Author's response to reviews

Title: Using e-mail recruitment and an online questionnaire to establish effect size: A worked example

Authors:

Helen M Kirkby (hmk592@bham.ac.uk)
Sue Wilson (S.Wilson@bham.ac.uk)
Melanie Calvert (M.Calvert@bham.ac.uk)
Heather Draper (Drapehja@bham.ac.uk)

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Author's response to reviews: see over
Dear Editor,

Thank you very much for your swift response to our submission and for the comments of the reviewers. We were pleased that the reviewers had taken the time to consider our paper and provide useful comments that have enabled us to improve the manuscript.

Reviewer #1 (Helen Atherton)

1. For clarity’s sake, and to match up with the questionnaire in the appendix, you may wish to describe the intervention (pgs 4/5) as the e-PIS.

‘Intervention’ has been replaced with ‘e-PIS’ as suggested. We have also described this study as the ‘questionnaire study’ for further clarity.

2. Is the cost of £1000 for the intervention a theoretical cost, or the actual cost? It would be interesting to know.

This was an estimated cost, and the text has been updated to read (page 6, paragraph 1):
“…. in which an e-PIS that aimed to increase recruitment rates had been developed that cost approximately £1,000 (based on an estimate from the Medical Education Technology Team at the University of Birmingham).”

3. Throughout this article I was confused by the terminology – often it was difficult to make the distinction between where you were talking about this study and the hypothetical study that you used in the questionnaire. Specific examples of this are found in the following places with examples for how to make it clearer in brackets:

a) Abstract, Methods: ‘It asked participants how much they would need to see recruitment rates increased by (in the hypothetical study) before they would consider using the intervention in their research. Reading the abstract before any other element of the study (as many people do) I wasn’t sure whether the recruitment rates concerned the intervention or the email recruitment

b) Abstract, Results: ‘Dependent upon (the) baseline recruitment results (presented to experts in the questionnaire), experts wanted recruitment rate to increase from 6.9% to 28.9% before they would consider using the (hypothetical) intervention’. At present this sentence is not clear if just reading the abstract alone. I think you should make it clearer what you mean by baseline recruitment rates for those who have not seen the questionnaire in the appendix. I had to read it a few times before I realised you were not referring to the use of an online questionnaire – the title of the study implies that the efficacy of the use of email recruitment/online questionnaire is what is being explored.

c) Results, page 6: ‘The effect size participants wanted from the intervention increased as the baseline recruitment rate (in the questionnaire) decreased.’

d) Discussion, pg 7: ‘The results of the questionnaire demonstrate that for this scenario (increasing recruitment rates), even though the cost of the (proposed e-PIS) intervention was relatively low,…..’.

The text has been amended to take into account these useful comments. It is now clear when we are talking about the e-PIS study and when we are talking about the questionnaire study (also see above, point 1).
4. I strongly feel that you should make changes to the title. On reading the title I expected to read a study focused more on recruitment via email and online questionnaires, and so the use of terms like ‘recruitment’ and ‘intervention’ throughout and referring to the questionnaire content rather than this study were misleading. Currently the title is vague and the study could be about any number of different things; using email to recruit, using online questionnaires, establishing effect size for an unspecified purpose. You require a title which gives a clear message about what you are doing and in order to do that the study requires a clear message. As I understand it you are trying to establish an estimate for effect size for use in a sample size calculation for an RCT, where an effect size is not currently available for the particular intervention – electronic PIS. In order to do this, you are canvassing the opinions of experts, using a questionnaire with an online format and administered to experts via email. I am currently unclear as to which element you are most interested in getting across here – methods used to administer (email/online) or response of participants with regard to effect size for this particular intervention.

We have changed the title to:

“Using e-mail recruitment and an online questionnaire to establish effect size: a worked example”

5. How did you produce the questionnaire? Was it based on evidence? If not, what was the rationale for compiling it in the way you did? Was it piloted? What was the rationale for the baseline recruitment rates used in the questionnaire? Are there any references available to back up your decision? If I were to use your methodology I would like to know how you made the decision about costs given and recruitment rates given. These are all important factors if others are to utilise your methodology.

We have added this to the sub section ‘development of the questionnaire’ within the methods section (page 6):

We have also added a paragraph to the ‘limitation’ sub-section to discuss the transferability of this questionnaire to other studies (page 10-11):
6. Similarly I would like to know more about your study participants. What sort of clinical trials were they involved with? How extensively did you search for experts? Do the MRC hubs incorporate the clinical trials units up and down the country.

Further information about the study participants has been included in an additional subsection, ‘study participants’ to the Methods section (page 6-7):

“If the provision of an e-PIS increases recruitment rates, the findings are likely to be of relevance to any researcher undertaking human research. For this questionnaire study, therefore, any academic involved in such research was eligible to participate. This questionnaire study used a convenience study sample and included researchers involved in the design and analysis of clinical trials at the University of Birmingham and from the MRC Hubs for Trials Methodology Research (HTMR) [13]. The HTMR include trialists based in seven regional hubs throughout the UK with expertise in trials methodology research, and expertise in a range of areas such as improving patient recruitment and retention into trials, assessing new trial designs, and testing different approaches to data analysis. Researchers were invited to participate in the study by email with a URL link to the survey.”

We also agree that choosing expert participants would be an issue for other studies wanting to use this methodology. This is now included as a limitation to the study (page 10-11):

Participants were chosen from a convenience sample, using all researchers in the MRC hubs and at the University of Birmingham, and this sampling technique has also listed as a limitation to the generalisability of results (page 10-11).
7. You explain that 26 participants failed to complete the questionnaire. Please could you provide some information on how far through the questionnaire they got? Did you have compulsory questions? The reason this is important is because if others are to utilise your methodology they will need to know if there was something in particular that put people off completing it.

We agree with the reviewer, and have addressed this in the discussion section (page 9-10):

“Twenty-six participants started but failed to complete the questionnaire, and since questionnaire responses were anonymous and no follow up of participants was conducted, reasons for non-completion could not be collected. It may be that once they started they realised they did not have experience required to provide answers, they did not understand the questions, or they became distracted and because it was online rather than a paper questionnaire on their desk, they forgot to go back to complete it. Participants also may have accidentally closed their browser before submitting the completed questionnaire meaning they would have lost their answers up to that point and did not want to complete it again. This is a further potential problem not encountered with paper questionnaires. If this questionnaire study were to be adapted for use in other studies it would be useful to collect feedback from participants.”

8. I would disagree that ‘the effect size estimates are therefore likely to represent the opinion of the research community.’ You only managed to get opinions from 38 academics, of unknown origin. You had a further 26 fail to complete. You provide no information about these two groups and how they differ (institution, subject, area etc). You do not provide enough information to allow me to decide if your sample is generalisable and you do not discuss this at any point. It is misleading to presume otherwise.

We have deleted this statement.
9. Throughout this study, and especially in the discussion, there is a lack of referencing. You discuss possible reasons for non-response/completion, including the method of delivery (online rather than paper). There are several references you could use (I suggest a couple below but there are lots more available).


It is well known that response rates to postal questionnaires are low, and this gives you an opportunity to discuss the potential merits of an email approach, however you do not do this.

We have updated the background and discussion chapters to this effect, and references 6, 7 and 9-11 have been added. We have added the following section to ‘Background’ (page 4 paragraph 3):

Two potential advantages of using the Internet rather than traditional mail to conduct questionnaires are lower costs [6,7] and quicker data collection[8], but a disadvantage of this method is a potentially lower response rate [7,9-11].

10. On page 8 you state ‘if this methodology is to be used by other researchers in their studies, care needs to be taken in choosing those participants who have sufficient expertise and whose views are likely to influence practice.’ This is a given, but as you don’t say anything in this manuscript about your participants I cannot tell if this is what you have achieved in this study. I am also still unsure as to exactly what you anted to achieve – an effect size or a test of the feasibility of the methods (using an email to recruit).
We have included a description of the participants in a separate sub heading in the Methods section, ‘Study Participants’ (page 6-7) (also see response to reviewer #1, point 6 above).

We have clarified the aim in the background section (page 4, paragraph 4):

“The aim of this study was to assess the feasibility of using a simple email recruitment strategy and online questionnaire to produce an estimated effect size based upon expert opinion to inform sample size estimation for a randomised controlled trial.

11. My concluding comments on this manuscript concern the message of the paper. Given this is a methodology journal I would have liked to see more focus on the methods used, and the transferability/generalisability of the methods. I would also have liked to more discussion of the methodology used (pros and cons) in the discussion section and fewer assumptions about the applicability of the method. There was simply not enough detail nor discussion to allow me to assess the strategy for estimating effect size.

By addressing the above points (5, 6, 7, and 10), and those of reviewer #2, we have addressed this point.

The methods section has been restructured to include how the questionnaire was developed (page 6) and how study participants were chosen (page 6-7), which focuses the paper on the methods used.

The pros of the study are outlined in the discussion section (page 8-9), and a ‘limitations’ sub-section has been added to the discussion (page 10-11), which discusses the limitations of the methodology used.

The issue of the transferability and generalisability of the methods is now included as part of the pros and cons of the study (above paragraph).
Reviewer #2 (Ramal Moonesinghe)

1. The authors have to define their “effect size of interest” in the methods section. It seems the effect size here is the increase in recruitment rate to the trial.

   We have clarified this in the methods section (page 5, paragraph 1):

   “An e-PIS has not been evaluated before, so no estimate of effect size (recruitment rate to the trial) exists to inform sample size estimation.”

2. The trial aims to identify the level of information needed by patients in order to decide whether or not to participate in a treatment trial. This trial involves a sample of patients not researchers (page 4, methods section). Is the effect size estimated used to calculate a sample size of patients or a sample size of researchers to evaluate the intervention?

   This has been clarified with the addition of a more clearly defined aim in the background section (page 4, paragraph 4) (Also see reviewer #1, point 10):

   It has also been further clarified in the methods section (page 5, paragraph 2):

   “If the e-PIS, once developed, is to be used by researchers, its effect on recruitment rate needs to be sufficient to justify its additional cost. The effect size estimation from this questionnaire study will be used to calculate the sample size i.e. the number of participants needed for the e-PIS study to detect a statistically significant difference in recruitment rates.”

3. The respondents to the survey estimate the increase in recruitment rates based on baseline recruitment rates and also the cost of intervention. Their estimates
are not based on the level of information needed by patients to participate in the trial. This has to be clearly explained in the methods section.

We agree that this is confusing, and have cut out the section explaining the aims of the e-PIS study, because we do not think it is relevant to this questionnaire study. The paragraph explaining the e-PIS study now reads (page 5, paragraph 1):

“A randomized controlled trial (RCT) is being developed at the University of Birmingham that aims to determine if an e-PIS (as compared to traditional paper based Patient Information Sheets), can improve recruitment to a study. The e-PIS differs from the more usual paper-based Patient Information Sheets in that it is available electronically (Internet-based) and gives potential research participants control/choice over the level and degree of detail of the information they access. An e-PIS has not been evaluated before, so no estimate of effect size (recruitment to the trial) exists to inform sample size estimation.”

4. The researchers will be using the intervention in their research. Is it possible to expect an increase in recruitment rate (effect size) using an intervention based on their own assessment? There are differences in estimates of effect size even between research fellows and senior research fellows. Are there any references to conclude that the increase in recruitment rate in an actual trial due to an intervention can be based on expert (researchers’) opinion?

The effect size estimated from this questionnaire based study will be used in sample size calculations for a RCT of an e-PIS. The RCT requires an effect size based on the average increase in recruitment rate researchers needed to see before using the e-PIS. Our results suggest that there will be differences between researchers’ perceptions of the extent to which recruitment rate must be increased before they would consider using the e-PIS. This questionnaire study aimed to establish the average effect size to be used in a sample size calculation. Since there is no previous evidence to suggest how much the intervention might increase recruitment size by, there was no other way to establish an effect size estimate. It seemed sensible to use an effect size based on what would be needed to change practice, rather than take a guess at an effect size. The use of this method to determine a sample size will be further considered (and reported) in the analysis and evaluation of the RCT of the e-PIS.
We trust that these modifications have addressed the points raised by the reviews.

Yours sincerely,

Professor S Wilson