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Information interventions for orienting patients and their carers to cancer care facilities (Protocol)

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[Intervention Protocol]

Information interventions for orienting patients and their carers to cancer care facilities

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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 information interventions which orient patients and their carers/family to a cancer care facility and the services available in the facility.

BACKGROUND

Description of the condition

Approximately 24.6 million people experienced cancer around the world in 2002 (WHO 2005). According to the World Health Organisation (WHO), the number of new cancer cases is projected to increase from 10.9 million per year in 2002, to 16 million per year by 2020 (WHO 2005). Around one third of all cancer patients experience prolonged psychological distress and anxiety levels that may contribute to ongoing adjustment difficulties, and interfere with treatment adherence (Sellick 2007; Sussman 1995). Further, the psychological distress does not only affect cancer patients, but also their partners, families and carers (Nijboer 2000; Welch 1996).

Description of the intervention

There is consensus that information needs exist across the continuum of cancer care for patients and family/carers (Rees 2000; Rutten 2005; Rutten 2006). However, we know little about the best timing for providing specific information. The initial visit of a cancer patient to the oncology centre can be especially distressing (Mohide 1996). Factors contributing to this anxiety and distress may include recent cancer diagnosis, uncertainty about treatment, needle phobias, concerns about treatment length, and unfamiliarity with the environment and with care providers (Carelle 2002; Wells 1995). It has been demonstrated that information provision can reduce anxiety and mood disturbances in cancer patients (Mills 1999).

While much attention has focused on preparing cancer patients for threatening medical treatment such as chemotherapy and radiotherapy (Dunn 2004; Schofield 2008), information in relation to the actual facility and supportive services available can easily be left out of structured information-giving interventions. Therefore, the intervention under consideration is any program or strategy that orients patients to a cancer care facility; that is, any intervention aiming to familiarise patients and their carers by giving them information about the cancer care facilities and services available to them therein (e.g. opening hours, role of the healthcare team). Cancer patients may be receiving treatment in various settings other than a specialised cancer centre. For example, cancer patients can receive treatment in a general medical centre without a specialised cancer department due to inconsistent resources available in various regions (Borras 2001). Information may be delivered using strategies such as audiovisual aids, written information, telephone helplines and face-to-face teaching (McPherson 2001). Moreover, there has also been an increasing awareness of different needs among cancer patients with varying levels of health literacy (ability to understand health materials) and diverse cultural backgrounds (Huang 1999; Wilson 2000). Although different information needs exist, orientation interventions aim to provide

generic information that is needed by all cancer patients during their early encounters with a cancer care facility.

How the intervention might work

Information provision may reduce distress by enhancing patients' sense of control. An enhanced sense of control, in turn, relieves anxiety and enhances management of illness (Chelf 2001). Specifically, evidence has suggested that providing cancer and surgical patients with information about the procedure they are about to undergo can significantly reduce their emotional distress and improve their psychological and physical recovery (Burish 1991; Johnston 1993). Other benefits related to the provision of information specifically for cancer patients may include increased patient involvement in decision-making and greater satisfaction with treatment choices (Luker 1995); improved ability to cope during the diagnosis, treatment, and post-treatment phases (Harrison-Woermke 1993); and improved communication with family members (Rutten 2006).

Why it is important to do this review

Information is important for cancer patients and their family/carers throughout the continuum of cancer care. Although the benefits of information have been emphasised, patients and family members often report that their information needs are not sufficiently met (Champman 2003; Rees 2000). Orientation programs aim to address information needs at the start of a person's dealings with a cancer care facility. These programs may consume considerable resources but the extent of any benefit is unknown. Indeed, we acknowledge that it is possible that harm may be caused. Dubois 2008 indicated that un-useful information may be undesirable in new cancer patients. We also acknowledge that this review is narrowly focused as we are considering the intervention at a particular time point (before the first cancer treatment). However, meeting information needs at different stages is important in cancer care.

Relationship to other relevant reviews

Rodin and colleagues conducted a systematic review on the effects of treatment for depression in cancer (Rodin 2007). The review focused on depression as an outcome; orientation programs were not the specific subject of the review. The authors found that an orientation program reduced depression, but they did not assess any of the other outcomes of interest in the current review.

OBJECTIVES

To assess the effects of information interventions which orient patients and their carers/family to a cancer care facility and the services available in the facility.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs), cluster RCTs and quasi-RCTs.

Types of participants

Participants must be new oncology patients and carers who receive an orientation intervention, which includes information and education about the facility or services where they are to receive care. The interventions must be given to patients who are about to receive treatment or care in a cancer centre or a cancer department of a general medical facility. This review will only consider adults (over 18 years old) due to the different nature of information needs in paediatric patient populations. Participants may have any type of cancer at any stage, and may be about to receive inpatient or outpatient treatment.

Types of interventions

Any information intervention with the primary goal of orienting patients and their carers to a cancer care facility or services. Content must include information about the care facility and services available in the facility (such as information about the healthcare team) as the core component of the intervention. The intervention can be delivered by healthcare professionals, administrative staff, volunteers or a combination. It can be delivered in any mode or a combination of modes, including:

- individual face to face;
- group intervention (including family-based interventions);
- telephone;
- video or audio materials;
- computer based/ technology based (e.g. internet);
- written materials.

The intervention could be a single intervention with the primary goal of orientation, or part of a complex intervention. If part of a complex intervention, it must be possible to separately identify the effects of the orientation intervention. The orientation intervention could be compared to usual care or compare different modes and intensities of the intervention. Intensities may be measured by duration of the intervention or number of components involved in the intervention.

Based on the nature of orientation, we will exclude interventions which are delivered after the first cancer treatment has commenced. This is to avoid the inclusion of educational interventions during the course of treatment. The intervention may be presented in any setting, for instance in hospital or at home.

Types of outcome measures

We will seek data on outcomes in the following categories:

Primary outcomes

Consumer-oriented outcomes:

- Knowledge and understanding (e.g. knowledge acquisition; retention of information; ability to recall information);
- Health status and wellbeing (e.g. physical or psychological health, coping or quality of life, measured by any instrument used by the trial investigator);
- Evaluation of care (e.g. satisfaction of patients and carers measured by any instrument used by the trial investigator);
- Harms (any adverse effects caused in the patients)

Secondary outcomes

Consumer-oriented outcomes:

- Communication e.g. improved communication or relationship with provider;
- Skills acquisition e.g. self-care skills;
- Behavioral outcomes e.g. adherence to visits/ adherence to treatment.

Service delivery oriented outcomes:

- Service delivery level e.g. cost of orientation interventions, service use;
- Health professional outcomes e.g. satisfaction.

We will extract outcome data irrespective of whether it was collected with a validated tool. However, in appraising the studies we will discuss the validity and reliability of the outcome measures used.

Search methods for identification of studies

Electronic searches

The Cochrane Consumers and Communication Review Group will search their Specialised Register.

We will search:

- MEDLINE Ovid SP (1966- present)
- Cochrane Central Register of Controlled Trials (CENTRAL)
- EMBASE Ovid (1966- present)
- CINAHL EBSCO (1982- present)

- PsycINFO Ovid (1966- present)
- Current Contents ISI (1998- present)
- Web of Science ISI (1966- present)

The search strategies have been developed to comprise searches using keywords and medical subject headings under existing database organizational schemes. The strategy for MEDLINE (Ovid SP) is presented at [Appendix 1](#).

There will be no restriction on language. Foreign language abstracts will be initially translated for the application of the inclusion and exclusion criteria, and where necessary the methods, results and discussion sections will be translated for inclusion in the review.

Searching other resources

We will search the reference lists of any relevant studies and reviews. We will also scan contents pages of relevant journals for articles about interventions which orient patients to cancer care facilities, as well as abstracts from relevant conference proceedings. The relevant journals will include *Patient Education and Counseling*, *Psycho-Oncology*, *Oncology Nursing Forum*, and *Cancer Nursing*. We will also contact experts in the field and authors of included studies for advice about other potentially relevant studies.

We will search the ProQuest Dissertations and Theses database for grey literature. We will search databases in TrialsCentral (www.trialscentral.org), the WHO Clinical Trial Search Portal (www.who.int/trialsearch) and Current Controlled Trials (www.controlled-trials.com) to identify ongoing or recently completed studies. If applicable, we will present relevant ongoing studies in a table in the review.

Data collection and analysis

Selection of studies

Two review authors will pre-screen all search results (titles and abstracts) for possible inclusion, and those selected by either or both authors will be subject to full-text assessment. Two review authors will independently assess the selected articles for inclusion. Any discrepancies will be resolved by consensus, overseen by a third author acting as arbiter, with approval by one review author and the arbiter being sufficient to include the study. We will list those studies excluded after full-text assessment in the table 'Characteristics of Excluded Studies', giving reasons for exclusion.

Data extraction and management

We will develop a data extraction form based on the Cochrane Consumers and Communication Review Group's template, and pilot and amend it as necessary (see [Appendix 2](#)). At least two authors will independently extract data using the data extraction

form. The forms will then be checked by a third author and any errors or inconsistencies resolved. The first author will enter the data into RevMan, with another author checking the accuracy of data entry.

Assessment of risk of bias in included studies

We will assess and report on the risk of bias of included studies in accordance with the guidelines in the Cochrane Handbook for Systematic Reviews of Interventions ([Higgins 2008](#)), which recommends the explicit reporting of the following individual domains:

- Sequence generation;
- Allocation concealment;
- Blinding of participants, personnel and outcome assessors (assessed for each main outcome or class of outcome);
 - Incomplete outcome data (assessed for each main outcome or class of outcome);
 - Selective outcome reporting;
 - Other sources of bias.

This will lead to an overall assessment of the risk of bias of the included studies ([Ryan 2007](#)). We will assess each of the risk of bias items as 'yes' (indicating a low risk of bias), 'no' (a high risk of bias), and 'unclear' (risk of bias is unclear) based on the trial reports and/or additional information provided by trial authors. We will also examine and report the following:

- Validation and reliability of outcome measures;
- Whether the study obtained ethics committee approval and ensured informed consent for participation;
- Use of standardised protocols for information delivery. We will check for consistency of the delivery of interventions where possible.

Two review authors will independently assess the risk of bias in included studies, with any disagreements resolved by discussion and consensus, and with a third author acting as arbiter. We will present our assessment in risk of bias tables for each included study. We will contact study authors for additional information about the study methods as necessary. We will incorporate the results of the risk of bias assessment into the review through narrative description and commentary about each of the items mentioned.

Measures of treatment effect

For individual trials, for dichotomous (binary) outcomes we will report odds ratios (ORs) and 95% confidence intervals (CIs). For continuous outcomes, we will report the mean difference (MD) or, if the scale of measurement differs across trials, the standardised mean difference (SMD), each with its 95% CI.

We will analyse data using the Cochrane Collaboration's Review Manager (RevMan) 5 software.

Unit of analysis issues

Unit of analysis errors will be checked if cross-over trials or cluster randomised trials are included, although we are unlikely to identify relevant cross-over trials due to the orientation intervention occurring before patients' treatment. If required, and sufficient data are available, we will recalculate the results using the appropriate unit of analysis (Higgins 2008).

Dealing with missing data

We will contact study authors for missing data. Where complete data are available, we will perform analysis on an intention-to-treat (ITT) basis. If some outcome data remain missing despite our attempts to obtain complete outcome data from authors, we will perform an available-case analysis, based on the numbers of patients for whom outcome data are known. If standard deviations are missing, we will impute them from other studies, or where possible, compute them from standard errors using the formula $SD=SE \times \sqrt{N}$, where these are available (Higgins 2008). We will also report on levels of drop outs in the intervention and comparison groups as an indicator of 'acceptability' of the intervention, and as a potential source of bias.

Assessment of heterogeneity

Heterogeneity will be tested using the Chi² statistic and any heterogeneity will be further quantified with the I² statistic (which describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error). A value greater than 50% will be considered to represent substantial heterogeneity (Higgins 2008).

Assessment of reporting biases

Reporting bias will be assessed using guidelines in Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2008). As we do not expect to find a large number of studies it is unlikely that publication or inclusion bias will be assessed. However, if enough studies are available to do a meaningful assessment of publication bias, we will test for asymmetry using a funnel plot. We will discuss the results of the funnel plot and possible explanations thereof, which include publication bias but also other sources of bias such as diverse methodological quality.

Data synthesis

For meta-analyses, for dichotomous outcomes, we will calculate odds ratios (ORs) and for continuous outcomes, the mean difference (MD) or a summary estimate for standardised mean difference (SMD), each with its 95% CI.

We will group data within the tables according to study design and type of intervention. If there are sufficient appropriate studies, they will also be categorised based on whether the intervention

is aimed at patients or carers. Within these categories the results will be further structured to reflect the comparisons detailed in the [Types of interventions](#) sections (i.e. mode of delivery). We will present separately the results of studies that compare the intervention to no intervention, then those that compare the intervention to other forms of orientation intervention (e.g. face to face versus audio/visual) and those that compare two or more types of mode (e.g. written materials and video; written material and face to face). We will use this synthesis to prepare a narrative review of the results, and to examine included studies to assess clinical and methodological heterogeneity. The narrative review will present the results of the studies as relative and absolute percentage change and direction of effect for each of the outcomes.

If the studies are sufficiently similar in terms of population, inclusion criteria, interventions and/or outcomes (including the time(s) at which these are assessed), we will consider pooling the data statistically using meta-analysis. We will perform a formal random-effects model meta-analysis, which will report pooled MDs (continuous variables using the same scale) or SMDs (continuous variables using different scales) or ORs (dichotomous variables), with 95% CIs.

If cluster randomised trials are included, we will account for the effects of clustering by adjusting each trial to its 'effective sample size' using intra-class coefficients where available, or external estimates from similar studies. We will analyse separately the comparisons detailed in the previous paragraph. Separate meta-analyses will be carried out for each of the primary outcomes and secondary outcomes. The decision to carry out meta-analyses will be made by consensus of RC and JW.

A summary of the results of the data synthesis and assessment of the quality of the evidence will be included in a Summary of Findings table.

Subgroup analysis and investigation of heterogeneity

No subgroup analysis is planned.

Sensitivity analysis

We will restrict the primary analysis to studies which are considered as having a low risk of bias (ie. those receiving a 'Yes' rating for the criteria of sequence generation and allocation concealment).

We will also perform sensitivity analyses where appropriate in order to explore the influence of the following factors on effect size:

- excluding unpublished studies;
- excluding any large studies to establish how they impact on the results;
- excluding studies using the following filters: criteria used for clinical diagnosis and eligibility for intervention, language of publication, country;
- the length of the interval between registration to the service and delivery of the intervention; and between delivery of the intervention and measurement of the effect.

We may also test the robustness of the results by repeating the analysis using different measures of effect size (risk difference, odds ratio etc.) and different statistical models (fixed-effect and random-effects models).

Consumer participation

The protocol has undergone standard Cochrane Consumers and Communication Review Group editorial and external peer review, which includes at least one consumer referee. This protocol also includes a number of consumer-focused outcomes, guided by the Cochrane Consumers and Communication Review Group taxonomy of outcomes.

ACKNOWLEDGEMENTS

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* Indicates the major publication for the study

APPENDICES

Appendix I. MEDLINE (Ovid) search strategy

1. exp neoplasms/
2. exp carcinoma/
3. (cancer* or oncolog* or neoplasm* or carcinom* or tumo?r* or malignan*).tw.
4. (leuk?emi* or AML or lymphom* or hodgkin* or T-cell* or B-cell* or sarcom* or Ewing* or osteosarcom* or wilms* or nephroblastom* or neuroblastom* or rhabdomyosarcom* or teratom* or hepatom* or hepatoblastom* or medulloblastom* or PNET* or retinoblastom* or meningiom* or gliom*).tw.
5. oncology service hospital/
6. exp medical oncology/
7. or/1-6
8. patient education as topic/
9. exp teaching materials/
10. (audio* or video* or cassette* or tape? or dvd* or compact dis* or cd or cds or multimedia or multi media).tw.
11. (internet or web or website* or online or on line or blog* or weblog* or podcast* or portal? or computer program* or computer mediated or computer based or computer assisted).tw.
12. computer assisted instruction/
13. exp telephone/
14. (telephon* or phone or phones or text messag* or sms).tw.
15. (pamphlet* or booklet* or leaflet* or flyer* or brochure* or print* material*).tw.
16. ((education* or teaching or instruction* or counseling or advisory) adj (material* or program* or session*)).tw.
17. information services/
18. or/8-17
19. (service* or facilit* or center* or centre* or hospital* or clinic or department* or unit or therap* or treatment* or staff* or personnel or team).tw.
20. 18 and 19
21. ((educat* or inform* or advis* or advice or counsel* or orient* or tour* or introduc* or familiar* or descri*) adj3 (service* or facilit* or center* or centre* or hospital* or clinic or department* or unit or therap* or treatment* or staff* or personnel or team)).tw.
22. (orientation* or familiari*).tw.
23. or/20-22
24. 7 and 23
25. randomized controlled trial.pt.
26. controlled clinical trial.pt.
27. randomized.ab.
28. placebo.ab.
29. clinical trials as topic.sh.
30. randomly.ab.
31. trial.ti.
32. or/25-31
33. exp animals/ not humans.sh.
34. 32 not 33
35. 24 and 34

Appendix 2. Data extraction form

The following main sets of data will be extracted from each included study:

- lead author; date;
- study participant inclusion criteria;
- participants (participant diagnoses/condition(s), stage of diagnosis and demographics: race/ethnicity, gender, religion/culture, socioeconomic status, age);
- study design and timetable; randomisation; allocation concealment;
- interventions (content and format of interventions)
- intervention setting and delivery provider; delivery of any co-interventions, timing of intervention, the use of standardised protocols, training of the intervention provider, components of intervention, theoretical basis of intervention if stated;
- numbers of participants in each trial arm;
- outcome measures; time(s) at which outcomes assessed;
- results;
- potential biases;
- analysis;
- additional comments.

HISTORY

Protocol first published: Issue 1, 2010

CONTRIBUTIONS OF AUTHORS

Writing the protocol: All

Developing the search strategy: JH

Searching for trials: JH

Selecting trials: RC, JW

Data entry: RC, JW

Analysis: RC, JW

Interpreting analysis: RC, JW

Drafting final review: RC, JW

Updating the review: RC

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- Royal Brisbane and Women's Hospital, Australia.
Royal Brisbane and Women's Hospital provided salary and facilities to RC and JW to conduct this systematic review.
- University of Queensland, Australia.
University of Queensland provided salary and facilities to JH to conduct this review

External sources

- No sources of support supplied