ARTICLE DETAILS

TITLE (PROVISIONAL)  Efficacy and Safety of Traditional Chinese Manual Therapy (Tuina) in Patients With Nonspecific Chronic Low Back Pain: A Study Protocol for A Randomized Controlled Trial

AUTHORS  Cao, Ben; Fang, Sitong; Wu, Zhiwei; Zhou, Xin; Kong, Lingjun; Zhu, Qingguang; Zhu, Bowen; Tang, Cheng; Fang, Min

GENERAL COMMENTS

1. This study will determine the feasibility of running a study of tuina as a treatment option on non-specific chronic low back pain.

2. The major weakness of this study is that the authors haven’t mentioned about the diagnostics for recruitment. Non-specific chronic low back pain was chosen as the diagnosis, but more information should be added about how this diagnosis was made, specifically how other conditions were ruled out. I would ask the authors to include this point as limitation of the study.

3. Regarding the qualifications of the practitioner, the author writes that he is a TUINA therapist, please specify the licensing qualifications such as a doctor, physiotherapist, etc.

4. Please describe the author’s plan for monitoring the study. Please specify the schedule and frequency of beginning monitoring, end monitoring, interim monitoring, etc.

All in all, this study is interesting and generally well written, provided the comments above are addressed properly.

REVIEWER  Adrian Traeger
The University of Sydney Faculty of Medicine and Health, Institute for Musculoskeletal Health, Sydney School of Public Health

REVIEW RETURNED  14-Dec-2023

GENERAL COMMENTS  Clearly written protocol that I recommend for publication

Some specific suggestions:
Abstract
Suggest adding a sentence summarising what Tuina involves

Introduction
Several studies of Tuina are cited but no systematic review. Are there any systematic reviews that have included the cited studies, that the authors could describe?

Methods
Page 5 line 25: “blinded assessors” the primary outcome is the pain NRS which is self-reported. In this case the assessor is the patient, who is not blinded. This should be corrected throughout
Page 5 line 25: Methods have been approved by an ethics committee and trial is registered
Page 7 line 35: as above the evaluator is the patient who is unblinded. I would suggest it is only realistic to blind the data analysis.
Page 12 line 38: “to reposition any misaligned…” please reword to reflect the speculative nature of this statement e.g. “which is thought to reposition…”
Page 12 Please expand the acronym “CSE” throughout
Page 18 line 38 How will serious AEs be defined?

Best wishes
Adrian Traeger
study, and we have been working diligently to overcome this difficulty. Therefore, we have designed strict and detailed **inclusion and exclusion criteria**, aiming to minimize the impact of the lack of recognized diagnostic criteria on the recruitment of participants. Also, following your suggestion, we have included this issue as one of the **limitations of our study**.

### 3. Regarding the qualifications of the practitioner, the author writes that he is a TUINA therapist, please specify the licensing qualifications such as a doctor, physiotherapist, etc.

I deeply apologize for any confusion caused. Our tuina intervention practitioners are all licensed medical professionals with nationally recognized credentials. Consequently, I have amended the term “tuina therapist” to “tuina doctor” in the main text.

### 4. Please describe the author’s plan for monitoring the study. Please specify the schedule and frequency of beginning monitoring, end monitoring, interim monitoring, etc.

I apologize for not explaining this issue clearly earlier. I have provided a supplement in **section 2.10** of the article. Please review it in the manuscript.

### Reviewer 2

<table>
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<tr>
<th>Comments</th>
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<tr>
<td><strong>1</strong> Abstract: Suggest adding a sentence summarising what Tuina involves</td>
<td>Thank you for your detailed guidance. I have <strong>added</strong> text and highlighted it in the abstract. Please review it in the manuscript.</td>
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<tr>
<td><strong>2</strong> Introduction: Several studies of Tuina are cited but no systematic review. Are there any systematic reviews that have included the cited studies, that the authors could describe?</td>
<td>Thank you for your advice. As you mentioned, systematic reviews have a higher level of evidence, and if relevant systematic reviews are available, they should be cited first. After searching and verifying, I have reorganized <strong>references 6 and 8</strong>, both of which are systematic reviews that meet the citation criteria. Please review them in the introduction.</td>
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<td><strong>3</strong> Methods: “blinded assessors” the primary outcome is the pain NRS which is self-reported. In this</td>
<td>I sincerely apologize for the confusion caused by my wording. Assessors refer to those <strong>collecting</strong> outcome measures, solely responsible for gathering study results and <strong>unaware</strong> of the</td>
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case the assessor is the patient, who is not blinded. This should be corrected throughout

Undoubtedly, the pain intensity reported by participants is subjective and can only be assessed by the individuals themselves. However, in this context, the researchers using NRS to collect/assess participants' pain intensity are referred to as assessors.

I hope my explanation is acceptable to you, and once again, thank you very much!

<table>
<thead>
<tr>
<th>④ Methods have been approved by an ethics committee and trial is registered</th>
<th>Yes, all these requirements have been met. Please refer to the main text.</th>
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<tr>
<td>⑤ Methods: as above the evaluator is the patient who is unblinded. I would suggest it is only realistic to blind the data analysis</td>
<td>Thank you for your careful consideration of this detail. As mentioned earlier, our outcome collectors (assessors) and data analysts are both unaware of patient groupings.</td>
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<td>⑥ Methods: “to reposition any misaligned…” please reword to reflect the speculative nature of this statement e.g. “which is thought to reposition…”</td>
<td>Thank you! The previous expression was indeed not precise enough. I have rephrased this sentence in section 2.8.1 and highlighted it. Please review it.</td>
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<td>⑦ Methods: Please expand the acronym “CSE” throughout</td>
<td>I expanded the abbreviation in the title of section 2.8.2, and for conciseness and clarity in the following paragraphs, I retained the abbreviation CSE. I wonder if this is acceptable. Thank you for your valuable suggestions!</td>
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<td>⑧ Methods: How will serious AEs be defined?</td>
<td>I apologize for not providing a clear definition. Following your advice, I have added text in the Adverse Events section to define SAEs.</td>
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VERSION 2 – REVIEW

| REVIEWER | Man-Suk Hwang  
Pusan National University, School of Korean medicine |
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<td>REVIEW RETURNED</td>
<td>30-Jan-2024</td>
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<tr>
<td>GENERAL COMMENTS</td>
<td>This study will determine the feasibility of running a study of tuina as a treatment on NCLBP. This study protocol is well-written and I hope the following comments can be of help for conducting and analysing</td>
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the upcoming results.

1. Please include the date of first enrollment in the methods section.

1. The primary outcome variable is that the average pain level over the past 6 weeks is evaluated using NRS. Please explain the method in detail. I’m not sure if the patient fills it out in a diary format or if it’s a one-time report after 6 weeks.

### REVIEWER
Adrian Traeger  
The University of Sydney Faculty of Medicine and Health, Institute for Musculoskeletal Health, Sydney School of Public Health

### REVIEW RETURNED
05-Feb-2024

### GENERAL COMMENTS
Acceptable revisions. Best of luck with the trial

**Reviewer 1**

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<td>① Please include the date of first enrollment in the methods section.</td>
<td>I sincerely apologize for any misunderstanding due to my limited English comprehension. I assume you may want me to specify the date of recruiting the first participant. I have added this sentence in section 2.2 and highlighted it for your review.</td>
</tr>
<tr>
<td>② The primary outcome variable is that the average pain level over the past 6 weeks is evaluated using NRS. Please explain the method in detail. I’m not sure if the patient fills it out in a diary format or if it’s a one-time report after 6 weeks.</td>
<td>I apologize once again for any misunderstanding caused by my expression. In section 2.9.1, I have provided a more precise explanation for the primary outcome of this study as the patients' one-time self-reported average pain intensity over the past week at the 6th week after randomization. It is the average pain level over the past 1 week, not the entire 6-week period. I am sorry for any confusion!</td>
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**Reviewer 2**

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<td>① Acceptable revisions. Best of luck with the trial</td>
<td>Thank you for your trust and encouragement. I will not disappoint you!</td>
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