Reviewer's report

Title: Transcranial bright light treatment via ear canals in seasonal affective disorder: a randomized, controlled, double-blind dose-response study

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Reviewer: Ybe Meesters

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Transcranial bright light treatment via ear canals in seasonal affective disorder: a randomized, controlled, double-blind dose-response study

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It is encouraging to see that the authors are investigating the effects of a new device in treating Seasonal Affective Disorders. However, this study has some serious flaws:

The major problem is that, till now, there is no evidence that TLB can treat SAD. There is an interesting study published in Medical Hypothesis, which should be the first step to an RCT. Unfortunately, this study is not that study.

There is no placebo condition. Just with this treatment modality, TLB, a placebo condition can be realized. A placebo condition is not possible in light treatment conditions where patient have to receive the light through the eyes. But using TLB as a treatment device, it is possible to create a real placebo condition. Therefore, the reason mentioned by the authors that: Since the treatment was carried out at home, without supervision through the investigators, it was not possible to create a proper placebo condition in this study, is not satisfying. If that is the case, this study should have carried out in the clinic in controlled surroundings, because, till today I don’t know a study in which the effect of TLB is shown.

If a placebo condition is not allowed (some ethical committees don’t approve such studies because of withholding a patient from an effective treatment) a comparison should be made with the effect of the most well known effective and accepted (light) treatment using light through the eyes.

Besides this major problem, there are some other issues:

- It is not clear why dose response differences should have any differences in treatment response using a light fixture in the ears. What are the theoretical assumptions?
- The population in this study suffers from SAD and, based on the scores on the Hamilton Anxiety Scale, anxiety. This combination of complaints is not mentioned
very clear and differs from other studies investigating treatments of SAD.
- The means scores on the BDI are related to a moderately severe depression
  The HAMD scores are also related to the same range of depression. The
  SIGH-SAD scores are rather high, and is the sum of HAMD and Atypical scores.
  The BDI shows lots of questions which are related to the Atypical scores of the
  SIGH-SAD. One should expect that the scores on the BDI should be higher in
  relation to the scores on the SIGH-SAD. The authors should discuss this
  phenomenon.
- It is curious the allow participant to use TLB till noon, and ask them to follow
  some bedtime instructions before the two measurement days. What is the
  reason?
- No reason is mentioned why participants should have no coffee or alcohol
  related to the assessment days, while no rules for the other days in the 4 weeks
  of investigation are mentioned. For example: is it allowed to drink lots of alcohol
  during the other days?
- There is a difference in response percentage related to the assessment
  instrument. The percentage of response of SIGH-SAD is lower than the response
  as assessed with the BDI. The BDI is a self rating instrument and the SIGH-SAD
  is rated by a blind rater. An explanation for this difference might be the effect of
  suggestion or placebo.
- In the abstract the high response rates as assessed with the BDI are only
  mentioned. That selection sounds as a commercial for TLB, in which in a
  selective way only the best results are mentioned.
- Related to this last point: In the list of affiliations on the title page, the CSO and
  share holder of Valkee, Juuso Nissila is mentioned to have a relation with the
  University of Oulou, Institute of Health Sciences. At the end of the paper his
  relation with Valkee is mentioned. At least, this way of presenting affiliations is
  remarkable.
- On page 4, 70 % sitting in front of bright light is uncomfortable and reason for
  some SAD sufferers to cease BLT for that reason. This seems a rather selective
  way of referring to the, rather old, literature. Nowadays light fixtures are more
  convenient and are improved ever since. It is also possible to refer to literature in
  which SAD sufferers are very happy with the light treatment.
- There is no reference to the article of Bromundt e.a. 2013 about some aspects
  of a possible working mechanism of TLB, which is not in favor of TLB. This article
  should be mentioned and discussed.

Although a lot of scientific work is presented, before publishing the present study,
at first an RCT study should be presented in which TLB has been showed to be
effective compared to placebo or ocular light studies. In the present study, most
results can be explained by a possible placebo effect.

Furthermore: a scientific paper should discus the results more critical and, as
mentioned before, not only mentioned the most favorable results in the abstract.
In the present presentation the impression exist that there is some competing
interests which is a leading factor in the paper

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests