Author’s response to reviews

Title: Efficacy of Melatonin for Sleep Disturbance Following Traumatic Brain Injury: A Randomized Controlled Trial

Authors:

Natalie Grima (nataliegrima@gmail.com)
Shantha Rajaratnam (shantha.rajaratnam@monash.edu)
Darren Mansfield (darren.mansfield@monashhealth.org)
Tracey Sletten (tracey.sletten@monash.edu)
Gershon Spitz (gershon.spitz@monash.edu)
Jennie Ponsford (jennie.ponsford@monash.edu)

Version: 2 Date: 10 Dec 2017

Author’s response to reviews:

Response to editor: Thank you for the positive feedback. We have addressed all of the reviewer comments point by point as detailed below.

Comment from Reviewer 2

Reviewer #2: The manuscript is improved considerably!

Response: We are glad you approve of our revisions.

Comments from Reviewer 3

Comment (1) This article has greatly improved and most my concerns from the initial submission have been adequately addressed. However, I think the rationale for a crossover design stated in the authors' response to the reviewers were more enlightening than the text that was kept in the manuscript. A parallel arm design would have also addressed concerns about confounding through randomization, albeit using a larger sample size.

Response: We are glad to hear that you think our manuscript has improved. To bolster our rationale regarding the use of a cross over design we have now included in the following in the discussion featured on page 12:
"The rationale to use a crossover design over a parallel design was to minimize confounding covariates such as TBI characteristics and factors underpinning sleep disturbance such as depression, anxiety and pain, which were inherently controlled by each participant serving as their own control. The implementation of a cross over design reduced the number of participants required, and it guaranteed all participants received the active treatment."

Comment (2) Also, now that it is clarified that it is an efficacy study, why is it still being called a Phase IV trial?

Response: Thank you for raising this important point and we apologize for this oversight. We agree that the current study was to designed to evaluate the efficacy of melatonin supplementation rather than the effectiveness of melatonin supplementation. As such as have replaced phase IV with phase III on page 3.

Comment (3) Finally, "ITI" instead of "ITT" still lingers in the CONSORT diagram.

Response: We apologize for this oversight. We have identified the errors and have corrected them.