Reviewer’s report

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

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Reviewer: Sebastien Haneuse

Reviewer’s report:

This paper describes a randomized trial designed to examine the impact of informed consent on the reporting of alcohol-related behavior. Overall the paper is interesting and well-written. Below are some comments, most of which require editing (rather than re-analysis).

Minor Essential Revisions

* 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.

* 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?

* 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?

* Were participants aware that the study was double-blinded?

* 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.

* 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 readers should be aware of.

Discretionary Revisions

* 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.

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

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

**Declaration of competing interests:**

I declare that I have no competing interests