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

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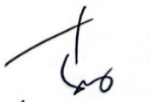
Signature of the person in charge of the project of the unit: 

List of researchers

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1. Research abstract

1. Purpose of the study

This study aims to verify the rehabilitation effect of a rehabilitation exercise program based on an artificial intelligence exercise prescription system on patients with rheumatoid arthritis through a randomized controlled trial, and to explore its effectiveness and safety in improving joint function, exercise ability, pain level and quality of life.

2. Study design

This study uses a randomized controlled trial. Based on the estimate (see below) to obtain the minimum sample size required for this study, 147 patients with rheumatoid arthritis who met the inclusion exclusion criteria were selected and randomly divided into three groups. In this study, patients were followed up on the day of enrollment, the end of the intervention, 3 months after the intervention, and half a year after the intervention, and the efficacy evaluation indicators completed by the patients were collected.

2. Research background and basis for project establishment

1.Research significance

Rheumatoid Arthritis (RA) is a chronic autoimmune disease characterized by joint inflammation, pain, swelling, and dysfunction, which seriously affects the quality of life of patients[1]。 With the advancement of medicine, the treatment of rheumatoid arthritis has expanded from medication alone to a comprehensive treatment model that includes rehabilitation exercises[2] 。 Patients with rheumatoid arthritis can not only reduce symptoms through reasonable rehabilitation exercise prescription, but also improve joint function and improve quality of life[3] 。 Traditional rehabilitation exercise programs generally have the problem of lack of personalization and accuracy, and it is difficult to provide customized guidance for individual differences in patients, resulting in significant individual differences in rehabilitation effects. At present, under the dual pressure of

accelerating population aging and the continuous rise in the prevalence of chronic diseases, the demand for rehabilitation medicine services in society is increasing exponentially. However, the total amount of rehabilitation medical resources in our country is insufficient and unevenly distributed[4], forming a sharp contradiction with the rapidly expanding patient population. In this context, the development of a rehabilitation exercise prescription system based on artificial intelligence technology has dual value: it can not only improve the quality and efficiency of rehabilitation through personalized programs, but also alleviate the pressure of medical resource supply with the help of technology empowerment.

This study aims to explore the rehabilitation exercise protocol for rheumatoid arthritis patients based on the artificial intelligence exercise prescription system, verify the effectiveness, safety and feasibility of this program through a randomized controlled study, and provide new ideas and methods for the rehabilitation treatment of rheumatoid arthritis patients.

2. Research status at home and abroad

In recent years, domestic scholars have conducted a lot of research on the rehabilitation treatment of rheumatoid arthritis and achieved a series of important results.Xie Benxiang and Wu Yijin's research showed that resistance exercise training can significantly improve hand function rehabilitation and self-care ability in rheumatoid arthritis patients[3]。 Li Wufen's research verified the significant effect of exercise prescription intervention on pain relief and physical function recovery in patients with rheumatoid arthritis[5]。 The "2024 Chinese Guidelines for the Diagnosis and Treatment of Rheumatoid Arthritis" also mentions that appropriate exercise and physical therapy (such as aerobic exercise, resistance exercise, and functional exercise) can enhance joint flexibility and stability, and improve patients' symptoms, physical function, and quality of life[6]。 However, traditional rehabilitation exercise programs are mostly based on experience and lack personalization and precision. In addition, rehabilitation outcomes are often difficult to predict and assess due to large patient variations. Therefore, domestic scholars have begun to explore the application of artificial intelligence technology to the formulation and implementation of rehabilitation treatment programs, such as Kong Lingkai and Wang Sen have used artificial intelligence technology to study posture recognition and exercise prescription systems, aiming to improve the effect and quality of adolescent physical exercise[7]。 However, the relevant

research is still in its infancy, and there is a lack of large-scale clinical trial validation and systematic theoretical system support.

Foreign research in the field of rehabilitation medicine started early, especially in the combination of artificial intelligence and rehabilitation exercise. Several studies have shown that AI-assisted gait training and rehabilitation robots can effectively improve independent walking ability and lower limb motor function in stroke patients[8,9]。 Thus, repeated walking stimulation of standardized physiological gait is realized, and normal walking movement patterns are re-established[10]。 These applications of artificial intelligence can not only provide patients with objective and accurate functional assessments and promote the adjustment of clinical treatment, but also optimize human-computer interaction in terms of vision, hearing and touch during rehabilitation treatment, so as to maximize the rehabilitation experience and improve the effectiveness of rehabilitation diagnosis and treatment. Some developed countries have developed rehabilitation exercise prescription systems based on artificial intelligence technology and have achieved good results[11,12]。 These systems enable personalized exercise prescriptions based on patient specifics and ensure that patients exercise according to prescribed requirements through real-time supervision and feedback mechanisms. However, due to differences in medical systems, cultural backgrounds, and patient needs in different countries and regions, these systems still need to be localized and optimized in practical applications.

3. Combine the development trend of scientific research and the needs of national economic and social development

At present, artificial intelligence has become one of the important tools and methods of scientific research. With the rapid development of big data, cloud computing and other technologies, artificial intelligence is becoming more and more widely used in various fields. In the field of rehabilitation medicine, the application of artificial intelligence technology will promote the development of rehabilitation treatment in a more personalized and precise direction. By deeply mining and analyzing multiple information such as clinical data and exercise data of patients, artificial intelligence can formulate rehabilitation exercise prescriptions that are more in line with the needs of patients, and supervise and adjust the patient's exercise status in real time to ensure the maximum rehabilitation effect.

With the increasing aging population and the increasing number of patients with

chronic diseases, the demand for rehabilitation medicine is growing. However, at present, our country's rehabilitation medical resources are relatively scarce and cannot meet the needs of the majority of patients. Therefore, exploring a rehabilitation exercise prescription system based on artificial intelligence technology can not only improve the efficiency and quality of rehabilitation, but also effectively alleviate the shortage of rehabilitation medical resources. In addition, the system can also provide reference for the rehabilitation treatment of patients with other chronic diseases, promote innovation and development in the field of rehabilitation medicine, and make greater contributions to our country's medical and health cause.

In summary, the rehabilitation exercise program for rheumatoid arthritis patients based on the artificial intelligence exercise prescription system proposed in this study has important scientific significance and application prospects. Through in-depth research and analysis of the effectiveness, safety and feasibility of this regimen, it can provide new ideas and methods for the rehabilitation treatment of rheumatoid arthritis patients, and inject new vitality into the innovation and development of the field of rehabilitation medicine.

3. Research purpose

This study aims to verify the rehabilitation effect of a rehabilitation exercise program based on an artificial intelligence exercise prescription system on patients with rheumatoid arthritis through a randomized controlled trial, and to explore its effectiveness and safety in improving joint function, exercise ability, pain level and quality of life.

4. Research methods and design

1. Research design type

This study adopts a single-center, randomized, parallel controlled trial design. Patients with moderate and low mobility with rheumatoid arthritis who met the inclusion and exclusion criteria were assigned to the following three groups in a 1:1:1 ratio by random number table method:

- AI exercise prescription group: Receive a personalized rehabilitation exercise regimen based on an AI system.
- Paper exercise prescription group: Receive the paper version of the exercise

prescription and exercise on your own.

- Routine care control group: Received standardized health education and basic exercise guidance from the Department of Rheumatology and Immunology.

The effectiveness and safety of the artificial intelligence exercise prescription system were verified by comparing the differences in joint function, exercise ability, pain level and quality of life among the three groups. No intervention was given to existing rheumatology treatment interventions.

2. Research objects and selection criteria

Research objects: Outpatients of the Department of Rheumatology and Immunology of Peking University People's Hospital clearly diagnosed patients with moderate and low activity levels according to the 2010 ACR/EULAR classification diagnostic criteria for rheumatoid arthritis. The study plans to recruit from August 2025 to December 2025 at the outpatient clinic of the Department of Rheumatology and Immunology, Peking University People's Hospital.

3. Selection criteria for research objects:

Selection Criteria:

a. Gender is not limited; Patients with rheumatoid arthritis were clearly diagnosed by rheumatoid immunologists in tertiary A hospitals according to the 2010 ACR/EULAR classification diagnostic criteria for rheumatoid arthritis

b. After standardized drug treatment, the doctor judged that the patient belongs to the rheumatoid arthritis with moderate and low activity;

c. Age≥ 18 years old;

d. 膝关节受累;

e. Signed informed consent.

Exclusion Criteria:

a.; Pre-existing joint ankylosis (fibrous or bony);

b.; Extra-articular soft tissue lesions or acute onset during study participation;

c.; Combined with other rheumatic immune diseases (such as systemic lupus erythematosus, Sjogren's syndrome, etc.), combined with severe liver and kidney function damage, mental disorders;

d.； Knee VAS pain score greater than 4 points (0 points for no pain and 10 points for worst pain).

4. Setting of intervention group and control group

Patients with rheumatoid arthritis who met the inclusion criteria were randomly divided into the usual care control group, paper exercise prescription group and artificial intelligence exercise prescription group in a 1:1:1 ratio using the Redcap system for six weeks of intervention, with an exercise frequency of once a day, and the treatment regimen of the three groups was as follows:

① Nursing routine control group

The routine nursing control group received standardized health education and exercise guidance led by rheumatology and immunology nurses, including the key points of rheumatoid arthritis disease management, knee joint protection principles, and explanation of basic joint activity training movements. The details are as follows:

(1) Wrist joint function exercise:

a) Massage: After rubbing the hands into the palms of the hands, massage the diseased hand joints and surrounding tissues, including the front and sides of the joints, for 1-3 minutes in each joint.

b) Stretching exercise: Make a fist with maximum strength until it is no tighter, then stretch as far as you can and repeat for 5 minutes.

c) Hand joint exercise: ensure that each joint moves according to its physiological and functional state, mainly flexing and extending the finger joints as much as possible, and repeat for 5 minutes.

d) Wrist joint activity: 5 rotations each of forward and reverse slow rotation of the wrist joint.

(2) Hand muscle strength training: You can prepare a square towel, lay it flat on the table, put your hands and elbows flat on the table at the same time, put your wrists on the square scarf, spread your fingers apart, hold the towel with your fingers, lift it up, and maintain it as much as possible, and repeat for 3-5 minutes. To delay muscle atrophy and enhance hand muscle strength.

(3) Shoulder joint exercise: Balance and fix both hands on both shoulders,

and perform shoulder joint forward and backward "circle" movements, repeating 10-20 times respectively.

(4) Elbow arthritis exercise: flexion and straightening of both elbow joints as much as possible, repeat 10-20 times.

(5) Knee joint exercise: Take a sitting position or lying down, flex and straighten the knee joint as much as possible, and do the repetitive action of "hooking the toes and stretching the instep" when straightening to exercise muscle strength. It can be done 2-3 times a day for 5-10 minutes per repetition.

(6) Aerobic exercise: In order to improve cardiopulmonary function and overall health, such as swimming, slow walking, brisk walking, cycling, yoga, tai chi, etc.

Precautions: The amount of exercise should not be excessive, it is appropriate to feel mild fatigue the next day, the pain cannot be relieved/aggravated 2 hours after exercise, considering that the amount of exercise is too large, the frequency or time of activity can be appropriately reduced. Exercise should be gradual and adhere to long-term rules.

② Paper exercise prescription group

Based on the assessment results, a paper exercise prescription was developed, covering aerobic training, progressive resistance training, joint mobility training and exercise precautions. After the initial evaluation, the therapist of the Department of Rehabilitation Medicine will explain and guide the exercise prescription in detail, and then instruct the patient to practice at home. The details are as follows:

Warm-up: 1. Standing in place (1 set, 50s/set)2. Seated knee extension and ankle pump (1 set, 30 reps/set)3. Knee Mobilization (1 set, 20 reps/set)

Formal training: 1. Gluteal bridge (1 set, 12 reps/set)2. Retreat Bird Dog Pose (2 sets, 6 reps/set) Shallow squat in place (2 sets, 20 reps/set) Alternate leg raises in place (2 sets, 16 reps/set) 3Standing calf raises (2 sets, 16 reps/set)

Cooling (1 set per action, 30s/set): 1. Prone quadriceps stretch 2. Cross-legged leg press 3. Foot calf stretch 4. Static back thigh stretch

③ Artificial Intelligence Exercise Prescription Group

The AI exercise prescription group uses the "Movement Health AI Exercise Prescription System" to implement exercise intervention. After the doctor or therapist formulates an exercise prescription for the patient, the system pushes the exercise prescription to the subject through the WeChat mini program, and collects patient feedback (which can include VAS score, RPE, joint swelling, mobility, etc.) through an online questionnaire after executing the exercise prescription. The system is equipped with an artificial intelligence question and answer module, which can analyze the problems of joint swelling and limited movement described by the patient's natural language, and

automatically generate a safe response strategy that meets the authoritative guidelines. The specific exercise prescriptions that can be selected are as follows:

Exercise Prescription A|Basic Activation (Main Goal: Activate Muscles, Relieve Stiffness)

Warm-up (10 reps or 30 seconds per movement)

1. Supine ankle pump exercise

2. Lie on your back and alternately bend and extend your knees
3. Pillow and knee extension

▶Formal training (static + auxiliary active, 10 reps each, hold for 5-10 seconds each time).

1. Dead insect retreat

2. Clam style

3. Sitting positions alternately extend your knees

4. No support - squat hold with both legs

▶ Cool down (hold for 15－30 seconds per action).

1. Prone quadriceps stretch

2. Cross-legged pressing legs

3. Supine hamstring stretching

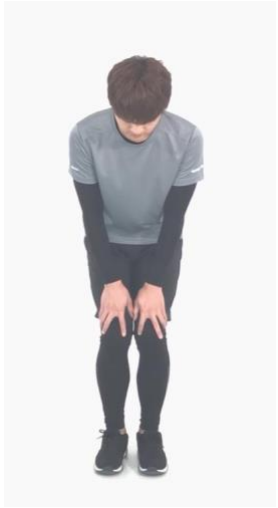
Exercise Prescription B Strength stabilization (main goal: improve lower limb stability + knee control).

▶ 热身

1. Stand in place (1 set, 50s/set).

2. Postural knee extension ankle pump (1 set, 30 reps/set).

3. Knee mobilization (1 set, 20 reps/set).



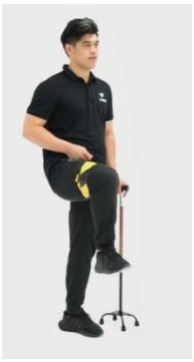
▶ formal training

1. Gluteal bridge (1 set, 12 reps/set).

2. Retreat Bird Dog Pose (2 sets, 6 reps/set).

3. Shallow squats in place (2 sets, 20 reps/set).

4. Alternate leg raises in situ (2 sets, 16 reps/set).



5. Standing calf raises (2 sets, 16 reps/set).

▶ Cooling (1 set per action, 30s/set).

1. Prone quadriceps stretch

2. Cross-legged pressing legs

3. Calf stretching

4. Static stretch on the back of the thigh

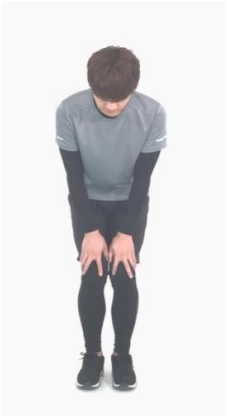
Exercise Prescription C Functional maintenance (primary objective: prevention of withdrawal and use, maintenance of joint mobility)

warm up

1. Alternate knee extension in a sitting position (1 set, 15 reps/set).

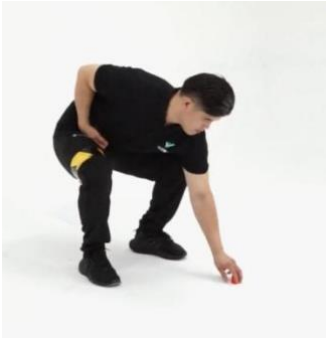
2. Seated strength push (1 set, 10 reps/set).

3. Knee mobilization (1 set, 20 reps/set).

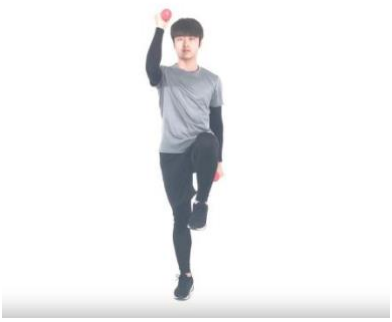


formal training

1. Squat pickup on both legs (2 sets, 10 reps/set).



2. Difficult standing in place (holding dumbbells) (2 sets, 12 reps/set).



3. Shallow squats in place (2 sets, 12 reps/set).

4. Side up and down steps (left) (right) (2 sets, 12 reps/set).

5. Stand on one leg in place (2 sets, 30s/set).

6. Clamped occipital gluteal bridge (2 sets, 12 reps/set).

▶ Cooling (1 set per action, 30s/set).

1. Calf stretching (left, right).

2. Gluteus maximus stretching (left and right).

3. Pray for stretching

5. Randomization design

After the study subjects signed the informed consent form and screened by the researchers, the subjects who met the exclusion criteria for the study were automatically randomly divided into 3 groups according to a ratio of 1:1:1: the nursing routine control group, the paper exercise prescription group and the artificial intelligence exercise prescription group.

6. Selection and confirmation of main measurement indicators or outcome indicators

(1) Effectiveness evaluation indicators

General information: On the day of enrollment, a self-designed general information questionnaire was used, mainly including the age, gender, occupation, education level, marital status, years of illness, and medication status of the subjects.

Main evaluation indicators:

Range of motion (ROM) refers to the maximum flexion and extension angle that can be achieved in active or passive movement of the knee joint, reflecting the motor function of the joint and the elastic state of soft tissues (muscles, ligaments, joint capsules), and its measurement requires a standard protractor (accuracy ± 1°). The flexion angle is measured by aligning the lower axis of the femoral condyle in the supine position and pointing the arm to the lateral malleolus, and the normal reference value is 0-140°. Patients were evaluated on the day of enrollment, at the end of the intervention, 3 months after the intervention, and half a year after the intervention. Knee flexion ROM at six months after surgery was used as the primary outcome measure.

Secondary evaluation indicators:

The following evaluations were performed on the day of enrollment, at the end of the intervention, 3 months after the intervention, and half a year after the intervention:

1）Hospital Special Surgery (HSS) in New York, USA

HSS is a scale used to evaluate changes in joint function and motor function, including a total of 100 points in 6 dimensions, namely: pain (30 points), function (22 points), joint mobility (18 points), muscle strength (10 points), knee flexion deformity (10 points), joint stability (10 points), and deduction items such as whether a walker is needed, varus deformity and dystonism, and the final score is > 85 points. 70-80 points are good; 60-69 points are acceptable; < 60 points difference. HSS has good reliability and validity, with ICC of 0.98-0.99 and Cronbach'S α of 0.87.

2）西安大略和麦克马斯特大学骨关节炎指数（the western ontario and mcmaster university osteoarthritis index, WOMAC）

The scale contains three dimensions: pain, stiffness and function, with a total of 24 items, including 5 items of pain, 2 items of stiffness, and 17 items of function, scored using

the Likert-5 scoring system, with a total score of 0-240 points, and the higher the score, the more severe the symptoms, and the worse the joint function. The study showed that the Cronbach'S α coefficients of the pain, stiffness, and functional dimensions were 0.84, 0.86, and 0.96, respectively, with strong internal consistency, and the ICC of the pain, stiffness, and functional dimension subscales were 0.81, 0.76, and 0.85, respectively, which had good test-retest reliability.

3）Time up and go (TUG)

TUG was used to evaluate the walking ability of the patients. During the test, the patient sat in a standard armchair (seat height approx. 46 cm, armrest height approx. 21 cm), leaned against the back of the chair, and determined a 3-meter long route on the floor. After starting the command timer, walk to the 3-meter line, turn around and return to the seat after crossing the 3-meter line with both feet, sit down, and lean on the back of the chair.

4）Berg 平衡量表（berg balance scale,BBS）

The scale contains 14 basic items, and each item is scored on a scale of 0-4 points, with a total score of 56 points. Those who cannot complete each item independently will be scored 0 points, those who can partially complete it will be counted as 1-3 points according to the degree of help required, and those who can complete it independently without help will be scored 4 points.

5）Muscle strength: Muscle endurance and absolute strength are measured using an isokinetic dynamometer

Absolute strength: Absolute strength refers to the maximum force a muscle can produce under certain conditions. In isokinetic strength testing, absolute muscle strength is usually measured by the peak torque, which indicates the maximum moment a muscle exerts during contraction. The angular velocity was set to 60°/s on an isokinetic dynamometer, and the subjects performed five flexion and extension movements. The peak moment value is the maximum moment value during each muscle contraction automatically recorded by the instrument. The maximum value of the five tests is usually taken as the subject's absolute strength index. Operated and evaluated by a rehabilitation therapist with experience in isokinetic strength testing.

Muscular Endurance: Muscular endurance refers to the ability of muscles to maintain strength during continuous or repetitive contractions. In isokinetic strength tests, muscle endurance is usually measured by total work, which reflects the total amount of work done by the muscle during repeated contractions. The angular velocity was set to 180° /s on the isokinetic dynamometer, and the subjects performed 20 flexion and extension exercises. The total work is calculated by adding the area under the moment curve generated by each muscle contraction to obtain the total amount of work done during the entire test process. Operated and evaluated by a rehabilitation therapist with experience in isokinetic strength testing.

6）Gait and plantar pressure measurement system

Gait analysis spatiotemporal parameters:

- Time parameters: including step time, stride time, single support phase time, double support phase time, standing phase time, swing phase time, single support phase percentage, double support phase percentage, pace and cadence frequency, a total of 10 items.
- Spatial parameters: including stride length, step width and step angle, a total of 3 items.

Peak plantar pressure: Peak plantar pressure is one of the most commonly used variables to indicate plantar load, and its calculation formula is as follows:

$$F_{1r} = \max_{n \in [1,N]} P_r(n)|_L$$

where n=1,2.....N is the length of plantar pressure signal; r= 1,2.....8, representing 8 regions of the plantar foot, respectively; Pr(n) is the plantar pressure value in a certain area of the foot. L/R stands for left/right foot. A rehabilitation therapist or professional technician is responsible for the operation of the equipment and data collection.

7）Pain measurement

The pain visual analogue scale (VAS), which is a straight line divided into 10 equal parts, is marked with numbers, and the subjects are asked to judge the number according to their own pain sensation, and then the researchers determine the degree of pain and score it. The leftmost edge of the line represents "no pain" (0), and the rightmost part of the line represents "the most severe pain" (10). The criteria were mild pain (1-3), moderate pain (4-6), and severe pain (7-10).

8）Arthritis Self-Efficacy Scale (ASES-8)

The scale consists of pain (2 items), other symptoms (4 items), and the patient's confidence in coping with the symptoms of the disease (2 items). Cronbach's α coefficient is 0.920, and the test-retest reliability is 0.986, which is stable and suitable for our country population, and each item is scored on a scale of 1~10, and the higher the score, the higher the self-efficacy.

9）Borg Subjective Fatigue Scale

Also known as self-perceived exertion grading (RPE), it is a semi-quantitative index that measures relative exercise level based on the degree of self-perceived exertion. The Borg rating scale divides self-fatigue perception on a scale of 6-20, with 6 equating to effortless and 20 referring to maximum effort. Reaching 12-14 points is a slight tiredness, indicating that the intensity of this exercise is appropriate, and the resistance can be gradually increased according to one's own situation after adapting to the intensity of this exercise.

10）PHQ-9 健康问卷(Patient Health Questionnaire-9,PHQ-9)

It is a simple and effective self-rating scale for depressive disorders based on the 9 items of the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders developed by the American Psychiatric Association), which has good reliability and validity in the adjunct of depression diagnosis and symptom severity assessment, answer this questionnaire according to the situation in the past two weeks. The answers to each question from left to right are "almost never", "a few days", "more than half", and "almost every day". The scores of the corresponding options are: 0, 1, 2, 3, and each question is added together to get the final score. When any of the core items 1, 4, and 9 score > 1 (i.e., 2 and 3), attention is needed (items 1 and 4 represent the core symptoms of depression, and item 9 represents self-harm thoughts).

12）广泛性焦虑量表（generalized anxiety disorder，GAD-7）

The scale was developed by Spitzer et al. for screening for generalized anxiety and for assessing symptom severity. GAD-7 consists of 7 items to understand how many times respondents have been troubled by 7 problems, including feeling nervous and worried, in the past 2 weeks. Each item is scored from 0-3, and the total score is summed up by the 7

items, with a total score of 0-21, 5-9 points of mild, 10-14 points of moderate, and 15-21 points of severe.

13）匹兹堡睡眠质量指数（The Pittsburgh Sleep Quality Index,PSQI）

PSQI is a widely used tool for evaluating sleep quality, consisting of 23 items, which can be divided into 7 components: subjective sleep quality, sleep onset time, sleep efficiency, sleep disorders, application of sleeping drugs and daytime function, which is suitable for evaluating sleep quality in the past 1 month. The cumulative score is a total score of 21 points, with PSQI >7 as the reference cut-off for sleep quality problems, and the higher the score, the worse the sleep quality.

14) Blood sampling to check laboratory indicators

Latex agglutination method and scattering turbidimetry were used to detect rheumatoid factor (RF) and C-reactive protein (CRP). And perform routine blood tests.

15）健康评估问卷（Health Assessment Questionnaire，HAQ）

The HAQ is the most commonly used scale to assess the general status of patients with rheumatoid arthritis, including dressing, getting up, eating, walking, personal hygiene, reaching, gripping, and daily activities, and comprehensively assesses the patient's ability to perform activities of daily living and health. When the patient answered each question, he chose from 0~3 points according to the degree of daily living activity ability (0=no difficulty; 1=There are certain difficulties; 2=Very difficult; 3=Cannot be completed). The scoring range is 0~3, and the average of each score is taken.

16) Improve the number of exercise prescriptions

The doctor/therapist of the artificial intelligence group should review the exercise prescription formulated by the system, and if there is a need to adjust, the doctor/therapist will modify it, and the number of modifications will be recorded as the number of improved exercise prescriptions.

(2) Safety evaluation indicators

1) Patient-reported safety indicators

Change in daily pain visual analogue score (VAS) (sudden increase≥ 2 points need to be recorded as an AE)

Exercise tolerance feedback (eg, fatigue, increased joint discomfort)

2) Adverse events and serious adverse events are adverse medical events

that occur after a patient or clinical trial subject receives a treatment, but it is not necessarily causally related to the treatment, it may be a new disease, worsening of symptoms or signs at the time of treatment, worsening of concomitant diseases, the effect of a comparator drug, or unrelated to participation in the trial. The evaluation of adverse reactions is based on five levels of evaluation, including positive related, likely related, possibly related, possibly irrelevant, and affirmatively irrelevant, and the first three are counted as the incidence of adverse reactions. Serious adverse events are events that require hospitalization, prolonged hospitalization, disability, affect work capacity, permanent damage to organ function, life-threatening or death, carcinogenesis, teratogenesis, birth defects, etc. during clinical trials.

7. Follow-up plan

Follow-up evaluation items and schedule table

Evaluate the project	On the day of enrolment	End of intervention	3 months after the intervention	6 months after the intervention	Follow-up method	Observe the key points
Joint mobility measurement (ROM)	✓	✓	✓	✓	Field testing	Knee joint mobility
Western Ontario and McMaster University Osteoarthritis Index (WOMAC).	✓	✓	✓	✓	Questionnaire survey	Arthritis-related pain, stiffness, and ability to perform daily activities
New York Hospital for	✓	✓	✓	✓	Face-to-face visit +	Knee functional

Special Surgery Score (HSS), USA					scale assessment	recovery level (pain, mobility, stability)
Timed Standing Walk (TUG).	✓	✓	✓	✓	Field testing	Lower extremity function and fall risk (completion time ≤12 seconds is normal)
Berg Balance Scale (BBS)	✓	✓	✓	✓	Face-to-face interview + action observation	Balance ability (56 points overall, < 40 points suggest a high risk of falling)
Blood tests (rheumatoid factor, blood routine, C-reactive protein laboratory tests).	✓			✓	Instrument testing	Disease activity and inflammation
Muscle strength (isokinetic dynamometer).	✓	✓	✓	✓	Instrument testing	Peak moment (absolute muscle strength), total work (muscle endurance) and affected side/healthy side ratio
Gait and plantar pressure measurement system	✓	✓	✓	✓	Gait laboratory testing	Symmetry of gait speed, stride length, plantar pressure distribution (abnormal gait and peak pressure area)

Psychological and quality of life assessment (PHQ-9, GAD-7, PSQI, HAQ, ASES-8).	✓	✓	✓	✓	Comprehensive questionnaire survey	Depression/anxiety level (PHQ-9≥10 points, GAD-7 ≥8 points requiring intervention), sleep quality (PSQI ≥7 points abnormal), and limitation of daily activities (HAQ ≥ 1.5 points indicate functional impairment).
Borg Subjective Fatigue Scale	✓	✓	✓	✓	Face-to-face visit + scale assessment	Post-exercise fatigue (6-20 points, ≥15 points suggest excessive fatigue)
Pain measurement (VAS score).	✓	✓	✓	✓	Face-to-face visit + scale assessment	Pain intensity at rest/activity (0-10 points)

Follow-up supplementary instructions

Standardized follow-up will be conducted every 2 weeks via telephone or online platform, focusing on monitoring Borg's subjective fatigue.

Time window requirements : Long-term follow-up (3 months, 6 months) allows ±7 days flexible window.

8. The basis for calculating the sample size

The purpose of this study was to verify whether there was a difference in improving joint mobility (ROM) between the AI-based exercise prescription system and paper exercise manual group in rheumatoid arthritis patients, and the control group was the usual care group. The study design was a three-arm randomised controlled trial (RCT) with the primary outcome measure being knee flexion ROM at 6 months postoperatively.

Refer to previous literature[13]The mean and standard deviation of the three groups were

113.17±6.91; 117.31±6.88; 119.49±6.86. Set α=0.05 Test efficacy (1-b）:Set β=0.05。 The sample size of each group was obtained by using Gpower software according to the sample size calculation method of three parallel groups41 cases, taking into account 20%shedding rate, and finally 147 participants needed to be included.

5. Research progress

Phase 1: Patient enrollment and baseline assessment (August-December 2025).

Phase 2: Intervention implementation and dynamic monitoring (January-March 2026).

Phase 3: End-of-intervention evaluation and follow-up review (April-June 2026).

Phase 4: Long-term follow-up (July-September 2026).

Phase 5: Data collation and analysis (October-December 2026).

6. Foundation of preliminary research

The research team members have rich clinical and scientific research experience in osteoarthritis and rheumatoid arthritis, which can ensure the smooth implementation of the project. Li Tao, the project leader, undertook and mainly participated in the research on related topics of knee osteoarthritis, including the Beijing Science and Technology Major Special Project "Research on the Rehabilitation Treatment of Knee Osteoarthritis Based on ICF" and "Research on the Clinical Efficacy of Extracorporeal Shock Wave in the Treatment of Knee Osteoarthritis", etc., and found"Compared with the current conventional conservative treatment regimen, the KOA rehabilitation treatment regimen based on the ICF-OA core classification combination can better improve the overall function and quality of life of patients with knee osteoarthritis. There is no significant difference between the rehabilitation treatment

based on the ICF condensed version and the rehabilitation treatment based on the full version, so relevant rehabilitation plans can be formulated according to the core classification combination of the ICF condensed version", "For KOA patients with KL grade 1-3, rehabilitation exercise combined with radiation shock wave therapy can achieve higher knee pain efficiency, better knee pain VAS improvement, and higher response rate of OMERACT-OARSI osteoarthritis treatment compared with the control group", The relevant content has been formed into a paper and published.

7. Research site and data management

(1) Research site: Rehabilitation Hall of Peking University People's Hospital (1st floor, Zhongyi Building)

(2) Data management: The investigator will load the data into the case report form in a timely, complete, correct and clear manner according to the subject's original observation records. The questionnaire after being reviewed and signed by the supervisor shall be sent to the clinical research data manager in a timely manner.

The corresponding database system is used for double and dual machine entry, and then the database is compared twice, and if any problems are found, the supervisor will be notified in time and the researcher will be required to answer. The exchange of various questions and answers between them should be in the form of a question sheet, and the question form should be kept for future reference.

When all case report forms are entered in duplicate and checked, the data administrator writes a database check report, which includes study completion (including the list of dropped subjects), inclusion/exclusion criteria check, completeness check, logical consistency check, outlier data check, time window check, combined medication check, adverse event check, etc.

At the review meeting, the principal investigator, representative of the sponsor, monitor, data administrator and statistician will make a resolution on the questions raised

in the subject's signed informed consent form and database inspection report, and write the audit report, and the database will be locked at the same time.

After completing the data entry and verification as required, the case report form shall be archived and stored in the order of numbering, and filled in with the search catalog for future reference. Electronic data files include databases, inspection programs, analysis programs, analysis results, code books and instruction files, etc., which should be stored in categories and stored on different disks or recording media with multiple backups to prevent damage. All original files shall be kept for the period specified in the corresponding regulations.

8. Statistical analysis methods

(1) Comparison of statistical descriptions with general demographic characteristics

Descriptive statistical analysis was performed on all randomized subjects, including general demographic characteristics such as age, gender, occupation, education, marital status, health insurance, length of illness, and treatment. Statistics such as mean, standard deviation, median, minimum, maximum, frequency and percentage are used. The comparison of the three groups of general conditions will be analyzed using appropriate methods according to the type of indicators, the analysis of variance or the Kruskal-Wallis H test will be used for comparison between groups of quantitative data, the chi-square test or the exact probability method (if the chi-square test is not applicable) will be used for categorical data, and the Bonferroni method will be used for comparison between groups. Demographic analysis is based on the full analysis set (FAS).

(2) Analysis of primary outcome measures

The main outcome measures, Intention-to-Treat (ITT) and Per-Protocol Set (PP), were performed on ROM at six months postoperatively to assess the rehabilitation effect of all randomised participants throughout the trial. According to the distribution of data, analysis of variance or Kruskal-Wallis H test was used to compare the changes in ROM at 6 months after surgery between the three groups.

(3) Analysis of secondary outcome measures

PP analysis was performed on secondary outcome measures (e.g., muscle strength, gait and plantar pressure parameters, pain measurements, psychological and quality of life assessments, etc.). Depending on the distribution of the data, ANOVA or the Kruskal-Wallis H test was used.

(4) Analysis of safety indicators

The patient's self-reported safety indicators (such as VAS score changes, exercise tolerance feedback), adverse events (AEs) and serious adverse events (SAEs) were statistically described and analyzed. The incidence of adverse events will be calculated and their association with the study intervention will be assessed.

(5) Statistical methods of repeated measurement data

Given that this study involves measures of outcome measures at multiple time points, repeated measures data will be processed using methods such as ANOVA for repeated measures data or generalized estimation equations.

(6) Statistical analysis software

Data were processed using SPSS 16.0 or later software, and all statistical tests were two-tailed tests, with a P-value of less than 0.05 being considered statistically significant (unless otherwise specified).

9. Safety evaluation

An adverse event is an untoward medical occurrence that occurs after a patient or clinical trial subject receives a treatment, but is not necessarily causally related to the treatment, and may be a new disease, worsening of symptoms or signs at the time of treatment, worsening of concomitant disease, effect of a comparator drug, or unrelated to participation in the trial. The evaluation of adverse reactions is based on five levels of evaluation, including positive related, likely related, possibly related, possibly irrelevant, and affirmatively irrelevant, and the first three are counted as the incidence of adverse reactions. Serious adverse events are events that require hospitalization, prolonged hospitalization, disability, affect work capacity, permanent damage to organ function, life-threatening or death, carcinogenesis, teratogenesis, birth defects, etc. during clinical trials.

In the event of any serious adverse event or significant adverse event, whether related to the study intervention or not, the sponsor must be notified by phone/fax within 24 hours of occurrence/notification.

10. Subject protection

1. Acquisition of informed consent:

The study began after the protocol of this study and the informed consent of the subjects were approved by the Medical Ethics Committee of Peking University People's Hospital. Before the start of the study, the investigator needs to explain the background, nature, significance, steps, benefits, risks, compensation, injury compensation, withdrawal, etc. to the subjects in writing and verbally, and obtain the informed consent signed by each subject or his legal representative. The informed consent form is dated and the informed consent form and its copy are kept by the investigator and the subject separately.

- Responsible signatories:

  The main researchers involved in the project

- Signing location:

  Department of Rehabilitation Medicine, Peking University People's Hospital (5th floor, outpatient building)

- Signing Process:

  Explain to the subjects the purpose, content, duration, risks and benefits, confidentiality protocol, research costs, withdrawal from the study, etc

  ↓

  Subjects choose whether to participate in the trial

  ↓

  If they choose to participate, they sign the informed consent form

  ↓

  Conduct a trial (or not conduct a trial if not signed or signed as disagree).

2. Examination and treatment, risk prediction and preventive measures for patients to be carried out 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.

3. Benefit::

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.

4. Information confidentiality measures:

If the subject decides to participate in this study, the test data and personal data recorded in the scales and samples throughout the study will only be used for scientific research and will not be used for any journalistic and commercial purposes, and the personal data of the subjects involved will be strictly confidential. Paper materials are scanned and stored in a lock-resistant cabinet. When the results of the study are published, we will display some of the data related to the subjects, but we will never disclose personal information such as names and contact information. After the publication of the research content, all research materials will be properly stored in Peking University People's Hospital for 5 years for the journal editorial department to review the original data, after which the data that can identify the subject's personal information will be destroyed. The state regulatory authorities, the scientific research management department of Peking University, and the ethics committee will consult the medical records of the subjects in order to verify the implementation of the study.

11. Research management

1、 Scheme modification:

This may be due to the fact that the inspectors found persistent non-compliance with the selection criteria, or it may be due to the fact that the selection criteria are too strict and the recruitment is too low.

2、**Quality control:**

During the trial study, clinical monitors are assigned to conduct regular on-site supervision visits to the research unit to ensure that all contents of the research protocol are strictly followed and that the information filled in is correct. During the patient recruitment phase, the inclusion/exclusion criteria should be as consistent as

possible.

The specific supervision content is:

- The researchers participating in this validation carefully implement the standard operating procedures for clinical validation before, during, and after the validation.
- During the verification process, the correctness and completeness of the data in the questionnaire are monitored by the supervisors of the clinical trial research unit and the implementer.
- Participating researchers must undergo unified training, unified recording methods and judgment standards.
- All observations and findings in clinical validation should be verified to ensure the reliability of the data, ensure that the conclusions in clinical validation come from the original data, and there are corresponding data management measures in clinical validation and data processing.

3、Study discontinuation early:

- Serious safety issues were found in the trial
- During the trial, it was found that there were major errors in the clinical trial protocol, making it difficult to evaluate the treatment effect. or found serious deviations in implementation
- The applicant requests termination or the administration requests termination of the experiment

12. References

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DOI:10.27366/d.cnki.gtyku.2020.001341.

13. Annex

关节炎自我效能感量表-8（ASES-8）

请在每行标出或圈出一个数字来表明目前你对完成如下任务的把握程度

1. 你有多大把握能够很大程度地减轻疼痛？

完全没把握 完全有把握

1 2 3 4 5 6 7 8 9 10

2. 你有多大把握能够避免关节或肌肉疼痛影响你的睡眠？

完全没把握 完全有把握

1 2 3 4 5 6 7 8 9 10

3. 你有多大把握能够避免关节或肌肉疼痛妨碍你想做的事？

完全没把握 完全有把握

1 2 3 4 5 6 7 8 9 10

4. 你有多大把握能够可以适当调节活动量，既能保持运动又不会加重疼痛？

完全没把握 完全有把握

1 2 3 4 5 6 7 8 9 10

5. 你有多大把握能够避免疲劳（由关节炎引起）妨碍你想做的事？

完全没把握 完全有把握

1 2 3 4 5 6 7 8 9 10

6. 当你情绪低落时，你有多大把握能够做些事使自己感觉好点儿？

完全没把握 完全有把握

1 2 3 4 5 6 7 8 9 10

7. 与其他病友相比，你有多大把握能够在日常生活中管理疼痛？

完全没把握 完全有把握

1 2 3 4 5 6 7 8 9 10

8. 你有多大把握能够应对关节炎引起的沮丧？

完全没把握 完全有把握

1 2 3 4 5 6 7 8 9 10

表 1 Borg 主观疲劳程度量表

评分（分）	主观疲劳程度
6	安静，不费力
7	极其轻松
8	
9	很轻松
10	轻松
11	
12	有点困难
13	
14	
15	困难
16	非常困难
17	
18	
19	极其困难
20	精疲力竭

PHQ-9量表内容简单、可操作性强。可作为筛查也可以评估抑郁严重程度；

根据过去两周的状况，请您回答是否存在下列描述的状况及频率，请看清楚问题后在符合您的选项前的数字上面画√

	完全不会	好几天	超过一周	几乎每天
1：做事时提不起劲或没有兴趣	0	1	2	3
2：感到心情低落、沮丧或绝望	0	1	2	3
3：入睡困难、睡不安稳或睡眠过多	0	1	2	3
4：感觉疲倦或没有活力	0	1	2	3
5：食欲不振或吃太多	0	1	2	3
6：觉得自己很糟——或觉得自己很失败，或让自己和家人失望	0	1	2	3
7：对事物专注有困难，例如阅读报纸或看电视时	0	1	2	3
8：动作或说话速度缓慢到别人已经察觉？或正好相反——烦躁或坐立不安、动来动去的情况更胜于平常	0	1	2	3
9：有不如死掉或用某种方式伤害自己的念头	0	1	2	3

每个条目0～3分，总分就是将9个条目的分值相加，总分值范围0～27分　　总分=_____+_____+_____+_____

Kroenke K, et al. J Gen Intern Med. 2001, 16(9):606-1

广泛性焦虑障碍量表(GAD-7)

(Generalized Anxiety Disorder,GAD-7)

姓名：_____ 性别:_____ 年龄:_____ 日期：_____ 测定次数:_____

根据过去两周的状况，请您回答是否存在下列描述的状况及频率，请看清楚问题后在符合您的选项前的数字上面画 √

	完全不会	好几天	超过一周	几乎每天
1：感觉紧张，焦虑或急切	0	1	2	3
2：不能够停止或控制担忧	0	1	2	3
3：对各种各样的事情担忧过多	0	1	2	3
4：很难放松下来	0	1	2	3
5：由于不安而无法静坐	0	1	2	3
6：变得容易烦恼或急躁	0	1	2	3
7：感到似乎将有可怕的事情发生而害怕	0	1	2	3

总分=_____+_____+_____+_____

评分规则：每个条目 0～3 分，总分就是将 7 个条目的分值相加，总分值范围 0～21 分

0-4 分	没有 GAD	5-9 分	轻度 GAD
10-14 分	中度 GAD	15-21 分	重度 GAD