

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Test reliability and comparability of paper and Chinese electronic version of the Western Ontario and McMaster University osteoarthritis index: protocol for a randomized controlled clinical trial
<b>AUTHORS</b>	Zhang, yujie; Zhao, ye; Liu, kaoqiang; Chai, yongli; Lin, fen; Zhan, Hongsheng; Zheng, Yuxin; Yuan, Weian

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Agel, Julie Harborview Medical Center, Orthopaedics
<b>REVIEW RETURNED</b>	09-May-2022

<b>GENERAL COMMENTS</b>	<p>I have reviewed your protocol and wish to offer the following comments for your consideration.</p> <p>I believe that what you are doing is evaluating modes of administration; yet no where in the manuscript do you state this. Please consider using this type of description.</p> <p>I am unclear about why you are choosing to add an intervention into this study and then a repeat of the two surveys - the WOMAC is known to measure change in an acceptable fashion so please clarify what further information you will gain from this extension of the project.</p> <p>References need to be added throughout your introduction Page 3 line 34,45,49,52 Page 4 line 29</p> <p>There are some word choices that could be improved upon from my perspective Page 3 Line 53 - demand Page 4 Line 10 - tendency Page 4 line 20 - please write out IT Page 4 Line 26 - emerged Page 4 Line 41 - response time Page 4 Line 50 - What is the concern with patient privacy in this setting? Page 5 Line 24 - Please justify why you think the Chinese version would show any different results compared to other languages Page 6 Line 52 - Why did you choose 240 patients - that is a very large number for this task Page 7 Line 7 - please define the groups here Page 8 Line 30 - If multiple other authors have already tested an electronic WOMAC then there should be plenty of information to help justify your sample size; thus I believe there is previous literature Page 9 line 8+ Please clarify if this is all done outside the medical record just for this project or if it will always be done this way and if so how will that work for the physicians to have to open another system</p>
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	Page 9 Line 32 - Please provide a better explanation for why you are including an intervention in this project. Page 14 Line 21 - What information is going to be put in the medical record?
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<b>REVIEWER</b>	Basaran, Sibel Cukurova University, Physical Medicine and Rehabilitation
<b>REVIEW RETURNED</b>	14-May-2022

<b>GENERAL COMMENTS</b>	<p>Strengths and limitations of this study: When listing the strengths of the study that “this is the first study to test the reliability of the Chinese WOMAC for KOA assessment”, the “electronic version” should be specified. Since the patients with KL classification <math>\leq</math> grade 3 KOA were included in the study, it should be considered among the limitations of the study that the results will not be valid for severe KOA patients.</p> <p>Sample size calculation: The sample size could be calculated based on a previous literature as it was mentioned in the study by Bellamy et al. (Osteoarthritis Index delivered by mobile phone (m-WOMAC) is valid, reliable, and responsive. J Clin Epidemiol 2011;64(2):182-90.)</p> <p>The date of the study is not included in the manuscript. Please clearly state whether or not the patients will be excluded from the final analysis in case of any side effects resulted from the intervention drug or drop out from other reasons.</p> <p>Primary and secondary outcomes: For comparison with other studies, it would be better if the authors convert WOMAC subscale scores to a scale of 0-100.</p>
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### VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

I believe that what you are doing is evaluating modes of administration; yet no where in the manuscript do you state this. Please consider using this type of description.

Reply: Thank you for your suggestion. We have used the description in the manuscript and we feel that the new mode of administration is patient-reported outcomes collected and recorded using electronic data capture tool.

I am unclear about why you are choosing to add an intervention into this study and then a repeat of the two surveys - the WOMAC is known to measure change in an acceptable fashion so please clarify what further information you will gain from this extension of the project.

Reply: Reasons for using intervention in the study protocol: 1. In order to more completely verify whether e-WOMAC can be the same as p-WOMAC in sensitively reflecting the actual changes of patients' conditions, we chose celecoxib, an effective treatment for knee osteoarthritis, to verify whether the changes of patients' conditions after intervention can also be the same as p-WOMAC. 2. Previous similar studies have also used intervention, such as references: Osteoarthritis Index delivered by mobile phone (m-WOMAC) is valid, reliable, and responsive. J Clin Epidemiol 2011; 64(2):182-90.

References need to be added throughout your introduction

Page 3 line 34,45,49,52

Page 4 line 29

Reply: Thank you for your suggestion. We have updated the references, see the introduction of the

article for details.

There are some word choices that could be improved upon from my perspective

Page 3 Line 53 - demand

Page 4 Line 10 - tendency

Page 4 line 20 - please write out IT

Page 4 Line 26 - emerged

Page 4 Line 41 - response time

Reply: Thank you very much for your valuable suggestion. We have changed the words “demand for” to “focus on” (see page 3 line 1 in the main article) , “while having little influence on the subjective tendency of the patients.” to “and it is also less affected by subjective factors of the patients” (see page 3 line 8 in the main article) , “IT” to “Information Technology” (see page 3 line 16 in the main article), “emerged” to “appears” (see page 3 line 21 in the main article), “shorter response time” to “faster response” (see page 4 line 1 in the main article) according to your suggestion, and other mistakes which were found in manuscript have also been corrected in the revised manuscript.

Page 4 Line 50 - What is the concern with patient privacy in this setting?

Reply: Thank you for this comment. We understand that the formulation “protect the patients’ privacy” in the introduction might be misleading and we have removed it from the introduction.

Page 5 Line 24 - Please justify why you think the Chinese version would show any different results compared to other languages

Reply: It is not only the Chinese version of the electronic and paper WOMAC index may show any different results, but the different carriers of all scales need to be proved the consistency in advance before putting into use officially.

Page 6 Line 52 - Why did you choose 240 patients - that is a very large number for this task.

Reply: We redid the sample size calculation. The sample size is calculated with based on a small sample pre-test we carried out in the early stage and the sample size calculation method studied by Bellamy et al. (Osteoarthritis Index delivered by mobile phone (m-WOMAC) is valid, reliable, and responsive. J Clin Epidemiol 2011;64(2):182-90.). The differences between e-WOMAC and p-WOMAC scores were expressed as the mean scores (with standard errors) as 2.95 (5.53). Consequently, with a type I error at 0.05 and type II error at 0.10 considering a 1:1 allocation rate and a drop-out rate of 10%, the minimum number of participants needed was 35 per group; a total of 70 subjects. The formula for calculating sample size is as follows: (see page 7 line 26 in the main article).

Page 7 Line 7 - please define the groups here

Reply: Thank you for this comment, we have removed “two groups” and replaced it with “group A and group B”. This has been made clear in the figure legends. (see page 5 line 12 in the main article).

Page 8 Line 30 - If multiple other authors have already tested an electronic WOMAC then there should be plenty of information to help justify your sample size; thus I believe there is previous literature

Reply: As the previous reply, we have recalculated the sample size. (see page 7 line 26 in the main article).

Page 9 line 8+ Please clarify if this is all done outside the medical record just for this project or if it will always be done this way and if so how will that work for the physicians to have to open another system.

Reply: At present, the paper version of the WOMAC index still occupies a major position in the clinic, but due to the advantages and practical use needs of electronic version of the WOMAC index, if the results of this study prove the consistency of e-WOMAC and p-WOMAC, it will provide a basis for the use of the e-WOMAC in the future in clinical and scientific research.

Page 9 Line 32 - Please provide a better explanation for why you are including an intervention in this project.

Reply: Reasons for using intervention in the study protocol: 1. In order to more completely verify

whether e-WOMAC can be the same as p-WOMAC can sensitively reflect the actual changes of patients' conditions, we chose celecoxib, an effective treatment drug for knee osteoarthritis, to verify whether the changes of patients' conditions after intervention can also be the same as p-WOMAC. 2. Previous similar studies have also used intervention, such as references: Osteoarthritis Index delivered by mobile phone (m-WOMAC) is valid, reliable, and responsive. J Clin Epidemiol 2011; 64(2):182-90.

Page 14 Line 21 - What information is going to be put in the medical record?

Reply: Thanks for the reviewer's kind reminder, the medical record of each patient includes descriptive characteristics like name initials, allocated study number, sex, age, BMI, outcome measures like primary outcomes and secondary outcomes, and laboratory results. We have revised this in the text. (see page 14 line 22 in the main article).

Reviewer: 2

Strengths and limitations of this study:

When listing the strengths of the study that "this is the first study to test the reliability of the Chinese WOMAC for KOA assessment", the "electronic version" should be specified.

Reply: Thank you for your suggestion. We have revised it in the article: this is the first study to evaluate the impact of electronic version of Chinese WOMAC index in normal clinical practice in a Chinese population. (see page 2 line 2 in the main article).

Since the patients with KL classification  $\leq$  grade 3 KOA were included in the study, it should be considered among the limitations of the study that the results will not be valid for severe KOA patients.

Reply: Thank you for your suggestion. We have added it in the article: Since the patients with KL classification  $\leq$  grade 3 KOA were included in the study, the results will not be valid for severe KOA patients. (see page 2 line 13 in the main article).

Sample size calculation: The sample size could be calculated based on a previous literature as it was mentioned in the study by Bellamy et al. (Osteoarthritis Index delivered by mobile phone (m-WOMAC) is valid, reliable, and responsive. J Clin Epidemiol 2011;64(2):182-90.)

Reply: The sample size is calculated with based on a small sample pre-test we carried out in the early stage and the sample size calculation method studied by Bellamy et al. (Osteoarthritis Index delivered by mobile phone (m-WOMAC) is valid, reliable, and responsive. J Clin Epidemiol 2011;64(2):182-90.). The differences between e-WOMAC and p-WOMAC scores were expressed as the mean scores (with standard errors) as 2.95 (5.53). Consequently, with a type I error at 0.05 and type II error at 0.10 considering a 1:1 allocation rate and a drop-out rate of 10%, the minimum number of participants needed was 35 per group; a total of 70 subjects. The formula for calculating sample size is as follows:

(see page 7 line 26 in the main article).

The date of the study is not included in the manuscript.

Reply: We apologize for this error. The date of the study is now included in the manuscript file. The start and end of the study was planned for September 2021 and December 2023, respectively. We have revised this in the text. (see page 6 line 6 in the main article).

Please clearly state whether or not the patients will be excluded from the final analysis in case of any side effects resulted from the intervention drug or drop out from other reasons.

Reply: The main purpose of this study is to verify the reliability of e-WOMAC, not to prove the efficacy of drugs, so we only collect the efficacy information of subjects with complete efficacy evaluation data before and after treatment. We have revised the article data collection and management. (see page 10 line 18 in the main article).

Primary and secondary outcomes:

For comparison with other studies, it would be better if the authors convert WOMAC subscale scores

to a scale of 0-100.

Reply: Thank you for your suggestion. In this study, WOMAC subscale scores will be rescaled to a 0-100 scale in Statistical Analysis. (see page 11 line 17 in the main article).

#### VERSION 2 – REVIEW

<b>REVIEWER</b>	Agel, Julie Harborview Medical Center, Orthopaedics
<b>REVIEW RETURNED</b>	18-Jul-2022

<b>GENERAL COMMENTS</b>	I think you have mis-interpreted my comment on mixed mode of administration - I think that is what you are doing - it is not a new mode - but you are comparing two different modes In addition please clarify if the version you are using is approved by Dr. Bellamy - and what the fees are for use as he imposes fees for use of the paper version
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<b>REVIEWER</b>	Basaran, Sibel Cukurova University, Physical Medicine and Rehabilitation
<b>REVIEW RETURNED</b>	17-Jul-2022

<b>GENERAL COMMENTS</b>	The authors' responses to my comments were appropriate and I am satisfied with the corrections made by the authors.
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#### VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

I think you have mis-interpreted my comment on mixed mode of administration - I think that is what you are doing - it is not a new mode - but you are comparing two different modes

Reply: Thank you for your suggestion. We appreciate what you mean and revised the expression of this point.

In addition please clarify if the version you are using is approved by Dr. Bellamy - and what the fees are for use as he imposes fees for use of the paper version

Reply: We gratefully acknowledge the contribution of Dr. Bellamy who invented the WOMAC index. The WOMAC index has been widely used in clinical trials and is extensively validated in and translated into over 100 language. Chinese WOMAC was translated from the original English version following standard guidelines in the previous study and it was well accepted in the pilot testing which was used in the subsequent validation study without any adaptation being made, according to Feng Xie.(Xie F, Li SC, Goeree R, et al. Validation of Chinese Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) in patients scheduled for total knee replacement. Qual Life Res. 2008;17(4):595-601. ) And in this study, the WOMAC index is used for scientific research purpose only, not for commercial purposes.