Author's response to reviews

Title: A randomised controlled trial testing the effects of cognitive behavioural therapy for insomnia on the mental health of university students

Authors:

Daniel Freeman (daniel.freeman@psych.ox.ac.uk)
Bryony Sheaves (bryony.sheaves@psych.ox.ac.uk)
Guy Goodwin (guy.goodwin@psych.ox.ac.uk)
Ly-Mee Yu (ly-mee.yu@phc.ox.ac.uk)
Paul Harrison (Paul.harrison@psych.ox.ac.uk)
Richard Emsley (Richard.Emsley@manchester.ac.uk)
Sophie Bostock (Sophie@sleepio.com)
Russell Foster (russell.foster@eye.ox.ac.uk)
Vanashree Wadekar (vanashree.wadekar@psych.ox.ac.uk)
Christopher Hinds (Chris.hinds@psych.ox.ac.uk)
Colin Espie (colin.espie@ndcn.ox.ac.uk)

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Dear Editors

We are very grateful to the reviewer for the very helpful and considered review of this paper. It has strengthened the paper. We have addressed the requested changes as follows:

“One use of a trial protocol is to enable replication of the study. While the content addressed within the intervention is well described, a more detailed description pertaining to the delivery of the intervention is required under the heading ‘Planned Intervention’ (page 7). Presently it is unclear how many sessions will be delivered over the 12-week treatment period. The frequency with which sessions must be ‘attended’ is also unclear (daily, weekly, or other) as is the average time participants will spend on each session. Rather than providing this level of detail as a text description, the authors may consider providing this through an additional figure depicting processes within the intervention. Inclusion of this detail will enable replication of the study.”

This is very helpful. We have added the following text on page 7: “The CBT for insomnia intervention is delivered predominantly via the World Wide Web. The delivery is structured into six sessions, lasting an average of 20 minutes each. The course takes a minimum of six weeks to complete, with sessions unlocked weekly. Participants can move at a slower pace, up to a maximum of twelve weeks. All participants have at least to start the programme online. Certain tools (e.g., sleep diaries, relaxation audios) can also be accessed using the web browser of any smartphone. All of the 6 core sessions, sleep diaries, relaxation audios and the scheduling tool can also be accessed using an iOS app, but this is only an option for participants who have an iPhone.”

Minor Essential Revisions
- On page 5, under the description of ‘Participants’, expand the inclusion criteria to indicate the cut-point at which a participant would screen positive for insomnia on the Sleep Condition Indicator.

This has been added on page 5.
- The fourth secondary hypotheses reports the intervention will lead to occurrence of fewer mental health disorders, as measured by screening tools for pre-specified disorders and treatment by mental health services. However, where the outcome measures are described on page 8, it is not clear which tools will be used as screening tools for psychosis, bipolar affective disorder, depression and anxiety (will the same symptomatic scales be used), or how any treatments used during the study will be systematically measured (e.g. through a validated questionnaire or some other means). I recommend this be clarified.

This is a useful clarification. On page 8 we have added: “To test the hypothesis concerning the potential development of mental health disorders by 22 weeks, specifically ultra-high risk for psychosis, bipolar affective disorder, depression, and anxiety, we will use established cut-offs on the Prodromal Questionnaire [46], Altman Mania Scale [50], PHQ [47], and GAD-7 [48], respectively. Participants will be asked at each online assessment time point (apart from week 3) whether they are in contact with mental health services, have received a mental health diagnosis, taken medication for a mental health problem, or are currently receiving psychological therapy.”

- Add ‘CBT’ to the list acronyms.
  This has been added.

Discretionary Revisions
- The authors note a smaller trial their team is completing within a (clinical) population with delusions and hallucinations. However it is unclear from the manuscript whether the trial has been designed in light of an assessment of previous research. As such, consider justifying the conduct of this trial in the context of the existing literature, preferably informed by systematic review.

We have carried out a systematic literature search. There are no studies of treating insomnia in the general population to examine the impact on psychotic-like experiences. We have added this on page 4.

- It is reported the intervention is digital, and delivered “entirely online using computer or smartphone” (see page 4). To further enhance replication of the study, report whether the intervention is web-based (delivered via a website which is also optimised for viewing through browsers on smartphones) or whether it is both web-based and provided as an Application within a smart phone.

This is now clarified (page 7).

- Under the assessment of safety (page 8) consider adding the method by which the research team would collect this information (presumably spontaneous contact by a participant given the online nature of trial).

Yes, that is correct. And we have added (page 9).

- Are there any adverse events, or other factors, that might warrant discontinuation or the forced withdrawal of participants?
We do not have any formal stop rules. Participants can clearly stop using the intervention at any time that they choose, and we do not have any contraindications for use of the intervention. The level of adverse events is likely to be very low in the sample overall.

- While recognising the trial will be conducted in a mentally healthy population, given the prevalence of common mental health conditions and the size of the intended sample, if self-report measures at any point of follow-up indicate serious psychological distress, or worsening symptoms, describe the processes in place (if any) to recommend referral to face-to-face clinical services or other appropriate treatment options.

This we have considered in setting up the study. We have added on page 9: “For participants concerned about their mental health, a list of UK support services is provided on the study website. If a participant makes contact via email or telephone then the clinical psychologist co-ordinating the trial can advise on appropriate clinical services.”

As requested, we have also included a statement in the methods section (page 5) that an information sheet is provided online and informed consent received online before participation in the trial can occur.

Thank you again for this helpful review and we hope the paper is now suitable for publication in Trials.

With kind regards

Daniel Freeman
Professor of Clinical Psychology