Author's response to reviews

Title: An Exploratory Randomised Controlled Trial of a Premises-Level Intervention to Reduce Alcohol-Related Harm Including Violence in the United Kingdom

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Author's response to reviews: see over
Dear Jim,

Very many thanks for your letter containing reviews of our manuscript “An Exploratory Randomised Controlled Trial of a Premises-Level Intervention to Reduce Alcohol-Related Harm Including Violence in the United Kingdom”. We would like to thank you and the two reviewers for what have turned out to be useful comments that have allowed us to greatly improve our work.

In your letter you asked “[w]e would be grateful if you could address the comments in a revised manuscript and provide a cover letter giving a point-by-point response to the concerns.” In accordance with your request, we have copied all comments into this letter and under each provide information on how we have addressed each point. We have combined comments that substantially overlap but distinguish between commentators using AE for Associate Editor, SR for Reviewer Stella Resko, LJ for Lisa Jones and then the suffix 1, 2, 3... and so on to denote comment number following the order in which they were received. Where it has been helpful to split one comment into two we have further appended the suffix a, b, c, and so on.

We have also adjusted the manuscript using information in the “[a]uthors' checklist for manuscript formatting”.

1. We have rewritten the manuscript and strengthened the overall structure.

AE 2

I would also like to ask if the authors could provide a bit more clarity around the data analysis and outcomes regarding violence. I am not familiar with the statistical techniques used, but from what I read it appears that the analysis compared case premises post intervention to the all premises pre intervention and control premises post intervention combined. It would be useful if the authors could provide failure figures pre and post intervention for cases and controls separately, as figure 4 appears to show the failure rate to be lower in case premises at both the beginning and end of the analysis period. I find it difficult to interpret the results of the analysis as they are reported.

You are correct in that the effect of the intervention is assessed against the three other cells (pre-intervention for experimental and control premises and control premises post intervention). However, the number of premise and assaults across the intervention period is low, as you might expect, and while the 12 month analysis of premises data suggests matching achieved it’s aim (presented in the manuscript) we have a fair bit of noise in these follow-up data. Further, the analysis as presented is exactly what we would use for a full trial, the reason being that count models are susceptible to censoring; something that is treated rather arbitrarily in many studies but is obviously an issue when an intervention is introduced into an ongoing process. It really makes a lot of sense to have the baseline data in there - the Nelson Aalen figure shows a bit of wobble in the pre-intervention period, which you picked up on, but it is reasonable to assume that this is an artefact rather than a systemic failure of the matching process.

If I start carving up the analysis then I make the model more susceptible to noise and depart from the intended purpose of this paper, to inform a full trial.
AE 3

It would also be useful if the authors could discuss in more detail the implications of the suggestion that 517 premises would need to be included in the study before significance emerged. In reality, few drinking environments would contain this number of pubs, bars and nightclubs, regardless of their risk status. Whilst it is feasible to conduct a multi-location study of this size, what does this actually mean for practitioners on the ground? Would the intervention be effective at a local level?

3. The number of at-risk premises in one UK city will likely be far lower than the required 517. However, a national trial could easily identify and intervene in sufficient premises. We have updated the conclusion to discuss this in more detail. In Wales, for example, police estimate there are at least 1500 at-risk premises.

AE 4

I think the paper is certainly useful and publishable following structural adjustments, but I would be concerned that readers may pick up on the 10% reduction (even if non-significant) and tout this as a measure of effectiveness, and I think the authors should exercise a bit of caution here.

4. Thank you for spotting this. All reference to "10% reductions" have been completely removed.

AE 5

Please include a 'Competing interests' section after the Conclusions. If there are none to declare, please write 'The authors declare that they have no competing interests'. Please check the instructions for authors on the journal website for a full list of questions to consider when writing your competing interests statement.

5. This Section has now been added.

AE 6

Please include the name of the group within the list of authors, by adding the name to the 'first name' box; and the bracketed abbreviation to the 'last name' box in the submission system. Please remove the names of the members of the group from the title page and place them in the Acknowledgements, as they are to be acknowledged as members of the study group. The groups' contribution as a whole can be given in the authors contributions section.

SR2

A double-blind study is an experimental procedure where neither the participants of study nor the persons administering the study know the critical aspects of the experiment. The authors of this paper describe their study as double-blind but it does not appear that the participants were unaware of their randomization to either the experimental or control group. Some of the comments in the results, for example, by the establishments suggests that they were aware that they were receiving an intervention (e.g. Implementation Barriers section: "I’d like to see how we stack up to see if anything has changed with implements that we’ve put
Based on the authors' description, it appears that the research staff were blinded but the participants were not.

6. Reference to premises being blinded has been removed.

SR3

In paragraph three of the introductory section, there is very little in-text description of the empirical and theoretical literature that supports the type of intervention that the authors have developed and are testing. This needs to be described more in this paper. This description may be somewhat brief given that the authors have already published a paper describing the intervention and study methods (prior to study completion). The authors do however need to provide a reasonable overview of these topics so this paper can be read as a stand-alone document.

7. This has been added to the introduction.

SR 5

The authors should consider changing the order of the sub-sections within the methods section in order to enhance readability. It might also make sense to combine some of the related sub-sections (e.g. the matching and recruitment of establishments; the randomization and blinding). The description of how premises were recruited could also be made more clear and could include a description of how many establishments refused to participate in the study. The role of the auditors should also be more clearly described in the methods section. Readers outside the UK would also find a brief description of what an auditor is to be helpful.

This has been addressed in the Intervention Theory section added to the Introduction.

SR 6

One aspect of the data collection that I had a question about is whether the surveyors were completing the ratings of drunkenness after seeing the participant’s reading on the alcometer. If that is the case, the two scores are not independent and it may be problematic to conclude based on the current study that the ratings of drunkenness would suffice on their own. If that is not the case the authors should be more clear about this point.

Our previous work did formally test inter-rater validity of these street measures of drunkenness. Here participants were scored by one surveyor and another independently breathalysed the participant. This study provided a fairly strong correspondence between BrAC and subject ratings. We did not enforce a similar methodology here given this previous work for two reasons. Firstly, we needed to focus on getting the primary data in (BrAC, location at which participants had been drinking). Subjective scores were used in two ways. In as secondary outcome measures to assess whether there was any discernible change in premises patrons’ visible indices of intoxication and to determine sampling biases. On the latter, surveyors had no BrAC score and so long as the measures remained valid under these circumstances (and we argue that they are) we would therefore have a means of assessing sampling biases in the street survey that might be attributable to prospective respondents’ levels of intoxication. This is not clear in the manuscript and has been addressed. Further, in the current project, surveyors also worked in pairs with one administering the alcometer test and the other the street survey. This has been clarified in the Methods, although we are unable to guarantee contamination of subjective scores did not occur.
SR 7

6. Figure one is included in the appendices but not mentioned until far into the results section (under the process evaluation subheading). It would help if the authors integrate Figure one and the content from the process evaluation section earlier in the paper (e.g. the methods section).

Thanks for highlighting this - tables and figures have been revised

SR 8

This pilot study is complex and involved a number of different data sources. The focus group data receives very little attention in this paper and it may make the most sense to remove this content from this paper. In the current format there is not enough space to adequately describe the methods and results of this aspect of the study.

The focus group data is essential as it prompts revisions to the logic model

SR 9

Some of the content presented in the results section (e.g. the first couple sentences in the violence results) could be moved to the methods section.

This has been revised

SR 10

The titles given to some of the subsections also could be improved. Much of the content in the statistical analysis section in the methods is information that is not typically included in such a section. In the results, the heading "missingness" also seems out of place with what is generally referred to when discussing missing data. The authors appear to be describing the participation and refusal rates not missing data (e.g. missing values for particular variables). This information could also be presented either at the beginning of the results section or in the methods.

"Missingness" is now "missing data"

SR 11

In the results the authors note 21% of participants experienced violence. There is no description of how violence was defined. This measure as well as the violence perpetration measure should be described in the methods section. Also, given the cross-sectional nature of the patron surveys it might behoove the authors to state there is a relationship between perpetration and victimization but not state that one predicts the other. The data was not collected in a sequential format so that they could determine whether victimization precedes perpetration or vice versa.

This has been adjusted as suggested

SR12

The analysis related to the cost-benefit analysis is a minor part of this paper and it might make sense to remove this section from the results since it is not mentioned earlier. In the discussion section, the authors could mention how this intervention and others like it may be attractive given their limited costs associated with implementation and the potential reduction in costs associated with violence.
The cost-benefit analysis is now flagged in the Introduction and discussed in the discussion.

SR 13

More detail on how the establishments received feedback from the site-visits and whether they were able to have any input in the development of the action plan would be helpful. Did the establishments receive a written report only? What happened when the establishments did not agree with the plans? Was there any consideration to renaming the “audit visits” something more neutral or less threatening to the establishments (e.g. site visits). These issues are only briefly addressed in the Implementation Barriers and Fidelity Section of the results.

Delivery is now discussed in the Intervention Theory section. We had not given much thought to nomenclature - we will do this in future projects.

SR 14a

In the first paragraph of the discussion section, the second sentence is long and unclear particularly since the authors do not describe the nature of alcohol outlet licensing and oversight until this point in the paper. Keep in mind that readers outside the UK are not likely to be familiar with these regulations.

This has been clarified

SR 14b

It also was not clear whether the auditors that conducted the audit-visits have some official oversight role and are able to suspend an establishment’s license.

This has been addressed in the Intervention Theory section.

SR 15

The language describing the results of the power analysis in paragraph 4 of the discussion section needs revised. The current wording states that a “12 month follow-up period across 517 premises would be required to raise this effect into significance...”. It might be more appropriate to reword this (e.g. to detect a significant improvement).

This has been revised as suggested

SR 16

In paragraph 4 of the discussion, the authors suggest the effectiveness of the intervention could be increased if the intervention receives police enforcement. Could such an intervention also decrease the motivation of the establishments to participate in such an intervention or be forthcoming during interviews given the higher potential risks (e.g. revocation of their license)?

This is a matter that we will assess in future projects. The realism is that, no, premises would be more likely to respond to statutory authorities input.

SR 17
I’m wondering about the use of the word failure throughout this paper. Did the authors choose to use this word because it is the language typically associated with the Andersen-Gill model or other cox proportional hazards models. Is there another word that might make more sense given the particular focus of this study? It comes across as a very negative term that includes a negative judgment of the establishments. The approach of this intervention seems more aligned with a criminal justice approach. I wonder if the authors/developers of the intervention considered whether another (e.g. motivational interviewing) would be more appealing to the establishments and be able to achieve better results.

This is connected to the analyses used and their origin. This form of recurrent event analysis finds its origins in manufacturing and have been used to investigate how such processes give rise to mechanical failure. Also, this work, as presented is not really for consumption by premises staff, more to communicate with those interested in harm in the night time economy. I suppose the question is what alternatives might we use? Violence is fairly negative, perhaps even more so than failure. Yet this is a useful and valid comment.

SR 18

Acronyms should be defined when they first appear in the paper (eg. NHS in paragraph 1 and DPS in paragraph 2 of the paper’s intro section, NTE in the methods section).

This has been addressed

SR 19

In paragraph 1, the comment “while alcohol is associated with young peoples’ risky sexual behavior” seems out of place given the focus of the rest of the text.

This has been removed as suggested

SR 20

In paragraph 2, the wording could be improved. It might be helpful to consider dividing the first sentence into 2 parts (e.g. ending the first sentence after the word violence, cutting out the words “suggesting that” and beginning the second sentence with premises level. In the sentence that begins with Whilst, the sentence would read better if the word “whilst” was deleted.

The text has been substantially revised

SR 21

In Figure 2 (the first box in the upper left corner), premises is misspelled.

This has been corrected

SR 22

In the Recruitment section (in the Methods), the authors could be clearer in describing the number of communities that are represented in their data
(e.g. the total as well as the characteristics of these communities as large cities, towns etc.).

This has been revised in the Methods Section as suggested

SR 23

In the first sentence in the measures section (“The outcome measures used in this study…”) the authors state that measures were selected based on their appropriateness and objectivity. It might make sense to say they were selected based on their appropriateness and feasibility for the particular setting. Some scholars would challenge the designation of all of the selected measures (e.g. the research staff’s ratings of drunkenness) as “objective”.

The description of outcome measures has been revised

SR 24

Is there a citation for the formula used to calculate estimated risk for each establishment (in the methods section)?

This has been added

SR 25

In the data collection section (of the methods), there is an extra period at the end of the first sentence in the second paragraph.

The text has been revised

SR 26

In the last sentence of the second paragraph of the results violence section, the last part of the sentence does not make sense and needs edited (“…and thereafter a modest reduction post-intervention in the experimental group.”)

This has been revised

SR 27

In the last sentence of the implementation barriers and results section there is a typo where the word stated is used and should be started.

This has been edited

SR 28a

In the second paragraph of the discussion section, the authors state “Street surveys are the only feasible mechanism…” The authors may want to remove the word “only” because while the street surveys are feasible, it may be overstating things to suggest they are the only feasible option.

We have changed as suggested - although I am not sure what else there is

SR 28b

Similarly in the last sentence of the 5th paragraph in the discussion section, it may be an overstatement to say that “premises are potentially
the only point at which interventions can be delivered to the majority of risky drinkers.” (note this sentence also has a typo—of is listed as or).

This has been revised

SR 29

The wording of the third paragraph of the discussion does not fit with the wording of the other sections. It might

This comment was truncated for some reason

SR 30

A typo is in the 5th paragraph of the discussion (see the acronym DPS).

Thanks

SR 31

In the second to last paragraph of the discussion, the sentence that begins “This in turn mediated…” could be clearer.

The text in the discussion has been substantially revised

SR 32

In the statistical analyses section the authors state that they “develop” the Andersen-Gill model. This is a minor wording issue, but it might be better to use another word (e.g. utilized, calculated) so that it does not sound like you developed the statistical test.

We now "use"

SR 33

In the second paragraph of the Intervention revisions section, the word "overhead" is a little awkward and it might be better to use another word (e.g. inconvenience).

Overhead is now burden

SR 34

When describing the breathalyzer survey (under measures in the methods section), it would also help to add another sentence or two describe the street survey methods more clearly.

We have added some clarification to the methods section overall

SR 35

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

LJ 1
Although the writing is generally acceptable there are a number of errors including misspellings and missing punctuation throughout the paper that makes some parts of the paper difficult to follow. For example, the following sentence is not clear: “However, risks may be cyclical, particularly as premises are subject to high staff turnover rates and numerous external factors that could be assessed analytically might influence premises-level failure rates, such as local sporting events and temporary closure.”

This has been revised

LJ2

The authors need to check the use of abbreviations. Some terms are abbreviated early in the document but the abbreviation is used inconsistently later in the text, e.g. premises level is abbreviated to PL in the second paragraph of the Introduction but is used in full throughout the rest of the Introduction. Other abbreviations used in the paper (e.g. DPS, NTE, ED) are not written out in full.

This has been addressed

LJ 3

Details of the methods used to generate the random allocation sequence are missing from the description of randomisation.

This has been revised

LJ 4

“Approximate cost of the intervention developed here was £600”. The authors do not report what costs were measured or over what period (e.g. are only the costs of implementation considered?). I understand that the estimates are provisional but it would be useful to have more information about how the £600 figure was determined.

More detail is provided

LJ 5

Could the authors provide references for the systematic review and Traffic Light scheme mentioned in the fourth paragraph of the Discussion.

These have been added

LJ 6

A clear description of the premises level intervention is not provided in the Methods section of the paper. It is not until the section on Process Evaluation in the Results that a sufficient level of detail is reported. I would suggest moving the text describing the intervention from the Results to section in the Methods.

More information on the intervention is added into the discussion

LJ 7

Within the Statistical Analysis section the use of the failure rate as the measure of violence should be more clearly reported.
More information is provided.