported in comments section): SF20 subscales (Blanchard 1996). Higher	The mean score in the intervention group was 0.14 standard deviations higher (0.11 lower to 0.40 higher)	239 (2)	⊕⊕○○ low ^{a,b}	One study which could not be pooled due to variation in outcome measure reported that there was improved mean QoL scores on subscales for the intervention group compared to the usual care group six-months post-intervention, but overall this was judged	

scores indicate better QoL Follow-up: 6 to 12-months post-intervention			as no effect of the intervention by the authors
<p>Any depression Multiple measures used. CES-D (Blanchard 1996; Kozachik 2001; Kuijer 2004; Kurtz 2005; McCorkle 2007). POMS Depression subscale (Bultz 2000; Campbell 2007). HADS-D (Nicolaisen 2018; Robertson 2016). Additional study (reported in comments section): SCL-90-R Depression subscale (Heinrich 1985). Higher scores indicate higher levels of depression. Follow-up: immediately to one-month post-intervention</p>	<p>The mean score in the intervention group was 702 (9) 0.01 standard deviations higher (0.14 lower to 0.15 higher)</p>	<p>⊕⊕⊕○ moderate ^a</p>	One additional study which could not be incorporated into the pooled analysis due to missing data found no evidence of an effect of psychosocial interventions on caregiver depression
<p>Any depression Multiple measures used. CES-D (Blanchard 1996; McCorkle 2007). POMS Depression subscale (Bultz 2000). HADS-D (Nicolaisen 2018; Robertson 2016). Higher scores indicate higher levels of depression. Follow-up: Three to six months post-intervention</p>	<p>The mean score in the intervention group was 379 (5) 0.03 standard deviations higher (0.33 lower to 0.38 higher)</p>	<p>⊕⊕○○ low ^{a,c}</p>	No comment
<p>Any anxiety STAI-S (Blanchard 1996). POMS Anxiety subscale (Bultz 2000; Campbell 2007). HADS-A (Nicolaisen 2018; Robertson 2016)</p>	<p>The mean score in the intervention group was 329 (5) 0.12 standard deviations lower (0.33 lower to 0.10 higher)</p>	<p>⊕⊕○○ low ^{a,b}</p>	One additional study which could not be incorporated into the pooled analysis due to missing data found no evidence of an effect of psychosocial

<p>Additional study (reported in comments section): SCL-90-R Anxiety subscale (Heinrich 1985)</p> <p>Higher scores indicate higher levels of anxiety. Follow-up: immediately post-intervention</p>				interventions on caregiver anxiety
<p>Any anxiety STAI-S (Blanchard 1996). POMS Anxiety subscale (Bultz 2000). HADS-A (Nicolaisen 2018; Robertson 2016). Higher scores indicate higher levels of anxiety. Follow-up: three to six months post-intervention.</p>	<p>The mean score in the intervention group was 0.25 standard deviations lower (0.64 lower to 0.13 higher)</p>	272 (4)	<p>⊕○○○ very low^{a,b,c}</p>	No comment
<p>Caregiver satisfaction with interventions</p>	See comment	Not estimable	-	No studies measured satisfaction with interventions
<p>Caregiver physical health status Studies (reported in comments section): Multilevel Assessment Instrument Total Score (Budin 2008).*** SF12 Physical Component Summary Score (Northouse 2007). Higher scores indicate higher levels of physical health status</p>	See comment	Not estimable	-	Two studies reported on caregiver physical health status but did not report the results in a form that could be extracted for meta-analysis. Both studies reported that psychosocial interventions had no effect on physical health status immediately post-intervention. A small effect of psychosocial interventions on physical health status in favour of the intervention was reported in one study 12 months post-intervention

Any adverse events	See comment	Not estimable	–	Three studies reported on adverse effects but did not report the results in a form that could be extracted for meta-analysis. One study reported higher levels of distress and lower levels of relationship satisfaction during or after the intervention, compared with low distress levels and high levels of marital satisfaction prior to intervention. Another reported that the content of a psychosexual intervention was perceived as insensitive to some participants not engaged in sexual activity prior to diagnosis. One further study reported greater sexual function-related distress for caregivers at follow-up, compared with the usual care group
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*More detail regarding the scoring and direction for each scale is detailed in [Table 2](#); [Table 4](#); [Table 5](#); [Table 7](#) **Mean scores on the Caregiver Strain Index were multiplied by -1 to convert to scale to same direction as FACT-G. ***Not enough information available on outcome measure in terms of scale and direction of scoring

CES-D: Centre for Epidemiological Studies- Depression; **CI:** Confidence interval; **FACT-G:** Functional Assessment of Cancer Therapy- General; **HADS-A:** Hospital Anxiety and Scale- Anxiety subscale; **HADS-D:** Hospital Anxiety and Depression Scale- Depression subscale; **POMS:** Profile of Moods State; **QoL:** quality of life; **SCL-90-R:** Symptom Checklist-90-Revised; **SF:** Short Form Medical Outcomes Study survey; **STAI-S:** State Trait Anxiety Inventory- State subscale

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.

^aRisk of bias (-1): Studies were rated as being at high risk of bias overall

^bImprecision (-1): The meta-analysis includes a small sample (less than 400 participants)

and confidence interval includes indicates little and appreciable benefit of the intervention (as minimal important difference is not known)

^cInconsistency (-1): High level of heterogeneity indicated by I² statistic

BACKGROUND

Improved survival has resulted in a growing population living with and affected by cancer and, increasingly, cancer is being viewed as a chronic disease. Cancer prevalence is estimated to be 11 million in the US (Horner 2006) and two million in the UK (Maddams 2009). These prevalence figures are expected to increase by three percent per year and approximately one million per decade (Maddams 2009, Maddams 2012). This growing prevalence is apparent also in other developed countries such as Australia and the Republic of Ireland, with one in three people being diagnosed with cancer during their lifetime (Ferlay 2008). The most common cancers worldwide are breast cancer, colorectal cancer and prostate cancer (Maddams 2009). There is an increasing emphasis on the role of informal caregivers in terms of providing support for cancer patients following completion of active treatment, particularly as the prevalence of cancer rises, survival improves and new models of care evolve.

Cancer may impact on caregivers (as well as patients) from the onset of symptoms through the illness trajectory to recovery and beyond. In the UK, approximately 40% of people caring for someone living with cancer spend more than 30 hours per week providing care (Macmillan 2008). The impact of cancer on a patient and their family may be influenced by many factors including the stage and nature of the diagnosis (Weitzner 1999), the associated treatment (Langer 2003; Nijober 1999) and patient and carer personality (Campbell 2004; Carver 1993). Caring may have detrimental effects on a caregiver's physical, psychological and social health and may reduce significantly their quality of life (QoL) (Ferrell 1995; Northouse 2007 Northouse 2012; Stenberg 2009). Recent research on the effects of caring for a cancer patient identified a range of problems including enduring periods of back and muscular pain, disturbed sleep patterns and general fatigue (Stenberg 2009), psychological difficulties such as intense worry about a patient's health, and stress associated with providing care and support while maintaining daily work and other responsibilities (Hagedoorn 2000; Kim 2012; Northouse 2000.). Furthermore, the time and costs of providing care may lead to gaps in, or loss of, employment and education, reduced income, increased bills and overall financial strain. The problems and needs associated with informal caring may last for prolonged periods even when a patient is 'free' of disease (Hodgkinson 2007, Kim 2010). Informal caregivers may experience equal or greater levels of depression than patients with cancer (Campbell 2009; Hodges 2005; Rhee 2008), live with fear that cancer may return (Hodgkinson 2007 Northouse 2012) and suffer anxiety and reduced QoL (Cella 1990; Mellon 2006; Sherif 2001). Caregivers may be overwhelmed by their changed circumstances and may need help and support to cope with the practical challenges of providing care. Increased needs among caregivers appear to be associated with being female, younger (Daly 2009; Harding 2003), lower socioeconomic status (Donnelly 2008), caring for someone with stage one or two cancer

(Daly 2009), unhealthy partner attachments, living alone with a patient and a higher level of patient dependency (Nijober 1999). Carers whose relationship with a patient had been troubled previously (Gritz 2004) or who lacked positive communication (Kim 2008) may experience significant difficulties in their caring role. Female caregivers, compared to men, may experience a greater burden of care because they tend to have multiple responsibilities such as caring for children and household management alongside being a primary caregiver (Campbell 2009; Matthews 2003). We lack a critically appraised synthesis of the best ways in which to meet the needs of informal cancer caregivers who care for close family relatives (or friends) who 'live with cancer'. For the purposes of this review, we used the term 'living with cancer' and its derivatives to define our review population as individuals who are living with potentially curable cancer or with cancer chronically.

Description of the condition

This review defined an informal caregiver as an unpaid individual who provides a family member or friend with emotional care and support in physical and/or practical life domains (Candy 2011; Harding 2003). In developed healthcare systems, partners or spouses tend to provide most of the physical care and emotional support for cancer patients following hospital discharge (Hodgkinson 2007), though the caring role may be undertaken by other relatives and, less commonly, by friends and neighbours (Mills 2008). This review included partners, other relatives and friends in the definition of an informal caregiver, but excluded caregivers of patients who were in the terminal phase of disease as this was beyond the scope of this review. The effectiveness of interventions provided to informal caregivers of people with terminal cancer has been assessed in a previous review (Candy 2011). Moreover, there is a need to recognise the particular demands, needs and roles of caregivers of patients who have terminal cancer compared to caregivers of patients who 'live with cancer' and thus interventions for each caregiver group should be tailored accordingly. The extent to which the health and social care needs of cancer caregivers (noted above) are met is unclear (Soothill 2003). It is important to note that the potentially detrimental impact of caring on health may, in turn, affect negatively patient health and well-being (Northouse 1995; Roberts 1994).

Description of the intervention

There is a lack of consistency regarding definitions of the term 'psychosocial intervention', perhaps especially in published cancer care studies (Hodges 2010). This review used a broad definition of a psychosocial intervention focused on non-pharmacological interventions that were designed to inform, educate and increase the coping capacity of informal cancer caregivers and that were delivered verbally by a healthcare professional. Examples of pro-

professionally-led, psychosocial interventions include psycho-educational groups (Bultz 2000), cognitive-behaviour therapy (Cohen 2006) and support groups (Kozachik 2001; Northouse 2005). A broad range of formats and settings for the delivery of interventions were included in the review, for example, the review included interventions that were delivered to individuals, groups, caregivers only and caregiver-patient dyads (pairs), respectively. A more detailed description of the types of psychosocial interventions that were included in the review is described below (Types of interventions).

How the intervention might work

Psychosocial interventions may be effective in terms of providing support and information to caregivers in a way that increases their coping capacity (Cohen 2006), thereby enabling them to manage more effectively the difficulties associated with caring for someone with cancer. Receipt of a psychosocial intervention may reduce psychological distress (Kozachik 2001) and so improve the QoL of caregivers. Interventions such as cognitive behavioural therapy (CBT) or psycho-educational programmes may result in self-efficacious beliefs among caregivers and new knowledge and skills regarding self-management strategies and their implementation in practice (Bandura 1977; Bandura 1997). Psychosocial interventions that focus their delivery towards couples may improve between-partner communication and satisfaction and enhance or assist adjustment to diagnosis by both parties (Bultz 2000; Hilton 1994). Furthermore, a psychosocial intervention for a caregiver may improve the quality of care afforded to their relative and lead to better patient psychosocial adjustment (Roberts 1994); and recognition of a caregiver's role by healthcare professionals may improve the caregiving experience and reduce hospital admissions (Minick 2010).

Why it is important to do this review

Informal caregiving is expected to continue to rise due to increasing cancer prevalence, improved survival and a drive to treat patients in their own communities. The potentially detrimental effects of caring on caregivers (as noted above) have been recognised internationally in cancer policy (Department of Health 2007; Department of Health and Ageing 2008; United States DHSS 2003). An evidence base of appropriate and effective interventions is required in order to improve decisions about the best ways in which to provide care and support for caregivers and to contribute to the aims of cancer reform strategies in various countries including the UK (Department of Health 2007). A Cochrane Review by our research team on psychosocial interventions for newly diagnosed cancer patients (Galway 2012), found that an increasing number of interventions were being targeted at caregivers. This evidence comes from an examination of the stud-

ies that were excluded as part of the Galway 2012 review. There are related Cochrane Reviews that have focused on the effects of interventions for caregivers but which are not cancer-specific (Legg 2011; Vernooij-Dassen 2011). Finally, studies of interventions that were delivered to informal caregivers of terminally ill patients were not included because they are the focus of another review (Candy 2011). Interventions targeted specifically towards the growing population of informal caregivers of cancer patients 'living with cancer' warrants dedicated rigorous, systematic attention and synthesis.

OBJECTIVES

- To assess the effectiveness of psychosocial interventions designed to improve the QoL, physical health and well-being of informal caregivers of people living with cancer compared to standard or usual care services.
- To examine the extent to which psychosocial interventions exerted an impact on different caregiver and patient-assessed domains (e.g. psychological health and physical functioning).
- To examine the extent to which different modes of intervention delivery and different settings influenced outcomes.
- To examine if there was a relationship between the number and duration of intervention sessions and the degree of change in measured outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs), and quasi-RCTs (using a quasi-random method of allocation such as alternation, date of birth, or case record number) were included. Cluster-RCTs were eligible for inclusion but none were identified. Non-randomised studies such as single-group before-and-after design, case-control, cohort, survey, qualitative studies or reviews were excluded.

Types of participants

We included studies in which caregivers met the following criteria:

- an adult (18 years and older) and not a professional or paid caregiver (unless they were receiving government financial social security benefits for being a caregiver) or a trained volunteer;
- provided informal care (including physical, practical and emotional care and support);

- provided care for a patient who was:
 - an adult (18 years and older) diagnosed with any type of cancer (including current patients and survivors); we did not include caregivers of patients who were in the terminal phase of cancer, that is, who were not expected to survive longer than days, weeks or months ([Candy 2011](#));
 - a spouse, partner, relative or friend and
- provided care in their own home and not in a hospital or hospice.

Types of interventions

We included psychosocial interventions that were delivered to an informal caregiver individually or in a group setting by a healthcare professional (including care professionals such as social workers and physiotherapists). Interventions that were delivered simultaneously to a patient and caregiver were included but were subjected to a separate analysis. A psychosocial intervention was deemed to be a non-pharmacological intervention that involved an interpersonal relationship between a caregiver or group of caregivers and one or more trained healthcare professionals. Psychosocial interventions that were described as psychological, psycho-therapeutic, psycho-educational or psychosocial were eligible to be included in the review. Interventions that did not state explicitly that they were psychosocial were included if they comprised a psychological or social component. Examples of eligible psychosocial interventions included: psychosocial support (an approach that provides help and encouragement to promote coping), self-help groups (therapist-facilitated groups providing peer support, advice and information), educational therapy or psycho-education (interventions designed to improve coping by promoting learning), cognitive behavioural therapy (CBT) (a therapeutic approach that aims to challenge and remove maladaptive thoughts, feelings and behaviours), counselling (talking therapy delivered by a therapist that tends to be less directive or instructive than, for example, CBT) and family therapy (a therapy that focuses on challenges and difficulties faced by families and/or couples). In the context of this review, we excluded education-only interventions that disseminate information without any ongoing interaction with a healthcare professional. Psycho-education interventions differed from education-only interventions because they incorporated or integrated therapeutic approaches alongside education or information provision ([Lukens 2004](#)).

Interventions were categorised according to a hierarchical framework ([Cunningham 1996](#)) which was used in a previous systematic review of interventions and QoL in adult cancer patients ([Rehse 2003](#)). This categorisation facilitated comparison between interventions. This hierarchy is based on the level of active participation that is present in an intervention ranging from the lowest level (information provision) to the highest level (spiritual or existential therapy). Each succeeding level of the hierarchical classification incorporates elements from the level below. Interventions were categorised into five different types.

- Information provision (informing individuals; only minimal activity required from participants in the form of listening)
- Support (acknowledging experience and facilitating expressions of feelings or emotions)
- Coping skills training (encouraging acquisition of new cognitive skills and promoting self-control)
- Psychotherapy (designed to help participants understand their experiences)
- Spiritual or existential therapy (participants are encouraged to search for meaning and use meditation or reflection)

It was planned that the different categories of interventions would be examined and compared. However, all but two interventions incorporated the first three levels of 'information', 'support' and 'coping skills training'. Any interventions that were conducted within acute or community settings were included. Non-face-to-face interventions such as online or telephone interventions (e.g. telephone counselling) that involved the instant exchange of dialogue between two or more people were included. We excluded interventions that had a non-verbal delivery mode only such as information leaflets and DVDs. We also excluded interventions that were 'peer led'. Control groups comprised caregivers who received usual or standard care, that is, caregivers who were not receiving any special or additional support. Studies with waiting-list control groups were included in the review whereby the control group was offered the intervention after the active treatment group completed the intervention and follow-up assessments as part of the study. We excluded studies that compared two or more different types of psychosocial interventions, for example, facilitated self-help with one-to-one counselling.

Types of outcome measures

Studies which captured the following outcomes were included in the review and, therefore, studies which did not capture the following outcomes were excluded from the review. (See [Characteristics of excluded studies](#)).

Primary outcomes

- Caregiver quality of life (QoL) that was measured by a reliable and validated scale ([Lipscomb 2005](#))

Secondary outcomes

- Patient QoL
- Caregiver depression (measured separately from QoL scale)
- Caregiver anxiety (measured separately from QoL scale)
- Caregiver psychological distress (measured separately from QoL scale)
- Caregiver satisfaction with interventions
- Caregiver physical health status (measured separately from QoL scale)

- Patient depression (measured separately from QoL scale)
- Patient anxiety (measured separately from QoL scale)
- Patient psychological distress (measured separately from QoL scale)
- Patient satisfaction with interventions
- Patient physical health status (measured separately from QoL scale)
- Any adverse events
- Cost-effectiveness
- Feasibility/acceptability of interventions

Caregiver- and patient-psychological distress and the feasibility and acceptability of an intervention were added as outcomes during the review stage.

In studies that used multiple outcome measures to assess the same outcome, data from one outcome measure only were used in the review. The outcome instrument in each paper that had the closest match with the construct that it purported to measure (e.g. Centre for Epidemiologic Studies Depression Scale (CES-D) and depression) was selected for use in the review. In addition, an outcome measure that had been tested and used with the target population of interest was preferred. For example, when multiple measures were used in a study to assess caregiver QoL, a generic outcome measure (e.g. WHO-Five Well-being Index) was selected over a disease-specific outcome measure (e.g. EORTC-QLQ-C30) that was developed and validated with cancer patients because the WHO index had been used successfully with a carer population (Ledderer 2013).

The data that were extracted in order to conduct a meta-analysis of caregiver and patient QoL were based on data pertaining to measures of global QoL. We did not extract data for our meta-analyses of caregiver and patient QoL from studies that used an individual subscale to measure a unidimensional aspect of QoL (e.g. social functioning (Kurtz 2005)) as they were not conceptually similar to the multidimensional construct of global QoL. Global QoL measured as a multidimensional construct takes into account social functioning as well as other domains such as perceived physical and mental functioning (see [Characteristics of included studies](#) for the list of outcome measures that were used in each study).

Outcomes for 'Summary of findings' tables

Findings regarding the outcomes noted above are reported in the [Summary of findings for the main comparison](#); [Summary of findings 2](#) (see [Data collection and analysis](#)).

- Caregiver QoL
- Patient QoL
- Caregiver depression
- Caregiver anxiety
- Caregiver satisfaction with intervention
- Caregiver physical health status
- Any adverse events

Search methods for identification of studies

Electronic searches

Searches were originally run in the following databases from inception until 3rd January 2018.

- Cochrane Central Register of Controlled Trials (CENTRAL, the Cochrane Library)
- MEDLINE (OvidSP)
- Embase (OvidSP)
- PsycINFO (OvidSP)
- ProQuest Dissertations and Theses
- Open SIGLE
- Web of Science

These searches were based on the MEDLINE strategy reported in [Appendix 1](#). However, it was determined after the original run of searches had been completed and run that the MEDLINE search strategy had been translated incorrectly to the other listed databases and, therefore, the yield of relevant studies was likely to be incomplete for the non-MEDLINE database results. In consultation with the Editorial base and Information Specialist in the Cochrane Consumers and Communication Research Group, a new search strategy of the Cochrane Library (Cochrane Database of Systematic Reviews and CENTRAL) was developed and re-run on 6th December 2018 (see [Appendix 2](#)). The Cochrane Library records were incorporated into the MEDLINE search results and were likely to identify any outstanding relevant studies for inclusion. We did not apply any language restrictions to the review although translation was not required because each included study was published in English.

Searching other resources

We searched conference abstracts. We checked the reference lists of included studies for any further potential studies that had not been identified via electronic searches. We contacted authors to obtain any data that were not presented in the published articles and to enquire about any related publications. We searched the following trial registers: ClinicalTrials.Gov (<https://clinicaltrials.gov/>) and the WHO Clinical Trial Search Portal (<http://apps.who.int/trialsearch/>).

Data collection and analysis

Selection of studies

We downloaded titles and abstracts from the electronic searches to a reference management database (Refworks) and removed duplicate studies. Two review authors worked independently to screen the titles and abstracts against study eligibility criteria. The full texts of studies which could not be excluded with certainty on the

basis of information contained in the title and abstract were obtained for further consideration. Two review authors worked independently through each full-text paper regarding eligibility criteria. The reason for excluding a study at this stage in the review is presented in the [Characteristics of excluded studies](#) table. Any disagreements were resolved through discussion with a third review author (MD). We also provided citation details and any available information about ongoing studies. We collated and reported details of duplicate publications so that the study rather than each report was the unit of analysis. We reported the screening and selection process in an adapted PRISMA flow Chart ([Liberati 2009](#)) (see [Figure 1](#)).

Figure 1. Study flow diagram.

Data extraction and management

Two review authors extracted the following data independently from the included studies using a pre-designed data extraction form. The data extraction form was piloted in previously published Cochrane Reviews (Galway 2012; Scott 2013). All extracted data were entered into RevMan by one review author and checked for accuracy against the data extraction sheet by a second review author working independently. The two authors met to discuss data extraction and a third author (MD) was available to discuss any discrepancies. Data extraction included the following.

- General: author, year of publication, title, journal, country and language of publication.
- Trial: study design, randomisation, sample size and distribution of caregivers in each arm of the trial.
- Caregiver information: age, gender, ethnicity, diagnosis and stage of cancer, relationship to patient.
- Patient information: diagnosis, cancer stage, age, gender, ethnicity.
- Intervention and control: components of intervention, method of delivery, setting, discipline of healthcare professional, duration of intervention, frequency, characteristics of the control group, type and nature of intervention, reported description of intervention and use of standardised protocols for intervention delivery.
- Risk of bias: See [Assessment of risk of bias in included studies](#).
- Outcomes: timing of data collection, number of data points, how outcome was measured, measurement tools used and if measures were valid and reliable, mean and standard deviation of primary and secondary outcome in intervention and control group
- Funding and ethical approval

Also we reported on the validity and reliability of outcomes measures, whether or not ethical approval had been granted and the use of standardised protocols for intervention delivery.

Assessment of risk of bias in included studies

Two review authors independently examined the risk of bias of included studies and discussed their findings. Consensus was reached through discussion with a third author (MD) if necessary. The criteria used to assess studies were outlined in the data extraction sheet. We addressed the main areas of assessment that are noted in the *Cochrane Handbook for Systematic Reviews of Interventions* i.e. sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data and selective reporting (Higgins 2011). The degree of bias in each of these domains is reported in the [Assessment](#)

[of risk of bias in included studies](#) tables. We assessed quasi-RCTs as being at high risk of bias on random sequence generation on the 'Risk of bias' tool. The overall risk of bias for each study was generated using the 'Risk of bias' tool in RevMan and categorised as: Low - all criteria rated as low; Moderate - one or two criteria unclear or high; and High - more than two criteria unclear or high.

Measures of treatment effect

Regarding continuous variables, we assessed treatment effects by extracting the mean difference (and corresponding standard deviations) between the intervention and control groups in scores for measures of QoL, depression, anxiety, psychological distress and physical health status. We planned to convert other statistics such as median or interquartile range (when they were reported) to obtain mean and standard deviation. However, these statistics were not reported (Hozo 2005; Higgins 2011). We planned to convert dichotomous outcomes (where reported) to odds ratios with respect to the treatment and control group, but this was not required because all outcomes were reported on a continuous scale. We used the first and last follow-up outcome assessment time points in studies that reported outcomes at several time points and included this data in meta-analysis when appropriate. Results were reported in a narrative form when it was not appropriate to include data in meta-analysis. Standardised mean differences (SMDs) with 95% confidence intervals (CIs) were calculated in order to combine estimates from studies that used different instruments to measure the same outcome (e.g. QoL, depression and anxiety).

Unit of analysis issues

The individual caregiver or patient was the unit of analysis. Randomisation was conducted at an individual level in every study and, therefore, no adjustment for unit of analysis was required.

Dealing with missing data

We did not impute missing outcome data for caregiver QoL (the primary outcome) or for any of the secondary outcomes. We contacted authors to obtain values or data to convert values when data were missing from their study and we excluded any study from the analysis when it was not possible to obtain relevant data.

Assessment of heterogeneity

We estimated heterogeneity using the I^2 statistic within the meta-analyses that were reported. The following criteria was used to guide categorisation of heterogeneity: low ($< 40\%$), moderate ($41\% < 60\%$) and high ($> 61\%$).

Assessment of reporting biases

Reporting bias was minimised by aiming to include publications in all languages and by contacting relevant authors in the field. We planned to investigate publication biases by using funnel plots if at least 10 studies were available. No meta-analysis included at least 10 studies, therefore, funnel plots were not created to assess reporting bias.

Data synthesis

We intended to undertake meta-analysis to statistically pool the results of highest quality studies. Due to the heterogeneity of studies only a limited number of meta-analyses were possible (e.g. for caregiver and patient QoL, depression, anxiety, psychological distress and patient physical health status). Data were analysed using a random-effects model in Revman 5.3 and pooled SMDs and 95% CIs regarding treatment effect scores were calculated. A random-effects model was used due to the complex and multi-faceted nature of the interventions. Remaining studies were synthesised in a narrative account.

Subgroup analysis and investigation of heterogeneity

There was an insufficient number of studies in any meta-analysis and therefore it was not possible or meaningful to follow the protocol in terms of conducting planned quantitative subgroup analysis. Instead, the following a priori stated subgroup analyses were assessed narratively: intervention type, mode of delivery, nature of intervention, caregiver characteristics and time since patient's diagnosis.

Sensitivity analysis

Similarly, a planned sensitivity analysis (for example, by excluding studies rated as having high risk of bias) was not conducted due to the findings that all studies were assessed as being at high risk of bias, only a small number of studies were eligible and the data varied widely.

'Summary of findings' tables

The 'Summary of Findings' tables display:

- all main outcomes (specified in the section entitled [Types of outcome measures](#));
- absolute and relative magnitude of effect;
- number of studies and participants;
- GRADE and overall quality of evidence.

Regarding GRADE assessments, all GRADE ratings were initially high as the evidence for the review was taken from RCTs and quasi-RCTs only. Two review authors independently assessed GRADE according to the following five criteria: risk of bias, inconsistency, indirectness, imprecision and publication bias. A third author

(MD) was available to resolve any disagreements that remained following discussion. We downgraded the initial high GRADE rating by one level if there were serious concerns and by two levels if there were very serious concerns. Explanations regarding downgrades and the overall GRADE score for each outcome are reported in the footnotes to the 'Summary of findings' tables (see [Summary of findings for the main comparison](#); [Summary of findings 2](#)). It was not possible to undertake GRADE assessment for all outcomes as pertinent data (e.g. effect sizes, confidence intervals) were absent from some studies. Reporting of results takes into account GRADE assessments ([Ryan 2016](#)). GRADE assessments were undertaken also for outcomes not reported in [Summary of findings for the main comparison](#); [Summary of findings 2](#).

RESULTS

Description of studies

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

Results of the search

The electronic searches identified 30,951 articles. A total of 23,917 titles were screened following removal of duplicates; and 20,192 were excluded when it was clear from the title screening that the article related to the following.

- A review or meta-analysis
- A guideline or a commentary/discussion paper
- Children (<18 years old)
- Non-cancer adults
- Cancer screening or prevention

We inspected the abstracts of the remaining 3,725 papers and excluded 3,549 for the following reasons.

- Not a RCT or quasi-RCT
- Cancer patients without informal caregivers
- Caregivers of patients in the terminal phase of cancer
- Not a psychosocial intervention e.g. education only
- Intervention delivered by peers or lay people

We examined the full texts of 176 papers and excluded 156 for the following reasons.

- Not a RCT or quasi-RCT
- Inappropriate control- control was not usual care
- Includes caregivers of patients receiving inpatient care
- Includes caregivers of patients receiving palliative care
- Includes only caregivers of patients with advanced cancer
- Includes caregivers of deceased patients
- Inappropriate population: children with cancer
- Intervention not delivered by an healthcare professional

- Inappropriate intervention: does not include instant dialogue component
- Inappropriate intervention: is not a psychosocial intervention
- Intervention not delivered to caregivers
- Includes caregivers of patients who do not have cancer
- Review outcomes of interest not assessed by study
- Intervention adopted into routine practice (results not published)
- Duplicate

A total of 20 articles were eligible for inclusion in the review, reporting 19 studies (see [Figure 1](#) for a flowchart of study eligibility).

Included studies

Study location

Twenty articles reported 17 randomised controlled trials (RCTs) (two articles reported results from the same RCT (see [Blanchard 1996](#) reference) and two quasi-RCTs ([Bultz 2000](#); [Heinrich 1985](#)). A total of 12 trials were conducted in the USA ([Baucom 2009](#); [Blanchard 1996](#); [Budin 2008](#); [Campbell 2007](#); [Heinrich 1985](#); [Kozachik 2001](#); [Kurtz 2005](#); [Manne 2004](#); [Manne 2005](#); [Manne 2011](#); [McCorkle 2007](#); [Northouse 2007](#)), two trials were conducted in the UK ([Robertson 2016](#) [Tsianakas 2015](#)), two trials were conducted in Denmark ([Ledderer 2013](#); [Nicolaisen 2018](#)), one trial each was conducted in Canada ([Bultz 2000](#)), the Netherlands ([Kuijer 2004](#)) and Australia ([Couper 2015](#)), respectively. All studies were reported in English.

Participants

The studies recruited between 14 ([Baucom 2009](#)) and 263 ([Northouse 2007](#)) participants. In total, 3, 725 participants (1, 967 and 1, 758 caregivers and patients, respectively) who were allocated to either an intervention or a control group. Seven trials comprised caregivers of prostate cancer patients ([Campbell 2007](#); [Couper 2015](#); [Manne 2004](#); [Manne 2011](#); [McCorkle 2007](#); [Northouse 2007](#); [Robertson 2016](#)), six trials focused on caregivers of patients with a range of different cancers ([Blanchard 1996](#); [Heinrich 1985](#); [Kozachik 2001](#); [Kuijer 2004](#); [Kurtz 2005](#); [Tsianakas 2015](#)), five trials were specific to caregivers of breast cancer patients ([Baucom 2009](#); [Budin 2008](#); [Bultz 2000](#); [Manne 2005](#); [Nicolaisen 2018](#)), and one study focused on caregivers of patients with lung cancer and gynaecological cancer ([Ledderer 2013](#)).

Interventions targeted two participant groups: caregivers only ([Blanchard 1996](#); [Bultz 2000](#); [Manne 2004](#); [Tsianakas 2015](#)) and caregiver-patient dyads ([Baucom 2009](#); [Budin 2008](#); [Campbell 2007](#); [Couper 2015](#); [Heinrich 1985](#); [Kozachik 2001](#); [Kuijer 2004](#); [Kurtz 2005](#); [Ledderer 2013](#); [Manne 2005](#); [Manne 2011](#);

[McCorkle 2007](#); [Nicolaisen 2018](#); [Northouse 2007](#); [Robertson 2016](#)). Dyadic-delivered interventions can be divided further in terms of interventions targeted towards spousal/partner couples ([Baucom 2009](#); [Campbell 2007](#); [Couper 2015](#); [Heinrich 1985](#); [Kuijer 2004](#); [Manne 2005](#); [Manne 2011](#); [McCorkle 2007](#); [Nicolaisen 2018](#); [Northouse 2007](#); [Robertson 2016](#)), or a dyad in the form of a cancer patient and any family member or friend ([Budin 2008](#); [Kozachik 2001](#); [Kurtz 2005](#); [Ledderer 2013](#)).

The average age of caregivers across the trials ranged from 49 years old ([Kuijer 2004](#); [Manne 2005](#)) to 64 years old ([Robertson 2016](#)). One trial did not report the average age of their caregiver participants ([Heinrich 1985](#)). The average age of caregivers in the majority of studies was between 50 and 59 years ([Baucom 2009](#); [Blanchard 1996](#); [Budin 2008](#); [Bultz 2000](#); [Campbell 2007](#); [Kozachik 2001](#); [Kuijer 2004](#); [Kurtz 2005](#); [Manne 2004](#); [Manne 2011](#); [McCorkle 2007](#); [Nicolaisen 2018](#); [Northouse 2007](#); [Tsianakas 2015](#)), whereas, the average age of caregivers in three studies only was between 60 to 64 years ([Couper 2015](#); [Ledderer 2013](#); [Robertson 2016](#)).

Most trials were delivered to mixed-gender caregivers i.e. male and female caregivers ([Blanchard 1996](#); [Budin 2008](#); [Kozachik 2001](#); [Kuijer 2004](#); [Kurtz 2005](#); [Ledderer 2013](#); [Manne 2011](#); [Robertson 2016](#); [Tsianakas 2015](#)); whereas, four trials each targeted male-only ([Baucom 2009](#); [Bultz 2000](#); [Manne 2005](#); [Nicolaisen 2018](#)), or female-only caregivers ([Campbell 2007](#); [Couper 2015](#); [Manne 2004](#); [McCorkle 2007](#)). The gender of caregivers was not clear in two trials ([Heinrich 1985](#); [Northouse 2007](#)).

Trajectory of patients

Five trials included caregivers of newly diagnosed patients about to begin or currently receiving treatment ([Kozachik 2001](#); [Kurtz 2005](#); [McCorkle 2007](#); [Nicolaisen 2018](#); [Tsianakas 2015](#)) and four trials included caregivers of patients who had completed treatment ([Campbell 2007](#); [Ledderer 2013](#); [Manne 2005](#); [Robertson 2016](#)). Other trials reported less definitive eligibility criteria regarding a recent diagnosis or diagnosis within the previous year and, thus, it was not clear if patients were still receiving or had completed treatment ([Blanchard 1996](#); [Budin 2008](#); [Bultz 2000](#); [Couper 2015](#); [Manne 2011](#)). A few studies included early stage or localised cancer as a criterion for eligibility ([Baucom 2009](#); [Bultz 2000](#); [Campbell 2007](#); [Couper 2015](#); [Manne 2005](#)). Two studies stated that caregivers of cancer patients with a prognosis of more than a year only were included ([Ledderer 2013](#); [Robertson 2016](#)); one study stated that caregivers of patients who were not palliative were included ([Blanchard 1996](#)). One trial included caregivers of men with prostate cancer who met one of the following criteria: were newly diagnosed or were experiencing a biochemical recurrence or had developed new metastases or progression of advanced disease ([Northouse 2007](#)). Three trials did not report specific criteria regarding stage or status of participant inclusion in the study

with the exception of a cancer diagnosis in one partner (Heinrich 1985; Kuijer 2004; Manne 2004).

Control groups

Receipt of standard care was stipulated as the comparator group for each intervention in the review. Therefore all studies included a standard care control group. The majority of studies reported standard care as receipt of usual or routine care (Blanchard 1996; Budin 2008; Campbell 2007; Heinrich 1985; Kozachik 2001; Kurtz 2005; Ledderer 2013; McCorkle 2007; Northouse 2007; Robertson 2016; Tsianakas 2015). The description of standard care was unclear in some studies or varied across studies. More specifically, standard care was described as providing participants with a list of community organisations that offered additional support (Baucom 2009), a prostate cancer information booklet (Couper 2015), psychosocial care from a social worker and a referral to a community mental health worker (Manne 2004; Manne 2005; Manne 2011). Two studies used a waiting-list control design in which the participants who were randomised to receive usual care were offered the intervention after the study had ended (Bultz 2000), or as the initial intervention group was nearing the completion of the study (Kuijer 2004). In one study (Nicolaisen 2018), usual care varied across the three recruitment centres. Patients received either verbal and written information about psychological reactions to a breast cancer diagnosis or were referred to a psychologist or social worker or attended a seminar about the medical, psychological and social impact of breast cancer.

Interventions

Content

The 19 trials examined the effects of 21 interventions. Table 1 provides a detailed description of the components of the interventions in each trial (see Table 1). According to Cunningham's hierarchy of interventions, the majority of interventions focused on psycho-education in the form of coping skills training (level three); two interventions (Couper 2015; Nicolaisen 2018) were psychotherapeutic in nature (level four). Although many studies shared similar features, there was a large amount of heterogeneity across interventions. Thirteen interventions comprised mainly the dissemination of information to participants (level one in the hierarchy); the type of information disseminated across studies included cancer or treatment-related information and information regarding its impact on patients and their families (Baucom 2009; Budin 2008; Bultz 2000; Campbell 2007; Heinrich 1985; Manne 2004; McCorkle 2007; Robertson 2016; Tsianakas 2015). The type of information that was provided in other studies included: lifestyle (Ledderer 2013; Manne 2004; Northouse 2007),

stress and coping (Heinrich 1985; Robertson 2016), skill development (Budin 2008), sources of support (Budin 2008) and practical advice (Tsianakas 2015). Eighteen interventions had a support component (level two in the hierarchy) in the form of peer discussion (Bultz 2000; Kuijer 2004; Ledderer 2013; Manne 2004; Manne 2005; Manne 2011; McCorkle 2007; Northouse 2007; Robertson 2016; Tsianakas 2015), support from an intervention facilitator (Blanchard 1996; Campbell 2007; Couper 2015; Kozachik 2001; Kurtz 2005; Ledderer 2013; Nicolaisen 2018) and telephone counselling (Budin 2008). Coping skills training (level three in the hierarchy) varied across the interventions and many interventions focused on the development of one or more skills: communication skills (Baucom 2009; Budin 2008; Campbell 2007; Couper 2015; Ledderer 2013; Manne 2004; Manne 2005; Manne 2011), problem-solving skills (Baucom 2009; Blanchard 1996; Campbell 2007; Heinrich 1985; Manne 2005; McCorkle 2007), cognitive skills e.g. cognitive restructuring or visualisation (Baucom 2009; Budin 2008; Campbell 2007; Couper 2015; Heinrich 1985; Kuijer 2004; Northouse 2007), stress or anxiety or distress reduction (Blanchard 1996; Budin 2008; Campbell 2007; Heinrich 1985; Manne 2004; Manne 2005; Northouse 2007), coping skills (not reported by the authors) (Blanchard 1996; Budin 2008; Manne 2004; Manne 2005; Northouse 2007), symptom management or self-care strategies (Kozachik 2001; Kurtz 2005; McCorkle 2007; Northouse 2007), and other skills (Campbell 2007; Robertson 2016; Tsianakas 2015). Some of the interventions comprised also components which were not covered by the hierarchy, for example, homework assignments (Baucom 2009; Heinrich 1985; Kuijer 2004; Manne 2004; Manne 2005; Manne 2011; Nicolaisen 2018), physical activity (Heinrich 1985; Ledderer 2013) or uptake of positive couple-based activities (Heinrich 1985).

Delivery/format

Interventions were facilitated predominantly by nurses (Budin 2008; Kozachik 2001; Kurtz 2005; McCorkle 2007; Northouse 2007; Tsianakas 2015) or other health professionals such as psychologists (Bultz 2000; Campbell 2007; Kuijer 2004; Nicolaisen 2018), mental health specialists (Couper 2015; Manne 2004; Robertson 2016), therapists (Manne 2005), an oncology social worker (Blanchard 1996) or trainee psychologists (Baucom 2009). The remaining interventions were facilitated by a multidisciplinary team (Ledderer 2013; Manne 2004) or the study authors (Heinrich 1985).

Whilst many interventions were delivered face-to-face in a hospital outpatient clinic/setting, components of the interventions were also delivered via telephone (Budin 2008; Campbell 2007; Kozachik 2001; Kurtz 2005; McCorkle 2007; Northouse 2007), via video/DVD (Budin 2008; Tsianakas 2015), at home (McCorkle 2007; Northouse 2007), in a residential setting

(Ledderer 2013) or in a third sector/voluntary organisation (Robertson 2016).

The majority of interventions were delivered to individual caregiver-patient dyads (Baucom 2009; Budin 2008; Campbell 2007; Couper 2015; Kozachik 2001; Kuijer 2004; Manne 2011; McCorkle 2007; Nicolaisen 2018; Northouse 2007; Robertson 2016), two interventions were administered also on a one-to-one basis to individuals within the dyad (Budin 2008; McCorkle 2007); five trials administered the intervention to groups of caregiver-patient dyads (Heinrich 1985; Manne 2005) or groups of caregivers only (Bultz 2000; Manne 2004; Tsianakas 2015). One trial delivered sessions to the individual patient-caregiver dyad and then to dyads as part of a larger group at a residential course (Ledderer 2013). The remaining two trials delivered the intervention to caregivers on a one-to-one basis (Blanchard 1996; Kurtz 2005).

Most interventions were standardised via use of manuals or protocols (Baucom 2009; Blanchard 1996; Campbell 2007; Couper 2015; Heinrich 1985; Kuijer 2004; Ledderer 2013; Manne 2004; Manne 2005; Manne 2011; McCorkle 2007; Northouse 2007; Robertson 2016; Tsianakas 2015), others were partially standardised with some tailoring (Budin 2008; Bultz 2000; Kurtz 2005; Nicolaisen 2018) or were unstructured (Budin 2008; Kozachik 2001).

Dose/frequency

Interventions varied in duration and ranged from having one contact during which participants were taken through a one-hour protocol-guided group consultation and a 19-minute supportive/educational DVD and booklet (though caregivers could contact a healthcare professional if necessary) (Tsianakas 2015) to 16 contacts during an eight-week period which included both home and telephone contact (McCorkle 2007). One study comparing three interventions (standardised psycho-education, telephone counselling or a combined standardised psycho-education and telephone counselling intervention) to usual care were delivered at four time points over the care trajectory: diagnostic phase, postsurgical phase, adjuvant therapy phase and ongoing recovery phase (two weeks after completion of chemotherapy or radiotherapy or six months after surgery). These interventions were delivered over the longest duration though there were minimal contacts at each phase (i.e. one telephone contact and/or one video at each phase over the course of the study depending on the type of intervention) (Budin 2008). A proportion of trials evaluated interventions which included one weekly contact (60 to 120 minutes duration) over the course of six or eight weeks (Bultz 2000; Campbell 2007; Couper 2015; Heinrich 1985; Manne 2004; Manne 2005; Nicolaisen 2018; Robertson 2016). Other interventions were more intense including one intervention of three one-hour sessions and a five-day residential stay (Ledderer 2013), or were more diluted whereby intervention contacts occurred less

frequently, often biweekly or longer (Baucom 2009; Blanchard 1996; Kozachik 2001; Kuijer 2004; Kurtz 2005; Manne 2011; Northouse 2007).

Outcomes

A variety of outcome measures were administered and participants (patients and caregivers) were assessed at different time points and over varying follow-up periods.

Caregiver quality of life (QoL)

Five studies measured the primary outcome, the QoL of caregivers (Blanchard 1996; Campbell 2007; Kurtz 2005; Ledderer 2013; Northouse 2007) - (see Table 2). The review used the following measures of caregiver QoL: Medical Outcomes Survey (MOS), the Caregiver Strain Index (CSI; Campbell 2007), the Functional Assessment of Cancer Therapy (FACT; Northouse 2007) and the WHO-Five Well-being Index (Ledderer 2013). Two versions of the MOS were used - the SF-36 (social functioning subscale only) (Kurtz 2005) and the SF-20 (Blanchard 1996). Other QoL outcomes assessed by the studies in the review but for which data were not used included: a cancer patient-specific QoL measure (Ledderer 2013) and sexual functioning (Baucom 2009; McCorkle 2007).

Patient quality of life (QoL)

Five studies assessed the QoL of patients (Baucom 2009; Blanchard 1996; Campbell 2007; Ledderer 2013; Northouse 2007) - (see Table 3). Many studies administered more than one outcome measure to assess patient QoL. Cancer-specific measures were administered in most studies including the FACT-B (Baucom 2009), FACT-G (Northouse 2007), Functional Living Index- Cancer (FLIC) (Blanchard 1996), Expanded Prostate cancer Index Composite measure (EPIC) (Campbell 2007) and the European Organisation for Research and Treatment for Cancer 30-item QoL scale (EORTC-QLQ-C30) (Ledderer 2013).

Caregiver depression

A total of 10 studies examined the effectiveness of an intervention on caregiver depression. Four different outcome measures were used to assess depression (see Table 4). The most commonly used scale was the Centre for Epidemiologic Studies Depression Scale (CES-D) (Blanchard 1996; Kozachik 2001; Kuijer 2004; Kurtz 2005; McCorkle 2007). Other measures included the depression subscales of the Profile of Mood States (POMS) (Bultz 2000; Campbell 2007), the Hospital Anxiety and Depression Scale

(HADS) (Nicolaisen 2018; Robertson 2016) and the revised 90-item Symptom Checklist (SCL-90-R) (Heinrich 1985).

Caregiver anxiety

Six studies assessed caregiver anxiety using four different outcome measures (see Table 5). The anxiety subscale of the POMS (Bultz 2000; Campbell 2007), the HADS (Nicolaisen 2018; Robertson 2016) and the SCL-90-R (Heinrich 1985) and the state subscale of the State Trait Anxiety Inventory (STAI) (Blanchard 1996).

Caregiver psychological distress

Five studies captured caregiver psychological distress as a separate construct to anxiety and depression (see Table 6). Caregiver psychological distress was assessed, predominantly, using the psychological distress subscale of the Mental Health Inventory (MHI) (Couper 2015; Manne 2004; Manne 2011), the total score of the Brief Symptom Inventory (Baucom 2009) and the 12-item General Health Questionnaire (GHQ-12) (Tsianakas 2015). Similar constructs to psychological distress were assessed by some studies but the data were not used in the review including: cancer-related distress (Couper 2015; Manne 2004; Manne 2011) and general symptom distress (Northouse 2007).

Caregiver satisfaction with interventions

No studies assessed caregiver satisfaction with the intervention that they received.

Caregiver physical health status

Two studies examined the physical health status of caregivers (measured separately from a QoL measure) using the Physical Component Summary Score of the SF-12 (Northouse 2007) and the total score from the Multilevel Assessment Instrument (Budin 2008) (see Table 7). Studies that delivered the intervention to caregivers only did not assess the effect of the intervention on the physical health status of caregivers (Blanchard 1996; Bultz 2000; Manne 2004; Tsianakas 2015).

Patient depression

All studies (with the exception of Campbell 2007) that measured caregiver depression also estimated the effect of their intervention on patient levels of depression (including the study by Heinrich 1985, though data from this study were not extracted or used as only a proportion of caregivers of patients in this study participated in the trial). One additional study (Manne 2005) measured

patient depression, but it did not measure caregiver depression (see Table 8). Five studies utilised the CES-D (Blanchard 1996; Kozachik 2001; Kuijer 2004; Kurtz 2005; McCorkle 2007) and the depression subscales of the POMS (Bultz 2000); the Mental Health Index (MHI) (Manne 2005) and the HADS (Nicolaisen 2018; Robertson 2016) were used by the remaining studies. A measure of hopelessness was captured in one study (Northouse 2007), and mood states were assessed in three additional studies (Bultz 2000; Campbell 2007; Couper 2015).

Patient anxiety

Four studies only assessed the impact of their interventions on patient-assessed anxiety using anxiety subscales of the POMS (Bultz 2000), the MHI (Manne 2005) and the HADS (Nicolaisen 2018; Robertson 2016) (see Table 9). Cancer-specific concerns were assessed in one study (Manne 2011). See 'Patient depression' section above for information regarding Heinrich 1985.

Patient psychological distress

A small number of studies captured patient-assessed psychological distress using the total score of the Brief Symptom Inventory (BSI) (Baucom 2009) and the psychological distress subscale of the MHI (Couper 2015; Manne 2011) (see Table 10). Constructs related to distress were captured in a few studies including: body image (Baucom 2009), distress specifically related to side effects (Budin 2008), cancer-related distress (Couper 2015; Manne 2005; Manne 2011; Nicolaisen 2018) and general symptom distress (Northouse 2007).

Patient physical health status

Seven studies administered physical health outcome measures to patients, five of which, administered derivatives of the SF measures including the physical component summary scores of the SF-36 (Campbell 2007), the SF-12 (Northouse 2007), the physical functioning subscales of the SF-20 (Blanchard 1996) and the SF-36 (Kurtz 2005). The Rotterdam Symptom Checklist was used in one study (Baucom 2009) and the total score of the MAI was administered in a further study (Budin 2008). The functional status subscale of the Cancer Rehabilitation Evaluation System (CARES) was used to assess physical health status as a moderator in analysis of intervention effects in one study and thus data were not extracted for the review (Manne 2005). (see Table 11).

Patient satisfaction with interventions

No studies assessed patient satisfaction with interventions.

Adverse events

Three studies reported adverse events that occurred during the period when the intervention was delivered (Manne 2011; McCorkle 2007; Robertson 2016).

Cost-effectiveness

The cost-effectiveness of an intervention was not evaluated in any of the included studies.

Excluded studies

Studies were excluded for the following reasons: duplicate studies, not a RCT or quasi-RCT, intervention was not delivered to a caregiver or it was delivered to caregivers of patients who were not the focus of this review (e.g. patients without cancer, children with cancer, deceased patients, inpatients, patients with advanced cancer or patients receiving palliative care), studies with a control group in which caregivers did not receive usual care, studies of an intervention which was not psychosocial (e.g. did not include an instant dialogue component) or was not delivered by a healthcare professional, studies that did not include outcomes of interest or the intervention was integrated into routine care and not published (see [Characteristics of excluded studies](#)).

Studies awaiting classification

Two studies are awaiting assessment due to insufficient study information available to include in the review (see [Characteristics of studies awaiting classification](#)). One study studied the effects of a couple-based psychosocial intervention for head and neck cancer

patients and their partners (Gremore 2014). The second study reported on a sexual health website and telephone counselling intervention for men with cancer and their partners (Schover 2012a).

Ongoing studies

Thirteen ongoing studies were identified from trial registries or during the electronic database searches (see [Characteristics of ongoing studies](#)). Many of the ongoing studies targeted caregivers of patients with breast cancer (Hendrix 2017; Juarez 2015; Nie 2017; Rush 2015), other studies included caregivers of patients with colorectal (Shum 2015), lung (Aubin 2017), colorectal or lung (O'Toole 2017), prostate (Manne 2013; McCaughan 2013; Sadler 2016), thoracic (Hendrix 2017) or multiple cancers (Ferrell 2013; Trevino 2017). One study trialled an intervention for caregivers of recipients of haematopoietic stem cell transplants (HSCT) (El-Jawahri 2017). Most interventions were psychoeducational in nature (Aubin 2017; El-Jawahri 2017; Ferrell 2013; Hendrix 2017; Juarez 2015; Manne 2013; McCaughan 2013; Nie 2017; Rush 2015; Sadler 2016; Shum 2015; Trevino 2017). One ongoing study appeared to test the effect of a psychotherapeutic intervention (O'Toole 2017).

Risk of bias in included studies

Included studies were assessed for risk of bias using the RevMan 'Risk of bias' tool. This tool addresses six potential sources of bias: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data and selective outcome reporting (see [Figure 2](#) and [Figure 3](#)). According to the criteria reported in [Assessment of risk of bias in included studies](#), all trials were rated as having a high risk of bias.

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)
Baucom 2009	+	?	+	+	-	-
Blanchard 1996	?	?	-	+	-	-
Budin 2008	?	?	?	+	-	-
Bultz 2000	-	-	+	+	-	-
Campbell 2007	?	-	-	+	-	-
Couper 2015	+	+	+	+	-	-
Heinrich 1985	-	-	-	+	-	-
Kozachik 2001	?	?	-	+	-	-
Kuijter 2004	?	?	+	+	-	-
Kurtz 2005	?	?	?	+	-	-
Ledderer 2013	+	?	-	-	-	-
Manne 2004	+	?	+	+	-	-
Manne 2005	?	?	+	+	-	-
Manne 2011	?	-	-	+	-	-
McCorkle 2007	?	?	-	+	-	-
Nicolaisen 2018	+	+	?	-	-	-
Northouse 2007	?	?	+	+	-	-
Robertson 2016	+	?	+	-	-	-
Tsianakas 2015	+	+	+	+	-	-

Allocation

Random sequence generation

The inclusion criteria required participants in each study to be randomised. However, only seven studies (Baucom 2009; Couper 2015; Ledderer 2013; Manne 2004; Nicolaisen 2018; Robertson 2016; Tsianakas 2015) stated clearly a method of random sequence generation using either a computer-generated or a random number list and, therefore, were classified as having low risk of bias. Ten of the remaining studies did not provide sufficient detail about method of randomisation and therefore were classified as having an unclear risk of bias (Blanchard 1996; Budin 2008; Campbell 2007; Kozachik 2001; Kuijer 2004; Kurtz 2005; Manne 2005; Manne 2011; McCorkle 2007; Northouse 2007). Two studies were classified as being at high risk of bias due to the use of a quasi-random sequence. Bultz 2000 stated that when a sufficient number of couples were recruited, half were assigned to receive the intervention by drawing their names randomly and blindly from an envelope. The study by Heinrich 1985 was deemed 'high risk' because participants were assigned to whichever arm or condition (intervention or control) that happened to be open or available at the time of recruitment. The first condition to be opened was determined randomly, and when this condition was full the alternative arm was opened.

Allocation concealment

Allocation concealment shields personnel who admit participants to a trial from knowing the upcoming assignments by, for example, using sequentially numbered opaque sealed envelopes or central randomisation (Schulz 2002). Only three studies in this review used appropriate measures of allocation concealment such as centralised computerised randomisation (Couper 2015), or by an individual not involved in recruitment (Nicolaisen 2018; Tsianakas 2015), and as a result were scored as having low risk of bias. One study was scored as being at unclear risk of bias because although they used sealed envelopes and opened the next in line, there was a lack of clarity surrounding whether the envelopes were opaque and sequentially numbered (Ledderer 2013). Several studies were scored as being at unclear risk of bias because there was insufficient detail to make a decision regarding allocation concealment (Baucom 2009; Blanchard 1996; Budin 2008; Kozachik 2001; Kuijer 2004; Kurtz 2005; Manne 2004; Manne 2005; McCorkle 2007; Northouse 2007; Robertson 2016). Four studies were scored as being at high risk of bias. In two studies, participants were allocated to the intervention group first and then remaining participants were allocated to the control group (Bultz 2000; Heinrich

1985). Some studies did not report the methods that were used to ensure allocation concealment or allocated individuals following completion of baseline assessments. Therefore, it is possible that those researchers were influenced by participants' scores or that participants indicated an allocation preference (Campbell 2007; Manne 2011).

Blinding

Performance bias

It was not possible for participants to be blinded to group assignment as caregivers or patients knew whether or not they were receiving an intervention. Therefore, all studies were rated as being at a high risk of bias for this domain.

Detection bias

All studies were deemed to be at high risk of bias because they included self-reported or self-assessed outcome measures as well as having participants who were aware of their group assignment.

Incomplete outcome data

In all studies, participants were analysed according to their original group assignment. Very few studies (Budin 2008; Couper 2015; Manne 2005; Manne 2011; Nicolaisen 2018) reported undertaking intention-to-treat analysis. Often, detailed descriptions of how an intention-to-treat analysis was conducted were absent thereby making it difficult to replicate. One study only (Manne 2005) undertook per-protocol analysis, as well as, intention-to-treat analysis and reported no differences in their findings. Unless otherwise stated, studies which had less than 15% differential loss of follow-up between the intervention and control groups were rated as having a low risk of bias (Baucom 2009; Bultz 2000; Couper 2015; Kuijer 2004; Manne 2004; Manne 2005; Northouse 2007; Robertson 2016; Tsianakas 2015). Three studies were rated as being at unclear risk of bias due to differential reasons for loss to follow-up i.e. higher proportion of control group failing to return questionnaires than the intervention group (Nicolaisen 2018) and failure to report distribution of reasons for loss to follow-up across groups (Budin 2008; Kurtz 2005). Studies were rated as being at high risk of bias due to differential loss to follow-up ($\geq 15\%$) between the intervention and control groups (Blanchard 1996; Campbell 2007; Kozachik 2001; Ledderer 2013; Manne 2011; McCorkle 2007) or failure to report on losses to follow-up, particularly, as later follow-up assessments could not be completed due to study attrition (Heinrich 1985).

Selective reporting

It was not possible to obtain a published study protocol or registered trial record for most studies. Therefore, decisions regarding risk due to selective reporting bias were made based on whether or not results for each outcome that were listed in the methods section of each published report were present in the analysis. Most studies were rated as having a low risk of bias (Baucom 2009; Blanchard 1996; Budin 2008; Bultz 2000; Campbell 2007; Couper 2015; Heinrich 1985; Kozachik 2001; Kuijer 2004; Kurtz 2005; Manne 2004; Manne 2005; Manne 2011; McCorkle 2007; Northouse 2007; Tsianakas 2015).

Reasons for high risk of bias ratings occurred because some outcomes were not reported according to the published protocol (Nicolaisen 2018; Robertson 2016) or listed trial registration (Ledderer 2013).

Effects of interventions

See: [Summary of findings for the main comparison; Summary of findings 2](#)

Caregiver quality of life (QoL)

Five studies assessed the effects of psychosocial interventions on caregiver QoL. We performed a meta-analysis of two studies (265 participants) (Campbell 2007; Northouse 2007) and found that psychosocial interventions may improve slightly global QoL immediately post-intervention (standardised mean difference (SMD) 0.29, 95% confidence interval) CI 0.04 to 0.53; $I^2 = 0\%$) (see [Analysis 1.1](#)) (See [Summary of findings for the main comparison](#) for more information). This evidence was found to be of low quality. A meta-analysis of two studies (239 participants) (Ledderer 2013; Northouse 2007) found that psychosocial interventions may have little to no effect regarding caregiver global QoL 12 months post-intervention (SMD 0.14, 95% CI -0.11 to 0.40; $I^2 = 0\%$) (see [Analysis 1.2](#)). This evidence was rated as being of low quality.

Results from two studies which assessed caregiver QoL could not be pooled due to the absence of conceptual similarity between a global QoL score and individual QoL subscale score (Blanchard 1996; Kurtz 2005). In Blanchard 1996, multiple subscales of QoL were reported; mean scores on each subscale (no overall summary score was calculated) showed effects in favour of the intervention but the authors reported that the intervention did not impact on any domain of caregiver QoL immediately post-intervention or six months post-baseline (See [Table 2](#) for information on means and standard deviations for each subscale). Similarly, Kurtz 2005 reported that there was no intervention effect on caregiver QoL (social functioning) though mean scores were higher for the intervention group compared to the usual care control group immediately post-intervention (Intervention mean (SD) = 89.4 (17.6); Control mean (SD) = 84.7 (24.0)). See [Table 2](#) for more information regarding caregiver QoL.

Overall, taking into account the pooled and unpooled findings, psychosocial interventions may improve slightly QoL for caregivers immediately post-intervention, but this benefit may not be maintained in the longer term (six to 12 months later).

Patient quality of life

In total, five studies contributed data to address the effectiveness of psychosocial interventions on patient QoL. A meta-analysis of two studies (292) participants) (Blanchard 1996; Northouse 2007) (SMD -0.03, 95% CI -0.50 to 0.44; $I^2 = 63\%$) (see [Analysis 2.1](#)) found uncertainty whether or not psychosocial interventions improve global patient QoL immediately post-intervention due to the very low quality of evidence. (See [Summary of findings 2](#) for more information). We performed a meta-analysis of three studies (Blanchard 1996; Ledderer 2013; Northouse 2007) (294 participants) and found that psychosocial interventions may have little to no effect on patient global QoL six to 12months post-intervention (SMD -0.05, 95% CI -0.37 to 0.26; $I^2 = 24\%$) based on the low quality of evidence (see [Analysis 2.2](#)).

The following summary refers to data taken from studies which were not included in the meta-analysis. Data from additional studies could not be combined in a meta-analysis due to use of domain-specific or unidimensional measures of patient QoL which were conceptually different from, and difficult to equate to, a global QoL measure score. Standardised mean difference in change scores were calculated for a couple-based relationship-enhancement intervention and found a large effect of the intervention on patient QoL immediately (Intervention mean (SD) = 3.08 (0.27); Control mean (SD) = 2.76 (1.15); effect size $d = 0.97$) and at 12 months (Intervention mean (SD) = 3.22 (0.34); Control mean (SD) = 2.89 (0.91); $d = 1.14$) post-intervention (Baucom 2009). Multiple subscales of QoL were assessed in a second study which reported higher mean scores (indicating better QoL) for most subscales for the coping skills training group (mean range = 30.35 to 89.79) compared to the usual care group (mean range = 23.44 to 95.57) (Campbell 2007). For more information about patient QoL see [Table 3](#).

Evidence in terms of findings from pooled and unpooled data were inconsistent and uncertain regarding whether or not psychosocial interventions improve patient QoL.

Caregiver depression

A total of 10 studies assessed the effects of psychosocial interventions on caregiver depression. The results from nine studies (702 participants) (Blanchard 1996; Bultz 2000; Campbell 2007; Kozachik 2001; Kuijer 2004; Kurtz 2005; McCorkle 2007; Nicolaisen 2018; Robertson 2016) were combined in a meta-analysis which indicate that psychosocial interventions probably have little to no effect on caregiver depression immediately to one month post-intervention (SMD 0.01, 95% CI -0.14 to 0.15; $I^2 =$

0%). The quality of evidence was rated as moderate (see [Analysis 1.3](#)).

Five studies (379 participants), albeit deemed to be low-quality evidence, ([Blanchard 1996](#); [Bultz 2000](#); [McCorkle 2007](#); [Nicolaisen 2018](#); [Robertson 2016](#)) were combined in a meta-analysis which indicated that psychosocial interventions may have little or no effect on caregiver depression three to six months post-intervention (SMD 0.03, 95% CI -0.33 to 0.38; $I^2 = 62\%$) (see [Analysis 1.4](#)). The following results pertain to data which could not be pooled in a meta-analysis. One study that was not included in the meta-analysis (due to missing data) did not find an effect immediately post-intervention on caregiver depression (Intervention mean = 0.66, no variance statistic reported; Control mean = 0.69, no variance statistic reported) ([Heinrich 1985](#)). See [Table 4](#) for more information about caregiver depression.

Pooled and unpooled findings indicated that psychosocial interventions probably have little to no effect on depression for caregivers.

Caregiver anxiety

Six studies provided data on the effectiveness of psychosocial interventions for caregiver anxiety. The results of five studies (329 participants) ([Blanchard 1996](#); [Bultz 2000](#); [Campbell 2007](#); [Nicolaisen 2018](#); [Robertson 2016](#)) were combined in a meta-analysis which found that psychosocial interventions may have little to no effect on caregiver anxiety immediately post-intervention (SMD -0.12, 95% CI -0.33 to 0.10; $I^2 = 0\%$), based on low quality of evidence (see [Analysis 1.5](#)).

A meta-analysis of four studies (272 participants) ([Blanchard 1996](#); [Bultz 2000](#); [Nicolaisen 2018](#); [Robertson 2016](#)) indicated uncertainty about whether or not psychosocial interventions reduced caregiver anxiety three to six months post-intervention (SMD -0.25, 95% CI -0.64 to 0.13; $I^2 = 53\%$), based on very low quality of evidence (see [Analysis 1.6](#)).

Regarding results that were not included in the meta-analysis, one study did not find an effect (and did not report effect sizes or statistics of variance) for their intervention on caregiver anxiety immediately (Intervention mean = 0.37; Control mean = 0.55) or two months post-intervention (no data reported) ([Heinrich 1985](#)). For additional information regarding caregiver anxiety see [Table 5](#).

Psychological interventions may have little to no effect on anxiety for caregivers based on both pooled and unpooled findings.

Caregiver psychological distress

Five studies assessed the effectiveness of psychosocial interventions on caregiver psychological distress at various time points. We performed a meta-analysis of three studies (134 participants) ([Baucom 2009](#); [Couper 2015](#); [Manne 2004](#)) and found that psychosocial interventions may have little or no difference on caregiver psycho-

logical distress immediately post-intervention (SMD -0.08, 95% CI -0.42 to 0.26; $I^2 = 0\%$) (see [Analysis 1.7](#)).

A two-study ([Baucom 2009](#); [Couper 2015](#)) meta-analysis (62 participants) found that psychosocial interventions may have little to no effect on psychological distress for caregivers seven to 12 months post-intervention (SMD 0.08, 95% CI -0.42 to 0.58; $I^2 = 0\%$) (see [Analysis 1.8](#)). The evidence at both time points was low quality and downgraded accordingly by one point for each of the following reasons: studies were rated as being at high risk of bias and there was an imprecise effect estimate.

The following results relate to data from studies which could not be included in the meta-analysis. Raw data were not presented in two studies (thus data could not be provided for the meta-analysis); both studies reported no intervention effect on psychological distress immediately post-intervention ([Manne 2011](#)) or two weeks post-intervention ([Tsianakas 2015](#)). See [Table 6](#) for additional information on caregiver psychological distress.

Pooled and unpooled findings indicate that psychosocial interventions may have little to no effect on psychological distress for caregivers.

Caregiver satisfaction with the intervention

This outcome was not assessed in any of the included studies.

Caregiver physical health status

Two studies of psychosocial interventions for caregiver physical health status were unable to be pooled in a meta-analysis. [Budin 2008](#) failed to report raw data in their study of standardised psycho-education, telephone counselling and combined telephone counselling and standardised psycho-education compared to usual care. However, study authors reported no evidence of an intervention effect immediately post-intervention. [Northouse 2007](#) calculated the standardised difference in means for the FOCUS psychosocial intervention and control group. They reported little to no intervention effect on caregiver physical health status immediately post-intervention (Intervention mean (SD) = 50.0 (7.8); Control mean (SD) = 50.3 (7.2); Effect size = 0.04) and a small effect on physical health status at 12 months post-baseline (Intervention mean (SD) = 44.6 (7.2); Control mean (SD) = 42.3 (7.2); Effect size = 0.32). For more information regarding caregiver physical health status see [Table 7](#).

There is not enough evidence to indicate whether or not psychosocial interventions make a difference to caregiver physical health status.

Patient depression

A total of nine studies examined the effects of psychosocial interventions on patient depression. A meta-analysis of the nine studies (852 participants) ([Blanchard 1996](#); [Bultz 2000](#); [Kozachik 2001](#); [Kuijter 2004](#); [Kurtz 2005](#); [Manne 2005](#); [McCorkle 2007](#);

Nicolaisen 2018; Robertson 2016) (of low-quality evidence: downgraded for high risk of bias studies and inconsistency) was undertaken for patient depression. Psychosocial interventions may have little or no effect on patient depression immediately to one-month post-intervention (SMD -0.12, 95% CI -0.31 to 0.07; $I^2 = 44\%$) (see Analysis 2.3). Six studies (534 participants) (deemed to comprise moderate-quality evidence: downgraded due to inclusion of high risk of bias studies) (Blanchard 1996; Bultz 2000; Manne 2005; McCorkle 2007; Nicolaisen 2018; Robertson 2016) were combined in a meta-analysis to assess the impact of psychosocial interventions on patient depression three to six months post-intervention. The meta-analysis found that psychosocial interventions probably have little to no effect on patient depression three to six months post-intervention (SMD -0.11, 95% CI -0.33 to 0.12; $I^2 = 33\%$) (see Analysis 2.4). More details regarding patient depression can be found in Table 8.

Findings indicate that psychosocial interventions probably have little to no effect on depression for patients.

Patient anxiety

Four studies assessed the effectiveness of psychosocial intervention on the anxiety reported by patients. The findings from the four studies (422 participants) (Bultz 2000; Manne 2005; Nicolaisen 2018; Robertson 2016) were combined in a meta-analysis to examine the effect of psychosocial interventions versus usual care on patient anxiety immediately post-intervention. The meta-analysis demonstrated that psychosocial interventions may have little or no effect on patient anxiety immediately post-intervention (SMD -0.13, 95% CI -0.41 to 0.15; $I^2 = 43\%$) (see Analysis 2.5). The evidence was low quality due to studies being rated as having a high risk of bias and the presence of moderate statistical heterogeneity ($I^2 = 43\%$). A meta-analysis of four studies (370 participants) (Bultz 2000; Manne 2005; Nicolaisen 2018; Robertson 2016) demonstrated that psychosocial interventions may have little to no effect on patient anxiety at three to six months post-intervention (SMD -0.22, 95% CI -0.45 to 0.02; $I^2 = 15\%$), though the evidence was considered to be low quality because studies had a high risk of bias status and an imprecise effect estimate (see Analysis 2.6). For more details relating to patient anxiety see Table 9.

Psychosocial interventions may have little to no effect on patient anxiety immediately or three to six months post-intervention.

Patient psychological distress

Three studies examined the effect of psychosocial interventions compared to usual care on patient psychological distress across a number of time points. A meta-analysis of two studies (74 participants) (Baucom 2009; Couper 2015) demonstrated that psychosocial interventions may have little or no effect on patient psychological distress immediately post-intervention (SMD -0.02, 95% CI -0.47 to 0.44; $I^2 = 0\%$) (see Analysis 2.7). A meta-analysis

of two studies (61 participants) found that psychosocial interventions may have little to no effect on patient psychosocial distress seven to 12 months post-intervention (SMD -0.27, 95% CI -0.78 to 0.24; $I^2 = 0\%$) (see Analysis 2.8). The evidence at both time points was rated low quality and downgraded accordingly by one-point for each of the following reasons: studies of high risk of bias were included and the effect estimate was imprecise.

One study which was not included in the meta-analysis reported no intervention effect for an Intimacy-enhancing couple-based intervention on patient psychological distress compared to usual care and did not provide any raw data (Manne 2011). See Table 10 for additional information regarding patient psychological distress. Psychosocial interventions may have little to no effect on psychological distress of patients immediately or seven to 12 months after the intervention has ended.

Patient satisfaction with the intervention

This outcome was not assessed by any of the included studies.

Patient physical health status

In total, six studies provided data regarding the effects of psychosocial interventions on the physical health status of patients. A meta-analysis of four studies (461 participants) (Blanchard 1996; Campbell 2007; Kurtz 2005; Northouse 2007) found that psychosocial interventions probably have little to no difference in patient-reported physical health status immediately post-intervention (SMD 0.17, 95% CI -0.07 to 0.41; $I^2 = 30\%$) (see Analysis 2.9). This analysis was based on evidence that was considered to be of moderate quality and was downgraded due to the high risk of bias status of included studies. The effectiveness of psychosocial interventions on patient physical health status six to 12 months post-intervention was examined in a meta-analysis of two studies (Blanchard 1996; Northouse 2007) (275 participants) (SMD 0.06, 95% CI -0.18 to 0.30; $I^2 = 0\%$) (see Analysis 2.10). Psychosocial interventions may have little to no difference on physical health status based on low-quality evidence (downgraded by two points due to studies that had a high risk of bias and the imprecision of the effect due to less than 400 participants contributing to the analysis).

The following section refers to studies which were not pooled in a meta-analysis. Although raw scores were not reported in the paper, Budin 2008 reported that physical health status scores were similar immediately post-intervention for all groups in a study that compared standardised psycho-education only, telephone counselling only or a combined psycho-educational and telephone counselling intervention with usual care. One study (Baucom 2009) could not be added to the meta-analysis because the scale structure differed from the scales used in other included studies (e.g. checklist versus multidimensional scale). A large intervention effect on patient physical health status was reported immediately (Intervention mean (SD) = 20.71 (3.82); Control mean (SD) = 27.17

(8.68)); effect size $d = 0.86$) and a moderate intervention effect 12-months (Intervention mean (SD) = 18.71 (2.36); Control mean (SD) = 23.80 (9.81); effect size $d = 0.61$) post-intervention (Baucom 2009). For supplementary information regarding patient physical health status, see Table 11.

There is little to no effect of interventions on patient's physical health status immediately post-intervention and evidence is inconsistent with regards to longer-term effects (12-month period) according to the results of the pooled and unpooled analyses.

Adverse events

Adverse events were reported in three studies, though no quantifiable data were reported. One study reported that caregivers of cancer patients who had low levels of distress at study enrolment experienced an increase in distress during or after the intervention. A negative change in relationship satisfaction post-intervention in caregivers despite high levels of marital satisfaction at study enrolment was also reported (Manne 2011). Moreover, the content of a psychosexual intervention was perceived to be insensitive to some participants who were not engaged in sexual activity prior to diagnosis (Robertson 2016). During follow-up in one study, patients allocated to the intervention experienced significantly greater distress and caregivers experienced more distress related to sexual functioning than individuals in the control group (McCorkle 2007).

Feasibility/acceptability of interventions

Qualitative data that were collected as part of trial evaluation indicated that caregivers and patients found that the interventions were acceptable, and good feasibility was demonstrated. Participants across a number of trials reported improvements in communication with their partners and recognised the value of communication skills training (Blanchard 1996; Bultz 2000; Campbell 2007). In general, interventions were valued and participants reported positive experiences (Heinrich 1985; Manne 2011; Tsianakas 2015).

Cost-effectiveness

This outcome was not assessed by any of the included studies.

Narrative subgroup analysis

The following subgroup analysis should be read with caution given concerns about the quality of the evidence. Overall, the studies in this review appeared to exert little or no effect on outcome variables of interest (and did not report effect sizes). Any differences that emerged according to planned subgroup parameters are noted below mindful of the typically low or very low quality of the evidence.

Intervention type

Although the majority of interventions might be labelled as psycho-educational, there was considerable heterogeneity across trials in terms of individual components. Specific intervention components did not appear to be associated with caregiver or patient outcomes.

Mode of delivery

Group or individual setting

There were not any clear patterns in the effects of interventions based on whether the intervention was delivered to groups or individuals.

Caregiver only or caregiver-patient dyads

There were no clearly identifiable patterns in the effects of the interventions based on whether the intervention was delivered to caregivers only or caregiver-patient dyads.

Face-to-face, telephone only and face-to-face combined with video/DVD or telephone

There were not any clearly identifiable patterns in the effects of interventions based on format of delivery. For example, a face-to-face delivered intervention demonstrated benefits ranging from small to large across a number of outcomes (Baucom 2009), while a study of another face-to-face intervention reported a medium effect on patient depression (Kuijer 2004). An intervention incorporating face-to-face and telephone delivery demonstrated a small effect on caregiver physical health status (Northouse 2007) and a telephone-only delivered intervention demonstrated mixed effects on patient QoL (Campbell 2007).

Nature of intervention

According to Cunningham's hierarchical framework, most interventions were defined as psycho-educational and one intervention was defined as psychotherapeutic (Couper 2015). Therefore, it was not possible to conduct a meaningful comparative assessment of different types of interventions.

Intervention intensity

It was not meaningful to undertake subgroup analysis by level of intervention intensity as most ($n = 12$) trials reported on interventions which had between four and six contacts.

Caregiver characteristics (gender, age, relationship with patient)

Gender

Most trials (n = 9) included interventions that were delivered to mixed gender caregiver groups. There were not any clear patterns in the effects of interventions based on whether the intervention was delivered to male- or female-only caregivers.

Age

The mean or median age of caregivers did not vary significantly across trials and ranged from 49 to 64 years old; it was not meaningful to compare intervention effects based on age of caregivers.

Relationship with patient (spouse/intimate partner or other)

Most studies included only spousal partners of individuals affected by cancer (n= 12) and all other studies included a nominated caregiver who may have been a spousal partner; therefore, it was difficult to discern whether or not interventions that were targeted at spousal or non-spousal partners of individuals affected by cancer had any particular effects.

Time since diagnosis

Included studies differed in terms of eligibility criteria regarding time since diagnosis or cancer care trajectory; for example, it was not clear in some studies how much time had passed since diagnosis (Heinrich 1985; Kuijer 2004; Manne 2004) or whether or not patients had completed treatment (Blanchard 1996; Budin 2008; Bultz 2000; Couper 2015; Manne 2011). Therefore, it was not possible to identify whether or not psychosocial interventions were more or less effective for patients or caregivers on any outcomes depending on time since diagnosis.

ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

Psychosocial interventions compared with usual care for informal cancer caregivers						
Patient or population: individuals with cancer (patients) Settings: outpatient Intervention: psychosocial interventions Comparison: usual care						
Outcomes*	Illustrative	comparative	risks	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	(95% CI)					
	Corresponding risk					
	Psychosocial intervention					
Global quality of life FLIC total score (Blanchard 1996) , FACT-G total score (Northouse 2007). Additional studies (reported in comments section): FACT-B physical functioning sub-scale (Baucom 2009). EPIC multiple subscales and overall scores (Campbell 2007). Higher scores indicate better QoL. Follow-up: immediately post-intervention	The mean score in the interven- tion group was 0.03 standard de- viations lower (0.50 lower to 0.44 higher)			292 (2)	⊕○○○ very low <i>a,b,c</i>	Two additional studies using a range of conceptually different measures or reported data collected at additional time points (and so could not be pooled) measured patient QoL. One study reported higher mean scores in the psychosocial intervention group compared to the usual care group. A second study found mixed effects of psychosocial interventions on do- mains of QoL
Global quality of life FLIC total score (Blanchard 1996) , EORTC-QLQ-C30 global health status score (Ledderer 2013), FACT-G total score (Northouse 2007). Additional study (reported in com- ments section):	The mean score in the interven- tion group was 0.05 standard de- viations lower (0.37 lower to 0.26 higher)			294 (3)	⊕⊕○○ low <i>a,d</i>	One study could not be included in the meta-analysis because of the use of a conceptually different measure of patient QoL. Higher scores were reported in the psychosocial interven- tion group compared to the control group 12-months post-intervention

FACT-B physical functioning subscale (Baucom 2009). Higher scores indicate better QoL. Follow-up: six to 12 months post-intervention				
Any adverse events	See comment	Not estimable	–	Two studies reported on adverse effects of their interventions but did not report the results in a form that could be extracted for meta-analysis One study reported higher levels of distress for cancer patients receiving the intervention, compared with the usual care group. Another study reported that the content of a psychosexual intervention was perceived to be insensitive to participants not engaged in sexual activity prior to diagnosis

* More detail regarding the scoring and direction for each scale is detailed in [Table 3](#).

CI: Confidence Interval; **EPIC:** Expanded Prostate Cancer Index; **FACT-B:** Functional Assessment of Cancer Therapy- Breast; **FACT-G:** Functional Assessment of Cancer Therapy- General; **FLIC:** Functional Living Index Cancer; **QoL:** quality of life;

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.

^aRisk of bias (-1): Studies were rated as being at high risk of bias overall

^bImprecision (-1): The meta-analysis includes a small sample (less than 400 participants) and confidence interval around the pooled estimate indicates no effects as well as indicating appreciable harm of the intervention as the minimal important difference is not known.

^cInconsistency (-1): High level of heterogeneity indicated by I^2 statistic of 63%

^dImprecision (-1): The meta-analysis includes a small sample (less than 400 participants)

DISCUSSION

Summary of main results

The aim of this review was to evaluate the effectiveness of psychosocial interventions designed to support informal caregivers of people living with cancer on caregiver quality of life (primary outcome) and on a range of patient and caregiver psychological and physical outcomes. A total of 20 papers reporting 19 studies comprising 3,725 participants met the eligibility criteria for the review. The trials comprised caregivers of individuals affected by a range of different cancers across the care trajectory from newly diagnosed to patients who had completed treatment. The included studies were separated into two categories: interventions that supported caregivers directly and interventions that supported (spousal or other) caregiver-patient dyads. All but two interventions were categorised as psycho-educational because they combined information giving with one or more aspects of coping skills training in an instructional format. Two interventions were psychotherapeutic in nature. There was huge heterogeneity in the components that formed the interventions. Additionally, there was variation in the use of outcome measures administered across the included trials and assessment time points also varied.

Pooled results indicated a small benefit ensuing from receipt of psychosocial interventions for caregivers in terms of improving their quality of life (QoL). However, the quality of evidence (which was low) led to the conclusion that psychosocial interventions may only improve slightly caregiver QoL and only immediately post-intervention, while there may be little or no effect on the QoL of caregivers 12 months after the end of intervention delivery.

The very low quality of evidence makes it difficult to be certain about whether or not psychosocial interventions improve the QoL of patients immediately post-intervention. According to the evidence (again deemed to be low quality), there may be little to no long-term difference in QoL for patients at least assessed at six to 12 months following completion of the intervention. Similarly, psychosocial interventions probably have little to no effect on caregiver depression immediately (based on moderate evidence) and may have little to no effect on caregiver depression three to six months post-intervention (based on low-quality evidence). Furthermore, in the same way, psychosocial interventions may have little to no effect on caregiver anxiety immediately (low-quality evidence); and there is uncertainty about whether or not interventions reduce anxiety three to six months post-intervention (very low-quality evidence) or improve health status immediately post-intervention or at 12 month follow-up.

Regarding psychological distress for both caregivers and patients, psychosocial interventions may have little to no effect on distress immediately post-intervention (low-quality evidence) or at seven to 12 months post-intervention (low-quality evidence). Similarly, there may be no effect for patient depression, anxiety and physical health status immediately after delivery of psychosocial in-

terventions, depression and anxiety three to six months later or physical health status six to 12 months later. Again, most of this evidence was considered low quality (moderate-quality evidence was present for patient-reported physical health status immediately and patient-reported depression three to six months post-intervention).

Very few studies reported intervention effect sizes or the clinical meaning of any effects detected and, so, it was difficult to discern the effect of interventions for trials which could not be pooled in a meta-analysis. Psychosocial interventions appeared to exert variable effects on patient and caregiver outcomes, for example, small to large effects on patient QoL were reported, small or no intervention effects on caregiver physical health status, and small to large effects on patient physical health status. No intervention effect was reported for caregiver- QoL, -depression, -anxiety and -psychological distress or patient-psychological distress. The apparent discrepancy between pooled and unpooled results may be explained in terms of differences regarding the quality of evidence, the clinical heterogeneity of study samples and the range of diverse outcome measures all of which made it difficult to draw conclusions across studies.

Whilst there may be some benefits for patients and caregivers, evidence suggested that some interventions may impact negatively on participants. Participants in three trials reported adverse effects including increased distress (Manne 2011; McCorkle 2007) and discomfort with intervention content (Robertson 2016). All three studies consisted of spousal couples who were facing prostate cancer. Intervention content did not appear to differ for spouses facing prostate cancer and who experienced or did not experience adverse effects. However, it is possible that further refinement and tailoring may be required in order to improve the match between the needs of particular couples and the intervention.

Two further objectives of the review were to investigate the extent to which different modes of intervention delivery and setting influenced outcomes and whether there was an association between number and duration of intervention sessions and degree of change in measured outcomes. Due to the level of heterogeneity across the studies, we were unable to undertake formal statistical analyses based on a priori subgroups and, therefore, subgroup analysis was addressed in a narrative discussion. However, most studies reported small or negligible effects and for most outcomes there were only a small number of studies contributing to the analysis for each comparison so these questions remain unanswered. Overall, there was insufficient evidence to determine whether outcomes were influenced by whether an intervention was delivered to caregivers only or caregiver-patient dyads or the nature of the relationship between caregiver and patient (i.e. spousal or parent-child, sibling, friendship etc.) or for one delivery format over another (i.e. face-to-face versus telephone).

It was difficult again to discern from the data which components or permutations of components were effective. Also, the mechanism by which intervention effects might have occurred was un-

clear. Moreover, the timing of outcome assessment may further complicate the understanding and interpretation of results across assembled studies. For example, study authors could not explain why their intervention led to improvements in terms of reduced 'bother with bowels' for men with prostate cancer, particularly given that receipt of surgery (which all study participants received) has typically less impact on bowel function than radiotherapy. It is possible that multiple testing (without correction) led to a spontaneous significant result as the Expanded Prostate Cancer Index Composite Scale (EPIC) tool has 14 subscales and was only one of a number of outcome measures used (Campbell 2007). Moreover, results were both positive and negative across domains of the EPIC highlighting inconsistent effects of the intervention.

We were unable to assess the extent to which caregivers and patients were satisfied with the interventions that they received as this outcome was not assessed by the included studies. Although psychosocial interventions did not appear to be effective for caregivers or patients in terms of most outcomes, they demonstrated good feasibility and acceptability by participants. It is possible that absence of evidence of effectiveness may be related to the selection of the given outcomes and the way in which they were measured. Perhaps, outcome measures lacked sensitivity or there was a mismatch between intervention aims and review outcomes and that a plausible theory of change was absent. For example, the individual trials that were included in the review captured a range of outcomes which were not the focus of this review and some interventions appeared to be effective in relation to these alternative outcomes. A trial of couple-based existential therapy was designed to improve relationship functioning which, in turn, led to, for example, improvements in relationship cohesion long after the intervention had ended (Couper 2015). Also, an intervention that was informed by cognitive behavioural theory and that aimed to restore equity and relationship quality led to improvements in relationship outcomes (e.g. relationship quality and inequity) for caregivers and patients (Kuijer 2004). The aims of some interventions and their proposed mechanism of action to bring about change in outcomes did not always map onto the outcomes of interest in this review. Improvements in outcomes with respect to relationships for example, did not lead to improvements in QoL. Global measures may not be sensitive enough to capture QoL improvement related to social well-being/relationship quality; and cancer-specific measures of QoL which are specific to the impact of the disease and disease experience may not pick up changes in relationship functioning. Moreover, disease-specific QoL measures may be more sensitive to detecting changes in QoL for patients compared to global measures, however, there were no clear patterns in the effects of interventions based on type of outcome measure in this review.

Overall completeness and applicability of evidence

The high degree of statistical and clinical heterogeneity did not afford an opportunity to pool results and conduct a meta-analysis of all studies or for all outcomes or the planned subgroup or sensitivity analyses. Thus, the narrative account that is presented here is constrained in terms of the extent to which definitive statements or firm conclusions may be drawn from the review. The results of the meta-analysis should be interpreted with caution as the quality of evidence was primarily low or very low. Some of the papers also presented unclear reports or data were absent that would have been helpful to understand the effectiveness of their respective interventions. Many of the included studies also comprised small samples or had a high level of attrition, thereby limiting further the statistical power of the studies.

More specifically, detailed reports about intervention and control conditions were sparse and would not easily permit trial replication. Efforts were made to classify and group interventions according to similar components and levels of active engagement by participants using a hierarchical framework (Cunningham 1996). This approach is limited in so far as decisions about where interventions 'fit' were only as good as the information that was reported in each trial; and interventions were poorly described. Although many interventions shared the same label in terms of being psycho-educational, they varied in terms of the nature and number of components and so meaningful comparisons could not be drawn. Ideally, future trials should be designed and undertaken in a way that would enable comparisons to be made between participants who receive one or more components in order to tease out the 'active ingredients' or effective components. Only two interventions were defined as psychotherapeutic indicating that there is a need for trials evaluating the effectiveness of psychotherapeutic interventions for caregivers of people living with cancer. Additionally, it is possible that trials which assessed psychotherapeutic or other psychosocial interventions or trials which captured a wider range of outcomes may have been excluded from the review (based on the eligibility criteria that was used in the review e.g. type of outcome measure). Descriptions of the processes undertaken to develop each intervention was not reported in most studies so it is not clear if caregivers were involved in this process, meaning that interventions may not be tailored to the specific needs of caregivers and may not be effective as a result.

The general pattern of findings whereby individuals in the intervention and control groups both experienced improvements over the course of study enrolment reflects the usual trajectory for most individuals adjusting to cancer, its treatment and recovery (Couper 2006; Northouse 2000). Interventions may not be effective and outcomes may improve over time anyway as caregivers and patients come to terms with the diagnosis, treatment and adjustment to living with cancer. Also, the lack of positive impact by psychosocial interventions may be due to the profile of individuals who were recruited. Arguably, many study participants were not in high need of an intervention and several studies excluded participants who, for example, had a history of, or current psychological illness, or

were caring for an individual with advanced disease. It is possible also that participants who consented to participate may have been coping well already compared to caregiver and patients who did not participate. Anxiety and depression among some cancer caregivers may not dissipate over time and chronic borderline/clinical anxiety and chronic clinical depression may be present up to two years after diagnosis (Lambert 2012). Caregivers with a high level of need might benefit significantly from the interventions described in this review. We could not identify a pattern of intervention benefits for participants at particular stages of the care trajectory or cancer site and, so, it is not possible to say whether interventions should be administered, for example, to individuals affected by specific cancers, post-diagnosis or once acute treatment side effects have dissipated.

There was an absence of economic evaluation studies. All of the interventions were facilitated by a healthcare professional and varied in terms of their intensity and how they were delivered (i.e. face-to-face or via telephone) and thus, the level of resource needed varied greatly across studies. The conduct of economic evaluations alongside randomised controlled trials (RCTs) would discern the cost-effectiveness of psychosocial interventions administered to caregivers alongside small potential benefits on pertinent caregiver outcomes (e.g. relationship quality).

Quality of the evidence

It was not possible to undertake a GRADE assessment for each outcome in the review because information surrounding effect estimates and precision were absent therefore, readers should attend to the 'Risk of bias' assessment of individual trials. Regarding GRADE assessments, the evidence surrounding most outcomes was rated low or very low quality which was due, predominantly, to each individual trial being rated as having high risk of bias as well as evidence of imprecision of effect estimates. Therefore, there is uncertainty about the effects of psychosocial interventions on outcomes for caregivers and patients. In some cases there was evidence of inconsistency. For example, there was a high level of heterogeneity ($I^2 > 60\%$) in the pooled analysis of patient QoL immediately post-intervention and caregiver depression at three to six months post-intervention which may be attributed to differences between the two studies in terms of their respective populations (caregivers of patients from different cancer sites versus caregivers of prostate cancer patients) or, the group that was targeted by each intervention study (caregivers only versus patient-caregiver dyads).

Each individual study was rated as being at 'high risk of bias'. In general, there was poor reporting across trials, particularly in terms of the descriptions of random sequence generation and allocation concealment. Each study was rated as having 'high risk of bias' regarding detection bias due to the difficulties blinding participants to psychosocial intervention allocation and the use of self-report outcome measures meaning that participants also acted as

their own outcome assessors. Very few studies utilised appropriate intention-to-treat analysis methods to take into account real world compliance to the intervention. Protocols and trial registry records could not be sourced for the majority of studies and it was therefore difficult to assess the extent to which reporting bias was present in the studies.

Potential biases in the review process

This review was limited to interventions that were targeted towards caregivers of patients who were not in receipt of palliative care. It is possible that some potential studies may have been excluded due to limited study information regarding prognosis and health status relating to this specific patient group. Also, the exclusion of studies that compared an intervention to an attention control group may have led to the loss of potentially informative insights. The wide variation in terminology used to describe psychosocial interventions and lack of a common definition may have been a potential source of bias. Although we employed a broad inclusive search strategy, it is possible that we missed some key terms or relevant papers. Additionally, it is possible that the included outcome measures within the trials were insufficiently responsive to detecting change though we used psychometrically valid scales.

Agreements and disagreements with other studies or reviews

The results of this review concur (regarding study heterogeneity) with similar reviews addressing the effectiveness of psychosocial interventions among caregivers of individuals with diseases that were not cancer such as stroke (Legg 2011) or caregivers of palliative care patients (Candy 2011; Hudson 2010). Two reviews that also included caregivers of palliative care patients found small (Waldron 2013) or no QoL effects (Northouse 2007) of psychosocial interventions over and above usual care, thereby suggesting that the impact of psychosocial interventions on caregiver QoL may be limited. However, it should be noted that other reviews have reported small to medium effects for other outcomes such as caregiver burden, communication, relationship functioning and coping (outcomes which were not covered in this review) (Applebaum 2013; Regan 2012). Other reviews of interventions targeting caregivers of individuals affected by cancer also identified a lack of consistency in the use of outcome measures to assess the same construct (Li 2014), the lack of application of interventions in non-Western populations (Li 2014), and under-use of theoretically-driven interventions (Li 2014). Future reviews on this topic should consider a different set of outcomes (e.g. relationship and dyadic communication outcomes) beyond the outcomes captured by the current and previous reviews.

Ensuring relevance to decisions in healthcare

A consumer has provided feedback on both the protocol and review as part of standard Cochrane Consumers and Communication Group editorial processes.

AUTHORS' CONCLUSIONS

Implications for practice

Due to the absence of high-quality studies in this area it is difficult to make recommendations for practice. There is little evidence to support the use of psychosocial interventions with cancer caregivers. Evidence is inadequate to determine whether or not these interventions cause harm as only a small number of studies reported adverse effects. There is some evidence to suggest that providing interventions for cancer caregivers may slightly improve outcomes for caregivers in terms of improving quality of life (QoL), but effects on other outcomes are equivocal or unclear.

Implications for research

There is limited available evidence in this area and there is a need for more high-quality studies, particularly high-quality, adequately powered randomised controlled trials (RCTs) implementing adequate random sequence generation, allocation concealment and statistical methods such as intention-to-treat analysis. Also, most studies were conducted in the USA or other high-income countries and there is a need to conduct studies internationally representing various countries and healthcare systems elsewhere. Future studies should represent the increasingly diverse nature of cancer caregiver populations. The trials included participants that, all things being equal, appeared to be reasonably healthy in terms of their QoL

and psychological well-being. Patients and caregivers with serious complications, mental illness or cognitive impairments were excluded from participation in the studies. Future studies might consider targeting only patients and caregivers who reach clinical thresholds for anxiety, depression or psychological distress at baseline. A major difficulty with this review was the heterogeneity of studies. The use of similar, robust outcome measures with demonstrable validity and reliability in caregiver and patient populations across studies would facilitate comparison and meta-analysis. Future studies should address a wider range of outcomes that are relevant to caregivers and patients beyond those reported in this and other reviews. Future reviews should consider reviewing the outcomes of studies that include attention-control groups in order to establish whether or not these studies produce different outcomes for caregivers and patients. The pooling together of results from evaluations of psychosocial interventions to examine their effectiveness is a complicated and complex task due to poorly defined and described interventions and wide variation in the number, types and duration of included components. Further research is required regarding which ingredients or combinations of ingredients may increase the likelihood of exerting positive effects.

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2012, Issue 6. DOI: 10.1002/14651858.CD009912
* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Baucom 2009

Methods	<p>Study design: pilot randomised controlled trial</p> <p>Intention-to-treat analysis or per-protocol analysis: participants were analysed according to the groups to which they were originally assigned</p> <p>Country of study: USA</p> <p>Language of publication: English</p>
Participants	<p>Target intervention group: spousal caregiver/patient dyads (Intervention: N = 8; Control: N = 6)</p> <p>Participant characteristics: male partners of female breast cancer patients (stage I and II). Caregivers median age = 50 years and 86% Caucasian</p>
Interventions	<p>Nature of intervention: relationship enhancement intervention which aims to improve communication and share feelings</p> <p>Content: developed from a Cognitive Behavioural approach including medical education, emotional and self-esteem support, communication, problem-solving, decision-making and sexual adaption</p> <p>Duration: six 75-minute biweekly dyad sessions.</p> <p>Setting: outpatient setting.</p> <p>Delivery by: therapists who were advanced clinical psychology doctoral students</p> <p>Standardised versus non-standardised protocol: Detailed intervention manual used</p> <p>Control group: treatment as usual to include list of community resources for support</p>
Outcomes	<p>Assessment time points: baseline (pre-intervention), post-treatment and 12 months post-treatment</p> <p>Caregiver psychological distress: Brief Symptom Inventory (BSI)</p> <p>Patient QoL: Functional Assessment of Cancer Therapy- Breast (FACT-B) functional well-being subscale</p> <p>Patient psychological distress: Brief Symptom Inventory (BSI)</p> <p>Patient physical health status: Rotterdam Symptom Checklist (RSC)</p> <p>Other caregiver outcomes captured by the study: relationship functioning (Quality of Marriage Index (QMI), Derogatis Inventory of Sexual Functioning (DISF-SR)), psychological functioning (Posttraumatic Growth Inventory (PGI))</p> <p>Other patient outcomes captured by the study: relationship functioning (Quality of Marriage Index (QMI), Derogatis Inventory of Sexual Functioning (DISF-SR)), psychological functioning (Posttraumatic Growth Inventory (PGI), Self-image Scale (SIS)), cancer-related symptoms (Brief Fatigue Inventory (BFI), Brief Pain Inventory (BPI))</p> <p>Each measure is valid and reliable. The study authors assessed the reliability of each measure at each assessment point</p>
Notes	<p>Funding: National Cancer Institute USA and Lineberger Comprehensive Cancer Centre</p> <p>Ethical approval: Medical Centre Institutional Review Board.</p> <p>Other: outcome data were extracted for post-treatment (first post-intervention time point) and 12-months post-treatment (last post-intervention time point)</p>

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "using a computer-based random number generator." page 279
Allocation concealment (selection bias)	Unclear risk	Quote: "a staff member randomly assigned couples to one of the two treatment conditions." Page 279. There is no further information available regarding how subsequent allocation were concealed from the research staff or participants
Incomplete outcome data (attrition bias) All outcomes	Low risk	Explained loss to follow-up and demonstrated attrition was balanced between the groups (between initial assessment and pre-intervention- Intervention group: caregiver (N = 1) and patient (N = 1) and, post-test and follow-up - Control: patient (N = 1) . Participants were analysed according to the groups to which they were originally assigned. Data from participants who completed follow-up assessments were analysed
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered, it was not possible to blind participants or researchers to participant allocation
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also became outcome assessors

Blanchard 1996

Methods	<p>Study design: randomised controlled trial</p> <p>Intention-to-treat analysis or per-protocol analysis: Participants were analysed according to the groups to which they were originally assigned</p> <p>Country of study: USA</p> <p>Language of publication: English</p>
Participants	<p>Target intervention group: caregiver (Intervention: N = 30; Control: N = 36)</p> <p>Participant characteristics: spousal caregivers of patients from a number of cancer sites with the majority breast cancer (Intervention = 55%, Control = 44%) and stage (diagnosed more than three months before and not eligible for hospice care). Intervention = 40% male, 100% white, mean age = 55 years. Control = 61% male, 94% white, mean age = 50 years</p>
Interventions	<p>Nature of intervention: problem-solving intervention</p> <p>Content: problem-solving, managing patients needs, communication, using problem-solving skills for self-care and emotional support</p> <p>Duration: four to six individual counselling sessions</p> <p>Setting: outpatient setting</p> <p>Delivery by: oncology social worker</p> <p>Standardised versus non-standardised protocol: standardised 'Coping with Cancer' protocol was used</p> <p>Control group: treatment as usual</p>
Outcomes	<p>Assessment time points: baseline (pre-intervention), immediately post-intervention and 6 months post-baseline</p> <p>Caregiver QoL: SF20</p> <p>Patient QoL: Functional living Index-Cancer (FLIC)</p> <p>Caregiver depression: Centre for Epidemiological Depression Scale (CESD)</p> <p>Caregiver anxiety: State-Trait Anxiety Inventory (STAI)</p> <p>Patient depression: CESD</p> <p>Patient physical health status: SF20 physical health status subscale</p> <p>Other caregiver outcomes assessed by the study: marital relationship (Dyadic Adjustment Scale), support (Health and Daily Living Social Functioning subscale), burden (Zarit Burden Inventory (ZBI), Lawton Caregiving Appraisal Composite Scale - Caregiving Mastery and Caregiving Satisfaction subscales, Montgomery and Borgatta Burden Scale (post-treatment only), help-seeking (Help Seeking Coping Index), Coping (Index of Coping Responses), pressing problems (rate a series of care-giving activities), drug and alcohol use (days in past week) and personal change (Personal Change Index)</p> <p>Other patient outcomes assessed by the study: Health Status (SF20: pain, role functioning, mental health, social functioning and health perceptions subscales), marital relationship (Dyadic Adjustment Scale) and help-seeking (Help Seeking Coping Index)</p> <p>The authors indicate that the measures used were valid and reliable</p>
Notes	<p>Funding: the American Cancer Society</p> <p>Ethical approval: not described</p> <p>Other: initial report of trial by Toseland 1995 describes shorter follow-up period. Outcome data were extracted for immediately post-intervention (first time point post-intervention) and six months post-baseline (last time point post-intervention)</p>

Blanchard 1996 (Continued)

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "We relied on randomization to create equivalent treatment and control conditions" page 4. Insufficient information available
Allocation concealment (selection bias)	Unclear risk	Quote: "We relied on randomization to create equivalent treatment and control conditions" page 4. Insufficient information available
Incomplete outcome data (attrition bias) All outcomes	High risk	Imbalance in numbers of missing data across the two groups (Intervention = 31.8%; Control = 14.2%). Reasons are described on page 5. Intention-to-treat analysis (available-case analysis) was undertaken
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to participant allocation
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

Budin 2008

Methods	Study design: randomised controlled trial Intention-to-treat or per-protocol analysis: authors state use of a modified intention-to-treat analysis (no description reported) Country of study: USA Language of publication: English
Participants	Target intervention group: 249 patient-partner dyads (assigned to one of four groups). (Control = 59, I1 = 66, I2 = 66, I3 = 58) Participant characteristics: early stage breast cancer patients, 54% spousal partner, 12% daughter, 34% other. 58% male, 70% Caucasian, 13% African American, 7% Hispanic, 10% other. Mean age = 51.6 years. Breakdown of demographics for each intervention arm not given, however groups were equivalent in sociodemographic characteristics

Interventions	<p>Intervention group 1</p> <p>Nature of intervention: standardised psycho-education (SE)</p> <p>Content: coping with diagnosis, recovering from surgery, understanding adjuvant therapy and your ongoing recovery under the broad topics of health-relevant information, information on skill development to facilitate effectiveness of coping and psychosocial support. Based on Lazarus and Folkman's (1984) Stress and Coping theory</p> <p>Duration: four, one-hour videos</p> <p>Setting: not clear</p> <p>Delivery by: video-delivered</p> <p>Standardised or non-standardised protocol: standardised protocols, however, tailoring to the perspective, role and needs of the group was permitted</p> <p>Intervention group 2</p> <p>Nature of the intervention: teleconference intervention (TC)</p> <p>Content: reduce anxiety, shape reality-based appraisals, facilitate coping strategies and attainment of support, process information, encourage adaptive behavioural change, promote functional communication and promote re-integration of a holistic concept of self under the framework of providing health-relevant information, skill development and psychosocial support</p> <p>Duration: four sessions</p> <p>Setting: Not clear</p> <p>Delivery by: telephone-based by nurse interventionists</p> <p>Standardised or non-standardised protocol: tailor made for each patient-partner dyad</p> <p>Intervention group 3</p> <p>Nature of the intervention: combination of interventions 1 and 2</p> <p>Control group: treatment as usual</p> <p>The four time points described above occur over the course of the care trajectory: diagnostic phase, postsurgical phase, adjuvant therapy phase and ongoing recovery phase (two weeks after completion of chemotherapy or radiotherapy or 6 months after surgery)</p>
Outcomes	<p>Assessment time points: T0 Baseline, T1 diagnostic phase (when diagnosis was determined), T2 postsurgical phase (2 days after surgery), T3 adjuvant therapy (when making decisions about therapy) and T4 ongoing recovery phase (2 weeks after completion of chemotherapy or radiation or 6 months after surgery)</p> <p>Caregiver physical health status: overall health status score from the Multi-level Assessment Instrument</p> <p>Patient physical health status: overall health status score from the Multi-level Assessment Instrument</p> <p>Other caregiver outcomes assessed: social adjustment (Vocational, Domestic and Social environment subscales of the Psychosocial Adjustment to Illness Scale (PAIS)), physical adjustment (Physical Symptoms subscale of the Profile Adaptation to Life- Clinical Scale (PAL-C)) and emotional adjustment (Psychology well-being subscale of the PAL-C)</p> <p>Other patient outcomes assessed: social adjustment (Vocational, Domestic and Social environment subscales of the Psychosocial Adjustment to Illness Scale (PAIS)), physical adjustment (side-effect severity scale of the Breast Cancer Treatment Response Inventory (BCTRI)) and emotional adjustment (Psychology well-being subscale of the PAL-C and Side-effect distress scale of the BCTRI)</p> <p>All measures were valid and reliable.</p>

Notes	Funding: National Cancer Institute Ethical Approval: not reported Other: due to intervention occurring across multiple time points of data collection, data for the review were extracted for T4 only	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	“Quote: A randomised block design was used” Page 202. No other information available
Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of 'low risk' or 'high risk'
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Missing data variable according to group allocation (Partners - DM: N = 26, SE: N = 32, TC: N = 36 and SE + TC: N = 29) and (Patients - DM: N = 9, SE: N = 21, TC: N = 24 and SE + TC: N = 18) with similar reasons for missing data across groups though specific numbers according to each reason are not reported. A modified intention-to-treat analysis method was reported but it is not clear how this was conducted and what effect this would have had on imputed values for missing outcome data
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated interventions and outcomes were also self-reported
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

Bultz 2000

Methods	Study design: quasi-randomised controlled trial intention-to-treat or per-protocol analysis: participants were analysed according to the groups to which they were originally assigned Country of study: Canada Language of publication: English	
Participants	Target intervention group: spousal caregivers of breast cancer patients Participant characteristics: thirty-six spouse/partner caregivers (Intervention n = 17 and Control n = 19) of early stage breast cancer (Stage 1-2), 100% male, average age 50 years	
Interventions	Nature of intervention:brief psychoeducational group programme Content: group work programme focused on medial and psychosocial information, marital relationships, communication and sexual issues . Fears, concerns and challenges Duration: six sessions delivered for 1.5-2 hours per week Setting: not described Delivered by: two experienced psychologists Standardised versus non-standardised protocol: first two sessions standardised, four sessions relatively unstructured Control group: waiting-list control	
Outcomes	Assessment time points: pre-intervention, at the end of the intervention and at three months post-intervention Caregiver Depression: POMS Depression subscale Caregiver Anxiety: POMS Anxiety subscale Patient Depression: POMS Depression subscale Patient Anxiety: POMS Anxiety subscale Other caregiver outcomes assessed: mood states (POMS anger, fatigue, confusion and vigour subscales and total mood disturbance), marital satisfaction (Index of Marital Satisfaction (IMS)) and Social Support (DUKE-UNC Functional Social Support Scale (FSSS)), open-ended questions to evaluate the intervention Other patient outcomes assessed: Mental Adjustment to Cancer (Mental Adjustment to Cancer Scale (MAC)), mood states (POMS anger, fatigue, confusion and vigour subscales and Total Mood disturbance), marital satisfaction (Index of Marital Satisfacation (IMS)) and Social Support (DUKE-UNC Functional Social Support Scale (FSSS)), open-ended questions to evaluate the intervention All measures were reliable and valid.	
Notes	Funding: Alberta Cancer Board Ethical approval: the Medical Ethics Board Other: outcome data were extracted for immediately post-intervention (first time point post-intervention). Data could not be extracted for individual anxiety and depression subscales of the POMS as analysis was done at the Total Mood Disturbance level at the 3month post-intervention (last time point post-intervention) time point	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Bultz 2000 (Continued)

Random sequence generation (selection bias)	High risk	Quote: "...they were randomly assigned to the intervention group by drawing six of the 12 names from an envelope. The remaining six partners were assigned to the control group." Page 306
Allocation concealment (selection bias)	High risk	Allocation following baseline measures were completed.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Two participants dropped out of the intervention group following group allocation (completed intervention but did not complete follow-up assessment). Participants were analysed in the groups to which they were originally assigned
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated interventions and outcomes were also self-reported
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

Campbell 2007

Methods	Study design: pilot randomised controlled trial intention-to-treat or per-protocol analysis: participants were analysed according to the groups to which they were originally assigned Country of study: USA Language of publication: English
Participants	Target intervention group: patient-spousal/intimate partner dyads (Intervention N = 12, Control N = 18) Caregiver characteristics: spouses or intimate partners of African-American men with early stage prostate cancer who were no longer in an active treatment phase, 100% female, average age = 58.3 years
Interventions	Nature of intervention: coping skills intervention. Content of intervention: medical information, physical, emotional and social side effects, marital relationships, communication skills, muscle relaxation, activity-rest cycles and cognitive restructuring. Based on a cognitive behavioural approach

	<p>Duration of intervention: one session a week for six weeks</p> <p>Setting: telephone</p> <p>Delivery: telephone-delivered by Africa-American doctoral level medical psychologist</p> <p>Standardised versus non-standardised protocol: standardised</p> <p>Control group: usual care</p>
Outcomes	<p>Assessment time points: baseline, pre-intervention and at the end of the intervention (6 weeks later)</p> <p>Caregiver QoL: Caregiver Strain Index (CSI)</p> <p>Patient QoL: Expanded Prostate Cancer Index Composite Scale (EPIC)</p> <p>Caregiver depression: Profile of Mood States- Short Form (POMS) Depression subscale</p> <p>Caregiver anxiety: POMS anxiety subscale</p> <p>Patient Physical Health status: Physical Component Score of the SF-36</p> <p>Other caregiver outcomes assessed: mood states (POMS anger, fatigue, confusion and vigour subscales), self-efficacy (Self-Efficacy for Symptom Control Inventory (SESCI)), evaluation of the intervention</p> <p>Other patients outcomes assessed: self-efficacy (Self-Efficacy for Symptom Control Inventory (SESCI)), evaluation of the intervention</p> <p>All measures were valid and reliable. Outcome assessments were administered via telephone</p>
Notes	<p>Funding: American Cancer Society</p> <p>Ethical approval: Institute review board</p> <p>Other: outcome measures are labelled as they were operationalised within the original study</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information about the sequence generation process to permit judgement of 'low risk' or 'high risk'
Allocation concealment (selection bias)	High risk	Did not randomise participants to intervention or control group until after recruitment and baseline measures had been completed
Incomplete outcome data (attrition bias) All outcomes	High risk	Nine couples dropped out of the intervention, no reasons reported. One further couple excluded from analysis based on outlier analysis. Quote: "...differential attrition was of concern... examination of demographic data and baseline measures did not reveal a pattern of systematic attrition." (Page 419). Attrition may be attributed to the intervention. Participants were analysed according to the groups to which they were originally

Campbell 2007 (Continued)

		assigned
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated interventions
Blinding of outcome assessment (detection bias) All outcomes	High risk	Though measures were self-reported they were administered via telephone whereby the interviewer was also the interventionist

Couper 2015

Methods	Study design: randomised controlled trial intention-to-treat or per-protocol analysis: intention-to-treat analysis reported (no description of the process) Country of study: Australia Language of publication: English
Participants	Target intervention group: patient-spouse dyads of localised prostate cancer (Intervention N = 30, Control N = 32) Participant characteristics: 100% of partners were female and 100% spousal partner, mean age of caregiver in intervention group = 60 years, mean age of caregiver in control group = 62 years. No breakdown of demographics in each arm of the study
Interventions	Nature of intervention: Cognitive Existential Couple Therapy Content of intervention: combined supportive, existential and cognitive therapy approaches to assist couples to develop a positive attitude and use adaptive coping strategies. Based on Supportive-expressive therapy, cognitive-behavioural therapy and existential psychotherapy Duration: sessions delivered for 60-90 minutes weekly for 6 weeks Setting: individual couple sessions, outpatient setting in treating cancer hospital Delivery by: mental health specialists with experience in cancer Standardised protocol versus non-standardised protocol: standardised as per treatment manual Control group: standard care group
Outcomes	Assessment time points: baseline, pre-treatment, (T0), 10 weeks post T0 (T1), and 9 months post T0 (T2) Caregiver psychological distress: Mental Health Index (MHI) psychological distress subscale Patient psychological distress: Mental Health Index (MHI) psychological distress subscale Other caregiver outcomes assessed: relationship function (Family Relationship Index), Coping (Brief COPE), cancer-specific distress (Impact of Events Scale- Revised (IES-R))

	Other patient outcomes assessed: relationship function (Family Relationship Index), coping (Brief COPE), cancer-specific distress (Impact of Events Scale- Revised (IES-R)) All measures were valid and reliable.	
Notes	Funding: Beyond blue Ethical approval: Institutional Human Research Ethics committee Other: outcome data were extracted for T1 (first time point post-intervention) and T2 (last time point post-intervention)	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "...random assignment was performed (in blocks of four) using an external computerised service" Page 36
Allocation concealment (selection bias)	Low risk	Quote: "...random assignment was performed (in blocks of four) using an external computerised service, ensuring allocation concealment" Page 36
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar rates and reasons for loss to follow-up and withdrawal between treatment (N = 7) and control groups (N = 4). intention-to-treat analysis reported but no description given
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated interventions and all outcomes were self-reported
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

Heinrich 1985

Methods	<p>Study design: quasi-randomised controlled trial</p> <p>Intention-to-treat or per-protocol analysis: participants were analysed according to the groups to which they were originally assigned</p> <p>Country of study: USA</p> <p>Language of publication: English</p>
Participants	<p>Target intervention group: patient-spouses dyads (Intervention N = 12, Control N = 13)</p> <p>Participant characteristics: mixed cancer sites and stage not specified. Further information on caregiver sample not provided</p>
Interventions	<p>Nature of intervention: Stress and Activity Management</p> <p>Content of intervention: groups focused on sharing feelings, information and applying information, stress management, relaxation. Walking component. Participants also received a manual and tape recordings. Based on a cognitive behavioural approach</p> <p>Duration: two hours once weekly for 6 weeks .</p> <p>Setting: group delivery. Outpatient hospital setting</p> <p>Delivered by: study authors</p> <p>Standardised versus non-standardised: participants receive a manual and the intervention is described as 'structured'</p> <p>Control group: usual care</p>
Outcomes	<p>Assessment time points: baseline/pre-intervention (self-report questionnaire measures and PAIS interview), immediately post-intervention (self-report questionnaire measures and PAIS interview), 2-months post-intervention (interview) and 4-months post-intervention (interview)</p> <p>Caregiver depression: Symptom Checklist-90-Revised (SCL-90-R) Depression subscale</p> <p>Caregiver anxiety: SCL-90-R Anxiety subscale</p> <p>Patient depression: SCL-90-R Depression subscale*</p> <p>Patient anxiety: SCL-90-R Anxiety subscale*</p> <p>Other caregiver outcomes assessed: unvalidated 6-point QoL scale, level of cancer knowledge (Cancer Information Test (CIT)), impact of illness (PAIS), activity log (Daily Activity Diary), evaluation of care (Evaluation of Current Care (ECC)), interview regarding use of strategies, attendance and recommendation of intervention (immediately post-intervention only) and interview of frequency and effectiveness of strategies, would participants re-attend or recommend groups (2 months post-intervention only)</p> <p>Other patient outcomes assessed: unvalidated six-point QoL scale, level of cancer knowledge (Cancer Information Test (CIT)), impact of illness (PAIS), activity log (Daily Activity Diary), evaluation of care (Evaluation of Current Care (ECC)), interview regarding use of strategies, attendance and recommendation of intervention (immediately post-intervention only) and interview of frequency and effectiveness of strategies, would participants re-attend or recommend groups (two months post-intervention only)</p> <p>Unless where indicated, all measures were valid and reliable</p>
Notes	<p>Funding: not described</p> <p>Ethical Approval: not described</p> <p>Other: the four-month interview could not be conducted due to participant attrition.</p> <p>*Data relating to patient anxiety and depression were not extracted as only a proportion of patient caregivers participated in the trial</p>

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "A condition remained open until a minimum of 5 or a maximum of 10 subjects had entered the condition, and no additional subjects could complete their evaluation within 1 week of the other subjects' completed evaluation. When one condition closed the other condition opened. The first condition to open was the treatment condition and this was determined randomly." Page 440
Allocation concealment (selection bias)	High risk	Quote: "A condition remained open until a minimum of 5 or a maximum of 10 subjects had entered the condition, and no additional subjects could complete their evaluation within 1 week of the other subjects' completed evaluation. When one condition closed the other condition opened. The first condition to open was the treatment condition and this was determined randomly." Page 440
Incomplete outcome data (attrition bias) All outcomes	High risk	Provided little detail on study dropouts and high attrition rates at the second follow-up precluded any further analysis being conducted. Not every dropout was accounted for
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated interventions
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors. The PAIS interviewer was blinded to group allocation

Kozachik 2001

Methods	<p>Study design: randomised controlled trial</p> <p>Intention-to-treat or per-protocol analysis: participants were analysed according to the groups to which they were originally assigned</p> <p>Country of study: USA</p> <p>Language of publication: English</p>
Participants	<p>Target intervention group: patient-caregiver dyad (Intervention N = 61, Control N = 59)</p> <p>Participant characteristics: cancer site (Breast: Intervention N = 27 (44%), Control N = 28 (48%)), Stage (Early: Intervention N = 26 (43%), Control N = 31 (53%)). Caregivers: female 33%, Intervention N = 33 (53%), Control N = 28 (48%), mean age Intervention 51.3 years, Control 53.0 years</p>
Interventions	<p>Nature of intervention: supportive nursing intervention</p> <p>Content: focused on decision-making, care strategies, problem-solving, self-efficacy and using available resources. Based on a family care model</p> <p>Duration: five fortnightly face-to-face meetings and 4 individual telephone calls (nine contacts) over the course of 16 weeks</p> <p>Setting: outpatient and telephone</p> <p>Delivered by: nurses</p> <p>Standardised versus non-standardised: directed by dyads based on needs during intervention</p> <p>Control group: not described</p>
Outcomes	<p>Assessment time points: baseline- pre-intervention, six weeks post baseline (mid-intervention) and 24 weeks post-baseline (immediately post-intervention)</p> <p>Caregiver depression: Centre for Epidemiological Studies- Depression scale (CES-D)</p> <p>Patient depression: CES-D</p> <p>Other caregiver outcomes assessed: none</p> <p>Other patient outcomes assessed: symptom experience (study-specific)</p> <p>The CES-D is a valid and reliable measure, the symptom checklist is an unvalidated study-specific measure</p>
Notes	<p>Funding: not reported</p> <p>Ethical Approval: Institute Review Board</p> <p>Other: outcome data were extracted for the 24 weeks post-baseline time point only</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "...were randomly assigned...randomized within each treatment site and stratified by site of cancer and caregiver employment status..." Page 1151 Insufficient information about the sequence generation process to permit judgement of 'low risk' or 'high risk'

Kozachik 2001 (Continued)

Allocation concealment (selection bias)	Unclear risk	Quote: "...were randomly assigned...randomized within each treatment site and stratified by site of cancer and caregiver employment status..." Page 1151 Insufficient information about the sequence generation process to permit judgement of 'low risk' or 'high risk'
Incomplete outcome data (attrition bias) All outcomes	High risk	Higher attrition in the intervention group (N = 21) compared to the control group (N = 10), reasons for attrition not reported. Participants were analysed according to the groups to which they were originally assigned
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated interventions
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

Kuijer 2004

Methods	Study design: randomised controlled trial Intention-to-treat or per-protocol analysis: participants were analysed according to the groups to which they were originally assigned (only participants with at least complete data records at T2 were included in the analyses) Country of study: the Netherlands Language of publication: English
Participants	Target participant group: spouse-patient dyads 59 spousal caregivers (Intervention N = 32, Control N = 27) Participant characteristics: mixed cancer sites (breakdown of cancer sites not reported), advanced stage (56%), caregivers mean age = (Intervention = 49 years, Control = 50 years)
Interventions	Nature of the intervention: brief couples counselling Content of intervention: the sessions focused on mutual support, sense of inequity, enhancing relationship quality and well-being. Based on Cognitive behavioural theory Duration: five 90-minute sessions over eight weeks, delivered bi-weekly Setting: outpatient hospital setting

	<p>Delivered by: face-to-face, led by a psychologist</p> <p>Standardised versus non-standardised: use of hypothetical stories was standardised across the intervention</p> <p>Control group: waiting-list control (began 2 months post-baseline, once experimental group had completed the intervention)</p>
Outcomes	<p>Assessment time points: baseline- pre-intervention, one week post-intervention and three-months post-intervention for the experimental group. Control participants completed questionnaires at 4 time points, twice before the intervention, one week post-intervention and three-months post-intervention</p> <p>Caregiver depression: CES-D*</p> <p>Patient depression: CES-D*</p> <p>Other caregiver outcomes assessed: perceptions of inequity (study-specific scale developed) and relationship quality (Ladder of 0-10)</p> <p>Other patient outcomes assessed: perceptions of inequity (study-specific scale developed) and relationship quality (Ladder of 0-10)</p> <p>The CES-D is a valid and reliable measure, there is no information regarding the psychometric validity or reliability of the other study measures</p> <p>*In this study, the CES-D was used to measure psychological distress, however, the CES-D was developed, and is most commonly used, to measure depression. Thus data regarding CES-D in this study contributed towards our depression outcome</p>
Notes	<p>Funding: Dutch Cancer Society</p> <p>Ethical approval: not described</p> <p>Other: the three-month assessment time point of the experimental group coincides with post-intervention assessment of the waiting-list control group. Therefore, outcome data were only extracted from the post-intervention assessment point for the experimental group and the coinciding time point for the waiting-list control group</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "...were randomly allocated to the experimental group or waiting-list group." Page 324. Insufficient information about the sequence generation process to permit judgement of 'low risk' or 'high risk'
Allocation concealment (selection bias)	Unclear risk	Quote: "...were randomly allocated to the experimental group or waiting-list group." Page 324. Insufficient information about the sequence generation process to permit judgement of 'low risk' or 'high risk'
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar rates and reasons for incomplete data across both groups. Participants were analysed according to the groups to which they were originally assigned

Kuijer 2004 (Continued)

Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated interventions
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

Kurtz 2005

Methods	Study design: randomised controlled trial Intention-to-treat or per-protocol analysis: participants were analysed according to the groups to which they were originally assigned (Only cases available at least one wave of data were included in the analysis) Country of study: USA Language of publication: English
Participants	Target intervention group: patient-family caregiver dyads (Intervention = 118 , Control = 119) Participant characteristics: Intervention group female (55.6%), Caucasian (94.0%), mean age = 55.2 years, patient cancer site breast n = 47 (39.8%) patient late stage of disease (65.8%) Control group female (51.3%), Caucasian (89.9%), mean age = 55.1 years, patient cancer site breast n = 46 (38.7%) patient late stage of disease (68.1%)
Interventions	Nature of intervention: symptom control intervention Content: sessions focused on information, caring skills, communication with healthcare professionals, plan and evaluate care strategies. Manage effects of role strain and burden on relationship. Increase self-confidence and maintain social support. Based on a Cognitive Behavioural Model Duration: five face-to-face contacts and five telephone contacts, alternating every two weeks for a total of 20 weeks Setting: outpatient hospital setting and telephone Delivery by: nurses Standardised versus non-standardised: based on protocol of symptoms and related interventions Control group: usual care
Outcomes	Assessment time points: baseline- pre-treatment, 10-weeks (mid-intervention) and 20-weeks (at the end of the intervention) Caregiver QoL: SF36 social functioning subscale Caregiver depression: CES-D Patient depression: CES-D

	Patient physical health status: SF-36 Physical functioning subscale Other caregiver outcomes assessed: social functioning (SF-36 Social functioning subscale) , caregiver involvement in symptom management (Symptom assistance index), mastery in tasks of caring (seven-item scale) Other patient outcomes assessed: social functioning (SF-36 Social functioning subscale) , Symptom severity (15-symptom scale) The CES-D and SF-36 are well validated and reliable measures	
Notes	Funding: National Cancer Institute Ethical approval: not described in the article Other: outcome data were extracted from the 20-week time point only. Cannot extract data relating to patient QoL i.e. SF36 social functioning subscale for patient QoL as patient physical health status was extracted from the SF36 physical functioning subscale	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "...dyads were stratified by the patient's cancer site and then randomised into either..." Page 114. Insufficient information about the sequence generation process to permit judgement of 'low risk' or 'high risk'
Allocation concealment (selection bias)	Unclear risk	Quote: "...dyads were stratified by the patient's cancer site and then randomised into either..." Page 114. Insufficient information about the sequence generation process to permit judgement of 'low risk' or 'high risk'
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Ninety-eight dyads were lost to follow-up during the study (retention rates at week 20 IV: 66.7% versus C: 71.4%), no details as to why participants dropped out are reported and if this was different across groups. Study author's attrition analysis found that patients with late stage disease and lung cancer and carers with worse base-line physical functioning were more likely to drop out over the course of the study
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated

Kurtz 2005 (Continued)

		interventions
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

Ledderer 2013

Methods	Study design: pilot randomised controlled trial Intention-to-treat or per-protocol analysis: participants were analysed according to the groups to which they were originally assigned Country of study: Denmark Language of publication: English
Participants	Target intervention group: relative-patient dyads (Intervention N = 20, Control N = 22) Participant characteristics: Intervention group: mean patient age = 63.9 years, mean relative age = 54.4 years, patient gender female N = 18, caregiver gender male N = 11, type of relative: spouse N = 11 spouse, cancer type, gynaecological N = 15, N = 4. Control group: mean patient age = 61.1 years, mean relative age = 60.1 years, patient gender female N = 20, caregiver gender male N = 17, type of relative: spouse N = 18 spouse, cancer type, gynaecological N = 15, lung N = 6
Interventions	Nature of intervention: psychosocial cancer rehabilitation intervention Content: content includes discussing everyday issues, expectations of each other, facilitate relational and emotional engagement, coping with feelings, lifestyle education, communication strategies, physical activity and opportunities to exchange experiences and create new relationships Duration: three one-hour supportive talks within two months and a five-day residential rehabilitation course within nine months of study enrolment Setting: outpatient and inpatient residential stay Delivery by: a nurse, two physiotherapists, a social worker, a dietician and a psychologist Standardised versus non-standardised: standardisation using only two nurses for talks and a log book, the residential programme had a fixed structure Control group: usual care
Outcomes	Assessment time point: baseline- pre-intervention, two months and 12 months post-baseline Caregiver QoL: WHO-Five Well-Being Index* Patient QoL: EORTC-QLQ-C30 Other caregiver outcomes measures: QoL (EORTC-QLQ-C30) Other patient outcomes assessed: well-being (WHO-Five Well-Being Index) All measures are reliable and valid *The WHO-Five Well-being Index was selected as the outcome measure for Caregiver QoL opposed to the EORTC-QLQ-C30 as this is a cancer patient-specific outcome measure

Notes	Funding: Danish Cancer Society Ethical approval: Scientific Ethics Committee in the Region of Southern Denmark Other: outcome data from the 12-month assessment time point only were extracted as this is the only time point that occurs after both components of the intervention have been delivered	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A computer program determined the 1:1 randomization...balanced in blocks. An independent statistician determined the block size to be six and programmed the randomization procedure." Page 205
Allocation concealment (selection bias)	Unclear risk	Quote: "...generated allocations were stored in sealed envelopes until the time of enrolment. The study nurse enrolled the pairs....by breaking the seal of the next envelope in line." Page 205
Incomplete outcome data (attrition bias) All outcomes	High risk	Clearly reported number of dropouts however the dropout rate was not balanced with a 22-41% dropout rate in the control group compared to 70% in the intervention group
Selective reporting (reporting bias)	High risk	Details from clinicaltrials.gov indicate that the POMS was planned to be administered also to study participants, these data are not reported in the final published study
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of intervention it is not possible to blind participants as it is clear in which group they are
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

Manne 2004

Methods	<p>Study design: randomised controlled trial</p> <p>Intention-to-treat or per-protocol analysis: participants were analysed according to the groups to which they were originally assigned</p> <p>Country of study: USA</p> <p>Language of publication: English</p>
Participants	<p>Target participant group: caregivers who were wives of men with prostate cancer (Intervention N = 29; Control N = 31)</p> <p>Participant characteristics: patient cancer stage 1-2 (80%), Caucasian (84%), mean caregiver age = 59.6 years</p>
Interventions	<p>Nature of intervention: group intervention</p> <p>Content: group work programme included medical information, nutrition, support, communication, intimacy and dealing with sexual concerns, stress management, coping skills and social support. Homework assignments</p> <p>Duration: one hourly session per week for six weeks</p> <p>Setting: outpatient</p> <p>Delivery by: two clinical psychologists, a nutritionist and a social worker</p> <p>Standardised versus non-standardised: called a 'structured' group intervention</p> <p>Control group: usual care</p>
Outcomes	<p>Assessment time points: baseline- pre-intervention and one-month post-intervention</p> <p>Caregiver psychological distress: Mental Health Inventory</p> <p>Other caregiver outcomes assessed: coping (COPE Acceptance, Positive Reappraisal and growth and denial subscales), post-traumatic growth (Post-Traumatic Growth Inventory (PTGI)) and cancer-specific marital interactions (Communications Patterns Questionnaire), cancer-specific distress (Impact of Events Scale)</p> <p>All measures are valid and reliable.</p>
Notes	<p>Funding: National Cancer Institute</p> <p>Ethical approval: not described</p> <p>Other: none</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "...randomized block design with block sizes of 14." Page 39
Allocation concealment (selection bias)	Unclear risk	There is no information reported about how allocation was concealed
Incomplete outcome data (attrition bias) All outcomes	Low risk	Four wives assigned to the intervention group and three wives assigned to the control group dropped out, though, no reasons were reported. Results did not demonstrate imbalance in characteristics between continued participation and dropouts. Groups

Manne 2004 (Continued)

		were analysed in the group to which they were originally allocated
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated interventions
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

Manne 2005

Methods	Study design: randomised controlled trial Intention-to-treat or per-protocol analysis: intention-to-treat and per-protocol analysis undertaken. No reported differences between both approaches (no description of how intention-to-treat analysis was undertaken) Country of study: USA Language of publication: English
Participants	Target intervention group: spousal patient-caregiver dyads. Early stage breast cancer patients who had undergone surgery in the past 6-months (Intervention n = 120; Control n = 118) Participant characteristics: patient mean age (Intervention = 49.25 years (SD = 10.4), Control = 49.76 years (SD = 10.5), ethnicity (intervention = 88.3% white, control = 90.7% white), at least college education (intervention = 65.8%, control = 66.9%)
Interventions	Nature of intervention: couple-focused group intervention Content: sessions focused on couple-level stress management, coping, communication concepts and skills and anticipating post-treatment transitioning. Based on a multiple family group techniques Duration: Six weekly 90-minute sessions. Setting: outpatient Delivery by: therapist Standardised versus non-standardised: manualised Control group: usual care
Outcomes	Assessment time points: baseline, one-week post-intervention and six-months post-intervention Patient depression: 18-item Mental Health Inventory (MHI-18) Depression subscale Patient anxiety: MHI-18 Anxiety subscale Patient physical health status: Cancer Rehabilitation Evaluation System (CARES) Functional Status subscale (moderator variable) Other patient outcomes assessed: loss of behavioural and emotional control (BEC)

	(MHI-18 BEC subscale), well-being (MHI-18 Wellbeing subscale), cancer-specific distress (Impact of Events Scale), partner unsupportive behaviours (Partner Unsupportive Behavior Scale), treatment expectancy, treatment evaluation and psychosocial care use	
Notes	Funding: National Cancer Institute Ethical approval: not reported Other: outcomes were only assessed for patients, though caregivers were included in the intervention	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomization was performed in blocks of 14..." Page 636 Insufficient information about random sequence generation to make a decision about low or high risk of bias
Allocation concealment (selection bias)	Unclear risk	There was no information reported about how allocation was concealed
Incomplete outcome data (attrition bias) All outcomes	Low risk	Rates of attrition were similar between groups (Intervention: 30% versus Control: 33%). Participants at Time 1 who did not complete follow-up assessments were significantly older and more likely to be married than those who completed Time 1 follow-up visits. Intention-to-treat and per-protocol analysis undertaken with no reported differences
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated interventions
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

Methods	<p>Study design: pilot randomised controlled trial</p> <p>Intention-to-treat or per-protocol analysis: intention-to-treat analysis (last value carried forward)</p> <p>Country of study: USA</p> <p>Language of publication: English</p>
Participants	<p>Target intervention group: intimate partner- prostate cancer patient dyad (Intervention N = 37, Control N = 34)</p> <p>Participant characteristics: Intervention: caregivers female = 94.6%, mean age = 55.7 years, Caucasian 86.5%, patient disease stage II = 91.9%; Control: caregivers female = 100%, mean age = 55.8 years, Caucasian 79.4%, patient disease stage II = 76.5%</p>
Interventions	<p>Nature of intervention: Intimacy Enhancing Therapy</p> <p>Content: sessions focused on improving communication, promoting discussion of mutual concerns and enhancing emotional intimacy. Intervention included homework practice assignments. Intervention developed from cognitive-behavioural and behavioural marital therapy</p> <p>Duration: five 90-minute sessions</p> <p>Setting: outpatient</p> <p>Delivery by: therapists</p> <p>Standardised versus non-standardised: treatment is manualised</p> <p>Control group: usual care</p>
Outcomes	<p>Assessment time points: baseline- pre-intervention and immediately post-intervention</p> <p>Caregiver psychological distress: Mental Health Inventory (MHI) psychological distress subscale</p> <p>Patient psychological distress: Mental Health Inventory (MHI) psychological distress subscale</p> <p>Other caregiver assessed outcomes: cancer-specific distress (Impact of Events scale), psychological well-being (Mental Health Inventory- psychological well-being subscale), cancer concerns (study-specific measure), relationship satisfaction (Dyadic Adjustment Scale (DAS)), relationship intimacy (the Personal Assessment of Intimacy in Relationships scale), self-disclosure (three-item measure), perceived partner disclosure (three-item measure), perceived partner responsiveness (four-item measure), mutual constructive communication (Communications Pattern Questionnaire (CPQ), mutual constructive communication subscale) and Demand-Withdraw Communication (CPQ Command-Withdraw subscale). Treatment evaluation of intervention (success, new learning and utility) and its components and fidelity</p> <p>Other patient assessed outcomes: cancer-specific distress (Impact of Events scale), psychological well-being (Mental Health Inventory- psychological well-being subscale), cancer concerns (study-specific measure), relationship satisfaction (Dyadic Adjustment Scale (DAS)), relationship intimacy (the Personal Assessment of Intimacy in Relationships scale), self-disclosure (three-item measure), perceived partner disclosure (three-item measure), perceived partner responsiveness (four-item measure), mutual constructive communication (Communications Pattern Questionnaire (CPQ), mutual constructive communication subscale) and Demand-Withdraw Communication (CPQ Command-Withdraw subscale) and Treatment evaluation of intervention (success, new learning and utility) and its components and fidelity</p> <p>Many of the measures are valid and reliable.</p>

Notes	Funding: National Cancer Institute Ethical approval: Institute Review Board Other: none	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "...were randomly assigned..." Page 1199 Insufficient information about the sequence generation process to permit judgement of 'low risk' or 'high risk'
Allocation concealment (selection bias)	High risk	Did not randomise participants to intervention or control group until after recruitment and baseline measures had been completed. No further information is available regarding allocation concealment
Incomplete outcome data (attrition bias) All outcomes	High risk	Reported intention-to-treat analysis (last value carried forward). Some differences across groups with the control group reporting 5 patients dropped out and 8 partner dropouts (retention rates: 85% and 76%)and intervention group 1 patient and 3 partner dropouts respectively (retention rates: 97% and 92%) ; reasons were not reported
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated interventions
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

Methods	Study design: randomised controlled trial Intention-to-treat or per-protocol analysis: participants were analysed according to the groups to which they were originally assigned Country of study: USA Language of publication: English	
Participants	Target intervention group: intimate partner-prostate cancer patient dyad (Intervention N = 54, Control N = 53) Participant characteristics: patient mean age = 59.9 years, Caucasian N = 93 (86.9%). Caregiver mean age = 56.0 years, Caucasian N = 91 (85.1%), 100% female	
Interventions	Nature of intervention: psychoeducation nursing intervention Content: intervention included: providing care, symptom management, counselling, executing care procedures, teaching self-care strategies, promoting use of community resources, encouraging use of supportive relationships and coordinating care Duration: one, one and a half hour face-to-face home session and telephone session weekly for eight weeks Setting: home and telephone Delivery by: advanced practice cancer nurse Standardised versus non-standardised: standardised protocol Control group: usual care	
Outcomes	Assessment time points: baseline- pre-intervention, one-month, three-month and six-months post radical prostatectomy Caregiver depression: CES-D Patient depression: CES-D Other caregiver outcomes assessed: sexual function (Cancer Rehabilitation Evaluation System (CARES) sexual subscale), marital interaction (CARES marital subscale) Other patient outcomes assessed: sexual function (Cancer Rehabilitation Evaluation System (CARES) sexual subscale), marital interaction (CARES marital subscale) All the measures are reliable and valid	
Notes	Funding: American Cancer Society Ethical approval: Institutional Review Board Other: intervention began following radical prostatectomy. Outcome data for time points three-months and six-months post-radical prostatectomy were extracted to coincide with the first and last follow-up post-intervention	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information about the sequence generation process to permit judgement of 'low risk' or 'high risk'
Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of 'low risk' or 'high risk'

McCorkle 2007 (Continued)

Incomplete outcome data (attrition bias) All outcomes	High risk	Similar dropout rates in intervention and control group with 8 patient/caregivers in the intervention group and 11 in the control group. Reasons for incomplete data were given but it is not clear to which groups they represent. Five participants were withdrawn by the Principal Investigator- not clear at what point these 5 participants were withdrawn and if they have been included in the analysis
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated interventions
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

Nicolaisen 2018

Methods	Study design: randomised controlled trial Intention-to-treat or per-protocol analysis: modified intention-to-treat analysis (no description given) Country of study: Denmark Language of publication: English
Participants	Target intervention group: cohabiting breast cancer patient-caregiver dyads during early treatment phase (Intervention N = 102, Control N = 96) Participant characteristics: patients 100% female with breast cancer, mean patient age = (Intervention = 54 years, Control = 52 years). Caregivers 100% male, mean caregiver age = (Intervention = 57 years, Control = 56 years)
Interventions	Nature of intervention: attachment-oriented intervention Content: intervention focused on patients care needs, providing support, communicating with healthcare providers, lifestyle, optimism, manage uncertainty, stress management, coping, social support and using resources effectively. Based upon Attachment theory Duration: four to eight intervention visits to individual couples (60-90 minutes) up to 8 weeks Setting: outpatient setting Delivered by: psychologist Standardised versus non-standardised: manualised with flexibility Control group: usual care

Outcomes	Assessment time points: baseline- prior to randomisation (T1), five-months post-surgery (Immediately post-intervention) (T2), and 10 months post-surgery (five months post-intervention) (T3) Caregiver depression: Hospital Anxiety and Depression Scale (HADS) depression subscale Caregiver anxiety: HADS anxiety subscale Patient depression: HADS depression subscale Patient anxiety: HADS anxiety subscale Other caregiver outcomes assessed: cancer-related distress (Impact of Events Scale), dyadic adjustment (Revised Dyadic Adjustment Scale) Other patient outcomes assessed: cancer-related distress (Impact of Events Scale), dyadic adjustment (Revised Dyadic Adjustment Scale) All measures are valid and reliable	
Notes	Funding: Region of Southern Denmark, The Danish Cancer Society and University of Southern Denmark Ethical approval: Health Research Ethics Committee System in Denmark Other: a number of outcomes reported in the protocol paper were not reported in the published study results paper	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Couples were randomised to the intervention or control group according to a computer-based randomisation procedure...developed by a statistician...and administered by an independent research assistant...each centre was block randomised in sequences calculated on the basis of each centre's annual number of breast cancer surgeries." Page 3 of protocol paper
Allocation concealment (selection bias)	Low risk	Quote: "All except the statistician were blinded to the block sizes and allocation sequence. Couples were phoned by the project manager and informed about randomisation allocation."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "All analyses were modified intention-to-treat analysis" Page 925 of results paper. The method of intention-to-treat analysis was not described. Imbalance of numbers lost to follow-up across intervention (n = 22; 22%) and control (n = 35, 36%) groups, however, reasons were provided and were not dissimilar with the ex-

		ception of a higher proportion in the control group failing to return questionnaires
Selective reporting (reporting bias)	High risk	There are a number of deviations between the protocol and subsequent published study results in terms of outcome reporting. A number of secondary outcomes reported in the protocol (general distress, intimacy, involvement of partner, health-related quality of life, fatigue, health economic effects and post-traumatic growth) were not reported in the published study findings
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated interventions
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

Northouse 2007

Methods	Study design: randomised controlled trial Intention-to-treat or per-protocol analysis: Participants were analysed according to the groups to which they were originally assigned Country of study: USA Language of publication: English
Participants	Target intervention group: spousal-prostate cancer patient dyads (Intervention N = 129, Control N = 134) Participant characteristics: 100% prostate cancer, 65% localised stage, 21% advanced stage, 14 % recurrent stage. Mean patient age = 63 years, mean caregiver age = 59 years, Caucasian (14%)
Interventions	Nature of intervention: supportive education intervention Content: intervention focused on patients care needs, providing support, communicating with healthcare providers, lifestyle, optimism, manage uncertainty, stress management, coping, social support and using resources effectively. Based upon a Stress and Coping framework Duration: three 90-minute home visits and two 30-minute telephone contacts over a 13-week period Setting: home visits and telephone contacts Delivered by: nurse Standardised versus non-standardised: manualised protocol Control group: usual care

Outcomes	Assessment time points: baseline- pre-intervention, four months, eight months and 12 months post-baseline Caregiver QoL: FACT-G* Patient QoL: FACT-G Caregiver Physical Health Status: SF12 Physical Component Summary Score Patient Physical Health Status: SF12 Physical Component Summary Score Other caregiver outcomes assessed: appraisal of care-giving (Appraisal of Caregiving Scales), coping (Brief Coping Orientations to Problems experienced scale), hopelessness (Beck Hopelessness Scale), self-efficacy (Lewis Self-Efficacy Scale), communication (Lewis Mutuality and Interpersonal Sensitivity Scale), general symptom distress (Omega Screening Questionnaire- Symptom subscale) Other patient outcomes assessed: cancer-related symptoms (FACT-P), appraisal of illness (Appraisal of Illness Scales), coping (Brief Coping Orientations to Problems experienced scale), hopelessness (Beck Hopelessness Scale), self-efficacy (Lewis Self-Efficacy Scale), communication (Lewis Mutuality and Interpersonal Sensitivity Scale), general symptom distress (Omega Screening Questionnaire- Symptom subscale) All measures are valid and reliable *The wording of the FACT-G was adapted to suit a non-cancer population. The amended questionnaire was not validated in a caregiver population	
Notes	Funding: National Cancer Institute Ethical approval: not described Other: outcome data were extracted for the four-month (immediately post-intervention) and 12-month time points to correspond with the first and last time points post-intervention	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information about the sequence generation process to permit judgement of 'low risk' or 'high risk'
Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of 'low risk' or 'high risk'
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data balanced in numbers across groups (Intervention group 19% and control group 15%), with similar reasons for missing data across groups. Participants were analysed according to the groups to which they were originally assigned
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper

Northouse 2007 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated interventions
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

Robertson 2016

Methods	Study design: feasibility pilot randomised controlled trial Intention-to-treat or per-protocol analysis: participants were analysed according to the groups to which they were originally assigned Country of study: Scotland Language of publication: English
Participants	Target intervention group: spouse-prostate cancer patient dyad (Intervention N = 21, Control N = 22) Participant characteristics: Intervention group: patient mean age = 64.15 years, Caucasian (100%), Control group: patient mean age: 63.27 years, Caucasian (100%)
Interventions	Nature of intervention: psychosexual support intervention Content: intervention focused on assistance, emotional disclosure, psycho-education, relational and sexual needs, dyadic adjustment and coping. Based on family systems theory and sex therapy Duration: six 50-minute sessions, one per week Setting: third sector organisation Delivered by: trained counsellor Standardised versus non-standardised: manualised Control group: usual care
Outcomes	Assessment time points: baseline- pre-intervention (T0), end of intervention (T1), and six months post-intervention (T2) Caregiver depression: Hospital Anxiety and Depression Scale (HADS) depression subscale Caregiver anxiety: HADS anxiety subscale Patient depression: HADS depression subscale Patient anxiety: HADS anxiety subscale Other caregiver outcomes assessed: family functioning in therapy (Systemic Clinical Outcome and Routine Evaluation (SCORE)), acceptability of intervention and its components Other patient outcomes assessed: (Expanded Prostate Cancer Index Composite (EPIC) sexual function subscale), family functioning in therapy (Systemic Clinical Outcome and Routine Evaluation (SCORE)), acceptability of intervention and its components All measures were reliable and valid

Notes	Funding: not described Ethical approval: NHS West of Scotland Research Ethics Committee Other: none	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "...block randomization with a 1:1 allocation ratio. The allocation sequence was computer generated using blocks of four. Randomization was carried out by a research administrator who had no involvement in the study." Page 1234
Allocation concealment (selection bias)	Unclear risk	Not enough information about how allocation was concealed.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar rates and reasons for loss to follow-up (Intervention 33% and Control 27%). Intention-to-treat analysis was undertaken. Available cases were analysed
Selective reporting (reporting bias)	High risk	Did not report use of health services and erectile dysfunction medication/technologies, collated via a self-report questionnaire designed by the investigators (as detailed in the protocol)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated interventions
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

Methods	<p>Study design: randomised controlled trial</p> <p>Intention-to-treat or per-protocol analysis: participants were analysed according to the groups to which they were originally assigned</p> <p>Country of study: London</p> <p>Language of publication: English</p>
Participants	<p>Target intervention group: caregiver of patients about to start chemotherapy (Intervention N = 24, Control N = 23)</p> <p>Participant characteristics: Intervention: mean age = 54.1 years, female N = 14 (67%), Caucasian N = 16 (76.2%), patient cancer site colorectal N = 9 (43%), breast N = 7 (33%), lung N = 5 (24%), relationship to patient spouses N = 11 (52%); Control: mean age = 51.5 years, female N = 14 (64%), Caucasian N = 15 (68%), patient cancer site colorectal N = 9 (41%), breast N = 7 (32%), lung N = 6 (27%), relationship to patient spouses N = 8 (36%)</p>
Interventions	<p>Nature of intervention: supportive education 'Take care' intervention</p> <p>Content: DVD- Information about chemotherapy, booklet (information, advice, practical tips from carers and healthcare professionals on treatment-related effects, impact of being a carer, dealing with emotions and importance for taking the time out for themselves) and group consultation (freely expressed concerns)</p> <p>Duration: 19-minute DVD, one hour group consultation pre-first chemotherapy cycle</p> <p>Setting: outpatient setting</p> <p>Delivered by: two chemotherapy nurses</p> <p>Standardised versus non-standardised: protocol-guided</p> <p>Control group: usual care</p>
Outcomes	<p>Assessment time points: baseline- pre-intervention and four weeks post-baseline</p> <p>Caregiver psychological distress: General Health Questionnaire-12 (GHQ-12)</p> <p>Other caregiver outcomes assessed: knowledge of chemotherapy and its side effects (Visual Analogue Scale), unmet needs for information (Supportive Care Needs Survey for Partners and Carers (SNCS-P&C44)), experience of care (study-specific measure), perceived confidence in supporting a friend/relative (study-specific) and acceptability of intervention (utility, fit with current care delivery and appropriateness of questionnaires used)</p> <p>Most measures were valid and reliable</p>
Notes	<p>Funding: Dimbleby Cancer Care</p> <p>Ethics approval: National Research Ethics Service Committee</p> <p>Other: none</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "...randomly assigned between the intervention and control groups by simple randomisation using a table of randomly generated numbers." Page 3071

Allocation concealment (selection bias)	Low risk	Quote: "Randomisation and group allocation were undertaken by a member of the research team not involved in recruitment." Page 3071
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reasons and rates for attrition were reported as similar. Participant characteristics were similar across study arms. Participants were analysed according to the groups to which they were originally assigned
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the interventions being delivered it was not possible to blind participants or researchers to the allocated interventions
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to group assignment and as outcomes were self-reported, participants also become outcome assessors

PAIS: Psychosocial Adjustment to Illness Scale; POMS: Profile of Mood States; QoL: quality of life; SD: standard deviation

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

Study	Reason for exclusion
Addington-Hall 1992	Includes caregivers of patients receiving palliative care
Applebaum 2015	Not a randomised controlled trial or quasi-randomised controlled trial
Applebaum 2016	Not a randomised controlled trial or quasi-randomised controlled trial
Badger 2007	Inappropriate control group - control was not usual care
Badger 2011	Inappropriate control group - control was not usual care
Badger 2013	Inappropriate control group - control was not usual care
Badger 2017	Not a randomised controlled trial or quasi-randomised controlled trial

(Continued)

Badr 2015	Includes only caregivers of patients with advanced cancer
Beaussier 2015	Intervention adopted into routine practice (results not published)
Beglund 2007	Intervention not delivered to caregivers
Belgacem 2013	Includes caregivers of patients receiving inpatient care
Berry 2017	Not a randomised controlled trial or quasi-randomised controlled trial
Bevans 2010	Not a randomised controlled trial or quasi-randomised controlled trial
Bevans 2014	Not a randomised controlled trial or quasi-randomised controlled trial
Birnie 2010	Not a randomised controlled trial or quasi-randomised controlled trial
Boele 2013	Includes only caregivers of patients with advanced cancer
Bowen 2017	Review outcomes of interest not assessed by study
Cain 1986	Intervention not delivered to caregivers
Canada 2005	Inappropriate control group - control was not usual care
Carlsson 1998	Not a randomised controlled trial or quasi-randomised controlled trial
Carter 2006	Includes only caregivers of patients with advanced cancer
Cartledge 2005	Not a randomised controlled trial or quasi-randomised controlled trial
Chambers 2008	Intervention not delivered by an healthcare professional
Chambers 2009	Inappropriate control group - control was not usual care
Chambers 2012	Duplicate
Chambers 2014	Inappropriate control group - control was not usual care
Chambers 2014a	Duplicate
Chambers 2015	Review outcomes of interest not assessed by study
Chen 2016	Not a randomised controlled trial or quasi-randomised controlled trial
Chiquelho 2011	Not a randomised controlled trial or quasi-randomised controlled trial

(Continued)

Christensen 1983	Intervention not delivered by a healthcare professional
Clark 2006	Includes only caregivers of patients with advanced cancer
Cochrane 2011	Not a randomised controlled trial or quasi-randomised controlled trial
Cohen 2006	Not a randomised controlled trial or quasi-randomised controlled trial
Collinge 2013	Inappropriate intervention: does not include instant dialogue component
Collins 2013	Not a randomised controlled trial or quasi-randomised controlled trial
Cunningham 1999	Not a randomised controlled trial or quasi-randomised controlled trial
D'Souza 2015	Not a randomised controlled trial or quasi-randomised controlled trial
Davison 2003	Inappropriate intervention: is not a psychosocial intervention
Derdiarian 1989	Review outcomes of interest not assessed by study
Dionne-Odom 2016	Includes caregivers of deceased patients
Dockman 2016	Not a randomised controlled trial or quasi-randomised controlled trial
Donnelly 2000	Not a randomised controlled trial or quasi-randomised controlled trial
Du Benske 2014	Inappropriate intervention: does not include instant dialogue component
Esbenshade 2013	Inappropriate population: children with cancer
Fergus 2013	Not a randomised controlled trial or quasi-randomised controlled trial
Follona 2013	Intervention not delivered to caregivers
Fu 2007	Includes only caregivers of patients with advanced cancer
Gessler 2015	Inappropriate control group - control was not usual care
Giarelli 2003	Review outcomes of interest not assessed by study
Giesler 2005	Intervention not delivered to caregivers
Given 2004	Review outcomes of interest not assessed by study
Given 2006	Review outcomes of interest not assessed by study

(Continued)

Goldberg 1985	Includes only caregivers of patients with advanced cancer
Grahm 1996	Not a randomised controlled trial or quasi-randomised controlled trial
Halverson 2000	Review outcomes of interest not assessed by study
Harden 2009	Not a randomised controlled trial or quasi-randomised controlled trial
Hawes 2006	Not a randomised controlled trial or quasi-randomised controlled trial
Heinrichs 2012	Review outcomes of interest not assessed by study
Hendrix 2013	Inappropriate intervention: does not include instant dialogue component
Hendrix 2016	Inappropriate control group - control was not usual care
Hoff 2005	Inappropriate intervention: is not a psychosocial intervention
Holm 2015	Includes caregivers of patients receiving palliative care
Holmes 1987	Not a randomised controlled trial or quasi-randomised controlled trial
Horowitz 2008	Not a randomised controlled trial or quasi-randomised controlled trial
Hudson 2005	Includes caregivers of patients receiving palliative care
Hudson 2015	Includes caregivers of patients receiving palliative care
Hutchison 2011	Not a randomised controlled trial or quasi-randomised controlled trial
Jepson 1999	Intervention not delivered to caregivers
Kalaitzi 2007	Inappropriate intervention: is not a psychosocial intervention
Kayser 2010	Inappropriate control group - control was not usual care
Keefe 2005	Includes caregivers of patients receiving palliative care
La Cour 2015	Not a randomised controlled trial or quasi-randomised controlled trial
La Cour 2016	Not a randomised controlled trial or quasi-randomised controlled trial
Lambert 2016	Intervention not delivered by a healthcare professional
Langer 2012	Intervention not delivered by a healthcare professional

(Continued)

Laudenslager 2015	Includes caregivers of patients who do not have cancer
Lawsin 2011	Review outcomes of interest not assessed by study
Ledderer 2011	Duplicate
Lepore 2003	Intervention not delivered to caregivers
Lewis 2008	Not a randomised controlled trial or quasi-randomised controlled trial
Lobchuk 2006	Not a randomised controlled trial or quasi-randomised controlled trial
Locke 2008	Review outcomes of interest not assessed by study
Lyons 2016	Inappropriate intervention: is not a psychosocial intervention
Mahendran 2017	Not a randomised controlled trial or quasi-randomised controlled trial
Malcarne 2002	Not a randomised controlled trial or quasi-randomised controlled trial
Manne 2010	Review outcomes of interest not assessed in this study
Mazanec 2017	Inappropriate control group - control was not usual care
McMillan 2006	Includes caregivers of patients receiving palliative care
Mishel 2002	Intervention not delivered to caregivers
Mishel 2009	Intervention not delivered to caregivers
Mokuau 2008	Review outcomes of interest not assessed by study
Mokuau 2012	Review outcomes of interest not assessed by study
Mosher 2016	Inappropriate control group - control was not usual care
Namkoong 2012	Inappropriate intervention: does not include instant dialogue component
Nejad 2016	Review outcomes of interest not assessed by study
Nezu 2003	Not a randomised controlled trial or quasi-randomised controlled trial
Northouse 2005	Includes only caregivers of patients with advanced cancer
Northouse 2013	Includes only caregivers of patients with advanced cancer

(Continued)

Northouse 2014	Inappropriate intervention: does not include instant dialogue component
Parker 2016	Inappropriate intervention: does not include instant dialogue component
Parker 2017	Not a randomised controlled trial or quasi-randomised controlled trial
Pasacreta 2000	Not a randomised controlled trial or quasi-randomised controlled trial
Paterson 2017	Includes only caregivers of patients with advanced cancer
Porter 2009	Inappropriate control group - control was not usual care
Porter 2011	Inappropriate control group - control was not usual care
Porter 2012	Inappropriate control group - control was not usual care
Rawl 2002	Intervention not delivered to caregivers
Reele 1994	Not a randomised controlled trial or quasi-randomised controlled trial
Richardson 2007	Not a randomised controlled trial or quasi-randomised controlled trial
Roberts 2002	Not a randomised controlled trial or quasi-randomised controlled trial
Robinson 1998	Not a randomised controlled trial or quasi-randomised controlled trial
Rowland 2009	Intervention not delivered to caregivers
Schover 2011	Inappropriate control group - control was not usual care
Schover 2012	Inappropriate control group - control was not usual care
Schover 2013	Inappropriate control group- control was not usual care
Schover 2015	Intervention not delivered to caregivers
Schumacher 2014	Inappropriate control group - control was not usual care
Schwartz 1998	Inappropriate control group - control was not usual care
Scott 2004	Inappropriate control group - control was not usual care
Scott 2013b	Not a randomised controlled trial or quasi-randomised controlled trial
Sefitel 2015	Not a randomised controlled trial or quasi-randomised controlled trial

(Continued)

Shaw 2016	Includes only caregivers of patients with advanced cancer
Sherwood 2012	Inappropriate control group - control was not usual care
Sherwood 2014	Inappropriate control group - control was not usual care
Shields 2004	Not a randomised controlled trial or quasi-randomised controlled trial
Silveira 2015	Inappropriate intervention: does not include instant dialogue component
Stephenson 2007	Inappropriate intervention: is not a psychosocial intervention
Sun 2017	Includes caregivers of patients receiving inpatient care
Thornton 2004	Inappropriate intervention: is not a psychosocial intervention
Todd 2002	Not a randomised controlled trial or quasi-randomised controlled trial
Toussaint 2014	Review outcomes of interest not assessed by study
Walsh 2007	Includes caregivers of patients receiving palliative care
Ward 2009	Inappropriate intervention: is not a psychosocial intervention
Watson 2017	Intervention not delivered to caregivers
Weber 2007a	Intervention not delivered to caregivers
Weber 2007b	Intervention not delivered to caregivers
Weingart 2009	Review outcomes of interest not assessed by study
Wooten 2015	Inappropriate intervention: does not include instant dialogue component
Xiao 2009	Includes only caregivers of patients with advanced cancer
Zimmermann 2011	Review outcomes of interest not assessed by study

Studies excluded due to inclusion of only caregivers of patients with advanced cancer; advanced cancer was conceptualised as life-limiting or with poor survival rates.

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

Gremore 2014

Methods	RCT
Participants	Head and neck cancer patients and their partners
Interventions	Couple-based psychosocial intervention including differentiation between problem-focused and support conversations, enhancing support communication, discussing current support needs and transitioning to survivorship support phase
Outcomes	Not reported
Notes	

Schover 2012a

Methods	RCT
Participants	Men with cancer and partners (not clear if partners are always involved)
Interventions	Website (sexual health after cancer) and telephone counselling versus intervention and patient reported outcome measure on satisfaction versus usual care
Outcomes	Not reported
Notes	

RCT: randomised controlled trial

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

Aubin 2017

Trial name or title	Multifaceted intervention
Methods	RCT
Participants	Target intervention group: lung cancer patients and their family caregivers
Interventions	Nature: supportive care Content: distress screening, privileged contact with oncology nurse and liaison between nurse and family practitioner Duration: unclear Setting: face-to-face outpatient Delivered by: nurse Control group: usual care

Aubin 2017 (Continued)

Outcomes	Patient QoL Patient psychological distress Caregiver QoL Caregiver psychological distress Other outcomes: carers unmet needs, caregiver burden, caregiver preparedness and service and healthcare utilisation
Starting date	Unknown
Contact information	Michele Aubin: Michele.Aubin@mfa.ulaval.ca
Notes	

El-Jawahri 2017

Trial name or title	Randomized trial of a psychological intervention to promote coping for caregivers of patients undergoing hematopoietic stem cell transplantation (HCT)
Methods	RCT
Participants	N = 100 to be enrolled to intervention or control groups Inclusion Criteria: Adult caregivers (≥ 18 years) of patients undergoing autologous or allogeneic Haemopoietic Stem Cell Transplantation (HSCT) and they must attend the HSCT consent visit with the patient A relative or a friend who either lives with the patient or has in-person contact with him or her at least twice per week and is identified as the primary caregiver for transplant Able to speak English or able to complete questionnaires with minimum assistance of an interpreter Exclusion Criteria: Significant uncontrolled psychiatric or other co-morbid disease, which the primary oncologist believes prohibits the ability to participate in study procedures
Interventions	Intervention: six psychological intervention sessions in-person or via video conferencing conducted by a trained psychologist. Sessions include psychoeducation component (preparedness, managing expectations and caregiving skills), psychosocial component (coping strategies, mindfulness and facilitating acceptance while living with uncertainty) and self-care component (promoting caregiver health and well-being) Control group: standard care and access to social work consultations upon request
Outcomes	Feasibility of intervention Caregiver quality of life (CARGOQOL and SF-36) at 30- and 90-days post-intervention Caregiver burden (Caregiver Reaction Assessment (CRA)) at 30- and 90-days post-intervention Caregiver mood (Hospital Anxiety and Depression Scale (HADS)) at 30- and 90-days post-intervention Caregiver self-efficacy (Cancer Self-Efficacy Scale- transplant (CASE-t) at 30- and 90-days post-intervention Caregiver stress management (Stress Management Scale of the Health-Promoting Lifestyle Profile II) at 30- and 90-days post-intervention
Starting date	1st January 2018
Contact information	

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Ferrell 2013

Trial name or title	Family caregiver palliative care intervention
Methods	Study design: RCT
Participants	Target Intervention group: caregivers of patients with Stage II-IV gastrointestinal, gynaecological, urological and lung cancer
Interventions	Nature: Caregiver Palliative Care Intervention Content: education and telephone support Duration: six months (four home education sessions once weekly and four x 30-minute telephone sessions) Setting: telephone Delivered by: advanced practice nurse Control group: usual care
Outcomes	Caregiver QoL Caregiver psychological distress Other outcomes: caregiver burden, caregiving skills preparedness, caregiver self-care behaviour, caregiver resource use, caregiver satisfaction and caregiver out-of-pocket costs
Starting date	October 2013
Contact information	Betty Ferrell
Notes	Clinical trials ID: NCT01846520

Hendrix 2017

Trial name or title	Williams LifeSkills - cancer caregiver intervention
Methods	RCT
Participants	N = 40 to be allocated to either intervention or control groups Inclusion Criteria: Patients are those with a confirmed medical diagnosis of breast or thoracic cancer regardless of stage and followed at DCC for management The cancer diagnosis should have been made less than a year from the next scheduled appointment to the DCC The caregiver is defined as unpaid individual involved in assisting the cancer patient with activities of daily living and/or medical tasks Patients and caregivers must be able to hear, read, and write in English; oriented to place, person, and time; and have an active telephone service, either cellular or land line Exclusion Criteria: Patients and caregivers who are less than 18 years of age

Hendrix 2017 (Continued)

Interventions	Intervention: learning of seven psychosocial skills Control: usual care
Outcomes	Primary outcomes: Feasibility (recruitment of dyads, consenting completion, participation in phone calls, completion of measures, retention to intervention group, recruitment for control group, interventionist completion of training) Fidelity to protocol Secondary outcomes: Caregiver quality of life (Caregiver quality of life questionnaire) Depression (HADS depression subscale) Anxiety (HADS anxiety subscale) Prepared in caregiving Social Support (Multidimensional Scale of Social Support) Quality of life (FACT-G)
Starting date	May 2017
Contact information	Cristina Hendrix cristina.hendrix@duke.edu
Notes	Clinicaltrials.gov (ID: NCT03174626)

Juarez 2015

Trial name or title	Bilingual breast cancer educational intervention for Hispanic women with stage I, stage II, or stage III breast cancer and their families or caregivers
Methods	RCT
Participants	N = 49 to be allocated to either intervention or control groups Inclusion criteria: Histologically-confirmed diagnosis of stage 0 (DCIS), I, II, or III breast cancer No evidence of recurrent, metastatic, or second primary cancer Completing primary treatment with surgery, radiation therapy (if indicated), and/or adjuvant chemotherapy (if indicated) Participants may be on hormonal therapy after treatment for initial breast cancer Self-identification as Hispanic/Latino Able to read and understand English or Spanish to participate in the patient teaching Able and willing to participate in the study The caregiver selection criteria is: self-identification as the primary caregiver; age 18 years or over; self-identification as Hispanic/Latino; able to read and speak English or Spanish; able and willing to participate in the study Exclusion criteria: Patients will be excluded if they are actively receiving treatment with surgery, radiation therapy, or chemotherapy; patients may be receiving adjuvant hormonal therapy such as Tamoxifen during the course of the study since it is recommended for five years after primary and adjuvant therapy Patients who have recurrence, metastasis, or a second primary cancer will not be recruited for the study; if however, they develop recurrence, metastasis, or a second primary cancer during the time of the study participation, the subjects will remain in the study

Juarez 2015 (Continued)

	Patients will not be recruited directly from support groups because of potential bias inherent in sample attending support groups; however, some patients may be participating in support groups or other forms of counselling
Interventions	Intervention: bilingual Breast Cancer Educational Intervention 50-65 minute sessions about physical, psychological, social and spiritual well-being) once weekly for one month. Telephone calls every other week Control: waiting-list control
Outcomes	Primary outcomes: Caregiver quality of life Patient quality of life Quality of intervention
Starting date	August 2006
Contact information	Gloria Juarez
Notes	Clinicaltrials.gov (ID: NCT01043003)

Manne 2013

Trial name or title	Intimacy-enhancing couples' intervention for localized prostate cancer
Methods	Study design: randomised controlled trial
Participants	Target intervention groups: caregiver-prostate cancer dyad
Interventions	Nature: intimacy-enhancing intervention Content: orientation and stories of the cancer experience, communication and listening to partner's concerns, being supportive to solve concerns and reflecting on changes and future adaptation Duration: five 90-minute sessions, once a week Setting: outpatient Delivered by: not clear Control group: active comparator (general health and wellness) and usual care
Outcomes	Psychological distress Other outcome: cancer-specific distress, relationship functioning, intimacy and relationship communication
Starting date	August 2011
Contact information	Sharon Manne
Notes	Clinicaltrials.gov: NCT01982058

McCaughan 2013

Trial name or title	CONNECT
Methods	RCT
Participants	Prostate cancer patients and their partners
Interventions	Nature: psychosocial Content: couple care, optimistic outlook, navigating the journey, new normality, empowering self, change lifestyle and target setting Setting: group and telephone Duration: nine weeks (three two-hour group meetings and two telephone calls) Delivered by: specifically trained HCPs Control group: usual care
Outcomes	Patient QoL Other outcomes: self-efficacy, symptom distress, communication about illness, benefits of illness, impact of illness on partner
Starting date	Unknown
Contact information	Eilis McCaughan: em.mccaughan@ulster.ac.uk
Notes	Trial ID: ISRCTN51971112

Nie 2017

Trial name or title	Help Her Heal
Methods	RCT
Participants	N = 108 to be allocated to intervention of control group Inclusion Criteria: (1) Individual diagnosed with breast cancer and partner (married or unmarried in a stable relationship) (2) Both individuals aged between 18 and 65 years old (3) Diagnosis of breast cancer carcinoma in situ, stage I-III; (4) Both participants aware of cancer diagnosis (5) Both participants having basic reading and language communication ability; (6) Both participants volunteering to participate in this study Exclusion Criteria: (1) Breast cancer recurrence, metastasis or advanced disease (2) Participation in other cancer interventions (3) Either patient or spouse with a history of mental illness
Interventions	Intervention: psychoeducation Control: not specified
Outcomes	(CSES-S) State Anxiety Inventory Centre for Epidemiological Studies- Depression subscale (CES-D)

Nie 2017 (Continued)

	(MAT) Spouse Skills Checklist With the exception of the Spouse Skills Checklist, it is not clearly specified whether outcome measures are completed by one or both participants
Starting date	1st May 2018
Contact information	Zhihong Nie 1291565839@qq.com
Notes	WHO trials registry ID (ChiCTR-INR-17012517)

O'Toole 2017

Trial name or title	Cancer caregiver burden: targeting emotion regulation in a randomized controlled trial
Methods	RCT: cross-over assignment
Participants	N = 80 to be allocated to intervention or control group Inclusion Criteria: Medium levels of distress (distress thermometer > 3) and at least moderate levels of worry or rumination and caregiver of patient with colorectal or lung cancer Exclusion Criteria: An expected survival of the patient of < 6 months, active substance abuse (alcohol or drugs), or participation in other psychosocial trials
Interventions	Intervention: eight sessions of Emotional Regulation Therapy Control group: usual care
Outcomes	Pre-, mid-, immediately, three and six-months post-intervention Primary outcome: Caregiver burden (The Caregiver Reaction Assessment) Patient quality of life (EORTC-QLQ-30) Anxiety (HADS) Depression (HADS) Worry (Penn State Worry Questionnaire) Brooding (Rumination Resoonse Scale- Brooding Subs-scale) Secondary outcomes: Emotional regulation (Difficulty in Emotional Regulation Scale, Emotional Regulation Questionnaire and Emotional Attention Coping) Caregiver quality of life (WHO-5) Mindfulness (Flve Facet Mindfulness Questionnaire) Psychological distancing (Experiences Questionnaire) Sleep quality (Pittsburgh Sleep Quality Index) Pro-inflammatory markers (CRP, TNFalpha, IL-1, IL-6- only pre and post intervention) Emotional closeness (2-item scale 0-10 (actual and wanted emotional closeness)) Cost-effectiveness
Starting date	August 2015

O'Toole 2017 (Continued)

Contact information	Mia O'Toole mia@psy.au.dk
Notes	Clinicaltrials.gov (ID: NCT02322905)

Rush 2015

Trial name or title	Nueva Vida intervention
Methods	RCT
Participants	N = 125 Latina breast cancer survivor-caregiver dyads to be allocated to intervention or usual care control group. Recruited from four community-based organisations
Interventions	Intervention: psychoeducational intervention led by trained interventionists. Core topics include: Impact of cancer on the family, spirituality and cancer, stress management, balancing physical and emotional needs and improving communication. Scope for tailoring of intervention from longer list of topics Eight group sessions of skill-building held twice a month for four months. Intervention delivered separately to survivors and caregivers with joint discussion between both participant groups Usual care: as delivered by community partners
Outcomes	Six-months Primary outcomes: Quality of life- physical functioning (Patient Reported Outcomes Measurement Information System (PROMIS) physical functioning scale) Quality of life- social roles (PROMIS satisfaction with social roles) Quality of life- anxiety (PROMIS anxiety) Quality of life- depression (PROMIS depression) Secondary outcomes: Communication (Communication with providers and between survivor and caregiver) Satisfaction with care
Starting date	May 2013
Contact information	Kristi D Graves
Notes	Registered on Clinicaltrials.gov (ID: NCT02222337)

Sadler 2016

Trial name or title	Problem solving therapy for prostate cancer spousal caregivers
Methods	RCT: factorial assignment
Participants	N = 338 to be allocated to intervention or control groups Inclusion Criteria: Diagnosed with prostate cancer within 18 months of study enrolment The patient and significant other cohabited

Sadler 2016 (Continued)

	Couples resided in San Diego County Both patient and significant other were sufficiently proficient in English
Interventions	Intervention: problem-solving therapy training programs to caregivers Control: usual care
Outcomes	Two-months and six-months post-intervention Primary outcomes: Stress Coping
Starting date	July 1997
Contact information	Georgia Sadler
Notes	Clinialtrials.gov (ID: NCT02085096)

Shum 2015

Trial name or title	Effectiveness of telephone intervention for colorectal cancer caregivers
Methods	RCT
Participants	N = 140 to be allocation to either intervention or control groups Inclusion Criteria: Family members with newly diagnosed colorectal cancer within the past 4 week and treated in Queen Mary Hospital Self-identified as formal or informal family caregivers Over 18 years old Chinese Cantonese speaking Exclusion Criteria: Cognitive disability Domestic helpers or maids Non Chinese
Interventions	Intervention: telephone-delivered counselling and education Control: usual care
Outcomes	Primary outcomes: Distress Secondary outcomes: Burden of care Quality of life
Starting date	June 2011
Contact information	N F Shum

Notes	Clinicaltrials.gov (ID: NCT01519895)
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Trevino 2017

Trial name or title	Managing Anxiety From Cancer (MAC): Testing an intervention for anxiety in older adults with cancer and their caregivers
Methods	RCT
Participants	<p>N = 80 to be allocated to intervention and control groups</p> <p>Inclusion Criteria:</p> <ol style="list-style-type: none"> 1. Patient age 65 years or older 2. Diagnosis of cancer 3. Patient and/or caregiver score of 8 or higher on the anxiety subscale of the HADS 4. A primary informal caregiver who is willing and able to participate 5. Patient and caregiver are able to communicate over the telephone 6. Caregiver is age 21 years or older <p>Exclusion Criteria:</p> <ol style="list-style-type: none"> 1. The patient's cancer is in remission 2. Patient or caregiver is not fluent in English 3. Patient or caregiver is too weak or cognitively impaired to participate in the intervention 4. Patient or caregiver has received cognitive behavioral therapy since the patient's cancer diagnosis 5. Patient or caregiver has an active major psychiatric condition such as schizophrenia 6. Patient only experiences anxiety in the context of a specific medical procedure <p>Patient or caregiver endorses active suicidal ideation</p>
Interventions	<p>Intervention: Cancer-caregiver dyad will separately receive seven 45- to 50-minute sessions of CBT via telephone by a trained interventionist</p> <p>Control: usual care</p>
Outcomes	<p>Baseline and follow-up (7 to 9 weeks post-baseline)</p> <p>Primary outcomes:</p> <p>Anxiety (Hospital Anxiety and Depression Scale (HADS)-anxiety subscale and Hamilton Anxiety Rating Scale)</p> <p>Secondary outcomes:</p> <p>Depression (HADS-depression subscale and Montgomery-Asberg Depression Scale)</p> <p>Distress (Dlstress thermometer)</p> <p>Patient quality of life (FACT-G emotional subscale)</p> <p>Caregiver quality of life (Caregiver Quality of Life-Cancer)</p>
Starting date	June 2017
Contact information	Chrystal Marte chm2075@med.cornell.edu
Notes	NCT03168971

CBT: cognitive behavioural therapy; CRP: C-reactive protein; HADS: Hospital Anxiety and Depression Scale; QoL: quality of life;
RCT: randomised controlled trial

DATA AND ANALYSES

Comparison 1. Psychosocial intervention versus usual care in caregivers

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Overall quality of life score immediately post-intervention	2	265	Std. Mean Difference (IV, Random, 95% CI)	0.29 [0.04, 0.53]
2 Overall quality of life score 12 months post-intervention	2	239	Std. Mean Difference (IV, Random, 95% CI)	0.14 [-0.11, 0.40]
3 Any depression immediately to one-month post intervention	9	702	Std. Mean Difference (IV, Random, 95% CI)	0.01 [-0.14, 0.15]
4 Any depression 3-6 months post-intervention	5	379	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.33, 0.38]
5 Any anxiety immediately post intervention	5	329	Std. Mean Difference (IV, Random, 95% CI)	-0.12 [-0.33, 0.10]
6 Any anxiety 3-6 months post-intervention	4	272	Std. Mean Difference (IV, Random, 95% CI)	-0.25 [-0.64, 0.13]
7 Any psychological distress immediately to one-month post intervention	3	134	Std. Mean Difference (IV, Random, 95% CI)	-0.08 [-0.42, 0.26]
8 Any psychological distress 7-12 months post-intervention	2	62	Std. Mean Difference (IV, Random, 95% CI)	0.08 [-0.42, 0.58]

Comparison 2. Psychosocial intervention versus usual care in patients

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Overall quality of life immediately post-intervention	2	292	Std. Mean Difference (IV, Random, 95% CI)	-0.03 [-0.50, 0.44]
2 Overall quality of life score 6-12 months post-intervention	3	294	Std. Mean Difference (IV, Random, 95% CI)	-0.05 [-0.37, 0.26]
3 Any depression measure immediately to one-month post-intervention	9	852	Std. Mean Difference (IV, Random, 95% CI)	-0.12 [-0.31, 0.07]
4 Any depression 3-6 months post-intervention	6	534	Std. Mean Difference (IV, Random, 95% CI)	-0.11 [-0.33, 0.12]
5 Any anxiety measure immediately post-intervention	4	422	Std. Mean Difference (IV, Random, 95% CI)	-0.13 [-0.41, 0.15]
6 Any anxiety 3-6 months post-intervention	4	370	Std. Mean Difference (IV, Random, 95% CI)	-0.22 [-0.45, 0.02]
7 Any psychological distress immediately post intervention	2	74	Std. Mean Difference (IV, Random, 95% CI)	-0.02 [-0.47, 0.44]

8 Any psychological distress 7-12 months post-intervention	2	61	Std. Mean Difference (IV, Random, 95% CI)	-0.27 [-0.78, 0.24]
9 Any physical health status measure immediately post-intervention	4	461	Std. Mean Difference (IV, Random, 95% CI)	0.17 [-0.07, 0.41]
10 Any physical health status 6-12 months post-intervention	2	275	Std. Mean Difference (IV, Random, 95% CI)	0.06 [-0.18, 0.30]

Analysis 1.1. Comparison 1 Psychosocial intervention versus usual care in caregivers, Outcome 1 Overall quality of life score immediately post-intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 1 Psychosocial intervention versus usual care in caregivers

Outcome: 1 Overall quality of life score immediately post-intervention

Analysis 1.2. Comparison 1 Psychosocial intervention versus usual care in caregivers, Outcome 2 Overall quality of life score 12 months post-intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 1 Psychosocial intervention versus usual care in caregivers

Outcome: 2 Overall quality of life score 12 months post-intervention

Analysis 1.3. Comparison 1 Psychosocial intervention versus usual care in caregivers, Outcome 3 Any depression immediately to one-month post intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 1 Psychosocial intervention versus usual care in caregivers

Outcome: 3 Any depression immediately to one-month post intervention

Analysis 1.4. Comparison 1 Psychosocial intervention versus usual care in caregivers, Outcome 4 Any depression 3-6 months post-intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 1 Psychosocial intervention versus usual care in caregivers

Outcome: 4 Any depression 3-6 months post-intervention

Analysis 1.5. Comparison 1 Psychosocial intervention versus usual care in caregivers, Outcome 5 Any anxiety immediately post intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 1 Psychosocial intervention versus usual care in caregivers

Outcome: 5 Any anxiety immediately post intervention

Analysis 1.6. Comparison 1 Psychosocial intervention versus usual care in caregivers, Outcome 6 Any anxiety 3-6 months post-intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 1 Psychosocial intervention versus usual care in caregivers

Outcome: 6 Any anxiety 3-6 months post-intervention

Analysis 1.7. Comparison 1 Psychosocial intervention versus usual care in caregivers, Outcome 7 Any psychological distress immediately to one-month post intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 1 Psychosocial intervention versus usual care in caregivers

Outcome: 7 Any psychological distress immediately to one-month post intervention

Analysis 1.8. Comparison 1 Psychosocial intervention versus usual care in caregivers, Outcome 8 Any psychological distress 7-12 months post-intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 1 Psychosocial intervention versus usual care in caregivers

Outcome: 8 Any psychological distress 7-12 months post-intervention

Analysis 2.1. Comparison 2 Psychosocial intervention versus usual care in patients, Outcome 1 Overall quality of life immediately post-intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 2 Psychosocial intervention versus usual care in patients

Outcome: 1 Overall quality of life immediately post-intervention

Analysis 2.2. Comparison 2 Psychosocial intervention versus usual care in patients, Outcome 2 Overall quality of life score 6-12 months post-intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 2 Psychosocial intervention versus usual care in patients

Outcome: 2 Overall quality of life score 6-12 months post-intervention

Analysis 2.3. Comparison 2 Psychosocial intervention versus usual care in patients, Outcome 3 Any depression measure immediately to one-month post-intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 2 Psychosocial intervention versus usual care in patients

Outcome: 3 Any depression measure immediately to one-month post-intervention

Analysis 2.4. Comparison 2 Psychosocial intervention versus usual care in patients, Outcome 4 Any depression 3-6 months post-intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 2 Psychosocial intervention versus usual care in patients

Outcome: 4 Any depression 3-6 months post-intervention

Analysis 2.5. Comparison 2 Psychosocial intervention versus usual care in patients, Outcome 5 Any anxiety measure immediately post-intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 2 Psychosocial intervention versus usual care in patients

Outcome: 5 Any anxiety measure immediately post-intervention

Analysis 2.6. Comparison 2 Psychosocial intervention versus usual care in patients, Outcome 6 Any anxiety 3-6 months post-intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 2 Psychosocial intervention versus usual care in patients

Outcome: 6 Any anxiety 3-6 months post-intervention

Analysis 2.7. Comparison 2 Psychosocial intervention versus usual care in patients, Outcome 7 Any psychological distress immediately post intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 2 Psychosocial intervention versus usual care in patients

Outcome: 7 Any psychological distress immediately post intervention

Analysis 2.8. Comparison 2 Psychosocial intervention versus usual care in patients, Outcome 8 Any psychological distress 7-12 months post-intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 2 Psychosocial intervention versus usual care in patients

Outcome: 8 Any psychological distress 7-12 months post-intervention

Analysis 2.9. Comparison 2 Psychosocial intervention versus usual care in patients, Outcome 9 Any physical health status measure immediately post-intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 2 Psychosocial intervention versus usual care in patients

Outcome: 9 Any physical health status measure immediately post-intervention

Analysis 2.10. Comparison 2 Psychosocial intervention versus usual care in patients, Outcome 10 Any physical health status 6-12 months post-intervention.

Review: Psychosocial interventions for informal caregivers of people living with cancer

Comparison: 2 Psychosocial intervention versus usual care in patients

Outcome: 10 Any physical health status 6-12 months post-intervention

ADDITIONAL TABLES

Table 1. Content of included interventions

Study ID	Author description of intervention	Target population	Level 1 Information	Level 2 Support	Level 3 Coping skills training	Level 4 Psychotherapy	Level 5 Spiritual/Existential therapy	Additional components not covered by the framework
Baucom 2009	Couple-based relationship enhancement	Spousal dyad	<ul style="list-style-type: none"> Impact of breast cancer on relationships and function 		<ul style="list-style-type: none"> Communication skills to aid decision-making Problem-solving skills Cognitive restructuring <ul style="list-style-type: none"> Adjust 			<ul style="list-style-type: none"> Homework assignments

Table 1. Content of included interventions (Continued)

					daily activities taking cancer into account			
Blanchard 1996	Coping with cancer using a problem-solving approach	Caregiver only		<ul style="list-style-type: none"> • Social worker helped caregiver to identify problems and develop appropriate solutions 	<ul style="list-style-type: none"> • Problem-solving by identifying the problem, generate solutions, apply, appraise and evaluate solutions • Strategies to reduce distress • Coping skills training 			
Budin 2008	Structured psycho-education only Telephone counselling only Structured psycho-education and telephone counselling combined intervention Informed by Lazarus and Folkman coping theory (Lazarus 1984) and Morley et al. cri-	Family/friend-patient dyad	Structured psycho-education only <ul style="list-style-type: none"> • Information related to health, skill development and psychosocial support • Information related to health 	Telephone counselling <ul style="list-style-type: none"> • Psychosocial support 	Telephone counselling <ul style="list-style-type: none"> • Anxiety reduction <ul style="list-style-type: none"> • Use of effective coping strategies • Communication skills • Cognitive restructuring • Enhance concept of self 			

Table 1. Content of included interventions (Continued)

	sis intervention model (Morley 1967)							
Bultz 2000	Brief psycho-educational support	Caregiver only	<ul style="list-style-type: none"> • Medical and psychological impact of cancer • Staging, treatment and risk of recurrence of cancer 	<ul style="list-style-type: none"> • Group discussion • Share experiences • Explore feelings and confront feelings 				
Campbell 2007	Coping skills training Guided by Cognitive Behavioural Therapy	Spousal/intimate partner dyad	<ul style="list-style-type: none"> • Cancer and long-term effects 	<ul style="list-style-type: none"> • Psychologist facilitators to help participants identify challenges 	<ul style="list-style-type: none"> • Problem-solving skills • Progressive muscle relaxation • Imagery techniques • Communication skills (effective speaking and listening skills) • Activity pacing <ul style="list-style-type: none"> • Goal-setting 			
Couper 2015	Cognitive existential couple therapy Supportive therapy, existential therapy	Spousal dyad		<ul style="list-style-type: none"> • Providing support to couple 	<ul style="list-style-type: none"> • Learning open communication styles • Promoting mutual 	<ul style="list-style-type: none"> • Dealing with grief and losses 		

Table 1. Content of included interventions (Continued)

	and cognitive therapy				support			
					<ul style="list-style-type: none">• Cognitive approach to anxiety (e.g. cognitive re-framing)• Problem-solving skills• Reevaluate life priorities as an individual and a couple• Fostering authentic living, meaning and purpose<ul style="list-style-type: none">• Learn to recognise automatic negative thoughts and maladaptive thinking styles			
Heinrich 1985	Stress and activity management intervention Adapted from Weisman 1980 cognitive therapy and problem-solving program	Spousal dyad	<ul style="list-style-type: none">• Cancer, it's treatment and psychosocial impact<ul style="list-style-type: none">• Stress and adaptive coping		<ul style="list-style-type: none">• Relaxation techniques (deep breathing, guided imagery and progressive muscle relaxation)• Cognitive therapy• Problem-solving skills			<ul style="list-style-type: none">• Walking• Contract to undertake positive individual and couple activities• Homework assignments

Table 1. Content of included interventions (Continued)

Kozachik 2001	Cancer Care Intervention- a supportive nursing intervention Family Care Model (problem-solving intervention approach)	Spousal dyad		<ul style="list-style-type: none"> • Support to select an appropriate intervention or modify and adapt an intervention 	<ul style="list-style-type: none"> • Select, implement and evaluate use of intervention strategies for symptom management and surveillance 			
Kuijer 2004	Brief counselling program Equity theory	Spousal dyad		<ul style="list-style-type: none"> • Mutual support • Discussion about relationship prior to and since cancer and changes • Expectations regarding intervention 	<ul style="list-style-type: none"> • Stimulated perspective taking • Cognitive restructuring • Writing of wishes and desires • Vignettes of other couples coping • Learning and application of behavioural strategies 		<ul style="list-style-type: none"> • Homework assignments 	
Kurtz 2005	Clinical nursing intervention targeting symptom management Adapted Bandura's framework of cog-	Caregiver only		<ul style="list-style-type: none"> • Discussion and prioritisation of need <ul style="list-style-type: none"> • Nurse supported caregiver to select intervention 	<ul style="list-style-type: none"> • Learning of self-management strategies through practice and mastery and verbal persuasion 			

Table 1. Content of included interventions (Continued)

	<p>native behavioural change (Bandura 1977; Bandura 1997)</p>			<p>from a pre-specified list</p> <ul style="list-style-type: none"> • Instrumental assistance, coping strategies, information provision and facilitation of communication • Interventions that were successful were kept • Unsuccessful interventions were adapted or discontinued 			
<p>Ledderer 2013</p>	<p>Multimodal</p>	<p>Family/ friend-patient dyad</p>	<ul style="list-style-type: none"> • Lifestyle information 	<ul style="list-style-type: none"> • Supportive talks with a trained and experienced nurse • Sharing experiences of illness and challenges • Opportunities to share and express feelings with peers 	<ul style="list-style-type: none"> • Communication techniques 		<ul style="list-style-type: none"> • Physical activity
<p>Manne 2004</p>	<p>Psycho-educational group Content based on Lazarus'</p>	<p>Caregiver only</p>	<ul style="list-style-type: none"> • Medical information about prostate cancer and 	<ul style="list-style-type: none"> • Disclosure of feelings • Discussion about 	<ul style="list-style-type: none"> • Stress management (e.g. progressive muscle relaxation) 		<ul style="list-style-type: none"> • Homework assignments

Table 1. Content of included interventions (Continued)

	stress and coping theory (Lazarus 1984) and multiple social processing theories for adaptation to difficult life events		treatment <ul style="list-style-type: none"> • Nutrition 	survivorship issues and concerns <ul style="list-style-type: none"> • Coping skills training • Communication and support skills • Maintaining intimacy and addressing sexual concerns 			
Manne 2005	Couple-focused group intervention Based on cognitive-social processing theory	Spousal dyad		<ul style="list-style-type: none"> • Group-based • Enhancing support exchanges and facilitate expressions of feelings 	<ul style="list-style-type: none"> • Stress management • Relaxation techniques • Coping skills • Problem-solving • Communication skills 		<ul style="list-style-type: none"> • Homework assignments
Manne 2011	Intimacy-Enhancing therapy Based on relationship Intimacy Model of Cancer Adaptation	Spousal dyad		<ul style="list-style-type: none"> • Sharing thoughts and feelings regarding cancer 	<ul style="list-style-type: none"> • Communication skills • Techniques from cognitive-behavioural and behavioural marital therapies 		<ul style="list-style-type: none"> • Homework assignments
McCorkle 2007	Standardised nursing intervention	Spousal dyad	<ul style="list-style-type: none"> • Care of wounds and how to identify 	<ul style="list-style-type: none"> • Discussion of issues and concerns 	<ul style="list-style-type: none"> • Self-care strategies • Pelvic 		

Table 1. Content of included interventions (Continued)

			symptoms or problems		floor muscle exercises			
					<ul style="list-style-type: none"> • Problem-solving skills <ul style="list-style-type: none"> • Long-term condition management 			
Nicolaisen 2018	Attachment-oriented couple intervention. Hand in Hand (HiH) intervention Based on Attachment theory (Bowlby 1982)	Spousal dyad		<ul style="list-style-type: none"> • Therapeutic alliance between caregiver-patient dyad and therapist <ul style="list-style-type: none"> • Safe and secure environment for couple to discuss 		<ul style="list-style-type: none"> • Couples-based therapy 		<ul style="list-style-type: none"> • Homework assignments
Northouse 2007	FOCUS- family-based supportive-educative intervention	Spousal dyad	<ul style="list-style-type: none"> • Lifestyle factors 	<ul style="list-style-type: none"> • Open communication about illness 	<ul style="list-style-type: none"> • Short-term goals • Encouraged to maintain optimism <ul style="list-style-type: none"> • Stress management • Active coping skills • Uncertainty reduction <ul style="list-style-type: none"> • Self-care strategies 			
Robertson 2016	RiPSToP- relational psycho-sexual treatment for couples with	Spousal dyad	<ul style="list-style-type: none"> • Prostate cancer and its effects 	<ul style="list-style-type: none"> • Discussion of current issues, concerns 	<ul style="list-style-type: none"> • Techniques from sex therapy 			

Table 1. Content of included interventions (Continued)

	prostate cancer, psychosexual support Systemic principles and principles from sex therapy			and problems				
Tsianakas 2015	Take Care intervention- information and supportive intervention	Caregiver only	<ul style="list-style-type: none"> • Treatment side effects, impact of being a carer, dealing with emotions and importance of looking after self • Hospital specific information including maps and contact numbers 	<ul style="list-style-type: none"> • Group discussion • Practical advice and tips 				

Table 2. Caregiver quality of life

Study ID	Measure	QoL Domain	N of Caregivers	Time point(s)	Intervention arm Mean (SD)	Control arm Mean (SD)
Blanchard 1996	SF20 (20-items, higher scores on each subscale (except pain) indicate better functioning)	Pain Health Perception Physical Functioning Role Functioning Mental Health Social functioning	N = 66 N = 66 N = 66 N = 66 N = 66 N = 66 N = 66 N = 66 N = 66	Immediately post-intervention Six-months post-intervention Immediately post-intervention Six-months post-in-	50.9 (20.4) 44.3 (15.6) 73.5 (14.1) 68.0 (14.9) 84.7 (25.0) 88.5 (19.0) 89.2 (26.7) 91.4 (27.0) 70.6 (17.9) 76.4 (16.0) 96.2 (11.4)	57.7 (20.1) 53.7 (19.2) 69.6 (13.2) 68.9 (11.7) 81.7 (25.8) 82.9 (27.2) 90.2 (25.5) 90.3 (23.4) 65.8 (20.4) 68.9 (19.7)

Table 2. Caregiver quality of life (Continued)

			N = 66	intervention Immediately post-intervention Six-months post-intervention Immediately post-intervention Six-months post-intervention Immediately post-intervention Six-months post-intervention Immediately post-intervention Six-months post-intervention	94.7 (18.1)	93.2 (15.2) 94.4 (11.3)
Campbell 2007	Modified Caregiver Strain Index (10-items with higher scores indicating higher levels of strain)	Total Score	N = 30	Immediately post-intervention	2.91 (0.485)*	3.73 (0.395)*
Kurtz 2005	SF36 (two-items with higher scores indicating better social functioning)	Social functioning	N = 139	Immediately post-intervention	89.4 (17.6)	84.7 (24.0)
Ledderer 2013	WHO-Five Well-being Index (five-items (0-5 scale) with higher scores indicating better well-being)	Total Score	N = 21	12-months post-baseline	68.0 (52.7-83.3) ***	59.7 (40.5-79.0) ***

Table 2. Caregiver quality of life (Continued)

Northouse 2007	FACT-G (27-items (0-4) with higher scores indicating better functioning)	Total Score	N = 235 N = 218	Immediately post-intervention 12-months post-baseline	86.5 (11.3) 85.2 (11.6)	83.5 (11.4) 83.6 (11.9)
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*Standard error was extracted from this study, **No value to indicate spread of scores was reported, ***95% Confidence Intervals were extracted from this study

SD: standard deviation

Table 3. Patient quality of life

Study ID	Measure	QoL Domain	N of patients	Time point(s)	Intervention arm Mean (SD)	Control arm Mean (SD)
Baucom 2009	FACT-B (six-items on a 5-point scale (0-4) with higher scores indicating better functioning)	Physical functioning	N = 14 N = 14	Immediately post-intervention 12 months post-intervention	3.08 (0.27) 3.22 (0.34)	2.76 (1.15) 2.89 (0.91)
Blanchard 1996	FLIC (22-item visual analogue scale with higher scores indicating better functioning)	Overall score	N = 57 N = 57	Immediately post-intervention Six months post-intervention	114.6 (20.6) 112.0 (20.7)	120.8 (16.5) 120.1 (19.9)
Campbell 2007	EPIC (50-item scores range from 0-100 with higher scores indicating higher QoL)	Urinary function Urinary bother Urinary irritation Urinary incontinence Urinary total Bowel function Bowel bother Bowel total Sexual function Sexual bother Sexual total Hormonal func-	N = 30 N = 30 N = 30 N = 30 N = 30 N = 30 N = 30 N = 30 N = 30 N = 30 N = 30 N = 30	Immediately post-intervention Immediately post-intervention Immediately post-intervention Immediately post-intervention Immediately post-intervention Immediately post-intervention Immediately post-intervention Immediately post-intervention Immediately post-intervention Immediately post-intervention Immediately post-intervention	72.39 (4.34)* 82.09 (3.70)* 87.09 (2.69)* 61.94 (6.38)* 77.98 (3.47)* 76.85 (3.12)* 95.57 (2.46)* 86.34 (2.48)* 30.35 (5.33)* 42.92 (7.08)* 34.36 (5.22)* 87.57 (3.20)* 89.79 (2.44)*	75.57 (3.53)* 74.24 (3.02)* 83.41 (2.19)* 62.11 (5.20)* 74.84 (2.82)* 76.28 (2.53)* 88.67 (1.99)* 82.39 (2.00)* 23.44 (4.33)* 28.68 (5.76)* 24.96 (4.25)* 81.07 (2.60)* 86.67 (1.99)*

Table 3. Patient quality of life (Continued)

		tion Hormonal bother Hormonal total		vention Immedi- ately post-inter- vention Immedi- ately post-inter- vention Immedi- ately post-inter- vention Immedi- ately post-inter- vention Immedi- ately post-inter- vention Immedi- ately post-inter- vention Immedi- ately post-inter- vention Immedi- ately post-inter- vention Immedi- ately post-inter- vention	88.79 (2.26)*	84.17 (1.84)*
Ledderer 2013	EORTC-QLQ-C30 (30-items scores range from 0-100 with higher scores indicating higher QoL)	Global health status score	N = 19	12 months post-baseline	83.3 (73.8-92.9) ***	76.9 (65.6-88.2) ***
Northouse 2007	FACT-G (27-items on a 5-point scale (0-4) with higher scores indicating better functioning)	Total score	N = 235 N = 218	Immedi- ately post-inter- vention 12 months post-baseline	87.2 (10.6) 86.1 (10.9)	85.5 (10.3) 85.8 (10.7)

*Standard error was calculated instead of standard deviation, **No value to indicate spread of scores was reported, ***95% confidence intervals reported

EPIC: Expanded Prostate cancer Index Composite measure; SD: standard deviation

Table 4. Caregiver depression

Study ID	Measure	N of Caregivers	Time point(s)	Intervention arm Mean (SD)	Control arm Mean (SD)
Blanchard 1996	CES-D (scores range from 0-60 with higher scores indicating presence of more symptoma- tology)	N = 66 N = 66	Immediately post- intervention Six months baseline	16.3 (6.2) 12.5 (7.4)	17.7 (6.7) 14.8 (8.4)
Bultz 2000	POMS depression sub-scale (15-items on five point scale (0- 4) with higher scores indicating greater mood disturbance)	N = 34 N = 32	Immediately post- intervention Three months post- intervention	11.2 (2.66)* 7.9 (1.23)*	10.6 (2.58)* 11.1 (2.63)*
Campbell 2007	POMS depression sub-scale (15-items on a five point scale (0- 4) with higher scores indicating greater mood disturbance)	N = 30	Immediately post- intervention	1.85 (0.891)**	3.78 (0.760)**
Heinrich 1985	Symptom Check- list-90-Revised (SCL-90-R) Depression sub- scale (13-items on a 5- point (0- 4) scale with higher scores indicating greater depression)	N = 37	Immediately post- intervention	0.66***	0.69***
Kozachik 2001	CES-D (scores range from 0-60 with higher scores indicating presence of more symptoma- tology)	N = 89	Immediately post- intervention	9.0 (7.4)	7.8 (7.0)
Kuijter 2004	CES-D (scores range from	N = 38	One week post-in- tervention	11.84 (6.93)	12.21 (9.65)

Table 4. Caregiver depression (Continued)

	0-60 with higher scores indicating presence of more symptoma- tology)				
Kurtz 2005	CES-D (scores range from 0-60 with higher scores indicating presence of more symptoma- tology)	N = 139	Immediately post- intervention	7.7 (9.1)	8.1 (10.1)
McCorkle 2007****	CES-D (scores range from 0-60 with higher scores indicating presence of more symptoma- tology)	N = 107 N = 107	One month post-in- tervention Four-months post- intervention	9.90 (6.82) 9.22 (7.14)	9.16 (6.57) 6.69 (5.70)
Nicolaisen 2018	HADS Depression sub-scale (seven items rated on 4 point scale (0- 3) with higher scores indicating greater depression)	N = 163 N = 144	Immediately post- intervention Five months post-in- tervention	2.7 (2.8) 2.6 (3.0)	2.3 (2.6) 1.6 (2.0)
Robertson 2016	HADS Depression sub-scale (seven items rated on 4 point scale (0- 3) with higher scores indicating greater depression)	N = 36 N = 30	Immediately post- intervention Six months post-in- tervention	1.72 (2.02) 1.62 (3.18)	2.39 (2.64) 3.07 (3.35)

*Standard error of mean is reported, **Standard error instead of standard deviation is reported, ***No value to indicate spread of scores was reported, ****Review authors have estimated the time points post-intervention as one and four months post-intervention to correspond with three and six months post radical prostatectomy. Intervention is a eight-week long programme beginning post radical prostatectomy.

CES: Centre for Epidemiologic Studies Depression Scale; HADS: Hospital Anxiety and Depression Scale; POMS: Profile of Mood States; SD: standard deviation

Table 5. Caregiver anxiety

Study ID	Measure	N of Caregivers	Time point(s)	Intervention arm Mean (SD)	Control arm Mean (SD)
Blanchard 1996	STAI State subscale (10 items rated on a 4-point scale (1-4) with higher scores indicating greater anxiety)	N = 66 N = 66	Immediately post-intervention Six-months post-intervention	36.8 (11.9) 32.2 (7.9)	38.9 (11.4) 38.0 (10.8)
Bultz 2000	POMS Anxiety subscale (9 Items rates on a 5-point scale (0-4) with higher scores indicating greater mood disturbance)	N = 34 N = 32	Immediately post-intervention Three-months post-intervention	6.0 (1.46)* 5.6 (1.50)*	5.6 (1.59)* 6.7 (1.54)*
Campbell 2007	POMS Anxiety subscale (9 items rates on a five-point scale (0-4) with higher scores indicating greater mood disturbance)	N = 30	Immediately post-intervention	3.95 (1.16)**	5.30 (0.989)**
Heinrich 1985	Symptom Checklist-90-Revised (SCL-90-R) Anxiety subscale (10 items on a 5-point (0-4) scale with higher scores indicating greater depression)	N = 37	Immediately post-intervention	0.37***	0.55***
Nicolaisen 2018	HADS Anxiety subscale (7 items rated on 4-point scale (0-3) with higher scores indicating greater anxiety)	N = 163 N = 144	Immediately post-intervention Five months post-intervention	4.0 (3.3) 4.1 (3.3)	4.2 (3.4) 3.8 (3.0)
Robertson 2016	HADS Anxiety subscale	N = 36 N = 30	Immediately post-intervention	5.17 (3.60) 4.31 (2.63)	6.33 (4.99) 6.60 (5.58)

Table 5. Caregiver anxiety (Continued)

	(7 items rated on 4-point scale (0-3) with higher scores indicating greater anxiety)		Six months post-intervention		
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Standard error of mean is reported, **Standard error instead of standard deviation is reported, *No value to indicate spread of scores was reported

HADS: Hospital Anxiety and Depression Scale; POMS: Profile of Mood States; SD: standard deviation; STAI: State Trait Anxiety Inventory

Table 6. Caregiver psychological distress

Study ID	Measure	N of Caregivers	Time point(s)	Intervention arm Mean (SD)	Control arm Mean (SD)
Baucom 2009	Brief Symptom Inventory total score (18 items on a 5-point scale (0-4) with higher scores indicating higher distress)	N = 13 N = 13	Immediately post-intervention 12 months post-intervention	8.00 (11.99) 8.00 (8.19)	9.67 (8.62) 10.00 (16.22)
Couper 2015*	Mental Health Inventory psychological distress summary score (24 items on a five or 6-point scale (1-5 or 1-6) with higher scores indicating higher distress)	N = 61 N = 49	Immediately post-intervention Seven months post-intervention	4.87 (0.08)** 5.11 (0.09)**	4.99 (0.07)** 5.05 (0.08)**
Manne 2004	Mental Health Inventory psychological distress summary score (12 items on a 5- or 6-point scale (1-5 or 1-6) with higher scores indicating higher distress)	N = 60	One month post-intervention	28.2 (9.6)	26.7 (9.7)
Manne 2011	Mental Health Inventory psychological distress summary score	N = 56	Immediately post-intervention	Raw data not reported	Raw data not reported

Table 6. Caregiver psychological distress (Continued)

	(24 items on a 5- or 6-point scale (1-5 or 1-6) with higher scores indicating higher distress)				
Tsianakas 2015	General Health Questionnaire 12 (12 items on a 4-point scale (0-3) with higher scores indicating higher distress)	N = 43	Two weeks post-intervention	Raw data not reported	Raw data not reported

*Review authors have estimated the time points post-intervention as immediately and seven months post-intervention to correspond with 10 weeks and nine months post baseline assessment. Intervention is a six-week long programme and we have assumed that participants are allocated to intervention or control within four weeks. **Standard error instead of standard deviation is reported

Table 7. Caregiver physical health status

Study ID	Measure	Number of Caregivers	Time point	Intervention arm(s) Mean (SD)	Control arm Mean (SD)
Budin 2008	Multilevel Assessment Instrument Total Score (not enough information reported on measure)	N = 126	Immediately post-intervention	Group 1: Raw data not reported ¹ Group 2: Raw data not reported Group 3: Raw data not reported	Raw data not reported
Northouse 2007	SF12 Physical Component Summary Score (12-items, higher scores indicate better physical health status)	N = 235 N = 218	Immediately post-intervention 12-months post-baseline	50.0 (7.8) 44.6 (7.2)	50.3 (7.2) 42.3 (7.2)

¹Means and SDs were not reported post-intervention

Table 8. Patient depression

Study ID	Measure	N of Patients	Time point(s)	Intervention armMean (SD)	Control armMean (SD)
Blanchard 1996	CES-D (scores range from 0-60 with higher scores indicating presence of more symptomatology)	N = 57 N = 57	Immediately post-intervention Six months post-baseline	16.3 (6.9) 11.7 (10.2)	15.9 (6.2) 13.9 (9.7)
Bultz 2000	POMS depression subscale (15-items on five point scale (0-4) with higher scores indicating greater mood disturbance)	N = 34 N = 32	Immediately post-intervention Three months post-intervention	3.7 (1.25)* 3.4 (1.39)*	10.2 (2.10)* 8.2 (1.43)*
Kozachik 2001	CES-D (scores range from 0-60 with higher scores indicating presence of more symptomatology)	N = 89	Immediately post-intervention	8.8 (6.7)	8.0 (7.4)
Kuijer 2004	CES-D (scores range from 0-60 with higher scores indicating presence of more symptomatology)	N = 38	One week post-intervention	10.68 (6.61)	15.53 (8.06)
Kurtz 2005	CES-D (scores range from 0-60 with higher scores indicating presence of more symptomatology)	N = 139	Immediately post-intervention	6.6 (7.7)	9.9 (9.2)
Manne 2005	MHI-Depression subscale (four-items on a five or six point scale (1-5 or 1-6) with	N = 187 N = 163	One week post-intervention Six months post-intervention	8.60 (2.69) 8.14 (2.98)	8.90 (2.77) 8.95 (3.90)

Table 8. Patient depression (Continued)

	higher scores indicating greater depression)				
McCorkle 2007***	CES-D (scores range from 0-60 with higher scores indicating presence of more symptomatology)	N = 107 N = 107	One month post-intervention Four months post-intervention	7.74 (6.81) 7.35 (7.62)	6.35 (5.34) 5.98 (5.42)
Nicolaisen 2018	HADS depression subscale (seven items rated on 4 point scale (0-3) with higher scores indicating greater depression)	N = 165 N = 145	Immediately post-intervention Five months post-intervention	3.3 (3.7) 2.6 (3.0)	3.3 (3.2) 2.6 (2.9)
Robertson 2016	HADS depression subscale (seven items rated on 4 point scale (0-3) with higher scores indicating greater depression)	N = 36 N = 30	Immediately post-intervention Six months post-intervention	3.17 (3.22) 3.92 (3.33)	3.22 (2.46) 3.75 (2.65)

*Standard error of measurement is reported, **No values reported to indicate spread of scores, ***Review authors have estimated the time points post-intervention as one- and four months post-intervention to correspond with three- and six months post radical prostatectomy. Intervention is a eight-week long programme beginning post radical prostatectomy.

CES: Centre for Epidemiologic Studies Depression Scale; HADS: Hospital Anxiety and Depression Scale; MHI: Mental Health Inventory; POMS: Profile of Mood States

Table 9. Patient anxiety

Study ID	Measure	N of Patient	Time point(s)	Intervention arm Mean (SD)	Control arm Mean (SD)
Bultz 2000	POMS anxiety subscale (9 items rates on a 5-point scale (0-4) with higher scores indicating greater mood disturbance)	N = 34 N = 32	Immediately post-intervention Three months post-intervention	1.6 (0.94)* 0.8 (1.19)*	5.1 (1.27)* 4.2 (1.23)*

Table 9. Patient anxiety (Continued)

Manne 2005	MHI-Anxiety subscale (4 items on a 5- or 6-point scale (1-5 or 1-6) with higher scores indicating greater anxiety)	N = 187 N = 163	One week post-intervention Six months post-intervention	9.86 (3.40) 9.21 (3.17)	9.81 (3.56) 10.28 (4.87)
Nicolaisen 2018	HADS anxiety subscale (7 items rated on 4-point scale (0-3) with higher scores indicating greater anxiety)	N = 165 N = 145	Immediately post-intervention Five months post-intervention	5.6 (4.0) 5.2 (4.1)	5.4 (3.9) 5.2 (3.3)
Robertson 2016	HADS anxiety subscale (7 items rated on 4-point scale (0-3) with higher scores indicating greater anxiety)	N = 36 N = 30	Immediately post-intervention Six months post-intervention	4.06 (3.42) 4.62 (3.07)	5.72 (4.11) 6.69 (5.89)

*Standard error of measurement is reported, **No values reported to indicate spread of scores,

HADS: Hospital Anxiety and Depression Scale; MHI: Mental Health Inventory; POMS: Profile of Mood States

Table 10. Patient psychological distress

Study ID	Measure	N of Patient	Time point(s)	Intervention arm Mean (SD)	Control arm Mean (SD)
Baucom 2009	Brief Symptom Inventory total score (18 items rated on a 5-point scale (1-5) with higher scores indicating greater distress)	N = 13 N = 12	Immediately post-intervention 12 months post-intervention	8.83 (5.91) 6.71 (5.77)	12.50 (14.73) 15.80 (20.91)
Couper 2015	MHI psychological distress summary score (24 items on a 5- or 6-point scale (1-5 or 1-6) with higher scores indicating greater distress)	N = 61 N = 49	Immediately post-intervention Seven months post-intervention	5.18 (0.08)* 5.11 (0.07)*	5.16 (0.08)* 5.18 (0.07)*

Table 10. Patient psychological distress (Continued)

	indicating higher distress)				
Manne 2011	MHI psychological distress summary score (24-items on a 5- or 6-point scale (1-5 or 1-6) with higher scores indicating higher distress)	N = 60	Immediately post-intervention	Raw data not reported	Raw data not reported

MHI: Mental Health Inventory

Table 11. Patient physical health status

Study ID	Measure	N of Patient	Time point(s)	Intervention arm Mean (SD)	Control arm Mean (SD)
Baucom 2009	Rotterdam Symptom Checklist (16 items, higher score indicating presence of more symptoms)	N = 14 N = 14	Immediately post-intervention 12 months post-intervention	20.71 (3.82) 18.71 (2.36)	27.17 (8.68) 23.80 (9.81)
Blanchard 1996	SF20 Physical functioning subscale (6 items, higher score indicating better physical functioning)	N = 57 N = 57	Immediately post-intervention Six months post-intervention	38.3 (22.0) 40.0 (22.0)	37.1 (22.2) 36.0 (22.4)
Budin 2008	Multilevel Assessment Instrument Total Score (not enough information reported on measure)	N = 177	Immediately post-intervention	Group 1: Raw data not reported Group 2: Raw data not reported Group 3: Raw data not reported	Raw data not reported
Campbell 2007	SF36 Physical Component Summary Score (36 items, higher scores indicate better physical health status)	N = 30	Immediately post-intervention	27.52 (0.814)*	26.10 (0.664)*

Table 11. Patient physical health status (Continued)

Kurtz 2005	SF36 Physical functioning subscale (10 items with higher scores indicating better physical functioning)	N = 139	Immediately post-intervention	77.2 (22.9)	67.0 (30.2)
Northouse 2007	SF12 Physical Component Summary Score (12 items, higher scores indicate better physical health status)	N = 235 N = 218	Immediately post-intervention 12 months post-baseline	48.6 (6.7) 42.7 (6.5)	48.7 (6.5) 42.5 (6.4)

* Standard error reported instead of standard deviation

APPENDICES

Appendix I. MEDLINE search strategy (OvidSP)

1. exp neoplasms/
2. (cancer* or oncology* or neoplasm* or carcinoma* or tumor* or malignan* or lymphoma or melanoma or leuk?emia or sarcoma).tw.
3. or/1-2
4. (family or families or parent\$2 or mother? or father? or friend? or relative? or spous\$2 or partner? or husband? or wife or wives or son? or daughter? or offspring? or sibling? or brother? or sister?).tw. and (care* or caring).mp.
5. caregivers/
6. (carer* or caregiv* or care giv*).tw.
7. exp home nursing/
8. exp family/
9. or/4-8
10. ((family or families or parent\$2 or mother? or father? or friend? or relative? or spous\$2 or partner? or husband? or wife or wives or son? or daughter? or offspring? or sibling? or brother? or sister?) adj10 (support* or inform* or train* or educat* or teach* or coach* or instruct* or advis* or advice* or counsel* or therap* or cbt or program* or psycho* or social or pastoral or spiritual or religio* or self help or selfhelp or problem solving)).tw.
11. social support/
12. exp social work/
13. exp psychotherapy/
14. exp counseling/
15. education/
16. health education/
17. teaching/

18. exp "religion and psychology"/
19. self help groups/
20. self care/
21. problem solving/
22. professional family relations/
23. or/10-22
24. 3 and 9 and 23
25. randomized controlled trial.pt.
26. controlled clinical trial.pt.
27. randomly.ab.
28. placebo.ab.
29. randomized.ab.
30. drug therapy.fs.
31. trial.ab.
32. groups.ab.
33. or/25-32
34. exp animals/ not humans.sh.
35. 33 not 34
36. 24 and 35

Appendix 2. CENTRAL search strategy (the Cochrane Library)

- #1 MeSH descriptor: [Neoplasms] explode all trees
- #2 ((cancer* or oncology* or neoplasm* or carcinoma* or tumor* or tumour* or malignan* or lymphoma or melanoma or leukemia or leukaemia or sarcoma)):ti,ab,kw
- #3 #1 OR #2
- #4 ((family or families or parent or parents* or mother* or father* or friend* or relative* or spouse or spouses or partner* or husband* or wife or wives or son* or daughter* or offspring* or sibling* or brother* or sister*) and (care* or caring))
- #5 MeSH descriptor: [Caregivers] explode all trees
- #6 ((carer* or caregiv* or care giv*)):ti,ab,kw
- #7 MeSH descriptor: [Home Nursing] explode all trees
- #8 MeSH descriptor: [Family] explode all trees
- #9 {OR #4-#8}
- #10 (((family or families or parent or parents or mother* or father* or friend* or relative* or spouse or spouses or partner* or husband* or wife or wives or son* or daughter* or offspring* or sibling* or brother* or sister*) AND (support* or inform* or train* or educat* or teach* or coach* or instruct* or advis* or advice* or counsel* or therap* or cbt or program* or psycho* or social or pastoral or spiritual or religio* or self help or selfhelp or problem solving))):ti,ab,kw
- #11 MeSH descriptor: [Social Support] explode all trees
- #12 MeSH descriptor: [Social Work] explode all trees
- #13 MeSH descriptor: [Psychotherapy] explode all trees
- #14 MeSH descriptor: [Counseling] explode all trees
- #15 MeSH descriptor: [Education] explode all trees
- #16 MeSH descriptor: [Health Education] explode all trees
- #17 MeSH descriptor: [Teaching] explode all trees
- #18 MeSH descriptor: [Religion and Psychology] explode all trees
- #19 MeSH descriptor: [Self-Help Groups] this term only
- #20 MeSH descriptor: [Self Care] this term only
- #21 MeSH descriptor: [Problem Solving] this term only
- #22 MeSH descriptor: [Professional-Family Relations] this term only
- #23 {OR #10-#22}

CONTRIBUTIONS OF AUTHORS

CT in the Centre for Public Health drafted the final review including conducting final or confirmatory analyses. OS, HC, CC, and MD developed the protocol. CT, OS, GP, HC, MD and PO'H identified eligible studies and extracted data. OS, CT and GP conducted 'Risk of bias' assessments of eligible studies. CC provided statistical advice. MD supervised the conduct and completion of the final review.

DECLARATIONS OF INTEREST

The review authors do not have any conflicts of interest to declare.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

There were a number of differences between the protocol and review which are highlighted below and reported in the main review text.

- The protocol reported one objective and three points for evaluation and the objectives were amended during the review to cover four objectives.
- The heterogeneity and variation between interventions led to difficulties in drawing meaningful comparisons between studies. We were unable to draw comparisons between, for example, psychological or psychotherapeutic interventions, as stipulated in the protocol as each intervention could be classified as being psycho-educational in nature. Therefore, the authors made a post-hoc decision to use a framework (described in [Types of interventions](#) section above) in order to help classify and identify common components across interventions.
- Only studies which reported data relating to the outcomes listed in the [Types of outcome measures](#) section were included in the review. Studies that did not report data relating to these outcomes were excluded from the review.
- Only studies which measured QoL using a validated scale were included in this review, therefore, we did not undertake subgroup analysis comparing studies using validated and unvalidated scales.
- Two additional outcome categories called 'Caregiver psychological distress' and 'Patient psychological distress' were created to capture details relating to caregiver-reported and patient-reported measures of distress.
- Unplanned supplementary searches of CENTRAL and the Cochrane Database of Systematic Reviews were conducted which were not reported in the protocol, a full description is found in the [Electronic searches](#) section of the review.
- Decisions around choice of outcome measure when multiple outcome measures were used were absent in the protocol, so decisions were made post-hoc and are described in [Types of outcome measures](#) section.
- Methods regarding GRADE assessment (not previously reported in the protocol) were added to the [Data collection and analysis](#) section.

- A header for 'Feasibility/acceptability of interventions' was added to the [Effects of interventions](#) section and these outcomes were included in the review.
- In the protocol, it was reported that data relating to the first and last post-intervention assessment time point would be included in a meta-analysis where there were multiple post-intervention assessments. Data for some outcomes were not suitable for inclusion in a meta-analysis and are therefore reported in a narrative format in the review.