Author's response to reviews

Title: Feasibility and Acceptability of a Novel, Computerized Screening and Brief Intervention (SBI) for Alcohol and Sweetened Beverage use in Pregnancy

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Version: 3 Date: 27 August 2014

Author's response to reviews: see over
Aug 27, 2014

Dr Peter O’Donovan

Editor BMC Pregnancy and Child Birth

Dear Dr. O’Donovan:

I write on behalf of my co-authors Drs. Korcha, Kaskutas, and Avalos-Ammon. We are delighted to submit a revised version of our manuscript (MS: 1988596258125210), originally submitted with the title “Testing a novel, computerized screening and brief intervention for alcohol and sweetened beverage use in pregnancy” on April 2, 2014.

In responding to referee comments, we have revised the title of our manuscript to “Feasibility and Acceptability of a Novel, Computerized Screening and Brief Intervention (SBI) for Alcohol and Sweetened Beverage use in Pregnancy.”

The following pages list point by point each of the 4 referee’s comments and our detailed responses to each comment. We have attempted to integrate the feedback of each referee and appreciated the attention to detail the referees gave our manuscript in their review.

Our work is innovative and important for improved maternal and child health. We hope to receive a positive response soon regarding the publication of our work in your journal.

Thanking you,

Madhabika B. Nayak, Ph.D.
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AUTHOR RESPONSE TO REFEREE COMMENTS FOR MS: 1988596258125210

Research article, entitled Testing a novel, computerized screening and brief intervention for alcohol and sweetened beverage use in pregnancy (Madhabika B Nayak, Rachael A Korcha, Lee A Kaskutas and Lyndsay A Avalos) BMC Pregnancy and Childbirth

REFEREE 1: D Paul Moberg

Major Compulsory Revisions

1. Reach: It is not clear how many of the eligible women in the clinic actually used the SBI program. My inference from data provided in the text and tables is that it is very low. About 800 women per month use the clinic; the intervention was available for 7 months and completed by 251 women. Thus reach may be as low as 251 of 5600 = 4.5%. This issue of penetration of the target population is essential to address in a revision by the authors. Figure 1 should include this entire eligible target population as the first entry to provide a true picture of reach. Informed consent only occurred after an individual chose to use the system, as I understand the study. For SBI, fairly large reach of the target population is essential.

   We have now included an estimated number for eligible women using the number of newly enrolled pregnant women for the same months in the past year as our study which occurred in the previous year (estimated as 140 per month). The clinic began keeping track of new enrollments recently and this information is not available for our study period in the data maintained by the clinic.

   Figure 1 is already very dense and given comments from another reviewer that we make the figure easier to read, we did not have space to indicate the number of eligible participants in the figure but have revised the title of the figure to include this number.

   We have also included relatively low “reach” (25%) as a limitation in the discussion (main findings section) and the need to increase such reach should the program be found to have to be an effective intervention.

2. Brief Intervention: More detail is needed on the “personalized plan” for reducing consumption. This is the critical brief intervention component. More detail on how it was individualized and what was included would be helpful in assessing likely effectiveness. Did the intervention differ for women who only report pre-pregnancy alcohol use versus those who report use while pregnant? What sort of advice was provided, and how much of it was individualized to individual circumstances?

   We have added text to the description of the alcohol intervention under materials and measures in the methods section. Text is included as follows: “Users who did not select complete abstinence (stop drinking), were encouraged to reduce consumption and to set a goal for reduced drinking. They were then guided through ways of doing so, such as replace half the drinks per week with non alcoholic drinks, drink one less each drink each week, or drink one less day each week.”

   Please also see added text at the end of paragraph 2 under the subheading “Alcohol Intervention” for additional text on how the intervention differed for women reporting alcohol use in different time frames as follows: “For users reporting current (past month) alcohol use, the intervention also provided information on the harmful effects of drinking during pregnancy. For users who did not report current use but use in the past 12 months prior to their pregnancy), information and feedback focused on reducing harms related to drinking alcohol in the future should the user choose to resume drinking.”

3. Behavioral outcome: It is important to include in the limitations section a lack of any real outcome data, which is critical to any assessment of this approach. While beyond the scope or intent of the present paper, it is important to suggest and plan for future outcome assessment for this program.

   We have now included this among study limitations.

4. Validity: Even if more alcohol use is detected in the sample of users of the SBI program than in the general WIC population (considered by the authors to be a validity measure), a number of alternative explanations for this result are available. I am not convinced that the detection rate is a good measure of validity, since it may reflect just an under-recording in the WIC records and/or hesitance to admit alcohol use by this population in face to face situations with a power figure.

   We do indeed believe that a key strength of computerized SBI is to overcome hesitancy in reporting alcohol use to clinic staff. Please see paragraph 4 in the discussion section under the “strengths” subheading for added text as follows: “When used as an anonymous, self-administered tool as in our study, e-SBI may help overcome barriers to the identification of alcohol use that are inherent in face-to-face situations, such as staff concerns regarding discussing a sensitive behavior like drinking, and respondent stigmatization concerns related to disclosure of alcohol use. Women may be more willing to accurately report drinking to a computer than a person.”
There is also a potential of selection bias, particularly since women with higher education attainment are more likely than those with less education to use alcohol, and the users of the SBI were of higher educational attainment that the general population of WIC clients.

We have added a sentence on this possible bias in the discussion section under the “main findings” subheading.

Discretionary Revisions:
5. I am curious why the size of the beverage container is considered relevant for this screening given the general agreement that any alcohol use by pregnant women is to be avoided. It would seem that a simple estimate of any drinking, and for women who drink the number of drinking occasions and an estimate of the number of drinks would be more than adequate. For the professed screening purposes with pregnant women, details on the size of serving seem to be more precision than is necessary. Assessing whether an individual’s drinking reaches risky levels among those who drank before pregnancy may warrant the additional precision, but it does not seem that that was done in this program.

We have now added text to the background that supports the detailed assessment of drink size assessment to help identify risky use and to facilitate harm reduction as a key innovation of our computerized SBI.

Data were collected on number of drinking occasions and number of drinks by size of drink and type of beverage, but not reported in the manuscript. There apparently was also data on drug use which is not reported. These data would be of interest from an epidemiological perspective—if the sample size were larger. The tables all treat alcohol use as a dichotomy.

The following text has been added to the results section under the subheading “Characteristics of women reporting alcohol use during pregnancy: Information on the detailed alcohol use patterns assessed by our program is not reported here due to being outside the scope of the present paper. Consumption information is also limited by the small sample of drinkers.”

6. Tables do not need to include both the percent and the n in each cell. If there is an n at the head of the column, the reader could calculate the n for each cell based on the percent entered. This would make the tables easier to follow.

We have revised all tables to include only percentages.

REFEREE 2 - Antonina Mikocka-Walus
Major compulsory
1. I would provide a more comprehensive literature review focusing particularly on other interventions in the area and clearly demonstrating the need and rationale for the present study.

We have now revised and expanded the Background to address the above comment and similar ones of other referees.

2. The authors mention no active recruitment has occurred, could they please explain how then the participants were informed about the study and whether there was anyone they could discuss their participation in it (ethical concerns).

The methods section (study design, paragraph 3) now includes these details.

3. Could the authors provide more details for the intervention, i.e. was it designed on previous studies / recommendations? Is it evidence-based?

The background (page 2, paragraph 2) now provides this information.

4. Limitations – I would mention this study was not controlled. Nothing wrong with it as this is a feasibility study but future studies should compare it to standard care through RCT designs.

These limitations are now included.

Minor Essential Revisions
5. I would modify the title to feasibility and acceptability of... as currently the title suggests this will be a trial.

We have changed the title as suggested.

6. Could the authors please state the type of design (within participant trial?).

We clarify in the methods section (study design, first sentence) that our study is an observational study (and not controlled). Since no pre and post-program outcomes were assessed, the use of the term “trial” is not appropriate for our study.

7. In few places there are some minor language problems / omissions (e.g. methods ‘whether they or not they’, ‘participants were recruited a Women’, some missing brackets, etc). Could the authors proof read the paper.
These typographical errors have been corrected (the first text has been deleted with sentences being revised; the second was missing the word “at” before “a”) and the paper has been carefully proof-read.

8. Results – I would not repeat the information presented in tables and thus this section can be reduced, e.g. descriptives could just be a couple of lines, similarly the section on feasibility is very repetitive of the table.

We have shortened this section as far as possible, retaining text on results not presented in tables to prevent the tables from getting too dense. We also retained the summary sentences on differences by group but have removed the percentages and p values which can be looked up in the tables.

In characteristics of women, could the authors add the % to 60 women.

This has been done in the first sentence under this section.

9. Discussion – this is overall very well written. Some suggestion to main findings, some assistance may indeed boost the numbers. It has been shown in many psychotherapy studies that self-directed therapies when even minimally assisted, are likely to be more effective and associated with better attrition.

We have added the need to increase use of the program, should it be found to be effective in future research (see last sentence of the main findings section).

10. Table 1 – could the authors add a column for sweetened beverages. I think it would be of interest.

We have added a column on the characteristics of women reporting past month use of sugar sweetened beverages to Table 1 and pertinent text to the results section.

REVIEWER 3 - Jessica Hanson

Major Compulsory Revisions

--The background section seemed lacking. It may be there is a limited amount of space for the background, but if possible, more information is needed. For instance, in Background, paragraph 2, it would be beneficial to provide more data by population/race and to provide comparison data. Also, it would be helpful to have information on the impact of SSB during pregnancy since that is one of the major focuses of the manuscript.

The background section has been appropriately revised and expanded.

--Methods, second paragraph. It needs to be made clear that this is the actual study-- the first paragraph focused on a pilot test, but there is no transition to the actual study in paragraph 2.

We revised the first paragraph of this section to clarify that the study was a test implementation of the computerized SBI. With this revision the description of the administration of the SBI in the second paragraph, provides more detail about the actual test implementation.

--Methods-- please add details about consent or implied consent for study participants.

This is included in the revised manuscript.

--Results-- typically the n goes before the percentage (i.e., (n = 237; 82%) as opposed to how it is written currently (82%, n = 237).

Given some of the other reviewer suggestions (e.g., Referee 1), we have retained mostly percentages in the text and tables and removed ns from most of the revised manuscript.

--Limitations section-- I feel there is a lot missing from this. Here are a few suggestions of other limitations to add: participants were self-selected; limited generalizability of the study; no follow-up or referrals with women to gauge the impact of the program; increased educational level of participants may have led to biased results.

These limitations are now included in this section.

--Figure 1: this seems a bit convoluted/busy-- is it possible to clean up this figure?

We have removed the notes about the numbers that drop off between program modules and believe it makes the figure less convoluted.

--Tables-- prefer to have n first with percentage in paragraph after n (perhaps this journal requires the % first). See response to similar column above

--Table 1-- percentage given for WIC participants in 2nd column, but no n given.

We had clarified in the text of original submission that the percentages are averaged over the months as there is significant overlap in the data across months (the same women are included in more than one month). Also per suggestions of other reviewers, we have now deleted ns in all tables, retaining only the percentages.

--Table 1-- significant findings reported in the prose but would also be helpful to indicate significant findings in the table.

Significant differences found are denoted with asterisks in the table, with footnotes regarding pertinent p values added at the bottom of Table 1.
2. Minor Essential Revision

--Alcohol screening section in Methods, 2nd paragraph-- was unclear what "limited resources meant" and if that should be further described since it impacted study protocol.

_Clarification regarding limited resources, specific to programming of different modules of the study computer program is provided in the revised Methods section (subheading “Alcohol Screening” under “Overview of the computerized SBI program”._

--Results, 1st paragraph, 1st sentence-- typo; "of" needs to be added before "users."

_This correction has been made._

--Results, first paragraph--can you make a reference to Figure 1.

_The reference is provided at the end of sentence 1 of the first paragraph of results._

--Results-- can you clarify if you asked if this was their first pregnancy; if they had other children?

_We did not assess if this was the users first pregnancy or if they had other children and clarify this in the results on “Descriptive characteristics of study participants” (paragraph 2, lines 3 and 4)._  

--Results, characteristics of women using alcohol during pregnancy, 1st sentence--there is a "")" missing from the end of this sentence after "pregnant."

_This correction has been made._

--Results-- feasibility of computerized SBI program-- can you clarify in 2nd sentence that it took some participants 2 minutes to complete all modules? That doesn't seem like it would be correct.

_We have carefully checked our data and the time computed is correct._

REVIEWER 4 - Tatiana Balachova

Background section is very brief. Including a brief overview of other computerized studies aimed at reducing alcohol use during pregnancy and providing data of the extent of SSB use during pregnancy would strengthen the background section.

_Overview of other studies is now included in the background._

Although some improvements are suggested and language editing/proofreading of the manuscript is necessary, these considered to be Minor revisions. The revisions are minor, but essential and would help to improve the quality of the manuscript. There are many places with repeated words, omitted commas, decimal places, inconsistencies in paragraphs, etc. These corrections would not require substantial efforts. Comments in regard to specific sections are included as an attachment. It is necessary that authors review and address the attached detailed comments prior to submitting a revised manuscript for publishing.

_All comments in the attachment (see below) are now addressed. We have also read the manuscript carefully for grammatical and typographical errors._

REVIEWER 4. (comments in Attachment) – Som Bohora?

ABSTRACT

In line 58, “…is” should be “…are”

_We have now reworded SBI as singular and retained the “is” instead of “are” consistent with use of singular as opposed to plural._

Needs proofreading and reviewing the use of commas and periods.

_We have carefully proof-read the abstract, removing additional commas and adding commas and periods where needed._

BACKGROUND

Consider adding other relevant work to support and justify your work with the existing literature.

_We have added information on prior computerized SBI for drinking during pregnancy and how our program builds/improves upon prior work._

Need to include a clarification of the use the term “beta testing”.

_We have now added the needed text immediately after the term “beta testing”._

Line 127, I believe “comprised of” instead of “comprised” would be appropriate to use. In addition, I think you mean to say just age instead of “…on age”, don’t you?

_We considered retaining “comprised” as “comprised of” would necessitate adding a “was” prior to comprised. Given the second comment above we revised the sentence to read as follows: “The second module included questions assessing basic demographics and health, including age, marital status, education, ethnicity, number of visits to the clinic, gestational age (months), diabetes and gestational diabetes.”_
The above referenced sentences are now revised to read as follows: “Women who screened positive for alcohol, i.e., reported alcohol use in the past 30 days or the 12 months prior to pregnancy, then completed the fourth and fifth modules. These modules assessed alcohol consumption in detail, including alcohol drink size, and delivered the alcohol intervention respectively.

In line 134, revisit this sentence for a grammatical error.

This sentence is revised as follows: “Women who did not report alcohol use skipped out of the fourth and fifth module and were taken to the sixth module that screened for SSB use. Women reporting alcohol use also completed this sixth module after completing the fourth and fifth module as described above.

Line 150-153, you stated that “Given limited resources,…” intervention was not provided to a subset of women who reported drinking during pregnancy but not in the past month. More details need to be provided. What would be the cost of including these participants? There were no incentives and the intervention is computerized. It is unclear what would be additional costs that overnighted benefits of providing SBI for these women. It would be more understandable if you could specify the cost to each intervention and why you would avoid further assessing and providing the intervention to those women. More details are needed.

We have added the needed details in the second paragraph under alcohol assessment including a sentence that reads as follows: “Women who reported drinking during pregnancy but not in the past month and denied use in the 12 months prior to pregnancy (n=4) were precluded from the detailed alcohol use assessment due to additional costs to program separate modules and limited resources we had for software programming”.

In addition, that points to an important aspect that seems to be missing from the evaluation. Computerized interventions are particularly appealing because they are considered to be low cost. Including information about the costs of the SBI would be very important for a feasibility study.

Please see the revision above.

Need to be consistent in the use of subheadings. Some subheadings are tabbed and some are not. This would improve visual quality of the manuscript.

Only the subheadings under main subheadings are tabbed. For example in the Methods section – the main subheadings, “Study Design” “Study Settings and Participants”, Material and Measures” and “pilot Implementation of the computerized SBI”. Headings such as alcohol screening under “materials and Measures” are tabbed. We have checked for consistency.

Line 180, “Implementation…”: I think this word may not be a right tem to use in the context of this manuscript. This manuscript describes a formative study, the first phase of developing an intervention while Implementation refers to a final phase of developing a protocol or program usually, Consider Procedures or similar words instead of Implementation.

We have revised this to pilot implementation – this is indeed what our study was about. I believe this reviewer is referring to “implementation science” which indeed examines how to better implement an evidence-based intervention.

In line 185, there is a repetition of “language of language of”.

We have deleted the repeated words.

What proportion of women who received information about the SBI/kiosks chooses to approach the kiosk? This would be a very important question for future and a true implementation. It seems that authors may have this information or could obtain from the clinics to estimate the number of women who received information about the study/kiosk.

Unfortunately we do not have this information as it would mean asking staff to keep a count for us, an additional demand that we could not place on the staff. We have now provided an estimate of all eligible women with data on new enrollments of pregnant women at the clinic and note that this may be a conservative estimate of reach of the SBI.

In line 217, what is “n’s”.

This is now spelled out as “numbers”

RESULTS

In line 231-233, it looks like 20 women were ineligible. Please revise this sentence and give correct numbers. Also “69% (310 of 450) of users agreed to participate in the study”

These sentences are revised as follows for clarity: “Fourteen users were subsequently deemed ineligible for the study due to not being currently pregnant (n=13), using the program before (n=1). Six additional users discontinued the program prior to the first beverage (alcohol) module and are not included in our analyses.”
Proofreading this section is advised. There are few places with inappropriate use of periods or commas.

*We have carefully proof-read this section.*

In Line 258, it would be better to state sixty in terms of % rather than the number.

*This revision has been made.*

Data format with “:” — it is unclear how Mean and SD were calculated. Were the data transformed prior to calculations? For example, 3:30 as 3.5 minutes. If the data were transformed, this needs to be specified.

*The statistical package we used does not need data to be transformed for the calculation of mean and sd. We believe this to be standard of several software packages.*

There are several places; you say “results not shown in table”. Authors may want to include the data to make these types of arguments. It would make the manuscript stronger.

*We did this to report overall findings (not by group) or findings of follow up analyses, which if presented in table, would make the tables hard to read by increasing the numbers of rows and columns. We do clearly report the findings in text and feel this is adequate.*

In line 284-285, Review the sentence and consider re-writing.

*This sentence is now revised as follows: “Fifteen women who received the alcohol intervention, reported consuming “just a sip” of the beverages they chose as their most frequently consumed alcoholic beverages. Because the intervention would be expected to have less salience for very light drinkers, we also examined program acceptability separately for these users.*
In many places, authors omit a p-value. Adding p-values to support authors’ arguments is advisable. For example, Line 293-295.

These lines refer to findings of no significant differences. It is not common practice to report p values for non significant findings. Hence we did not report these p values to prevent the text from becoming too dense and hard to read.

Line 302-304, revising this sentence would make it clearer to the readers.

We have revised and shortened these sentences in the process of reducing content in the results section as recommended by another reviewer. See paragraph 4 under “acceptability”

Line 305, you will need a comma to separate “91%” from “p<.001”

Line 305 has no 91%. Line 315 did. However, we have deleted this entire sentence as part of shortening the results section to respond to another reviewer’s comments, including deleting percentages reported in tables to prevent repetitiveness.

**DISCUSSION**
Proofreading this section would definitely help improve the quality of the manuscript.

We have now carefully proofed the manuscript.

**TABLES and FIGURES**
We suggest converting minutes and seconds into just decimal values which is a usual practice.

Please see our comment/response to a similar reviewer comment above. We believe it is easier for readers to interpret time in minutes and seconds as decimal values will necessitate the reader having to do computations in their head, such as 27 minutes: 12 seconds for 27.2 minutes.

Proofreading for errors in notations would improve the manuscript.

We have proof-read all Table notations and needed corrections have been made.