Author's response to reviews

Title: Improving participation rates by providing choice of participation mode: Two randomized controlled trials.

Authors:

Naomi Heijmans (Naomi.Heijmans@radboudumc.nl)
Jan van Lieshout (Jan.vanLieshout@radboudumc.nl)
Michel Wensing (Michel.Wensing@radboudumc.nl)

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Author's response to reviews: see over
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Dear Editors-in-Chief,

Thank you so much for considering our manuscript ‘Improving participation rates by providing choice on participation mode: two randomized controlled trials’ for publication in BMC Medical Research Methodology and for the opportunity to revise it. We also would like to thank the reviewers for their highly useful comments and suggestions. We feel sure they helped us to improve the manuscript. Please find our reactions to the reviewers’ comments and suggestions in our point by point response and in the revised manuscript.

We would like to thank you again for your consideration and look forward to your answer on the revised manuscript.

Yours sincerely,
Naomi Heijmans, MSc

Scientific Institute for Quality of Healthcare
Radboud University Nijmegen Medical Centre
Geert Grootplein Noord 21
6525 EZ Nijmegen
The Netherlands
Tel: +31 24 36 19641
E-mail: naomi.heijmans@radboudumc.nl
Patient participation rates in primary care studies have progressively declined over the last ten years or more and the development of methods for improving participation is of growing importance. This paper makes a useful contribution to the literature on this subject. However, the statistical analysis is sub-optimal in not allowing for (a) a possible effect of host RCT trial arm on participation and (b) potential clustering of participation outcomes within practices (see below).

This was an observational study conducted within a cluster RCT of an intervention to improve cardiovascular risk management by nurses in general practices. Consent for the social network (SN) study was taken at baseline alongside consent for the RCT, but SN questionnaire/interview data was collected two months later, with the RCT follow-up at 6 months (ie 4 months later). Thus patients would have two months experience of the intervention at the time their SN data was collected. In addition, patients were not blind to the arm of the intervention they were randomised to. There is therefore a potential risk that a patient’s participation in the SN study could have been influenced by their experience of the intervention or knowledge of trial arm. For example, patients not in the intervention arm may have been less motivated to provide SN data. Consequently the analysis of participation outcomes should ideally include trial arm as a covariate. Including trial arm would also reveal whether host RCT arm assignment in itself impacted on participation in the SN survey.

The RCT used practice as a cluster variable and took account of this in the calculation of sample size. The SN study randomised patients (to participation mode) within practices (ie used practice as a stratification variable) and did not adjust for clustering. It is a common misnomer to believe that randomising within practices removes the need to take clustering into account: in fact, it does not. If outcomes are clustered by practice, this will still affect the variance estimates associated with group comparisons. In the present case, the group difference in SN survey participation may well have varied non-randomly across practices. Therefore the analysis should ideally also adjust for practice clustering.

The present analysis is based on simple chi-square tests. To include the changes discussed above, of including host RCT trial arm as a covariate and practice as a cluster variable, a more sophisticated method would be required, specifically logistic regression. The authors should either conduct an improved analysis or justify why they do not control for host RCT arm or adjust for practice clustering.

RESPONSE: Several new analyses, taking general practice clustering, RCT trial arm, and patient characteristics (sex, age, and patient group: high risk or CVD) into account have been added to the manuscript. Patient characteristics were added to meet suggestions of another reviewer. We first examined presence of clustering by calculating ICCs for all outcomes, using general practice as unit of clustering. In trial 1, ICCs for all outcomes were 0. In trial 2, ICCs for both participation rate and conditional participation rate were 0.02, while ICC for willingness to participate was 0.

For outcomes with ICC = 0, specifying multilevel models with random intercepts for general practice, and adding RCT trial arm and patient characteristics as predictors, failed to provide stable results. So, we analyzed these outcomes using logistic regression analyses. In these analyses, effect of choice of participation mode was controlled for RCT trial arm and patient characteristics. Nevertheless, we have controlled for any potential impact of clustering by including practice specific fixed effects in these models as well. As additional check for possible clustering of general practice, we repeated logistic regression analyses excluding general practice. Estimates for odds ratios of
choice of participation mode and other variables did not differ substantially compared to analyses including general practice. Although results of these analyses are not reported on in the tables, this information is now included in the endnote.

For outcomes with ICC > 0, we performed multilevel logistic regression analyses with random intercepts specified for general practice.

Effects of choice of participation mode remained stable for all outcomes in both trials.

The paper needs a section detailing and discussing any limitations of the research. If the authors decide to justify their present analysis rather than refine it, that decision should be explained in the limitations section.

RESPONSE: A section on limitations of the study is now added to the discussion section.

Minor Essential Revisions

A flow diagram, one for each trial, along the lines of a Consort diagram, showing the flow of patients in each arm through the various stages of the study, would help readers to better understand what was done.

RESPONSE: We have now added a flow diagram to the manuscript. However, as we felt that the subsequent design of the two trials would become more clear by including a time line in the flow diagram, the two trials are represented in one flow diagram.

The use of English could be improved. There are a number of poor uses that are repeated frequently throughout the manuscript. Particular ones are: “telephonic interview” which should be “telephone interview”; “choice on participation mode” which should be “choice of participation mode”; and use of “was” when referring to a percentage, which should be “were” (eg “21% was willing” (21% were willing)).

RESPONSE: Language corrections have been made throughout the manuscript.

Participation rate is specified as the primary outcome, but the results section presents results for Willingness to Participate (a secondary outcome) first. Results for the primary outcome should be given first.

RESPONSE: Results for the primary outcome are now provided first.

Results; Trial 1; Willingness to participate. “In trial 1, less patients were....” Would be better as “In trial 1, fewer patients were....”

Results; Trial 2; Participation rates. “lower than that of patient who” should be “lower than that of patients who”

RESPONSE: Corrections were made according to your suggestions.

Discussion, para 2. “Although this may be a limitation of this study....”. This sentence is not at all clear.

RESPONSE: We have decided to remove this sentence here and discussed limitations in a newly added and separate paragraph.
Reviewer 2 = Maureen Murdoch

Reviewer’s report:
Thank you for the opportunity to review this interesting manuscript. The authors raise a nuance related to improving response rates that I had not previously considered, and I hope their work will spur more research in this area.

Major Compulsory Revisions
Stylistically, this manuscript would benefit from crisper, clearer language; more concise writing; and a more active voice. For example, the first several paragraphs in the introduction could be combined into one paragraph to concisely convey the essential point of this paper. Namely,

1. “Low participation rates [in survey research] reduce one’s effective sample size [and] statistical power and may *increase risk* for selection bias.” 2. Intriguing evidence suggests that offering potential participants a choice of response mode could increase response rates. 3. But there are few head-to-head trials.

Then discuss those head-to-head trials in the second paragraph. When doing so, please be clearer about the contrasts studied in previous literature. For example, in the cancer study cited [reference 13], were individuals randomized to a choice versus no-choice arm, or were they randomized to telephone (not telephonic) interviews v. postal questionnaire? If the latter, then the citation does not really belong in this paper. If the former, what mode did the no-choice participants receive – Telephone or postal questionnaire, or something else? That study’s negative findings could have resulted if offering a choice had no effect on response rate*or* if the type of mode offered in the no-choice arm was particularly desirable and deflated the apparent difference between the two groups. I have similar questions about reference 14. Were participants in reference 14 actually assigned to a choice or no-choice arm?

Finish the introduction by explicitly stating your study hypotheses.

RESPONSE: Thank you for your extended and helpful suggestions for improving this manuscript. We feel that your examples surely helped to improve this paper.
We followed your examples to surely help to improve this paper.

Methods
The methods section is unclear, partly because too much time was spent discussing the larger study (TICD) from which this sample was derived and not enough time discussing the present study. I suggest giving the present study a short, snappy name, such as the “Social Networks in CVD Study,” and using that title throughout the paper. Open the methods section with the study population, and start with language more like the example below:

“The Social Networks in CVD Study (or whatever name they choose) was an observational study of social networks among individuals in [whatever location/state/city/institution] with known CVD or high risk for CVD. Potential participants were identified from a larger randomized controlled trial of two different interventions for CVD case management. [In *one* sentence describe the eligibility criteria for the larger study and how participants were identified for enrollment.] [X] number of enrollees in the larger randomized controlled trial were approached [describe how they were approached] and invited to participate in the Social Networks in CVD Study. Two trials were conducted. The first ran from [dates]. During this time potential participants were either randomly invited to participate in a telephone interview that asked about their social networks (the no-choice arm) or invited to participate in either a telephone interview or postal questionnaire that asked the
same questions (the choice arm). The second trial ran from [dates]. In this trial potential participants were randomized to participate in a postal questionnaire (the no-choice arm) or given the option of a postal questionnaire or telephone interview. “

How did you determine if someone had cognitive impairments or poor language skills?

RESPONSE: We followed your suggestions to explicitly provide the social networks study and larger TICD study with separate names. Throughout the document, we now use abbreviations to name these studies (SNS for the social network study and TICD-RCT for the larger RCT). The methods sections has now been revised entirely, with information added on matters to be clarified as pointed out by you and the other reviewers.

Adding a study flow chart would help readers understand the methods better (e.g., a flow showing the number potentially eligible for study, the number agree to participate, drop outs and losses to follow up, and the number analyzed).

Table 1 is not terribly useful and should be deleted.

RESPONSE: A study flow is added to the manuscript and we have dropped table 1.

Clarify that, while the Social Networks in CVD Study is an observational study (at least, I assume it is from the description given), the present effort is a randomized controlled trial.

RESPONSE: We have now described this in the first paragraph of the methods section.

Add a new subheading corresponding to data collection procedures. Please explain why two trials were run. Please explain why the n was twice as large in the second trial. Please explain why these trials were run sequentially and not concurrently. It doesn’t sound as if true randomization occurred in this study—is this correct? Rather, it sounds as if 2 different consent documents were prepared and randomly interleaved. If so, were the documents truly randomly interleaved, or were they systematically interleaved (e.g., every other document was no-choice). How was random interleaving assured? Did recruiters simply take the top consent document and, depending on which form it was, determine which arm the participant went into? If not, please clarify how randomization was achieved. Could recruiters access or guess the patient’s assignment prior to enrollment? Typically randomization occurs after participants agree to participate, but that doesn’t seem to be the case here. Please indicate whether recruiters, participants, and analysts were blinded to study hypotheses and/or study arm assignment.

RESPONSE: A subheading for data collection procedures has been added, information on the questions you raise is now included in the methods section.

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RESPONSE: A subheading for data collection procedures has been added, information on the questions you raise is now included in the methods section.

Under measures and outcomes, I suggest you choose one primary outcome—presumably overall participation rate—and identify the rest as secondary outcomes. Please always report results for the primary outcome first in the text and in the Tables.

RESPONSE: Done.
I suggest you choose one of the AAPOR standard definitions for their primary outcome. (American Association for Public Opinion Research: Standard Definitions: Final dispositions of case codes and outcome rates for surveys, 4th edn. Lenexa, Kansas: AAPOR; 2006.) Most studies of this type choose definition #2 (AAPOR, 2006, pg 32), and that seems to come closest to what is described here. To be entered in the numerator, did participants have to fully complete the questionnaire or telephone interview, or were some missing answers allowed? If so, how many missing answers were allowed before the individual was considered a non-participant? Or was the return of a questionnaire, whether completed or not, sufficient to count as a participant? If a participant answered just one telephone question and then aborted the interview, was s/he counted as a participant? I was not entirely certain who went into the denominator—again, using the AAPOR definitions and providing a study flow chart could help clarify this for readers. Was this an intention-to-treat analysis?

RESPONSE: We have now added corresponding AAPOR definitions to the outcomes and specified completion, partial completion and withdrawal in the methods section. However, please note that completion of the SNS interview and questionnaire is dependent on the social network composition of specific patients. If networks contained few persons, fewer questions needed to be completed than when networks contained many persons. This explanation is now also added to the methods section.

I did not understand the definition of the conditional participation rate. Perhaps if I understood the recruitment and enrollment process better, this would be clearer. As best I can tell the numerator is the same as the main outcome, but the denominator is different. Somehow, you are assessing what proportion of people said they would participate and then actually did. However, I really cannot tell who is going into this denominator. Again, a study flow chart would help (as would clearer language). The same basic critique applies to “willingness to participate.” The figure was helpful to some degree, but if the authors used a flow chart and clearer language in the text, the figure could actually be deleted.

RESPONSE: the definition of conditional participation mode is now clarified and we have added information to which AAPOR this outcome corresponds. A study flow has been added (as also noted by the other reviewers) to the manuscript. The figure has now been adjusted as well.

If I understand “preference for participation mode” correctly, you are reporting [the number of people who selected telephone interviews divided by all those offered a choice] to the [number of people who selected a mailed questionnaire divided by all those offered a choice]. Correct? Perhaps this would be clearer if it were restated, “Among those offered a choice, we also compared the proportion of people choosing telephone interviews to the proportion choosing postal questionnaires.” This does not map to the Figure’s definition. Please clarify. In the introduction, you should explain why you are looking at this outcome, and there should be a specific hypothesis linked to it. Consider shortening the term “preference for participation mode” to “mode preference.”

RESPONSE: We have accepted your suggestion to use ‘mode preference’ instead of ‘preference for participation mode’.

Mode preference was defined as [number of patients who selected a participation mode divided by those offered choice AND who were willing to participate in the SNS]. This information was missing in the methods section and has been added now.

Initially no specific hypotheses were derived for mode preference as this outcome was determined additional to the other outcomes. We now included in the introduction section that it was expected that patients would voice preference for a particular participation mode.
Consider rewriting the sample size and analysis section to something more concise, such as, “Assuming a two-tailed alpha of 0.05 [it was two-tailed, yes?], 80% power, a response rate 50% in the two no-choice arms and 65% in the two choice arms (or 35%, because this is two-tailed), we estimated we needed 338 participants in each of the two no-choice arms and 338 in each of the two choice arms (total N = 1,352).” Or did you need just 338 participants spread across both no-choice arms and 338 participants spread across both choice-arms (total N = 676)? By the way, please consider using the terms “choice” and “no-choice” to describe the study arms. The “choice format invitation” and “single format invitation” terms are confusing.

RESPONSE: The sample size and analysis section has been adjusted according to your suggestions. Please note that the power calculation applied to each trial separately so that we needed a total of 338 patients in each trial (no-choice and choice arm together).

Results
Instead of using the terms, “Trial 1” and Trial 2,” which force the readers to constantly refer back to earlier segments of the manuscript to remind themselves what was studied in each, please consider using the terms “No Choice (telephone) versus Choice” and “No Choice (postal questionnaire) versus Choice”—or something along that line. Please do this for the text subheadings and for the Tables. Again, always report the main outcome first.

RESPONSE: Done.

Table 2 would be more useful if it were additionally stratified by study arm assignment. Reporting the overall summaries is important, but please also describe the stratified results. For example, how many women were randomized to Trial 1 no choice (telephone) versus choice? How many women were randomized to Trial 2 no choice (postal questionnaire) versus choice? Systematic differences in the characteristics of people assigned to the different treatment arms could bias study results. Table 2 is where readers get a sense of whether that happened.

RESPONSE: This table has now been adjusted and contains information stratified by study arm assignment.

Table 3 and 4 should be combined into a single table. N’s should not have their own row but should be reported in the columns directly under the subheadings (e.g., No choice/interview/n = 198). Participation rate should be listed first in the rows. Present separate column headings for the test statistic, degrees of freedom, and p-values.

RESPONSE: Done.

For Table 5, please pivot the table so that the column subheadings are Trial 1/no choice (telephone)/n, Trial 1/choice/n, Trial 2/no choice (postal)/n, and Trial 2/choice/n. Wasn’t conditional participation already reported in Tables 3 and 4? I would omit these data from Table 5. Where are the test statistics, degrees of freedom and p-values for Table 5?

RESPONSE: We have not adjusted Table 5. However, your reaction clearly indicates its content was not clear. Therefore, we have expanded our explanation and description of this table in the methods and results section. Results on mode preference (table 5) are additional to other outcomes and concern only data of patients from choice arms in the two trials. Therefore, no formal testing of mode preference is provided.

Critical information about the methods is reported in footnote in the Tables.
Please move this text to the Methods section of the paper.
Discussion
The discussion is difficult to critique because so many methodological issues are unanswered for me. This section would also benefit from clearer, crisper language. I might suggest, instead of reporting results for Trial 1 and Trial 2 separately, that the authors embrace their mixed findings and discuss the two results side by side. For example, start the first paragraph thus: “Findings from this study were mixed. Individuals offered only a telephone interviews were as likely to return a survey as those offered a choice of mode, whereas those offered a only a postal questionnaire were substantially less likely to return a survey compared to those offered a choice.”
Regrettably, until the methodological issues raised above are addressed, I don’t feel I can further critique the discussion.

RESPONSE: We have accepted your suggestions for the first paragraph of the discussion.

Minor Essential Revisions
In line 78, please substitute the words, “in the present study” for “In this study.” Otherwise readers will think you are still talking about citation 14.

RESPONSE: Done.

Please omit the sentence starting on line 163. It has nothing to do with the present study.

RESPONSE: Done.

The text in the results should briefly summarize the Table’s results, not exhaustively repeat the same information.

RESPONSE: results are now described as concise as possible, for table 1 this has resulted in a shortened text.
Reviewer's report:

Major Compulsory Revisions
1. The authors briefly mention that readers should be cautious when interpreting the generalisability of their findings. In the discussion the authors could perhaps state again that patients with cognitive impairments and poor language skills were excluded from the study.

RESPONSE: Following your, and the other reviewers, suggestions we have added a more extended limitations section to the discussion. Here, we more broadly describe concerns on generalizing findings from our study.

Minor Essential Revisions
1. How was an interview or questionnaire judged to be ‘completed’ for the follow-up survey? Given the survey population I would have expected a number of partial interviews (i.e. terminated interviews / partially completed questionnaires).

RESPONSE: We have now added a more detailed description of the questions on social networks and added that the number of questions patients could answer is dependent on their social networks. E.g. in case patients did not received any information on CVRM or had no persons within their networks which they consider as important for handling their condition or disease, answering only two questions would mean a complete interview or questionnaire. However, for patients who had received information from multiple persons and who had multiple persons within their networks they considered as important for handling condition/disease, total number of questions could increase up to a maximum of 45. However, we had in fact missing data in the SNS. Therefore it was added that we also counted partial completions as participants.

2. The sample characteristics for each Trial (Table 1) could be shown separately for the single format vs. choice groups.

RESPONSE: Done.

3. Tables 3 and 4 could be written as: willing to participate, n (%): participation, n (%). Telephonic interview would be clearer than interview. X2 (chi-square test) and RR (relative risk) need to spelt out as abbreviations to the table.

RESPONSE: Tables 3 and 4 are adjusted according to your suggestions and those of the other reviewers. Abbreviations for chi square and relative risk are spelt out.

4. References: There are a number of typos in the references (e.g. American Association of Public Opinion Research).
RESPONSE: the reference list has been checked for spelling mistakes. We specifically considered the spelling of the reference you have cited and noticed that the American Association for Public Opinion Research itself uses ‘for’ instead ‘of’ in its name.

Discretionary Revisions
1. Given the data collected in the baseline survey (including sex, age and risk of cardiovascular disease) I would have liked the researchers to examine subgroup differences in the participation rates. This would allow some consideration of the issue of bias.

RESPONSE: Considering your suggestions and those of reviewer 1, we have now added analyses taking such differences into account.

2. The authors explain that participants who indicated that they were willing to participate by both modes of participation were all sent a questionnaire. This may have had a detrimental impact on response – a patient indicated a willingness to participate by both modes but could not in practice respond by telephone – and so may have been discouraged to participate. Perhaps the authors could do a sensitivity analysis and compare participation rates between single vs choice excluding those participants who expressed no preference in their mode of participation.

RESPONSE: Sensitivity analyses were performed and added to the manuscript.

3. Abstract: Line 28 could be made clearer (e.g. conditional participate rate was higher for those offered a single format invitation for interview).

RESPONSE: The abstract has been revised.

4. It would be useful to know the proportions of younger/middle-aged adults who used the Internet on a daily basis to put the figures given for older adults into context.

RESPONSE: This information is now added to the introduction.

5. The results would be clearer - in my opinion - if the Relative Risks were presented comparing those who were offered choice vs those offered a single format invitation (i.e. opposite to the way presented).

RESPONSE: We have considered this suggestion but propose to stick to the current presentation.

6. The authors compare their findings with Denniston et al (reference 13) with respect to the participation rate and the willingness to participate. They do not mention any comparison with respect to conditional participation. Was this also examined by Denniston et al, and if so, what did they find?
RESPONSE: Thank you for making this remark. After reconsidering the study of Denniston et al (2000), we saw that Denniston et al were actually reporting conditional participation rates ('initial completion rates given that consent was obtained'). This section in the discussion has now been corrected and we have added a comparison to another study.
Reviewer 4 = Linda Ng Fat

Major compulsory revisions

1. I think what is missing is references to the literature on telephone versus questionnaire mode. For example in line 258, you suggest that it might be ‘participation mode’ that has influenced the higher participation rates in trial 1, than trial 2 with choice option, what does the literature say about telephone versus questionnaire? Does it support your suggestion? (e.g. Siemiatycki, ‘A comparison of mail, telephone, and home interview strategies for household health surveys’)

RESPONSE: Literature which compares choice and no-choice for participation mode using telephone interviews and questionnaires, is scarce. Therefore, we have now inserted a comparison to literature on no-choice interviews and no-choice questionnaires.

2. Following on from this it might be useful to expand on lines 264-265, where you mention that some patients might be lost when participating by questionnaires. While it was not the aim of your study to compare these two modes of data collection, I think it requires a substantive interpretation. Why might postal questionnaires be less successful? Did the questionnaires have to be posted back by the participants themselves meaning additional effort on their part? Particularly as more individuals selected questionnaires when given a choice (Table 5), yet a smaller proportion actually participated.

RESPONSE: We have clarified our explanation on why interviews seemed more successful than questionnaires in the discussion.

3. In the Methods ‘design’ section can you please provide further information on the telephone interview for example how many attempts were made to reach the participant? At what time of day where participants called? Likewise with the questionnaire, did this have to be posted back by participants? Did the participants have to pay for the questionnaire to be posted back?

RESPONSE: This information is now added in the methods section.

4. In table 2 you provide characteristics such as mean age of trial 1 or 2. Can these characteristics also be provided for the ‘no choice’ versus ‘choice’ groups? As it could be possible that different characteristics in each of the sub groups may have skewed the results?

RESPONSE: Table 2 is now expanded to include information for no-choice and choice arms.

5. Can you please expand on how general practices were chosen? And also provide brief geographical information as to where these practices were based? From my reading it is not clear in what location the study has taken place.
RESPONSE: It is now described in the methods section that general practices were from several geographical areas from the Netherlands. Although this is a very summary description, we feel hesitant to include too much information on the larger program evaluation (now named as ‘the TICD-RCT’ in the manuscript) which was responsible for the inclusion of the general practices and has its own study protocol published elsewhere. Therefore, we would like to refer to the TICD-RCT study protocol where possible.

6. Lines 135-136 you mention what patients were excluded. I think this is a limitation to the generalizability of your findings which you may want to include to the final sentence in the discussion.

RESPONSE: This information is now added to the newly added limitations section in the discussion.

Minor Essential Revisions
There are a few spelling mistakes
1. Lines 53 to 54, ‘..and found that response rates declined’ ... for what? Although it is clear that you mean ...i.e. ‘when using web based modes’, given the rest of the paragraph, but it currently reads like half a sentence.

RESPONSE: we have added ‘of those allowed to choose a participation mode’ to this sentence.

2. Line 65 ‘percentage’ should be ‘percentages’
3. ‘Send’ should be ‘sent’ e.g. lines 105, 270, 390
4. Line 111, ‘by’ should be ‘in’
5. Line 273 ‘questionnaired’ is not an English word

RESPONSE: We have corrected the spelling mistakes.