Informed Consent•informed consent page

Dear Sir/Madam ：

You are invited to participate in the study "**Test reliability and comparability of paper and Chinese electronic version of the Western Ontario and McMaster University osteoarthritis index: a randomized controlled clinical trial**".

Read the instructions on this page carefully which can help you understand the study including the procedure and duration of the study, and the benefits, risks and discomforts that may be brought to you after participating in it and why it was conducted, before you decide whether or not to take part in this research study. Discuss it with friends and relatives if you wish, or please consult your doctor to help you to reach a decision.

Introduction

Background and Study Aims

Knee osteoarthritis (KOA) is the most common chronic, progressive and degenerative joint disease in middle and old age. It is characterized by articular cartilage degeneration, osteosclerosis and hyperplasia. 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. 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. There is radiographic evidence of knee osteoarthritis in up to 14% in asymptomatic uninjured adults aged < 40 years and 43% of middle-aged population. In China, approximately 8.1% of Chinese people are affected by KOA. KOA can greatly affect the patients' health and quality of life. Today, its incidence tends to increase with the advent of an aging society. With increased demand for 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 diagnosis and treatment for chronic progressive diseases.

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

This study will be conducted at Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine (1 clinical research center) in China. A total of 70 patients volunteered to participate in this study. This research project is supported by the Shanghai Municipal Health Commission (Project No. 201940063). The protocol for this trial has been approved by the Independent Review Board of SGH (approval number: 2020-814-21-01) and complies with relevant provisions of Helsinki Declaration on the protection of the rights and interests of subjects.

Inclusion and exclusion criteria

Inclusion criteria

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;

②patients aged 40 to 70 years, including 40 and 70 years, male or female;

③KL classification≤ grade 3；

④patients who have a mobile phone and can use the application proficiently;

⑤ patients who understand Chinese language and can complete the WOMAC independently;

⑥patients who have signed the informed consent;

Exclusion criteria

① patients with acute meniscus injury, peripheral ligament rupture injury, rheumatic arthritis, rheumatoid arthritis, peripheral tumor of knee joint, tuberculosis, idiopathic osteonecrosis of the knee;

② patients with serious cardiovascular, lung, liver, kidney and hematopoietic diseases, hemophilia and other hemorrhagic diseases, mental illness, pregnancy and lactation;

③patients 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;

⑤patients who are deemed unsuitable for the clinical trial.

What do you need to do if you participate in this study?

1、If you meet the inclusion criteria and agree to participate, the study will be conducted as follows:

After you have determined that you can participate in this study, you will have a treatment plan developed by your clinician and perfect routine laboratory tests. In the first stage, you will be evaluated by paper version of WOMAC index and electronic version of WOMAC index on day 1, In the second stage, 200mg celecoxib will be administered orally once a day starting from the second day of enrollment for a period of 21 days. In the third stage, you will complete both scales again and the tendency questionnaire, and count changes in the condition in the hospital and during follow-up. In addition to this, you do not need laboratory tests such as blood tests throughout your study. Your research doctor will give you health guidance, and you can always contact your research doctor for any questions you may have related to knee osteoarthritis.

2、Other things you need to cooperate with:

During the study period, without affecting your health and daily life, please not to use any kind of medication including analgesics that might affect the study outcomes. If you need additional treatment for various reasons, please also provide us with the relevant information.

Benefits from participating in the study

Participating in this clinical study, your condition may improve. You can get more medical advice and guidance related to this disease as you proceed with this trial.

Your participation will also contribute to the research of rehabilitation exercises for knee osteoarthritis, which is of social significance for the treatment of this disease and for other patients with such diseases.

Risks from participation in this study

This study was designed as a interventional study. During the intervention, taking celecoxib has a very small probability of certain digestive tract symptoms, such as vomiting and constipation.

If you experience any discomfort during the study, there is a new change in your condition or any unexpected circumstances, whether or not related to the study, you should promptly notify your doctor, who will judge and give appropriate medical treatment.

During the study period, you need to follow up at the hospital on time and do some tests, which take up some of your time and may cause trouble or inconvenience.

Costs and compensation for study participation

Patients do not need to pay out-of-pocket expenses for the diagnosis and treatment of KOA in clinical trials. Additionally, there will be no financial compensation for the study participation because the examination items in this study are clinical follow-up programs.

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".

The evaluation, diagnosis and treatment required for combined diseases will not be covered free of charge.

Is personal information confidential?

Information about your participation in this study will be recorded in the study medical records/case report form. All the medical record of the original studies including descriptive characteristics like name initials, allocated study number, sex, age, BMI, outcome measures like primary outcomes and secondary outcomes and laboratory results are treated with standard medical confidentiality and confidential to the extent allowed by law.

In the clinical record form, only your name initials and allocated study number will appear. In relevant research summaries, articles, and public journals, only the initials and numbers of your name will appear if necessary.

When necessary, pharmaceutical supervisory and administrative departments, the ethical committee and the project funding department may consult the information of the subjects participating in the study according to regulations. However, they would not use the data of the participants in the study for other purposes or leak it to other groups without permission.

How to get more information?

You can ask any questions about this study at any time.

Your doctor will leave you his/her phone number so that he/she can answer your questions。

If there is any important new information during the course of the study that may affect your willingness to continue with the study, your doctor will notify you in a timely manner.

You may voluntarily choose to participate in the study and quit the study halfway

Whether you participate in this research is entirely voluntary. You are free to refuse to participate in this study or to withdraw at any time without affecting any benefits to which you

would otherwise be entitled and be discriminated against or be subject to any reprisal.

Your doctor or researcher may suspend your participation in this study at any time for the best interest of the subject. You may be consulted about your use of the study drug if you quit the study for any reason.

If clinician feel examination is required, you may also be asked for physical examination and laboratory tests. You may also refuse without discrimination or retaliation for it.

If you choose to participate in this study, we expect you to complete the research.

If you do not participate in this study, your research physician will provide you with alternative treatment options, such as other drug or exercise therapies for knee osteoarthritis.

What should you do at the present time?

It is up to you to decide whether or not to participate in this study. You can discuss with your family or friends and ask your doctor as many questions as possible until you fully understand the study before making a decision.

Ethics committee

If you have questions or need to ask anyone other than the investigator, please consult the Ethics Committee of Shanghai Shuguang Hospital.

Ethics Committee Office: The second floor of the eastern administration of Shuguang Hospital

Tel.: 20256070

Thank you for reading the above material. If you decide to participate in this study, tell your doctor and he/she will arrange everything for you to do with the study.

Please keep this information sheet.

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Project name: Test reliability and comparability of paper and Chinese electronic version of the Western Ontario and McMaster University osteoarthritis index: a randomized controlled clinical trial

Project source: Shanghai Municipal Health Commission

Project version: V1.0

Project date: January 10, 2019

Consent statement

I have read the above statements of this study and were given the chance to discuss the study with and ask questions to the investigator. Any questions I had were answered to my full satisfaction.

I am aware of the risks and benefits that may arise from participating in this study. I am aware that participation in the study is on a voluntary basis. I have had enough time to think about my participation in the study, and I understand that:

- I can always ask the doctor for more information.
- I can withdraw from the study at any time without detriment, and medical care and treatment will not be affected.

I was also very much aware that if I tell the doctor about the change in my condition and complete the physical examination and laboratory test particularly for reasons of drug in case of dropout, it will be very beneficial to me and the whole research.

In case any other treatment needed, I will call for a doctor's opinion in advance or tell the doctor truthfully afterwards

I give permission for pharmaceutical supervisory and administrative departments, the ethical committee and the project funding department to have access to my research materials.

I will receive a copy of the signed and dated written informed consent form.

Finally, I agree to participate in the study and try to conform to the advice of the doctors as far as possible.

Subjects Signature：_____ Date：_____

Subjects Tel.：_____

I confirmed that the entire protocol of this study was explained to all subjects, including their rights, risks and benefits, and were given a signed copy of the informed consent form.

Investigator Signature：_____ Date：_____

Investigator Tel.：_____