Rehabilitation exercise intervention for rheumatoid arthritis patients based on artificial intelligence exercise prescription system

Informed consent

Hello!

We are going to conduct a rehabilitation exercise intervention study for patients with rheumatoid arthritis based on an artificial intelligence exercise prescription system, and we would like to invite you to participate in this study because you have rheumatoid arthritis and your specific condition may be eligible for enrollment in this study.

This informed consent form will introduce you to the background, purpose, steps, benefits, risks and inconveniences of this study, as well as your rights and interests, please read it carefully before making a careful decision on whether to participate in this study. When the researcher explains or discusses the contents of the informed consent form to you, you can always ask questions and ask the researcher to explain to you what you don't understand. You can also discuss it with your family, friends or your doctor before making a decision.

The project leader of this study is Li Tao, director of the Department of Rehabilitation Medicine, Peking University People's Hospital.

1. Why is this study being conducted?

1) Why was this study undertaken?

Rheumatoid Arthritis (RA) is a chronic condition that causes inflammation, pain, swelling, and even interference with daily activities. In the past, people mainly relied on medication for treatment, but now that medicine has advanced,

rehabilitation exercises have also been proven to be very helpful in treating RA. However, traditional rehabilitation exercise programs are "one-size-fits-all" and do not take into account everyone's differences, so the effects vary greatly. In addition, the aging population is serious, and more and more people are suffering from chronic diseases, and rehabilitation medical resources are not enough. So, we need a smarter, more personalized approach to this problem.

2) Brief introduction of this study

The system we are studying is an AI-based prescription system for rehabilitation exercises. To put it simply, this system can tailor a set of rehabilitation exercise plans for you according to your physical condition, and tell you what exercises to do every day through mobile phone WeChat. After exercising, you can also feedback your feelings through the system, and the system will adjust the exercise plan based on your feedback. In this way, you can get more suitable rehabilitation exercise guidance for you.

2. Who will be invited to participate in this study?

Subjects participating in this study are required to meet the following conditions:

Age range: ≥ 18 years old, regardless of gender;

Diagnosis of disease: Definitive diagnosis of rheumatoid arthritis (meeting the 2010 ACR/EULAR diagnostic criteria) and knee involvement;

Disease status: stable condition (moderate and low activity) after standardized drug treatment;

Health status: No severe liver and kidney impairment, mental disorders or other rheumatic immune diseases (such as systemic lupus erythematosus);

Voluntary participation: Signed informed consent form and able to cooperate with the completion of rehabilitation exercises and follow-up assessments.

Excluded population: Pre-existing joint rigidity (immobility) or extra-articular soft tissue lesions; Extra-articular soft tissue lesions or acute onset during study

participation; Combined with other rheumatic immune diseases (such as systemic lupus erythematosus, Sjogren's syndrome, etc.), combined with severe liver and kidney function impairment, and mental disorders. Knee VAS pain score greater than 4 points (0 points for no pain and 10 points for worst pain).

3. How many people will take part in this study?

This study plans to enroll 147 subjects, divided into three groups (artificial intelligence exercise prescription group, paper exercise prescription group, and usual care control group), with 49 cases in each group.

4. How was the study conducted?

This study aims to verify the rehabilitation effect of a rehabilitation exercise regimen based on an artificial intelligence exercise prescription system on patients with rheumatoid arthritis through a randomized controlled trial.

Research process and methodology

1) Inspection and inspection:

The diagnosis was made by a rheumatology immunologist in a tertiary A hospital according to the 2010 ACR/EULAR classification diagnostic criteria for rheumatoid arthritis. Evaluate the patient's knee involvement and whether they are in moderate or low mobility. Check whether the patient has signed the informed consent form. Patients with pre-existing joint ankylosis, extra-articular soft tissue lesions, acute attacks, other rheumatic immune diseases, severe liver and kidney impairment, and mental disorders were excluded.

2) Subject grouping

Random grouping: You will be randomly (like a coin toss or a lottery) assigned to any of the three groups, each with the same probability. The three groups are the artificial intelligence exercise prescription group, the paper exercise prescription group and the usual care control group.

Double-blind setting: This study does not involve double-blinding, as the treatment methods of each group are different, and double-blinding cannot be

achieved.

3) Interventions

Artificial Intelligence Exercise Prescription Group :

Use the "Artificial Intelligence Exercise Prescription System for Dynamic Health". The system pushes personalized rehabilitation exercise plans through WeChat mini programs and adjusts them every week according to feedback. From the beginning of enrollment to the end of the intervention, followed by long-term follow-up.

Paper exercise prescription group: Receive the paper version of the exercise prescription and exercise on your own. Treatment cycle and duration : same as the AI exercise prescription group.

Usual care control group :

Receive standardized health education and basic exercise guidance from the Department of Rheumatology and Immunology. Treatment cycle and duration : same as the AI exercise prescription group.

4) Follow-up plan

Time points: The day of enrollment, the end of the intervention, 3 months after the intervention, and 6 months after the intervention.

1) Number of visits: A total of 4 main follow-ups, with standardized follow-up by phone or online platform every 2 weeks, and the content of the telephone or platform follow-up is the Borg Subjective Fatigue Scale, also known as the self-perceived fatigue grading method (RPE), which is a semi-quantitative index to measure the relative exercise level based on the degree of self-perceived exertion. Used to monitor exercise intensity and for individuals to subjectively assess how much effort they are exerting during exercise or exercise testing. Time spent on each follow-up: Depending on the evaluation items, each follow-up visit will take about 1 hour.

Follow-up :

- Face-to-face interview: scale assessment, action observation, etc.
- Questionnaires: Collect patient feedback through questionnaires.

- On-site testing: such as timed standing walking (TUG), isokinetic dynamometer measurement, etc.

Follow-up contents: joint function assessment (HSS, WOMAC), exercise ability assessment (TUG, BBS, gait and plantar pressure measurement), pain level assessment (VAS score), quality of life assessment (PHQ-9, GAD-7, PSQI, HAQ), muscle strength assessment (isokinetic dynamometry measurement), laboratory tests (blood routine, rheumatoid factor, C-reactive protein).

Scope of use of research data and personal data : for scientific research only. All personal data will be kept strictly confidential and will not be used for any journalistic and commercial purposes. When the research results are published, personal information such as names and contact information will not be disclosed.

5. Duration of the study

If you participate in this study, it will take about half a year.

6. What is the impact of participating in the study on daily life?

When you decide whether to participate in this study, carefully consider the possible impact of the examinations and follow-up listed above on your daily work, family life, etc. Consider the time and transportation of each return visit. If you have any questions about the tests and steps involved in the study, you can contact us.

Consult and inform your study doctor before taking any new medications.

For your safety and to ensure the validity of the study results, you cannot participate in any other clinical studies involving drugs and medical devices during the study period.

7. Risks and adverse reactions of subjects/study participants participating in this study?

Risk: There may be a risk of muscle injury due to exercise, which can be treated symptomatically by stopping exercise, applying ice, etc., and sending to the hospital in time if necessary.

8. Possible benefits for subjects/study participants in this study?

Direct benefit: Participants may not benefit from participating in this study and may gain a relatively comprehensive understanding of their rheumatoid arthritis (by clinical assessment).

Indirect benefits: More patients with rheumatoid arthritis can receive rehabilitation treatment in the future, helping to improve their life functioning.

9. Are there any other treatment options if I do not participate in this study?

You may choose not to participate in this study, which will not have any adverse effects on your access to routine medical care. Currently, conventional treatment methods for the health of patients with rheumatoid arthritis (RA) mainly include the following:

Medication, physical therapy, surgical treatment; For patients with severe joint destruction, deformity, or loss of function, joint replacement or arthrofusion may be considered

Key benefits: Medication can effectively control disease activity and reduce pain and inflammation. Physical therapy can improve joint function and ability to perform daily activities. Surgical treatment can restore joint function and improve quality of life if necessary.

Main risks: Drug treatment may bring side effects such as gastrointestinal

discomfort and liver and kidney function damage. Physiotherapy requires long-term adherence, and the results vary from person to person. Surgical treatment carries risks, such as infection, bleeding, loosening of the prosthesis, etc.

10. Is it mandatory to participate in and complete this study?

Whether or not you participate in this study is completely voluntary. If you do not wish, you can refuse to participate, which will not negatively affect your current or future medical treatment and you will not be discriminated against in any way.

You can withdraw from this study at any time and without any reason, even after you have agreed to participate. Withdrawing from the study will not affect your access to normal medical care and will not be subject to any discrimination. When you decide not to take part in this study, we want you to let your study doctor know as soon as possible, who can advise and guide you about your health.

During the study, we will keep you informed of any new information that may affect your decision to continue participating in the study.

11. Who is responsible for the cost of participating in the study?

If you meet the enrollment conditions and the patient voluntarily participates in this project, your post-enrollment examinations (such as HSS, WOMAC, TUG, BBS, etc.) will be paid by the researcher. However, you need to bear the cost of two blood routine, rheumatoid factor, and C-reactive protein tests.

12. Are subjects/study participants paid for participating in the study?

No research remuneration will be provided for this study.

13. What do you do if you have a research-related damage?

If you are harmed by participating in this study, the Department of

Rehabilitation Medicine, Peking University People's Hospital will bear the treatment cost and corresponding financial compensation.

14. Will personal information be kept confidential?

If you decide to participate in this study, your personal information about your participation in and during the study will be kept confidential. Specimens collected from you will be identified with a study code instead of your name. Any information that can identify you will not be disclosed to members outside of the study group without your permission. All study members and study parties will be required to keep your identity confidential. Your archives will be kept in a locked archive cabinet for researcher access only. When necessary, members of government administrations or ethical review committees may access your personal data at the research institute as required. When the results of this study are published, no identifying information will be disclosed about you.

In principle, if you withdraw from the study early, the investigator will no longer collect new information from you. The research institution and the research doctor will not use the information data and biological samples collected before you withdraw from this study, and your consent will be obtained again if you want to continue to use it. The information obtained will be used as agreed and will be destroyed within 5 years after the completion of the study.

15. Follow-up processing plan for research related information and samples

After the end of this study, the study data and the personal data of the study participants will be destroyed within 5 years.

16. Who should I contact if I have questions or difficulties?

If you have any questions related to this study, please contact the researcher (Li Tao 010-88316683, 13811397872).

If you have any questions related to your own rights and interests, you can contact the Ethics Review Committee of Peking University People's Hospital at 010-88324516

Informed consent form (signature page).

Statement by the researcher

I have informed the subject of the research background, objectives, steps, risks and benefits of rehabilitation exercise intervention for rheumatoid arthritis patients based on the artificial intelligence exercise prescription system, and given him/her enough time to read the informed consent form, discuss with others, and answer his questions about the study. I have informed the subject that he can contact Deputy Chief Physician Li Tao at any time when encountering problems related to the study, and contact the Ethics Review Committee of Peking University People's Hospital at any time when encountering issues related to his rights/interests, and provide accurate contact information. I have informed the subject that he/she can withdraw from this study without any reason; I have informed the subject that he/she will be given a copy of this informed consent form with my and his/her signatures.

_____ _____

Signature of the investigator with informed consent (italics)

date

_____ _____

Signed by the investigator with informed consent (handwriting)

date

Subject/study participant statement

I have been informed about the background, objectives, steps, risks and benefits of the study of rehabilitation exercise intervention for rheumatoid arthritis patients based on the AI exercise prescription system. I had enough time and opportunity to ask questions, and I was satisfied with the answers to the questions. I was also told who to contact when I had questions, wanted to report difficulties, concerns, suggestions for research, or wanted to obtain further information, or help with research. I have read this informed consent form and I agree to participate in this study. I know that I can withdraw from this study at any time during the study

without any reason. I was told that I would be given a copy of this informed consent form with my signatures and the investigator's.

_____ _____

Subject/study participant signature (italics) date

_____ _____

Subject/study participant signature (handwriting) date