Author's response to reviews

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

Authors:

Lambert M Felix (lambert.felix@lshtm.ac.uk)
Patrick Keating (patrickkeating1@gmail.com)
Jim McCambridge (jim.mccambridge@york.ac.uk)

Version: 4 Date: 21 January 2015

Author's response to reviews: see over
Dear Professor Haneuse,

Thank you for considering our manuscript for publication in *The 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.

1. On page 10, line 215, the authors report that the mean age of the participants was 23 years. This strikes me as being quite old for an average age of university students in the UK and deserves better consideration. The authors should report more detail on the overall distribution possibly via categorization. Was it skewed to the right, for example? Either way, I suspect the authors considered a simple linear interaction for the intervention effect. Assuming this is the case, is a linear interaction plausible? I wonder if categorizing age would be more reasonable but can’t tell because we don’t have sufficient information.

**Response:** Age distribution is now described in lines 186 – 187. Further data on age, with categories constructed, and study of interactions by age categories on primary outcome is reported in lines 200-201 and on secondary outcome in line 209. It is also described in table 3 on page 19.

2. In the reviewer #1’s comments, they asked the authors to provide an explanation (in simple words?) of the interactions that they report. One such explanation is in lines 239-240, although I find this to be inadequate. Specifically the new sentence actually describes a main effect for gender rather than an interaction between phase and gender.

**Response:** Thank for spotting this. The interaction effects are described in lines 195-201 and 205-209. A sentence is added to further describe the interaction effect in lines 199-200 and 208.

3. Although this wasn’t asked for during the first review, I think the paper could benefit from a table reporting the interaction terms. They are mentioned in the text but a table would be helpful for readers. To minimize the number of tables in the paper, I’d suggest combing the current tables 2 and 3 into a single one.

**Response:** The original tables 2 and 3 are combined in the current table 2 while the new table 3 summarises the interaction terms.

4. In my first set of comments I commented on the difference between the intent-to-treat analysis that the authors perform and a possible as treated analysis that might consider adherence to the intervention? (i.e. the study participants actually read the informed consent form/information sheet). The authors mention in their response that they
don’t have access to timing. While I appreciate that, there should be better discussion on this broader point in the manuscript. For example, how would the authors have done things differently? One possibility is to ask a question of the participants who received the intervention that, perhaps indirectly, evaluates whether or not they read the information sheet. In the discussion, the authors have an opportunity to be a little creative in what they suggest.

**Response:** This is very helpful and is now discussed towards the end of the discussion section.

5. Reviewer #1 requested that the authors report response rates across stages of recruitment. Table 1 goes some way to address this but not completely. For a start, the authors only report numbers and not rates. Secondly, it isn’t clear how many students satisfied all three screening questions. For example, in the first row, should we take the smallest number as the appropriate number (i.e. 106)?

**Response:** Table 1 is now updated

Thank you for your consideration.

Sincerely,

Lambert