


BMJ Open Test reliability and comparability of paper and Chinese electronic version of the western Ontario and McMaster University osteoarthritis index: protocol for a randomised controlled clinical trial

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To cite: Zhang Y, Zhao Y, Liu K, *et al.* Test reliability and comparability of paper and Chinese electronic version of the western Ontario and McMaster University osteoarthritis index: protocol for a randomised controlled clinical trial. *BMJ Open* 2022;**12**:e063576. doi:10.1136/bmjopen-2022-063576

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-063576>).

YZ and YZ are joint first authors.

Received 06 April 2022

Accepted 19 October 2022



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ABSTRACT

Introduction The Western Ontario and McMaster University osteoarthritis index (WOMAC) is the most commonly used indicator of disease-specific outcome in knee osteoarthritis for its convenience and reliability. It has two formats the paper-based WOMAC (p-WOMAC) and the electronic WOMAC (e-WOMAC). In China, the p-WOMAC has been widely used though e-WOMAC is yet untested. This study aims to test whether e-WOMAC is consistent with the p-WOMAC before and after the intervention.

Methods and analysis A total of 70 patients from Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine will be randomly assigned in two groups, named, group A and group B. This study is divided into three stages. In the first stage, patients in group A will be evaluated first by p-WOMAC and then by e-WOMAC. Patients in group B will be evaluated by e-WOMAC and then by p-WOMAC. In the second stage of the study, drug interventions will be implemented. 200 mg celecoxib will be administered orally once a day starting from the second day of enrolment for a period of 21 days. In the third stage, postintervention evaluation will be conducted after administration. Patients in group A will be evaluated first by e-WOMAC and then by p-WOMAC. Patients in group B will be evaluated first by p-WOMAC and then by e-WOMAC. In order to avoid the possible bias because of patients' potential memory, e-WOMAC and p-WOMAC will be taken for each patient at 15 min apart. The primary outcome of the study is the mean score difference in WOMAC, and the secondary outcomes are the score differences in WOMAC subscales: pain, stiffness and physical function.

Ethics and dissemination The protocol has been approved by the Independent Review Board of SGH (approval number: 2020-814-21-01). The results of the trial will be submitted for publication in a peer-reviewed journal.

Trial registration number ChiCTR2100050914.

INTRODUCTION

Knee osteoarthritis (KOA) is the most common chronic, progressive and degenerative joint disease in middle and old age. It

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study approach and design enable a comprehensive analysis of the reliability and comparability of paper-based and Chinese electronic version of Western Ontario and McMaster University osteoarthritis Index (WOMAC) in normal clinical practice in a Chinese population.
- ⇒ This study is a randomised, cross-over design with intervention that can verify whether electronic-WOMAC is the same as paper-based WOMAC in sensitively reflecting the actual changes in patients' conditions.
- ⇒ In this study, patient satisfaction was added as an outcome to investigate subjects' propensity for paper based or Chinese electronic version of WOMAC.
- ⇒ As the instruments will be collected using electronic tablets, a certain level of computer literacy is required, and the study may not be able to include participants who are not capable of handling the devices.
- ⇒ Since the patients with KL classification \leq grade 3 knee osteoarthritis (KOA) were included in the study, the results will not be valid for severe KOA patients.

is characterised by articular cartilage degeneration, osteosclerosis and hyperplasia.¹ Major clinical manifestations of KOA include progressive knee joint pain, swelling, stiffness, dysfunction, severe deformation of joints and even loss of joint function. KOA can lead to pain and dysfunction of the lower limb and affect patients' normal life and work.²

The worldwide prevalence of KOA is increasing, reported to be between 3.8% in 2010, and with an estimated 25 000 people suffer from KOA in 2018.^{3 4} There is radiographic evidence of KOA in up to 14% of asymptomatic uninjured adults aged <40 years and 43% of the middle-aged population.⁵ In China, approximately 8.1% of Chinese



people are affected by KOA.⁶ KOA can greatly affect the patient's health and quality of life. Today, its incidence tends to increase with the advent of an ageing society.⁷ With increased focus on health, people are becoming more aware of the need for early diagnosis, timely intervention, minimal damage and better prognosis. Patient-reported outcomes (PRO) can truly reflect patients' health status and treatment outcomes, and have played a significant part in the diagnosis and treatment of chronic progressive diseases. The Western Ontario and McMaster University osteoarthritis (WOMAC) index invented by Bellamy is a specific PRO scale, which has high reliability and sensitivity for KOA severity assessment and can accurately reflect the patient's symptoms and functional limitations, and it is also less affected by subjective factors of the patients.⁸ For those who have mild symptoms of OA, it shows high reliability and is currently the most widely used tool to assess the severity level of KOA.⁹

Although the paper-based WOMAC (p-WOMAC) has already been accepted and widely used, there are still several shortcomings, such as difficulties in collecting and analysing pen and paper-based data. Especially when it comes to the quality of clinical research, traditional paper-based data are hard to be accessed retrospectively. In times of information technology and communication technologies, smartphone application provides the technical basis for online assessment and telemedicine.¹⁰⁻¹² Meanwhile, another method of collecting PRO data or mode of administration (MOA), PRO collected and recorded using the electronic data capture (EDC) tool came into being and received increasing attention in recent years. Nowadays, many different forms of WOMAC on the mobile phone, tablet or pc appear in large numbers, namely electronic WOMAC (e-WOMAC), which has been favoured by researchers and become a very useful tool for objective assessment of KOA in clinical practice and research gradually.^{13 14}

The Visual Analogue Scale (VAS) is used in e-WOMAC for the assessment of KOA. Pain, stiffness and dysfunction assessment can be completed directly at any time at home through e-WOMAC application, and then physicians can rapidly understand the patient's condition and adapt treatment to achieve personalised healthcare by telemedicine.¹⁵ The main advantages of the e-WOMAC include high efficiency, lower data collection error rate, faster response and increased response rates.¹⁶⁻¹⁹ Practically, online medical service is potentially beneficial for patients with KOA: electronic questionnaire can be completed almost anytime and anyplace, alleviating the influence of environmental factors. The online medical models of care also avoid multiple visits to the clinic. In addition, paper-less records reduce the waste of resources, which is beneficial for the environment.

Before being put into use, many countries, including the UK, Australia, Switzerland and Austria, have demonstrated the reliability of the e-WOMAC because the difference in MOA may induce bias, even when the index is consistent across modes. R.Theiler argues that English

e-WOMAC has similar responsiveness in detecting clinically meaningful change to the traditional p-WOMAC.²⁰ HA Bischoff-Ferrari makes a similar point in his study of consistency between German e-WOMAC with the original format as well.²¹ Similarly, R.Theiler found that the Swiss computerised WOMAC 3.1 and conventional p-WOMAC are similar in all three subscales.²² Overall, these studies illustrate the point that electronic MOA is a promising alternative to the traditional mode.

In China, the existing body of research on the Chinese p-WOMAC Numerical Rating Scale 3.1 suggests its psychological robustness in reliability and validity.²³ The research also shows that compared with the Lysholm score, IKDC score, HSS score, KSS score and other scales used in the assessment of KOA, Chinese WOMAC 3.1 is the most suitable assessment scale. However, the Chinese e-WOMAC hasn't been put into use, so research to date has not yet determined the equivalence of Chinese e-WOMAC and the traditional p-WOMAC.

Objective

By this research, we aim to evaluate the electronic MOA and provide conclusive evidence for developing patient-centred online health applications. We hypothesise that the equivalent between two formats of the WOMAC will be proved, then our study objective is to assess: (1) The comparability of results generated from these two WOMACs and (2) Subjects' acceptance and satisfaction with the Chinese e-WOMAC index.

METHOD

Study design

This study is a randomised controlled trial that aims to evaluate the consistency between the Chinese e-WOMAC and paper WOMAC (p-WOMAC) evaluations of patients with KOA. The study schedule of enrolment, interventions and assessments are shown in [table 1](#). The start and end of the study was planned for September 2021 and December 2023, respectively.

Recruitment and randomisation

A total of 70 patients with KOA will be recruited from the Orthopaedic Clinic of Shuguang Hospital affiliated to SHUTCM. The KOA patient will receive a clinical examination by an orthopaedic surgeon. Patients with KOA meeting the inclusion criteria will be given detailed information of this study. The importance of patients' active participation in the study and self-monitoring of the disease will be emphasised to improve their enthusiasm. All participants will be provided with an information sheet and sign the informed consent by a research nurse. After participation acceptance, the patients will be divided into group A and group B by randomly generated computer numbers, with 35 patients in each group. A researcher not involved in patient care will prepare and administer the randomization schedule. Neither the researchers nor

Table 1 Study schedule of enrolment, interventions and assessments

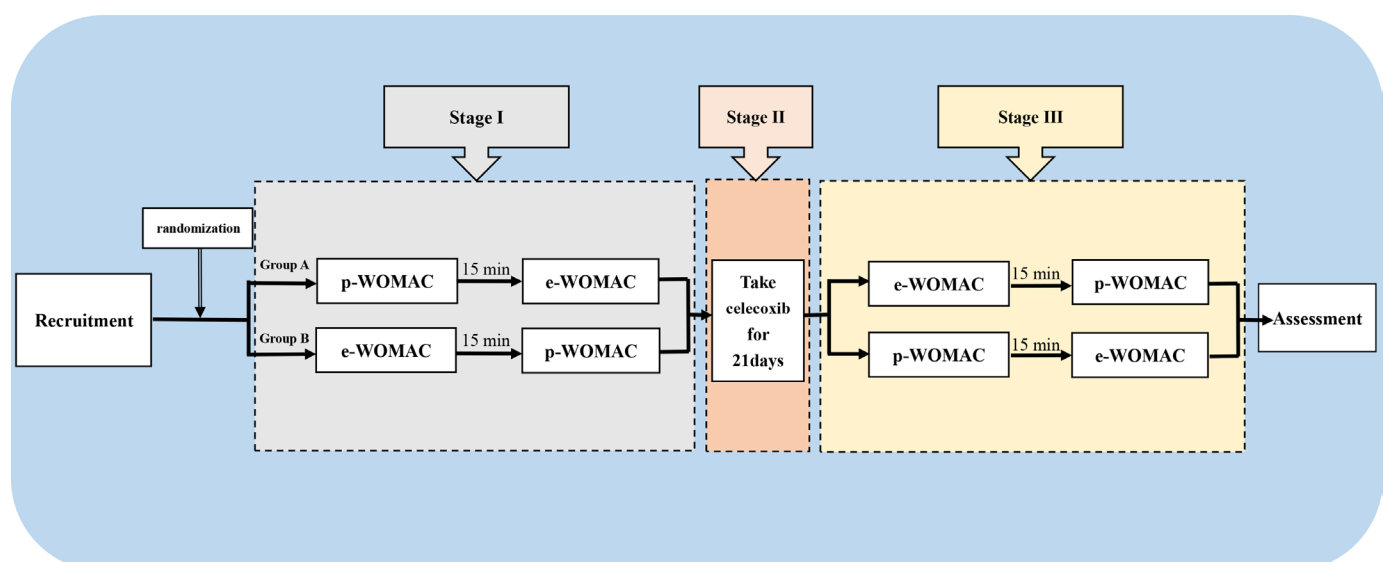
Study period	Pre-intervention	Intervention period	Close-out
Time point	T ₀ Preintervention	T ₁ Between assessments	T ₂ 1-month follow-up
Enrolment			
Eligibility screen	√		
Informed consent	√		
Allocation	√		
Intervention			
Medical treatment		√	
P-WOMAC analysis	√		√
E-WOMAC analysis	√		√
Assessments			
Demographics	√		
Primary outcomes			
WOMAC total score	√		√
Secondary outcomes			
WOMAC pain score	√		√
WOMAC stiffness score	√		√
WOMAC function score	√		√

e-WOMAC, electronic Western Ontario and McMaster University osteoarthritis; P-WOMAC, paper-based WOMAC.

the patients will be blinded to the evaluation and treatment assignment.

Figure 1 provides an overview of the flow of study. The study is divided into three stages. In the first stage (T₀), patients in group A will be evaluated first by p-WOMAC and then by e-WOMAC. Patients in group B will be evaluated by e-WOMAC and then by p-WOMAC. In the second stage of the study, drug interventions will be implemented. A 200 mg of celecoxib will be administered orally once a day starting from the second day of enrolment for a period

of 21 days. The third stage is the consistency evaluation stage after intervention. The post-intervention evaluation will be conducted after administration on day 21 (T₂). Patients in group A will be evaluated first by e-WOMAC and then by paper WOMAC. Patients in group B will be evaluated first by p-WOMAC and then by e-WOMAC. In order to eliminate the possible bias because of patients' potential memory, e-WOMAC and p-WOMAC evaluation will be taken for each patient at 15 min apart in the first and third stage. This study has been registered in Chinese


Figure 1 Provides an overview of the flow of study.

Clinical Trial Registry (ChiCTR2100050914) and will be conducted in strict accordance with Chinese ethical laws and regulations.

Blinding

Because of the nature of the study protocol, the blinding method will not be used in this study. The data collection and analysis will be carried out by a single researcher who is not aware of the study grouping and intervention arrangements.

Inclusion and exclusion criteria

Inclusion criteria are as follows: (1) patients who meet the KOA diagnostic criteria of Osteoarthritis Diagnosis and Treatment Guidelines (2018 edition) issued by the Joint Surgery Group of the Orthopaedic Society of the Chinese Medical Association; (2) patients aged 40–70 years, including 40 and 70 years, male or female; (3) KL classification \leq grade 3; (4) patients who have a mobile phone and can use the application proficiently; (5) patients who understand Chinese language and can complete the WOMAC independently and (6) patients who have signed the informed consent.

Exclusion criteria are as follows: (1) patients with acute meniscus injury, peripheral ligament rupture injury, rheumatic arthritis, rheumatoid arthritis, peripheral tumour of knee joint, tuberculosis, idiopathic osteonecrosis of the knee; (2) patients with serious cardiovascular, lung, liver, kidney and haematopoietic diseases, haemophilia and other haemorrhagic diseases, mental illness, pregnancy and lactation; (3) patients who are allergic or intolerant to trial medication; (4) patients who had received other treatments in the last 2 months has an effect on the study and (5) patients who are deemed unsuitable for the clinical trial.

Sample size calculation

The sample size is calculated based on a small sample pretest we carried out in the early stage and the sample size calculation method studied by Bellamy *et al.*²⁴ 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:

$$n = \frac{(t_{\alpha} + t_{\beta})^2 \sigma^2}{\delta^2}$$

Instrument

WOMAC is a widely used self-administered evaluation tool, which can be completed within 5–10 min. Research shows that this scale has objective reliability, effectiveness and sensitivity for evaluation of the knee joint, and it is an evaluation scale that has been widely used for patients with OA. The WOMAC rating scale assesses

the structure and function of the hip and knee in terms of pain, stiffness and joint function. There are 24 items in all covering the basic symptoms and signs of OA, 5 items for the pain part, 2 items for the stiffness part and 17 items for the joint function part, among which each item has a scale bar without a scale line, representing the range of 0–10 points, the starting point on the left side of the scale is 0 point, representing none and the end point on the right side is 10 points, representing extreme severity.²⁵ The regular p-WOMAC requires the patient to fill out based on his or her symptoms and signs within 48 hours, which is then measured by a physician based on the location. E-WOMAC, a Chinese-language electronic scale for self-assessment of patients with KOA, used in the study was developed by Shanghai Jsurre Health Co. The text portion of e-WOMAC is identical to WOMAC VAS 3.1. For the first time, the patient needs to scan the QR code and download the Epdata software. After registration and login, patients can fill in the electronic version of WOMAC (figure 2), swipe the ruler on the screen according to their symptoms and signs within 48 hours, and submit after completing the answers. Doctors can directly receive the score data of patients in the EpData database (figure 3).

Additional questions

At the end of the study, a simple questionnaire has been designed to investigate subjects' perceptions of the study and the propensity for the paper based or electronic version of WOMAC. The questions will involve the description of the advantages and disadvantages of two WOMACs.

Interventions

Other medications and treatments for KOA, including oral medications, topical plasters, acupuncture, acupotomy and arthroscopy will not be available during the study period. If the patient needs additional treatment, they need to contact the doctor in advance. To increase the participation of the patients, we make sure all the treatment of the subjects during the study is free of charge, and the subjects in the trial can have X-ray and MRI free of charge and receive appropriate transportation subsidy. During the intervention, taking celecoxib has a very small probability of certain digestive tract symptoms, such as vomiting and constipation. The investigator will make every effort to prevent and treat any harm that may result from this study. If adverse events occur in the clinical trial, a committee of medical experts will determine whether it is associated with the treatment. The sponsor will provide the cost of treatment and the corresponding financial compensation for the damage related to the trial in accordance with the Provisions of China's 'Standard of Quality Management of Clinical Trials for Drugs'. Moreover, we need them to record their medication-taking behaviour in time so as to improve their adherence to the study, which helps minimise the error.

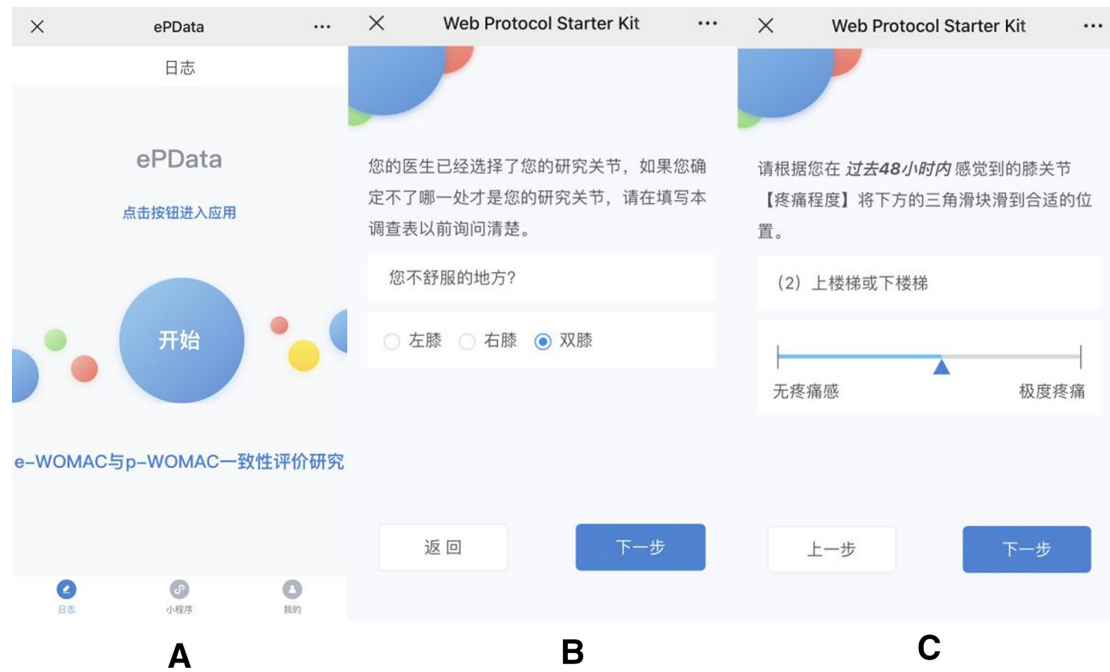


Figure 2 Examples of the web for the subjects the Chinese e-WOMAC app interface after login; location of knee osteoarthritis: The picture shows the assessed joint (‘您不舒服的地方’ means where do you feel uncomfortable? ‘左膝’ means left knee; ‘右膝’ means right knee; ‘双膝’ means both sides of knee); e-WOMAC assessment of pain intensity: The picture shows a question about the level of the pain up and down the stairs in the WOMAC pain subscale. (‘上楼梯或下楼梯’ means go upstairs and downstairs. Then choose pain level according to your feelings, the right end of the scale bar means extreme pain and the left means no pain.) e-WOMAC, electronic Western Ontario and McMaster University osteoarthritis.

Primary outcomes

The primary outcome of the current study is the mean score difference in WOMAC. This method has been found to be a semiquantitative rating scale with better reliability and validity and more balanced empirical evidence.¹⁸ The Chinese e-WOMAC, which contains 24 different items split up into three subscales: pain subscale (5 items), stiffness subscale (2 items) and physical function subscale (17 items) will be asked to patients. Primary outcomes will be analysed and reported in two ways. First, we will compare the difference in the respective score of e-WOMAC and p-WOMAC before and after the intervention. Then, we will investigate patients’ acceptance of two forms of the WOMAC through a simple self-made questionnaire.

Secondary outcomes

In addition, the secondary outcomes include the WOMAC VAS V.3.1 Pain Scale (ranging from 0 (no pain during movement) to 500 (extreme pain during movement)), the WOMAC Stiffness Scale (ranging from 0 to 200 with higher scores meaning more severe limitation) and the WOMAC Physical Function Scale (ranging from 0 to 1700, with higher scores indicating more serious impairment during activities). The secondary outcome analyses will be assessed similarly to the main endpoint analyses.

Data collection and management

We will gather information at every stage of recruitment, randomisation and treatment so that we can report flow of patients according to the Consolidated Standards of

Reporting Trials guidelines. Once a subject is enrolled or randomised, the study site will make every reasonable effort to follow the subject for the entire study period. Considering the purpose of this study, the data of subjects with complete efficacy data before and after treatment will be included in the statistical analysis.

The paper questionnaire will be completed by subjects alone, and data will be collected by trained investigators, then reach the database. The electronic questionnaire will be completed by subjects alone via the smartphone application. The score of e-WOMAC will be entered into an excel file and then analysed by SPSS. Note that time intervals between two assessments should be 15 min in order to eliminate the influence of memory and maintain data quality and objectivity.

Statistical analysis

The aim of the study is to describe a randomised trial designed to test the effectiveness and reliability of mobile phone application for the assessment of KOA compared with the traditional mode of pen and paper based, episodic, onsite evaluation. As the average scores of the two versions of the outcome measures are the same, there may also be significant differences in the scores of individual respondents, and/or differences on certain items. The total score and each dimension of e-WOMAC and p-WOMAC will be separately analysed. All data analysis will be performed by SPSS V.17.0 statistics software, mean±SD is used to describe the metrological data



Figure 3 Examples of the web for the physician (A) details and operation of subjects' data; (B) the score of each question; (C) total score as well as pain, stiffness and physical function subscale scores of e-WOMAC. e-WOMAC, electronic Western Ontario and McMaster University osteoarthritis.

following the normal distribution, while median (M) and IQR (Q) are used to describe the data not following the normal distribution.

First, two conditions will be compared at baseline with a between-group analysis via a t-test in order to ensure there is no difference between randomisation groups. To test our hypothesis, in the first stage calculate the difference scores of each participant (difference $d = \text{paper WOMAC score} - \text{e-WOMAC score}$) and the data will be analysed for normality by the Shapiro-Wilks test. For the primary outcomes, we will use the total WOMAC score directly, while for the secondary outcomes, WOMAC subscale scores will be rescaled to a 0–100 scale before calculation. A paired t-test will be used to calculate the mean score difference if data is normally distributed, and the results will be reported as 95% CIs between differences in means; if not, Wilcoxon rank-sum test will be used. Two-factor analysis of variance model will be used to account for any differences due to the order of completing the paper and e-WOMAC index. In the third stage, statistical analysis will be performed after the intervention the same as in the first stage in order to investigate whether the

WOMAC score of both high and low levels of KOA has good consistency.

To test the consistency of two versions of the WOMAC, an allowed range is defined (ie, a value for the mean difference that needed to be exceeded to determine that the two WOMACs are not equivalent). As there is great interindividual variability between different patients, a limit of equivalence will be determined based on the outcome measure of the pre-experiment to provide a strict test of the equivalence of two WOMACs. If the mean (and its 95% CI) of the difference falls within the allowable ranges, then we can gain credible evidence of the equivalence of the scoring system of the WOMAC.

Answers to open-ended questions will be subjected to a simple content analysis, categorised as positive, negative or neutral comments on the e-WOMAC or p-WOMAC.

For the condition of shedding samples that may occur in the current study, we will have strict criterion and the statistical analysis will only include patients who participate in the whole process of the study from enrolment to postintervention assessment.

Data monitoring

An external data monitoring committee was not deemed to be necessary for this trial. Data will be monitored by the research team, which includes clinicians, statisticians and information technology experts. This study is considered to be a low-risk trial where both the intervention and control groups will receive their usual medical care. The expected duration of the trial lasts only 1 month and the use of the application does not present with high risk, there will not be any stopping guidelines to terminate the trial or interim analysis planned.

Patient and public involvement

This research is planned to be done without patient involvement. The patients will not be invited to comment on the study design or be consulted on developing patient-relevant outcomes. The future manuscript will not be edited by patients for readability or accuracy.

DISCUSSION

Since KOA is characterised by chronic progressive degeneration of articular cartilage, its assessment involves a complex process and requires an overall evaluation of the patient's condition for a better clinical outcome. However, today in China, many residents do not have access to family doctors, so they usually need to go to hospital for treatment. The inconvenience of visiting doctors may cause delay in treatment. Smartphone application for EDC appears to be an innovative and promising alternative to the original assessment methods, as smartphone application has already been proved to be accurate tools.

However, it would be unwise to consider transforming a traditional paper-based PROs measure to an electronic version for use in clinical practice and research if the equivalence of the two versions has not been proved.

In this study protocol, we describe an unblinded trial designed to test a newly developed technology-based KOA assessment consisting of a mobile phone application for patients, which is linked to the physicians. Specifically, we want to explore the reliability and comparability of electronic and paper versions of the WOMAC and whether electronic MOA can help improve treatment adherence by meeting patients' preferences.

To the best of our knowledge, this is the first study to test the reliability of the Chinese e-WOMAC for KOA assessment. If our hypothesis is confirmed, the findings will serve to demonstrate the equivalence of electronic and paper versions of WOMAC and patients' acceptance of Chinese e-WOMAC so that it can be implemented in clinical practice and research. Likewise, our results will further demonstrate the feasibility of e-health for personalised KOA therapy (ie, timely adjustment of the treatment plan can be rapidly given to patients based on self-reported ePRO with the help of a smartphone application).

We anticipate that with the support of electronic MOA, physicians will be able to receive timely feedback on patients' conditions, which will significantly improve the visiting rate and treatment rate due to the convenience of telemedicine and rapid response to unwanted events. Note that KOA is a common chronic disease in the elderly, the study will explore the feasibility of enabling the Chinese e-WOMAC for patients' long-term use.

However, using EDC systems may still have some limitations. The degree of familiarity with the electronics is not entirely consistent between different populations, especially considering the factors of age, social status and other general factors. For example, some patients who do not have communication vehicles or cannot permit proper use of the application may be excluded from the online medical service. In addition, psychological factors may have a relevant influence on filling out the questionnaire leading to the condition that patients feel non-adapted, have difficulty in using the smartphone or even fail to complete the questionnaire.²⁶ Accordingly, we can make some necessary adjustments to the application. In sum, the results of the present investigation may help to find new ways of developing smartphone applications and information and communication technology in the medical field. In addition, it will also be more favourable to select the most appropriate MOA for PROs, including electronic MOA, paper-based MOA or mixed-mode designs.

Data management and oversight

In order to ensure protocol compliance, proper study management and timely completion of study procedures, members of the research team from Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine will take responsibility for the conduct of all research staff and study participants.

Protocol and registration

The trial is registered with the ChiCTR, ChiCTR2100050914, registered on 8 September 2021, <https://www.chictr.org.cn/showproj.aspx?proj=133521>

Data storage security and patient confidentiality

Patient's medical records (descriptive characteristics like name initials, allocated study number, sex, age, body mass index, outcome measures such as primary outcomes and secondary outcomes and laboratory results) will be kept in the respective hospital, and physicians will document the findings of the study in it, allowing researchers and ethics committees to access the data. Personal information of patients will not be revealed in the results of this study, and we will try everything we can to protect patients' privacy and medical data within Chinese law. According to medical research ethics, experimental data, especially personal privacy information, will not be allowed to be accessed and shared by the public and will be limited to web-based databases to ensure that personal privacy information is not disclosed.

Ethics and dissemination

The protocol for this trial has been approved by the Independent Review Board of SGH (approval number: 2020-814-21-01). All participants will be required to sign an informed consent form before enrolment in this study. The model consent form and other related documentation given to participants can be provided on request (see online supplemental file 1).

Acknowledgements Acknowledgment is given to Shanghai Jsurre Health Co. for its technical support of the application. The authors would also like to thank staff and students at Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine, for their contributions to the implementation of this study.

Contributors YujieZhang and YeZhao are the co-first authors. Wei'anYuan, YuxinZheng and HongshengZhan are the co-corresponding authors. Wei'anYuan, YuxinZheng and HongshengZhan designed the study. YujieZhang, YeZhao, KaoqiangLiu and YongliChai interpreted data. YujieZhang was responsible for writing of report, literature search, and selection of relevant articles. FenLin was responsible for the technical service of e-WOMAC. All authors agreed to be held accountable for all aspects of this article.

Funding This trial was funded by (1) Special project for clinical research of Shanghai Municipal Health Commission (201940063); (2) Special project for biomedical science and technology support of Shanghai 'science and technology innovation action plan' (20S21902100); (3) Shanghai Shengkang Hospital Development Center 'municipal hospital hospital enterprise collaborative clinical trial management project' (20CR4003B); (4) 'Xinglin Xinxing' project of Shanghai Municipal Commission of health and family planning (ZYSNXD011-RC-XLXX-20130049); (5) National Natural Science Foundation of China (81403414); (6) 'Integrated traditional Chinese and Western Medicine-Chinese patent medicine clinical evaluation platform' (A1-U21-205-0103). (7) Three-year clinical action plan of Shanghai Shengkang Hospital Development Center (SHDC2020CR1051B) and (8) Shanghai chronic musculoskeletal disease clinical medical research center (20MC1920600).

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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