Psychosocial interventions for informal caregivers of people living with cancer


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Psychosocial interventions for informal caregivers of people living with cancer (Protocol)

Santin O, Coleman H, Mills M, Cardwell CR, Donnelly M

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Psychosocial interventions for informal caregivers of people living with cancer

Olinda Santin¹, Helen Coleman², Moyra Mills³, Chris R Cardwell², Michael Donnelly²

¹School of Nursing and Midwifery, Queen's University Belfast, Belfast, UK. ²Centre for Public Health, Queen's University Belfast, Belfast, UK. ³Northern Health and Social Care Trust, Antrim, UK

Contact address: Olinda Santin, School of Nursing and Midwifery, Queen's University Belfast, Institute of Clinical Sciences B, Royal Victoria Hospital Site, Grosvenor Road, Belfast, Northern Ireland, BT12 6BJ, UK. o.santin@qub.ac.uk.

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effects of psychosocial interventions designed to improve the quality of life, physical health and psychosocial well being of informal caregivers of people living with cancer compared with standard services.

The review will also evaluate the extent to which:

- Psychosocial interventions exert an impact on different domains (e.g. psychological health and physical functioning).
- Different modes of intervention delivery and settings influence outcomes.
- There is a relationship between the number, duration of intervention sessions and the degree of change in measured outcomes.
BACKGROUND

Improved survival has resulted in a growing population living with and affected by cancer, which is increasingly viewed as a chronic disease. Cancer prevalence is estimated to be 11 million in the US (Horner 2006) and 2 million in the UK (Maddams 2009). This growing prevalence is also apparent in Australia and Ireland with one in three people being diagnosed with cancer in each country (Ferlay 2008). These prevalence figures are expected to increase by 3% per year (Maddams 2009). The most prevalent cancers worldwide are breast cancer, colorectal cancer and prostate cancer (Maddams 2009). As the prevalence of cancer rises and models of care change, there is increasing emphasis on the role of informal caregivers providing support in the community for cancer patients following active treatment.

Cancer may impact on caregivers, as well as patients, from the onset of symptoms and throughout the illness trajectory. In the UK, approximately 40% of people caring for someone living with cancer spend more than 30 hours per week providing this care (Macmillan 2008). The impact of cancer on a patient and family may be influenced by many factors, including personality (Carver 1993; Campbell 2004), the stage and nature of the diagnosis (Weitzner 1999), and the associated treatment (Nijober 1999; Langer 2003). Caring can have detrimental effects on the caregiver's physical, psychological and social health, and may significantly reduce their quality of life (Ferrell 1995; Stenberg 2009). A recent review of the effects of caring for a cancer patient identified over 200 accompanying problems (Stenberg 2009). For example, physical difficulties associated with caring for someone with cancer can include enduring periods of back and muscular pain, disturbed sleep patterns and general fatigue (Stenberg 2009). In addition, informal cancer caregivers may face psychological difficulties such as intense worry about the patient's health, and stress associated with providing care and support while maintaining their daily work and other responsibilities (Hagedoorn 2000; Northouse 2000). The time and costs of providing care may cause many social issues such as financial strain arising from reduced income, increased bills, and gaps in or loss of employment/education. The problems and needs associated with informal caring may last for prolonged periods of time, even when a patient is ‘free’ of disease (Hodgkinson 2007). Informal caregivers may experience equal or greater levels of depression than patients with cancer (Hodges 2005; Rhee 2008; Campbell 2009), live with fear that cancer will return (Hodgkinson 2007), and suffer anxiety and reduced quality of life (Cella 1990; Sherif 2001; Mellon 2006).

Caregivers may be overwhelmed by their changed circumstances and may need help and support to cope with the practical challenge of providing care. Certain factors may be associated with further increased needs in caregivers, such as being female, younger (Harding 2003; Daly 2009), having a lower socio-economic status (Donnelly 2008), caring for someone with stage 1 or 2 cancer (Daly 2009), having unhealthy partner attachments, living alone with a patient, having a distressed relationship, or having a higher level of patient dependency (Nijober 1999). Carers whose relationship with a patient was previously troubled (Gritz 2004) or lacked positive communication (Kim 2008) may experience significant difficulties in their caring role. Female caregivers may experience an increase in needs compared to men as they tend to have multiple responsibilities such as caring for children and household management alongside being a primary caregiver (Matthews 2003; Campbell 2009). There is a need to understand the best possible way to meet the needs of informal cancer caregivers.

Description of the condition

Informal caregivers have been defined as unpaid individuals who provide one or a combination of physical, practical and emotional care and support to a family member or friend (Harding 2003; Candy 2011). In developed healthcare systems, partners or spouses (inclusive of the range of different types of partnerships) provide most of the physical care and emotional support for cancer patients once patients are discharged from hospital (Hodgkinson 2007), though the caring role may be undertaken by friends and, less commonly, neighbours (Mills 2008). This review includes partners, other relatives and friends (Candy 2011), in the definition of an informal caregiver. Unlike Candy 2011 this review excludes carers of patients who are in the terminal phase of disease. As noted above, providing informal care for someone who has or has had cancer can have negative physical, psychological and social health consequences (Stenberg 2009). These negative impacts on informal caregiver health may negatively affect patient health and well-being (Roberts 1994; Northouse 1995). Many health and social care needs of cancer caregivers appear to be unmet (Soothill 2003).

Description of the intervention

This review will consider non-pharmacological, psychosocial interventions that are designed to support, inform, educate and increase the coping capacity of informal cancer caregivers. There is a lack of consistency in defining the term ‘psychosocial intervention’ within the cancer literature (Hodges 2010). In this review we will consider any psychosocial intervention delivered verbally by healthcare professionals that aims to alleviate the difficulties faced by informal cancer caregivers. In most cases, healthcare professionals are the main form of professional health and social care support for a patient and their caregiver. Trials have evaluated a number of professionally-led interventions, such as psycho-educational support groups (Bultz 2000), cognitive-behaviour therapy (Cohen 2006), nursing and social interventions such as support groups that encourage symptom management and rehabilitation (Kozachik 2001; Northouse 2005).
The rising number of individuals providing care to people with cancer implies the need for focused support strategies in chronic care, including people with cancer, but only includes interventions delivered by caregiver peers. Interventions that are delivered to informal caregivers of terminal patients will not be included as they are the focus of another review (Candy 2011). The rising number of individuals providing care for curable cancer patients warrants a separate investigation.

**O B J E C T I V E S**

To assess the effects of psychosocial interventions designed to improve the quality of life, physical health and psychosocial well-being of informal caregivers of people living with cancer compared with standard services.

The review will also evaluate the extent to which:

- Psychosocial interventions exert an impact on different domains (e.g. psychological health and physical functioning).
- Different modes of intervention delivery and settings influence outcomes.
- There is a relationship between the number, duration of intervention sessions and the degree of change in measured outcomes.

**M E T H O D S**

**Criteria for considering studies for this review**

**Types of studies**

Randomised controlled trials (RCTs), cluster RCTs and quasi-RCTs (using a quasi-random method of allocation such as alternation, date of birth, or case record number).

**Types of participants**

We will include studies in which the primary participants meet the following criteria:

- The caregiver must be an adult (18+ years old) and not a professional or paid caregiver, or a trained volunteer. Caregivers who receive financial benefits from the government in order to support their caring role will be included in this review, with the impact of financial support considered in the data analysis.
- The caregiver must provide informal care (including physical, practical and emotional care and support) to the patient.
- The caregiver provides care for a patient who is an adult (18+ years old) diagnosed with any type of cancer (including current patients and survivors). The patient must not be in the terminal phase of the disease (a patient is considered to be in the terminal phase of disease when the disease is “not amenable to cure; their health is progressively deteriorating, the aim of treatment is supportive or palliative, and health professionals do not expect her or him to survive longer than days, weeks or months” Candy 2011). The patient must be a spouse, partner, relative or friend of the caregiver. If included studies provide data...
on outcomes for secondary participants i.e. patients, this will be considered in analysis.

- The caregiver provides care for a patient living in their own home and not in a hospital or hospice.

The intervention must be delivered by a healthcare professional (including allied health professionals such as social workers and physiotherapists).

**Types of interventions**

We will include psychosocial interventions that are delivered to an informal caregiver individually or in a group setting by a healthcare professional. Interventions that have been delivered simultaneously to the patient and caregiver will also be included, but will be the subject of separate analysis.

A psychosocial intervention is a non-pharmacological intervention that involves an interpersonal relationship between a patient or group of patients and one or more trained professionals. Psychosocial includes interventions described as psychological, psycho-therapeutic, psycho-educational or psychosocial. Interventions that do not explicitly state that they are psychosocial will be included if they comprise a psychological or social component. Examples of psychosocial interventions are:

- psychosocial support systems (systems that provide help and encouragement to promote coping),
- self-help groups (therapist-led groups providing support, advice and information),
- educational therapy (intensive interventions designed to promote learning),
- cognitive behavioral therapy (CBT) (therapeutic approach that aims to solve difficult thoughts, feelings and behaviours),
- counselling (talking therapy delivered by a therapist to one or more people) and
- family therapy (a type of therapy that works with families or couples experiencing difficulty).

All interventions will be considered in overall analysis, and further analysis will then be conducted based on the nature of intervention i.e. psychological, psycho-therapeutic etc, and the type of intervention i.e. CBT, counselling. Interventions must comprise ‘instant dialogue exchange’ between a caregiver and a trained professional within the care giving /healthcare setting. Interventions which have been conducted within acute or community settings will be included. We will include non-face-to-face interventions such as online or telephone counselling, as they involve the instant exchange of dialogue between two or more people.We will exclude interventions that include non-verbal delivery, such as information leaflets and DVDs. We will also exclude interventions that are ‘peer led’. Control groups will comprise caregivers who receive usual or standard care, that is, caregivers who are not receiving any additional support. We will exclude studies that compare two different types of psychosocial interventions, for example facilitated self-help with one-on-one counselling.

**Types of outcome measures**

**Primary outcomes**

- Caregiver quality of life (QoL) (mental, physical and social domains)

Anticipated QoL scales that may be featured in the review include: HADS, SF-36, POMS; these measures have strong empirical evidence regarding their validity and reliability (Lipscomb 2005).

**Secondary outcomes**

- Patient quality of life (QoL) (mental, physical and social domains)
- Caregiver depression (measured separately from QoL scale)
- Caregiver anxiety (measured separately from QoL scale)
- Caregiver satisfaction with interventions
- Caregiver physical health status (measured separately from QoL scale)
- Patient depression (measured separately from QoL scale)
- Patient anxiety (measured separately from QoL scale)
- Patient satisfaction with interventions
- Patient physical health status (measured separately from QoL scale)
- Any adverse events
- Cost- effectiveness. This may be cost-effectiveness of interventions with regard to caregivers, measured as a definable entity such as cost per increment in health status, or indirect cost-effectiveness of caregiver interventions on patient outcomes such as quality adjusted survival data (Quality-Adjusted Life Years (QALYs)).

**Outcomes for Summary of Findings table**

We will report on the following main outcomes in a Summary of Findings table (see Data collection and analysis).

1. Caregiver QoL
2. Patient QoL
3. Caregiver depression
4. Caregiver anxiety
5. Caregiver satisfaction with interventions
6. Caregiver physical health status
7. Any adverse events

**Search methods for identification of studies**

**Electronic searches**

We will search the following databases systematically from inception:
• Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library)
• MEDLINE (OvidSP)
• EMBASE (OvidSP)
• PsycINFO (OvidSP)
• ProQuest Dissertations and Theses
• Open SIGLE
• Web of Science

See Appendix 1 for the MEDLINE search strategy which will be adapted for searching all other databases. We will not apply any language restrictions. Non-English studies will be translated though services supplied at Queen’s University Belfast, Northern Ireland.

Searching other resources
We will search conference abstracts. We will check the reference lists of included studies for any further potential studies that have not been identified via electronic searches. We will contact authors to obtain any further data that are not presented in the published articles and enquire if there are related publications. We will also search the following trial registers; ClinicalTrials.gov (http://www.clinicaltrials.gov/) and the WHO Clinical Trial Search Portal (http://apps.who.int/trialsearch/).

Data collection and analysis

Selection of studies
We will download all titles and abstracts from the electronic searches to a reference management database (Refworks), and remove duplicate studies. Two review authors working independently will screen the titles and abstracts against the inclusion criteria. We will exclude studies that do not meet the review’s criteria. Studies which cannot be excluded on title and abstract alone will be retrieved in full text; two review authors working independently will assess these for inclusion. Studies excluded at this stage will be recorded and their reason for exclusion presented in the review’s ‘Characteristics of Excluded Studies’ table. Any disagreements will be resolved through discussion with a third review author.

Data extraction and management
Two review authors will extract data independently from the included studies using pre-designed data extraction forms. Data extracted will include:
• General: author, year of publication, title, journal, country and language of publication.
• Trial: study design, randomisation.
• Caregiver information: age, gender, ethnicity, diagnosis and stage of patient they are providing care for, relationship to patient, sample size and distribution of caregivers in each arm of the trial.
• Patient information: diagnosis, cancer stage, age, gender, ethnicity.
• Intervention and control: components of intervention, method of delivery, setting, health professional involved, length of intervention, frequency, control intervention characteristics, type and nature of intervention, how the intervention was described.
• Risk of bias: See Assessment of risk of bias in included studies.
• Outcomes: quality of life measures, any physical, psychosocial, satisfaction outcomes and adverse events, timing of data collection, number of data points, how outcome was measured, measurement tools used, cost.
• Funding and ethics approval.

Assessment of risk of bias in included studies

Two review authors will independently examine the risk of bias of included studies. The criteria used to assess studies will be outlined in the data extraction sheet. The main areas of assessment will include those outlined in the Cochrane Handbook i.e. sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias (Higgins 2008). We will also report on validity and reliability of outcome measures, whether ethics approval has been granted, and use of standardised protocols for intervention delivery. The risk of bias table will be used to report on the degree of bias in each of these domains, the overall risk of bias for each study will be generated using the risk of bias tool in RevMan and categorised as:
• Low: all criteria met,
• Moderate: One or two criteria unclear or not met,
• High: More than two criteria unclear or not met.

Measures of treatment effect

For continuous variables (such as quality of life (QoL)), we will assess treatment effects by extracting the mean difference (MD) (and corresponding standard deviations) in scores on measures of quality of life, depression and anxiety, patient satisfaction and physical status between the intervention and control groups. Where other statistics (such as median or interquartile range) are reported, we will attempt to convert these to obtain mean and standard deviation as previously suggested (Hozo 2005; Higgins 2008). Where dichotomous outcomes are reported, the proportion within the treatment and control group will be extracted and converted to odds ratios (OR). Where studies report outcomes at several time points, we will identify the first and last follow up. In order to deal with the potential issue of studies using various instruments, a standardised mean difference (SMD) analysis will be conducted.

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to combine estimates from studies using different instruments to measure the outcome (e.g. QoL, depression, anxiety).

**Unit of analysis issues**

All interventions will be considered in an overall intervention analysis, further analysis will then be conducted based on nature/type of intervention and the type of measurement tool used. We anticipate for most studies randomisation will be conducted at the individual level. If cluster RCTs are identified, we will check that adjustments for clustering have been conducted in the estimate of treatment effects. If not, we will use intra-cluster correlation coefficients either from the study or from an external source to correct the effect estimate as described in 16.3.4 of the Cochrane Handbook (Higgins 2008).

**Dealing with missing data**

Where missing data are observed in studies we will contact authors to obtain missing values. If data are not obtained the study will be excluded from the relevant analyses.

**Assessment of heterogeneity**

The degree of statistical heterogeneity within the subgroups outlined below will be tested and quantified using the Cochrane Chi^2^{2} statistic and the I^2 statistic and corresponding 95% Confidence Intervals (CIs) to assess the variation in study results due to reasons other than chance. Where heterogeneity is less than 40% a fixed-effect model (Higgins 2008; 9.5.2) will be used to combine estimates. Where statistical heterogeneity is greater than 40% the Dersimonian and Laird random-effects meta-analysis model will be used to pool results accounting for the heterogeneity (Higgins 2008; 9.5.3-4). We will attempt to determine the cause of heterogeneity by conducting additional subgroup analysis. If statistical heterogeneity is greater than 75% no pooled estimate will be calculated.

If there are a sufficient number of studies, we will perform a meta-regression to investigate the effect of study characteristics discussed above on the intervention effects.

**Assessment of reporting biases**

The extent of reporting bias will be minimised by including publications of all languages and by contacting relevant authors in the field. Publication biases will be investigated using funnel plots, bearing in mind their current limitations (Bandolier 2001). Additionally, the Begg and Mazumdar adjusted rank correlations test (Begg 1994) and the Egger regression asymmetry test (Egger 1997) will be applied to funnel plots to formally test for funnel plot asymmetry.

**Data synthesis**

Where appropriate data will be analysed using fixed-effect or random-effects meta-analysis models to calculate pooled mean differences and 95% CIs in treatment effect scores in RevMan 5. If results cannot be meta-analysed they will be described narratively.

**Subgroup analysis and investigation of heterogeneity**

We will conduct analysis separately within the following groups because of the clinical heterogeneity which could make combining results across these groups less meaningful:

1. Within intervention type (e.g. CBT, counselling, health professional-led support group)
2. Mode of delivery of intervention (e.g. one to one, group, online)
3. Type of measurement used (Validated versus non-validated, to assess the robustness of outcomes)
4. Nature of intervention (psycho-logical,-therapeutic,-educational or social, studies may be included in more than one of these categories)
5. Caregiver characteristics (gender, age, relationship with patient)
6. Time since patient’s diagnosis

The above exploratory tests of heterogeneity will also be applied to the subgroup meta-analysis and interpreted cautiously.

**Sensitivity analysis**

Studies that are deemed to be high risk of bias based on a risk of bias assessment will be removed from the meta analysis and we will examine the impact of their removal on the results. Psychosocial interventions that have been delivered to caregivers and patients at the same time will be analysed in a separate sensitivity analysis. We will conduct various sensitivity analyses including:

1. We will rerun the analysis based on random-effects or fixed-effect models to see how this affects this outcome.
2. We will calculate a pooled estimated removing each study in turn to evaluate how each individual study influences the pooled estimate.
3. The analyses will be repeated using relative risks instead of odds ratios to see how this affects the outcome.

**Summary of Findings table**

We will include a Summary of Findings table displaying the following elements:

1. All main outcomes (specified at Types of outcome measures).
2. Absolute and relative magnitude of effect.
3. Numbers of studies and participants.
4. Grade of overall quality of evidence.
ACKNOWLEDGEMENTS

- OS is funded as a Cochrane Review Training Research Fellow by the R+D office Northern Ireland to undertake this review (see Sources of support)

- Alex McIlroy, Librarian in the School of Medicine and Dentistry, Queens University Belfast in the development of search strategy.

- Northern Ireland Cancer Network for providing consumer input in the review.

REFERENCES

Additional references

Bandolier 2001

Bandura 1977

Bandura 1997

Begg 1994

Bultz 2000

Campbell 2004

Campbell 2009

Candy 2011

Carver 1993

Cella 1990

Cohen 2006

Daly 2009

DHA 2008

DoH 2007

Donnelly 2008

Doull 2005

Egger 1997

Ferlay 2008
Ferrell 1995

Galway 2006

Gritz 2004

Hagedoorn 2000

Harding 2003

Higgins 2008

Hilton 1994

Hodges 2005

Hodges 2010

Hodgkinson 2007

Horner 2006

Hozo 2005

Kim 2008

Kozachik 2001

Langer 2003

Legg 2011

Lipscomb 2005

Macmillan 2008

Maddams 2009

Matthews 2003

Mellon 2006

Mills 2008

Minick 2010
Nijober 1999

Northouse 1995

Northouse 2000

Northouse 2005

Rhee 2008

Richardson 2007

Roberts 1994

Sherif 2001

Soothill 2003

Stenberg 2009

US DHSS 2003

Vernooij-Dassen 2011

Weitzner 1999

* Indicates the major publication for the study

**APPENDICES**

**Appendix 1. MEDLINE search strategy (OvidSP)**

1. exp neoplasms/
2. (cancer* or oncology* or neoplasm* or carcinom* or tumo?r* or malignan* or lymphoma or melanoma or leuk?emia or sarcoma).tw.
3. or/1-2
4. (family or families or parent$2 or mother? or father? or friend? or relative? or spous$2 or partner? or husband? or wife or wives or son? or daughter? or offspring? or sibling? or brother? or sister?).tw. and (care* or caring).mp.
5. caregivers/
6. (caregiv* or care giv*).tw.
7. exp home nursing/
8. exp family/
9. or/4-8
10. (family or families or parent$2 or mother? or father? or friend? or relative? or spous$2 or partner? or husband? or wife or wives or son? or daughter? or offspring? or sibling? or brother? or sister? adj10 (support* or inform* or train* or educat* or teach* or coach* or...
instruct* or advis* or advice* or counsel* or therap* or cbt or program* or psycho* or social or pastoral or spiritual or religio* or self help or selfhelp or problem solving).tw.
11. social support/
12. exp social work/
13. exp psychotherapy/
14. exp counselling/
15. education/
16. health education/
17. teaching/
18. exp "religion and psychology"/
19. self help groups/
20. self care/
21. problem solving/
22. professional family relations/
23. or/10-22
24. 3 and 9 and 23
25. randomized controlled trial.pt.
26. controlled clinical trial.pt.
27. randomly.ab.
28. placebo.ab.
29. randomized.ab.
30. drug therapy.fs.
31. trial.ab.
32. groups.ab.
33. or/25-32
34. exp animals/ not humans.sh.
35. 33 not 34
36. 24 and 35

HISTORY

CONTRIBUTIONS OF AUTHORS
OS is the lead author and RDO-funded Cochrane Review Training Fellow. MD is supervising the review. All authors were involved in the development of the protocol. OS will be involved in all aspects of the review and will be responsible for the review update. HC, MM and OS will identify eligible studies and conduct risk of bias assessments of eligible studies. CC will provide statistical advice on meta-analysis. OS, HC and MM will draft the final review with guidance and supervision from MD. The review team have a close working relationship with the Northern Ireland Cancer Network; the Network staff will help us to involve people who have been affected by cancer in this review.
DECLARATIONS OF INTEREST

None known

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Internal sources

• No sources of support supplied

External sources

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