Reviewer's report

Title: Virtual restorative environment therapy as an adjunct to pain control during burns dressing changes

Version: 1
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Reviewer: Joaquín Sáez-Peñataro

Reviewer's report:

The authors describe a unicentric randomized controlled clinical trial. The study aims to evaluate the efficacy of a virtual reality device, a ‘Virtual restorative environment’, in patients with burns requiring at least three dressing changes. The trial comprises three treatment arms: a passive Virtual Restorative Environment Therapy (VRET), an active VRET and a standard arm with conventional analgesia without VRET. Analgesia will also be administered in VRET treatment arms. Overall, the design and methodology of the trial are deemed ethical and well-explained in the text. Further, the objectives and outcome measures are considered relevant for the trial.

I do not have any issue for a major compulsory revision. However, some minor essential revisions should be considered by the authors:

1.-Typographical issues:
1.1.-When the times of analgesic administration are described, hours should be rewritten using the standard format with two points (e.g. 07:00 instead of 0700).
1.2.-The abbreviation ‘COTS´ controller should be explained at the end of the text, together with the other abbreviations.

2.-Statistical assumptions and analysis of the results:
2.1.-The calculation of the sample size, being a relevant statistical assumption, should be referred to in the abstract.
2.2.-In the sample size calculation the authors assume a mean percentage reduction from the control value of 30 for Interactive VRET and a mean percentage reduction of 15 for Passive VRET. This assumption of the theoretical treatment effect should be further explained and justified in the light of previous results.
2.3.-Regarding the analysis of the results, the authors describe the use of a Likert scale for the evaluation of pain control, patient usability, nausea and nursing satisfaction. The total possible score of these Likert scales should be referred to complete the description of the secondary outcome measures.
2.4.-With respect to data analysis, the authors state the following: ‘For VRET condition only Wilcoxon signed rank test will be a possible alternative to paired t test’. This sentence should be further clarified and explained. Does the ‘VRET condition’ refer to both active and passive VRET treatments, in their comparison...
to control treatment without VRET? This should be adviceably clarified.

2.5.-In addition, regarding to data analysis, it is recommendable that the authors include a reference to the type of programme used in statistical data analysis.

3.-Discussion section:

3.1.-With respect to the discussion, the authors state that recruitment rate is being low because of the nature of burns care, the ability of burns inpatients to provide informed consent and the ability of patients to use the VR equipment. This is an important limitation for the performance of this type of studies, and its discussion in this section is endorsed. However, being an important constraint for the study implementation, further explanation on measures that could be taken at this point to improve recruitment rate, also for the implementation of future studies, would be welcome.

3.2.-Indeed, the authors should better discuss the following statement: ´The within-subject design with graded exposure to the VR intervention was chosen to reduce bias within the study. Unfortunately this design may have consequently reduced the feasibility of accruing participants´.

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 declare that I have no competing interests