PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Acupuncture for Acute Musculoskeletal Pain Management in the Emergency Department and Continuity Clinic: A Protocol for an Adaptive Pragmatic Randomized Controlled Trial
AUTHORS	Eucker, Stephanie; Glass, Oliver; Staton, Catherine; Knisely, Mitchell R.; O'Regan, Amy; De Larco, Christi; Mill, Michelle; Dixon, Austin; TumSuden, Olivia; Walker, Erica; Dalton, Juliet C.; Limkakeng, Alexander; Maxwell, Ann Miller; Gordee, Alex; Kuchibhatla, Maggie; Chow, Sheinchung

VERSION 1 – REVIEW

REVIEWER	Tze Chao Wee Changi General Hospital
REVIEW RETURNED	11-May-2022

GENERAL COMMENTS	This is an interesting and clinically relevant study. The use of acupuncture in the ED is not new but the focus of the study brings a new dimension to this area of research. I would suggest revising the title to better describe the longitudinal nature of the study. Please clarify the decision to exclude acupoints on the torso? Is this a logistic consideration or a clinical consideration. Otherwise I am happy to accept the manuscript in its current form and I look forward to the results of the study.

REVIEWER	Shiu-Lin Tsai Columbia University Medical Center, Emergency Medicine
REVIEW RETURNED	07-Jun-2022

GENERAL COMMENTS	Congratulations on putting this wonderful team together, proposing a thoughtful and in depth protocol, and for procuring funding to study acupuncture in the ED for musculoskeletal pain locations. As you have stated, this study goes beyond pain outcomes with acupuncture in the ED, since you also provide outpatient continuation of acupuncture. Additionally the secondary outcome measures including biopsychosocial factors, quality of life and patient function are novel and will provide new dimensions around acupuncture therapy. Some suggestions and points for clarification: 1- Battlefield Acupuncture should be stated early in the manuscript under Methods as your primary protocol for Auricular Acupuncture (AA). 2- State the type of needle you intend to use for AA - ASP? Pyonex? 3- There are powerful acupuncture points over the back to treat lower back pain. Why did you decide NOT to use these and other torso points ? (Page 9, line 40-41)

	4- The outpatient acupuncture will be determined by the acupuncturist, not to continue the same type of acupuncture that patient was randomized to in the ED. Given the different outpatient acupuncture therapy, will this data be evaluated separately from those obtained from the ED? (Page 9, line 46-48) 5- Measurement of pain should be from ED baseline to 1 hour post treatment, not post-randomization? (Page 10: line 18; Page 13: line15-16) 6- Please clarify Page 10: line 19-20 "The primary combined ED-Outpatient clinic effectiveness ... post-ED visit". Wat does 7- Will you collect the mechanism of injury? Depending on the cause/etiology of the pain, AA or PA is known to be more effective for pain from certain causes. Sub-analysis of the etiologies or mechanism of injury may be needed. 8- Outcome from PA may depend on acupuncture point selection, acupuncturist skill. These would make a direct comparison of PA to AA difficult. 9- On page 15: line 34-36 "Lastly, while the battlefield protocol was ..., outside of the military both AA and PA can only be performed by licensed and trained acupuncturist." While this is true for lay person and acupuncturists, physicians can perform Battlefield Acupuncture as well as peripheral body acupuncture without formal training. This is because a majority of states across United States do not have specific training requirements before a physician can administer acupuncture. (Bleck RR, et al. Training hour requirements to provide acupuncture in the United States. Acupuncture in Medicine. 2021, Vol. 39(4) 327–333). This fact should also be included in your manuscript. 10- While access and "... extension of acupuncture to a more broadly representative ED population, ..." were stated in the Article Summary as a strength, your Eligibility Criteria states that "... participants must be able to read and understand the consent form in English." This precludes patients from minority groups and may appear to contradict your article summary strength statement. How would you address this? Look forward to seeing your results!

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Tze Chao Wee, Changi General Hospital

Comments to the Author:

1) This is an interesting and clinically relevant study. The use of acupuncture in the ED is not new but the focus of the study brings a new dimension to this area of research.

I would suggest revising the title to better describe the longitudinal nature of the study.

Thank you for the positive comments on this paper. We have updated the title to reflect this:

"Acupuncture for Acute Musculoskeletal Pain Management in the Emergency Department and Continuity Clinic: A Protocol for an Adaptive Pragmatic Randomized Controlled Trial"

2) Please clarify the decision to exclude acupoints on the torso? Is this a logistic consideration or a clinical consideration.

This was both a logistic and implementation consideration. In order to increase both the efficiency of the treatment and patient as well as ED staff receptivity to receiving the treatment while in the emergency department and in follow up clinic, we chose to restrict acupoints to only those accessible when patients are fully clothed and sitting or laying in a stretcher. ED patients with acute musculoskeletal pain frequently do not want to or cannot disrobe and/or change positions to be able to access torso points. Removing this requirement also increased acceptability to ED staff by decreasing the amount of time and resources (e.g. rooms) required for delivering treatment in a busy ED. We have updated the methods to explain this:

"Acupuncture sites on the torso (i.e., chest, back and abdomen) will not be used, as accessing these sites is often logistically challenging in a busy ED environment."

Otherwise I am happy to accept the manuscript in its current form and I look forward to the results of the study.

We greatly appreciate your feedback.

Reviewer: 2
Dr. Shiu-Lin Tsai , Columbia University Medical Center
Comments to the Author:
Congratulations on putting this wonderful team together, proposing a thoughtful and in depth protocol, and for procuring funding to study acupuncture in the ED for musculoskeletal pain locations. As you have stated, this study goes beyond pain outcomes with acupuncture in the ED, since you also provide outpatient continuation of acupuncture. Additionally the secondary outcome measures including biopsychosocial factors, quality of life and patient function are novel and will provide new dimensions around acupuncture therapy.

Thank you for the thoughtful comments on this paper.

Some suggestions and points for clarification:
1- Battlefield Acupuncture should be stated early in the manuscript under Methods as your primary protocol for Auricular Acupuncture (AA).

We have added this statement to the first mention of AA on Page 6:

"The objective of the first (treatment selection) stage is to determine the more effective style of ED-based acupuncture, i.e., Auricular Acupuncture (AA) based on the Battlefield Acupuncture protocol, or Peripheral Acupuncture (PA), as compared to no acupuncture (NA)."

2- State the type of needle you intend to use for AA - ASP? Pyonex?

Pyonex. We have added this to the Methods:

" <u>Auricular acupuncture (AA)</u> will involve the placement of pyonex needles"

3- There are powerful acupuncture points over the back to treat lower back pain. Why did you decide NOT to use these and other torso points ? (Page 9, line 40-41)

See response to Reviewer 1's Question #2.

4- The outpatient acupuncture will be determined by the acupuncturist, not to continue the same type of acupuncture that patient was randomized to in the ED. Given the different outpatient acupuncture therapy, will this data be evaluated separately from those obtained from the ED? (Page 9, line 46-48)

Yes, this will be evaluated using the 1-month pain scores and other outcome measures. As there may still be a small effect of the two different ED treatments, the analysis will initially be performed as if there are 3 treatment arms which we call the "combined ED-outpatient clinic treatment" (1-Control/No acupuncture, 2-AA-Clinic, 3-PA-Clinic). If groups 2 and 3 are found to be statistically similar, they may be combined as the overall "acupuncture clinic" group vs no acupuncture.

5- Measurement of pain should be from ED baseline to 1 hour post treatment, not post-randomization? (Page 10: line 18; Page 13: line15-16)

Correct, we have updated the description to "post-treatment" throughout the text.

6- Please clarify Page 10: line 19-20 "The primary combined ED-Outpatient clinic effectiveness ... post-ED visit". Wat does

See response to #4 above.

7- Will you collect the mechanism of injury? Depending on the cause/etiology of the pain, AA or PA is known to be more effective for pain from certain causes. Sub-analysis of the etiologies or mechanism of injury may be needed.

A brief assessment of mechanism will be collected, specifically 1) traumatic, 2) sudden, 3) gradual. More granular mechanisms than this are challenging from both an analysis and veracity of information standpoint (ie., the patient may not know exactly what specific mechanism brought about their pain, and too many options becomes under-powered for analysis).

8- Outcome from PA may depend on acupuncture point selection, acupuncturist skill. These would make a direct comparison of PA to AA difficult.

We are tracking which acupuncturists are treating which patients, as well as how many acupuncture points are used, for both reporting and to determine whether there are any acupuncturist-dependent variations in the treatments. We may add a sub-analysis if we find differences.

9- On page 15: line 34-36 "Lastly, while the battlefield protocol was ..., outside of the military both AA and PA can only be performed by licensed and trained acupuncturist." While this is true for lay person and acupuncturists, physicians can perform Battlefield Acupuncture as well as peripheral body acupuncture without formal training. This is because a majority of states across United States do not have specific training requirements before a physician can administer acupuncture. (Bleck RR, et al. Training hour requirements to provide acupuncture in the United States. Acupuncture in Medicine. 2021, Vol. 39(4) 327–333). This fact should also be included in your manuscript.

Thank you for sharing this paper. I have removed this sentence, as this discussion would go beyond the scope of this methods paper, but will definitely think about how to incorporate this information into the future results manuscript.

10- While access and "... extension of acupuncture to a more broadly representative ED population, ..." were stated in the Article Summary as a strength, your Eligibility Criteria states that "... participants must be able to read and understand the consent form in English." This precludes patients from minority groups and may appear to contradict your article summary strength statement. How would you address this?

We have removed this statement from the summary, and updated the main text to specify U.S. population. While it is true that non-English speaking patients would be excluded, which is an important limitation, in our ED this represents less than 5-10% of our patients. By contrast, few acupuncture studies in the U.S. have included many non-white or lower socioeconomic status populations, thus our study is more broadly representative than the existing U.S.-based studies, although not perfectly representative.

Look forward to seeing your results!

Thank you!