## PEER REVIEW HISTORY



## ARTICLE DETAILS

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| **TITLE (PROVISIONAL)** | A trauma-informed substance use and sexual risk reduction intervention for young South African women: a mixed-methods feasibility study |
| **AUTHORS** | Myers, Bronwyn; Carney, Tara; Browne, Felicia; Wechsberg, Wendee |

## VERSION 1 – REVIEW

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| **REVIEWER** | Kathleen J Sikkema<br>Duke University United States |
| **REVIEW RETURNED** | 18-Aug-2018 |

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| **GENERAL COMMENTS** | The primary purpose of this research was to utilize a mixed methods approach to assess the feasibility, acceptability and preliminary effects of a trauma-informed group intervention to reduce substance abuse and sexual risk, and improve mental health, among young women in South Africa. My comments are organized around three main issues: intervention, study design and feasibility conclusions, and interpretation of findings with regard to intervention approach.<br><br><u>Intervention Focus</u><br><br>The focus of the intervention is highly significant, and innovative in the South African context, particularly with regard to young women recruited through community outreach. Similar/related interventions have been conducted in the United States (e.g., Sikkema, Wyatt), as well as interventions in LMICs on gender based violence more broadly (e.g., Bass), that could be noted and utilized to bolster the unique population targeted in this intervention. The intervention content appears to have a strong conceptual/theoretical foundation that is not noted.<br><br>Although the intervention development process paper is referenced, more information on the rationale for study format and content would be helpful for interpreting the findings. For example, given the focus on coping and skill development, what was the rationale for the two week intervention period, especially given the focus on skills development and behavior change over time? Was the case management intended for follow up on these skills / behavior change / mental health?<br><br><u>Study Design</u><br><br>A number of questions arise related to the study design that highlight potential limitations with regard to trial feasibility:<br><br>- Although the flow diagram lists a number of reasons why women were ineligible, it is hard to understand |

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| | andinterpret only 12% of participants screened being eligible for the study. This data in itself points out a potential key barrier with regard to feasibility of the intervention / recruitment, and seems critical for discussion and reconsideration. Among those screening, majority reports of trauma and more than half substance use, must one interpret that age, place of residence and no recent unprotected sex are main reasons for exclusion? If so, why not consider broadening inclusion to enhance scalability? The requirement that all three inclusion criteria be met does maximize the focus on intersecting risks, but may also limit intervention reach, when considering future implementation.<br>- Clarity of the study design earlier in the manuscript would be beneficial, as the reader needs both methods, results and tables to gather necessary information on the study. For example, it remains unclear to this reviewer what happens at the "one month" – on page 11, 75% complete the one-month and 93% the three-month follow up. In other sections of the paper, relying primarily on the flow diagram, the one month appears to be the case management sessions following the group interventions and is not an assessment point. At the end of this paragraph, it states no baseline differences on those who completed one- and three – month appointments. Please distinguish assessment from intervention sessions.<br>- Related to above, the high level of follow up assessment completion (93%) is excellent. This supports the potential feasibility of an RCT, and should be further discussed. The one month appointment also had reasonable retention, although the only place I believe the second case management sessions is noted is the flow diagram.<br><br><u>Intervention attendance and conclusions on potential effect</u><br>- As noted, the single arm feasibility design is a significant limitation and conclusions cannot be drawn on the potential intervention effect. Most RCTS related to mental health / trauma, whether pilot or full scale trials, demonstrate a reduction (often significant) in the control/comparison condition whether it is a treatment as usual or treatment comparison.<br>- The improvements in mental health (with reliable and valid measures), and reduction in substance use and sexual risk are impressive. However, the issues with intervention attendance are of concern, and would suggest the intervention is not feasible, and consideration of modifications to the intervention are appropriate.<br>- Thus, a few recommendations to consider in interpretation and possible support of intervention feasibility and potential outcome, and whether possible approaches other than reduction to 3 sessions should be considered.<br>o Were any exploratory analyses completed |

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| | related to intervention exposure? If a 3 session intervention is proposed for a phase II RCT pilot trial, what pattern of potential effect exists for those receiving three or fewer sessions? While it is noted that 68% attended 3 or more, 55% attended 5 or more, and it is possible/likely that those with more intervention exposure contributed to the greatest reductions?<br>o Were mental health outcomes examine for clinically significant changes? This could support finding without a comparison/control condition.<br>o The qualitative findings suggest it was the brief 2 week period, rather than the six sessions, that was the barrier to attendance.<br>o The content of the two case management sessions is not presented, and it is also possible that these follow up intervention sessions contributed to the effect at follow up?<br>o Group sessions were not described as open or closed? If closed, were scheduling issues a barrier to groups? How were women able to make up missed sessions – does that suggest groups were open? These details and discussion of potential influences would assist in conclusion regarding feasibility and acceptability.<br>o Quantitatively acceptability ratings might be useful, if available.<br>- Almost half of the women were HIV positive. Since rapid HIV testing was conducted at enrollment (although not clear why, as it was not a study inclusion criteria), is this number based on study protocol testing? If so, were these women not aware of their HIV status? If newly diagnosed, were there any issues in group participation or intervention process? Also as per suggested above, an exploratory analysis as to whether HIV status influence intervention/study feasibility might be of interest.<br><br>The qualitative interview quotes are interesting and enlightening, although more detail on various questions above would provide essential information on study design, intervention approach and rationale for conclusions and proposed intervention modifications. If necessary, fewer quotes could be included. |

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| **REVIEWER** | Melissa Watt<br>Duke Global Health Institute, Duke University, United States |
| **REVIEW RETURNED** | 04-Sep-2018 |

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| **GENERAL COMMENTS** | This is a well written article presenting the results of a pilot feasibility trial of the trauma-informed Women's Health Co-op in Cape Town South Africa. The authors do an excellent job presenting data to evaluate the feasibility, acceptability and potential efficacy of the intervention in this setting. The study design is obviously limited by the single intervention condition with no comparison, but for the most part the manuscript is clear about this limitation. I have the following suggestions to improve the manuscript for publication. |

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| | Abstract<br><br>1. In the abstract, the results and discussion should be more explicit that this was a single arm study design. Although this is stated in the design, someone who hones into the results section may miss this. Additionally, I am uncomfortable having reports of the robust p-values in the abstract, as I think this overstates the findings. Without a comparison condition, there is no way to determine whether the significant change is due to the intervention exposure or to other factors (maturation, measurement bias, regression to the mean, etc.).<br><br>Methods<br><br>2. It is unclear why the GRAMMS checklist was used, as this appears to be more geared to observational studies. More appropriate would be the CONSORT extension for pilot and feasibility trials (http://www.consort-statement.org/extensions/overview/pilotandfeasibility).<br><br>3. Please provide additional description of the two communities where the research was conducted.<br><br>4. Please provide additional description of the community-based street outreach techniques. Where was outreach conducted? How? Over what time period?<br><br>5. Do you have data on the number of women who were approached for screening, and the number who refused to take part in screening?<br><br>6. Please describe where the study activities (i.e., assessments and intervention) took place.<br><br>7. Please describe the modality of survey data collection, e.g., was it self- or interviewer- administered?<br><br>8. Please describe the process of forming the intervention groups. How many participants were assigned to each group? Were the groups closed or open? If a participant missed a group, was she able to make up a group session by participating in another group?<br><br>Results<br><br>9. Regarding intervention exposure, please also report the number of participants (if any) who attended “0” sessions.<br><br>10. Overall, the qualitative data are reported very clearly and grounded in the data. However, there was one place where it feels that the authors overstep in advocating for the intervention – on page 13 “The intervention’s person-centered approach helped participants….”<br><br>11. In the qualitative interviews, did insights emerge about challenges to attending the intervention, to add more context to the data presented in Fig 1?<br><br>12. I was surprised that your findings did not identify any patient-level barriers to being part of a group intervention focused on trauma |

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| | histories. In reasons for missing groups (Fig 1), no one mentioned that they did not want to be part of a group, and reflection on the group modality was not mentioned in the in-depth interviews. In our qualitative work (Watt, Dennis et al, AIDS Behav 2017) we found very limited disclosure of sexual trauma experiences and high levels of shame and stigma related to IPV. Subsequent intervention work with women with sexual trauma histories (Sikkema, Mulawa et al, AIDS Behav 2018) found generally low uptake of a group modality due to concerns of stigma and privacy. In your pilot trial, did you assess comfort with the group setting (either through observations and/or debriefings?). If you found that a group modality was acceptable in this setting among a group of women with trauma histories, I would be interested in additional thoughts (perhaps in the discussion) about why you think it was effective and what was done to promote comfort and trust and in the group.<br><br>Discussion<br><br>13. In discussing a future RCT, you suggest (bottom of Pg 18) a modality of three sessions, one week part, with a six-week window to complete the program. To me, this suggests that it is not important that women are part of a cohort of participants – rather that they can be in an open group as long as they get exposure to three sessions. I would appreciate some reflection on the value of developing a peer group as part of the intervention, or whether you think that is unnecessary to have an impact on the target outcomes.<br><br>14. Given that this intervention is a modification of the WHC model (modified to be trauma-informed), I would be interested in a reflection on how the findings of this trauma-informed approach was similar or different from previous research with the WHC. |

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| **REVIEWER** | Lori A. J. Scott-Sheldon<br>The Miriam Hospital/Brown University |
| **REVIEW RETURNED** | 14-Oct-2018 |

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| **GENERAL COMMENTS** | This paper describes Stage I of Behavioral Intervention Development. The study uses mixed-methods to determine the feasibility of a novel trauma-informed substance use and sexual risk reduction intervention for South African women. Developing and testing interventions for women experiencing interpersonal violence is of great importance especially in a geographical region where (a) one in five women experience domestic violence and (b) rates of HIV among women are higher than among men. The paper will make an excellent contribution to the substance use-risky sex literature.<br><br>I have several comments for your consideration.<br><br>The authors state that there are “few programmes that offer an integrated approach to addressing [syndemic, intersecting risks]” (pg. 4). I would argue that there are more than a few programs that have addressed trauma/substance use/risky sex (see, for example a review by Scott-Sheldon et al. 2017; https://onlinelibrary.wiley.com/doi/abs/10.1002/9781119057574.whbva074) but these pale in comparison to the broader research on behavioral HIV interventions.<br>Biological samples were collected from participants which provided an objective measure of recent substance use but similar tests were not conducted for alcohol use. It’s unclear why the investigators |

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| | used objective measures for some but not all substances. Alcohol can be detected in urine for up to 3-5 days if using a sensitive test of alcohol biomarkers (i.e., ethyl glucuronide and ethyl sulfate).<br>The sample characteristics would be better presented as part of Table 1 (including results from the chi-square/t-tests completers and non-completers) rather than in the text (pg. 10-11).<br><br>Minor change: Subscript reference #18 in the first line of the discussion (pg. 16). |

**VERSION 1 – AUTHOR RESPONSE**

| **Reviewer 1** | |
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| The authors state that there are “few programmes that offer an integrated approach to addressing [syndemic, intersecting risks]” (pg. 4). I would argue that there aremore than a few programs that have addressed trauma/substance use/risky sex (see, for example a review by Scott-Sheldon et al. 2017; but these pale in comparison to the broader research on behavioral HIV interventions. | Thank you for this comment. We have gone back to the literature, including the review you recommended we look at. We have revised the introduction to clarify that there are few (rather than no) interventions that address psychological trauma and substance use and sexual risk as main outcomes, particularly in LMIC settings. We have also clarified that the focus of our intervention is on psychological trauma rather than violence prevention. |
| Biological samples were collected from participants which provided an objective measure of recent substance use but similar tests were not conducted for alcohol use. It’s unclear why the investigators used objective measures for some but not all substances. Alcohol can be detected in urine for up to 3-5 days if using a sensitive test of alcohol biomarkers (i.e., ethyl glucuronide and ethyl sulfate). | We agree that the lack of a reliable measure of recent alcohol use is a limitation. We lacked the resources for EtG and Peth testing in this small study, but have noted this as a limitation and something that needs to be addressed in future studies (in the discussion) |
| The sample characteristics would be better presented as part of Table 1 (including results from the chi-square/t-tests completers and non-completers) rather than in thetext (pg. 10-11). | Thank you for this observation- we have changed the text accordingly |
| **Reviewer 2:** | |
| Abstract<br>1.In the abstract, the results and discussion should be more explicit that this was a single arm study design. Although this is stated in the design, someone who hones into the results section may miss this. Additionally, I am uncomfortable having reports of the robust p-values in the abstract, as I | Thank you for this observation. We have revised the abstract to remove references to p values and to emphasise that this was a single arm design |

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| think this overstates the findings. Without a comparison condition, there is no way to determine whether the significant change is due to the intervention exposure or to other factors (maturation, measurement bias, regression to the mean, etc.). | |
| Methods<br>2.It is unclear why the GRAMMS checklist was used, as this appears to be more geared to observational studies. More appropriate would be the CONSORT extension for pilot and feasibility trials | While not using a randomised design, we have changed our checklist and now use the Cohort extension for randomised pilot and feasibility trials |
| 3. Please provide additional description of the two communities where the research was conducted. | We have added some additional information. We have not named the communities as this was a requirement for our ethical clearance. |
| 4.Please provide additional description of the community-based street outreach techniques. Where was outreach conducted? How? Over what time period? | We have added some additional information about our recruitment strategy. The references we have listed also describe the methods in greater detail. |
| 5.Do you have data on the number of women who were approached for screening, and the number who refused to take part in screening? | Unfortunately we did not keep detailed accounts of the number of women approached for and who declined screening. This is something we will strive to correct in future studies. |
| 6.Please describe where the study activities (i.e., assessments and intervention) took place. | This has been added to the methods section. |
| 7.Please describe the modality of survey data collection, e.g., was it self- or interviewer-administered? | This has been added to the description of the methods. |
| 8.Please describe the process of forming the intervention groups. How many participants were assigned to each group? Were the groups closed or open? If a participant missed a group, was she able to make up a group session by participating in another group? | Thank you for identifying this gap. We have added more information to our description of the groups under the **Intervention** sub-section and also in the discussion |
| **Results**<br>9.Regarding intervention exposure, please also report the number of participants (if any) who attended “0” sessions. | We have added this information to the text. |
| 10.Overall, the qualitative data are reported very clearly and grounded in the data. However, there was one place where it feels that the authors | We agree with this comment and have revised the text so that we do not overstate the value of the intervention. |

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| overstep in advocating for the intervention – on page 13 “The intervention’s person-centered approach helped participants….” | |
| 11.In the qualitative interviews, did insights emerge about challenges to attending the intervention, to add more context to the data presented in Fig 1? | We did not explore this in great detail during the interviews as we had examined some of this information in our initial formative work. Participants did describe their level of comfort with participation (discussed below) |
| 12.I was surprised that your findings did not identify any patient-level barriers to being part of a group intervention focused on trauma histories. In reasons for missing groups (Fig 1), no one mentioned that they did not want to be part of a group, and reflection on the group modality was not mentioned in the in-depth interviews. In our qualitative work (Watt, Dennis et al, AIDS Behav 2017) we found very limited disclosure of sexual trauma experiences and high levels of shame and stigma related to IPV. Subsequent intervention work with women with sexual trauma histories (Sikkema, Mulawa et al, AIDS Behav 2018) found generally low uptake of a group modality due to concerns of stigma and privacy. In your pilot trial, did you assess comfort with the group setting (either through observations and/or debriefings?). | Thank you for this reflection. We have gone back to the qualitative data to examine whether any other factors impacted on comfort with participation. We found that group-related issues did emerge for some participants (particularly around stigma, knowing other women, and being able to relate to other women’s experiences). We have added this to the results section. In the discussion, we have also added some thoughts on how switching from a group to an individual format may enhance participation for those women who are concerned about being in a group |
| **Discussion**<br>13.In discussing a future RCT, you suggest (bottom of Pg 18) a modality of three sessions, one week part, with a six-week window to complete the program. To me, this suggests that it is not important that women are part of a cohort of participants – rather that they can be in an open group as long as they get exposure to three sessions. I would appreciate some reflection on the value of developing a peer group as part of the intervention, or whether you think that is unnecessary to have an impact on the target outcomes. | This is an important point. We have expanded this section of the discussion to clarify. Given that the group format could have adversely impacted on treatment completion, we are proposing switching to an individual format. We do believe that peer support groups offer a potentially efficient way of extending the gains of a short-term individual programme, particularly for ongoing skills development and rehearsal but that more formative work is needed to ensure the groups are acceptable to potential service users. |
| 14.Given that this intervention is a modification of the WHC model (modified to be trauma-informed), I would be interested in a reflection on how the findings of this trauma-informed approach was | This is an interesting consideration. We would need to compare the effects of the original 2 session WHC with the trauma-focused WHC for participants with similar |

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| similar or different from previous research with the WHC. | characteristics. The original WHC targeted a different age group and risk profile so we are unable to answer this question at this time, but have highlighted it as an area for future research. |
| **Reviewer 3:** | |
| Intervention focus:<br>Similar/related<br>interventions have been conducted in the United States (e.g., Sikkema, Wyatt), as well as interventions<br>in LMICs on gender based violence more broadly (e.g., Bass), that could be noted and utilized to bolster<br>the unique population targeted in this intervention.<br><br>The intervention content appears to have a strong conceptual/theoretical foundation that is not noted. Although the intervention development process paper is referenced, more information on the rationale for study format and content would be helpful for interpreting the findings. For example, given the focus on coping and skill development, what was the rationale for the two week intervention period, especially given the focus on skills development and behavior change over time?<br><br>Was the case management intended for follow up on these skills / behavior change / mental health? | Thank you for the positive responses. We have added a few sentences to the introduction and to the discussion highlighting how our target population is unique and how our intervention's focus on psychological trauma, substance use and sex risk differs from interventions focused on violence prevention, substance use and sex risk.<br><br>We have now addressed this oversight to the description of the intervention.<br>We have added more information on why a 2 week intervention period was selected. We have also noted that the addition of the peer support groups could support the continued development and reinforcement of new skills (in the discussion).<br><br>We have clarified the role of case management in the methods section. This was to check-in with women, to explore any possible barriers to change and provide additional linkages to services. |
| Although the flow diagram lists a number of reasons why women were ineligible, it is hard to understand and interpret only 12% of participants screened being eligible for the study. This data in itself points out a potential key barrier with regard to feasibility of the intervention / recruitment, and seems critical for discussion and reconsideration. why not consider broadening inclusion to enhance scalability?<br><br>- Clarity of the study design earlier in the manuscript | We agree and have noted this limitation and impact on the feasibility of recruitment for a future trial and scale up. We have noted that we will relax these criteria to reach more women who may need these services.<br>In the methods we have also clarified the main reasons for ineligibility. |

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| would be beneficial, as the reader needs both methods, results and tables to gather necessary information on the study. For example, it remains unclear to this reviewer what happens at the “one month” – on page 11, 75% complete the one-month and 93% the three-month follow up. In other sections of the paper, relying primarily on the flow diagram, the one. Please distinguish assessment from intervention sessions. | Thank you for this observation. We have provided additional information and have corrected some errors in terms of how these contact points were described. |
| Related to above, the high level of follow up assessment completion (93%) is excellent. This supports the potential feasibility of an RCT, and should be further discussed. The one month appointment also had reasonable retention, although the only place I believe the second case management sessions is noted is the flow diagram. | Thank you- we now discuss the retention rate in the discussion.<br><br>We also now describe the second case management visit in the text. |
| Were any exploratory analyses completed related to intervention exposure? If a 3 session intervention is proposed for a phase II RCT pilot trial, what pattern of potential effect exists for those receiving three or fewer sessions? While it is noted that 68% attended 3 or more, 55% attended 5 or more, and it is possible/likely that those with more intervention exposure contributed to the greatest reductions? | We have conducted exploratory analyses related to intervention exposure. We found similar outcomes for those who attended 3 or fewer sessions to those who attended 4 or more sessions. We have added this information to the paper. |
| Were mental health outcomes examine for clinically significant changes? This could support finding without a comparison/control condition. | We have now examined the depression outcome for clinically significant change, which we identified. This is now reported |
| The qualitative findings suggest it was the brief 2 week period, rather than the six sessions, that was the barrier to attendance. | This has been clarified in the text. |
| The content of the two case management sessions is not presented, and it is also possible that these follow up intervention sessions contributed to the effect at follow up? | We have clarified the content of the case management sessions. It is possible that these contacts contributed to change- we hope we have highlighted now that without a definitive trial we will not know whether the changes we note are due to the intervention. |

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| Group sessions were not described as open or closed? If closed, were scheduling issues a barrier to groups? How were women able to make up missed sessions –<br>does that suggest groups were open? These details and discussion of potential influences would assist in conclusion regarding feasibility and acceptability. | Thank you. This was raised by another reviewer and has been addressed in the methods, results and discussion. |
| Quantitatively acceptability ratings might be useful, if available. | We agree but unfortunately did not include this in our quantitative assessments |
| Since rapid HIV testing was conducted at enrollment (although not clear why, as it was not a study inclusion criteria), is this number based on study protocol testing? If so, were these women not aware of their HIV status? Ifnewly diagnosed, were there any issues in group participation or intervention process? Also<br>as per suggested above, an exploratory analysis as to whether HIV status influence intervention/study feasibility might be of interest. | We wereinterested to see whether HIV status impacted on response to the programme and also to link women to required sexual and reproductive health services, hence HIV testing was conducted. The testing results were based on the protocol testing (not self-report data)- this has been clarified in the paper. About a third of the women who were positive were diagnosed as a result of their involvement in this study. We have conducted an exploratory analyses and found no differences in intervention /study feasibility as a result of HIV status (generally), but women who were newly diagnosed were less likely to complete treatment. This has been reflected upon in the discussion. |

**VERSION 2 – REVIEW**

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| **REVIEWER** | Kathleen Sikkema<br>Duke University USA |
| **REVIEW RETURNED** | 25-Nov-2018 |

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| **GENERAL COMMENTS** | The authors have been highly responsive in revision and substantially improved the manuscript. This is particularly true in the presentation of the study design, exploratory nature of the findings given no control/comparison condition, and limitations acknowledged in the discussion.<br>Further question and suggestions for consideration:<br><br>1. First point in “Article Summary” should be “explore” rather than “compare” given the one condition nature of the study design.<br><br>2. A remaining key issue is related to intervention exposure and the resulting conclusion to examine the effect of a 3 session intervention in a phase II trial. The presentation of descriptive intervention exposure data (second paragraph Results) used a different cutoff (68% 3 or more) than the outcome analysis (4 or more vs 3 or less). |

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| | It is not clear why this cutoff was used for the analysis and why the intervention exposure data is not presented in parallel to support the analysis and conclusions. The average number of sessions attended was 4, so this might be part of the rationale, but why are 3 sessions then recommended? Since the exploratory findings suggests 3 or less has the same potential effect as 4 or more, on what was the decision to recommend 3 sessions based?<br><br>Of note, the figures are not included in the pdf and I am not able to find them online. It may be that this data is presented clearly in that figure, my apology if it was included. Also, sample sizes are needed in subanalysis in Table 2 for 3 or less vs 4 or more sessions. I would recommend a consistent manner of presenting intervention exposure and the exploratory analysis, to support the 3 session recommendation.<br><br>Related to above point, the qualitative response recommended the intensity of the intervention be reduced, although not the number of sessions. Curious whether this might not fully support the move to 3 sessions?<br><br>3. In addition, the case management visits are now described but details are not presented on exposure and whether these sessions were considered in the intervention dosage analysis. Is it recommended that these sessions be included in the phase II trial, or does data support they are not necessary? |

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| **REVIEWER** | Lori Scott-Sheldon<br>The Miriam Hospital and Brown University USA |
| **REVIEW RETURNED** | 20-Nov-2018 |

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| **GENERAL COMMENTS** | I appreciate the authors careful revision of the above referenced manuscript; the manuscript has been substantially improved by the revisions. All of my concerns have been sufficiently addressed and I have no further concerns, comments, or suggestions regarding this manuscript. |

## VERSION 2 – AUTHOR RESPONSE

| **Reviewer 1** | |
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| 1. First point in “Article Summary” should be “explore” rather than “compare” given the one condition nature of the study design. | Thank you for this, we have made the change. |
| 2. A remaining key issue is related to intervention exposure and the resulting conclusion to examine the effect of a 3 session intervention in a phase II trial. The presentation of descriptive intervention exposure data (second paragraph Results) used a different cutoff (68% 3 or more) than the outcome analysis (4 or more vs 3 or less). It is not clear why this cutoff was used for the analysis and why the intervention exposure data is not presented in parallel to support the analysis and conclusions. The average number of sessions attended was 4, so this might be part of the rationale, but why are 3 sessions then recommended? Since the exploratory findings suggests 3 or less has the same potential effect as 4 | Thank you for this observation. We can see how our description of the cut off and rationale for using this cut-off was unclear. We have re-looked at the data and now propose using a cut off of 4 group sessions (given that this is the average number of sessions attended)- so we now compare outcomes among participant who received up to four sessions and those who received five or more sessions. As there were no differences observed for participants who received fewer sessions (up to 4), we have proposed reducing the number of groups to 4. |

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| or more, on what was the decision to recommend 3 sessions based?<br><br>Of note, the figures are not included in the pdf and I am not able to find them online. It may be that this data is presented clearly in that figure, my apology if it was included. Also, sample sizes are needed in subanalysis in Table 2 for 3 or less vs 4 or more sessions. I would recommend a consistent manner of presenting intervention exposure and the exploratory analysis, to support the 3 session recommendation.<br><br>Related to above point, the qualitative response recommended the intensity of the intervention be reduced, although not the number of sessions. Curious whether this might not fully support the move to 3 sessions? | All of these changes are reflected in the results and discussion (and Table 2). Table 2 also includes the sample sizes.<br><br>We have also checked that the figure is now included in the submission.<br><br>Yes, participants in the qualitative interviews did not explicitly discuss the preferred number of groups. We agree that our discussion may have brushed over this and not adequately reflected that their focus was on the intensity of the programme. We hope that our edits to this section have made this clearer. |
| 3. In addition, the case management visits are now described but details are not presented on exposure and whether these sessions were considered in the intervention dosage analysis. Is it recommended that these sessions be included in the phase II trial, or does data support they are not necessary? | We apologise for this omission, which we have now corrected. Although we did not consider the case management activities as part of the intervention, we acknowledge that this additional contact may have impacted on outcomes. We have explored whether receipt of case management was associated with better outcomes- we found limited evidence in support of this. This has been presented in the results section (but not in a table). Despite few differences, as we found a trend towards better retention of people who received case management, we propose retaining these activities in a phase 2 trial. This has been added to the discussion. |

**VERSION 3 – REVIEW**

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| **REVIEWER** | Kathleen Sikkema<br>Duke University United States |
| **REVIEW RETURNED** | 11-Dec-2018 |

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| **GENERAL COMMENTS** | Authors have been responsive to comments and suggestions, and have nicely integrated edits into this revision. |