

First contact with primary investigators regarding information for a systematic review: a randomised trial

Protocol

Version 1.0 [12th July 2000]

Background

Systematic reviews aim to identify, appraise and synthesise results from all studies addressing a common research question, using techniques which minimise bias. Many such reviews are undertaken by members of the Cochrane Collaboration,¹ an international network of healthcare workers, researchers and consumers committed to the principles of evidence-based healthcare. This randomised trial, called 'First Contact', addresses one key aspect of the conduct of these reviews.

In order to appraise studies which are identified, and to extract preliminary data for a qualitative or quantitative synthesis (when appropriate), the systematic reviewer often has to depend on information available from published reports of the relevant studies. However, these published reports rarely provide sufficient evidence necessary to complete a thorough and unbiased systematic review.² In particular, allocation concealment and other aspects of study design have been poorly described in reports of randomised trials,³⁻⁵ and selective reporting of outcomes may result in biased availability of data to the meta-analyst.⁶ Some important statistics may not be reported, for example standard deviations of continuous data (particularly changes from baseline), intra-class correlation coefficients for cluster-randomised trials and total number of patients both randomised and analysed. Further problems associated with extracting data from published reports are connected with inconsistencies between the analysis of different studies such as transformation of raw data, use of intention-to-treat analyses and varying approaches to outcome data such as ordinal and survival data.

To obtain missing information, systematic reviewers might approach the investigators of the studies they have identified. Some reviewers put considerable effort into tracking down investigators and data. The appropriate amount of effort will depend on the importance of the missing information to the validity of the systematic review. Contact details of a primary author may be obtained from most published papers, and in recent publications an email address and/or a telephone number may also be available. However, it is unclear which of various possible methods of first contact is most effective, both at establishing whether the contact details are correct and at obtaining information on the study.

The principle of contacting investigators is encouraged within many groups of the Cochrane Collaboration. The *Cochrane Reviewers' Handbook*⁷ recommends researchers be contacted with a view to identifying additional trials. This can be a useful process,⁸ though no specific guidelines are provided in the *Handbook* for collecting additional data from trialists apart from in the context of individual patient data reviews in which the trialists are contacted for the raw data from their studies.⁹ Chalmers *et al.* discuss issues of bias which may arise from including unpublished data, but conclude that these are unlikely to be more significant than biases associated with selective reporting. They also list a number of publications in which contacting investigators appeared to be beneficial.¹⁰

In May 1999 we surveyed the 44 then-existing Cochrane Review Groups to determine what recommendations they provide to their reviewers on contacting trialists. Thirty-one Groups (70%) responded and we obtained four example letters and three generic letters that were supplied to reviewers. Two were simple letters that included a request for explicit data or information; two would be accompanied by a table to be completed; two would be accompanied by a form to be completed and the last appended a form which had been partially completed by the reviewer with data extracted from

published reports, in which missing or unclear information was highlighted. Four letters provided some information on the Cochrane Collaboration, three in an introductory paragraph and one in the form of enclosed literature. An additional example letter was identified¹⁰ with which summaries of extracted data were sent, along with a request that missing items be supplied.

Methods for approaching primary investigators for specific information have not been studied in detail, though there is a wealth of literature on methods for improving survey response. A Cochrane review has been initiated to systematically review studies of methods to influence the response rates to surveys.¹¹ Existing meta-analyses of controlled studies have indicated that preliminary notification,¹² follow-up,¹³ monetary or non-monetary incentives¹⁴ and appeals for help in a covering letter¹⁵ can significantly improve response to surveys. Follow-up using special mail services or telephone has been advocated,¹⁶ as have numerous other techniques including pre-paid postage using stamps¹⁷ and obtaining prior agreement to participate¹⁸ (the so-called ‘foot-in-the-door’ method). These results have not all been replicated in eliciting responses from clinicians. Randomised trials have demonstrated that general practitioners can respond to monetary incentives^{19:20} and free pencils²¹ and that advance telephone calls can influence the response of gynaecologists.²² However, pre-notification has not been found to affect physicians.²³ A qualitative study of reasons why general practitioners fail to respond highlighted that recipients might be too busy and that questionnaires might be lost or discarded.²⁴

Whether findings from survey research are relevant to requesting information from principal investigators of trials to be included in Cochrane reviews is unclear. The principal barrier may be failure to make contact with the investigators rather than poor response to a request that is actually received. First Contact assesses whether implementing a selection of appropriate techniques can affect the collection of missing information for systematic reviews.

Aim of the trial

We aim to evaluate whether response and information retrieval rates from investigators, when contacted with a request for information to contribute to a systematic review, can be affected by how they are approached. We plan to do this by conducting a randomised trial of a standard letter compared with a more intensive approach involving advance warning, additional information, follow-up and other techniques aimed at improving response.

Terminology

Some care is appropriate in the terminology used to describe the people involved in First Contact since trialists and participants in the traditional sense might be seen as, conversely, participants and trialists in the context of this trial. Therefore, in this protocol, the following terms are used.

Systematic reviewer, or reviewer

A collaborator, or participant, in First Contact who is conducting a systematic review and is willing to randomise methods of obtaining information from the studies he or she identifies, (analogous to a centre in a multi-centre clinical trial).

Primary investigator, or investigator

The author or contact person of a published study who is to be approached by the systematic reviewer, (analogous to a patient in a multi-centre clinical trial since they will be randomised to receive one intervention).

Recruitment of ‘centres’

First contact will be run along the lines of a multi-centre trial, in that we will recruit ‘centres’ to participate in the trial. These ‘centres’ will be individuals or groups conducting systematic reviews. Cochrane reviewers will be recruited using

- mailing to CCINFO, the email distribution list delivering general information to members of the Cochrane Collaboration

- poster presentations at Cochrane Colloquia
- a short article in the Cochrane Methods Group newsletter and Cochrane News
- correspondence with each Cochrane Review Group Co-ordinator (with permission from Collaboration Secretariat)
- advertising on appropriate Cochrane Collaboration internet pages, with links to an HTML version of this protocol
- personal correspondence with selected reviewers
- other measures judged appropriate by the First Contact steering group.

Eligibility

Contact persons or authors (primary investigators) of published studies are eligible for the study if (i) the study has been identified as probably or definitely fulfilling the criteria for inclusion in a Cochrane review, (ii) any information needed to complete the systematic review is missing from the published report, and (iii) a postal, or email, address is available for them. The reviewers should have completed assessment of studies for inclusion in the review and any data extraction.

The essential criterion for entry into First Contact is that the reviewer is uncertain how first contact should be made with the investigator in order to obtain missing information. In particular, the reviewer must be uncertain whether the experimental or the control intervention of First Contact will produce the best results. Thus, if the reviewer is confident that a particular approach (for example, a telephone call) should be used for a specific investigator, then that investigator should not be included in First Contact.

Reviewers may include investigators in the trial for whom previous contact attempts have yielded only a new postal, or email, address.

There is no minimum number of investigators with which a reviewer may participate in First Contact.

An investigator who is the contact person for more than one trial should be included only once by any particular reviewer. Should an investigator be randomised more than once by mistake, he or she will be treated as two separate investigators in the analysis (with appropriate sensitivity analyses).

Randomisation

Randomisation will be performed centrally at the UK Cochrane Centre in Oxford. A minimisation scheme will be used to attempt to balance suspected potential confounding variables across intervention groups. We consider the following to be factors highly likely to affect response from investigators:

- Most recent date of certainty about the investigator's address (or date of trial publication)
- Amount, and nature, of information required
- Surface mail or email contact
- Previous contact between the investigator and the reviewer
- Involvement of the investigator with the Cochrane Collaboration

Reviewers will be required to assign codes for each of these items before randomising an investigator into First Contact.

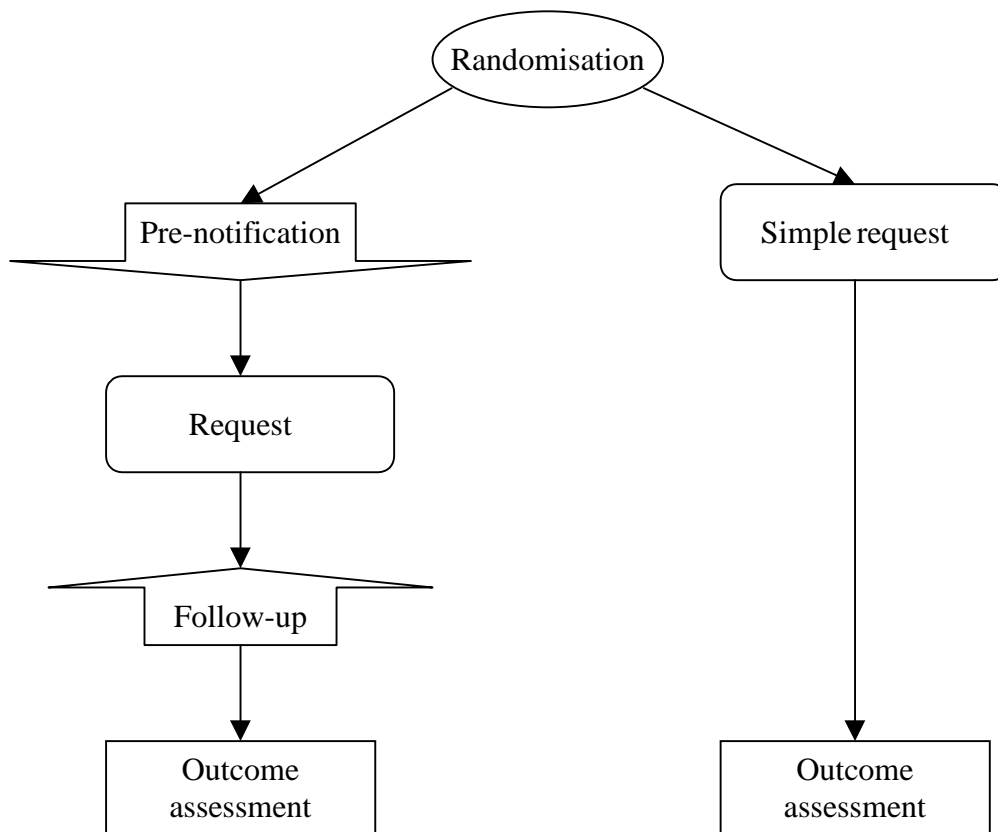
On contacting the randomisation centre, usually by email or fax, reviewers will submit their name; the title of their review; the Cochrane Review Group in which this review is being performed; an ID for the study; and details of each investigator sufficient to enable the minimisation randomisation (including whether surface mail or email will be used). The Data Collection Form (Appendix A) will facilitate the collation of this information. The randomised allocation and a unique identifier will be sent to the reviewer. Once randomised, the investigators will be part of the trial and will be included in the analysis irrespective of whether or not they receive the allocated intervention (an intention-to-treat analysis).

Interventions

Two approaches to contacting investigators will be compared. The control intervention consists of a single request for missing information and the experimental intervention a multistage approach involving pre-notification and follow-up among other techniques aimed at improving response. Ideally a reviewer will follow the strategies we describe below. However, an element of flexibility is permitted such that certain elements in the experimental group may be dropped and others added.

Reviewers may include additional material in both interventions in ways that do not confound the comparison of interventions. For example, reviewers might wish to include a list of all trials so far identified, and request that additional trials with which the investigator is familiar are made known to the reviewer.

Strategies for surface mail and for email are described separately.



Flow chart

Surface mail: Control intervention

A single standard letter, amended as necessary by the reviewer, containing

- a short introduction to the review being undertaken
- a request for data or pieces of information which are missing

An example for this letter appears in Appendix B.

This letter should be sent by surface mail to the postal address of the investigator.

If they receive no reply, the reviewer should wait twelve weeks after sending the letter before attempting to contact the investigator again. After this period the reviewer may proceed in any way they feel appropriate.

This intervention is intended to replicate the usual approach taken by Cochrane reviewers. However, we do not wish to hinder any attempts to obtain important information that are used as standard by individual reviewers.

Surface mail: Experimental intervention

A multi-stage approach to requesting data or information consisting of

1. A letter/pack of pre-notification to be sent by regular mail to the postal address of the investigator. This should contain

- a Cochrane leaflet and, at the discretion of the individual reviewer, details of the Cochrane Review Group to which he or she belongs;
- the protocol, or a brief version of the protocol, for the current review;
- the citation(s) so far obtained for the investigator's study with a comment concerning its qualities or importance to the systematic review;
- a request that extra or new contact details (telephone/email address), or any new contact person for the trial, be forwarded to the reviewer as soon as possible (the envelope may be marked so as to encourage someone to open it in case forwarding to the addressee is inconvenient or impossible);
- advance notification of a forthcoming request for further information;
- an invitation to contact the reviewer with any questions regarding the review. Multiple modes of reply should be offered to the investigators, including surface mail, telephone, email and fax.

An example covering letter appears in Appendix C.

This stage of the intervention has three specific objectives: (i) to allow the investigator to initiate the retrieval of information for their study; (ii) to identify, if necessary, more appropriate contact information for the study; and (iii) to improve the likelihood of response to the main letter by providing pre-notification and information.

2. If the investigator responds to the pre-notification, the reviewer may enter into correspondence of any type with the investigator in order to retrieve the missing information by the most convenient means. If no reply is forthcoming then the reviewer should proceed to number 3.

3. A letter requesting the missing information, posted three weeks after the pre-notification, containing

- a reminder of the pre-notification;
- the citation(s) so far obtained for the investigator's study;
- a form or table (perhaps the data extraction form being used for the review), which has been completed as far as possible by the reviewer. This should make clear which pieces of information are missing or unclear from the published report. It may be helpful to enclose an uncompleted data collection form for the investigator to fill in;
- notification that all contributions will be acknowledged;
- notification that investigators approached by the reviewer will be mentioned in the review irrespective of any response;
- an invitation to contact the reviewer with any questions regarding the review.

Multiple modes of reply should again be offered to the investigators, including surface mail, telephone, email and fax.

An example covering letter appears in Appendix D.

This stage of the intervention aims to (i) confirm the accuracy of the extracted information; (ii) request missing information; and (iii) improve the likelihood of response by promising acknowledgement in the final report.

4. An attempt to follow-up investigators who have not replied approximately four to six weeks after the letter of request. This may be by any means available to the reviewer. We encourage the use of telephone and email.

This stage of the intervention aims to further improve the response rate by reminding investigators who may have forgotten to reply, by increasing the speed of any response, and by increasing the

likelihood that correct contact information will be obtained if the postal address for the investigator was incorrect.

email: Control intervention

As surface mail, but sent by email. The observation time for email interventions is twelve weeks. If the investigator responds, the reviewer may enter into email, or other, correspondence with the investigator in order to retrieve the missing information by the most convenient means. If the email is unsuccessful (for example, is returned because the email address no longer exists) then the reviewer should immediately initiate the control arm using surface mail (unless the Steering group has received notification prior to randomisation that this action will not be taken, in which case the outcome for this investigator will be 'failure to contact'.)

email: Experimental intervention

A multi-stage approach to requesting data or information consisting of

1. A letter of pre-notification to be sent by email to the investigator. It is inadvisable to send email attachments without the consent of the recipient. The body of the email should therefore contain

- a brief introduction to the Cochrane Collaboration, with links to web sites for further details;
- an offer to send further details of the protocol for the current review;
- the citation(s) so far obtained for the investigator's study with a comment concerning its qualities or importance to the systematic review;
- a request that extra or new contact details (telephone/surface mail address), or any new contact person for the trial, be forwarded to the reviewer as soon as possible;
- advance notification of a forthcoming request for further information;
- an invitation to contact the reviewer with any questions regarding the review. Multiple modes of reply should be offered to the investigators, including surface mail, telephone, email and fax.

The example covering letter in Appendix C may be used as a template.

This stage of the intervention has three specific objectives: (i) to allow the investigator to initiate the retrieval of information for their study; (ii) to identify, if necessary, more appropriate contact information for the study; and (iii) to improve the likelihood of response to the main letter by providing pre-notification and information.

2. If the investigator responds, the reviewer may enter into email, or other, correspondence with the investigator in order to retrieve the missing information by the most convenient means. If no reply is forthcoming then the reviewer should proceed to number 3. If the email attempt is unsuccessful (that is, 'bounces' because the email address no longer exists) then the reviewer is encouraged to immediately initiate the experimental arm using surface mail. The surface mail option may produce a beneficial outcome since the letter may still reach the investigator (since email addresses may change more frequently than postal addresses), or the letter may be forwarded or opened by a colleague. If the reviewer prefers, attempts to contact the investigator may cease, in which case the outcome for this investigator will be 'failure to contact'.

3. A letter to be sent by email requesting the missing information, posted three weeks after the pre-notification, containing

- a reminder of the pre-notification;
- the citation(s) so far obtained for the investigator's study;
- the request for missing data;
- notification that all contributions will be acknowledged;
- notification that investigators approached by the reviewer will be mentioned in the review irrespective of any response;
- an invitation to contact the reviewer with any questions regarding the review.

Multiple modes of reply should again be offered to the investigators, including surface mail, telephone, email and fax.

An example covering letter appears in Appendix D.

This stage of the intervention aims to (i) confirm the accuracy of the extracted information; (ii) request missing information; and (iii) improve the likelihood of response by promising acknowledgement in the final report.

4. An attempt to follow-up investigators who have not replied approximately four to six weeks after the letter of request. This may be by any means available to the reviewer. We encourage the use of telephone.

This stage of the intervention aims to further improve the response rate by reminding investigators who may have forgotten to reply, by increasing the speed of any response, and by increasing the likelihood that correct contact information will be obtained if the email address for the investigator was incorrect.

Variations on these strategies

Minor variations on these strategies are permitted. For example, it may not be convenient to send Cochrane brochures, or a reviewer may wish to add to the experimental group by including return envelopes, or impressive headed paper. Substantial amendments should be approved in advance by the Steering Group. The minimal criteria for the interventions are

1. the control group receives a single uninvited communication within a 12 twelve week period
2. the experimental group receives at least two communications within a 12 week period, with at least three elements *in addition to the control group* from the following list:
 - pre-notification
 - follow-up
 - incentive (e.g. acknowledgement, stamped addressed envelope)
 - additional information

Measures of outcome

The primary outcome of interest is the amount of missing information retrieved from the investigator within twelve weeks of sending the original letter. A four point ordinal scale will be used:

1. No response: no requested information retrieved
2. Inadequate response: some, but not all, requested information retrieved, and insufficient information to include the trial in the review with no important gaps
3. Satisfactory response: some, but not all, requested information retrieved, and sufficient information to include the trial in the review with no important gaps
4. Perfect response: all requested information retrieved

Three secondary outcomes will be collected:

1. The time taken to receive some or all of the requested information
2. Any response or acknowledgement from the investigator or someone else involved with the study or its data. (This will include a response from an ex-colleague stating the author has moved or died.)
3. Cost, in terms of
 - i. postage and telephone calls
 - ii. time

Outcomes will be collected on a Data Collection Form (Appendix A). The observation period is twelve weeks from the date of sending the initial letter.

Analysis

Primary outcome

The primary analysis will be undertaken with a Bayesian logistic model using BUGS.²⁵ The effectiveness of the experimental intervention will be measured by way of an odds ratio, defined as the ratio of the odds

of being in a better category on the experimental intervention relative to the odds of being in a better category on the control intervention. Thus an odds ratio greater than 1.0 indicates superiority of the experimental intervention.

The proportional odds assumption will be examined when sufficient data have been collected. Should it not appear to hold we will perform logistic regression analyses yielding separate odds ratios for (i) all or some requested information versus none, and (ii) all versus some or none. The former will be the primary outcome.

Stopping rule

An advantage of the Bayesian framework²⁶ is that a trial may be continuously monitored without fear of obtaining spuriously significant results. First Contact will be analysed at regular intervals and the results will be made available to all participants (though not before results from six different reviewers are available). Participants will therefore be able to use the results to change the certainty or uncertainty they have about how to contact investigators. The trial will continue for a minimum of two years. Thereafter it will be stopped when potential participants are sufficiently certain of the superiority of one intervention, or the equivalence of the two, to refrain from randomising. As a last resort, the trial will be stopped when the primary analysis indicates that (i) there is 99% probability that the odds ratio is greater than 1; or (ii) there is 99% probability that the odds ratio is less than 1; or (iii) there is 99% probability that the odds ratio lies between 0.9 and 1.1.

Sample size issues

Though the primary analysis will take a Bayesian approach, indications of appropriate sample sizes²⁷ are given in the table below. These are based on the supposition that 50% of investigators will respond and 20% will provide complete information, though the sample sizes are robust to some variation in these.²⁷ The calculations indicate the following for a trial with 80% power and a 5% significance level: to detect an increase in the response rate from 50% to 60%, 663 investigators would need to be approached; to detect an increase from 50% to 64% would require 224 investigators.

<i>sig. level</i>	<i>power</i>	Control proportions			Experimental proportions			<i>Odds ratio</i>	<i>Sample size</i>
		<i>no response</i>	<i>some response</i>	<i>full response</i>	<i>no response</i>	<i>some response</i>	<i>full response</i>		
5%	80%	0.5	0.3	0.2	0.40	0.33	0.27	1.5	663
5%	80%	0.5	0.3	0.2	0.36	0.33	0.31	1.75	345
5%	80%	0.5	0.3	0.2	0.33	0.33	0.33	2	224
5%	90%	0.5	0.3	0.2	0.40	0.33	0.27	1.5	887
5%	90%	0.5	0.3	0.2	0.36	0.33	0.31	1.75	462
5%	90%	0.5	0.3	0.2	0.33	0.33	0.33	2	298

The initial recruitment target for First Contact is at least 450 investigators though, as described above, the Bayesian approach to the analysis renders sample size issues unimportant. Assuming a minimum average of six investigators per reviewer this would require the participation of 75 reviewers. The first issue of the *Cochrane Database of Systematic Reviews* in 2000 contained 672 protocols, 98 of which were new to that issue. Assuming a consistent rate of reviews being undertaken, a recruitment of 10% of Cochrane reviewers would see the target reached within two years. These estimates are considered conservative, given the expected recruitment of keen reviewers with many more than six investigators to contact.

Secondary outcomes

The first of the secondary outcomes (time to response) will be analysed using standard log-rank “survival” analyses techniques for time to first response (of any type) and time to first complete response. The second secondary outcome (contact made, irrespective of data retrieval) will be analysed using an overall odds ratio. The cost and time outcomes will be analysed using *t*-tests. Postage and telephone calls will be transformed to equivalent costs in the United Kingdom.

A further secondary analysis will be performed if the trial stops in favour of the experimental intervention. Logistic regression will be used to determine whether response rates differ according to (i) time since publication and (ii) request for information or data (the distinction being that the investigator would normally be able to provide the former without needing to refer to files) and (iii) surface mail or email. The dichotomised outcome of some or all information retrieved versus no information retrieved will be used for this analysis.

Exploratory analyses may be undertaken if the trial stops in favour of the experimental intervention in order to generate hypotheses concerning which aspects of the experimental intervention are responsible for the improved response. Pre-notification and follow-up may be investigated by examining the time at which responses were received. Investigation of other factors is dependent on there being variability in how the experimental intervention is implemented.

Bayesian analyses of the primary outcome will be undertaken using a community subjective prior distribution elicited from members of the First Contact Steering Group, participants in First Contact and experienced systematic reviewers. All elicitation will take place before any results are available.

Organisation

Steering Committee

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Collaborators

(Systematic reviewers who have already agreed to take part in First Contact will be listed here.)

Acknowledgements

We wish to thank Cochrane Review Group Co-ordinators for their response to our request for examples of letters sent to investigators.

Funding

(To be sought)

Publication

All collaborators will be named in the main reports arising from First Contact.

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Data Collection Form

Please see the form 'Data Collection Form: Notes for completion' for help in filling in this form.

Page 1: randomisation form

1. Reviewer (Your details. All forms must include your Reviewer ID; other details need only be filled in on your first form)	
Name:	Reviewer ID (assigned by us; based on your initials):
Email:	
Fax, address or telephone number if no email:	
Your location (country):	Review Group:
Review title:	

2. Investigator (Details of the person to whom you will write. This information will be used to maximise balance in the randomisation process)	
Study ID: (usually surname and year of publication)	Date last known at address: (please use dd/mm/yyyy format for all dates)
Amount of information to be requested (tick one): Small (approx 1-3 items) <input type="checkbox"/> / Medium (approx 4-10 items) <input type="checkbox"/> / Large (approx over 10 items) <input type="checkbox"/>	
Mode of contact: surface mail <input type="checkbox"/> / email <input type="checkbox"/>	
Have you had previous contact with this investigator? Yes <input type="checkbox"/> / No <input type="checkbox"/> / Don't know <input type="checkbox"/>	
Is this investigator involved with the Cochrane Collaboration? Yes <input type="checkbox"/> / No <input type="checkbox"/> / Don't know <input type="checkbox"/>	
Please send the above details (or a copy of this page) to Mike Clarke for assignment: email: mclarke@cochrane.co.uk or fax: +44 1865 516311 or post: UK Cochrane Centre, Summertown Pavilion, Middle Way, Oxford, OX2 7LG, UK	

3. Assignment (the response to your request)	
This investigator is assigned to Experimental <input type="checkbox"/> / Control <input type="checkbox"/>	
This investigator is assigned the Unique First Contact Identifier	FC.....
Please write this in the box at the top of this form (and the next page) and use it in future correspondence with us about this investigator.	

4. either Control Intervention					FC.....
<u>0 weeks</u>	sent <input type="checkbox"/>	on (date):	by surface <input type="checkbox"/> / email <input type="checkbox"/>	to (country):	costs:
contained: request letter <input type="checkbox"/> other (specify):					
or Experimental intervention					
<u>0 weeks</u>	sent pre-notification <input type="checkbox"/>	on (date):	by surface <input type="checkbox"/> / email <input type="checkbox"/>	to (country):	costs:
contained (tick all that apply): letter <input type="checkbox"/> Cochrane leaflet <input type="checkbox"/> protocol <input type="checkbox"/> other (specify):					
<u>4 weeks</u>	sent request <input type="checkbox"/>	on (date):	by surface <input type="checkbox"/> / email <input type="checkbox"/>	to (country):	costs:
contained (tick all that apply): letter <input type="checkbox"/> table/form <input type="checkbox"/> promise of acknowledgement <input type="checkbox"/> other (specify):					
<u>7-9 weeks</u>	follow-up <input type="checkbox"/>	on (dates):		to (country):	costs:
attempted: surface mail <input type="checkbox"/> email <input type="checkbox"/> fax <input type="checkbox"/> telephone <input type="checkbox"/> other (specify):					
Any other attempts to contact the investigator					
<u>Other attempts: 1</u>	on (date):		to (country):		costs:
by surface mail <input type="checkbox"/> / email <input type="checkbox"/> / fax <input type="checkbox"/> / telephone <input type="checkbox"/> / other:					
details (specify):					
<u>Other attempts: 2</u>	on (date):		to (country):		costs:
by surface mail <input type="checkbox"/> / email <input type="checkbox"/> / fax <input type="checkbox"/> / telephone <input type="checkbox"/> / other:					
details (specify):					

5. Diary (Please log all responses from this investigator)	
(1) Date received:	Response to: pre-notification* <input type="checkbox"/> / request <input type="checkbox"/> / follow-up* <input type="checkbox"/> / other(specify):
Got: rejection <input type="checkbox"/> / new contact details <input type="checkbox"/> / some requested information <input type="checkbox"/> / all requested information <input type="checkbox"/>	
(2) Date received:	Response to: pre-notification* <input type="checkbox"/> / request <input type="checkbox"/> / follow-up* <input type="checkbox"/> / other(specify):
Got: rejection <input type="checkbox"/> / new contact details <input type="checkbox"/> / some requested information <input type="checkbox"/> / all requested information <input type="checkbox"/>	
(3) Date received:	Response to: pre-notification* <input type="checkbox"/> / request <input type="checkbox"/> / follow-up* <input type="checkbox"/> / other(specify):
Got: rejection <input type="checkbox"/> / new contact details <input type="checkbox"/> / some requested information <input type="checkbox"/> / all requested information <input type="checkbox"/>	

*applicable to experimental intervention only

6. Outcomes	
At 12 weeks <input type="checkbox"/> / other (specify):	measured on (date):
<i>Primary outcome: Information retrieved of that requested:</i> No information <input type="checkbox"/> / Inadequate response <input type="checkbox"/> / Satisfactory response <input type="checkbox"/> / Perfect response <input type="checkbox"/>	
<i>Secondary outcome: Response:</i> Did you receive any response (from anyone) as a result of your letter(s)? Yes <input type="checkbox"/> / No <input type="checkbox"/>	

7. Comments

Please return the form (keeping a copy for yourself) to Julian Higgins by mail to MRC Biostatistics Unit, Institute of Public Health, Robinson Way, Cambridge CB2 2SR, UK or by fax on +44 1223 330 388

Appendix B

Example letter: Control group

Dear Dr Studelieder,

You may be aware of the Cochrane Collaboration, a world wide collaboration with the goals of preparing, maintaining and making accessible up-to-date systematic reviews of the effects of health care. As part of the Cochrane Everyday Ailments and Annoyances Group a systematic review is being undertaken in the effectiveness of xampal in the treatment of Lakov-Ezdee's disease. I am writing on behalf of our collaborative team regarding the following published study which is being included in this review:

Studelieder, D., Trigh-Liszt, N.E., Urthawan, N. The effect of oral xampal on Lakov-Ezdee's disease: A randomised placebo-controlled trial. Journal of Controlled Trials. 1992;31:196-203.

In order to represent your study adequately in our meta-analysis we need additional information and hope you can help us. We would greatly appreciate if you could provide us with the some information on the trial.

1. Would you be able to provide us the number of patients, mean and standard deviation or standard error for the number of days off work for both the treatment and control groups.
2. We would also like information which would allow us to classify the study according to our methodological criteria. Could you confirm whether the randomisation of patients to their treatment/control group was concealed from the person responsible for the randomisation process? Who was blinded in the trial (for example patients, investigators, assessors)?

If you have any further questions regarding our requests, please feel free to contact me.

Thank you very much for considering this request.

Yours sincerely

Ima Revyuer

Appendix C

Example letter: Experimental group pre-notification

Dear Dr Studelieder,

You may be aware of the Cochrane Collaboration, a world wide collaboration with the goals of preparing, maintaining and making accessible up-to-date systematic reviews of the effects of health care. As part of the Cochrane Everyday Ailments and Annoyances Group a systematic review is being undertaken in the effectiveness of xampal for the treatment of Lakov-Ezdee's disease. I am writing on behalf of our collaborative team regarding the following published study which is being included in this review:

Studelieder, D., Trigh-Liszt, N.E., Urthawan, N. The effect of oral xampal on Lakov-Ezdee's disease: A randomised placebo-controlled trial. Journal of Controlled Trials. 1992;31:196-203.

We would like to include this important study in a meta-analysis with other, similar studies that we have also identified. However, some of the information we would need to do this is not available from the article. We intend to write to you shortly with a breakdown of what information we would need to fully represent your study in the review.

In the meantime I would be delighted to answer any questions you have about our review. I enclose a brief version of the protocol, and a leaflet which outlines the activities of the Cochrane Collaboration and it's product, *The Cochrane Library*.

A particular reason for this advance notification is in case there are other personnel from your study whom it would be more appropriate for us to contact (for example, the person who holds the data). I would be very grateful if you could send me contact details of any such people, or forward this and any subsequent letters to them.

Thank you in advance.

Yours sincerely

Ima Refyuer

Encs: Cochrane leaflet
Protocol for Cochrane review

Appendix D

Example letter: Experimental group request

Dear Dr Studelieder,

I hope you received a letter from me a short while ago concerning a systematic review of xampal for the treatment of the common cold which is being prepared under the auspices of the Cochrane Collaboration. We are including the following published study:

Studelieder, D., Trigh-Liszt, N.E., Urthawan, N. The effect of oral xampal on Lakov-Ezdee's disease: A randomised placebo-controlled trial. Journal of Controlled Trials. 1992;31:196-203.

The Cochrane review process follows explicit methods. These relate, for example, to the strategies for identifying relevant studies and including these in the review, as well as data extraction and data synthesis.

The attached details have been obtained from your paper. Where it has not been possible to obtain the necessary information from the given text or illustrations, some items have been marked "UNCLEAR" or "MISSING". In order to facilitate the review process we would greatly appreciate it if you could examine the extracted information and inform us of

1. **Any errors or misinterpretations in the extracted data.** Please state clearly your reasons for believing that the information extracted is wrong.
2. **Any information you have available which is currently described as "UNCLEAR" or "MISSING".**

Any information you are able to provide will be gratefully acknowledged in the published review. Even if the data are not available, please let me know as failure to collect the data should be noted in the review.

Please do not hesitate to contact me if you have any questions regarding the review, or this letter. Your assistance in this important health issue will help us in our aim of presenting and synthesising the worldwide randomised evidence with regards to the use of xampal in the treatment of Lakov-Ezdee's disease.

Yours sincerely

Ima Refyuer

Encs: Data extracted from study