

13 July 2000

Welcome to First Contact! This document provides guidelines for First Contact participants in the form of a list of 'frequently asked questions' (FAQs). The most up-to-date version can be found in the members area of the First Contact web site, <http://www.mrc-bsu.cam.ac.uk/firstcontact>.

## **General**

### *What is First Contact?*

Many published reports do not contain sufficient information to allow systematic reviews to fully represent the reported studies. First Contact is a randomised trial of ways to contact authors of published studies in order to obtain such information.

### *How do I find out more about First Contact?*

The Protocol for First Contact, and a lot of other information about the trial, is available from the First Contact web site, <http://www.mrc-bsu.cam.ac.uk/firstcontact>.

### *How do I contact First Contact?*

email **[firstcontact@mrc-bsu.cam.ac.uk](mailto:firstcontact@mrc-bsu.cam.ac.uk)**.

If you do not have access to the internet you may write to

**First Contact, MRC Biostatistics Unit, Institute of Public, Cambridge CB2 2SR, UK.**

You may alternatively fax on +44 1223 330 388 (labelled for the attention of Julian Higgins).

Please remember that these contact details do not apply to the randomisation.

### *Who is behind First Contact?*

The First Contact Steering Group includes active members of numerous Cochrane entities, including Mike Clarke (Associate Director of the UK Cochrane Centre), Ian Roberts (co-ordinating editor of the Injuries Group), editors of other Review Groups, and Cochrane reviewers. The trial is co-ordinated in Cambridge, UK, by Julian Higgins.

### *Am I eligible to join First Contact?*

You can join First Contact if you are undertaking a review within the Cochrane Collaboration. To participate in the trial proper you must have at least one included (or likely to be included) study about which you would like more information. More details below...

### *What is the 'Cochrane Collaboration'?*

If you want more information about the Cochrane Collaboration, go to <http://www.cochrane.de> or one of the mirror sites listed therein.

### *What's in it for me?*

By joining First Contact you will be contributing to the evidence base of methods for systematic reviewing. If you are uncertain about the best way to contact an author it provides the best way to resolve your dilemma, and you may also find it makes it easier to contact authors than if left to your own devices! Your help will be duly acknowledged in our main publication(s).

We appreciate that many reviewers contact authors as a matter of course, and have particular methods that they find effective. Participating in First Contact should not feel like a 'sacrifice'. Join the trial if you like the protocol.

### *What's an 'investigator' and what's a 'participant'?*

We use particular terminology in First Contact to try to avoid confusion. If you are undertaking a Cochrane review and are interested in joining First Contact, or are participating already, then we call you either a 'reviewer' or a 'participant'. You may have identified a study, say a randomised trial, that you would like to include in your review (as an 'Included study'). If that study has been published, but the report does not give you sufficient information to complete your review, then we refer to the author(s) of that report as the 'investigator'. We imagine there is only one investigator per study. First Contact is about how reviewers should contact investigators in order to maximise the chance of retrieving the missing data. We will do this by recruiting reviewers as participants in First Contact.

### *Why did First Contact choose this particular protocol?*

There are very many factors that might influence whether the recipient of a request responds. For example, a letter of pre-notification may increase response rates, as may promising an acknowledgement (or a threat that non-responders will be declared) or undertaking intensive follow-up. Measures like this have been studied in population surveys and are the topic of a Cochrane review\*. We could have studied one of these in isolation, or two or more in a factorial design. Such a trial would either have been very specific, and perhaps of limited practical value, or have become too complicated to answer its component questions without randomising thousands of investigators.

Instead we have decided to start research in this new area with the wider question, "is it possible to improve on the status quo?". In order to do this we are randomising investigators to the typical 'status quo' (a single, simple request) or an intensive approach in which we implement as many methods as appears sensible or evidence-based. If the answer to the wider question is 'yes', we may subsequently investigate particular components of the experimental intervention. An exploratory analysis of the First Contact data may also be able to generate hypotheses regarding which aspects of the intervention were most effective.

\*Edwards P, Clarke M, DiGiuseppi C, Roberts I, Wentz R. Methods to influence response to postal questionnaires.

### *Is First Contact needed?*

One might legitimately question whether we need to randomise between methods that have been shown to be effective for population surveys. We believe the situation in First Contact is somewhat different from these. A principal difference is that we expect many investigators will no longer be at the correspondence address published in a study report. Thus, even the most effective interventions to improve response will be unsuccessful. In this way we hope to be able to examine whether the

additional effort of the proven methods are worth the time and effort; it could be that anyone who will respond will do so after the slightest contact.

#### *What documentation should I have?*

The major sources of information for participants in the trial are (i) the First Contact Protocol, (ii) these FAQs, and (iii) the notes for completing the Data Collection form. You should read the Protocol before deciding whether to join the trial. We advise you to read through these FAQs when you join, and you should always keep them handy – they will hopefully address problems and queries you have as you proceed through the trial. The notes for completing the Data Collection form address the technicalities of the paperwork, and you may wish to keep these with your Data Collection forms.

All the documents may be downloaded from the Downloads page of the web site, where we will keep the most up-to-date version of the important documents. In addition, you are encouraged to consult the web site for latest news, current results, and publications arising from the trial.

#### *How do I suggest more FAQs?*

Please write to First Contact using the contact details above. Your suggestions are very welcome.

#### *How can I help recruit for First Contact?*

We have a page on the web site with leaflets and other promotional documents available for downloading. We particularly encourage Cochrane Review Group Co-ordinators to bring First Contact to the attention of reviewers who may be interested in participating. Providing links to our web site from Review Group web sites would be a simple and potentially effective step.

## **Participating**

#### *Where do I start?*

If you haven't already done so, look at the Protocol to decide whether you would like to participate. If you would, then write to us. We will give you a Reviewer ID for use in First Contact correspondence.

In preparation for your full participation you should

1. read these FAQs
2. obtain some First Contact Data Collection forms, and the associated notes for their completion
3. check that you are comfortable with how you will participate in the trial. Contact us if you want to ask any questions about the design.

When you have identified investigators to whom you wish to write, enter their details on Data Collection forms (one for each investigator), and submit the information necessary for them to be randomised. On receipt of the allocations you are ready to proceed with either the control intervention or the experimental intervention. Log everything you do with regard to each investigator on their Data Collection form. After the observation period, return the Data Collection forms to us and wait for the update of the First Contact results. More details of each of these processes follow.

*What are all these IDs and what are they for?*

You will find three types of ID mentioned in First Contact documentation: Reviewer IDs, Study IDs and Unique First Contact Identifiers (FC IDs).

Reviewer IDs are codes we assign to you so that we can easily locate your details and investigators you randomise. They start with your initials and have a number appended. As an example, if your initials are IR, then a Reviewer ID of IR8 indicates that you are the 8<sup>th</sup> reviewer to participate in First Contact. Please quote your reviewer ID in correspondence with us.

Study IDs are assigned by you. Each study in a Cochrane review should be assigned an ID within RevMan. This usually comprises the surname of the first authors and the date of publication. We collect these only to ensure the randomisation is undertaken correctly. They are included on the randomisation page of the Data Collection form for two reasons. First, to ensure you have an identifiable study in front of you which you intend to randomise (and which can be followed-up to ensure they received the correct intervention). Second, to help you identify which study the form relates to in the context of your review.

Unique First Contact Identifiers (FC IDs) are codes we assign to you when you enter an investigator for randomisation. The FC ID is unique to the particular investigator, so that each investigator randomised into First Contact can be isolated. We create an FC ID by taking the number from your reviewer ID and appending a number indicating how many investigators you have randomised. As an example, the first three investigators randomised by reviewer IR8 would have FC IDs of 800001, 800002 and 800003. Please quote FC IDs when you correspond with us about investigators.

*What should I say in my review protocol?*

**We ask you not to mention First Contact, or that you will be randomising methods of writing to authors, in your protocol.** A simple statement such as, “authors of trials will be contacted for missing information,” should suffice. The reason for this is simple: potential recipients of your letters may well read a published protocol and realise he or she is a participant in the trial. The resulting lack of blindness to which intervention group he or she belongs may introduce bias into their response. We do not believe there are ethical considerations in not informing letter recipients that they are subjects of a study, since the two types of first contact under investigation are consistent with routine practice and prior consent would not be sought for either.

*Which study investigators can I randomise?*

You can randomise an investigator who is an author of a study that you hope to include in your systematic review as an Included study, if

- (i) there is information missing from the report that prevents you from deciding whether the study should be included or excluded, or
- (ii) there is insufficient detail in the report to describe the methodological quality, nature of participants, nature of interventions, nature of outcomes, or results of the study.

We recommend you determine as many as possible of the investigators you wish to write to before you start randomising. This is because you may wish to write to an investigator about more than one study (and we ask you not to randomise the same investigator twice; see later FAQ).

*What about reports of studies with more than one author?*

For the purposes of taking part in First Contact, we ask you to select one author to be the investigator you will contact. This will usually be the first author. However, when there are several authors with the same address it may be wise to choose one of these, since it may increase the chance of obtaining some response.

*What about authors of more than one study?*

We ask you to enter any particular investigator only once into First Contact, but you are free to write to them about more than one study when you do write to them. For this reason we recommend that you collate all the investigators you wish to write to before you start randomising.

*Can I randomise the same trialist twice?*

We ask you not to randomise the same investigator twice. We appreciate that you may identify more than one study by the same investigator or team. This is why we recommend that you collate all the investigators you wish to write to before you start randomising. If the same investigator gets randomised more than once by accident, then we still intend to include all occurrences in the analysis.

*Won't investigators have changed addresses since the publication of the report?*

Yes – especially if the report is quite old. This is one of the factors that makes First Contact different from trials of population survey techniques. Determining whether the listed address is still applicable can be time consuming and painstaking, which is why writing to the published address may be a sensible first step. One of the purposes of the pre-notification in the experimental group is to ask whoever reads the letter to provide updated contact details. You may wish to mark the envelope to the effect that you wish it to be opened if the addressee has departed. You can do this for the experimental intervention only or for both the control and experimental interventions. Please note what you do on the Data Collection form.

We hope the follow-up stage of the experimental intervention will enable you to determine whether or not contact is possible with the investigator. In this way we will be able to estimate the proportion (if any) of 'contactable' investigators in the control group who did not respond to the simple request. Note that you may follow up all investigators after the end of the observation period. We'd be interested to hear about successes/failures during subsequent follow-up, since these may confirm conclusions from the First Contact results proper.

*How do I decide whether to randomise a particular investigator?*

Your decision to randomise an investigator into First Contact should be based on the uncertainty principle. This means that

(i) You are uncertain whether the experimental arm or the control arm will produce the best overall outcome. This will depend on first, whether you believe First Contact is addressing a reasonable question; and second, how you interpret the current results of the trial. Results will regularly be updated on the web site when we have outcome data from at least six separate reviewers. We plan to continue the trial until the results convince all potential participants that the question has been resolved (in favour of one or other intervention, or in terms of establishing equivalence of the interventions).

(ii) You are uncertain whether either the experimental arm or the control arm will produce a better overall outcome than any third alternative you wish to use. This will depend on what other alternatives available, for example, whether you have a telephone number for the investigator.

Note that 'overall outcome' involves more than whether or not the information needed for your review is eventually retrieved. It should involve a judgement of the importance of this compared with the time, energy and resources involved in each procedure.

*What if I want to make first contact with an investigator by telephone?*

If you prefer to make first contact by telephone, then we encourage you to do so: many experienced reviewers advocate this as an effective procedure. This investigator would not be eligible for First Contact and should not be submitted for randomisation. If you have many investigators to telephone, but do not have the resources or inclination to call each one then you might consider entering them into First Contact on the basis that, even though telephoning may be more effective for some investigators, you are uncertain whether the additional time and cost are worth the effort. Note that telephoning is built into the experimental arm of First Contact as a means of following-up non-responders, and that once the observation period of First Contact is over, investigators in both the control group and the experimental group may be contacted by any means available to the reviewer.

*What if I want to alter an intervention?*

We recognise that our suggested strategies for the control and experimental interventions are explicitly defined. We hope that these will be followed in general, but appreciate that for some participants and some investigators this may not be appropriate. Rather than exclude you or an investigator from First Contact, we may be able to negotiate suitable variations on the proposed interventions. To try and ensure similar control and experimental groups, we would normally expect you to have a relatively large number of potential investigators (perhaps at least ten) for us to agree to substantial modifications.

The essential comparison must be of

Control: a single request, so as to emulate the typical followed by Cochrane Review Groups;

Experimental: an intensive approach that 'pulls out the stops'. Details of the minimum criteria may be found in the protocol.

Acceptable variations to the interventions may include

- (i) adding further to the experimental group, say by including pre-paid addressed envelopes;
- (ii) altering the observation period to be slightly longer, or shorter;
- (iii) not using the pre-notification.

We will need detailed reasoning for your suggested modifications. The Steering Group (or a representative of it) will need to approve these before randomisation, so that we can ensure that all changes will still help us answer the First Contact question. Therefore, if you wish to modify either intervention, you should send us details of the control intervention and experimental intervention prior to randomisation (contact details above), and, if approved, describe your modifications on the Data Collection form.

*What if I want to alter both interventions?*

If you wish to apply a modification equally to both the control intervention and the experimental intervention, then this will normally be acceptable as long as the control intervention does not become

too similar to the experimental intervention. An example of a modification to both interventions might be to ask all investigators whether they are aware of studies that your search strategy has not identified. If you are unsure of the suitability of a modification please contact us. Please describe any modifications on the Data Collection form.

*Can I change an intervention after I've been given the randomised allocation?*

Yes, you are free to do as you choose, but we would prefer you to keep the protocol. Note that once you get a response from an investigator the protocol frees you to pursue this in any way so as to obtain the data.

We will conduct an intention to treat analysis, which means that all investigators who are randomised into First Contact will be included in the analysis whether or not you followed the protocol. We would like to collect information about the extent to which you keep to the protocol – please be honest! We will find it more difficult to interpret the results if you stray from the protocol, but – even worse – may produce inappropriate conclusions if you do not tell us that you do so. The Data Collection form allows you to record exactly what you do.

*How do I choose between surface mail and email?*

First Contact was originally designed to compare methods for surface mail. We decided to incorporate email since the medium is readily accessible by most reviewers, and is likely to be used more and more for scientific correspondence in the future. Email addresses are now published regularly within trial reports. Further, it is often possible to find email addresses by searching the world wide web – a process that might even yield updated details for the investigator.

If you have an email address for an investigator (from a trial report, the internet or any other source) then you may join First Contact and randomise to methods of approaching them. If you have both a surface mail address and an email address then you are free to decide which to use. You must decide, however, before you submit the investigator for randomisation.

*What's special about choosing email?*

Email should decrease the time taken to get a response by removing delays related to the postal system. However, because many email users object to unsolicited email attachments, **we advise participants in First Contact not to send attached files by email without the consent of the recipient.** This means that the pre-notification when email is used should not normally contain as much information as the pre-notification when surface mail is used. However, the use of electronic communication does make it easier to include links to world wide web sites. Thus, instead of including a leaflet about the Cochrane Collaboration, a single introductory sentence along with a link to the Cochrane web site (say, <http://www.cochrane.de>) is sufficient.

*The follow-up period looks too long for me; what can I do?*

If you think that the 12 week period is too long for a particular trial in your review, it would be best not to offer it for randomisation. However, if after randomisation, you decide that you do not wish to wait 12 weeks, you are free to do whatever seems most appropriate to you. Please make sure that you tell us this on the outcome form. In addition, if you think that the 12 weeks period, or any other aspect of the design of First Contact, is a barrier to your participation in the trial, please let us know. In order to have

outcome information that will be comparable across First Contact we have had to choose a fixed time point for which each participant will provide their response data. This has been set to 12 weeks for a number of reasons: the typical approach for many Cochrane reviews involves a letter asking for additional information being sent to an investigator, without immediate plans for follow-up of those who do not reply; to allow sufficient time for all 3 steps in the experimental intervention; to allow enough time for a high proportion of all likely replies to be received; to minimise the time that participants need to wait before contacting non-responders.

#### *How do I randomise?*

To randomise an investigator, complete the randomisation page of the Data Collection form. You can fax or post this to Mike Clarke (fax: +44-1865-516311; UK Cochrane Centre, Summertown Pavilion, Middle Way, Oxford, OX2 7LG, UK), or email the details to [mclarke@cochrane.co.uk](mailto:mclarke@cochrane.co.uk) using the email template you will find in the members pages of the First Contact web site. The randomised allocation (based on a minimisation programme) for each investigator and a unique identification code for that investigator will be sent to you within two working days.

You should retain the original or a copy of the completed Data Collection form however you submit your randomisation request. We hope to build electronic submission of randomisation requests into the First Contact web site at a later stage.

#### *What is minimisation?*

Minimisation is a process of allocation which ensures that key characteristics of the trialists being written to are balanced between the control and experimental groups.

#### *What if I get no response when I ask for a randomisation?*

If you have not received the allocation (or a notification of a delay) within three working days you may take the following actions until the situation is resolved. **Please do not re-send a request for randomisation** unless asked to do so, as this may result in the investigator being randomised twice.

- (i) contact Mike Clarke by phone or email (+44 1865 516300; [mclarke@cochrane.co.uk](mailto:mclarke@cochrane.co.uk)).
- (ii) consult the First Contact web site for details of unforeseen problems and vacation periods. For example, it is unlikely that randomisation will be performed during Cochrane meetings and colloquia.
- (iii) contact Julian Higgins (+44 1223 330396; [julian.higgins@mrc-bsu.cam.ac.uk](mailto:julian.higgins@mrc-bsu.cam.ac.uk)).

#### *Is this allocation concealment “level A” (adequate concealment)?*

We believe our allocation to interventions is well concealed. Randomisation is undertaken centrally by a party with no vested interest in the assignment of any particular investigator. Furthermore, the use of software for undertaking the randomisation by minimisation prevents us from flipping a coin until we get the assignment we want! The ultimate assignment will be random since we can never predict it with certainty, even though the probabilities of allocation to the different groups may vary.

#### *Where do I find a data collection form?*

You can download Data Collection forms from the Downloads page of the First Contact web site. These are available only as Portable Document Format (PDF) files. You must have Adobe Acrobat

Reader installed to print them (details on the web page). You may request a hard copy of the Data Collection form by writing to First Contact (details above).

*How do I fill in the data collection form?*

The Data Collection form consists of a randomisation page and a process and results page. You will find a set of notes for filling in the Data Collection form on the Downloads page of the First Contact web site. They will also be available on-line.

*What do I do if an investigator gets assigned to the control intervention?*

If an investigator gets assigned to the Control intervention, tick that box on your randomisation page of the Data Collection form (you may also wish to strike through the section related to the Experimental intervention on the process and results page). You may immediately start implementing the intervention, which is a simple, single letter. See Control intervention FAQs below.

*What do I do if an investigator gets assigned to the experimental intervention?*

If an investigator gets assigned to the Experimental intervention, tick that box on your randomisation page of the Data Collection form (you may also wish to strike through the section related to the Control intervention on the process and results page). You may immediately start implementing the intervention, which starts with a letter of pre-notification. See Experimental intervention FAQs below.

*What happens at the end of the waiting period?*

After 12 weeks we ask you to fill in the Outcomes section of the Data Collection form if you have not already done so. Make sure that what you write reflects the situation 12 weeks after the first letter or email was posted. Check also that you have filled in all the other sections (including the Diary and any additional attempts you made to contact the investigator). Then send a copy of the form to us by mail or fax.

*What do I do with a completed Data Collection form?*

We request that you keep a copy of each Data Collection form as a safeguard. Please send one copy of the form by mail to Julian Higgins, MRC Biostatistics Unit, Institute of Public Health, Robinson Way, Cambridge CB2 2SR, UK or by fax on +44 1223 330388. You can wait until you have several forms to post together, though you may be contacted to find out when the package might be expected!

*Who will analyse the results and how?*

The results will be analysed at the MRC Biostatistics Unit in Cambridge, UK, under the supervision of its Director. A Bayesian approach will be used, of which details are provided in the First Contact protocol.

*What's a Bayesian approach to the analyses?*

A Bayesian analysis starts with a prior distribution, which describes uncertainty about the relative effectiveness of the two interventions. This is updated as data accumulate to produce a posterior

distribution, which combines prior uncertainty with the information in the data. The main analysis will make use of a non-informative prior distribution, that is an expression of prior ignorance. However, we will conduct additional analyses using informative prior distributions based on genuine prior beliefs in order to determine whether the results are sufficiently strong to convince practising reviewers of their worth.

*How can I describe my prior uncertainty?*

We have developed a form which you can use to tell us about your prior beliefs concerning the effectiveness of the two interventions before you get involved in the trial. We encourage everybody participating and anyone interested in First Contact to complete a form. Forms may be found on the Downloads page of the First Contact web site.

## **Control intervention**

*How do I start?*

You only need to write one letter or email to implement the control intervention. (You need to have told us whether you will use surface mail or email before you randomised the investigator.)

*How do I write the letter/email?*

Details are provided in the First Contact protocol, and we provide an example letter in an appendix to the protocol and on the First Contact web site. Feel free to amend this as necessary, and to write using your own style. Remember that the control intervention is intended to emulate a typical approach of Cochrane reviewers. We would expect it to be grammatically correct, courteous and respectful. However, we do not expect it to offer substantial incentives to respond in order to ensure sufficient distinction between the intervention groups. You are free to use headed paper, and/or to include a reply envelope, but only if you would have done this had the investigator been assigned to the experimental intervention.

*What if my email bounces?*

If the computer to which you send an email does not recognise the email address, the message may 'bounce'. This normally results in the message being returned to you soon after you send it, with the information that the addressee is unknown at that address. If your first email attempt bounces and you have a surface mail address, we ask you to immediately re-initiate the control intervention using surface mail rather than email. Note the surface mail attempt to contact the investigator as an additional attempt on the Data Collection form.

If the email bounces and you do not have a surface mail address, we request that you wait for twelve weeks (and record a No response) before pursuing alternative routes. You are free to follow a different course, but please let us know what you do on the Data Collection form so that we may account for it in our interpretation of the results.

### *How long must I wait, and why?*

Wait 12 weeks from the date of posting the letter or email. This may seem like a long time, but the experience of reviewers on the steering group would suggest that this is not a long time within the context of undertaking a Cochrane review. We need to allow this amount of time in order for it to be possible to implement the experimental intervention. Outcomes must be collected at the same time in both groups if we are not to introduce a bias!

### *What if I get a perfect response?*

We define a perfect response as retrieving all the information you requested within 12 weeks of posting the request. If this happens, note down the correspondence in the Diary section of the Data Collection form and tick the outcome 'Perfect response' in the Outcomes section. The investigator is released from the protocol and you are free to enter further correspondence with him or her if you wish.

### *What if I get a satisfactory response?*

We define a satisfactory response as retrieving sufficient information to enable the study to be included in your review with no important gaps, even though you did not get a perfect response. For example, if the investigator confirms that the study was randomised and gives you data for your primary outcome, but not some missing standard deviations for minor secondary outcomes then you may consider the response to be satisfactory. If this happens, note down the correspondence in the Diary section of the Data Collection form. The investigator is released from the protocol and you are free to enter further correspondence with him or her if you wish. Please describe all additional attempts to contact the investigator and any responses received on the Data Collection form. Twelve weeks after the initial letter was posted, tick either the outcome 'Perfect response' or the outcome 'Satisfactory response', depending on whether you have obtained the remaining missing information by this time.

### *What if I get an inadequate response?*

We define an inadequate response as retrieving some of the information that you requested, but not enough to include the study in your review without some important gaps remaining. For example, if the investigator sends you some missing standard deviations but does not confirm whether the study was randomised and hence eligible for your review, then you may consider the response to be inadequate. If this happens, note down the correspondence in the Diary section of the Data Collection form. The investigator is released from the protocol and you are free to enter further correspondence with him or her if you wish. Please describe all additional attempts to contact the investigator and any responses received on the Data Collection form. Twelve weeks after the initial letter was posted, tick one of the outcomes 'Perfect response', 'Satisfactory response' or 'Inadequate response', depending on whether you have obtained remaining missing information by this time.

### *What if I get new contact details?*

If your letter results in somebody sending new contact details to you, you are free to follow up the investigator using the new contact details. However, we suggest that

- (i) if you obtain an email address, surface mail address or fax number, you re-send the letter to this (if possible using the same writing medium as the initial letter).
- (ii) if you only obtain a telephone number only, you use this.

Please note down all additional attempts to contact an investigator and any responses received on the Data Collection form.

*What if I want to telephone the investigator?*

You are free to telephone an investigator after you have received any response to your initial letter. Otherwise, we ask you to refrain from telephoning until you have waited 12 weeks. If it is important that you telephone for any other reason, please note that you have made other attempts to contact the investigator on the Data Collection form, and outline your reasons in the Comments box.

*What if I want to write another letter or email to the investigator?*

You are free to write to an investigator after you have received any response to your initial letter. Otherwise, we ask you to refrain from writing until you have waited 12 weeks. If it is important that you do write for any other reason, please note that you have made other attempts to contact the investigator on the Data Collection form, and outline your reasons in the Comments box.

## **Experimental intervention**

*How do I start?*

Your first task for an investigator assigned to the experimental intervention is usually to write a letter or email of pre-notification. (You need to have told us whether you will use surface mail or email before you randomised the investigator.)

*How do I write a pre-notification letter?*

Details are provided in the First Contact protocol, and we provide an example letter in an appendix to the protocol and on the First Contact web site. Feel free to amend this as necessary, and to write using your own style. We encourage the use of quality headed paper when available. We ask you to enclose some additional information with the pre-notification to stimulate their interest: a brochure or leaflet about the Cochrane Collaboration and a brief version of the protocol for your review. This protocol may be the full protocol, or you may wish to provide a brief version to give the investigator the feel for the review without the full methodological details.

*How do I write a pre-notification email?*

A pre-notification email should be similar to the example pre-notification letter. However, we recommend you do not attach files to the email. Instead of including a Cochrane brochure you may provide a link to a local Cochrane Collaboration web site (see later FAQ). Instead of including a protocol for your review, offer to send them one as an attachment or by post. If you are invited to send an attachment, remember that the investigator probably will not have RevMan. If your protocol is in RevMan format you may wish to Export > Text of review > RTF format, and edit the resulting file in, say, Microsoft Word to add a title, author(s) and date.

It may be wise to ask for confirmation of a postal address in the pre-notification email so that you may send the request by surface mail, particularly if you will wish to send a table for the investigator to fill in.

*What if my pre-notification email bounces?*

If the computer to which you send an email does not recognise the email address, the message may 'bounce'. This normally results in the message being returned to you soon after you send it, with the information that the addressee is unknown at that address. If your first email attempt bounces and you have a surface mail address, we ask you to immediately re-initiate the experimental intervention using surface mail rather than email. Note the surface mail pre-notification as an additional attempt to contact the investigator on the Data Collection form.

If the email bounces and you do not have a surface mail address, we request that you wait for twelve weeks (and record a No response) before pursuing alternative routes. You are free to follow a different course, but please let us know what you do on the Data Collection form so that we may account for it in our interpretation of the results.

*Where do I get a Cochrane brochure?*

The main Cochrane brochure may be found on the Cochrane Collaboration web site (for example, [www.cochrane.org/cochrane/cc\\_broch.htm](http://www.cochrane.org/cochrane/cc_broch.htm)). You might be able to obtain printed copies from your Review Group or local Cochrane Centre. Alternatively, you may wish to include other literature about the Cochrane Collaboration, such as a leaflet for your Review Group if it has prepared one.

*How do I link to a Cochrane web site?*

You may insert one of the following URLs into your email (or indeed a surface mail letter). Some of these are mirror (identical) sites. The closest site, geographically, to the investigator may provide their quickest connection, and includes a prominent link to a local Cochrane centre, sometimes with material in local languages.

USA	<a href="http://www.cochrane.org">http://www.cochrane.org</a>
Australia	<a href="http://www.cochrane.org.au">http://www.cochrane.org.au</a>
Canada	<a href="http://hiru.mcmaster.ca/cochrane">http://hiru.mcmaster.ca/cochrane</a>
Germany	<a href="http://www.cochrane.de">http://www.cochrane.de</a> (including information for German speakers)
Spain	<a href="http://www.cochrane.es/default.html">http://www.cochrane.es/default.html</a> (including information for Spanish speakers)
Denmark	<a href="http://www.cochrane.dk">http://www.cochrane.dk</a>
UK	<a href="http://www.update-software.com/ccweb">http://www.update-software.com/ccweb</a>
Japan	<a href="http://www.nihs.go.jp/acc/default.html">http://www.nihs.go.jp/acc/default.html</a>

*What if I get a response to the pre-notification?*

If you get a response to the pre-notification, you are free to act on any course of action it suggests that is different from the intervention strategy for the experimental group in order to retrieve the missing information. However, we suggest that you keep following the protocol unless there is good reason not to. For example, if the investigator writes back only to state that he or she will be pleased to help and looks forward to the request, then you may wish to keep to the time scale of the protocol. If the investigator asks not to be contacted further, we encourage you to respect his or her wishes.

### *How do I write the request?*

Details are provided in the First Contact protocol, and we provide an example letter in an appendix to the protocol and on the First Contact web site. Feel free to amend this as necessary, and to write using your own style. We encourage the use of quality headed paper when available. We ask you to include a summary of the important information you have successfully extracted from the published report(s) related to the investigator's study, highlighting those which are missing. The investigator may be able to fill in the gaps, or provide you with sufficient data for you to do so yourself.

### *Can I send the request by mail if I opted for email contact?*

Yes, if you have good reason to. Sending an email request may prove awkward if you wish to send a table for the investigator to fill in. We discourage the use of unsolicited attachments to emails. It may be wise to ask for confirmation of a postal address in the pre-notification email so that you may send the request by surface mail with confidence.

### *How do I follow-up?*

You may follow-up non-responders in the experimental group using any means available to you. We particularly encourage telephone contact, as well as email and other means of direct contact. You may at this stage invest time in searching the world wide web for updated contact details. If you discover that an investigator has moved and suspect they have not received the pre-notification or request letter, we encourage you to make contact by any means you choose.

### *How long must I wait, and why?*

The period from posting the first pre-notification to collection of final outcomes should be 12 weeks. We suggest the request be sent approximately three weeks after the pre-notification, and that you start following up non-responders approximately 4 to 6 weeks after the request. You may treat these timings as flexible, but the 12 week outcome assessment is fixed. We request that you ensure all stages of the experimental intervention will have been undertaken before the 12 week assessment.

### *What if I get a perfect response?*

We define a perfect response as retrieving all the information you requested within 12 weeks of posting the first letter. If this happens at any stage, note down the correspondence in the Diary section of the Data Collection form and tick the outcome 'Perfect response' in the Outcomes section. The investigator is released from the protocol and you are free to enter further correspondence with him or her if you wish.

### *What if I get a satisfactory response?*

We define a satisfactory response as retrieving sufficient information to enable the study to be included in your review with no important gaps, even though you did not get a perfect response. For example, if the investigator confirms that the study was randomised and gives you data for your primary outcome, but not some missing standard deviations for minor secondary outcomes then you may consider the response to be satisfactory. If this happens, note down the correspondence in the Diary section of the

Data Collection form. The investigator is released from the protocol and you are free to enter any further correspondence with him or her if you wish. Please describe all additional attempts to contact the investigator and any responses received on the Data Collection form. Twelve weeks after the initial letter was posted, tick either the outcome 'Perfect response' or the outcome 'Satisfactory response', depending on whether you have obtained the remaining missing information by this time.

*What if I get an inadequate response?*

We define an inadequate response as retrieving some of the information that you requested, but not enough to include the study in your review without some important gaps remaining. For example, if the investigator sends you some missing standard deviations but does not confirm whether the study was randomised and hence eligible for your review, then you may consider the response to be inadequate. If this happens, note down the correspondence in the Diary section of the Data Collection form. The investigator is released from the protocol and you are free to enter any further correspondence with him or her if you wish. Please describe all additional attempts to contact the investigator and any responses received on the Data Collection form. Twelve weeks after the initial letter was posted, tick one of the outcomes 'Perfect response', 'Satisfactory response' or 'Inadequate response', depending on whether you have obtained remaining missing information by this time.

*What if I get new contact details?*

If at any stage somebody sends new contact details for the investigator to you, you are free to follow up the investigator using the new contact details. However, we suggest that

- (i) if you obtain an email address, surface mail address or fax number, you re-send the pre-notification and /or request to this (if possible using the same writing medium as the initial mailings).
- (ii) if you only obtain a telephone number only, you use this.

Please note down all additional attempts to contact an investigator and any responses received on the Data Collection form.

*What if I want to telephone the investigator?*

You are free to telephone an investigator after you have received any response to your pre-notification or request. Otherwise, we ask you to refrain from telephoning until the follow-up period (approximately within five weeks before the 12 week assessment time). If it is important that you telephone for any other reason, please note that you have made other attempts to contact the investigator on the Data Collection form, and outline your reasons in the Comments box.

*What if I want to write another letter or email to the investigator?*

You are free to enter additional written correspondence with an investigator after you have received any response to your pre-notification or request. Otherwise, we ask you to refrain from writing until the follow-up period (approximately within five weeks before the 12 week assessment time). If it is important that you do write for any other reason, please note that you have made other attempts to contact the investigator on the Data Collection form, and outline your reasons in the Comments box.