Reviewer’s report

Title: Recruiting vulnerable populations in survey research: a comparative trial of 'opt in' versus 'opt out' approaches

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Reviewer: Sarah Damery

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This was an interesting paper that addresses the important issue of the impact that different survey recruitment approaches (opt in vs. opt out recruitment) may have on survey response rates and thus on generalisability and the validity/robustness of the resulting research findings. However, I believe that there are a number of issues with the paper and inconsistencies in the text throughout that will need to be satisfactorily addressed before it can be considered worthy of publication. All of the following comments should be considered major compulsory revisions.

ABSTRACT

1. There needs to be a specific ‘methods’ section in the abstract rather than just background/results/conclusion. This is particularly important because of the somewhat complex design of the study described in the paper. Some sense of the number of people who were included in the opt in and opt out groups; the nature of the population that was included in the research etc. needs to be provided.

BACKGROUND

2. The authors (correctly) state that a high response rate is necessary for yielding a representative sample. However, some indication as to what constitutes a ‘high’ response rate (backed up from the literature) is needed i.e. how high is high? 60%? 70%?

3. In the first paragraph of the background section, the authors state that survey response rates have been reducing over time. Yet to back this claim up, they cite a reference from 1981! A reference from 31 years ago is hardly a recent piece of evidence that lends weight to the claim about a trend for falling response rates.

4. 2nd paragraph of background: “Although ethical decision-making positively informs the design, planning and execution of research...” What does ‘ethical decision-making’ mean?

5. Much of the argument in the paper hinges on the assertion that ‘some research ethics committees now insist in certain circumstances that researchers can only approach those who have responded positively to a letter of invitation...’ The authors need to clarify how widespread amongst RECs this requirement is; how recently this requirement was introduced, and the ‘circumstances’ in which
such a recommendation is made. I have been undertaking survey research with vulnerable populations for a number of years and have never been required to take an 'opt in' approach to survey recruitment. Therefore, I wonder how many RECs this assertion applies to. Is the requirement formalised in NRES guidance? (if so, reference needs to be made to the relevant document).

6. I am not sure of the validity of the authors' argument that a requirement for participants to opt in to research without seeing a questionnaire obstructs the informed consent process. Surely informed consent is made possible through a well constructed participant information sheet which is provided to potential participants when they are initially invited to participate in a piece of research.

7. Again, the references used in the paper do not give the impression that much of what is being discussed represents the most recent or up-to-date situation. The authors say that the opt in method is favoured by most RECs, but that there are some RECs that say that opting out is acceptable. Aside from my point 5 which questioned how widespread the requirement for participant ‘opt in’ actually is, the references used to back up the claims about REC behaviour and requirements here are 6, 5, and 6 years old respectively. Does this really represent current REC practice?

METHODS

8. The text in the first paragraph of the methods section refers to the IMPROVE survey, but the reference given is for the VOICES survey, and subsequent text refers to the VOICES questionnaire. A clearer explanation of how these two studies/surveys fit together is needed as this is currently difficult for the reader to understand.

9. How did the ONS derive the sample of deaths in the two districts? Was it a random sample? Or were all deaths during the specified time period extracted?

10. The odd numbered records were assigned to the ‘opt in’ group and the even numbered records were assigned to the ‘opt in’ group. This is clearly incorrect as one of these groups must refer to the ‘opt out’ group.

11. Further to point 10 above, what do the authors mean even or odd numbered records? Were these ‘numbers’ randomly assigned within strata and groups chosen following this assignment? Or were records numbered consecutively in some other way to derive the odds and evens?

12. Further to point 11 above, presumably the Group 1 and Group 2 invitees were split equally across the two districts rather than all the opt in people coming from one district and all the opt out people coming from the other. Whether or not this is the case is not particularly clear from the descriptive text and needs to be clarified.

13. Were the opt in group also given the opportunity to telephone ONS to request no further contact (rather than this being solely done via reply slip in this group?) If not, why not?
14. “If informants did not decline or had not yet returned the questionnaire, two reminder letters were sent after three, and then two weeks.” This sentence does not make sense.

15. It’s not clear how ‘time to response’ was defined. For example, this could mean time between invitation and the research team receiving the completed questionnaire, or (for the opt in group) it could mean time between invitation and the research team receiving a positive response or ‘correspondence’ from the informant indicating that they would like to have access to the questionnaire. Clearly in the former context where the participation process inevitably takes longer for the opt in group who have the additional step of requesting the questionnaire before it can be completed, comparison of time to response based on receipt of a completed questionnaire is a spurious comparison to make between the two groups. If time to response was indeed defined as the time between invitation and receipt of a completed questionnaire, these analyses are questionable and add little to the argument of the paper when the response process was longer for opt in participants by default. Thus, these results ought to be removed or a sound justification for their inclusion offered.

RESULTS

16. What constitutes a ‘formal complaint’ about the survey? Detail is needed here about the procedures for complaint that were communicated to those in the opt in and opt out groups i.e. was it the standard text in the participant information sheet “if you wish to make a complaint about any aspect of this research please do x”? Or was some other means of complaint made available to people?

17. The final paragraph of the ‘response’ paragraph states that only 2 calls were made to the bereavement support line. This is the first reference to bereavement support as part of the study – more explanation is needed earlier in the paper to describe the options for participants here.

18. Did analyses control for the period of time since the death that the informant received the questionnaire? More recently bereaved individuals may have found the survey more distressing than those for whom a longer time had elapsed since bereavement, thus this could be a significant confounder for the results obtained in the opt in and opt out groups. The authors should address this point.

19. I'm afraid that I did not understand the text in the paragraph beginning “An additional quality indicator which measures the contrast between respondents and non-respondents...” at all. This section needs to be rewritten so that it can be understood.

20. The fact that opt in respondents were found to be more likely to have had poor or unsatisfactory experiences or insufficient support seems to run counter to the assertions evident in the other literature (and in the authors’ own argument in the background section) that opt in methods restrict the nature and range of responses where it was asserted that non responders are less likely to be satisfied than responders. It appears in this case that those for whom
participation was made more difficult by the necessity to opt in were actually more likely to be dissatisfied than those individuals being put off by the complex participation process and their views going unrecorded. This warrants comment and explanation/justification by the authors. This is particularly important as the authors pick up on this in the discussion as a negative point because they perceive the higher proportion of negative or dissatisfied responses in the opt in group as evidence of bias and unrepresentativeness. I do not agree that this is necessarily the correct interpretation.

DISCUSSION

21. The 'opt out' method was associated with a higher response rate than the 'opt in' method, which was considered by the authors to represent a conclusive finding that opt out methods are superior to opt in methods. However, the authors need to consider the extent to which this finding is generalisable. It may be an artefact of the types of questions that formed the content of the survey used in the research being undertaken. Similarly, it may be due to the specific population that was included in the research. How can we know that a similar study undertaken in a different topic area and/or with a different study population would not find very different results re the relative merits of an opt in vs. opt out approach?

22. There were a number of limitations to the approach taken in this study (many of which I raise in my comments in this review). The authors need to show awareness of these and address them in a standalone ‘limitations’ section.

23. At what point in the invitation process were members of the opt in group given details of how they could access the questionnaire online? Was a link given in the participant information sheet/invitation letter? Or did a reply slip have to be returned before either a paper copy of the questionnaire or the link to the online version were communicated to interested individuals? I would hope it was the latter, otherwise giving people in the opt in group the link to the online survey ‘up front’ takes away one of the main distinctions between the opt in and opt out groups i.e. that those opting in did not have access to the survey as a means of helping them make up their minds whether or not to participate in the research. The authors need to clarify this.

OTHER CHANGES AND TYPOGRAPHICAL ISSUES

24. In the abstract (‘results’ section), the text which reads “...assignment to the ‘opt out’ group was an independent significant independent predictor of response” has one too many ‘independents’.

25. Throughout the paper, p values should be given as e.g. 0.02 or 0.001 rather than .02 or .001.

26. The phrasing at times is quite unwieldy. For example, saying ‘...participants assigned to the ‘opt in’ group were statistically significantly more likely to...’ is rather a mouthful. Simply saying ‘significantly more likely to’ will suffice throughout the paper (particularly as the p values given to illustrate the degree of
significance make it clear where this was ‘statistically significant’ and where this was not).

27. In the paragraph labelled ‘scientific rigour and bias’ there are missing words in the sentence which begins ‘For instance’.

28. Tables: The usual convention is for the absolute numbers to be given first, and the % in brackets afterwards rather than the other way round as figures are presented here.

29. Chi-squared figures only need to be quoted to 2 decimal places.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests.