Author’s response to reviews

Title: The effect of adding TENS to stretch on improvement of ankle range of motion in inactive patients in intensive care units: A pilot trial

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Reply to the reviewers’ comments (SSMR-D-19-00017)

-Editor Comments: 1. In the Trial registration subsection of the Abstract, please indicate the date of your trial’s registration. If your trial was registered retrospectively please declare so.

--Respond to specific editor comment 1: Done.

-Editor Comment 2: Please note that the Consent for publication statement refers to consent obtained to include any individual person’s data in any form (including individual details, images or videos). Therefore, please state "Not applicable" in this section as no personal information is provided in your manuscript. The statement regarding authors’ approval of the final manuscript should instead be included in the Authors’ contributions section of the Declarations.

--Respond to specific editor comments: Amended in the manuscript.

-Editor Comment 3: Please further clarify your statement on participants’ consent in the Ethics approval and consent to participate subsection of the Declarations. You may consider revising your statement to read something to the effect of:

“Participants provided written informed consent for participation in this study.”

--Respond to specific editor comment: Amended in the manuscript.
-Editor Comment 4: At this stage, please upload your manuscript as a single, final, clean version that does not contain any tracked changes, comments, highlights, strikethroughs or text in different colours. All relevant tables/figures/additional files should also be clean versions. Figures (and additional files) should remain uploaded as separate files.

--Respond to specific editor comments: Done.

Reviewer comments (Reviewer 2):

Title

1. The sample size calculation has not been completed using the primary outcome measure. Please therefore, include the word 'pilot' as a descriptor in the title. Either the study is a 'Double-blind, pilot randomised clinical trial' or change to:…in intensive care units: A pilot trial.'

--Respond to specific reviewer comment: Amended in the manuscript.

Methods

2. By the author's admissions, there were differences between the baseline primary measures between groups suggesting a failure of randomisation or a systematic difference between the groups. At what time after admission to ICU did the trial start? Please list as a limitation if patients had differing trial starting points as it is feasible that any patient who had a prolonged stay prior to recruitment may have had a measurable limitation of ROM before treatment started and therefore, the intervention group, who started with more stiffness, may have responded more readily to the stretching intervention than the control group.

--Respond to specific reviewer comment: A statement added to the Limitation section (4-Patients had different trial starting points, as it is feasible that any patient who had a prolonged stay prior to recruitment may have had a measurable limitation of ROM before treatment started).

Results

3. Line 10 - The comments about the patient use of medication add little value. Please remove them. They restate the values in the table and create more questions than they answer.

--Respond to specific reviewer comment: Amended in the manuscript.
Discussion

4. There are a number of statements which encourage the reader to believe that TENS in the context of the study is linked to long term benefits in terms of balance, strength or pain and short term benefits for spasm. Please temper the statements in paragraph 2 and the last two paragraphs prior to limitations (last paragraph).

--Respond to specific reviewer comment: We did not understand what is the exact opinion of the reviewer in comment number 4 (There are a number of statements which encourage ...) and we do not know how to temper the statements. If necessary, please explain more.

Conclusion

5. Remove the last sentence. It is not in line with the outcomes assessed during the study. Neither cost, nor need for surgery were variables in this study.

--Respond to specific reviewer comment: Amended in the manuscript.