Reviewer’s report

Title: The effects of using cognitive behavioural therapy to improve sleep for patients with delusions and hallucinations (The BEST study): study protocol for a randomised controlled trial

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Reviewer: Matthias M Schwannauer

Reviewer’s report:

This is a well described protocol for a pilot randomised controlled trial of using cognitive behavioural therapy to improve sleep for patients with delusions and hallucinations.

The study is well described and aspects of design and methodology and clearly outlined. The authors give a clear rationale and base the study on appropriate development work. This is an important trial that has the potential to add significantly to our understanding of the active components of psychological treatments of psychosis.

The manuscript could be improved, however, by adding some details and clarifications on the following points, these are all minor essential revisions:

1) In the introduction the authors highlight that within the target population about 27% of individuals had severe clinical insomnia, 27% had moderately severe clinical insomnia and 30% had sub threshold insomnia, with only 16% sleeping well. It would be helpful to detail how the proposed sleep assessment and inclusion criteria for insomnia relate to these described levels of sleep difficulties in this population. What is the sensitivity to detect moderate and inconsistent sleep difficulties and therefore what is the anticipated incidence and severity of sleep difficulties in the target sample. How is a skew or bias towards the most severe sleep difficulties in the experimental group avoided?

2) The authors state that they will use a score of at least 2 on the PSYRATS distress scale for either delusions or hallucinations as the inclusion criteria; they also propose to use the PANSS within their baseline assessments. How are varying levels of severity on other psychotic symptom dimensions considered in the analysis and controlled for. One could imagine that a number of psychotic symptoms could have a direct effect on sleep.

3) Given that there is significant variation in the medication treatment of schizophrenic patients with hallucinations and delusions and a number of neuroleptic medications have significant effect on mood energy levels, drowsiness, etc. – how are medication effects (including side effects) and variations in medication treatments considered within the sample and in the analysis?
4) By the inclusion criteria, individuals within the target population will have significant residual symptoms and are therefore by definition treatment resistant. It would be helpful for the authors to clarify how this may effect the sample characteristics from previous samples that report on sleep difficulties in psychosis and previous cohorts treated for sleep difficulties.

Level of interest: An article of outstanding merit and interest in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

no competing interests