Reviewer's report

Title: Feasibility, double-blind, randomised, placebo-controlled, multi-centre trial of hand-held NB-UVB phototherapy for the treatment of vitiligo at home (HI-Light trial: Home Intervention of Light therapy)

Version: 1  Date: 5 November 2013

Reviewer: Jinhui Ma

Reviewer's report:

I read this article with interest as it addresses the safety of using the hand-held NB-UVB device at home for the treatment of vitiligo, a field with very limited attention has been paid in the literature. The authors examined the feasibility of conducting a large multi-center RCT on the use of this device and provided recommendations for the future trials. There are a number of points which need to be addressed.

Major compulsory revisions:

1. I think the abstract of this paper need to be revised in order to act as a stand-alone statement that briefly and clearly conveys the essential information of the manuscript. Here I only listed two examples for the authors to consider: (1) ‘examined the feasibility of conducting a large multi-centre RCT on the use of such devices by exploring …’ is the objective of the pilot trial, and it should be move from the Methods section to the Background section; (2) the Results section is not clearly presented. The authors stated that ‘eighty three per cent of people who expressed interest in the trial were willing to be randomised’. It will be helpful to provide readers brief information about who these people are (any vitiligo patients?).

2. In the section of ‘Phototherapy for the treatment of vitiligo’ on page 9, the authors mentioned ‘secondary care’. If the authors expect that non-clinical experts would also be the readers of this paper, they should briefly introduce what the primary and secondary care mean.

3. In the section of ‘Randomisation and blinding’ on page 12, the author stated that ‘permuted blocks of randomly varying size’ was used in the randomization process. The size of permuted blocks could be any integer number between 1 and infinity?

4. The primary and secondary outcomes described on page 13 should completely match with the primary and secondary objectives of the study. It is not clear which objective was matched with the secondary outcome ‘withdrawal rates and missing data’; and which secondary outcome was matched to the secondary objective ‘to prepare a training package for patients explaining how to use intervention and how to deal with possible side effect.

5. In the section of ‘Outcomes’ on page 13, a few outcomes were not clearly
defined. For examples (1) how the secondary outcomes ‘proportion of participants expressing interest in the trial and fulfilling eligibility criteria’ were calculated (i.e. what are the denominators and numerators); (2) what is the definition of ‘cessation of spreading of vitiligo during the past year’; (3) what are the definitions for bad, fair or excellent color match of newly repigmented vitiliginous lesions; (4) what is the definition of ‘adhering to the treatment’ (for example, complete more than 80% of scheduled treatment sessions per week and treatment times?) etc.

6. The author did not mention if the patients got any other treatment such as topical steroids besides the NB-UVB device.

7. In the section of ‘Withdrawals’ on page 17, I think it is helpful to provide the readers the intervention group for each of the 3 participants who withdrew from the study.

8. In the section of ‘Side effects’ on page 18, I would like to see the frequency of side effects across different treatment groups.

Minor essential revisions:

1. Table 3 second line: what is the meaning of “-“-0?
2. There are two Table 4s. One should be changed to Table 5.

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

Quality of written English: Acceptable

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

Declaration of competing interests:

I have nothing to declare.