Efficacy and experiences of telephone counselling for informal carers of people with dementia (Protocol)


This is a reprint of a Cochrane protocol, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2011, Issue 5

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Efficacy and experiences of telephone counselling for informal carers of people with dementia

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Editorial group: Cochrane Dementia and Cognitive Improvement Group.


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ABSTRACT

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

This review focuses on three main objectives:

1) Quantitative review of the efficacy of telephone counselling for carers of people with dementia.

2) Synthesis of qualitative studies to explore carers’ experiences of receiving telephone counselling.

3) Integration of the first and second objective to identify aspects of the intervention that are valued and working well, as well as those interventional components which should be improved or redesigned.

In general, the nature and quality of the evidence available will be indicated, so that practitioners and researchers can get an up-to-date overview.

BACKGROUND

Description of the condition

Caring for people with dementia is a challenge for the involved persons and for society as a whole. In North America, 3.4 million of 69.4 million seniors aged over 60 years suffer from dementia, and in Western Europe, 4.9 million of 96.4 million people aged over 60 years are affected (Ferri 2005, United Nations 2005). It can be assumed that every care recipient with dementia living at home has at least one informal carer (Brodaty 2003). Informal carers of people with dementia are on average 55 years old and 65% are female. More than half are a child of the patient and 28% are the spouse (Ferrario 2003).

Caring often leads to several negative psychological, physiological and financial consequences for informal carers (Baumgarten 1992, Max 1995). The trials conducted by Baumgarten and colleagues...
reveal that a long caring period results in physical discomfort. If people with dementia have functional restrictions and show behavioural syndromes, informal carers suffer more often from depression and physical discomfort (Baumgarten 1992). It has been estimated that 30% of informal carers suffer from depressive symptoms (Taylor 2008); over 40% state they have high or very high emotional stress (Alzheimer’s Association 2004). Half of the informal carers are likely to give up their holidays, hobbies or social contacts; 18% of the carers of people with dementia remark that caring harmed their health (Alzheimer’s Association 2004). Men deal with care-related burdens differently from women (Almberg 1998). Men perceive a lack of positive prospects and need support. Women, on the other hand, report an increased strain in their relationships with other family members and an increase in their own health problems. Caregivers’ burden can lead to early entry of the patient into a nursing home (Yaffe 2002).

**Description of the intervention**

The use of telecommunication for health care purposes is widespread. Telephone counselling is one way of using the technology. It is an attractive option for participants who do not have the opportunity to participate in traditional face-to-face counselling (Reese 2006). Different occupational groups like nurses or psychotherapists use telephone counselling for diverse issues and situations. Telephone consultation is defined in the 5th Interventions Classification from 2008 as: Eliciting patient’s concerns, listening, and providing support, information, or teaching in response to patient’s stated concerns, over the telephone (College of Nursing 2005).

**How the intervention might work**

Telephone counselling for a variety of issues like depression, anxiety, relationship problems, grief or work-related difficulties was investigated by Reese and colleagues (Reese 2002). Participants described the telephone counselling as helpful for global and specific improvements and they were satisfied with the received counselling.

The efficacy of telephone counselling is also confirmed by the results for smoking cessation (Stead 2009). The results show that telephone counselling has the potential to help for example with marital and relationship problems, anxiety, grief and depression. Carers of people with dementia suffer more often from depressive symptoms. So in theory, carers of people with dementia could also benefit from telephone counselling.

**Why it is important to do this review**

Informal carers are an important resource in the care of people with dementia. Therefore, interventions should be available which support informal carers and reduce their burden. Only one low-quality narrative review has been published (Mason 2008). Thus, there is a need for a high quality and up-to-date systematic review.

The results of this review could show that telephone counselling might be a valid alternative to face-to-face interventions in rural areas where health care professionals have to travel long distances to reach the carers.

Alongside summarising randomised controlled trials (RCT) for the question of efficacy, qualitative evidence will be used to address people’s experiences with the intervention. Carers’ perspective and the range of carers’ needs for example may help understand whether the carers find telephone counselling helpful but miss the face-to-face contact because of their limited social contacts. Study results indicate that for some people telephone support is not helpful (Chang 2004). A synthesis of qualitative evidence may help explain why some people benefit more than others and provide more detailed information about the context, characteristics and circumstances of this group of people.

An earlier Cochrane protocol on the efficacy of cognitive and behavioural interventions for carers of people with dementia was published in The Cochrane Library in 2005 (Vernooij-Dassen 2005). This Cochrane protocol does not consider the experiences of the carers of people with dementia and includes interventions aimed at cognitive reframing but excludes interventions aimed at practical support. In contrast, our planned Cochrane review will include telephone counselling which gives practical advice but will exclude interventions delivered by face-to-face contact. In 2008, a review of telephone interventions for family caregivers of patients with dementia was published (Mason 2008). In contrast to these earlier approaches to review telephone counselling, we aim to conduct a comprehensive and systematic search strategy; assess the methodological quality of the included studies; and synthesise the evidence for the two questions separately. For a clear differentiation of the two questions, each section has a heading.

**OBJECTIVES**

This review focuses on three main objectives:

1) Quantitative review of the efficacy of telephone counselling for carers of people with dementia.
2) Synthesis of qualitative studies to explore carers’ experiences of receiving telephone counselling.
3) Integration of the first and second objective to identify aspects of the intervention that are valued and working well, as well as those interventional components which should be improved or redesigned.
METHODS

Criteria for considering studies for this review

Types of studies
Question of efficacy:
Individually randomised, parallel-group controlled trials comparing telephone counselling for carers of people with dementia with no treatment, usual care or friendly calls for chatting will be included. Crossover trials will also be considered.

Question of experience:
The review will include studies which use qualitative methods of data collection and analysis, i.e., either a stand-alone study or a discrete part of a larger mixed-method study. Qualitative elements from process evaluations conducted alongside trials will also be considered.

Types of participants
Both questions:
We will involve informal caregivers who provide care for a person with dementia without reimbursement of care. The adult carer can be a relative, a friend or a neighbour of the person with dementia. The carers look after a person with dementia at home and not in an institutional setting. There will be no restriction regarding sex, age or ethnic background.

Types of interventions
Both questions:
Telephone counselling is a complex intervention. It is also used in combination with face-to-face consultations or computer-involved interventions. For this review, all telephone counselling interventions without any face-to-face contact that address informal carers of community dwelling people with dementia will be considered. The telephone counselling should not be part of a complex intervention. It should be conducted for a minimum of 2 months, but we will make no restrictions to the frequency, length or number of telephone calls. The telephone counselling should be performed by a health professional, such as a nurse or a psychologist, with an expertise in dementia. The informal carer should care for the person with dementia in their home.
Telephone counselling comprises at least three components:
1. General information about dementia.
2. Education of caregivers about coping skills and caring about their own health.
3. Psychosocial support where carers can share their feelings and are shown how to build up their social network.

Types of outcome measures
Question of efficacy:
The primary outcome is defined as depressive symptoms, since they are very common among informal carers of people with dementia (Baumgarten 1992). Of the informal carers, 30% have depressive symptoms (Taylor 2008). But the caregivers’ burden caused by caring for a person with dementia presents itself differently (Baumgarten 1992, Max 1995). Secondary outcomes are defined as:
Carer related:
- caregivers burden
- distress
- anxiety
- quality of life
- care giving self-efficacy
- satisfaction
Person with dementia related:
- institutionalisation
- mood
- quality of life

Question of experience:
All experiences regarding the intervention are of interest and will be included.

Primary outcomes
Carer related: Depressiv symptoms

Secondary outcomes
Carer related:
- caregivers burden
- distress
- anxiety
- quality of life
- care giving self-efficacy
- satisfaction
Person with dementia related:
- institutionalisation
- mood
- quality of life

Search methods for identification of studies
The question of efficacy and the question of experience with telephone counselling address the same intervention and population...
Electronic searches

We will search ALOIS (wwwmedicine.ox.ac.uk/alois): the Cochrane Dementia and Cognitive Improvement Group's Specialized Register. Our approach will be to assess all Caregiver Focused studies within ALOIS. ALOIS is maintained by the Trials Search Co-ordinator of the Cochrane Dementia Group and contains dementia and cognitive improvement studies identified from:

1. Monthly searches of a number of major healthcare databases: MEDLINE, EMBASE, CINAHL, PsycINFO and LILACS
2. Monthly searches of a number of trial registers: meta Register of Controlled Trials (mRCT); UMIN (Japan Trial Register); ICTRP (WHO portal which covers ClinicalTrials.gov; ISRCTN; Chinese Clinical trials Register; German Clinical trials register; Iranian Registry of Clinical trials and the Netherlands National Trials Register, plus others)
3. Quarterly search of The Cochrane Library's Central register of Controlled trials (CENTRAL)
4. Six-monthly searches of a number of grey literature sources: ISI Web of Knowledge Conference Proceedings; Index to Theses; Australasian Digital Theses

To view a list of all sources searched for ALOIS see About ALOIS on the ALOIS website.

Additional separate searches will be run in many of the above plus the following sources to ensure that both qualitative studies and the most up-to-date results of quantitative trials are retrieved. The search strategy that will be used for the retrieval of reports of trials from MEDLINE (via the Ovid SP platform) can be seen in Appendix 1.

We will also search Medline in Process & other non-indexed citations (Ovid SP); PsycINFO (EBSCOhost); Global Health; CCMed; DAHTA-Database; Heclinet (1969 to 2001); ISTRP + ISTR/IS-SHP; Social SciSearch; SOMED (1978 to 2000); Science Citation Index (Thomson Reuters); Springer (via Springerlink); Science Direct (Elsevier) and Publishers’ databases: Hogrefe, Karger, Kluwer, Krause & Pachernegg, Thieme.

Searching other resources

Reference checking of relevant literature, citation searches in the Science Citation Index, Google Scholar and in Cinahl and the use of the “Related Articles” feature for relevant papers will be conducted to identify further quantitative and qualitative trials and sibling studies like process evaluations. We will handsearch abstracts of the following congresses: International Conference of Alzheimer's Disease International; Alzheimer Europe Conference; Dementia Services Development Centre International Conference; Dementia Congress; and International Congress on Vascular Dementia. A handsearch for relevant journals which are not included in the databases above will be performed. We will also contact experts to ask for relevant studies and especially the investigators of the identified RCTs to find qualitative studies that were associated with, or conducted alongside the effectiveness studies.

Data collection and analysis

Selection of studies

Both questions:
The identified references will be transferred into reference management software. Two independent authors will review the titles and abstracts. Based on the full texts, two un-blinded authors will independently examine whether the studies fulfil the inclusion criteria. In the preliminary search the authors get to know the names and institutions of study authors and the journal of publication of most of the relevant articles, so a blinded assessment of articles’ relevance is no longer possible. Disagreement will be resolved by discussion with a third review author. Multiple articles of the same study will be linked together and the information will be used for the decision which studies are eligible for inclusion. Study authors will be contacted in case of ambiguity.
Selected studies that seemed to meet the eligibility criteria but did not on further inspection and studies that do not meet all of the criteria will be listed. The reason for exclusion will be mentioned.

**Data extraction and management**

Data extraction will be performed differently for both questions and will consider the quantitative and qualitative study designs.

**Question of efficacy**

The data extraction form for the quantitative studies will be based on the recommended items from the Cochrane Handbook, Chapter 7.3.1. The form will cover information on the authors; publication date; country; study design; characteristics of the study population including setting; inclusion and exclusion criteria; credentials of those who provided the treatment; treatment type, duration, intensity, frequency; control intervention and outcomes among other criteria.

The form will be pre-tested using two randomly-selected studies and adapted afterwards. Data extraction will be performed by two independent review authors. Disagreement will be resolved by discussion with a third author. Missing data will be requested from the original investigators. All essential steps in data extraction will be documented as requested in the PRISMA statement (Liberati 2009).

**Question of experience**

The data extraction form will include the following items: authors; publication date; country; methodology; method; phenomena of interest; characteristics of the study population including setting; inclusion and exclusion criteria; credentials of those who provided the study; intervention outcomes; the methods of the data collection and analysis; and findings such as data from participants and commentary of the study authors.

However, the final data extraction form will be evolved in the process of extracting the data. One review author will extract the data from the included studies and a second author will check the extracted data. Disagreement will be resolved by discussion with a third review author. Missing data will be requested from the original investigators.

**Assessment of risk of bias in included studies**

**Question of efficacy**

Critical appraisal will follow The Cochrane Collaboration’s tool for assessing risk of bias. Two authors will independently perform the assessment. A blinding to the names of the authors, institutions, journal and results of a study will not be feasible because most of the studies are known by the review authors through the first specific literature search. The possibility of different judgments about the risk of bias will be considered. Thus, an exchange will be arranged between the authors who will conduct the assessment. Disagreement will be resolved by discussion with a third review author. Missing data will be requested from the original investigators by using open ended questions.

**Question of experience**

For assessing the methodological quality of qualitative studies it is important to evaluate the researcher bias as a core criterion (cf. Cochrane Qualitative Research Methods Group). In qualitative studies the researcher has an impact on the data. So they must show their ability and the efforts undertaken to prevent this influence on the data. The researcher has to state that the process was rigorous and trustworthy, so the credibility of the results can be assumed. The appraisal of qualitative research includes three stages:

- The first stage is filtering the identified hits according to the inclusion and exclusion criteria.
- The second stage is the technical appraisal with the evaluation of the credibility, transferability, dependability and confirmability of the included original research papers.
- In the third stage the methodological coherence will be judged. Thus, the congruity between paradigms that guide the research project and the methodology and methods chosen will be evaluated. The Cochrane Qualitative Research Methods Groups recommends the third stage whenever the instrument for critical appraisal does not cover a paradigmatic approach.

For the judgment of the included qualitative studies the Critical Appraisal Skills Programme (CASP) will be used. The CASP does not include a question related to the paradigm that guides the study. Therefore, an evaluation of methodological coherence will be conducted.

The quality assessment process will be undertaken by two researchers. One will perform the critical appraisal and another person with longstanding experience in qualitative research will check the judgments.

The consequence of the critical appraisal of the qualitative research will be a weighting of the studies found in the search. High quality studies will be given more weight than those with low quality. Up to now there are no established parameters to determine the weight of qualitative studies. But the process of weighting will be discussed in the review team with consultation of the Qualitative Research Methods Group and will be described in a transparent way. Additionally, a sensitivity analysis with removing low quality studies will be conducted.

Consequences of the quality assessment of the quantitative and qualitative studies will be reflected in sensitivity analysis, the discussion and the author’s conclusion.

**Measures of treatment effect**

**Question of efficacy**

Longer ordinal scales are often analysed in meta-analyses as continuous data. Depression scales can have different types of outcome data. For continuous data measured by different psychometric scales, we will calculate the standardised mean difference. If only one assessment is used in the trials, the weighted mean difference will be used. The scales will be checked with regard to whether they
have been validated or not and whether the original or an adapted questionnaire has been used. Due to the expected heterogeneity, pooling will be done by a random-effects model. If pooling is not possible, the results of the studies will be presented narrative. For analysis as well as graphical display, the standard software of The Cochrane Collaboration will be used (Review Manager 5).

**Unit of analysis issues**

**Question of efficacy**

Three armed trials with two different control groups will be analysed in two separate meta-analyses. We will conduct one meta-analysis comparing the intervention with no treatment and another meta-analysis comparing the intervention with general friendly calls. If the outcome is measured at different time points, the results of comparable time points of different studies will be pooled in several meta-analyses. Crossover trials will be included; only the first phase will be considered whereas the second phase will be ignored. The results of the first phase will be analysed like a parallel group trial.

**Dealing with missing data**

**Question of efficacy**

For each randomised controlled trial the missing data and dropout rates will be evaluated. Missing data could be an outcome, summary data, individuals or study-level characteristics in the case of subgroup analysis or meta-regression. Every kind of missing data will be requested from the original investigators. The method applied to cope with missing data will be stated and a sensitivity analysis will be performed. Depending on the available data an ITT analysis will be conducted at best or an available case analysis at least.

**Assessment of heterogeneity**

**Question of efficacy**

Heterogeneity will be assessed by Cochrane's Q and quantified by I² statistics. We will use a random-effects model for pooling the data. If heterogeneity is severe (I² > 60%) we will try to explain the heterogeneity by subgroup analysis or meta-regression as described under the heading "subgroup analysis and investigation of heterogeneity".

**Assessment of reporting biases**

**Question of efficacy**

Different steps will be taken to detect reporting bias. Each study will be checked whether outcomes are mentioned in the protocol, the method section and the result section of the report and the conference presentation, if available. The protocol will be searched in Pub Med and the trial registry or by the author's website links or directly by the author. If outcomes mentioned in the protocol or in the methods section of the report were not presented in the results section of the report or the conference presentations, the study authors will be contacted.

If at least 10 studies are available, Egger's test for funnel plot asymmetry will be conducted for continuous outcomes. Additionally, a modified Egger's test by Harbord for dichotomous outcomes will be done to assess possible publication bias, although evidence of small-study effects could have other reasons than publication bias (Egger 1997, Harbord 2006). Vice versa publication bias does not always become visible by doing an asymmetric funnel plot.

**Data synthesis**

**First synthesis: Question of efficacy**

In the absence of clinical and statistical heterogeneity, an aggregate meta-analysis will be conducted by using the random-effects model in Review Manager 5. Corresponding to the continuous data, the random-effects model will be an inverse variance. The separate control interventions will be analysed in separate meta-analyses. If meta-analysis is not possible the results of each study will be presented in the forest plot without pooling.

**Second synthesis: Question of experience**

A meta-synthesis will be conducted for the qualitative evidence. Meta-synthesis is the generic term for a number of methods for synthesising the findings from primary qualitative studies. The meta-synthesis can produce new insights and understanding. In a meta-synthesis, studies with different important aspects, like population and settings, can be combined to achieve a greater degree of conceptual development and insights than is possible in single studies.

The choice of synthesis methods depends on three main aspects. The first aspect is the review question and purpose. In our case it is the question of the carers’ experience of telephone counselling. The second aspect is the identified evidence. If descriptive qualitative studies, called "thin descriptions", are available, an integrative method should be used. If the identified evidence is in-depth qualitative studies, called "thick descriptions", an interpretative method can be applied. Also, the third aspect of choosing a method depends on the evidence identified. It should be considered if an accepted theoretical model for the phenomenon of interest exists or not.

Based on the previously identified qualitative studies which are descriptive with no known theoretical model, we would choose a thematic analysis. But the decision of which methods to use will be reconsidered after the systematic literature search.

The aim of a thematic analysis is to synthesise all published qualitative studies exploring patients’ experiences with a specific disease. The process would look like this: The themes and concepts
from each included qualitative study will be extracted. These will then be translated into findings, which will be illustrated by a direct data extract. After that the findings will be grouped into categories. Finally the categories will be combined to create synthesised themes.

The process of extracting themes and forming categories and themes will be done by two independent review authors. Disagreement will be resolved by discussion with a third person.

Third Synthesis: Integration of the first stream and the product of the second synthesis

In the third synthesis the interventions of the RCTs will be juxtaposed in a matrix with the experiences of the participants (Thomas 2004). The comparative analysis in the matrix will be guided by two questions:

1. Which themes of experience will be addressed by the interventions of the RCTs?
2. Which aspects of the RCT interventions will not be mentioned by the participants?

Based on the first question, those interventions can be identified that contain more items of positive experience than others. Consequently, these results can be used for subgroup analyses. The second question indicates aspects which may be not that important for the participants.

Subgroup analysis and investigation of heterogeneity

Question of efficacy:

If 5 studies per planned aspect are available, subgroup analysis or meta-regression will be conducted for the following:

A) Carer-related: relation to the person with dementia; support by other family members; pre-existing stress of the carer; in employment or not; gender.
B) Intervention-related: duration; intensity
C) Disease-related: stage of dementia
D) Experience-related: positive experienced aspects of the intervention

Sensitivity analysis

Both questions:

1. Sensitivity analyses will address the robustness of the meta-analysis findings with respect to the differences in methodological quality assessed by 'The Cochrane Collaboration's tool for assessing risk of bias'.
2. Sensitivity analyses will also be applied to check the impact of different ways of handling missing data as described under the heading "Dealing with missing data".

ACKNOWLEDGEMENTS

We would like to thank Jane Noyes (Cochrane Qualitative Research Methods Group), Joan Edwards (Consumer editor) and the Cochrane Dementia and Cognitive Improvement Review Group for their support and comments on the draft Cochrane protocol and Caroline Mavergames (German Cochrane Centre, Freiburg, Germany) for her perusal on correct English.

REFERENCES

Additional references

Almberg 1998

Alzheimer’s Association 2004

Baumgarten 1992

Brodaty 2003

Chang 2004

Cochrane Qualitative Research Methods Group

College of Nursing 2005
Egger 1997

Ferrario 2003

Ferri 2005

Harbord 2006

Liberati 2009

Mason 2008

Max 1995

Reese 2002

Reese 2006

Stead 2009

Taylor 2008

Thomas 2004
Thomas, J, Harden, A, Oakley, A, Oliver, S, Sutcliffe, K, Rees, R, Brunton, G, Kavanagh, J. Integrating qualitative research with trials in systematic reviews. *British Medical Journal* 2004;328:1010–2.

United Nations 2005

Vernooij-Dassen 2005

Yaffe 2002

* Indicates the major publication for the study
# Appendix I. MEDLINE search strategy

<table>
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<th>Source</th>
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<tr>
<td>MEDLINE (Ovid SP)</td>
<td>1. exp Dementia/</td>
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<tr>
<td></td>
<td>2. Delirium/</td>
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<tr>
<td></td>
<td>3. Wernicke Encephalopathy/</td>
</tr>
<tr>
<td></td>
<td>4. Delirium, Dementia, Amnestic, Cognitive Disorders/</td>
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<tr>
<td></td>
<td>5. dement*.mp.</td>
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<tr>
<td></td>
<td>6. alzheimer*.mp.</td>
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<td>7. (lewy* adj2 bod*).mp.</td>
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<tr>
<td></td>
<td>8. deliri*.mp.</td>
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<tr>
<td></td>
<td>9. (chronic adj2 (cerebrovascular or cerebro-vascular)).mp.</td>
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<tr>
<td></td>
<td>10. (&quot;organic brain disease&quot; or &quot;organic brain syndrome&quot;).mp</td>
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<tr>
<td></td>
<td>11. (&quot;normal pressure hydrocephalus&quot; and &quot;shunt&quot;).mp.</td>
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<tr>
<td></td>
<td>12. &quot;benign senescent forgetfulness&quot;.mp.</td>
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<td>13. (cerebr* adj2 deteriorat*).mp.</td>
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HISTORY


CONTRIBUTIONS OF AUTHORS

SL: correspondence; drafting review versions; search for trials, selection of RCTs; extraction of data; assessing risk of bias; entry of data, data analysis; interpretation of data analyses, updating review

GR: data analysis, interpretation of data analyses, updating review

EM: search for trials, obtaining copies of trial reports, updating review

GL: assessing risk of bias, interpretation of data analyses

GA: selection of RCTs; interpretation of data analyses

GM: selection of RCTs; extraction of data; assessing risk of bias; interpretation of data analyses, updating review

DECLARATIONS OF INTEREST

The contributing authors have no conflicts of interest to declare.

SOURCES OF SUPPORT

Internal sources
- No sources of support supplied

External sources
- Cochrane Qualitative Research Methods Group, Not specified.
Comments on the draft Cochrane protocol