Reviewer’s report

Title: TREATMENT OF SLEEP DISTURBANCES IN TRAUMA-AFFECTED REFUGEES - STUDY PROTOCOL FOR A RANDOMISED CONTROLLED TRIAL

Version: 0 Date: 12 Jul 2017

Reviewer: Nikolaos Boumparis

Reviewer's report:

Sleep disturbances in individuals suffering from PTSD are one of the key symptoms of this disorder and given the large number of refugees suffering with PTSD more evidence is crucial in decreasing their burden. The manuscript is important and noteworthy. Rationale for conducting the RCT is given in the introduction and the objective is clearly stated. The authors describe with sufficient detail the planned treatments. Nevertheless, the manuscript would benefit if:

Abstract:

1. The discussion part in the Abstract would be more specific. Currently this part starts with: "The trial will contribute with important knowledge in this field" which is a very generic sentence. I would suggest going into detail and stating the important knowledge specifically.

Background:

2. In the Background section the authors state: "Approximately 21.3 million of these people were refugees." Were should be replaced by "became".

3. Same section, the authors state: "These numbers are increasing every year" Could you briefly elaborate?

4. Same section, the authors state: "Clinical guidelines for treatment, derived from research on populations with single or few traumatic experiences, fail to account for the specific, prolonged and repeated trauma and post migration stressors experienced by refugees, and cannot be assumed to apply to trauma-affected refugees in general (5,6)." Why not? Please elaborate based on the literature.
Sleep Disturbances:

5. Please mention in the text were the Competence Centre for Transcultural Psychiatry (CTP) is located.

6. The authors state: "Following treatment of PTSD, sleep disturbances often persist (11,12). Untreated sleep disturbances can contribute to maintenance and exacerbation of both sleep-related and not sleep-related PTSD symptoms (7,11)." The authors should elaborate what specific type of treatment they mean. Psychotherapeutic treatments, such as CBT or EMDR? Or perhaps Psychopharmacological treatments? Furthermore, how much is often?

Treatment of sleep disturbances:

7. The authors should state the target groups being addressed in these trials.

8. The authors state: "Current CBT for PTSD have been found less effective in treating sleep disturbances (12)." Less effective compared to which comparisons?

9. The authors state: "A number of treatment manuals exist for both CBT-I and IRT which differ in content complicating comparison and identification of active components of the two treatments" please cite.

10. The authors state: "In 2015, CTP completed a pilot study on IRT focusing on compliance and acceptability. The pilot study delineated IRT as a fully acceptable treatment for this population, but did not allow for statistical analysis on outcome (29)." How can a treatment be considered fully acceptable if the study couldn't analyse their results?

11. Is this IRT manual published or available online? If yes please cite.

Research objectives and hypotheses:

12. Words such as "and, or" do not need to be in italics. Please change

Methods:

13. The authors state: "The course of treatment is divided in two phases: phase 1 (initial app. 2 months) and phase 2 (app. 4-6 months)." What does app. mean? Please describe your abbreviations or write in full. Furthermore, after this sentence the following paragraph misses a title such as "outcome measures".
14. When the authors mention the secondary outcomes the objective sleep length is not stated anymore although it was in the abstract.

15. I would suggest moving the blinding and randomization section after the methods for the sake of clarity.

Trial fidelity:

16. Are these manuals the authors mention available online? If yes please cite.

17. The authors mention: "It is also registered whether topics of social character dominated in the session" Could the authors briefly explain the reason for this?

Inclusion criteria:

18. The authors state the following as an inclusion criterion: "Refugees or persons who have been family reunified with a refugee" Please describe this point clearer. Do you mean you are also including family members who didn't became refugees themselves but have been reunified with a family member who became a refugee?

19. In the exclusion criteria the authors mention "lack of informed consent". Since this criterion has already been mentioned in the inclusion criteria I would not mention it again in the exclusion criteria.

20. I would suggest describing the treatment conditions and TAU more concise (3 pages are definitely too much!) and without repeating information that has been mentioned before, such as "CBT is recommended as first-line" or the fact that interpreters are present.

Outcomes:

21. The authors already mentioned briefly after the methods section certain details about the outcomes. I'd suggest combining this parts with this section for the sake of clarity.

22. The authors describe their outcome measurement tools very detailed. I'd suggest to report them in a more concise way.

23. The authors mention: "The CTP Predictor Index was developed in relation to a previous trial at CTP to register and rate the psychosocial resources of the individual participant." Please cite.
24. The authors stated: "At each consultation with a physician, the participant's condition is assessed through a standardised clinical examination covering 14 parameters." What are these parameters?

25. Please describe briefly the structure of the patient satisfaction survey.

Randomisation:

26. The authors state: "All participants are randomised after the two-three hour pre-treatment assessment by a physician in accordance with inclusion and exclusion criteria including informed written consent" Since the authors included the informed consent in their inclusion and exclusion criteria there is no need to mention it again separately.

27. The authors use the term participant and patient interchangeably. I would suggest using the term patient and stick to it.

Discussion:

28. The discussion section is rather short compared to the size of the other sections of the manuscript.

29. Abbreviations should be described in the text. There is no need for an extra list after the trial status section.

Table and figure:

30. I suggest the authors to adapt the current table of collection of data and make it according to APA. This should enhance clarity. Furthermore, abbreviations need to be described under the table.

31. In the flowchart one of the last boxes below includes certain lines that need to be deleted.

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Please indicate how interesting you found the manuscript:

An article of importance in its field

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All images and figures within the manuscript should be genuine i.e. without evidence of manipulation. No specific feature within an image may be enhanced, obscured, moved, removed, or introduced. If you have concerns about the veracity of the figures you should choose the first option below.

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Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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