Author's response to reviews

Title: Can obtaining informed consent alter self-reported drinking behaviour? A methodological experiment

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

Thank you for considering our manuscript for publication in *BMC Medical Research methodology* Journal. Please find attached a revised version of the manuscript taking into account the editorial comments and those of the reviewers. You will also find below a point-by-point response to these comments.

**Editorial comments:**

1. Kindly add a sentence of adherence to CONSORT in the text of the manuscript.

   **Response:** We have added this sentence in the beginning of the results section

**Reviewer #1 comments:**

**Abstract**

2. P2, line 44, run in phase is an unclear statement for an abstract, need Explanation

   **Response:** This sentence now reads as ‘two phases (an initial run-in phase followed by the main phase)’ p2, line 36.

3. P3: line 51, which……dependence’ delete

   **Response:** The referred texts have been deleted.

4. AUDIT score ranges from x to x

   **Response:** AUDIT score range has been added, p3, line 45.
Introduction

5. Can you please explain the Zelen design

Response: Have briefly explained the Zelen design on p4, lines 67-70.

6. Line 98: can you provide more detail or examples on what the various types of social desirability are and their impact on underreporting

Response: Have explained social desirability on p5, 6 (lines 106-114), including description of how we think it could have an impact on our research.

7. I am not convinced that a consent form would lead to different reporting in drinking behavior, it is discussed but not convincingly. Are there clear studies that show this is an issue or a theory why this would be or other reasons?

Response: We have added couple of sentences discussing under-reporting of health risk behaviour and anonymity on p4 (lines 73-76). Then in lines 81-82, we state that informed consent prevents anonymity and hence has an impact on participant’s behaviour, cognitions, or emotions. We also have added content in lines 76-78 specifically on issues concerned with self-reporting of alcohol consumption and related behaviours.

Methods/Results

8. Can aim move to introduction.

Response: Aim has been moved to Introduction.

9. The population that was recruited from was not very clear.

Response: The population that was recruited has been made clearer, reported in lines 147-150.
10. Line 198 to 206 can that go in flowchart to reduce text.

**Response:** Table 1 provides an overview of the recruitment profile of participants by phases that include the text in line 198 to 206 of the original manuscript.

11. Was the study powered enough to detect interaction effects, was this just interaction effects without the single variables that were compared in the model?

**Response:** The power calculation performed at the end of the run-in phase was based on the primary outcome, i.e. mean AUDIT score, obtained in the run-in phase. So it is possible that the study was not powered enough to detect interaction effects. Interaction effect terms were added to main effect regression models.

12. Line 223-226: can you explain in simple words what that means

**Response:** Have now explained the interaction effects on p11, lines 228 - 229; 236-238; 240-241.

**Discussion**

13. Line 237: can you tell us about the specific locations, was there a systematic difference? Later on you discuss the differences again re location, maybe discuss together for clarity

**Response:** The specific locations are discussed in the 2nd paragraph. The 1st paragraph describes all extrinsic factors that we think could explain the differences in the outcomes by phases while the 2nd para investigates the influence of each factor in this study.

14. Please put in the flow chart: in which phase which locations were used, with the associated response rates, or response rates can go in table
Response: This data now appears in table 1.

Reviewer #2 comments:

15. In the last sentence of the introduction, the authors state the main goal of the experiment. Along with this should be a statement regarding what the authors believe was/is the main mechanism hypothesized to drive differences between individuals who do and not receive informed consent. Put another way, how does being informed influence reporting behavior? This, to me, is particularly important because the direction of the observed effect in the run-in phase is opposite to the hypothesized direction.

Response: We have stated our hypothesis in 1st paragraph of the Methods section, line 126-128.

16. On page 9, the authors describe power calculations to detect “a statistically significant difference between the two groups”; what would the authors have considered significant? In particular, what would have been a meaningful difference (for either outcome) that, if it had been seen, might change practice?

Response: At the outset, although we hypothesised that those in the intervention group will report reduced drinking behaviour compared to the comparator group, we were not aware of any similar studies upon which to base our effect size calculation. So, we conducted an initial run-in phase and decided to proceed further if there was a difference in the primary outcome between the groups. As there was a difference of almost one point between the groups, we decided to proceed further with the main trial with the sample size based on the mean AUDIT score at the run-in phase. All considerations of statistical significance are at the conventional 95% level.
17. I don’t understand the numbers in Table 2. In particular, why don’t the IG and CG columns have a total of N=189 each, as suggested by Figure 1?

Response: Table 2 reports the secondary outcome, AUDIT 8+. The numbers in Table 2 refer to those who scored an AUDIT score of 8 and above. The percentage in parenthesis is calculated from the total number of participants in that group, for example, for Combined (3rd row), 101 is 53% of 189; 92 is 49% of 189.

18. Were participants aware that the study was double-blinded?

Response: Participants were unaware of the true nature of the study and this is now reported on p6, lines 108-109 in the updated manuscript.

19. The main analysis is an intent-to-treat type analysis that ignores whether or not the individual actually read the informed consent form. This is all very well but I wonder if the authors are in a position to speak at all about differences on an “as treated” basis. They do comment on the time taken to complete the questionnaire and I wonder if that was actually measured and could possibly be used as a proxy for whether or not the individual read the forms properly. I also wonder if there were differences in whether or not individuals read the forms across the two phases.

Response: That would have been a very interesting observation and agree that it could be used as a proxy for whether or not the individual read the forms properly. However, we did not record the time taken to complete and to do so very obviously (i.e. being closely watched) may have interfered with questionnaire completion.

20. Although I realize that the authors did not pre-hypothesize differences across the phases, I think the conclusion that “setting” requires consideration, at least with “phase” as a surrogate, is one that deserves a little more attention in the Abstract. It is the main focus of the Discussion and, to me, one of the more interesting results that reaches should be aware of.
Response: We agree, this has been added to the Results, in line 51-52.

21. It strikes me that the phenomenon that the authors are addressing is related to the Hawthorne effect which does have a modest literature in the social sciences. I think it would be worth pointing this out, likely in the discussion.

Response: In the introduction, we refer to ‘demand characteristics’ (p5, line 93) and ‘research participation effects’ (p6, lines 117-118), both the terms are related to the Hawthorne effect, which is also now more explicitly referenced (p5, lines 89-92).

Thank you for your consideration.

Sincerely,

Lambert