Author's response to reviews

Title: A pilot study to assess the feasibility and impact of a brief motivational intervention on problem drug and alcohol use in adult mental health inpatient units: study protocol for a randomised controlled trial

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Author's response to reviews: see over
Dear Professor Altman/Sean Perrin

Re: MS: 1494322877129923
A pilot study to assess the feasibility and impact of a brief motivational intervention on problem drug and alcohol use in adult mental health inpatient units: study protocol for a randomised controlled trial
Hermine L Graham, Max Birchwood, Emma Griffith, Nick Freemantle, Paul McCrone, Chrysi Stefanidou, Kathryn Walsh, Latoya Clarke, Arsal Rana and Alex Copello

Thank you for your email of 26th June 2014 with comments from the Reviewer and the two outlined editorial requests. I have addressed each using track changes on the manuscript as requested.

1. The Ethical approval reference number: The reference number; REC reference:12/WM/0369 is now included in the methods section on Page 8.
2. I have included a sentence on Page 21, in the Authors Contribution section confirming that all authors have read and approved the final manuscript.
3. Regarding the Reviewer’s comment below, which is under the heading: Will the study design adequately test the hypothesis?
   “Yes. I do have one small query and that is whether the authors considered the possibility that as as the participants in the trial are all inpatients that patients randomized to MI might discuss or share materials from their interventions with fellow patients who had been randomized to TAU on the same unit. Leakage of the experimental treatment into TAU on an inpatient ward is probably unavoidable - and I understand that any leakage is not systematic nor a an intervention itself - but I think other readers like myself might wonder about this issue in relation to outcome. Perhaps the authors could insider adding a sentence or two to the manuscript to address this issue.”

This is something we also have given quite a bit of consideration to. The alternative study design, a 'cluster randomised trial' where subjects are randomised in groups (eg by ward), while avoiding contamination, can be extremely inefficient as site information
and allocation are often confounded, which is typically addressed by randomising a very large number of wards. However, due to the pragmatic nature of the current trial we aimed to limit any contamination bias by a number of steps taken by the trial team. Therefore we have included the following on Page 13 which seeks to address this issue. "Given the pragmatic design of the trial and the nature of inpatient units it is possible that some leakage of MI components into TAU may occur through participants or staff. Participants may inadvertently discuss or share information about the MI or inpatient staff trained to use the intervention may provide parts of it to those participants in the TAU arm. Any contamination bias will be limited by steps taken by the trial team. A number of steps will be taken to reduce potential leakage. Participants will be informed of the nature of the study during the consenting process and asked not to share any information about the treatment they receive. An important component of the training sessions for Inpatient staff and Peer Mentors in the intervention arm will involve education and awareness about the importance of blinding and ensuring only those allocated to the MI received the elements of the intervention. This is also to be discussed during supervision sessions."

We look forward to hearing from you.

Yours sincerely

Dr Hermine L. Graham
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