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Psychosocial interventions to improve quality of life and emotional wellbeing for recently diagnosed cancer patients

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Psychosocial interventions to improve quality of life and emotional wellbeing for recently diagnosed cancer patients (Review)

Galway K, Black A, Cantwell M, Cardwell CR, Mills M, Donnelly M



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[Intervention Review]

Psychosocial interventions to improve quality of life and emotional wellbeing for recently diagnosed cancer patients

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ABSTRACT

Background

A cancer diagnosis may lead to significant psychological distress in up to 75% of cases. There is a lack of clarity about the most effective ways to address this psychological distress.

Objectives

To assess the effects of psychosocial interventions to improve quality of life (QoL) and general psychological distress in the 12-month phase following an initial cancer diagnosis.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2010, Issue 4), MEDLINE, EMBASE, and PsycINFO up to January 2011. We also searched registers of clinical trials, abstracts of scientific meetings and reference lists of included studies. Electronic searches were carried out across all primary sources of peer-reviewed publications using detailed criteria. No language restrictions were imposed.

Selection criteria

Randomised controlled trials of psychosocial interventions involving interpersonal dialogue between a 'trained helper' and individual newly diagnosed cancer patients were selected. Only trials measuring QoL and general psychological distress were included. Trials involving a combination of pharmacological therapy and interpersonal dialogue were excluded, as were trials involving couples, family members or group formats.

Data collection and analysis

Trial data were examined and selected by two authors in pairs with mediation from a third author where required. Where possible, outcome data were extracted for combining in a meta-analysis. Continuous outcomes were compared using standardised mean differences and 95% confidence intervals, using a random-effects model. The primary outcome, QoL, was examined in subgroups by outcome measurement, cancer site, theoretical basis for intervention, mode of delivery and discipline of trained helper. The secondary outcome, general psychological distress (including anxiety and depression), was examined according to specified outcome measures.

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Main results

A total of 3309 records were identified, examined and the trials subjected to selection criteria; 30 trials were included in the review. No significant effects were observed for QoL at 6-month follow up (in 9 studies, SMD 0.11; 95% CI -0.00 to 0.22); however, a small improvement in QoL was observed when QoL was measured using cancer-specific measures (in 6 studies, SMD 0.16; 95% CI 0.02 to 0.30). General psychological distress as assessed by 'mood measures' improved also (in 8 studies, SMD - 0.81; 95% CI -1.44 to - 0.18), but no significant effect was observed when measures of depression or anxiety were used to assess distress (in 6 studies, depression SMD 0.12; 95% CI -0.07 to 0.31; in 4 studies, anxiety SMD 0.05; 95% CI -0.13 to 0.22). Psychoeducational and nurse-delivered interventions that were administered face to face and by telephone with breast cancer patients produced small positive significant effects on QoL (in 2 studies, SMD 0.23; 95% CI 0.04 to 0.43).

Authors' conclusions

The significant variation that was observed across participants, mode of delivery, discipline of 'trained helper' and intervention content makes it difficult to arrive at a firm conclusion regarding the effectiveness of psychosocial interventions for cancer patients. It can be tentatively concluded that nurse-delivered interventions comprising information combined with supportive attention may have a beneficial impact on mood in an undifferentiated population of newly diagnosed cancer patients.

PLAIN LANGUAGE SUMMARY

Individual therapy for people diagnosed with cancer

Cancer occurs in one in four of the population with over a quarter of a million people in the UK diagnosed each year (excluding non-melanoma skin cancer). A diagnosis of cancer can be emotionally challenging. UK government policy recommends that all individuals who are diagnosed with cancer should be assessed for emotional problems and given access to appropriate psychological support services. However, the nature and content of services and their delivery is unclear. This review examines the effectiveness of individual psychosocial interventions in the first 12 months after diagnosis. The psychosocial interventions involve a 'trained helper' providing therapeutic dialogue, sometimes referred to as talking therapy, with an individual diagnosed with cancer with the aim of improving quality of life and emotional wellbeing. The review combines research data from 1249 people who took part in clinical trials to test psychosocial interventions. The results are inconclusive. No improvement in general quality of life was found, but small improvements in 'illness related' quality of life were observed. No improvements in anxiety or depression were found, but small improvements in mood were detected. Nurse-led interventions using telephone and face-to-face delivery appear to show some promise. Future research should test assessment methods designed to identify patients who may benefit from psychosocial interventions, such as patients who are at risk of emotional problems; evaluate which type of 'trained helper' is the most appropriate professional to deliver psychosocial interventions for cancer patients; and conduct economic appraisals of the cost-effectiveness of interventions.

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

Psychosocial interventions to improve quality of life and emotional wellbeing compared with usual care for newly diagnosed cancer patients		
Patient or population: newly diagnosed patients with cancer Settings: hospital and community based settings Intervention: psychosocial interventions Comparison: usual care		
Outcomes	Standardised Mean Differences (95% CI)	No of Participants (studies)
Measures of Quality of Life [Psychometric measures of quality of life] [6 months]	0.11 [-0.00, 0.22]	1249 (9)
General Psychological Distress [Psychometric measures of general psychological distress] [6 months]	0.08 [-0.05, 0.21]	1502 (9)
Mood Measures [Psychometric measures of mood] [6 months]	-0.81 [-1.44, -0.18]	683 (8)

BACKGROUND

Description of the condition

Cancer has a significant impact on the lives of many people. It is experienced personally by one in four of the population and over a quarter of a million people in the UK are diagnosed with the disease each year (CRUK 2007) (excluding non-melanoma skin cancer). Cancer of the breast, colon, prostate and lung account for over 50% of cases. Due to the ongoing improvements in cancer diagnostics and clinical therapies, the prognosis for many people with cancer is improving steadily. The resulting advances in years of life gained are often achieved using invasive therapies that can lead to significant morbidity amongst patients (Weis 2003). Improvements in years or quantity of life (QoL) are now being followed, with an increasing recognition of the QoL of people with cancer and in particular the importance of giving attention to ways of maintaining and improving QoL in policy and practice (DoH 2004; NICE 2004).

A diagnosis of cancer can be psychologically and emotionally challenging and associated needs must be addressed appropriately. The

prevalence of psychological distress amongst cancer patients is difficult to estimate and reports of psychological morbidity vary from 6% (Sellick 1999) to 75% (Macmillan 2006) depending on the diagnostic tools and criteria. In the UK, prevalence appears to be greatest among people under 65 years and higher amongst patients seeking care through the NHS compared to patients receiving private treatment (Macmillan 2006).

The psychological and emotional impact of a cancer diagnosis can be influenced by many factors including the way in which clinicians impart a diagnosis, previous history of psychological morbidity and patient personal characteristics (Sellick 1999; Turton 2000). The most common reaction to a cancer diagnosis is emotional distress followed by a phase of taking control, which involves seeking information and sourcing appropriate help (Turton 2000). This common reaction has recently been illustrated in a survey in which 50% of cancer patients reported the need for emotional support services (Macmillan 2006). The survey also found that people affected by cancer appointed a higher priority to the need for studies on living and coping with cancer, and available support, than for research aimed at curing cancer (Macmillan 2006). Fur-

thermore, given the complex relationship between psychological distress and clinical aspects of care such as treatment compliance and immune function, the importance of identifying and providing effective forms of emotional support is widely accepted (NCI 2007; Sellick 1999).

Key points of psychological and emotional vulnerability include the time of diagnosis, treatment endpoints and episodes of recurrence (Turton 2000), and more is being gleaned about the distress trajectories experienced according to personal and disease characteristics (Henselmans 2010). This review aims to assess the impact of interventions during the phase directly after diagnosis. However, as the chronology of the cancer journey will depend heavily on the cancer stage and site, along with numerous other patient and provider variables, it is difficult and perhaps inappropriate to specify precisely the boundaries around periods of vulnerability. Best evidence suggests that levels of depression and anxiety in cancer patients generally tend to subside after the first 12 months (Stanton 2006).

Description of the intervention

Over the past three decades a variety of individual and group-based interventions have been developed specifically for people with cancer. Psychosocial interventions are wide ranging in terms of theoretical background, complexity, content and mode of delivery (Stanton 2006; Weis 2003). In essence, a psychosocial intervention is non-pharmacological and involves an interpersonal relationship between a patient or group of patients and one or more trained (usually professional) helpers. The psychosocial aspect includes interventions described as psychological, psychotherapeutic, psychoeducational or psychosocial (see [Types of interventions](#) below for the range of interventions that will be covered in the review).

Why it is important to do this review

Current UK government policy recommends that all patients should undergo systematic psychological assessment at key points during their cancer journey complimented by access to appropriate psychological support services (DoH 2004; NICE 2004). The National Institute for Clinical Excellence (NICE) states that there is a need for further evaluative research to “determine which psychotherapeutic interventions are most effective for different groups of patients at different stages of the patient pathway” (NICE 2004). Despite the flourishing growth of literature in this area of cancer care and the wide range of treatments available to ease symptoms of anxiety and depression, no evidence-based guidelines exist to inform methods of assessing and addressing emotional wellbeing in people during the early diagnostic phase. Previous reviews of the literature have suggested that psychosocial therapies have a positive impact on emotional adjustment, QoL, psychological distress and coping skills (Chan 2012; Edwards 2004; Jacobsen

2002; Linden 2012; Newell 2002; Sellick 1999; Stanton 2006; Weis 2003).

To date, no review focuses exclusively on the early stage of coping with a cancer diagnosis. It is also commonplace for review conclusions to be drawn tentatively due to concerns about the quality of the research methods employed when testing psychosocial interventions (Jacobsen 2008; Linden 2012; Newell 2002). Given the volume of publications that has emerged over the last decade, it was hoped that the current review would reveal a higher standard of methodology and reporting than had previously been found by review authors.

This review took account of the NICE recommendations for further research by assessing the value of psychosocial (including psychotherapeutic) interventions that have been designed to ameliorate the emotional symptoms accompanying and following a cancer diagnosis in adult cancer patients. A focused systematic review of studies in this area can help to identify appropriate service responses for cancer patients at this first stage in their cancer journey.

OBJECTIVES

To assess the effects of psychosocial interventions to improve QoL in recently diagnosed cancer patients.

The review also assessed the effects of psychosocial interventions with recently diagnosed cancer patients to address:

- general psychological distress;
- anxiety;
- depression.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) and quasi-RCTs of psychosocial interventions with recently diagnosed adult cancer patients.

Types of participants

Adults (18+ years) who had been formally diagnosed with any type or stage of cancer within the past 12 months.

Types of interventions

An intervention must comprise 'talking' in the form of a verbal dialogue between an individual and a trained 'helper'*. The review exclusively assessed psychosocial interventions involving interpersonal dialogue and therefore excludes interventions based solely on the following: physical therapy, that is massage; alternative therapy, that is acupuncture; educational media, that is leaflets, brochures, CDs or DVDs, or other media.

Control groups must have been free of any intervention, that is must be receiving standard care only. Trials that included other interventions combined with psychosocial interventions in the active intervention arm were excluded.

*Group and couple-based interventions were excluded. See changes made to the original scope of the review in [Differences between protocol and review](#).

Types of outcome measures

Primary outcomes

- Quality of life (QoL)

Secondary outcomes

- General psychological distress
- Depression
- Anxiety

All outcome measures must have been assessed using a validated scale, for example: European Organisation for Research and Treatment of Cancer (EORTC) or Functional Assessment of Cancer Therapy Scales (FACT), Short Form-36 (SF-36), General Health Questionnaire-12 (GHQ-12), Beck Depression Inventory, Hospital Anxiety and Depression Scale.

Search methods for identification of studies

Electronic searches

To identify studies for inclusion in this review, detailed search strategies were developed for each of the following electronic databases:

- Cochrane Central Register of Controlled Trials (CENTRAL) (up to January 2011);
- MEDLINE (to January 2011);
- EMBASE (to January 2011);
- CINAHL (to January 2011);
- PsycINFO (to January 2011).

The search used a combination of controlled vocabulary and free text terms in addition to the Cochrane highly sensitive search

strategy for identifying reports of RCTs (*Cochrane Handbook for Systematic Reviews of interventions* Version.2.4.6; Appendix 5b). The search strategy was developed for MEDLINE and revised appropriately for each database. The search terms are presented in [Appendix 1](#); [Appendix 2](#); [Appendix 3](#); [Appendix 4](#).

Research in progress

The following online registers of ongoing trials were searched:

- <http://controlled-trials.com>;
- <http://clinicaltrials.gov>.

Language

No language restriction was placed on searches. Foreign language abstracts were initially translated for the application of the inclusion and exclusion criteria and, where necessary, the methods, results and discussion sections were translated for inclusion in the review.

Searching other resources

Reference lists

The reference lists of all studies were checked for further potentially relevant studies.

Correspondence

Authors of significant papers were contacted to find other potentially relevant studies and to confirm any queries.

Data collection and analysis

Selection of studies

All titles and abstracts retrieved by electronic searching were downloaded to a reference management database (Refworks) and duplicates removed. The remaining abstracts (or an extract) were examined by pairs of review authors and independently screened for applicability according to the criteria for selecting studies for this review. In situations where information about the criteria was not apparent within the abstract, the complete text was acquired and checked for eligibility.

Data extraction and management

The review authors independently extracted data from original reports in pairs, with two authors extracting data from each study, using data extraction forms. Any disagreement was resolved by consensus between the two or, where necessary, between all the authors. Extracted data included country of origin, health professional group involved, nature and content of psychosocial intervention and patient group involved, duration of study, setting, sample size, quality and outcomes including the names of validated instruments utilised.

Assessment of risk of bias in included studies

The review authors worked in pairs to assess the methodological quality of each selected study.

Random allocation

We coded the randomisation of participants to intervention groups as:

- a) adequate, e.g. computer-generated random sequence, or table of random numbers;
- b) quasi-randomised, e.g. date of birth, hospital identity (ID) number or surname;
- c) unclear, e.g. not reported.

Allocation concealment

We coded the concealment of allocation sequence from treatment providers and participants as:

- adequate, e.g. where the allocation sequence could not be foretold;
- inadequate, e.g. where the allocator or treatment provider could see which arm the next participant was being assigned to;
- unclear, e.g. not reported.

Blinding

Participants cannot be blinded to the intervention. However, we coded the blinding of outcome assessors as follows.

- Yes.
- No.
- Unclear.

Loss to follow-up

We recorded the number of participants in each intervention arm whose outcomes were not reported at the end of the study, and we noted whether or not loss to follow-up was reported.

Assessment of reporting bias

A funnel plot corresponding to the primary outcome was generated to assess the potential for publication bias.

Data synthesis

Measures of treatment effect

Data were entered into RevMan where standardised mean differences (SMD) and 95% confidence intervals (CI) were calculated and pooled using a random-effects model. SMDs are the appropriate choice of measure of efficacy when different scales have been employed across trials, for example the EORTC QLQ-30, SF-36, and FACT-B.

Assessment of heterogeneity

Heterogeneity between studies was assessed using the I^2 statistic. I^2 greater than 50% was considered indicative of heterogeneity. Where marked heterogeneity was suspected, sources were investigated, and where excessive heterogeneity was found estimates were interpreted with caution. Random-effects models were used for all meta-analyses.

Subgroup analysis

It was intended that the effectiveness of the interventions be examined in subgroups classified by: (1) cancer site; (2) training and qualifications of intervention facilitator or 'trained helper'; (3) mode of intervention for example face to face, telephone, or a combination; (4) emotional state at the time of the intervention; and (5) stage and mode of clinical treatment programme. The review team used a descriptive typology of interventions to conduct subgroup analyses of studies by type given the wide range of interventions that can be described as psychosocial, such as cognitive behavioural therapy, psychoeducation, and other counselling approaches with an unspecified theoretical basis.

When the characteristics of data had been extracted from the selected studies, the range of psychometric measures used as primary outcome measures was recognised as qualitatively different, and therefore an important potential source of heterogeneity. In order to take this into consideration a post hoc subgroup analysis was added to examine results according to general health-related quality of life measures and illness-specific quality of life measures.

Summary of findings table

The [Summary of findings for the main comparison](#) presents the results of meta-analyses carried out on primary and secondary outcomes: QoL (n = 9 studies), general psychological distress (anxiety, n = 4 studies; depression, n = 6 studies) and mood measures (n = 8 studies).

A brief narrative description of studies not suitable for meta analyses has been included in the results section of the review (n = 10 studies, plus Sandgren's pilot (Sandgren 2000) and long-term follow-up publication (Sandgren 2007)).

RESULTS

Description of studies

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

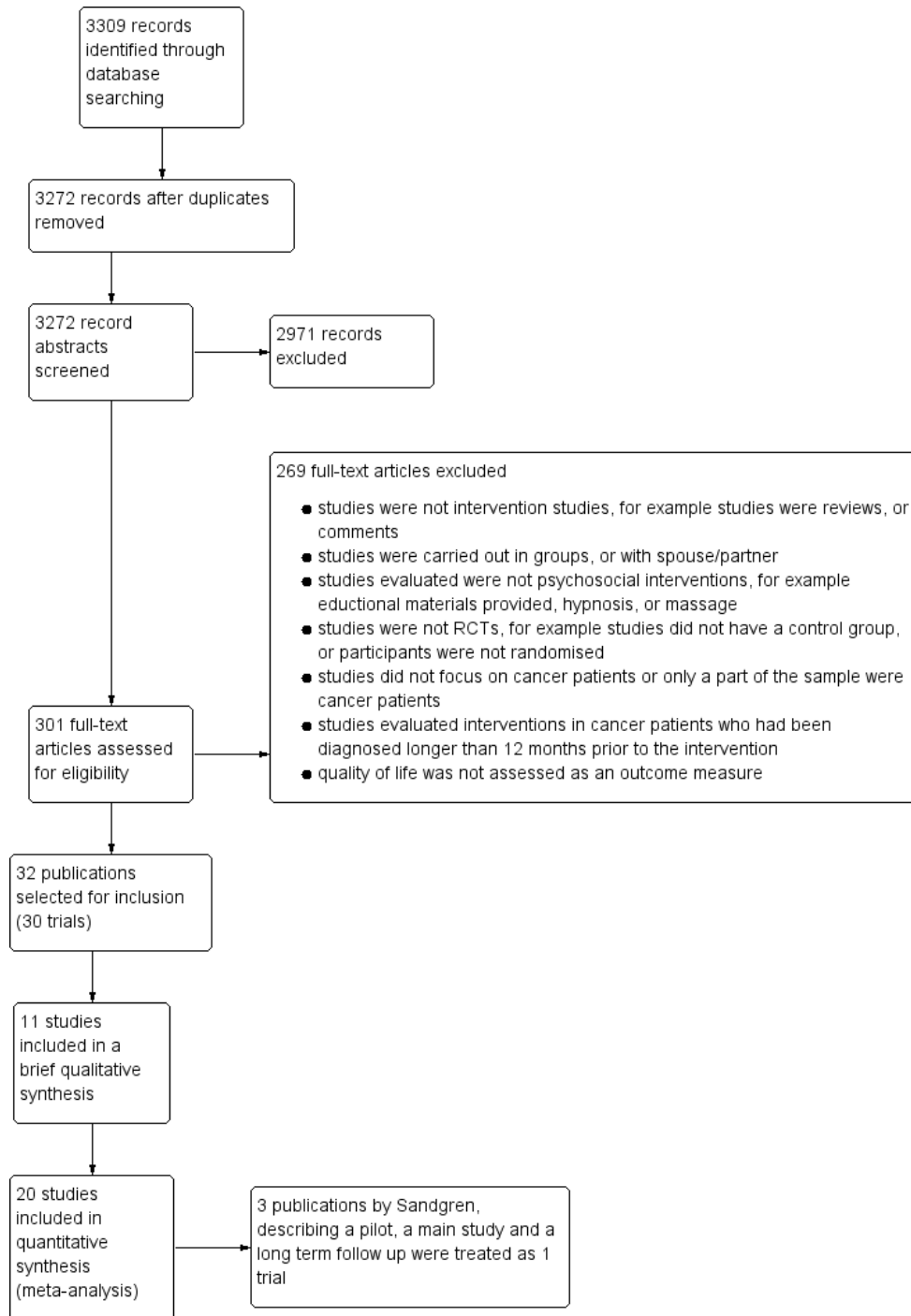
Thirty studies were included, and an important comment should be made. Sandgren 2000 reported on a pilot study which was expanded and reported on in Sandgren 2003. The later paper, Sandgren 2007, included the long-term follow-up data. Follow-

up data closest to six months were extracted where possible across all studies, so the results of the 2003 paper were selected for the meta-analyses. Therefore, 32 publications were evaluated as 30 separate studies.

Results of the search

Figure 1 illustrates the process of study selection for the review. The search of the electronic databases retrieved 3309 publications. After eliminating the duplicates, 3272 publications were identified for screening. After this initial screening, the full-text articles were retrieved for the remaining 301 potential studies. From these full-text articles 268 publications were excluded leaving 32 publications included in the review. These 268 publications were excluded for the reasons stated in the 'Excluded studies' section below, however the reason for exclusion did not become apparent until the full text of the article had been examined in detail.

Figure 1. Study flow diagram.



Included studies

Design

Only RCTs were included in the review. Therefore, all 30 included studies reported a baseline assessment and a post-intervention assessment. However, the total number of post-intervention assessments varied between two and eight, with a median of two. The format of reporting precluded data extraction for meta-analytic combination in 10 studies (Burton 1995; Forester 1985; Jacobsen 2002; Lee 2006; Lev 2000; Linn 1981; Mishel 2002; Ross 2005; Scura 2004; Scholten 2001).

Sample sizes

The sample size across the 30 included studies varied between 17 and 558, with a total of 5155 participants. The mean number of participants was 172. Tables 1 and 2 provide an overview of study characteristics, indicating those studies that provided appropriate data for inclusion in the meta-analyses (Table 1; Table 2).

Setting

In the context of this review, setting describes the discipline of the intervention administrator and mode of delivery. The most common discipline to administer psychosocial interventions with newly diagnosed patients was registered nurses, across 11 trials (Allard 2007; Dow Meneses 2007; Downe-Wamboldt 2007; Fawzy 1995; Lee 2006; Lev 2000; McArdle 1996; Mishel 2002; Moynihan 1998; Ross 2005; Sandgren 2003). Psychologists delivered interventions in five studies (Chan 2005; Jacobsen 2002; Johansson 2008; Nezu 2003; Scholten 2001), medical practitioners were the interventionists in four studies (Burton 1995; Forester 1985; Holtedahl 2005; Petersen 2002) and counsellors were involved in two studies (McQuellon 1998; Puig 2006). A further four interventions in studies were administered by multi-disciplinary teams of social workers, psychologists and nurses (Edgar 2001; Manne 2007; Parker 2009; Stanton 2005), one was delivered exclusively by social workers (Linn 1981), one by a researcher at PhD level (Scura 2004), and one study failed to report the discipline of the facilitator (Trask 2003).

Mode of delivery also varied across studies, with four telephone intervention studies (Allard 2007; Downe-Wamboldt 2007; Sandgren 2003; Scura 2004) and six interventions featuring a combination of face-to-face and telephone contacts supplemented by additional media such as video tapes and written manuals (Dow Meneses 2007; Johansson 2008; Lev 2000; Manne 2007; Mishel 2002; Stanton 2005). All the remaining studies utilised the most

common mode of face-to-face delivery (n = 20). No trials of web-based interventions met the criteria for the review.

Participants

Disease characteristics

A majority of the studies focused on patients with a single site malignancy (n = 18) (Allard 2007; Burton 1995; Dow Meneses 2007; Fawzy 1995; Kanzaki 2002; Lev 2000; McArdle 1996; Mishel 2002; Moynihan 1998; Parker 2009; Petersen 2002; Puig 2006; Ross 2005; Sandgren 2003; Scholten 2001; Scura 2004; Stanton 2005; Trask 2003). The remainder examining a mixed site group (n = 12). The majority of single site studies focused on patients with breast cancer (n = 9) (Allard 2007; Burton 1995; Dow Meneses 2007; Lev 2000; McArdle 1996; Puig 2006; Sandgren 2003; Scholten 2001; Stanton 2005). The remainder of the single site studies focused on colon (Ross 2005), gastric (Kanzaki 2002), skin (Fawzy 1995; Trask 2003), prostate (Mishel 2002; Scura 2004), and testicular cancer (Moynihan 1998; Parker 2009). Some trials appeared to have included sites according to the speciality of the centre in which the trial took place, whereas others stated that they had included all cancers.

Psychiatric selection and exclusion criteria

Eleven trials excluded patients with a history of psychological problems (Allard 2007; Fawzy 1995; Holtedahl 2005; Kanzaki 2002; Lee 2006; Mishel 2002; Nezu 2003; Parker 2009; Petersen 2002; Stanton 2005; Trask 2003). One specified excluding those with suicidal thoughts (Moynihan 1998) and one specified excluding those with senile dementia (Ross 2005). One trial with a sample size of 200 included 40 individuals with a psychiatric history, (Burton 1995). The remaining 16 studies did not specify current or previous psychiatric conditions separately from exclusion criteria that generally referred to serious co morbidities. No screening criteria were employed with the aim of targeting interventions for pre-existing levels of distress, although all participants were subject to baseline screening of QoL or psychological distress to provide 'time 1' measures for the trials.

Interventions

In order to consider the use of pooled estimates in a systematic review, the studies need to be considered homogeneous to ensure that a combined analysis is valid. The basis on which we have approached this is founded on the principle that the effect of a psychosocial intervention is a function of the supportive relationship

between the 'trained helper' and the individual diagnosed with cancer. The supportive human interaction is present across all trials, as is the common aim to alleviate distress and improve quality of life in the event of a cancer diagnosis. It is argued that when carrying out systematic reviews, "heterogeneity should be considered the expectation as opposed to the exception [and where possible] analyses of heterogeneity should be pursued and interpreted cautiously in the spirit of an exploratory data analysis" (Berlin 1995). In the current review, features of the selected studies have been considered in this way and, to facilitate careful planning, we have used a priori definitions and analytic strategies. Subgroup analyses examined the factors relating to the content of the interventions, the mode of delivery of interventions, the discipline of the trained helper and the types of outcome measures used. These subgroups were selected to address the variations across outcome measures, cancer site, intervention types, discipline of 'trained helper' and mode of delivery in included studies. Post hoc subgroup analyses were also carried out according to the use of general health-related QoL measures and illness-specific measures of QoL.

Theoretical basis

All the studies included some form of supportive relationship, defined by interpersonal dialogue involving a 'trained helper' and an individual participant. All group, family and couple-based interventions were excluded from the review. See [Differences between protocol and review](#) for details. The theoretical basis within the interventions varied markedly. Some were based on one or two elements, while others used multiple techniques. Fourteen studies specifically referred to Cognitive Behavioural Therapy (CBT), or to recognised techniques within that discipline (Chan 2005; Downe-Wamboldt 2007; Edgar 2001; Fawzy 1995; Johansson 2008; Kanzaki 2002; Lev 2000; Mishel 2002; Moynihan 1998; Nezu 2003; Parker 2009; Scholten 2001; Stanton 2005; Trask 2003). Eight studies described the intervention as a form of counselling (Allard 2007; Holtedahl 2005; Linn 1981; Manne 2007; McArdle 1996; Petersen 2002; Ross 2005; Sandgren 2003), including many varied techniques ranging from supportive listening to detailed, referenced intervention 'packages', such as the Attentional Focus and Symptom Management Intervention (AFSMI) (Allard 2007). Four studies took the form of brief, preparatory interventions timed immediately prior to treatment, particularly invasive procedures such as surgery (Burton 1995; Forester 1985; Jacobsen 2002; McQuellon 1998). These four used a combination of theoretical approaches including counselling, psychotherapy and relaxation techniques. Three studies were classified by the authors as psychoeducational in nature (Dow Meneses 2007; Puig 2006; Scura 2004), although art therapy played an important role in Scura 2004. Finally, a single study specified a 'meaning-making' approach (Lee 2006).

Duration

Out of the 30 studies only 21 reported a specific number of sessions delivered to the intervention group. Amongst those 21 studies the number of sessions varied from one to 10, with a median of four sessions. The remaining nine studies reported a variety of permutations, including 'as required', 'while treatment took place'; and some stated the percentage of the intervention group who took part in more than a specified number of sessions. The length of sessions were between 10 and 90 minutes, whereas the frequency of sessions fell between 'several times a week' and 'once every two months'.

Control conditions

In one study 11% of participants were already receiving psychological interventions prior to and during the trial (Lee 2006). In another study the authors declared that a psychological assessment was part of standard care and therefore was implemented with the control group (Jacobsen 2002). In the remaining studies, the participants in the control group did not receive the intervention but received standard care and standard information on treatment.

Outcomes

Eleven studies focused on the primary outcome of QoL using validated psychometric measurement tools such as the European Organisation for Research and Treatment into Cancer Quality of Life Questionnaire-30 (EORTC QLQ-30) *(Chan 2005; Holtedahl 2005; Johansson 2008; Ross 2005), Functional Assessment of Cancer Therapy Breast/General (FACT-B/G) (Edgar 2001; Lev 2000; Sandgren 2003; Scura 2004) and SF-36 (Jacobsen 2002; Stanton 2005; Trask 2003). Three studies used less well known validated measures of QoL (Dow Meneses 2007; Linn 1981; Scholten 2001). The remaining 16 reported on general psychological state, extrapolating from the results of a wide variety (and multiple use of) of psychometric tools as a proxy measure of QoL, including Profile of Mood States (POMS), General Health Questionnaire-28 (GHQ-28), Hospital Anxiety and Depression Scale (HADS), Mini-Mental State Examination (MMSE), State Trait Anxiety Inventory (STAI), Centre for Epidemiological Studies-Depression (CES-D), Beck Depression Inventory (BDI), Rosenberg Self-Esteem Scale (RSES) and a number of other less well known validated measures. Four studies provided appropriate data for meta-analyses of the primary outcome QoL as well as the secondary outcome general psychological distress (Chan 2005; Edgar 2001; Johansson 2008; Trask 2003), whereas 11 provided data suitable for meta-analyses of the general psychological distress outcome only (Allard 2007; Downe-Wamboldt 2007; Fawzy 1995; Kanzaki 2002; Manne 2007; McArdle 1996; McQuellon 1998; Moynihan 1998; Nezu 2003; Petersen 2002; Puig 2006) and five provided data suitable for meta-analysis of QoL outcomes only (Dow Meneses 2007; Holtedahl 2005; Parker 2009; Sandgren 2003; Stanton 2005).

Excluded studies

Reasons for excluding publications were:

- studies were not intervention studies, e.g. studies were reviews, or comments;
- studies were carried out in groups, or with spouse or partner;
- studies evaluated were not psychosocial interventions, e.g. educational materials provided, hypnosis, or massage;
- studies were not RCTs, e.g. studies did not have a control group, or participants were not randomised;
- studies did not focus on cancer patients, or only a part of the sample were cancer patients;
- studies evaluated interventions in cancer patients who had been diagnosed longer than 12 months prior to the intervention;
- studies did not focus on first diagnosis, or only part of the sample were experiencing a first diagnosis;
- QoL was not assessed as an outcome measure.

Due to the volume of studies identified by the search, usually only the first occurrence of an exclusion criterion in the publication was noted, although it was common for studies to feature a combination of the reasons for exclusion listed above. Therefore, it was neither valid nor helpful to present the number of papers excluded under each of the reasons listed above.

The extent of exclusion at the full-paper stage (268 publications excluded from 301) provided the first indication of problems associated with quality of reporting in this research arena. Due to the high number of studies that were initially identified and subsequently excluded, it would not have been helpful to enter details of each into the 'Characteristics of excluded studies' section of this review.

Risk of bias in included studies

The results of the methodological quality assessment are described in the 'Risk of bias' tables.

The possibility of bias could be found in the characteristics of the samples. The exclusion criteria varied between the included studies, for example some studies excluded patients with co morbidities, while some studies did not describe any additional exclusion criteria. The methodological quality might also introduce bias. This is described in the discussion in more detail.

Effects of interventions

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

The following section provides a description of the results of the meta-analytical examination of the primary outcome QoL and the secondary outcome general psychological distress. Also presented is a brief narrative description of the studies that did not present adequate data for meta-analysis.

Primary outcome - quality of life (QoL)

Eleven studies focused on the primary outcome of the review using validated measures to gauge the impact of an intervention on QoL. Nine of these provided adequate data for meta-analysis ([Ross 2005](#) and [Lev 2000](#) could not be included). A funnel plot corresponding to the primary outcome was generated to assess the potential for publication bias ([Figure 2](#)). There was no evidence of funnel plot asymmetry which would potentially indicate publication bias. ([Figure 3](#)).

Figure 2. Funnel plot of comparison: Quality of Life; all studies.

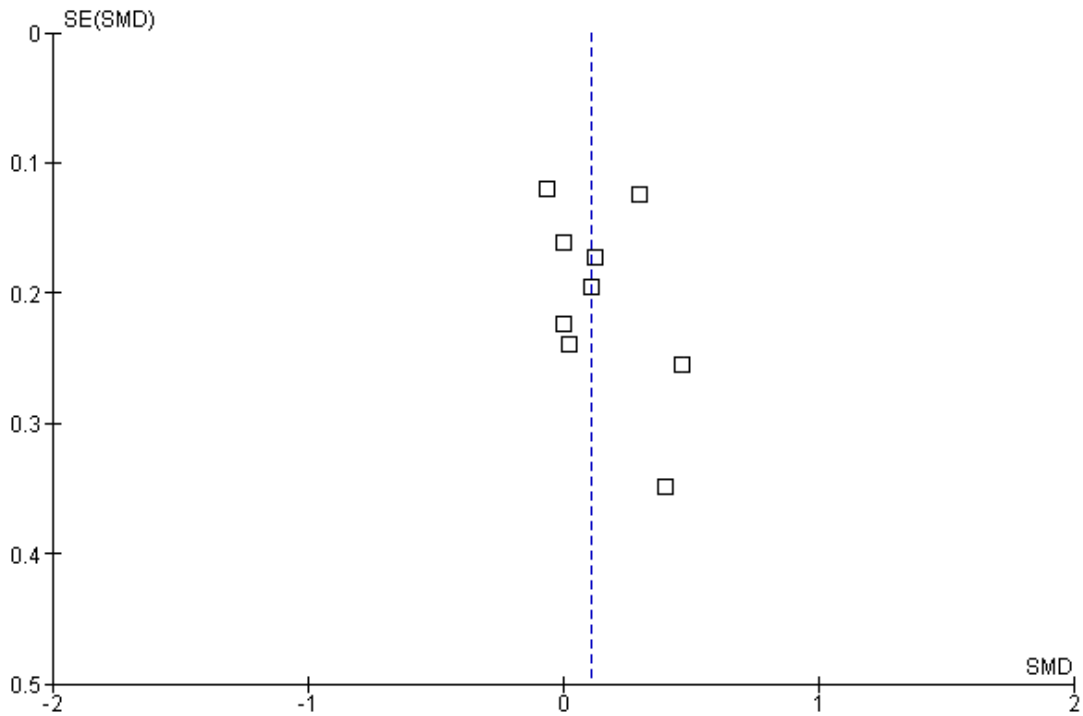
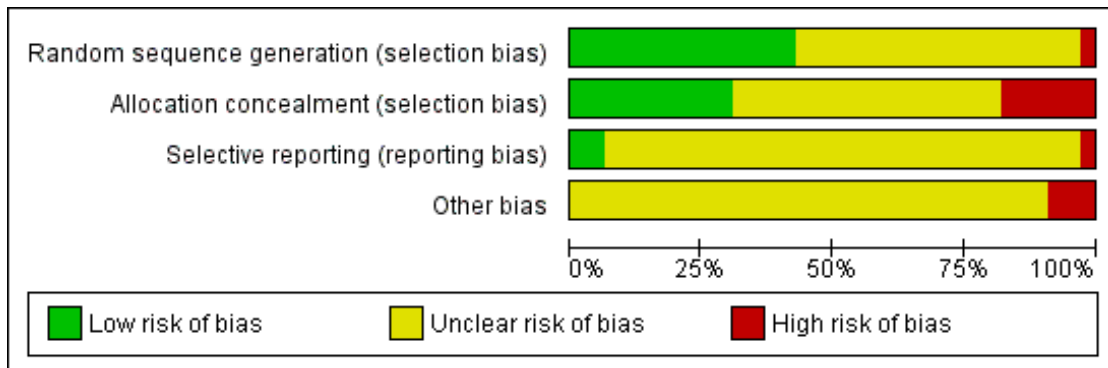


Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



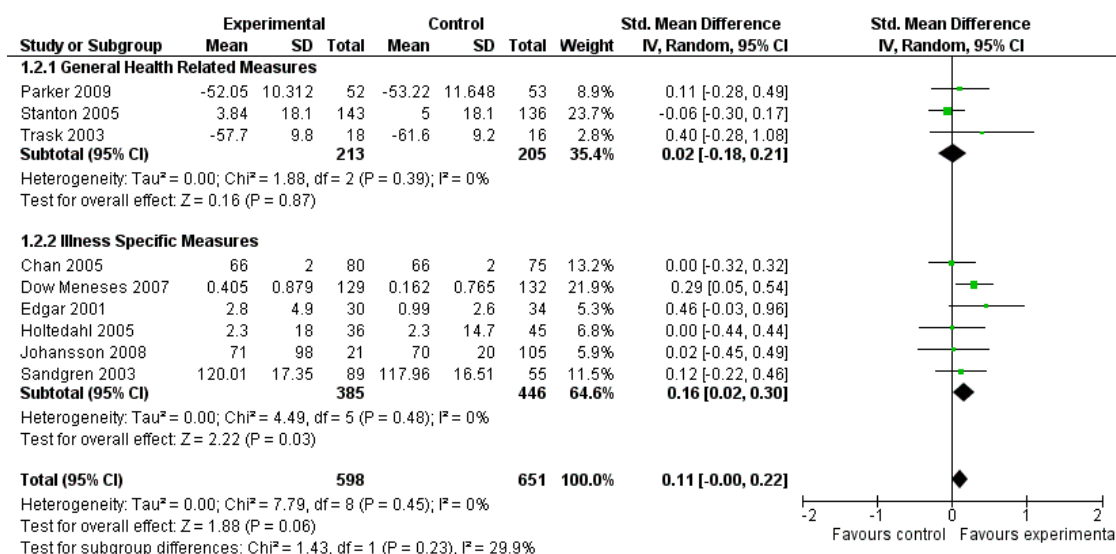
Analysis 1.1 presents the combined results for all validated measures of QoL across the reported follow-up period closest to six months (varied between four and six months) in the relevant nine studies. It clearly indicated that only one study had a significant

effect on QoL (Dow Meneses 2007) and none had a large effect. Analysis at this macro-level suggests there was no clear evidence of a benefit of providing a psychosocial intervention to improve QoL

for patients recently diagnosed with cancer (SMD 0.11; 95% CI 0.00 to 0.22). There was no marked evidence of statistical heterogeneity between study estimates ($P = 0.48$, $I^2 = 0\%$).

However, when the analysis was divided into general health-related and illness-specific QoL measures, a small but significant positive result was observed in the data utilising illness-specific measures (SMD 0.16; 95% CI 0.02 to 0.30). The illness-specific measures used in the six combined studies were the EORTC QLQ-30, FACT-B/G, and the QoL Breast Cancer Survivors Scale. The general health measure of QoL used in the remaining three studies was the SF-36. With the use of cancer-specific QoL measures, there appeared to be evidence that supported the use of psychosocial interventions for QoL in newly diagnosed cancer patients (Analysis 1.2; Figure 4). However, the effect size was small and may not be considered clinically significant.

Figure 4. Forest plot of comparison: I Primary outcome Quality of Life, outcome: I.2 Measures of Quality of Life.



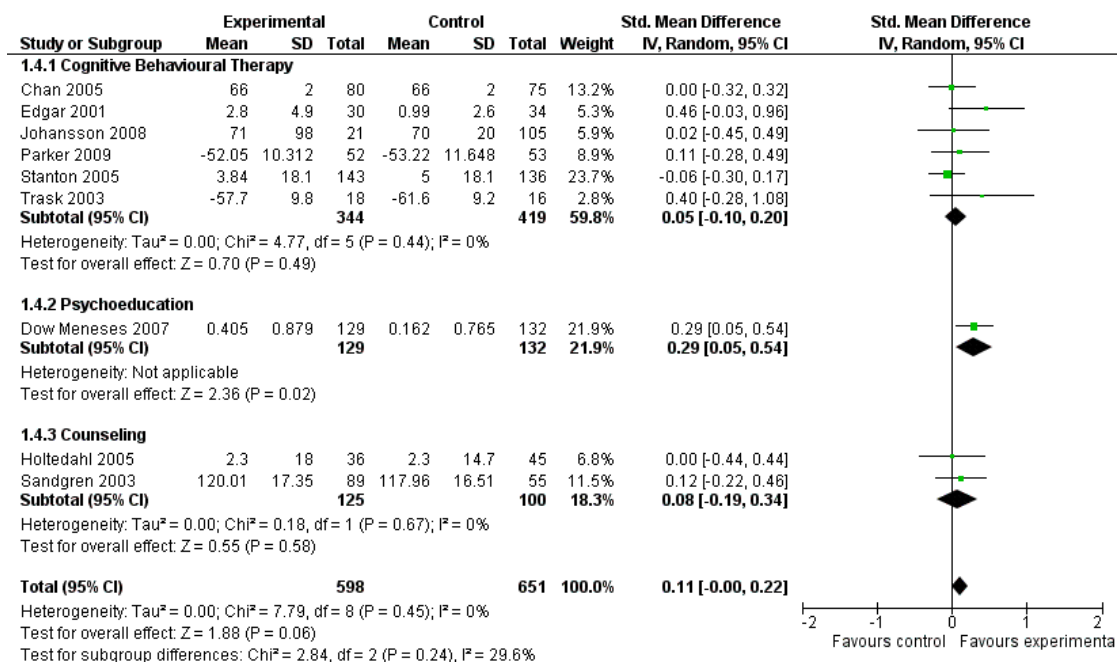
Analysis 1.3, Analysis 1.4, Analysis 1.5, Analysis 1.6 presented the results of examining the primary outcome in four subgroups according to: cancer site; theoretical basis or type of intervention; mode of delivery; and discipline of 'trained helper'. Across these subgroup analyses two significant results emerged that could indicate stronger beneficial features of interventions designed to improve QoL in newly diagnosed cancer patients, namely psychoeducational interventions and nurse-delivered interventions. Again, the effect sizes were small.

Analysis 1.4 and Figure 5 present the theoretical basis subgroup analysis, classified into counselling, CBT and psychoeducation.

Only one study was classified as primarily psychoeducational (Dow Meneses 2007), although a number of others were designed with an educational component. Although a less well known validated measure of QoL was used, the Dow Meneses et al RCT involved 261 breast cancer participants in an adequately randomised design with no indication of other methodological concerns (SMD 0.29; 95% CI 0.05 to 0.54). Further replication of the results would increase confidence in the conclusions about the value of a psychoeducational intervention across wider groups of cancer patients and cancer sites, particularly if they used more commonly recognised

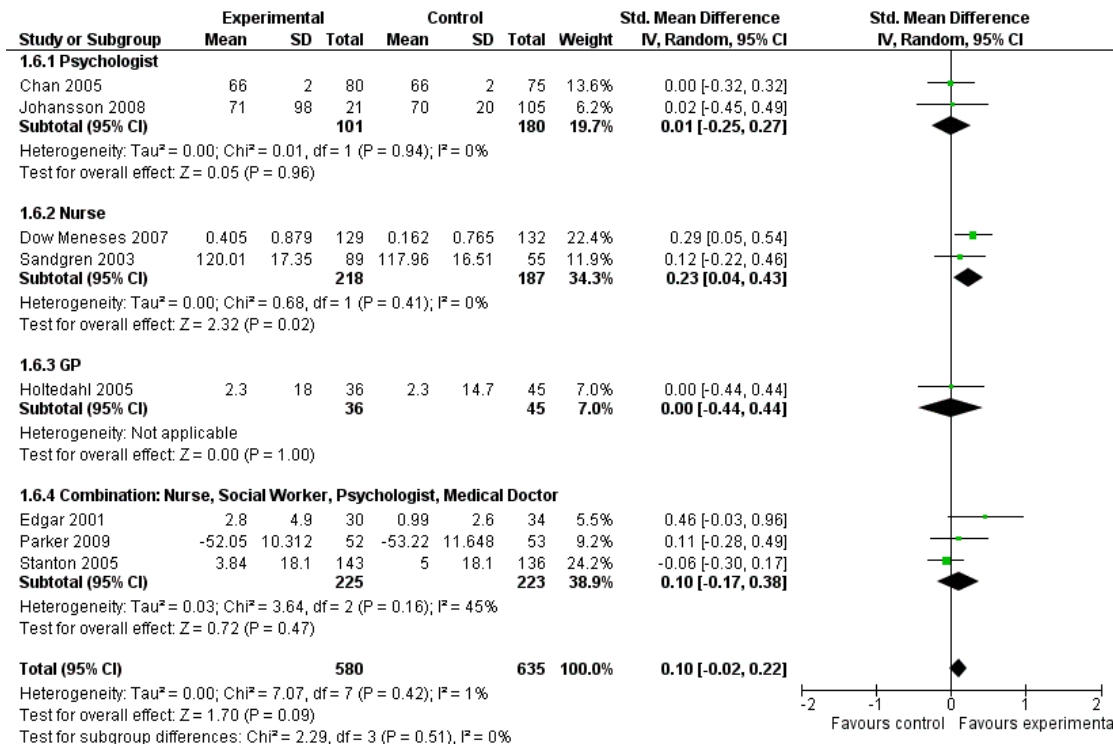
validated measures of QoL to promote more robust comparisons across studies.

Figure 5. Forest plot of comparison: I Primary outcome Quality of Life, outcome: I.4 Type of Intervention.



Analysis 1.6 and Figure 6 indicate positive results achieved through nurse-delivered interventions (SMD 0.23; 95% CI 0.04 to 0.43) in a combined analysis of two studies (Dow Meneses 2007; Sandgren 2003). The interventions involved a total of 405 participants recently diagnosed with breast cancer and receiving two distinct interventions with counselling and psychoeducational approaches. Sandgren et al delivered the intervention with six 30-minute telephone sessions whereas Dow Meneses et al used a combination of two telephone sessions and five face-to-face sessions. The follow-up data were collected at five and six months respectively. The effect size was small, indicating that in terms of QoL measures the impact of the interventions may only approach clinical significance.

Figure 6. Forest plot of comparison: I Primary outcome Quality of Life, outcome: I.6 Discipline of 'Trained Helper'.



Subgroup analyses were planned for gauging the impact of emotional state at the time of the intervention and the stage and mode of the clinical treatment programme, however the studies examined did not provide adequate assessments or breakdown of results to answer these questions.

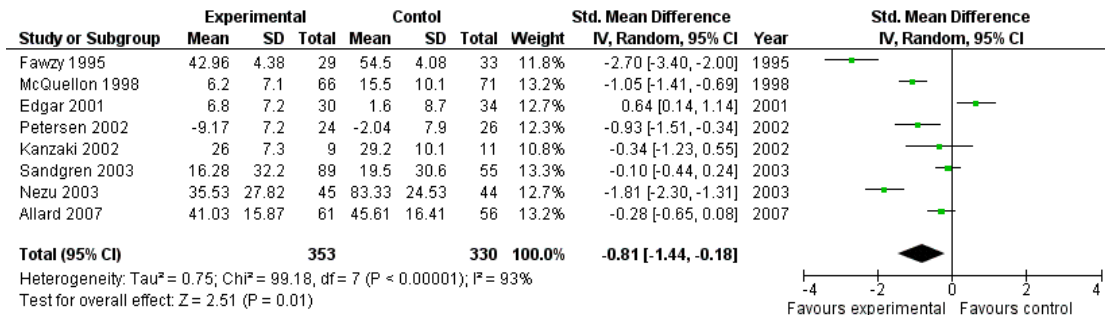
Secondary outcome - general psychological distress

Analysis 3.1 presents a combined analysis of results across 10 studies that represented general psychological distress using validated measures of depression (Chan 2005; Edgar 2001; Johansson 2008; Manne 2007; Puig 2006; Stanton 2005) and anxiety (Johansson 2008; McArdle 1996; Moynihan 1998; Trask 2003). The analysis did not provide evidence of the effectiveness of psychosocial interventions to alleviate anxiety or depression amongst newly diagnosed cancer patients. The effect sizes were not statistically significant, and statistical heterogeneity was present in the outputs of

both sets of pooled estimates.

Analysis 3.2 and Figure 7 present a combined analysis of results gathered using 'mood measures'. The results indicated a significant impact of psychosocial interventions on mood (SMD -0.81; 95% CI -1.44 of -0.18). However, the percentage variability in effect estimates that was due to heterogeneity rather than sampling error (chance) was high ($P \leq 0.01$, $I^2 = 93\%$). The heterogeneity found was likely to reflect differences in size and character of the patient populations examined, possible differences in the contents of the intervention, the mode of delivery or the discipline of the 'trained helper', as well as differences in the methodological quality of the different trials. However, if that was the case, we might expect heterogeneity to be high across every meta-analysis in the review. The unexplained level of heterogeneity rendered the results inconclusive.

Figure 7. Forest plot of comparison: 3 Secondary outcomes, outcome: 3.2 Mood measures.



Risk of bias

No-significant findings were revealed by analysing the combined results according to study quality, either by examining the use of intention- to treat (ITT) analyses or by risk of bias measures (Analysis 2.1).

Brief narrative description of studies not suitable for meta analyses

- **Burton 1995** (preparation for surgery): although the GHQ-28 Goldberg 1978 and HADS Zigmond 1983 measures were used, the figures presented in the results section were inadequate for combination in meta analyses. Two 30-minute psychotherapeutic interventions were delivered prior to mastectomy and after the operation. Results based on case-ness and mean score on GHQ-28 and HADS were not significantly different across intervention and control groups. However, the authors reported that the rate of declining participation was 33%. They pointed out that many older patients actively expressed a wish to avoid discussion of emotional need, therefore it may be useful to screen for emotional need prior to introducing psychotherapeutic interventions (null result).
- **Forester 1985** (preparation for surgery): no self-report measures were presented, only results of the clinician administered diagnostic scale Schedule of Affective Disorders and Schizophrenia (SADS) (Endicott 1978). The SADS results indicated that a one-week psychotherapeutic course significantly reduced emotional and physical manifestations of distress in the intervention group compared to the control group over the course of radiotherapy treatment (positive result).
- **Jacobsen 2002**: change scores were presented graphically making it impossible to extract accurate data for inclusion in meta-analyses. The results indicated that a self-administered stress management training intervention improved QoL during chemotherapy treatment, measured with the SF-36. However, the professionally-administered intervention produced no

significant differences when compared to the control group (positive result with self-administration or 'trained helper').

- **Lee 2006**: participants received four sessions of individual therapy in the form of a meaning making intervention. Outcomes measured included self esteem (Rosenberg Self-Esteem Scale), optimism (Life Orientation Test) and Generalised Self Efficacy (GSES). None of these measures alone are comparable to QoL, anxiety, depression or general psychological distress and therefore could not be combined in a meta-analysis. Significant improvements were found across each scale measured within the experimental group compared to the control group (positive result).
- **Lev 2000**: although the well validated FACT was employed to measure the primary outcomes, the results were not presented in a format suitable for meta-analysis (only interaction effect sizes were presented). The results suggested that interventions to promote self-efficacy increased QoL and decreased symptom distress for women diagnosed with breast cancer (positive result).
- **Linn 1981**: although a number of validated scales were used, no figures were presented that could be extracted for meta-analyses. Results indicated that response to counselling in recently diagnosed late stage terminal cancer was positive in both younger and older patients (positive result).
- **Mishel 2002**: the outcomes included a sub scale of a QoL measure devised for use in cancer patients by the Southwest Oncology Group. The other outcomes were not appropriate for combining with QoL, general psychological distress, anxiety or depression measures. Although there was a suggestion of a trend towards a positive impact of the nurse-delivered psychoeducational intervention, the authors stated that replication would be required prior to making any firm conclusions on psychoeducational telephone interventions for men with prostate cancer (null result).
- **Ross 2005**: the authors presented only figures representing the difference between the intervention and control group on both HADS and EORTC QLQ-30 without number of

participants, standard deviation or change scores; therefore, it was not possible to extract data for meta-analyses. The results suggested that a set of 10 unstructured home visits by a doctor or nurse for approximately 60 minutes had no significant impact on wellbeing. The authors recommended screening for baseline levels of distress as well as the use of trained therapists delivering short, more intensive interventions (null result).

- [Sandgren 2000](#) and [Sandgren 2007](#): in 2000 the authors carried out a pilot study; the results were excluded from the meta-analyses in favour of the data produced during their main trial in 2003. The 2007 publication presented the long-term follow-up data from the 2003 study. Outcomes recorded closest to six months after the intervention were selected from all included publications for combining in the meta-analyses.

- [Scholten 2001](#): results were presented in two categories representing non-health related and health-related QoL, using a measure based on an unvalidated visual analogue scale. The findings provided support for early psychosocial counselling in newly diagnosed patients and conversely showed that the acceptance of such interventions later in the disease trajectory was low (positive result).

- [Scura 2004](#): this pilot study of telephone social support counselling over 12 months in men within four weeks of a prostate cancer diagnosis found no significant difference in QoL scores between the intervention and control groups. Only 17 participants were involved, and it was deemed appropriate to exclude the results of any such small scale pilot study from the meta-analyses. The qualitative findings indicated that the participants found the information and social support useful for coping with both the diagnosis and subsequent treatment (trial data null result; qualitative data positive result).

Summary of results

Small significant positive QoL effects were observed when data across individual RCTs were combined. The analysis suggested that psychosocial interventions exerted a positive impact on the cancer-related QoL of newly diagnosed cancer patients compared to cancer patients who received standard care. However, the effects were not significant when generic measures of quality of life were employed.

A small statistically significant effect was observed when the results of mood measures across trials were combined. The results for the effects of psychoeducational interventions and for nurse-delivered interventions (using face-to-face and telephone delivery) indicated the most promising results. It is important to note, however, that the high level of statistical heterogeneity rendered the mood results inconclusive.

These results should be interpreted with caution for two main reasons. Firstly, the effect sizes were small; and secondly, the RCTs included in the review were not entirely homogenous. There were differences in the size and character of the patient populations;

in the content of the intervention, the mode of delivery and the discipline of the 'trained helper'; as well as in the methodological quality of the different trials. The high level of observed variation presented challenges in terms of conducting a synthesis of populations, interventions and outcomes, and coming to a clear statement about effectiveness.

DISCUSSION

The findings indicate that, to date, there is a lack of convincing evidence to support universal implementation of individual therapeutic psychosocial interventions that are designed to improve the general QoL of newly diagnosed cancer patients. Psychosocial interventions exerted beneficial effects as measured by illness-specific measures of quality of life (SMD 0.16; 95% CI 0.02 to 0.30) and by measures of mood (SMD -0.81; 95% CI -1.44 to -0.18). However, the combined effect sizes were small and may not be considered clinically significant. There was notable variation in the style and delivery of psychosocial interventions and the statistically combined results may be susceptible to criticism in terms of the high level heterogeneity. Heterogeneity across the type of intervention, mode of delivery and discipline of 'trained helper' presented challenges to the review process despite the combined estimates for the primary outcome QoL indicating no significant statistical heterogeneity. Overall, the results suggested that psychosocial interventions add value to cancer care, though more rigorous research is required.

Participants or population examined

It was not possible to analyse subgroups of patients (for example by gender, age, previous mental health conditions or attitudes towards help seeking) due to the limited detail provided in the trial publications included in the review. Cancer is a condition that generally affects older populations, so age at intervention should be considered in assessments of the impact of interventions. Older patients are reported to experience less 'perceived' need to explore emotional reactions to cancer ([Burton 1995](#)). Therefore, they may not be offered psychosocial interventions or indeed may not be considered to benefit from them in the same way as those who are more likely to seek help, such as younger patients and those who experience higher levels of cancer-related distress ([Campbell 2004](#); [Grande 2006](#); [Owen 2007](#)). Additionally, those with a history of serious illness or those who are aware of genetic cancer risks have a higher risk of distress after a cancer diagnosis ([Montgomery 2010](#)) and, therefore, may benefit more from supportive interventions. Individuals who expect psychosocial support to be helpful and who feel that other people in their lives would expect them to use such services are more likely to seek support ([Steginga 2008](#)). Research is required to ascertain the potential impact of attitudes towards help seeking on psychosocial outcomes ([Weich 2007](#)).

People with previous emotional instability, especially if they have sought help to cope with their emotions, are likely to benefit most from psychosocial interventions. In a recent review of the evidence, the chronically anxious tended to display more anxiety after diagnosis (Montgomery 2010). It was not possible to examine these subgroups in the current review because the majority of trials excluded anyone with a previous diagnosis of mental illness and no author reported results separately for patients who had availed themselves of psychosocial support in the past. In this review it was not possible to analyse results by age, levels of distress or attitudes towards help seeking for emotional problems due to a lack of relevant data.

Discipline of trained helper

Nurse-delivered interventions appear to show promise in producing a positive impact on QoL (SMD 0.23; 95% CI 0.04 to 0.43). This may be due to a number of interconnected factors. Firstly, asking for psychological support is still considered to involve an element of stigma, as indicated by negative attitudes towards help seeking for depression in primary care (Weich 2007); but nursing staff can offer psychological support as part of a package of cancer care, allowing patients to avoid any perceived stigma attached to seeking additional help for emotional concerns. Secondly, psychosocially trained nurses bring specific knowledge from their biomedical training and their cancer nursing specialism to the role of psychosocial support agent (Arving 2011). Therefore, an intervention delivered by a psychosocial nurse may bring something unique to a psychosocial intervention in cancer care, which cannot be delivered by a social worker or a psychologist (Arving 2011).

Type of intervention

The promising nature of the results examining psychoeducational interventions may be related to the value of knowledge in times of extreme uncertainty. Psychoeducational interventions specifically address emotional concerns arising from the distress that can be caused by being overwhelmed or confused (with, for example, medical terminology, treatment options, side effects, prognosis and how to process and discuss all of the above with loved ones). “Women [with breast cancer] who are adequately informed about the process experience less psychological distress. However, in many studies, the majority of the women reported needing increased educational support, including written information and the availability of access to a healthcare provider” (Montgomery 2010).

Measurement tools

The current review examines results based on validated measures of QoL and psychological distress (including anxiety, depression and mood measures). No significant effect was observed with generic

QoL tools in contrast to the cancer-specific measures, which indicated tentatively that psychosocial interventions improve QoL; and the analysis of secondary outcome measures indicated that psychosocial interventions improve mood. The results may suggest that generic measures of QoL are not sufficiently sensitive to capture change and that future studies and reviews should focus on cancer-specific measures or psychological measures that have been tried and tested with cancer populations.

Inevitably, cancer impacts on an individual's QoL, both physically and emotionally. Cancer-specific measures of QoL assess the impact of cancer and its treatment and, therefore, are designed to be sensitive to cancer-related changes. Equally when interventions are planned within a population that is effectively free of formal psychiatric morbidity we might not expect measures of clinical anxiety and depression to be as sensitive as measures of mood (which are validated across a healthy population). This problem has been discussed in relevant recent meta-reviews of psychosocial interventions in cancer patients (Jacobsen 2008; Linden 2012) and it is a recognised gap in the cancer care research trial literature. The vast majority of trials measure the impact of a psychosocial intervention on distress in a given population, a proportion of whom are not experiencing distress. This approach appears to significantly dilute the treatment effects of psychosocial interventions across trial populations (Linden 2012).

A recent study of psychosocial adjustment amongst cancer survivors concluded that despite the increased risk of psychological disturbance in cancer survivors, which paradoxically tends to be more pronounced in younger patients, cancer survivors can also show increased resilience in other domains of psychosocial adjustment thought to be related to post-traumatic growth, such as social wellbeing, spirituality and personal growth (Constanzo 2009). For these reasons, the appropriateness and sensitivity of measures used to assess risk and outcomes form a critical element of any RCT designed to test the effectiveness of psychosocial support for cancer patients.

AUTHORS' CONCLUSIONS

Implications for practice

The review suggests tentatively that nurse-led interventions delivered in person or by telephone could provide valuable improvements in illness-specific QoL and mood, as part of a package of cancer care. However, currently there is not enough evidence to support universal application for all patients. Risk screening is required to identify and target patients who are at most risk of emotional difficulties and, therefore, most in need of support, along with consideration of a range of possible intervention types to suit identified need. The use of tiered intervention approaches in response to strategic periodic risk screening to identify levels of need is recommended in the international guidelines for psycho-oncology (Coleman 2011). Oncology teams may benefit from consid-

ering and assessing the economic and practical viability of formalising psychosocial support provision as part of the role of specialist cancer nurses within existing health service structures.

Implications for research

A key finding of the review is that existing comorbidity and risk assessment have not been robustly explored in the RCT context, making this an obvious next step in developing advanced research knowledge about appropriate services that can fulfil the existing NICE guidelines and emerging international psycho-oncology practice guidelines for supporting cancer patients at the time of diagnosis.

Research trials identified for this review targeted patients according to cancer diagnosis alone, rather than primarily considering patients' perceived need for support. Randomised controlled trials testing psychosocial interventions that are targeted according to need in newly diagnosed cancer patients are lacking. It is necessary to improve the evidence based on need, that is, based on what works for people experiencing increased levels of distress. This approach would help to reduce the potential for measurement 'floor effects', in those who are not experiencing distress, to dilute the observed effects of psychosocial interventions.

The varied quality of reporting has led to difficulties identifying and classifying studies, due to the wide ranging variations in terminology that is used interchangeably in the field of psychosocial support. There is a need to agree upon common definitions of psychological distress and psychosocial interventions and impose the use of the conventions set out in the CONSORT statement (CONSORT 2010). Jacobsen and Jim have outlined a typology that could form the basis for consistency across future work on psychosocial interventions (Jacobsen 2008). Future studies should report on all validated measures in terms of summary measure results (rather than single subscales which are less valid and not directly comparable with summary scores).

In the fields of psychological, psychosocial and social care research it is particularly important that publishers remain mindful of the need for authors to provide results according to gender and age, given the documented gender differences seen in accessing psy-

chosocial cancer support (Krizek 1999) and the general lack of gender-specific or age-specific results presented in the trials included in the present review (with the exception of intervention trials carried out with gender-specific cancers such as breast cancer).

The measurement of outcomes is more complex in psychosocial research than in most drug-based studies and clinical measures. However, the increasing number of publications of psychosocial interventions indicates this is an area of huge interest that is gaining increased support from funding bodies. A key feature of the RCT methodology design is the aspect of blinding, but a placebo cannot be effectively administered in trials of psychosocial interventions. Blinding outcome assessors would add to the rigour of the research in this field. Additional insights might be gained by generating synthesised qualitative accounts of the impact of interventions. The development of effective ways to combine mixed qualitative and quantitative data in systematic review terms is in its infancy (Hannes 2012). Future RCT work in this field should address more specific populations based on need; and provide high quality reporting standards.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Allard 2007

Methods	RCT	
Participants	117	
Interventions	The Attentional Focus and Symptom Management Intervention (AFSMI); cognitive therapy focused on coping	
Outcomes	Profile of Mood States (POMS), Symptom Impact Profile (SIP)	
Notes	Intervention timed to be carried out post-day surgery	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	High risk	Open random allocation schedule
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Author (PhD student and Principle Investigator) designed and delivered the intervention

Burton 1995

Methods	RCT	
Participants	200	
Interventions	All: Pre-operative interview with a Clinical Psychologist Group 1, 30 minute counselling session Grp 2, 30 minute chat Grp 3, no counselling or chat	
Outcomes	GHQ-12, HADS, Present State Examination, Coping Scale	
Notes	Preparation for surgery	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Burton 1995 (Continued)

Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	High risk	Open random allocation schedule
Selective reporting (reporting bias)	Low risk	The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Chan 2005

Methods	RCT	
Participants	155	
Interventions	Individual psychological intervention using CBT techniques	
Outcomes	EORTC QLQ-30, BDI, Rosenberg Self-esteem Scale, Impact of Events	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer random number generator
Allocation concealment (selection bias)	Low risk	Opaque, sealed envelopes.
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Dow Meneses 2007

Methods	RCT	
Participants	256	

Dow Meneses 2007 (Continued)

Interventions	Breast Cancer Education Intervention (BCIP); Psychoeducational support for practical, physical and emotional concerns	
Outcomes	Quality of Life - Breast Cancer Survivors	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Statistician performed randomisation
Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'. Promotion of oncological nursing is strong throughout

Downe-Wamboldt 2007

Methods	RCT	
Participants	175	
Interventions	Telephone problem solving counselling	
Outcomes	CES-D, Jalowec Coping Scale, PAIS-SR	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer random number generator
Allocation concealment (selection bias)	Low risk	Concealed random number allocation
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Downe-Wamboldt 2007 (Continued)

Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
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Edgar 2001

Methods	RCT
Participants	225
Interventions	CBT; enhance sense of personal control and learning emotional and instrumental coping responses
Outcomes	FACT, POMS
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information 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'
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Fawzy 1995

Methods	RCT
Participants	61
Interventions	Comprehensive health seeking and coping paradigm (CHSCP); Education, stress management, teaching practical emotional coping skills
Outcomes	POMS, BSI-53, Dealing with illness inventory
Notes	

Risk of bias

Fawzy 1995 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information 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'
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Forester 1985

Methods	RCT
Participants	100
Interventions	Supportive educational therapy, interpretive, explanatory therapy and catharsis
Outcomes	Schedule of Affective Disorders and Schizophrenia (SADS)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information 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'. Assessor was blinded
Selective reporting (reporting bias)	Low risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Holtedahl 2005

Methods	RCT	
Participants	91	
Interventions	Counselling provided by the general practitioner to “let the patient tell about experiences as a cancer patient, and to tell the patient explicitly that she or he would be welcome to contact the GP [with any related questions]”	
Outcomes	EORTC QLQ-30 and a satisfaction questionnaire	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Low risk	Concealed random number allocation
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Jacobsen 2002

Methods	RCT	
Participants	382	
Interventions	Breathing exercises, relaxation exercises, stress inoculation training	
Outcomes	SF-36, CES-D, STAI-S	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer random number generator
Allocation concealment (selection bias)	High risk	Open random allocation schedule

Jacobsen 2002 (Continued)

Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Standard care included a psychological assessment and information about available sources of support

Johansson 2008

Methods	RCT
Participants	481
Interventions	Individual psychological support, intensified primary health care (liaison improved and training for nurses and GPs) and nutritional support (dietary assessment and advice)
Outcomes	EORTC QLQ-30, Hospital Anxiety and Depression Scale HADS
Notes	Nutritional dietary support and liaison with general practice staff (including training for GPs and nurses) also formed part of the intervention

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated random allocation
Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Kanzaki 2002

Methods	RCT
Participants	26
Interventions	Counselling and journal writing based on stress coping theory (Lazarus) and Social Learning theory (Bandura)
Outcomes	Depression and Anxiety Mood Scale, General Self Efficacy Scale, Stress Response Scale

Kanzaki 2002 (Continued)

Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Allocation concealment (selection bias)	Low risk	Concealed from staff
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Lee 2006

Methods	RCT	
Participants	82	
Interventions	Meaning-making intervention to acknowledge the present, contemplate the past, commit to the present, for the future	
Outcomes	Rosenberg Self-esteem Scale, Life Orientation Test (optimism), Generalised Self Efficacy Scale	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated random allocation
Allocation concealment (selection bias)	High risk	Open random allocation schedule
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	High risk	11% of participants already receiving psychosocial support

Lev 2000

Methods	RCT
Participants	18
Interventions	Combination of information provided by videotape and booklet, along with 5 counselling sessions based on Bandura principles of practicing behaviours to increase self-efficacy
Outcomes	FACT, Symptom Distress Scale (SDS), Strategies used by patients to promote health (SUPPH)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information 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'
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	High risk	Selected effect sizes provided in text, but no tables of figures presented

Linn 1981

Methods	RCT
Participants	120
Interventions	Therapeutic relationship developed, based on trust and open communication
Outcomes	Quality of life described by depression, self-esteem, alienation, life satisfaction, locus of control
Notes	All participants classified as diagnosed within 6-10 months, with prognosis of being terminally ill

Risk of bias

Bias	Authors' judgement	Support for judgement
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Linn 1981 (Continued)

Random sequence generation (selection bias)	Unclear risk	Insufficient information 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'
Selective reporting (reporting bias)	High risk	Only descriptive data is provided
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Manne 2007

Methods	RCT
Participants	353
Interventions	Two types of intervention: (1) counselling for coping and communication, (2) supportive psychotherapy
Outcomes	BDI, IES (Intrusive and Avoidant Ideation), Emotional Expressiveness Questionnaire, Treatment expectancy, treatment evaluation
Notes	Query diagnosis within 12 months - described by authors as a weakness/limitation of the study, due to lack of information about time since diagnosis

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Allocation concealment (selection bias)	High risk	Open random allocation schedule
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	High risk	Usual care included assessment by a social worker and subsequent referral to supportive services if indicated

McArdle 1996

Methods	RCT
Participants	272
Interventions	Group 1, Nurse provided pre and post-operative information and a listening ear. Group 2, as group 1 with counselling from a voluntary sector organisation also offered (with membership of a support group also offered as an option)
Outcomes	GHQ-28, HADS
Notes	9% experiencing recurrence, remaining participants were newly diagnosed (within 12 months), Group1, nursing intervention included the option of having a partner present - results not disaggregated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information 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'
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

McQuellon 1998

Methods	RCT
Participants	150
Interventions	Single session orientation programme including time with an oncology counsellor to express concerns
Outcomes	STAI, POMS, CES-D
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
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McQuellon 1998 (Continued)

Random sequence generation (selection bias)	Unclear risk	Insufficient information 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'
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Mishel 2002

Methods	RCT
Participants	239
Interventions	Patient-led telephone CBT intervention with supplemental audio/video tapes provided
Outcomes	MMSE, Uncertainty in illness scale, Cancer knowledge scale, (subscales reported; symptom distress or QOL and problem solving and cognitive restructuring as self-control scale)
Notes	Number of participants in each arm not reported (one arm included family member) also 0.1 significance level used

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Block randomisation (randomisation process not described)
Allocation concealment (selection bias)	High risk	Open random allocation schedule
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Moynihan 1998

Methods	RCT
Participants	73
Interventions	Adjuvant psychological therapy; a cognitive and behavioural treatment programme designed specifically for patients with cancer
Outcomes	HADS, Mental adjustment to cancer scale, Psychosocial adjustment to illness scale, Emotional concealment subscale of the Brannon Masculinity Scale, Reiker sexual adjustment scale
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Carried out by an independent trials office
Allocation concealment (selection bias)	Low risk	Concealed random number allocation
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Nezu 2003

Methods	RCT
Participants	150
Interventions	Problem Solving Therapy (PST) teaching to better formulate problems, generate alternative solutions, evaluate consequences, select and evaluate outcome
Outcomes	POMS, Cancer Rehabilitation Evaluation System (CARES), BSI 53-item psychiatric symptoms, Omega Vulnerability Rating Scales, HRSD
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random numbers table

Nezu 2003 (Continued)

Allocation concealment (selection bias)	Low risk	Concealed random number allocation
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Parker 2009

Methods	RCT
Participants	159
Interventions	60-90 minute stress management cognitive behavioural sessions including diaphragmatic breathing and guided imagery
Outcomes	SF-36
Notes	Correspondence with author confirmed only two participants had been diagnosed more than 12 months prior to the intervention

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information 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'
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Petersen 2002

Methods	RCT
Participants	53
Interventions	"Counselling interview"; relaxation music (5min) relaxation exercise (20min) and discussion on patient emotional and physical condition

Petersen 2002 (Continued)

Outcomes	GHQ-28, HADS	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Allocation concealment (selection bias)	Low risk	Concealed random number allocation
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Pitcheathly 2008

Methods	RCT	
Participants	465	
Interventions	Three-session brief intervention, delivered by trained non-specialists, focused on coping strategies	
Outcomes	DSM Structured clinical interview, Hospital Anxiety and Depression Scale (HADS)	
Notes	Designed to prevent depression and anxiety, rather than to improve quality of life, per se	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information 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'
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Pitcheathly 2008 (Continued)

Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
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Puig 2006

Methods	RCT
Participants	39
Interventions	Creative arts therapy - psychoeducational and subjective understanding of body-mind-emotions and spiritual experiences and connections
Outcomes	Satisfaction with intervention, Expressions of spirituality inventory, Emotional approach coping scale
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information 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'
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Ross 2005

Methods	RCT
Participants	249
Interventions	Home visit, average 1 hour, emotional and educational support, encouraging use of participant's social networks for support
Outcomes	EORTC QLQ-30, EORTC CR38, HADS
Notes	

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated block randomisation
Allocation concealment (selection bias)	Low risk	Concealed random number allocation
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Sandgren 2000

Methods	RCT
Participants	53
Interventions	Patient generated problems, cognitive restructuring, coping skills, managing anxiety and stress, emotional expression, relaxation
Outcomes	POMS, Medical Outcomes Scale, Coping Response Indices-Revised
Notes	

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information 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'
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Sandgren 2003

Methods	RCT
Participants	222
Interventions	Emotional Expression - Participants encouraged to express deepest emotions and thoughts about cancer experience, facilitator listened and provided 'support'
Outcomes	FACT-B, POMS, Perceived Stress Scale, Cancer Behaviour Inventory, Social Constraints measure
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information 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'
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Sandgren 2007

Methods	RCT
Participants	218
Interventions	Emotional Expression - Participants encouraged to express deepest emotions and thoughts about cancer experience, facilitator listened and provided 'support'
Outcomes	FACT-B, POMS, Perceived Stress Scale, Cancer Behaviour Inventory, Social Constraints measure
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Sandgren 2007 (Continued)

Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Scholten 2001

Methods	RCT
Participants	84
Interventions	Crisis intervention tailored individually, by choice out of 20 intervention areas, modelled on CBT principles
Outcomes	Quality of life (visual analogue scale), health status (visual analogue scale), semi-structured interview on coping
Notes	Study included a second intervention group of participants experiencing recurrence and control group were half newly diagnosed and half experiencing recurrence

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information 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'
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Scura 2004

Methods	RCT
Participants	17
Interventions	Telephone social support and educational resource kit based on Roy Adaptation Model of Nursing - biopsychosocial model
Outcomes	Fact-G, Symptom Experience Scale-Prostate, Relationship Change Scale, International Index of Erectile Function Scale
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information 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'
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Stanton 2005

Methods	RCT
Participants	558
Interventions	An 80-min face-to-face meeting and video tape with manual provided, followed with a 30-min telephone meeting
Outcomes	SF-36 (Vitality Scale), CES-D, Revised Impact of Events Scale, Post-traumatic Growth Scale
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number tables

Stanton 2005 (Continued)

Allocation concealment (selection bias)	Low risk	Concealed random number allocation
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

Trask 2003

Methods	RCT
Participants	48
Interventions	Relaxation training, cognitive challenging and problem solving
Outcomes	SF-36, STAI, BSI, Global severity index
Notes	Part of a larger RCT study

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number tables
Allocation concealment (selection bias)	Low risk	Concealed random number allocation
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'
Other bias	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'

DATA AND ANALYSES

Comparison 1. Primary outcome: quality of life

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All Studies	9	1249	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.00, 0.22]
2 Measures of Quality of Life	9	1249	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.00, 0.22]
2.1 General Health Related Measures	3	418	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.18, 0.21]
2.2 Illness Specific Measures	6	831	Std. Mean Difference (IV, Random, 95% CI)	0.16 [0.02, 0.30]
3 Cancer Site	9	1249	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.00, 0.22]
3.1 Breast	3	684	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.11, 0.34]
3.2 Other sites	6	565	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.07, 0.28]
4 Type of Intervention	9	1249	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.00, 0.22]
4.1 Cognitive Behavioural Therapy	6	763	Std. Mean Difference (IV, Random, 95% CI)	0.05 [-0.10, 0.20]
4.2 Psychoeducation	1	261	Std. Mean Difference (IV, Random, 95% CI)	0.29 [0.05, 0.54]
4.3 Counseling	2	225	Std. Mean Difference (IV, Random, 95% CI)	0.08 [-0.19, 0.34]
5 Mode of Delivery	9	1249	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.00, 0.22]
5.1 Telephone	2	270	Std. Mean Difference (IV, Random, 95% CI)	0.09 [-0.19, 0.36]
5.2 Face to Face	5	439	Std. Mean Difference (IV, Random, 95% CI)	0.12 [-0.07, 0.31]
5.3 Combination (Tel and FTF)	2	540	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.24, 0.46]
6 Discipline of 'Trained Helper'	8	1215	Std. Mean Difference (IV, Random, 95% CI)	0.10 [-0.02, 0.22]
6.1 Psychologist	2	281	Std. Mean Difference (IV, Random, 95% CI)	0.01 [-0.25, 0.27]
6.2 Nurse	2	405	Std. Mean Difference (IV, Random, 95% CI)	0.23 [0.04, 0.43]
6.3 GP	1	81	Std. Mean Difference (IV, Random, 95% CI)	0.0 [-0.44, 0.44]
6.4 Combination: Nurse, Social Worker, Psychologist, Medical Doctor	3	448	Std. Mean Difference (IV, Random, 95% CI)	0.10 [-0.17, 0.38]

Comparison 2. Risk of bias

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Allocation Concealment	4	499	Std. Mean Difference (IV, Random, 95% CI)	0.01 [-0.16, 0.19]
2 Intention to Treat Analysis	6	898	Std. Mean Difference (IV, Random, 95% CI)	0.14 [-0.03, 0.31]

Comparison 3. Secondary outcomes

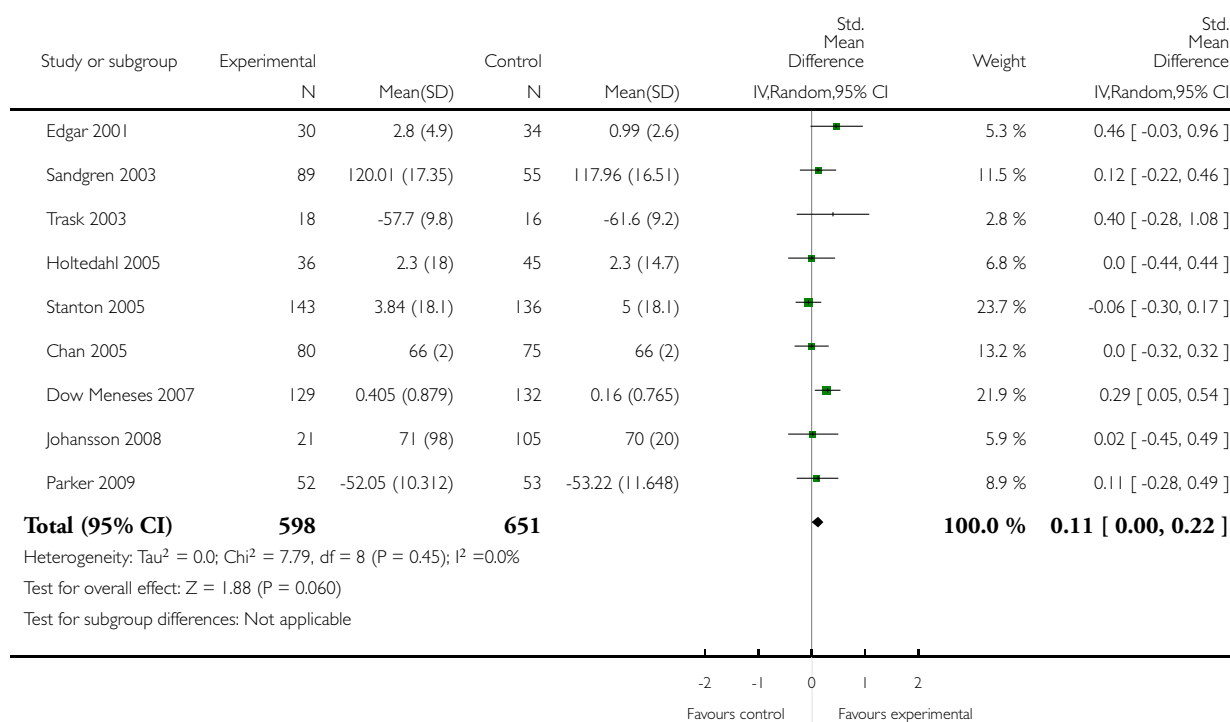
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 General Psychological Distress	9	1502	Std. Mean Difference (IV, Random, 95% CI)	0.08 [-0.05, 0.21]
1.1 Depression Specific Measures	6	1014	Std. Mean Difference (IV, Random, 95% CI)	0.12 [-0.07, 0.31]
1.2 Anxiety Specific Measures	4	488	Std. Mean Difference (IV, Random, 95% CI)	0.05 [-0.13, 0.22]
2 Mood Measures	8	683	Std. Mean Difference (IV, Random, 95% CI)	-0.81 [-1.44, -0.18]

Analysis 1.1. Comparison 1 Primary outcome: quality of life, Outcome 1 All Studies.

Review: Psychosocial interventions to improve quality of life and emotional wellbeing for recently diagnosed cancer patients

Comparison: 1 Primary outcome: quality of life

Outcome: 1 All Studies

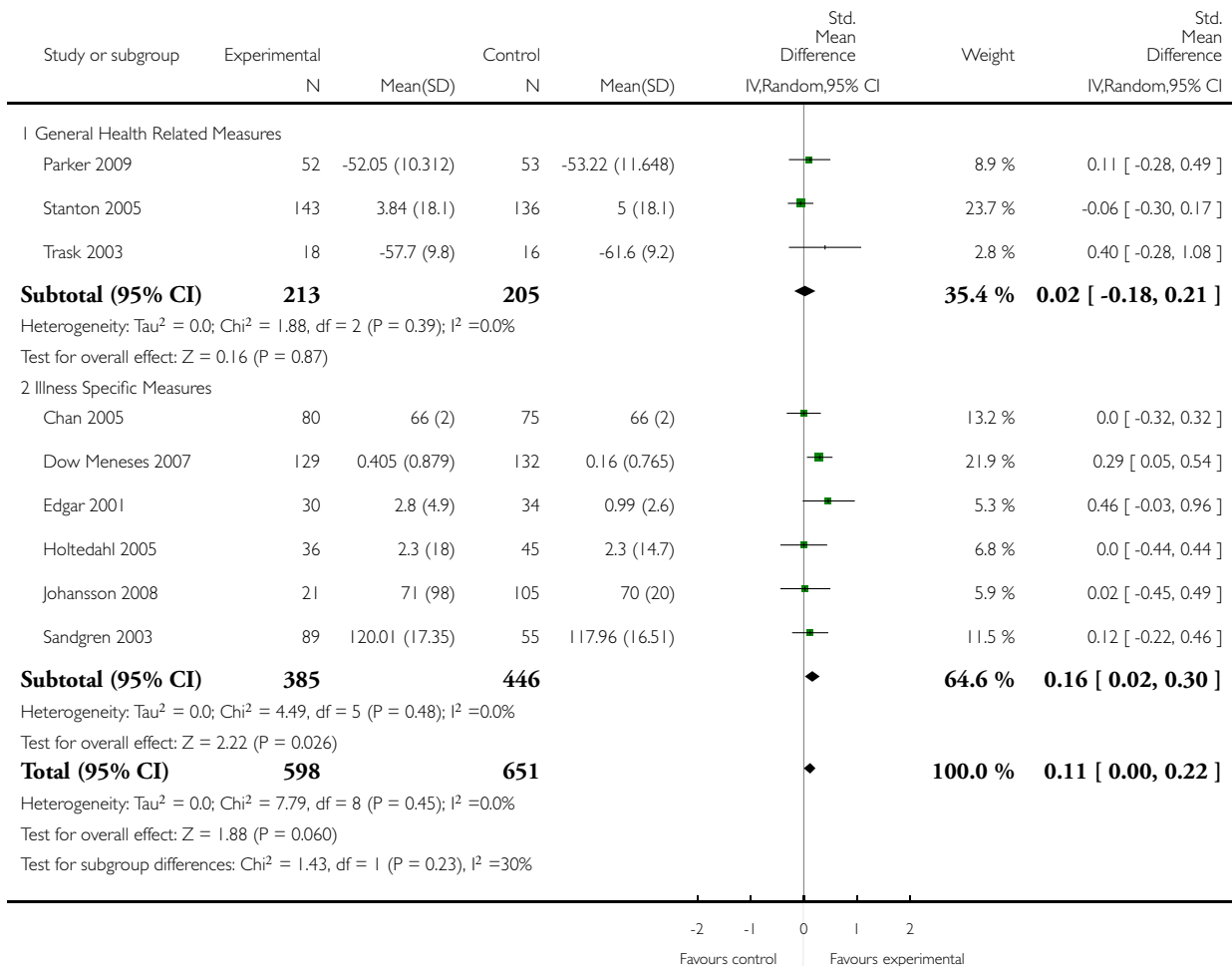


Analysis 1.2. Comparison 1 Primary outcome: quality of life, Outcome 2 Measures of Quality of Life.

Review: Psychosocial interventions to improve quality of life and emotional wellbeing for recently diagnosed cancer patients

Comparison: 1 Primary outcome: quality of life

Outcome: 2 Measures of Quality of Life

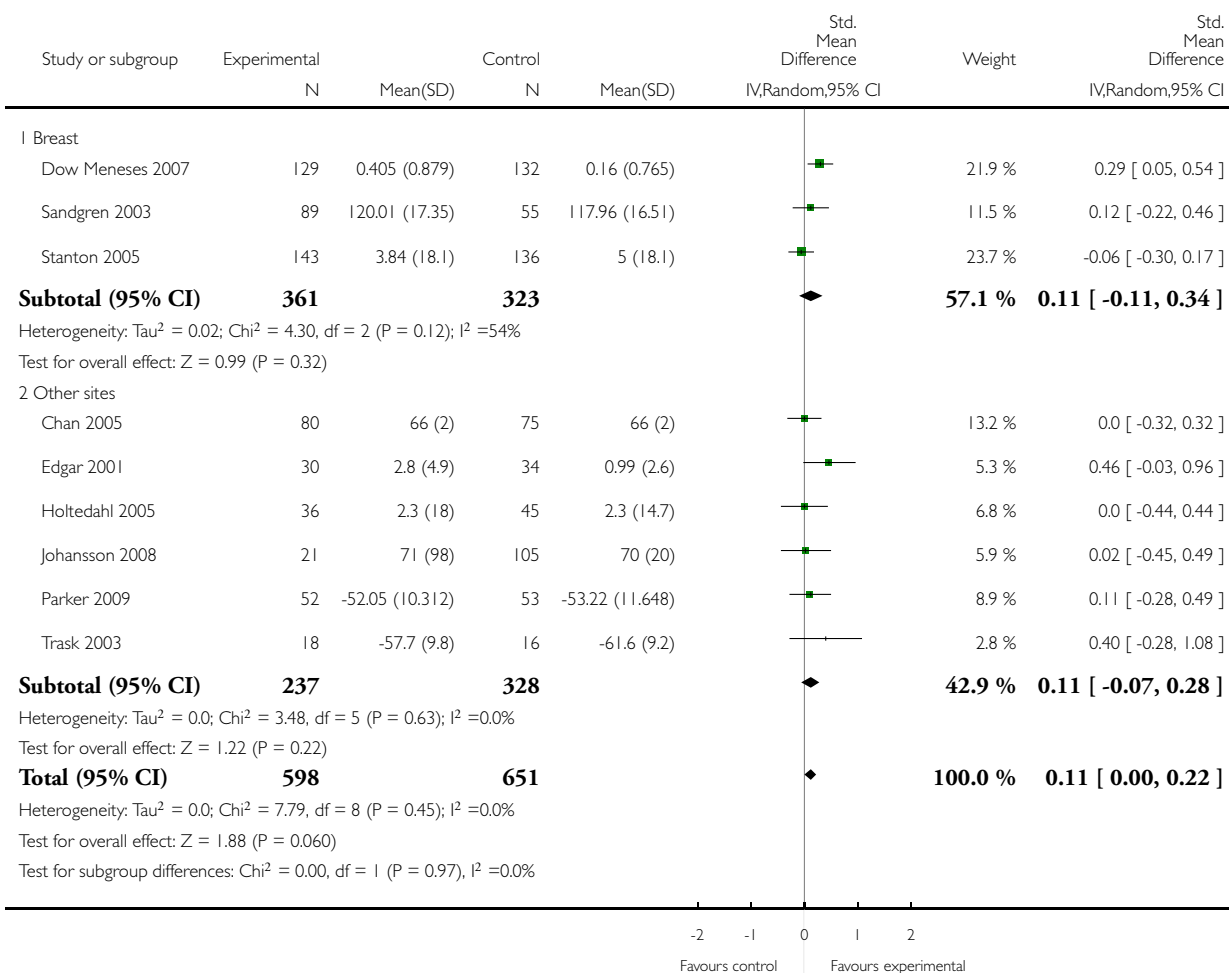


Analysis 1.3. Comparison 1 Primary outcome: quality of life, Outcome 3 Cancer Site.

Review: Psychosocial interventions to improve quality of life and emotional wellbeing for recently diagnosed cancer patients

Comparison: 1 Primary outcome: quality of life

Outcome: 3 Cancer Site

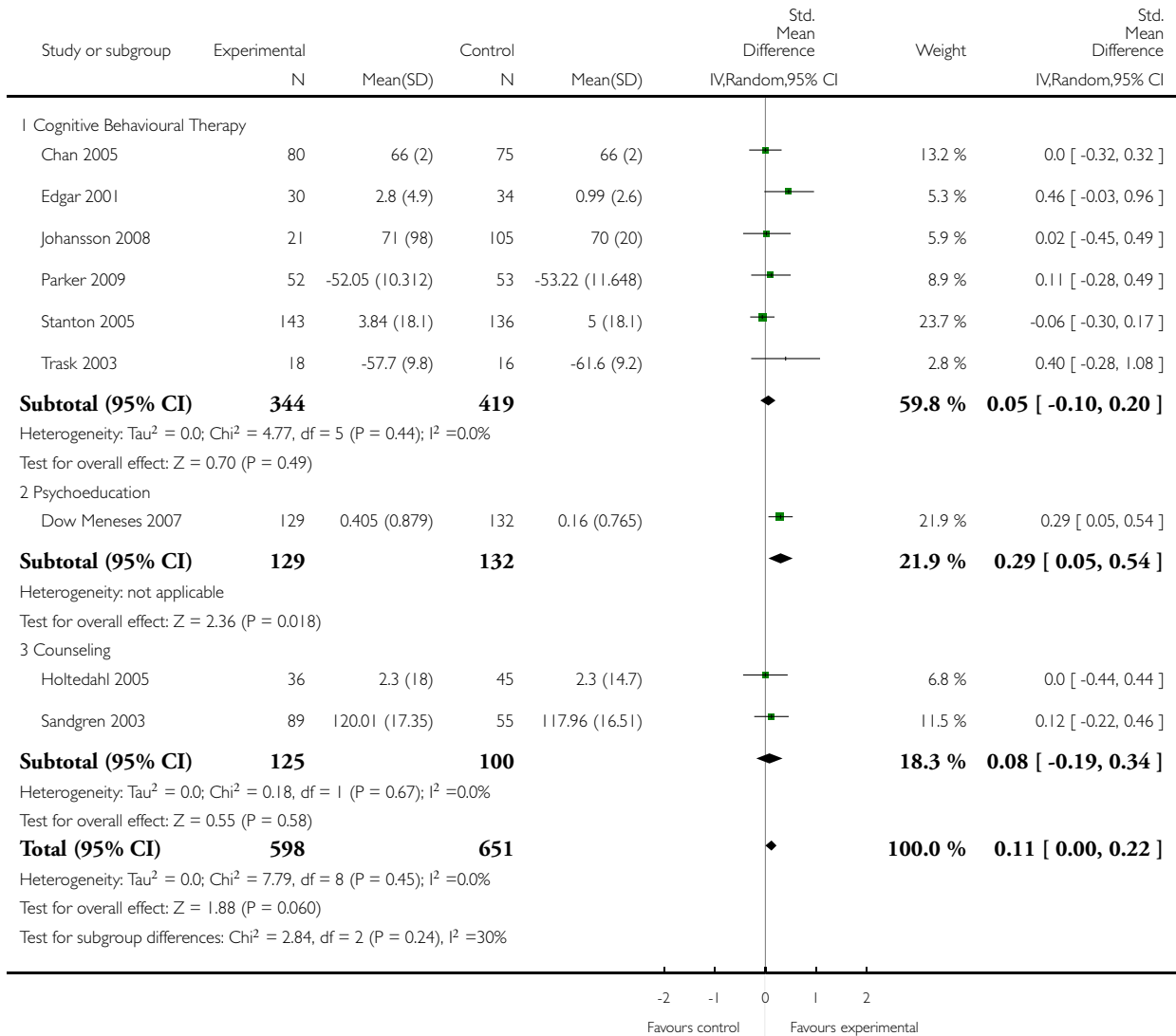


Analysis I.4. Comparison I Primary outcome: quality of life, Outcome 4 Type of Intervention.

Review: Psychosocial interventions to improve quality of life and emotional wellbeing for recently diagnosed cancer patients

Comparison: I Primary outcome: quality of life

Outcome: 4 Type of Intervention

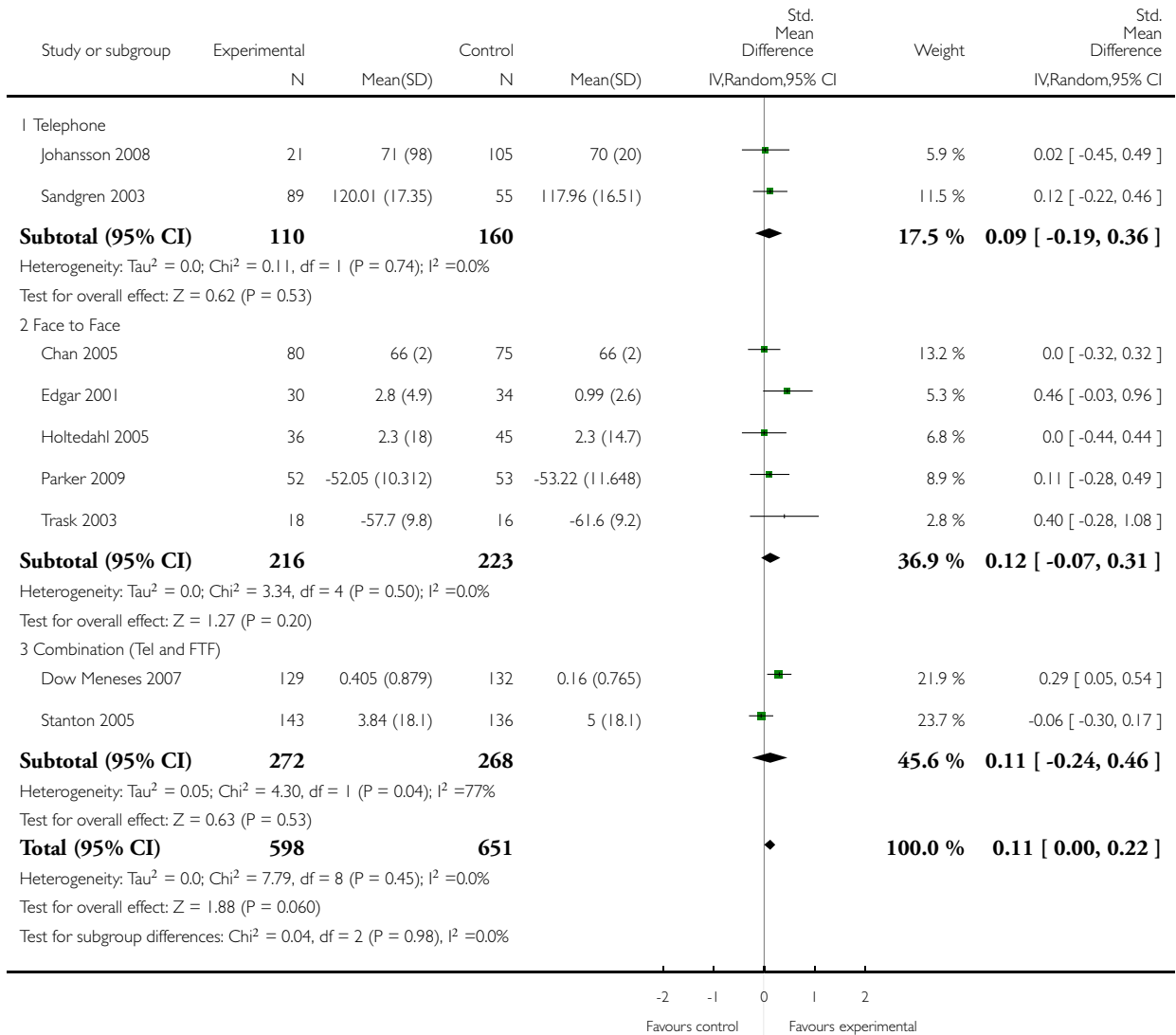


Analysis 1.5. Comparison 1 Primary outcome: quality of life, Outcome 5 Mode of Delivery.

Review: Psychosocial interventions to improve quality of life and emotional wellbeing for recently diagnosed cancer patients

Comparison: 1 Primary outcome: quality of life

Outcome: 5 Mode of Delivery

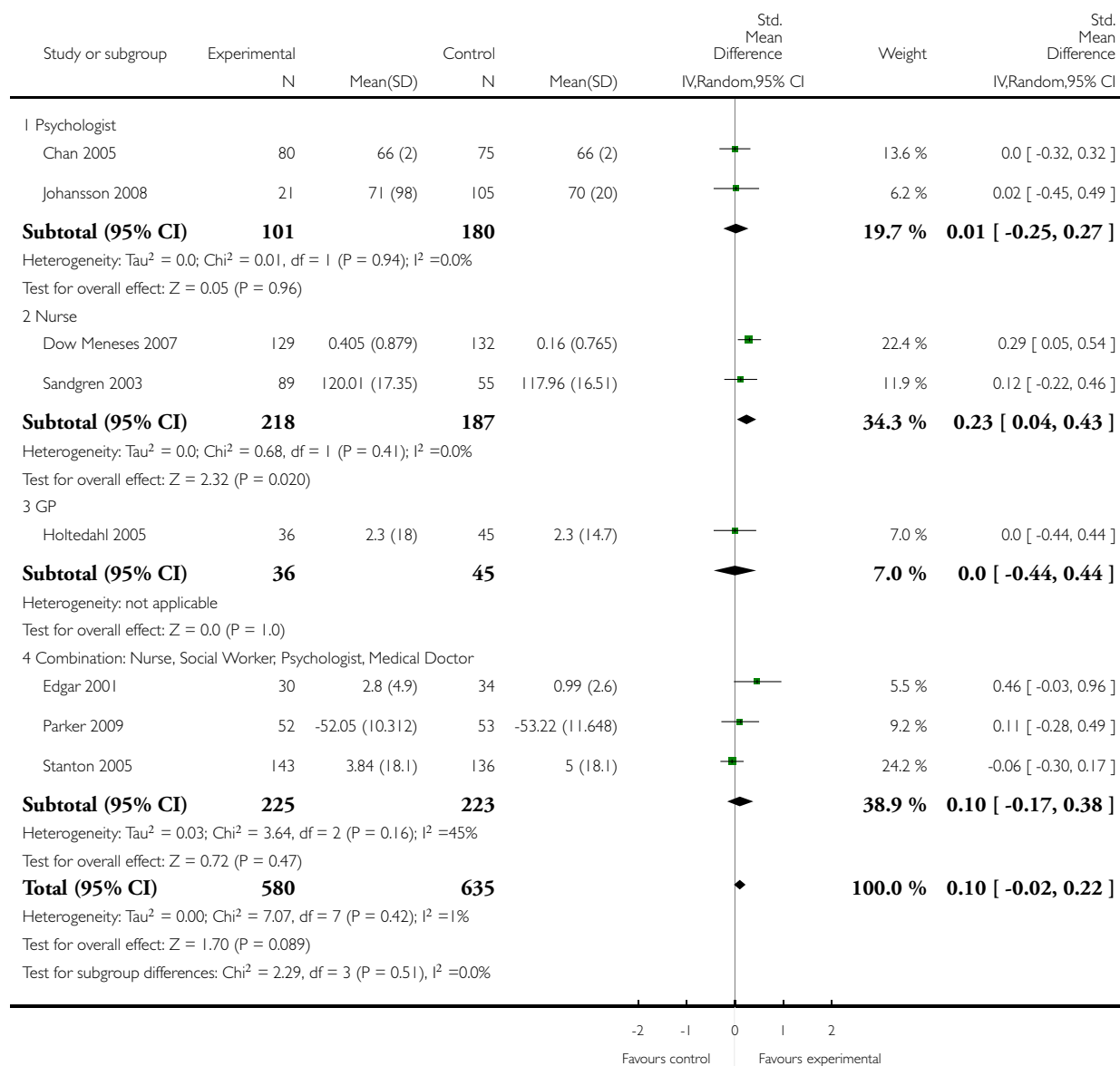


Analysis 1.6. Comparison 1 Primary outcome: quality of life, Outcome 6 Discipline of 'Trained Helper'.

Review: Psychosocial interventions to improve quality of life and emotional wellbeing for recently diagnosed cancer patients

Comparison: 1 Primary outcome: quality of life

Outcome: 6 Discipline of 'Trained Helper'

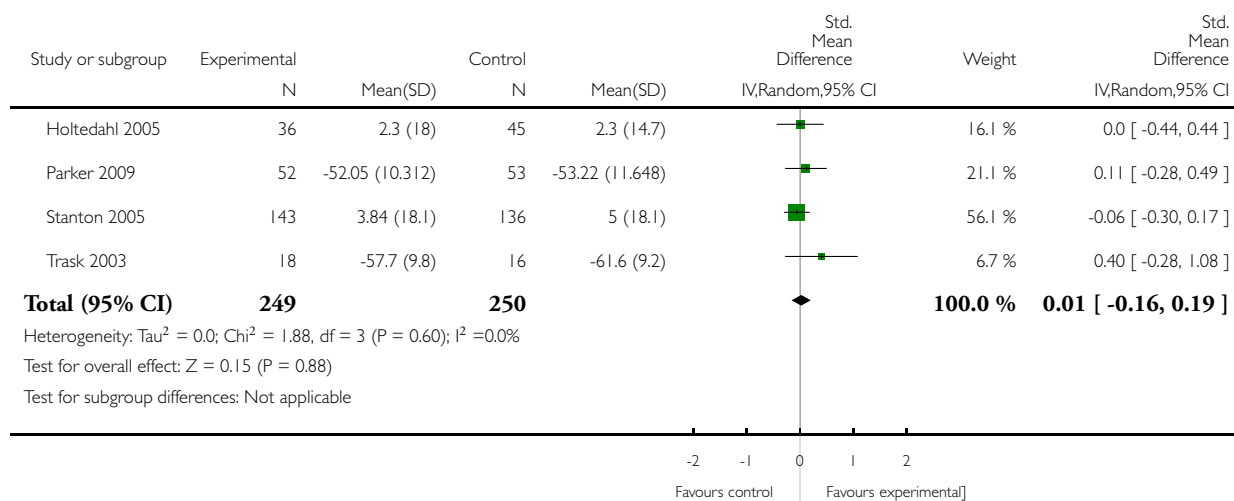


Analysis 2.1. Comparison 2 Risk of bias, Outcome 1 Allocation Concealment.

Review: Psychosocial interventions to improve quality of life and emotional wellbeing for recently diagnosed cancer patients

Comparison: 2 Risk of bias

Outcome: 1 Allocation Concealment

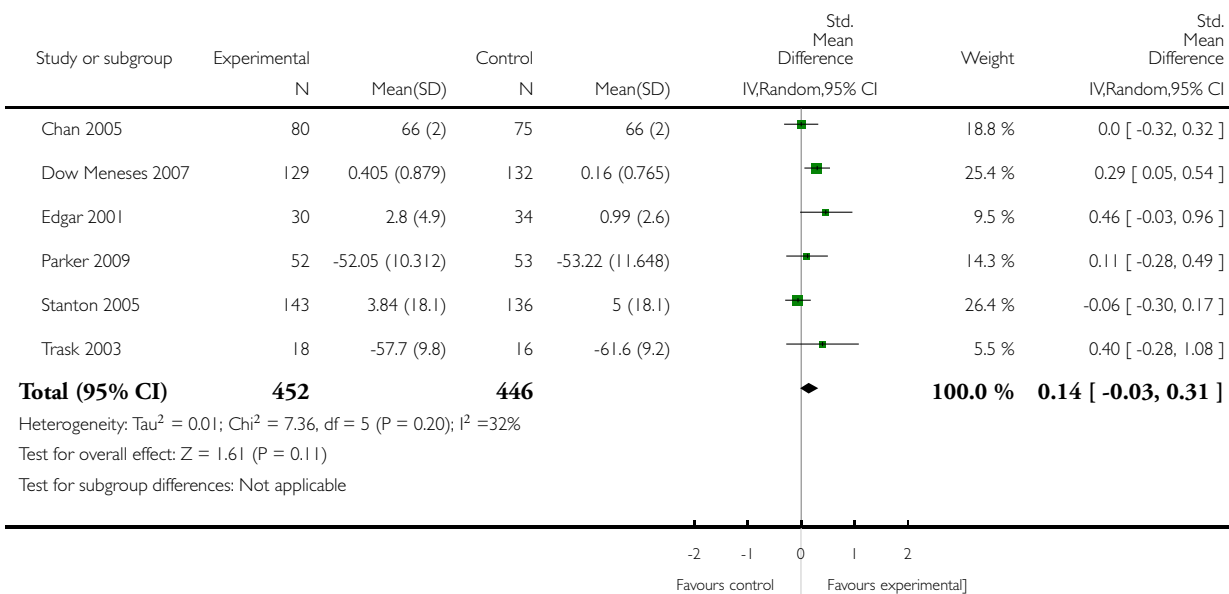


Analysis 2.2. Comparison 2 Risk of bias, Outcome 2 Intention to Treat Analysis.

Review: Psychosocial interventions to improve quality of life and emotional wellbeing for recently diagnosed cancer patients

Comparison: 2 Risk of bias

Outcome: 2 Intention to Treat Analysis

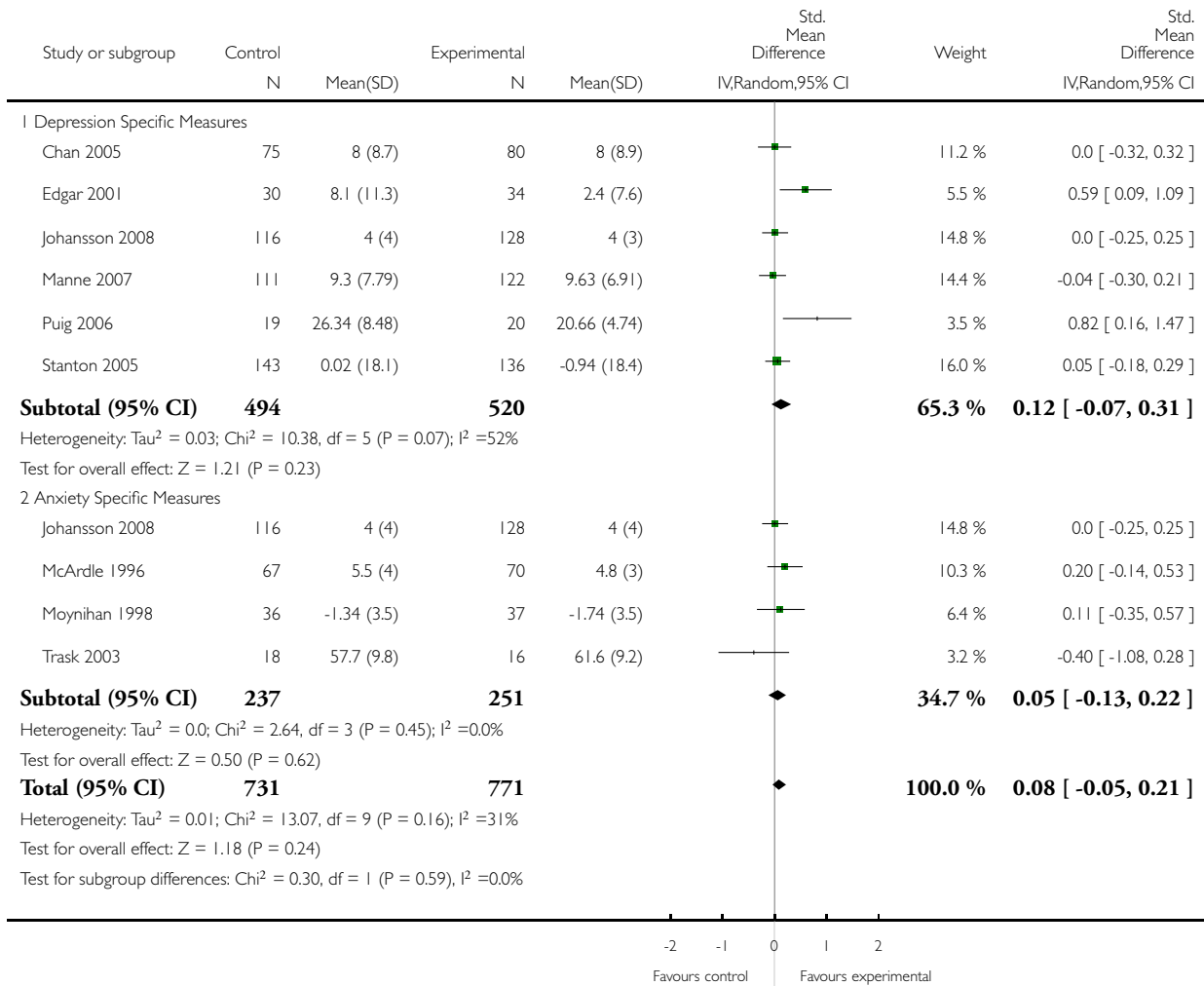


Analysis 3.1. Comparison 3 Secondary outcomes, Outcome 1 General Psychological Distress.

Review: Psychosocial interventions to improve quality of life and emotional wellbeing for recently diagnosed cancer patients

Comparison: 3 Secondary outcomes

Outcome: 1 General Psychological Distress

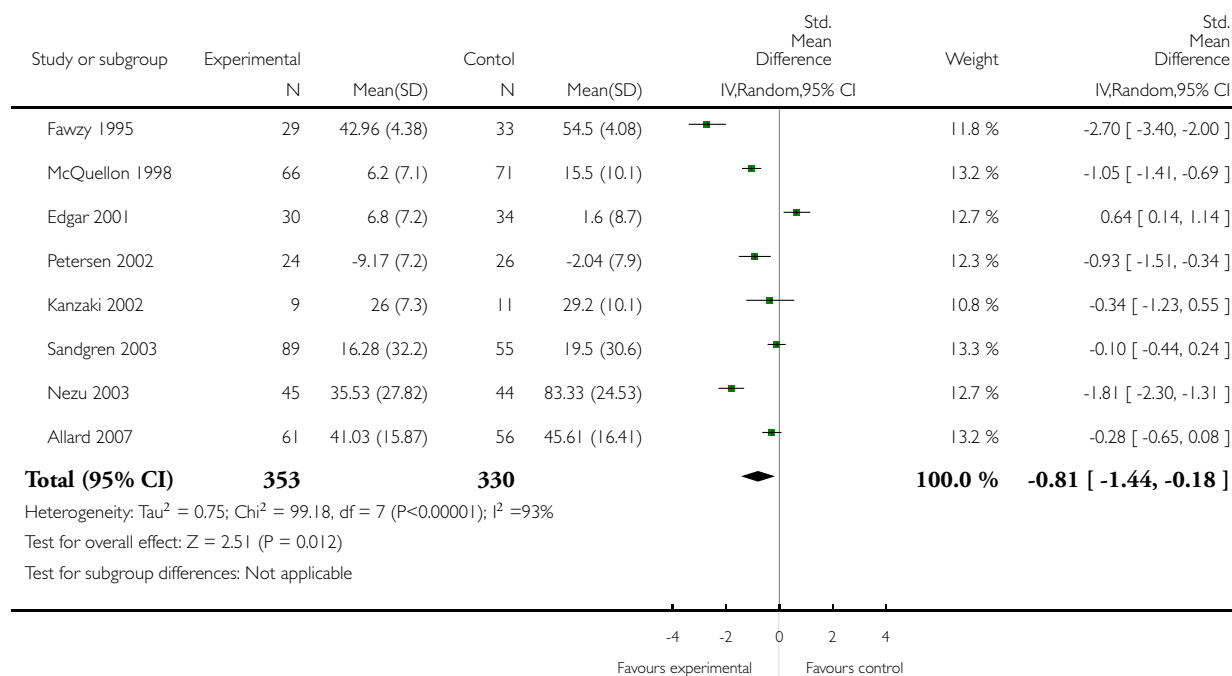


Analysis 3.2. Comparison 3 Secondary outcomes, Outcome 2 Mood Measures.

Review: Psychosocial interventions to improve quality of life and emotional wellbeing for recently diagnosed cancer patients

Comparison: 3 Secondary outcomes

Outcome: 2 Mood Measures



ADDITIONAL TABLES

Table 1. Features of studies included in review: data not suitable for meta-analyses

1st Author Year Country Language	N	Cancer site	Mode	no of contacts	Follow ups	Discipline	Classification
Sandgren 2000 USA English	53	Breast	telephone	10 x 30mins (weekly, then bi-weekly - over 16 weeks)	3	psychologist	CBT
Burton 1995 UK	200	breast	face-to-face	grp1&2= 2x30min, grp3=	2	MD	Preparation

Table 1. Features of studies included in review: data not suitable for meta-analyses (Continued)

English				1x30min			
Forester 1985 USA English	100	lung, prostate, uterus, bladder, cervix, ovary, other	face-to-face	10 (10 weeks)	4	MD	Preparation
Jacobsen 2002 USA English	382	breast, lung, ovarian, lymphoma, colon, prostate, endometrial, other	face-to-face	1 x 60 mins +5 mins at each chemo session	4	psychologist	Preparation
Lee 2006 Canada English	82	Breast & col- orectal	face-to-face	4 x up to 120 mins (un- clear over what period)	1	nurse	Meaning-making
Lev 2000 USA English	18	Breast	combination	videotape, book- let, 5 counselling sessions (monthly)	2	nurse	CBT
Linn 1981 USA English	120	lung, colon, stomach, prostate, blad- der & unknown	face-to-face	sev- eral times a week (no description of length)	5	social worker	Counselling
Mischel 2002 USA English	239	prostate	combination	8 weekly phone calls (supple- mental audio/ video tapes pro- vided)	2	nurse	CBT
Ross 2005 Denmark English	249	colon	face-to-face	10 (5 in 1st 12 weeks, and 5 over follow- ing 18 mths+ op- tion of telephone calls)	4	nurse	Counselling
Sandgren 2007 USA English	218	Breast	telephone	6 x 30mins (5 weekly, then fi- nal call at 3 months)	1	nurse	Counselling

Table 1. Features of studies included in review: data not suitable for meta-analyses (Continued)

Scholten 2001 Austria English	84	Breast	face-to-face	maximum 4 (83% 2-4 contacts)	2	psychologist	CBT
Scura 2004 USA English	17	prostate	telephone	10 weekly, 10 bi-weekly, monthly (up to 12 months)	3	Researcher	Other

Table 2. Studies included in the review: data suitable for meta-analyses

Ist Author Year Country Language	N	Cancer site	Mode	no of contacts	Follow ups	Discipline	Classification	Qol Measure	Fol- low up in weeks	Gen- eral Psy- cholog- ical State Measure	Fol- low up in Weeks
Allard 2007 Canada English	117	breast	tele- phone	2 x tele- phone calls (3 x data col- lection research calls)	2	nurse	Counsel- ing (prepara- tion)			POMS	2
Chan 2005 China English	155	ovary, cervix, corpus	face-to- face	bi- weekly dur- ing treat- ment, 6- weekly post- treat- ment, up to 18 months	6	psychol- ogist	CBT	EORTC QLQ-30	24	BDI	24
Dow Meneses 2007 USA English	256	Breast	combi- nation	7; 3 face to face, 2 tele- phone, 2 face to face fol- low up	2	nurse	psy- cho edu- cation	QoL Breast Cancer Sur- vivors Scale	24		

Table 2. Studies included in the review: data suitable for meta-analyses (Continued)

Downe-Wambolt 2007 Canada English	175	lung, prostate, breast	tele-phone	various 57% >5 (3 month period)	1	nurse	CBT			CES-D	32
Edgar 2001 Canada English	225	breast, colon	face-to-face	5 (5 month period)	3	combination	CBT	FACT (Em)	52	POMS	32
Fawzy 1995 USA English	61	skin	face-to-face	2 (+option of tele-phone calls to nurse)	2	nurse	CBT			POMS	12
Holtedal 2005 Norway English	91	all cancer sites	face-to-face	2	1	MD	Counselling	EORTC QLQ-30	24		
Johansson 2008 Sweden English	481	breast, GI= colorectal or gastric, prostate	combination	median= 3 (range 1-24)	4	Psychologist	CBT	EORTC QLQ-30	24	HADS (Depression, Anxiety)	24
Kanzaki 2002 Japan Japanese	26	gastric	face-to-face	5 (5 week period)	2	nurse	CBT			DAMS	4
Manne 2007 USA English	353	gynaecological	combination	6 x 60 mins (+ 1 x tele-phone call at the end)	3	combination	Counseling			BDI	24
McArdle 1996 UK English	272	breast	face-to-face	1 x 20-30 minutes & as necessary after that	4	nurse	Counseling (preparation)			HADS (Anxiety)	52

Table 2. Studies included in the review: data suitable for meta-analyses (Continued)

Mc-Quellon 1998 USA English	150	all cancer sites	face-to-face	1 orientation Programme including time with an oncology counsellor to express concerns	1	counsellor	Counselling (preparation)			POMS	<1
Moynihan 1998 UK English	73	testicular	face-to-face	6 x 60 mins	3	nurse	CBT			HADS (Anxiety)	16
Nezu 2003 USA English	150	breast, leukaemia, lung, ovarian, head/neck, prostate, non-Hodgkins, colon	face-to-face	10 (10 weeks) x 90 mins	3	psychologist	CBT			POMS	24
Parker 2009 USA English	159	prostate	face-to-face	4	3	Combination	CBT (preparation)	SF-36 MCS	24		
Peterson 2002 Australia English	53	gynaecological	face-to-face	1 x 60 mins	1	MD	Counselling			GHQ	24
Puig 2006 USA English	39	Breast	face-to-face	4 x 60 mins	1	counsellor	psycho education/ Creative Arts			POMS (Depression-dejection)	4
Sandgren 2003	222	Breast	telephone	6 x 30mins (5	1	nurse	Counselling	FACT-B	24	POMS	

Table 2. Studies included in the review: data suitable for meta-analyses (Continued)

USA English				weekly, then fi- nal call at 3 months)							
Stanton 2005 USA English	558	Breast	combi- nation	2: one face- to-face meeting, a video& man- ual pro- vided, follow up face-to- face meeting	3	combi- nation	CBT	SF-36 Vitality	24		
Trask 2003 USA English	48	skin	face-to- face	4 x 50 mins	2	not stated	CBT	SF-36	24	STAI	24

APPENDICES

Appendix I. MEDLINE search strategy

Medline on Ovid

- 1 psychosocial intervention*.mp.
- 2 psychosocial support system*.mp. or Social Support/#
- 3 self help group*.mp. or Self-Help Groups/
- 4 educational therapy.mp.
- 5 Psychotherapy/ or psychoeducational.mp.
- 6 behavio*r therapy.mp. or Behavior Therapy/.
- 7 cognitive behavio*r therapy.mp. or Cognitive Therapy/
- 8 CBT.mp.
- 9 cognition therapy.mp.
- 10 family therapy.mp. or Family Therapy/
- 11 psychoanalytic therapy.mp. or Psychoanalytic Therapy/
- 12 Counseling/ or counselling.mp.
- 13 mental health services.mp. or Mental Health Services/
- 14 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
- 15 quality of life.mp. or "Quality of Life"/
- 16 QoL.mp.

17 Mental Health/ or emotional wellbeing.mp.
 18 psychological wellbeing.mp.
 19 emotional well-being.mp.
 20 psychological well-being.mp.
 21 life change event.mp. or Life Change Events/
 22 affective symptom*.mp. or Affective Symptoms/
 23 mental health.mp.
 24 depression/ or depression.mp.
 25 depressive disorder/ or dysthymic disorder/
 26 anxiety.mp. or anxiety/ or anxiety disorders/
 27 psychological stress.mp. or stress, psychological/
 28 psychiatric status rating scales/ or psychometrics/
 29 patient satisfaction.mp. or patient satisfaction/
 30 benefit finding.mp.
 31 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
 32 exp Neoplasms/
 33 (cancer* or neoplasm* or carcinoma* or lymphoma*).mp.
 34 32 or 33
 35 14 and 31 and 34
 36 randomized controlled trial.pt.
 37 controlled clinical trial.pt.
 38 randomized.ab.
 39 placebo.ab.
 40 clinical trials as topic.sh.
 41 randomly.ab.
 42 trial.ti.
 43 36 or 37 or 38 or 39 or 40 or 41 or 42
 44 35 and 43
 key:
 [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]

Appendix 2. EMBASE search strategy

Embase on Ovid

1 exp neoplasm/
 2 (cancer* or neoplasm* or carcinoma* or lymphoma*).mp.
 3 1 or 2
 4 social support/
 5 support group/
 6 behavior therapy/
 7 cognitive therapy/
 8 family therapy/
 9 psychotherapy/
 10 psychoanalysis/
 11 counseling/
 12 mental health service/
 13 (psychosocial adj (intervention* or support system)).mp.
 14 self help group*.mp.
 15 (therap* adj5 (educational or psychoeducational or behavior or behaviour or cognitive or cognition or family or psychoanalytic)).mp.
 16 CBT.mp.
 17 mental health services.mp.

18 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
 19 "quality of life"/
 20 mental health/
 21 life event/
 22 emotional disorder/
 23 depression/
 24 dysthymia/
 25 anxiety/
 26 anxiety disorder/
 27 mental stress/
 28 psychological rating scale/
 29 psychometry/
 30 patient satisfaction/
 31 ((psychological or emotional) adj (wellbeing or well-being)).mp.
 32 life change event.mp.
 33 affective symptom*.mp.
 34 mental health.mp.
 35 anxiety.mp.
 36 psychological stress.mp.
 37 patient satisfaction.mp.
 38 benefit finding.mp.
 39 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38
 40 3 and 18 and 39
 41 random*.mp.
 42 factorial*.mp.
 43 (crossover* or cross over* or cross-over*).mp.
 44 placebo*.mp.
 45 (doubl* adj blind*).mp.
 46 (singl* adj blind*).mp.
 47 assign*.mp.
 48 allocat*.mp.
 49 volunteer*.mp.
 50 crossover procedure/
 51 double blind procedure/
 52 randomized controlled trial/
 53 single blind procedure/
 54 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53
 55 40 and 54

Appendix 3. CENTRAL search strategy

#1 MeSH descriptor Neoplasms explode all trees
 #2 cancer* or neoplasm* or carcinoma* or lymphoma*
 #3 (#1 OR #2)
 #4 MeSH descriptor Social Support, this term only
 #5 MeSH descriptor Self-Help Groups, this term only
 #6 MeSH descriptor Behavior Therapy, this term only
 #7 MeSH descriptor Cognitive Therapy, this term only
 #8 MeSH descriptor Family Therapy, this term only
 #9 MeSH descriptor Psychotherapy, this term only
 #10 MeSH descriptor Psychoanalytic Therapy, this term only
 #11 MeSH descriptor Counseling, this term only

- #12 MeSH descriptor Mental Health Services, this term only
- #13 psychosocial next (intervention* or (support system))
- #14 self help group*
- #15 therap* near/5 (educational or psychoeducational or behavior or behaviour or cognitive or cognition or family or psychoanalytic)
- #16 CBT
- #17 mental health services
- #18 (#4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17)
- #19 MeSH descriptor Quality of Life, this term only
- #20 MeSH descriptor Mental Health, this term only
- #21 MeSH descriptor Life Change Events, this term only
- #22 MeSH descriptor Affective Symptoms, this term only
- #23 MeSH descriptor Depression, this term only
- #24 MeSH descriptor Depressive Disorder, this term only
- #25 MeSH descriptor Dysthymic Disorder, this term only
- #26 MeSH descriptor Anxiety, this term only
- #27 MeSH descriptor Anxiety Disorders, this term only
- #28 MeSH descriptor Stress, Psychological, this term only
- #29 MeSH descriptor Psychiatric Status Rating Scales, this term only
- #30 MeSH descriptor Psychometrics, this term only
- #31 MeSH descriptor Patient Satisfaction, this term only
- #32 (psychological or emotional) next (wellbeing or well-being)
- #33 (life change event)
- #34 affective symptom*
- #35 mental health
- #36 anxiety
- #37 psychological stress
- #38 patient satisfaction
- #39 benefit finding
- #40 (#19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39)
- #41 (#3 AND #18 AND #40)

Appendix 4. PsycINFO

PsychInfo on Ovid

- 1 exp neoplasms/
- 2 (cancer* or neoplasm* or carcinoma* or lymphoma*).mp.
- 3 1 or 2
- 4 social support/
- 5 Support Groups/
- 6 behavior therapy/
- 7 Cognitive Therapy/
- 8 Family Therapy/
- 9 Psychotherapy/
- 10 Psychoanalysis/
- 11 Counseling/
- 12 Mental Health Services/
- 13 (psychosocial adj (intervention* or support system)).mp.
- 14 self help group*.mp.
- 15 (therap* adj5 (educational or psychoeducational or behavior or behaviour or cognitive or cognition or family or psychoanalytic)).mp.
- 16 CBT.mp.

17 mental health services.mp.
18 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
19 "Quality of Life"/
20 Mental Health/
21 Life Changes/
22 Affective Disorders/
23 "Depression (Emotion)"/
24 Dysthymic Disorder/
25 Anxiety/
26 Anxiety Disorders/
27 exp Psychological Stress/
28 Rating Scales/
29 Psychometrics/
30 Client Satisfaction/
31 ((psychological or emotional) adj (wellbeing or well-being)).mp.
32 life change event.mp.
33 affective symptom*.mp.
34 mental health.mp.
35 anxiety.mp.
36 psychological stress.mp.
37 patient satisfaction.mp.
38 benefit finding.mp.
39 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38
40 3 and 18 and 39
key:
[mp=title, abstract, heading word, table of contents, key concepts]

HISTORY

Protocol first published: Issue 2, 2008

Review first published: Issue 11, 2012

CONTRIBUTIONS OF AUTHORS

Contribution to protocol: KG; conception of review, development of search strategies and drafting of protocol. CC; statistical advice on meta-analysis. AB, MC and MM; conception and initial development of review. MD; editorial supervision.

Contribution to review: KG, AB, MC, CC, MM and MD; selection and data extraction process (including decisions on scope), development and editing of main text. KG; meta-analysis, narrative analysis, drafting text of review. MD; editorial supervision.

DECLARATIONS OF INTEREST

None

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- Research and Development Office, Northern Ireland, UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The scope of the review was reduced to include only interventions carried out with individuals. All group, family and couple-based therapeutic interventions have been excluded from the review. This decision was made on the basis of the volume and variety of intervention formats appearing in the search results that could be usefully compared. Subgroup comparisons (3) examined mode of intervention delivery, that is face-to-face or telephone. It was not possible to carry out proposed subgroup analyses (4) emotional state at the time of the intervention as the majority of studies excluded participants with a history of psychiatric morbidity, and did not report separate data for participants who displayed suspected psychological distress at baseline. Subgroup analysis (5) was not carried out between or within studies because authors generally report stage and mode of clinical treatment programme at a group level, rarely carrying out sensitivity analyses to examine individual differences related to stage or mode of treatment within trials.