Trials

STUDY PROTOCOL

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Validation of a long-term and effective physical exercise management for ankylosing spondylitis: study protocol for a decentralized randomized controlled trial

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Abstract

Background Ankylosing spondylitis (AS), a chronic inflammatory disease, leads to significant physical and psychosocial burdens due to progressive spinal rigidity and high disability rates. Although exercise is well-established as a key factor in delaying deformity and enhancing function, maintaining long-term adherence poses a significant hurdle. This study aims to validate the effectiveness of an *Exercise Management Mode based on the Attitude-Social Influence-Self-Efficacy (ASE) model (EMM-ASE)* in enhancing exercise behavior and clinical outcomes among AS patients.

Methods This decentralized randomized controlled trial (D-RCT) will enroll 120 AS patients from the Guangdong Rheumatology and Immunology Specialty Alliance. Participants will be randomized 1:1 into an intervention group (EMM-ASE) or a control group (routine management). The intervention group receives personalized, stage-based exercise strategies via the AS Exercise Mobile Intelligent Management Platform, including real-time feedback, social support, and biweekly network-broadcasted exercise sessions. The control group receives standard exercise guidance and access to patient support groups. Primary outcomes are exercise level (measured by the International Physical Activity Questionnaire, IPAQ). Secondary outcomes include functional capacity (Bath Ankylosing Spondylitis Functional Index, BASFI), disease activity (Bath Ankylosing Spondylitis Disease Activity Index, BASDAI), fatigue severity (Fatigue Severity Scale, FSS), quality of life (Ankylosing Spondylitis Quality of Life, ASQoL), and exercise adherence. Data will be collected at baseline, 1, 3, and 6 months. Statistical analyses include intention-to-treat analysis using mixed linear models, trajectory analysis via latent class models, and sensitivity analyses.

Discussion The intervention group in this D—RCT, which innovatively applies a mobile platform to AS exercise management, is expected to show more significant improvements in primary and secondary outcomes than the control group. Specifically, at follow—up points, it is anticipated that they will have higher IPAQ scores, lower BASFI scores, and better performance in other indicators. This design would prove the superiority of the EMM—ASE strategy, offering a new effective model for AS treatment.

Trial registration The study protocol was registered with Chinese Clinical Trial Registry on 12 May 2025, https://www.chictr.org.cn/showproj.html?proj=272057 (registration number: ChiCTR2500102260).

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Keywords Ankylosing spondylitis, Exercise adherence, Decentralized trial, Behavioral intervention, ASE model

Administrative information

Title {1}	**Validation of a Long-term and Effective Physical Exercise Management for Ankylosing Spondylitis: Study Protocol for a Decentralized Randomized Controlled Trial**
Trial registration {2a and 2b}	Chinese Clinical Trial Registry (registration number: ChiCTR2500102260) Date of registration:12 May 2025
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Role of sponsor {5c}	The study sponsor and funder have no roles in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication. They do not have ultimate authority over any of these activities

Introduction

Background and rationale {6a}

Ankylosing spondylitis (AS) is a systemic disease primarily characterized by chronic inflammation of the sacroiliac joints, spine, and peripheral joints, as well as other organs. AS is characterized by adolescent onset, incurability, and a high disability rate [1, 2]. The recurrent and persistent joint pain causes significant physical and mental suffering, imposing a significant burden on patients [3–5]. In the advanced stage, the affected area can cause severe ossification, leading to irreversible spinal deformity. This condition results in impaired limb function and a disability rate of up to 30% [6, 7]. Exercise plays a more important role than simple drug therapy in preventing spinal or joint deformities and reducing disability rates in patients with AS. Currently, the main exercises for AS include NASS exercises, whole-body posture reshaping, various forms of exercise such as aerobic exercise, stretching exercise, and pulmonary exercise, as well as multimodal exercise incorporating Pilates, the Mckenzie method, and the McKenzie method [8, 9]. Participating in suitable exercises can effectively enhance lung capacity, improve muscle tension in the spinal region, maintain spinal mobility and flexibility, realign joints, enhance joint flexibility, stretch weakened muscles, and enhance skeletal muscle strength [10–12]. Numerous studies have provided evidence of the benefits of exercises in improving spinal function and muscle vitality, enhancing physical function index, and reducing limb disability in individuals with AS [10–12]. The Assessment in Ankylosing Spondylitis international Society/European League Against Rheumatism (ASAS/EULAR) has strongly recommended the implementation of these findings in clinical practice guidelines.

For patients with AS, it is crucial to Maintain exercises throughout the duration of the disease in to Maximize its benefits. However due to the chronic and persistent nature of AS, patients often struggle to adhere to exercises in the long term, which the biggest challenge. According to Rodrig et al., although patients initially agreed to the exercise program proposed by healthcare, 50% of them after 6 months due to difficulties in adhering [13]. In a 6-follow-up study conducted by Fang et al. on AS patients at home, it was found that the adherence to the exercise program gradually decreased from 90% at 1 week after discharge to 60% at 6 months after discharge, while medication adherence nearly 100% [14]. It is evident that the Main obstacle to sustaining exercises lies in the low adherence over the medium to long term, and the inability to Maintain exercises will significantly impact clinical outcomes and increase disability rates for patients. Considering that most AS patients are in their prime working years, high disability rates directly contribute to a loss of the social labor force. Research has indicated that the overall economic burden of AS patients in the UK amounts to 19,016 euros per year, with over 80% of this attributed to unemployment, work absenteeism, and early retirement caused by disability [15]. Therefore, achieving sustainable management of exercise to maintain a high level of exercise behavior for AS patients has become a shared concern.

The factors that affect the exercise behavior of patients with AS are quite complex, including

physiological, psychological and social factors. Existing studies have shown that the disease activity, BASFI, pain and fatigue are related to the exercise behavior of AS patients. The higher the disease activity and BASFI score, the more severe the pain and fatigue, the lower the exercise level of patients [16, 17]. In addition, the level of anxiety/depression and perceived exercise disorder can also affect the exercise behavior of patients. The higher the level of anxiety and depression and the more serious the perceived disease disorder, the easier it is to reduce or even give up exercise [18, 19]. Economic status and social support are also important influencing factors, and both higher economic income and high social support can promote patients to actively exercise [20, 21]. These factors should be fully considered when making exercise plan and managing exercise behavior. Currently, recommended exercises for AS patients include NASS, posture remodeling, jogging, swimming, tai chi, Pilates,

Herkscher method and Mackenzie method [8, 9]. At the same time, most researchers implement these exercise plans through self-management, continuous care, peer training, virtual game interactive training, etc. [10, 22–24]. Although these studies have achieved some good results, the Management of exercise plan implementation is still insufficient. A systematic review of rehabilitation exercise for osteoporosis patients found that only 26% of the 54 RCT studies included proposed specific methods for the implementation of exercise plans [13], and the exercise process was still dominated by the education and reminder of medical personnel, lacking the two-way feedback of medical personnel on the exercise process and patients on the effect of professional guidance, which leads to a poor compliance of exercise plan [24].

The exercise behavior of AS patients is influenced by a multitude of factors, encompassing physiology, psychology, and societal influences. These factors comprise both internal individual elements and external environmental factors, the intricate functions of which are not yet fully understood. The Attitude-Social Influence-Self-Efficacy (ASE) model is a theoretical framework used to examine health behavior. It posits that all potential influencing factors indirectly impact behavior through behavioral intention. Behavioral intention, in turn, is shaped by attitude, social influence, and self-efficacy. The interplay of these three factors can drive changes in behavioral intention and ultimately lead to changes in behavior. Additionally, these proximal factors can be influenced by external factors, including triggering elements such as demographic characteristics and social and cultural factors, as well as intervening factors like artificial interventions [25–27] (Fig. 1).

This study focuses on AS patients in remission and assumes that changes in exercise behavior progress through the stages of "unintentional period—intentional period—preparation period-action period-maintenance period" based on the stage of behavioral intention, thus forming the trajectory of exercise behavior during this period. Therefore, by leveraging the ASE theory and considering the exercise behavior trajectories in different stages, a sustainable exercise management model for AS patients can be developed. This management model comprises four fundamental elements: exercise plan, intention stage, exercise behavior intervention strategy, and exercise behavior. The exercise plan serves as the foundation of this management model, and compared with the actual exercise behavior of the patient, the intentional stage can be evaluated. Management strategies for exercise behavior are designed according to different intention stages. Through the implementation of these intervention strategies, the patient's exercise behavior can be

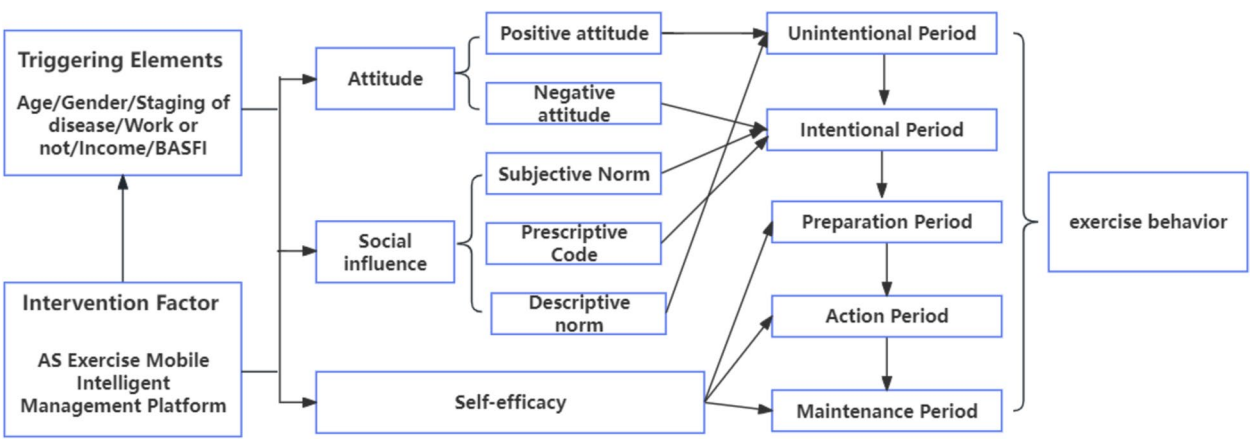

Fig. 1 Attitude-Social Influence-Self-Efficacy (ASE) model

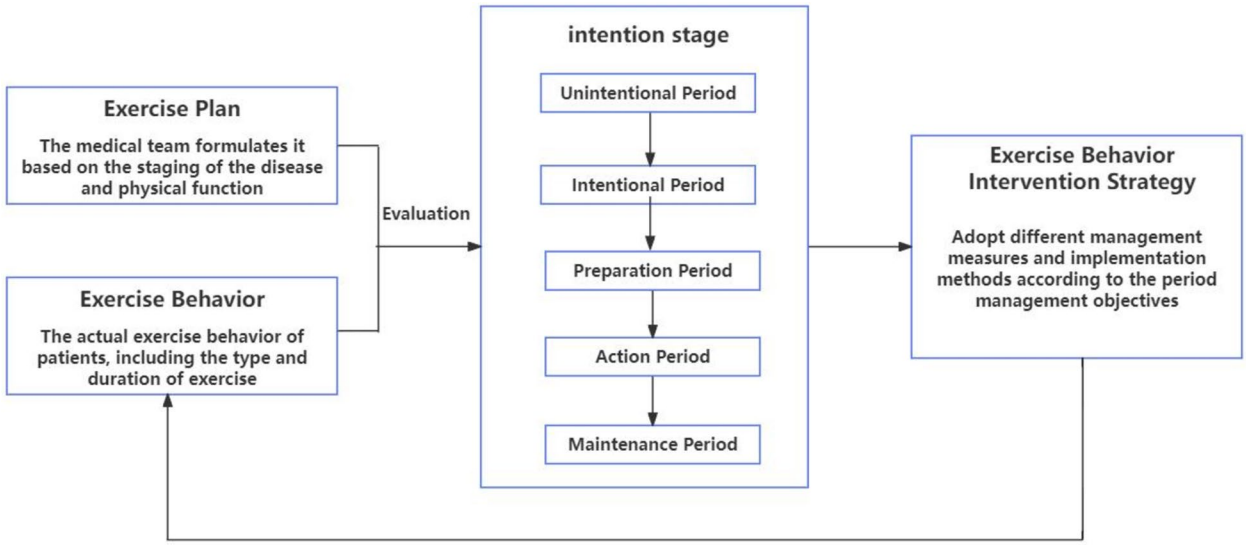

Fig. 2 Management mode frame diagram

elevated, subsequently facilitating changes in behavioral intention (Fig. 2).

Objectives {7}

In this study, we have developed a management model for exercise during different periods of AS patients, managing exercise behavior through the "AS Exercise Mobile Intelligent Management Platform" established in our previous study and network broadcast exercise, and suggests a decentralized intervention study to validate its effectiveness. The sustainable management approach for exercise, derived from this research, holds practical significance in guiding the management of exercise in AS patients and has the potential for widespread adoption and application.

Trial design {8}

The design of this clinical trial follows the recommendations of the SPIRIT guidelines. In this study, we intend to employ a Decentralized Randomized Controlled trial (D-RCT) design. Participants who complete the baseline survey will be randomly assigned to an experimental group and a control group in a 1:1 ratio. D-RCTs do not rely on a single center or location, and allow participants to participate in studies in their daily environment without frequent visits to Trial centers by utilizing digital technologies and telemedicine tools. This experiment adopts a superiority trial design to evaluate the effects of a personalized exercise management strategy based on a "Exercise Management Mode based on ASE model (EMM-ASE)" compared with routine management methods on the exercise level and functional capacity of patients with AS [28].

Methods: participants, interventions, and outcomes

Study setting {9}

The research subjects for this study are AS patients from hospitals affiliated with the Guangdong Rheumatology and Immunology Specialty Alliance, including the Third Affiliated Hospital of Sun Yat-sen University, the First People's Hospital of Foshan, and the Seventh Affiliated Hospital of Sun Yat-sen University. These hospitals adopted a unified and standardized diagnosis and treatment plan for AS.

Eligibility criteria {10}

Inclusion criteria

(1) Patients diagnosed with AS who meet the 2009 ASAS classification criteria for ankylosing spondylitis and are admitted to the hospital for the first time;

(2) Patients over 18 years old who have been hospitalized and have had their condition alleviated, with a BASDAI score of less than 4 and meeting the discharge criteria;

(3) Patients who understand the purpose, procedures, and contents of the study, voluntarily participate in the trial, and sign an informed consent form;

(4) Patients who can communicate verbally with the researchers in Mandarin or Cantonese.

Exclusion criteria

(1) Patients with fibromyalgia syndrome, or osteitis condensans ilii, or local pain caused by lumbar or cervical compression, or moderate to severe pain associated with nerve root pain or other pain that may be confused with AS-related pain;

(2) Patients with a severe osteoporosis or a pathological fracture.

(3) Patients with severe systemic diseases that have significant impairments in important organ functions;

(4) Patients who have no experience using WeChat software on a computer or smartphone.

Who will take informed consent? {26a}

The main researchers will explain to the patients the possible benefits and drawbacks of taking part in the study, the specific details of the clinical examinations during the follow—up period, and the patients' right to quit the study at any time. After that, the researcher will obtain the patients' informed consent. Patients will be given at least one week to think about whether they want to participate in the study and to ask any questions they may have.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

This experiment does not involve the collection of biological samples for storage.

Interventions

Explanation for the choice of comparators {6b}

The intervention group is managed by "Exercise Management Mode based on ASE model (EMM-ASE)". First of all, according to the exercise plan proposed by specialty doctors, participants in the intervention group will be asked to answer a question of "During the past 6 months, have you followed the exercise plan recommended by your doctor?" to evaluate their exercise behavioral intention. If the answer is "I cannot do it and I have no intention to do it in the future", it means "precontemplation stage". "It cannot be done and I intend to implement it within the next six months" means "contemplation stage", "It cannot be done, but I intend to implement it within the next 1 month" means "preparation stage", "It can be done, but it has lasted less than 6 months" indicates "action stage", and "I have persisted for more than 6 months" indicates "maintenance stage". Then, different behavior management strategies will be implemented according to the intention stage, as shown in Table 1.

Intervention description {11a}

(1) Log-in system: Specialty nurses will issue the "AS Exercise Mobile Intelligent Management Platform User Manual" to guide patients in using the platform and assist them in logging into the network broadcast exercise system.

(2) Exercise behavior and related factor assessment: Patients enter the "Exercise Behavior Assessment Module" and input corresponding information for each assessment item displayed in the system. The system will automatically assess and form the assessment results,

Table 1 Intervention implementation plan of Exercise Management Mode based on ASE model

Stage	Aim	Intervention contents	Intervention frequency	Intervenor
Precontemplation stage	Establishing behavioral intentions	• Education and exercise guidance	• Once per week, pushing through the platform until the next stage is reached	Specialists/nurses
Contemplation/preparation stage	Consolidating behavioral intentions	• Addressing difficulties • Developing an implementation plan • Exercise guidance • Social support • Network broadcast exercise	• Information pushing and healthcare feedback once a week • Telephone/network guidance, clinic/home visits if necessary • Experience sharing every two weeks • Everyday, participating according to exercise plans	Specialists/nurses, patient family members, and patient volunteers
Action/maintenance stage	Strengthening behavioral intentions	• Providing feedback and rewards for exercise behavior • Network broadcast exercise	• Healthcare feedback once a week • Experience sharing every two weeks • everyday, participating according to exercise plans	Specialists/nurses, and patient volunteers

which will be stored in the system's background as one of the bases for the management procedure.

(3) Exercise behavior management: As listed in Table 1. Among them, the network broadcast exercises are provided on the public network broadcast platform, and the full-time rehabilitation specialist nurses deliver the class online. Patients can choose the appropriate time according to their own exercise plan to participate in exercise activity simultaneously.

(4) Intervention feedback: Specialty nurses will review the patient's exercise behavior feedbackingly reported by the system every week and further handle patients with poor exercise compliance. Firstly, they will communicate with patients through network or phone to understand issues and difficulties during exercise, and provide online guidance through specialty doctors or nurses. When online guidance is not sufficient, refer patients for clinical visits, and specialty nurses will be responsible for referring them to the relevant personnel. For patients who have difficulty moving or are unable to travel, refer them to community medical staff for home visits.

(5) Stage evaluation: Conduct a monthly re-evaluation of the stage of behavioral intention and adjust the intervention content accordingly.

Criteria for discontinuing or modifying allocated interventions {11b}

(1) Patients are lost to follow-up for any reason during the study;

(2) Patients experience severe complications or adverse events necessitating their withdrawal from the study.

Strategies to improve adherence to interventions {11c}

First, we plan to establish a core research group. The Guangdong Rheumatology and Immunology Specialized Alliance will lead the establishment of the core research group, which will mainly consist of specialty doctors, nurses and research assistants.

The core research group will develop a unified research plan, including the selection of research subjects, grouping, intervention methods, data collection methods and provide training to all members of the research groups. Also, the "AS Exercise Mobile Intelligent Management Platform User Manual," which will be divided into medical care and patient versions will be wrote by core research group, and provide training to all members of the research groups.

Relevant concomitant care permitted or prohibited during the trial {11d}

During the entire trial, both the original treatment regimen and the adjusted treatment regimen (including drug therapy and physical therapy) are permitted, and details of these treatments will be recorded. However, exercises or labor that may increase patient fatigue, cause exhaustion, or result in injuries (such as excessive fatigue, obvious shortness of breath, difficulty breathing, joint sprains, muscle strains, and aggravated pain) are not recommended.

Provisions for post-trial care {30}

The exercise methods in the protocol are all measures recommended by the guidelines. Patients may experience normal post—exercise reactions, such as moderate fatigue and mild muscle soreness. We will assist patients in dealing with these reactions through post—exercise guidance.

Outcomes {12}

Primary outcome

Exercise level Recorded using a brand of sports bracelet, referring to the International Physical Activity Questionnaire (IPAQ), which was developed by the International Physical Activity Measurement Group in 2001. Different types of exercise were assigned a value from 1 to 8 according to their metabolic equivalent. The level of exercise is calculated according to the formula "exercise level = metabolic equivalent × duration of each time × frequency" over the past seven days. The results are categorized into: (i) vigorous activity; (ii) moderate activity; and (iii) low activity. The Chinese version was introduced by Qu Ning et al. in 2004, with test–retest reliability ranging from 0.689 to 0.934 and criterion validity, using accelerometers, of 0.50.

Secondary outcome

Bath Ankylosing Spondylitis Functional Index (BASFI) As a widely used international index, BASFI evaluates the overall physical function in AS through ten questions. The total score is the sum of individual question scores, ranging from 0 to 10, with higher scores indicating poorer function.

Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Another index assesses disease activity in AS and comprises six questions evaluating the patient's symptoms over the past week. The total score is the average of the individual scores, ranging from 0 to 10, with higher scores indicating greater disease activity.

Fatigue Severity Scale (FSS) This scale assesses the impact of fatigue on patients with AS. It includes nine items, and the FSS score is calculated as the total score

divided by nine. Scores greater than 4 indicate severe fatigue, while scores of 4 or below suggest no fatigue or mild fatigue.

Quality of Life Assessed using the Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire, which consists of 18 questions. Each question is answered with a "yes" (scored 1) or "no" (scored 0). The total score is the sum of all item scores, with higher scores indicating poorer quality of life.

Exercise Adherence This measure includes exercise completion rate and exercise compliance. Patients record their exercise behavior in a exercise diary. Exercise completion rate is calculated as the number of activities completed according to standard divided by the number of required activities. Exercise compliance is self-evaluated by patients against the standard for each activity, classified into: fully achieved (100% standard completion), mostly achieved (over 50% standard completion), occasionally achieved (below 50% standard completion), and not achieved (unable to meet the standard).

Participant timeline {13}

The study period spans from June 2025 to October 2026. The detailed timeline is presented in Table 2.

Sample size {14}

To estimate the sample size using the BASFI as the indicator, the formula for sample size calculation based on the comparison of two sample means was applied.

$$n = 2\left[\frac{(u_a + u_\beta)\sigma}{\delta}\right]^2$$

With a significance level (α) of 0.05, power (β) of 0.1, and a two-sided test for differences, the standard deviation (σ) was set at 7.5 and the effect size (δ) at 5.375 based on similar experimental results [29]. Considering previous research experience, a preliminary dropout rate of 20% was estimated. Therefore, it was determined that each group would require 60 participants, resulting in a total recruitment of 120 individuals.

Recruitment {15}

The research subjects for this study are AS patients from hospitals of Guangdong Rheumatology and Immunology Specialty Alliance, which adopted a unified and standardized diagnosis and treatment planning for AS.

Assignment of interventions: allocation

Sequence generation {16a}

We will utilize simple randomization to allocate intervention recipients into either the intervention or control groups. Random numbers for group assignment will be generated using IBM SPSS Statistics version 26.0 by a researcher who was not involved in the intervention.

Concealment mechanism {16b}

The randomization information is placed in sequentially numbered, opaque, sealed envelopes, with cards inside indicating the assigned group. This ensures that the group assignment remains concealed until the envelopes are opened.

Implementation {16c}

The randomization process will be conducted by a research assistant, who will open the sequentially numbered, opaque, sealed envelopes to determine the group assignment for each participant.

Assignment of interventions: blinding

Who will be blinded {17a}

This study adopts a non-blind method.

Table 2 Schedule of data collection

Outcomes	T0(baseline)	T1(1-month)	T2(3-month)	T3(6-month)
General information	√			
Primary outcome				
Exercise level	√	√	√	√
Secondary outcome				
BASFI	√	√	√	√
BASDAI	√	√	√	√
FSS	√	√	√	√
ASQoL	√	√	√	√
Exercise adherence		√	√	√

Procedure for unblinding if needed {17b}

This study is non-blind and there is no need for unblinding.

Data collection and management

Plans for assessment and collection of outcomes {18a}

All research subjects will establish research files and undergo baseline measurements upon entry into the study (T0), including general information, exercise level, BASFI, BASDAI, FSS and ASQoL. Exercise level, BASFI, BASDAI, FSS, ASQoL and exercise adherence will be measured at 1 month (T1), 3 months (T2), and 6 months (T3) during the intervention. Exercise level is caculated from data sended to the Mobile Intelligent Management Platform by sports braclets. BASFI, BASDAI, FSS and ASQoL questionaires are pushed to patients by the platform at the times of T1, T2, T3, and are self-reported by patients. Data of exercise adherence are also derived from the platform.

Plans to promote participant retention and complete follow-up {18b}

To minimize bias, this study will strictly select research subjects based on its inclusion and exclusion criteria. The research team will thoroughly explain the significance and research plan of the study to gain the cooperation of the subjects and minimize loss to follow-up bias. A project research team will be established, staff will receive uniform training, and a guidance manual will be drafted. Before the formal implementation of the study, a pilot experiment will be conducted to adjust the intervention plan based on the results. Intervention and management will strictly follow the requirements of the guidance manual to ensure consistency in the implementation of the intervention plan. During the study, researchers regularly sent messages to each participant according to their intervention plan to remind them to exercise on time.

Data management {19}

The research data will be specially collected and stored by two people. The exercise intervention data (intervention time, live-broadcast duration, number of online participants, intervention content, etc.) will be recorded in real-time by one implementer and verified by another researcher. The patient compliance data and the evaluation data of observation indicators will be transmitted to the intelligent management platform through sports bracelets or patient self-reports. One researcher will regularly check, store and back up these data. All data will be saved in an encrypted form on a password-protected computer.

Confidentiality {27}

To safeguard participants' privacy, personal information will not be recorded on data sheets or electronic data files. Each participant will receive a unique study code. The document linking the code to the patient's identity will be stored separately from study data.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

In this trial, there are no plans to collect biological specimens.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Primary analysis of intervention effects

The primary analysis of this study will use an intention-to-treat (ITT) approach, utilizing Python and R for statistical computations. Taking into account the decentralized study, based on the intention-to-treat population, a mixed linear model will be used to analyze the primary outcome using a generalized linear model with unstructured covariance and robust standard error. The difference in exercise levels and BASFI between the two groups at the end of the intervention will be analyzed, and the corresponding effect size and its 95% confidence interval will be reported.

Secondary analysis of intervention effects

Similar generalized linear model analysis will be conducted according to predefined secondary outcome indicators, BASDAI, FSS, ASQoL, and exercise adherence, to investigate the treatment effect in different dimensions.

Interim analyses {21b}

An interim analysis will be conducted at the third month of the study. A statistician who is unaware of the study protocol will analyze the observation indicators of the two groups. The data collectors and Managers will export the patient compliance data, and another researcher will supervise and inspect the process. If the patient compliance is less than 80% or the intervention effect of the intervention group is lower than that of the control group in the interim analysis, the trial steering committee will terminate the study.

Methods for additional analyses (e.g., subgroup analyses) {20b}

Descriptive analysis

Descriptive statistics will include frequencies and percentages to describe categorical data such as general demographic information and exercise compliance for both the intervention and control groups. Differences between the two groups will be compared using the chi-square test. Means and standard deviations will be used to describe continuous variables such as pre-intervention exercise levels, BASFI, BASDAI, FSS, ASQoLand exercise completion rates. Differences between the groups will be compared using independent samples t-tests.

Trajectory analysis

Repeated measures ANOVA will be employed to compare the scores of measurement indicators for AS patients at time points T0 to T3. A latent class trajectory model will be used to fit the exercise levels from T0 to T3. Model fit will be assessed using the chi-square/df ratio, Comparative Fit Index (CFI), Root Mean Square Error of Approximation (RMSEA), Standardized Root Mean Square Residual (SRMR), and Bayesian Information Criterion (BIC). A chi-square/df ratio < 5, CFI > 0.90, RMSEA and SRMR < 0.08, and lower BIC values indicate better model fit.

Sensitivity analysis

This study employed the Per-Protocol (PP) method, As-Treated analysis, and Complete Case analysis for sensitivity analysis. A sensitivity analysis was conducted to compare the changes in adjusted estimates of primary and secondary outcomes.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

We will use MiceForest to impute missing data.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

Within 3 years after data collection ends, the principal investigator will provide the protocol and de—identified dataset upon reasonable request.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

This study is supervised and managed by the Clinical Trial Management Office. This management office is located in the Third Affiliated Hospital of Sun Yat—sen University and is led by the office director. It includes two independent researchers and a statistician, none of whom are from the same department as any members of the research team. The Clinical Trial Management Office is responsible for ensuring the implementation of the protocol as planned and regularly reviewing the research progress.

Composition of the data monitoring committee, its role and reporting structure {21a}

The research data is managed and reviewed by an independent management team of the Research Data Deposit (RDD) platform. This management team consists of six members, including two statisticians, none of whom belong to the same department as any members of the research team. After the study is completed, the research team will upload the research data to the RDD platform. The RDD management team is responsible for reviewing the research data and reporting to the researchers when any action needs to be taken.

Adverse event reporting and harms {22}

In this study, adverse events are defined as sports injuries that occur during exercise, including muscle strains, joint injuries, fractures, falls, etc. At each follow—up point, the researchers will investigate the occurrence of adverse events, or patients can report adverse events to the researchers as soon as they occur. Adverse events are reported and Managed through standardized case report forms. Serious adverse events will be reported to the Medical Ethics Committee Office within 24 h. The principal investigator will be responsible for tracking the handling of serious adverse events until they are resolved or a conclusion is reached. The researchers and the trial steering committee will determine whether the adverse events or serious adverse events are related to the research intervention.

Frequency and plans for auditing trial conduct {23}

A clinical research management team independent of the researchers will monitor the completeness and accuracy of the data reported in the clinical research forms, ensuring the recording and reporting of all adverse events and serious adverse events. Ethical follow—up reviews will be conducted annually.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Any modifications to the protocol shall be submitted by the project leader to the Hospital Clinical Trial Management Office and the Hospital Ethics Committee for review. The modifications can only be implemented after obtaining approval.

Dissemination plans {31a}
Trial results will be presented at international scientific conferences and published in peer—reviewed journals.

Discussion

The intervention group in this D—RCT, which innovatively applies a mobile platform to AS exercise management, is expected to show more significant improvements in primary and secondary outcomes than the control group. Specifically, at follow—up points, it is anticipated that they will have higher IPAQ scores, lower BASFI scores, and better performance in other indicators. This design would prove the superiority of the EMM—ASE strategy, offering a new effective model for AS treatment.

One of the strengths of our study is that we use a D-RCT design, enabling remote participation through digital tools (e.g., AS Exercise Mobile Intelligent Management Platform), which enhances accessibility and real-world applicability for geographically dispersed patients. Second, we integrate the ASE model to deliver stage-specific, personalized exercise interventions, addressing both psychological and behavioral barriers to adherence. Third, this design employes objective measures (e.g., wearable sports bracelets) and validated scales (BASFI, BASDAI, IPAQ) for multidimensional outcome assessment, reducing recall bias. There are several limitations to this study. First, this design relies on smartphone/WeChat proficiency for platform engagement, potentially excluding older or technologically inexperienced patients and introducing selection bias. Besides, limited to a 6-month follow-up period, we may not capture long-term sustainability of exercise adherence or disease progression in chronic AS patients.

Trial status

The planned start date for study recruitment is June 2025, and recruitment has not commenced yet. The recruitment completion date is October 2026. Protocol version V1 (December 2025).

Abbreviations

AS	Ankylosing spondylitis
EMM—ASE	Exercise Management Mode based on the Attitude-Social Influence-Self-Efficacy (ASE) model
D—RCT	Decentralized randomized controlled trial
IPAQ	International Physical Activity Questionnaire
BASFI	Bath Ankylosing Spondylitis Functional Index
BASDAI	Bath Ankylosing Spondylitis Disease Activity Index
FSS	Fatigue Severity Scale
ASQoL	Ankylosing Spondylitis Quality of Life
ASAS/EULAR	The Assessment in Ankylosing Spondylitis international Society / European League Against Rheumatism
ITT	Intention-to-treat
CFI	Comparative Fit Index
RMSEA	Root Mean Square Error of Approximation
SRMR	Standardized Root Mean Square Residual
BIC	Bayesian Information Criterion
PP	Per-Protocol
RDD	Research Data Deposit

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Not applicable.

Authors' contributions {31b}
LH led the study with contributions in conceptualization, formal analysis, methodology, software, visualization, and writing (original draft and review/editing). YP was involved in conceptualization, formal analysis, methodology, software, and writing review/editing. XY contributed to methodology, validation, and writing review/editing. HD, QRW, QM, and HF participated in methodology. HY took charge of conceptualization, funding acquisition, project administration, resources, supervision, validation, and writing review/editing. All authors read and approved the final manuscript.

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Data availability {29}
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate {24}
Ethical approval was granted by the Ethics Committee of the Third Affiliated Hospital of Sun Yatsen University (No. II2025-081-02). Results will be disseminated through peer-reviewed journals, conferences, and patient education platforms.

Consent for publication {32}
These are available from the corresponding author on request.

Competing interests {28}
The authors declare that they have no competing interests.

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