Author’s response to reviews

Title: Pilot randomised controlled trial of Weight Watchers® referral with or without dietitian-led group support for weight loss in women treated for breast cancer: the BRIGHT (BReast cancer weIGHT loss) trial.

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Version: 2 Date: 26 Nov 2018

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Author’s response to reviews (revision 2)

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Author’s response to reviews:

Many thanks for considering our manuscript for publication and for providing us with a set of helpful comments. We found these suggestions very useful in clarifying our thinking and improving the manuscript. We have responded to each comment in turn below and reference specific portions of the revised manuscript where the reviewer’s comments are addressed. Changes in the revised text have been made using the track changes mode. We have assumed that previous versions up to now have been acceptable. Therefore, in order to avoid confusion we have added the new revisions to a cleaned document without the previous tracked changes.

We look forward to hearing from you.

Yours sincerely,

Dr Rumana Newlands
(On behalf of all authors)

1. Thank you for clarifying that this study indeed is a pilot trial. Please can you change the title to "Pilot randomised control trial ....." and also throughout the manuscript.

Our response: The title has been edited as Pilot randomised controlled trial of Weight Watchers® referral with or without dietitian-led group support for weight loss in women treated for breast cancer: the BRIGHT (BReast cancer weIGHT loss) trial. Please see Page 1. We have also edited as appropriate throughout the manuscript.

2. The trial objective and research question should be inline with that of a pilot trial. The research question stated in the manuscript is what you would address in your future definitive trial. Pilot trial should be focusing on feasibility of trial procedures, not comparing treatment groups. Please revise the research question and primary outcome measures. Given this is a pilot trial and small sample size statistical comparisons between groups are not appropriate. Results section should be amended to reflect this.

Our response: The research question has been revised. Please see Page 5, line 24.
The objectives are revised and between group comparisons have been removed throughout the manuscript (Page 5, line 32 and also as stated under comment 3, 4).

3. Please revise the sentence "The secondary objectives outcomes assessed were changes in body weight and quality of life (QoL) (trial outcomes). for each group from their baseline as well as between the groups following the intervention." TO "The secondary objectives outcomes assessed were changes in body weight and quality of life (QoL) (trial outcomes). for each group from their baseline."

Our response: Thank you. We have amended the text as suggested. Page 5, line 33

4. Please change the sentence "Therefore, the proportion of participants who had lost 5% or more of their initial body weight at 12 months was calculated and compared between groups using a chi-squared test." to "Therefore, the proportion of participants who had lost 5% or more of their initial body weight at 12 months was calculated."(Data collection, management and analysis section, page 11).

Our response: We have amended the text as suggested. Page 11, line 32.

5. Remove the sentence "Quantitative data analysis for secondary outcomes was performed by intention to treat" (Data collection, management and analysis section, page 11).

Our response: This sentence has been removed as suggested. Page 11, line 22.

6. Please remove the sentences "When comparing the two intervention groups to control, the weight change was significantly more in both cases (p<0.001)", "Comparison between groups showed no significant difference in weight change at 12 months (p=0.578).", "The change from baseline to 3 months in the BCS subscales werein section Secondary outcomes Changes in body weight. significantly different between WW Plus and Control group (p = 0.021) and WW and Control group (p = 0.03) with the two intervention groups showing greater improvement.", "There were no significant differences from baseline in WW Plus or Control group and no significant differences between groups in any subscales at 12 months."

Our response: These sentences have been removed from the manuscript as suggested. Page 20 (line 31); Page 21 (line 7, 13); Page 22 (line 1, 6).
7. Your response below to reviewer 1, comment 6 (Although it was stated that women were recruited from a breast clinic at ARI, I am unclear of how and when patients consented to join the pilot trial. Furthermore, I am unclear of why baseline measurements were taken prior to randomization. Since this was an open-label trial, there may be a disproportional rate of drop-outs.) should be added to manuscript to improve clarity.

Our responses: Thank you for this query. Women were recruited from a breast clinic at the local hospital, ARI by sending out an invitation letter. Then women who were interested in taking part in the trial sent the opt-in form back to the researcher. Based on this opt in form eligible participants were contacted to attend the Maggie’s centre for a baseline meeting. At this meeting, women were asked to give their written informed consent (see Page 7, line 10-11) and then, for consenting participants, their height and weight were measured.

We decided to use these methods to avoid recruiting participants with a ≤healthy BMI and/or to minimise differences between groups. We learned from previous work that often patients could not remember their current height and weight or reported a weight and/or height that were taken a long time ago. Please see Page 7, line 12-13.

Our response: Thank you very much for this suggestion. Text to address these comments has been inserted under ‘Recruitment and group allocation, and Baseline meeting. Page 6 (line 27), Page 7 (line 16).

8. Please address reviewer 1, minor limitations point 3 by adding the time period to this sentence.

Our response: This section has been moved under ‘Adherence’ based on reviewers’ comments on the previous version of this manuscript. A time period has been added at the beginning as At 12 months follow-up, …. Please see Page 17 and line 10.

9. Table 2, column "criteria used" - no major issues. it is not clear what you mean by no major issues. please clarify in the manuscript.

Our response: A sentence has been added under Primary outcomes section to address this comment. Page 10 (line 7).

A footnote has also been added to Table 2 (Page 14, line 2).

10. Table 4, results show greater weight loss in WW group than in WW plus (though confidence intervals overlap). Given that both groups had received WW intervention, I would expect
both groups to have similar weight loss if not more in WW plus group. Please provide plausible mechanisms for these results. Your explanation in discussion, page 30 "Our study finding was contrary to expectation but may indicate that the breast cancer-tailored dietitian led support group sessions provided excess or conflicting information, or encouraged the participants to reduce their engagement in the WW programme." need to supported by your data or provide reference. If you do have qualitative data to support this argument, please do provide that in results. Methods section say that this is something you are planning to measure, and results in Table 2 says "All facilitators adhered to the study protocol.". this is contradictory to your explanation in discussion.

Our response: Thank you for these suggestions.

New sentences have been added under Background to support the changes we have made to the Discussion section to address these comments. Please see Page 5, line 8.

We anticipated that WW Plus (received dietetic led sessions) would have better outcomes compared to WW only due to extra support they received from the dietitian to change lifestyle behaviour. This hypothesis was based on the previous study by Djuric et al 2002 (title: Combining Weight-Loss Counseling with the Weight Watchers Plan for Obese Breast Cancer Survivors) which showed that combination of weight loss support (dietitian’s contact plus WW) could provide better weight loss compared to any one type of support. However, we have now amended the entire paragraph on this within the discussion to address this important comment. Please see Page 24 (line 23), Page 25 (line 1-9).

Details on the qualitative (group observation) data have been added under ‘Delivery of the intervention’ and for further clarity we have included ‘observation of dietetic led sessions from researcher’ in this heading. See Page 17, line 20.

We feel by making these amendments, evidence is now provided by qualitative (observational data/field notes) to support our statement we made in the discussion about participants in the WW plus group reducing their engagement in the WW programme. We have included data showing that participants mentioned in the last group meeting of the dietitian led programmes that they followed the approach suggested by the dietitian rather than following the WW ProPoints system to lose the extra weight. See page 19, line 12.

11. Section "Delivery of the intervention", first sentence. In here what does "Observational data" referring to; is it qualitative study findings. Please clarify in the manuscript.

Our response: Yes, qualitative data was collected through group observation. This has now been clarified as suggested. Page 11 (line 4, 17).
We agree that using ‘observational data’ was confusing. The term qualitative data has now been used throughout the manuscript (Page 19, line 21).

12. Section "Delivery of the intervention", second para (It was not possible to observe WW sessions to report their fidelity due to the different timings and locations at which our participants attended. However, the organisation have a matrix of QA and audit in place to oversee fidelity of programme delivery in the network of 6,000 meetings in the UK). Did you have access to data in the pilot trial? Can you provide a summary of findings. Are you planning to get this data for the future definitive trial.

Our response: No we did not have access to these data as WW was not willing to provide these data. This has been clarified on Page 19, line 29. It’s not realistic to assess these as it’s not feasible to check fidelity of the programme delivered all over the UK, as participants are free to attend whichever WW meeting is most suitable for them.

13. Please ensure all appendices are attached.

Our response: We have uploaded all four appendices as a supplementary document.

14. Please remove the sentence "The high retention rate (>80%) indicates that the trial was considered important by the participants [35] [39]" (result, retention section), unless you did ask this question from participants and you have corresponding results.

Our response: This sentence has been deleted as suggested. Page 15, line 25.

15. Unintended consequences section - "Discussion on sensitive issues, if unrelated to trial aim and objectives such as issues with hair loss or relationship, should be avoided." Can you provide a explanation on how you came to this conclusion.

Our response: Qualitative data from group observation support this statement which we have now added to the manuscript. Please see page 18, line 4. The section on Unintended consequences has now been edited to clarify. Please see Page 20, line 22.

16. Discussion - first para. The trial procedures appeared sufficiently were feasible and ... Please clarity what you mean by "appeared sufficiently were feasible". This should relate back to your feasibility criteria in Table 2.
17. **Discussion** - second para. "Therefore, it would seem prudent to refine the trial procedures further prior to any further evaluation." Please add what those proposed changes are.

Our response: This sentence has been removed now (Page 24, line 3) as this point has been discussed under 1st paragraph (Page 22, line 21).

18. **Discussion**, page 30, "As an example, ...., with some participants reporting that the transition to WW was difficult after the counselling." Please can you add the reasons given; readers would find it useful.

Our response: As suggested, reasons stated by the participants of this particular study have been added. Please see page 25, line 1.

19. heading strengths and limitations, first para, first sentence "The strength of the study is that we have demonstrated feasibility and applicability of the trial procedures in a definitive trial and shown that there is little evidence to suggest proceeding with the WW Plus arm in a future definitive trial.". Throughout the manuscript readers are told you are assessing the feasibility in the pilot trial, not applicability. Please remove in this sentence.

Our response: As suggested "and applicability" has been removed from the sentence (page 25, line 31).

20. **Conclusion**, second sentence - "There is insufficient evidence that including a WW Plus group in a future RCT would add value.". Not clear how you came to this conclusion. Please add your reasons behind this conclusion to the discussion.

Our response: Reasons behind this conclusion have been discussed in the Discussion section. Page 22 (line 30), 25 (line 10-29).

The text under ‘conclusion’ has been edited for further clarity (page 28, line 4).
Additional edits

1. Version number and date have been updated.

2. Abstract section has been edited: Background (Page 2, line 5) and Conclusions (Page 2, line 32) based on the edits in the entire manuscript.

3. Page 4, line 20: The overall purpose of the study has been edited to match with our research question.

4. Page 5, line 8: The original plan that we had initially and then how the protocol was changed based on discussion with WW programme have been added to highlight the reasons for the different arms in this study.

5. Page 5, line 21: changed to ‘pilot’.

6. Page 11, line 32: Part of the sentence has been deleted to remove between group comparisons.

7. Page 22, line 34: ‘and pilot’ has been added.

8. Page 25, line 12: ‘Pilot’ has been added.

9. Some new references have been added using Write-N-cite but we have not updated the list/bibliography or the references within the texts (these are within brackets {{ }} now). We intend to do this once the manuscript is finalised by the journal.