Reviewer’s report

Title: Immersive virtual reality as analgesia for women during hysterosalpingography: study protocol for a randomized controlled trial

Version: 0 Date: 16 Oct 2019

Reviewer: Catherine Arundel

Reviewer's report:

This is an interesting paper investigating an interesting and novel concept for pain management.

General
- Thank you for providing further details of the associated funding for this work. Unfortunately there remains a lack of clarity with regards the funding and the link to this work. As a result, we must request that the reference to funding be removed from this submission, and so this treated as an 'unfunded' study. Please could you remove funding references accordingly.

- There are some typographical and grammatical errors throughout the manuscript e.g. Abstract - Background - Sentence 3 'AS' rather than 'As'; Background - Sentence 2 'stage' perhaps should be 'age'. A full proof reading of the manuscript is recommended to resolve these issues and increase readability.

Specific
Background - Please ensure acronyms are spelled out in full when first used in the main body of the manuscript. For example Background Sentence 4 commences with 'HSG' which has not previously been detailed in the main body of the manuscript.

Background - Paragraph 1 - Is there a reference to support the statement made in sentence 1?

Background - Paragraph 2 - You mention that the uncomfortable experience can lead to poor coordination. It wasn't clear who or what this was referring to - is this coordination of the patient or clinician, how is coordination affected.

Background - Paragraph 3 - This includes one very long sentence ('Although studies have shown...') which is difficult to follow. I suggest this would benefit from review and reduction.

Background - Paragraph 3 - You note that patients receive no analgesics during HSG as routine care, is this a reflection of your own institution or more generally. It would be useful to be specific here to help contextualise for the reader.

Background - Paragraph 4 - You mention 'immersive VR'. It would be helpful to explain this concept in a little more detail, to help to contextualise for the reader.

Methods - Study Design - Is your study design superiority or inferiority etc?

Methods - Study Setting - This includes one very long sentence ('This institution...') which is difficult to follow. I suggest this would benefit from review and reduction.

Methods - Study Setting - What is your expected duration of recruitment?
Methods - Study Participants - What does 'Indications for HSG' mean? Can this be detailed further?
Methods - Study Participants - What does 'Operator Difficulty' mean? Can this be detailed further?
Methods - Study Participants - What does 'All healthcare workers...will be willing to participate' mean?
Presumably participation is for the patients not the professionals, who would be doing their routine clinical work with these patients?
Methods - Study Participants - How will recruitment take place? Have any strategies been identified or implemented to help recruitment? Some further detail on this would be helpful.

Methods - Randomisation - Is any form of stratification used?
Methods - Randomisation - How is the randomisation sequence implemented - who completes this? are individual participant envelopes used? Be more specific to aid replication.

Methods - HSG procedures/VR Prototype/Interventions - It feels that this would benefit from some reworking, to streamline the description. I suggest it might be useful to start with a description of how participants will be recruited and consented, followed by details of the HSG procedure, followed by details of the intervention element, followed by details of the control.

Methods - Interventions - What does 'participants will be numbered according to the order of operation' mean? Further description is required.

Methods - Measurement - What information will you collect at Baseline?
Methods - Measurement - Given the study type and setting, I expect that retention will not be a significant issue here. It would be useful though to be clear about whether you have considered any specific mechanisms to ensure data collection is completed.
Methods - Measurements - It would be useful to provide some additional detail for the measurements e.g. what physiological parameters will be collected, and to detail when specific outcomes will be collected

Methods - Data Monitoring - Are there any other committees involved in this study? Is there any planned audit or monitoring? Are there any planned interim analyses?
Methods - Data Monitoring - Are the DMC members also independent of the study team recruiting and treating patients? Where protocol changes are required how will these be implemented?

Methods - Data Storage - How will participant confidentiality be protected?
Methods - Data Storage - Are there any data entry checks included e.g. double data entry? checking of entered data?

Methods - Sample Size - You note use of previous studies to determine the sample size, but then also note a pilot. This section needs some clarity as to the sources of information used to determine your sample size.
Methods - Sample Size - Please confirm your calculation of drop out rate; 120% of 158 is not 200.

Methods - Statistical analysis - Will the analyst be independent to the researchers recruiting and treating participants? Will the analyst be blinded to treatment allocation during analysis?
Methods - Statistical analysis - Please provide more detail on the analytical methods to be used for the primary outcome analysis
Methods - Statistical analysis - Will a separate analysis plan be generated?
Discussion - Sentence 2 - 'Hence the ideal...' this doesn't seem to fit with subsequent sentences. I wondered if this might be better situated at the end of Paragraph 2/start of paragraph 3?

Discussion - Limitations - You note a multi-centre study would be more representative. Is this planned at this time?

Availability of Data - Will the data derived from this work be accessible?

Figure 1 - It would be useful to note in this diagram the point at which eligibility is assessed, consent taken and Baseline data collected.

Spirit Checklist - Where elements are not applicable and so noted as ' --', it would be helpful for transparency to document why this is not relevant here.

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Please indicate how interesting you found the manuscript:

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