Author’s response to reviews

Title: Identifying strategies to maximise recruitment and retention of practices and patients in a multicentre randomised controlled trial of an intervention to optimise secondary prevention for coronary heart disease in primary care.

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Author’s response to reviews: see over
Identifying strategies to maximise recruitment and retention of practices and patients in a multicentre randomised controlled trial of an intervention to optimise secondary prevention for coronary heart disease in primary care.

Claire S Leathem, Margaret E Cuppes, Mary C Byrne, Mary O'Malley, Ailish Houlihan, Andrew W Murphy and Susan M Smith

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Dear Editor,

Thank you for the opportunity to address reviewer comments for the above paper.

We are grateful to both reviewers for their encouraging positive comments about this paper. As requested, a point-by-point response to their concerns is provided in the following pages. I also attach a revised manuscript.

Please don’t hesitate to contact me if there are any further queries.

Yours sincerely,

Mary Byrne
Corresponding Author
Reviewer 1

1.1 Reviewer comment
The authors draw conclusions about “what worked for them”, which is useful, but the external reader, wishing to judge the relevance of the findings will probably have further questions. For example, did the enterprise have a novelty element, limiting the findings to more established research settings?

1.1 Our response
We thank the reviewer for acknowledging the usefulness of our conclusions. However, we would wish to stress that our intention was never simply to report ‘what worked for us’ but to highlight the relevance of our experiences for external readers. We made this explicit in our aim (“…to identify practical guidance for improving recruitment and retention of practitioners and patients to benefit future research studies”) and conclusion (“Our experiences…should inform future primary care-based research studies and help improve practice and patient participation and retention”). [italics added]. The application of the lessons we learned beyond our own context is implicit throughout the paper, particularly in the Discussion section. We are disappointed that this was not evident for the reviewer, whose opinion we value highly, but we are unsure how we can make this clearer for other readers. The findings are not limited to more established research settings – our findings apply to a wide range of practices: of the exclusion criteria listed, the only really significant criterion which distinguished participating practices from others was that they had a practice nurse involved in general patient care – and even this applies now to the vast majority of practices in the UK and RoI.

1.2 Reviewer comment
And crucially, it appears that the effort that went into establishing and maintaining recruitment and retention was substantial. Could this be quantified? The resources available to this research team might not be available to others. What would be essential and desirable in replicating the approach elsewhere?

1.2 Our response
In response to this comment, we have now added a short reflection on resources to the introductory paragraph of our discussion. In writing our paper we have hoped that our description of the effort made in respect of recruitment and retention has emphasized to others that there is a need, in applications for funding of projects, not to underestimate the considerable resources required especially in relation to recruitment. We do have detailed costings of the resources we invested in recruitment and retention (and yes, they are substantial!) While lists of costings are not appropriate for this paper, we did give one example in Figure 3 (and associated text on page 12 re 288 phone calls made to recruit 16 practices). Figure 3 was inadvertently omitted from the original submission so the reviewer didn’t see it – apologies.

1.3 Reviewer comment
There is also the rather fundamental issue of whether and to what extent this level of support for trial participants and practices, apparently more on the intervention side of the trial than on the control side, may introduce bias in relation to the study design and findings. That needs some discussion.

1.3 Our response
We have now added a sentence addressing this just before the Results section. This paper is about recruitment and retention. The level of support around recruitment applies equally to intervention and control arms of the study. Intervention practices do need more support than controls around retention, as they have more work to do. This support is an explicit component of our intervention (see study protocol, reference 24) and therefore doesn’t introduce bias.
Reviewer 2

Initial general response to this review

We fear that this reviewer has misinterpreted the basis for the paper, a misunderstanding for which we apologetically accept some responsibility. Reference in our abstract to a ‘qualitative study embedded within the RCT’ may have led the reviewer to believe that this would be a report of a qualitative study. In fact, as the other reviewer highlights positively, this is a ‘largely descriptive account’ of our experiences in recruitment and retention. The aim of the paper (as stated in the introduction) is to ‘report on the difficulties and successes experienced in attempting to apply previous knowledge to the recruitment and retention of [study] participants… and to identify practical guidance for improving recruitment and retention…’. We did not set out to systematically evaluate our recruitment strategy using qualitative methodologies. We drew on some material from the qualitative arm of our RCT (reported in full elsewhere) to support our reflections.

Thus our methods section describes how we recruited and retained participants, not how we carried out interviews and focus groups. Our results section describes our experiences and achievements in recruitment and retention, not thematically analysed quotations from participants. Given this background, we feel many of the comments made regarding rigorous reporting of a qualitative study would be inappropriate for our descriptive paper, for example:

- The paper needs a clear and precise description of how the qualitative data in this parallel qualitative study was collected… We need to know how interviewees were chosen, how qualitative data were collected, how much data was collected, how this was analysed.
- What we need is a results section which tells us why, from the perspectives of researchers and participants, each stage of the process (Initial recruitment contact, practice visits, patient contacts, consent, retention strategy) worked or did not, supported by evidence of their actual experiences and thoughts (most helpfully in quotes).
- The current discussion merely extends the reflective account of the RCTs recruitment strategy. What I would want to see here is a summary of the information obtained from the qualitative interviews with researchers and participants.

To address the ambiguity these comments raise, we have now a) added some clarification just before the ‘Methods’ section and b) removed reference to the embedded qualitative study from the abstract. We hope that this will serve to prevent other readers similarly misinterpreting the purpose of the paper.

Other specific comments from this reviewer which do not relate to the issue above are addressed in turn on the following two pages.
2.1 Reviewer comment
The current introduction is appropriate and well written. However, a major omission is any mention of the MRC framework for the design and evaluation of complex healthcare interventions. The topic and approach that the authors report is so closely related to this major current topic, that I think they need to show how what they are doing is related, or different, to the MRC framework.

2.1 Our response
We agree that the MRC framework is a critical tool in a study like ours and we have previously published a full paper devoted to its application in our study (Byrne et al. Development of a complex intervention for secondary prevention of coronary heart disease in primary care using the UK Medical Research Council framework. American Journal of Managed Care 2006; 12:261-266). In response to this review we have now added a sentence on page 6 (end of ‘Setting and Sample’ section of the Introduction) stating that we have used the MRC framework and how our work is related to it:

‘The study follows the MRC framework for developing and evaluating complex interventions: this descriptive report highlights how preliminary findings inform a definitive trial and how details of the context of a trial are relevant to its evaluation.’

2.2 Reviewer comment
The paper needs a section comprising a detailed description of the recruitment process used in this study, and precisely how it was informed by their pilot work. The pilot work is currently only referenced. The necessary detail is there but is currently spread throughout the methods and results section of the paper as written.

2.2 Our response
We are puzzled by this comment as pages 6-10 of the methods section in the paper are devoted exclusively to describing the process of recruiting practices and patients to the study. We agree that it’s important to detail how this was informed by our pilot work, and we feel the following extracts from the paper which refer to our pilot work do achieve this:

- p.6: During a pilot study of the intervention…qualitative research [26] provided valuable insights into issues surrounding recruitment and retention. Such issues included, the value of phone call contact for improving uptake, the shortage of space in premises, the need for strategies to deal with waning enthusiasm, clear protocol structures, patient non-attendance due to duplication in chronic disease management clinics and minimizing research workload for practitioners. These issues informed the design of our intervention and our approach to recruiting and retaining practices and patients.
- p.11: Based on findings of our pilot work, training on delivering the intervention (recalling participating patients and delivering a consultation at 4 monthly intervals for the duration of the study) was provided for intervention practices during two 90 minute in-house training sessions. The time and detail of this training was tailored to individual practice and practitioner needs.
- p.11: The red storage box was designed following feedback from the pilot study where practice nurses identified that they did not always have a designated room for their clinics but were assigned any available room on a daily or weekly basis.
- p.16: Based on the pilot work findings, practices were encouraged to combine patient visits where possible if overlap with other chronic disease clinic attendance was identified, in order to avoid duplication of service provision and minimize patient expenses in travel and time.

2.3 Reviewer comment
The authors describe very different healthcare systems in the RoI and in NI. This is very important and presumably they will be able to present qualitative data on the challenges of this and how they were overcome. It also needs to be reflected upon in the discussion.
2.3 Our response
We have now added a sentence acknowledging this to the introductory paragraph of our Discussion. For the reasons presented earlier, we don’t have qualitative data on the subject.

2.4 Reviewer comment
In the patient recruitment (p9) section the detail on patient inclusion criteria is superfluous for this work. We only need to know that they had CHD.

2.4 Our response
We included this detail to highlight the complexity of identifying (for recruitment) eligible patients, particularly in the Republic of Ireland where CHD registers and comprehensive computer records are rare. For this reason we would prefer not to delete this section.

2.5 Reviewer comment
The first paragraph of the Retention Strategy seems like unnecessary detail. Unless of course it was suggested by the pilot work, which could all be outlined in revised section 2 as outlined above.

2.5 Our response
We agree that we have not made clear the reason for providing such detail in this paragraph, which is to describe ways of making life easier for participating practices and thus increasing the likelihood of retention in the study. We have now added a sentence to this effect at the end of that paragraph.

2.6 Reviewer comment
The response rates - both patient and practice are strikingly high. Is this typical for Ireland? It might be worth reflecting upon this in more detail in a discussion point.

2.6 Our response
The reviewer may be referring to our retention rates (100% for practices, 85% for patients) rather than our participation rates (33.9% for practices, 56% for patients) which are broadly in line with other similar studies. Our discussion does reflect on reasons for high retention rates.

2.7 Reviewer comment
Page 13 (last line) refers to a "dynamic document." This needs to be explained.

2.7 Our response
This refers to the fact that the document is regularly updated. We agree that the term is ambiguous and have now deleted it, with no consequent loss of meaning.

2.8 Reviewer comment
I thought some of the headings in the current results section were a bit misleading. For example "Participation rates and reason" referred to a paragraph that might more appropriately be headed "Initial practice recruitment." Similarly "Patient information" seemed to relate to more to "Initial patient recruitment." I also wondered if the second paragraph on page 13 (currently unlabelled) should be "Overall retention issues."

2.8 Our response
We thank the reviewer for these observations, agree the current headings are misleading and have now made some changes.