PEER REVIEW HISTORY

This paper was submitted to a another journal from BMJ but declined for publication following peer review. The authors addressed the reviewers' comments and submitted the revised paper to BMJ Open. The paper was subsequently accepted for publication at BMJ Open.

(This paper received three reviews from its previous journal but only two reviewers agreed to published their review.)

ARTICLE DETAILS

TITLE (PROVISIONAL)	Acupotomy versus acupuncture for cervical spondylotic radiculopathy: protocol of a systematic review and meta-analysis
AUTHORS	Chen, Bin; Zhang, Cai; Zhang, Ren-pan; Lin, An-yang; Xiu, Zhong-biao; Liu, Jing; Zhao, Hong-jia

VERSION 1 – REVIEW

REVIEWER	Xu Wei China Academy of Chinese Medical Sciences
REVIEW RETURNED	31-Jan-2019

GENERAL COMMENTS	The aim of this study is to evaluate the efficacy and safety of acupotomy in cervical radiculopathy (CR). There are some problems as follows. Q1: Please give more introductions for acupotomy and the previous studies. Q2: Why do choose acupuncture as the controlled intervention? The clinical efficacy and high-quality evidence of acupuncture for CR is not clear. Q3: Please improve the English written expression.

REVIEWER	Sang-hoon, Yoon Chung-Yeon Central Institute, Republic of Korea
REVIEW RETURNED	19-Feb-2019

GENERAL COMMENTS	Page 6, line 29 The author needs more detailed techniques and standards for "randomization". For example, if the title of the article is "randomized" but the method is wrong, will the article be included in the analysis? Page 7, line 21 Since "total effective rate and curative rate" is not a validated outcome, it can not be a primary outcome. Page 7, line 27 Data sources should include "gray literature". Page 7, line 56

	In search strategy, the sensitivity of "term" decreases. You will need to add search terms based on existing research. (ref; PMID: 30328566) Page 8, line 47 There is a need to elaborate information on the procedure of acupuncture and acupotomy. When extracting data on acupuncture and acupotomy, extract it according to the STRICTA regulations. Page 8, line 53 Before classifying at the risk of bias, a detailed description of the classification criteria is needed in the confusing part (i.e. randomization, other bias).

REVIEWER	Eun Jung Kim Department of Acupuncture & Moxibustion, Dongguk University Bundang Oriental Hospital, Gyeonggi-do, South Korea
REVIEW RETURNED	05-Mar-2019

GENERAL COMMENTS	For Chinese literature, I would like to know how to specify the search term. In this study, questions about safety as well as efficacy will be important. There is a lack of skills on how to evaluate safety.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Xu Wei
Institution and Country: China Academy of Chinese Medical Sciences
Please state any competing interests or state ‘None declared’: I have no competing interests.

Please leave your comments for the authors below
The aim of this study is to evaluate the efficacy and safety of acupotomy in cervical radiculopathy (CR). There are some problems as follows.
Q1: Please give more introductions for acupotomy and the previous studies.
Thank you very much for your suggestion.
According to the reviewer’s suggestion, some sentences have been added in the introduction section of this revised version of the manuscript.

Q2: Why do choose acupuncture as the controlled intervention? The clinical efficacy and high-quality evidence of acupuncture for CR is not clear.
Because acupuncture therapy has been widely applied for the clinical treatment of cervical spondylosis with satisfied efficacy in China. As shown below, there is some evidence on the effectiveness of acupuncture.
1. Deng Y Z , Xu L G , Chen L , et al. Effectiveness of acupuncture in the management of cervical spondylosis: a meta-analysis[J]. J Biol Regul Homeost Agents, 2017, 31(4):1017-1022.
2. Ting F , Fushui L , Hongwu X , et al. Meta-analysis of Acupotomy Versus Acupuncture for Neck Type Cervical Spondylosis[J]. Liaoning Journal of Traditional Chinese Medicine, 2017.
3. Li W , Cong W , Yan C , et al. [Clinical observation of fast acupuncture for cervical type of cervical spondylosis].[J]. Chinese Acupuncture & Moxibustion, 2017, 37(9):951-954.
4. Wei X, Wang S, Li J, et al. Complementary and Alternative Medicine for the Management of Cervical Radiculopathy: An Overview of Systematic Reviews. Evid Based Complement Alternat Med. 2015, 2015: 793649.

5. Yan-Wen W , Wen-Bin F U , Ai-Hua O U , et al. A Systematic Review of Randomized Controlled Clinical Trials of Abdominal Acupuncture Treatment of Cervical Spondylosis[J]. Acupuncture Research, 2011, 36(2):137-144.
6. Zhi-Yun B O , Qing-Qiang N , Wen-Gang Z , et al. Multicenter controlled study on abdominal acupuncture for treatment of nerve root type cervical spondylosis[J]. Chinese Acupuncture & Moxibustion, 2005, 25(6):387-389.

Q3: Please improve the English written expression.
Thank you for your attention and we have tried our best to improve the English written expression.

Reviewer: 2
Reviewer Name: Sang-hoon, Yoon
Institution and Country: Chung-Yeon Central Institute, Republic of Korea
Please state any competing interests or state ‘None declared’: I have no conflicts of interest

Please leave your comments for the authors below
Page 6, line 29
The author needs more detailed techniques and standards for "randomization". For example, if the title of the article is "randomized" but the method is wrong, will the article be included in the analysis?
Thank you for your positive comments on our manuscript. We have modified the standards for "randomization", as follows:
We will include such studies if the expression “randomization” is mentioned. However, we will grade these studies as high in the “risk of bias assessment” if the detailed description on the randomization process is not provided. Furthermore, if an incorrect randomization method such as coin toss was used, the study will not be included.

Page 7, line 21
Since "total effective rate and curative rate" is not a validated outcome, it can not be a primary outcome.
Changes in visual analog scale (VAS) and symptom score will be assessed as primary outcomes. The total effective rate and curative rate will be evaluated as secondary outcomes. The secondary outcome measures are as follows:
(1) Total effective rate and curative rate
The total effective rate and curative rate are non-validated outcome measures that are processed secondarily according to certain evaluation criteria such as clinical symptom improvement or the improvement rates of other quantified outcomes. In the assessment of the total effective rate, participants are generally classified as “cured”, “markedly improved”, “improved”, or “non-responder” after treatment. The total effective rate is calculated consistently using the following formula:
Total effective rate = N1 + N2 + N3 / N
Curative rate = N1 / N
where N1, N2, N3, and N are the number of patients who are cured, markedly improved, improved, and who comprise the sample size, respectively.
(2) The incidence of adverse events.
(3) Amount of rescue medication required.

Page 7, line 27
Data sources should include "gray literature".
Thank you for your suggestion, we have allowed the resources of "gray literature" and “ambiguous literature”, such as conference proceedings.

Page 7, line 56

In search strategy, the sensitivity of "term" decreases. You will need to add search terms based on existing research. (ref; PMID: 30328566)
We have modified the search term #1 as follows:
Mesh term #1: ((acupotomy) OR (acupotome) OR (needle knife) OR (needle scalpel) OR (acupotomlogy) OR (miniscalpel acupuncture) OR (miniscalpel needle) OR (stiletto needle) OR (sword like needle) OR (Xiaozhendao))

Page 8, line 47
There is a need to elaborate information on the procedure of acupuncture and acupotomy. When extracting data on acupuncture and acupotomy, extract it according to the STRICTA regulations. The procedure of acupuncture and acupotomy should be reported in full compliance with the standardized reporting methods such as the Standard of the Basic Manipulations of Acupotomy (ZJ/T D001-2014) and Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA).

Page 8, line 53
Before classifying at the risk of bias, a detailed description of the classification criteria is needed in the confusing part (i.e. randomization, other bias).
The Cochrane risk of bias tool will be applied to evaluate the quality and risk of bias in the ultimately included studies by two authors (Renpan Zhang and Anyang Lin) independently. Risk of bias assessment categories will include the following: (1) random sequence generation; (2) allocation concealment; (3) blinding of participants; (4) blinding of outcome assessors; (5) completeness of outcome data; (6) selective outcome reporting; and (7) other biases. The assessments for each item will be graded as low risk, unclear risk, and high risk to evaluate several risks of bias that can occur in RCTs. In the case of other sources of bias, it was evaluated as “low” if the characteristics of participants in each group were reported to be statistically homogeneous at baseline, but was otherwise rated “high”. The results were presented as a risk of bias graph and risk of bias summary using the Cochrane Collaboration’s software program Review Manager (RevMan) version 5.3 for Windows (Copenhagen, The Nordic Cochrane Centre, the Cochrane Collaboration, 2012).

Reviewer: 3
Reviewer Name: Eun Jung Kim
Institution and Country: Department of Acupuncture & Moxibustion, Dongguk University Bundang Oriental Hospital, Gyeonggi-do, South Korea
Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below
For Chinese literature, I would like to know how to specify the search term.
The established search strategy for PubMed was displayed, as follows:
Mesh term #1: ((acupotomy) OR (acupotome) OR (needle knife) OR (needle scalpel) OR (acupotomlogy) OR (miniscalpel acupuncture) OR (miniscalpel needle) OR (stiletto needle) OR (sword like needle) OR (Xiaozhendao)): ti, ab, kw
Mesh term #2: ((acupuncture) OR (manual acupuncture) OR (auricular acupuncture) OR (scalp acupuncture) OR (fire needling) OR (warm needling) OR (electro-acupuncture)): ti, ab, kw
Mesh term #3: ((cervical radiculopathy) OR (cervical spondylotic radiculopathy) OR (cervical spondylopathy) OR (cervical spondylosis) OR (neck pain) OR (neck syndrome): ti, ab, kw
Mesh term #4: ((clinical trials) OR (random control trials))
#1 AND #2 AND #3 AND #4
The equivalent search words will be used in Chinese databases.

In this study, questions about safety as well as efficacy will be important. There is a lack of skills on how to evaluate safety.

The secondary outcomes including the incidence of adverse events and the amount of rescue medication required will be used to evaluate safety.

VERSION 2 – REVIEW

REVIEWER	Xu Wei China Academy of Chinese Medical Sciences
REVIEW RETURNED	09-Apr-2019

GENERAL COMMENTS	1. VAS scores or other validated tool (such as NDI) should be considered as the primary outcome. 2. The discussion is very short. It should include:evidence summary, comparison with the similar systematic review, limitation and implication for the clinical practice and research.

REVIEWER	Sanghoon Yoon Chung-Yeon Central Institute, Republic of Korea
REVIEW RETURNED	16-Apr-2019

GENERAL COMMENTS	Review results correction requests reflected without problems. I hope this research will proceed well.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Xu Wei
Institution and Country: China Academy of Chinese Medical Sciences
Please state any competing interests or state ‘None declared’: I have no competing interests.

Please leave your comments for the authors below
1. VAS scores or other validated tool (such as NDI) should be considered as the primary outcome.
Thank you very much for your suggestion.
According to the reviewer’s suggestion, we have added the neck disability index (NDI) as one of primary outcomes.

2. The discussion is very short. It should include: evidence summary, comparison with the similar systematic review, limitation and implication for the clinical practice and research.
Thank you for your remind.
Discussion section is not required by BMJ Open as this is a protocol submission.

Reviewer: 2
Reviewer Name: Sang-hoon, Yoon
Institution and Country: Chung-Yeon Central Institute, Republic of Korea
Please state any competing interests or state ‘None declared’: I have no conflicts of interest

Please leave your comments for the authors below
Review results correction requests reflected without problems.
Thank you.