STUDY PROTOCOL

An m-Health Intervention for Rheumatoid Arthritis in China ("Rheumatism Center" app): Study Protocol for a Prospective Randomized Controlled Trial

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Abstract

Aim: To study the feasibility and effectiveness of a m-Health app in improving the management of rheumatoid arthritis.

Design: Randomized controlled trial.

Methods: Sixty rheumatoid arthritis participants will be recruited for a 6-month feasibility study. Patients meeting the inclusion criteria will be randomly allocated to receive standard care or standard care plus the m-Health intervention. The primary outcome is the feasibility of a randomized controlled trial. In addition, we will investigate patient satisfaction in using the "Rheumatism Center" app in the intervention group. The secondary outcomes include the scores for the simplified disease activity index, clinical disease activity index, disease activity score 28, health assessment questionnaire and 6-item self-efficacy scale for chronic diseases. The assessments will be performed at baseline and at 4 weeks, 3 months and 6 months after the study is initiated. At the end of the study, we will also collect user views of the app through qualitative interviews.

Results: This study is ongoing. The findings of this study will determine the feasibility and effectiveness of m-Health intervention in the management of rheumatoid arthritis, hoping to enhance the awareness of disease management and quality of life for rheumatoid arthritis patients.

KEYWORDS
disease management, m-Health, nurses, nursing, protocol, rheumatoid arthritis

1 | INTRODUCTION

Rheumatoid arthritis (RA) is a systemic immune disease that is characterized by symmetrical, erosive and chronic arthritis lesions; has a long disease course; and is associated with poor prognoses, a high disability rate and large social burdens (Ma et al., 2018). RA is more common in women than in men. The lesions mainly occur at the wrists, hands, ankle joints and foot joints. Globally, the prevalence of RA is 0.5%–1.0% (Kvien et al., 2020). In China, the prevalence rate is 0.2%–0.37% (Hu et al., 2017) and increases each year. The disability

rate of untreated RA patients within 3 years is as high as 75% (Crane et al., 2015), and RA has become one of the major causes of the decreasing size of the labour force in China. The aetiology of the disease is unclear, and even after correct diagnosis and treatment, it cannot be fully cured (Jiang et al., 2014; Viens et al., 2007). Currently, primarily drugs are used to control the disease, but RA patients tend to have a negative psychological state due to the long disease course and recurrence of symptoms. In addition, patients requiring long-term treatment and rehabilitation need out-of-hospital self-assessment and management support, and their lack of knowledge on the disease and self-management strategies likely hinder pain control and recovery, thereby hindering improvements in quality of life (Zhai & Zheng, 2019). Compared with other types of rheumatism, RA patient is associated with a poor life quality (Druce et al., 2018; Symmons et al., 2002; Verstappen et al., 2004). The development process and treatment response of RA are unpredictable, and there are obvious individual differences in drug efficacy or adverse reactions, and the efficacy will also change over time. Medical staff need to regularly track and monitor the patient's disease activity. Therefore, an effective chronic disease management model is of great significance for controlling the progress of RA, reducing the disability rate of RA patients, ensuring mental health and improving the quality of life.

Some scholars have pointed out that the key to chronic disease management lies in the initiatives and interactions between doctors and patients (Hu, 2015). That is, chronic disease management requires long-term follow-ups and treatment for patients. It is difficult to establish a strong relationship between patients and medical staff because patients have a limited amount of time, patient participation is low, there is a lack of continuity of care, patients' self-monitoring ability is limited, and the follow-up execution rate of medical staff is low (Liu et al., 2015). Based on the obstacles to maintaining the long-term cooperative relationship between medical staff and patients, there is an urgent need for a fast and effective chronic disease management model.

M-Health is a rapidly growing healthcare field, and mobile applications on mobile devices, especially smartphones, have been widely used in medical and public health practices. In 2015, Premier Ke-qiang Li upgraded the "Internet Plus" action plan to a national strategy for the first time in his government work report, and mobile health care became a key project. In 2016, the "two sessions" again raised the issue of Internet medical treatment. With the application of the Internet and information and communication technology in the field of medical treatment and nursing, an increasing number of patients with chronic diseases have started to use various websites, m-Health apps and other electronic resources to seek disease and health information. In 2021, data from the China Internet Network Information Center revealed that by the end of 2020, there were 989 million Internet medical users in China, among whom the Internet penetration rate was as high as 70.4% (China Internet Network Information Center, 2021). In conclusion, these factors contribute to the accessibility of mobile health care in China.

M-Health has been suggested to be useful in enabling chronic disease patients to participate more actively in disease management

(Becker et al., 2014; Debon et al., 2020; Gong et al., 2020; Li et al., 2020). Evidence supports that m-Health interventions markedly accelerate self-management ability and are met with high levels of acceptance and user satisfaction among patients with RA (Nishiguchi et al., 2014; Najm et al., 2019; Mollard and Michaud, 2020). Hence, some countries, such as Japan, France, Brazil, et al., have begun to highly value patients' ability to participate in disease management, started to discuss the self-management strategies for RA patients regarding mobile medical treatment and developed apps for RA management. RA patients have a positive attitude towards medical staff helping them execute self-management, and medical staff play an important role in patients' self-management.

The "Rheumatism Center" app is a domestic first-class and professional rheumatism patient self-management and doctor–patient interaction platform. Patients need to be able to obtain online health services such as consultations and disease education. At present, holistic nursing has been widely concerned by nursing professionals. It is imperative to carry out patient-centred holistic nursing. This m-Health intervention model helps nurses to allocate reasonable time in busy clinical work and improve the implementation rate of health education and the effect of health education. However, there are insufficient studies on the application of mobile apps in the health management of RA patients in China, and studies have limitations. Furthermore, many health applications do not follow evidence-based guidelines and are not being developed by medical experts. Therefore, these apps are not safe for patients or for general health management. The apps cannot yield good disease management outcomes and consume a large amount of medical human resources (Subhi et al., 2015). Currently, the trial explores firstly the overall role of m-Health interventions in the course of RA management in China. The feasibility and effectiveness of the "Rheumatism Center" app intervention is the research question that this study will address.

2 | THE STUDY

2.1 | Aim

This trial protocol was designed to examine the feasibility and effectiveness of the "Rheumatism Center" in managing RA, and the results of the trial will provide evidence useful for improving the RA chronic disease management model and, eventually, health management models for patients with other chronic diseases.

2.2 | Hypotheses

We hypothesize that upon completion of the m-Health intervention, the participants in trial group will report low clinical disease activity index (CDAI), simplified disease activity index (SDAI) and disease activity score 28 (DAS28) scores; high health assessment questionnaire (HAQ) and 6-item self-efficacy scale for chronic diseases (SECD6) scores; and high satisfaction in using m-Health for

chronic disease management. Thus, we hypothesize that the application of m-Health in the management of RA will prove to be feasible. This hypothesis is expected to be supported by a pleased proportion of RA patients in keeping with the eligibility criteria but refusing to participate, good adherence to the intervention group and a low withdrawal rate.

3 | METHODS/DESIGN

3.1 | Trial design

This study is a randomized controlled trial (RCT) conforming to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (online additional file SPIRIT Checklist and Figure 1) (Chan et al., 2013). The participant inclusion process is illustrated in a flow chart in Figure 2. The total study duration, depending on the process of enrolment and follow-up visits, is 24 months. Two sets of tracking time will be 6 months. Taking into account the intervention ethics, we will encourage the control group patients to join the same m-Health treatment after study completion. Additionally, there is a qualitative interview process evaluation with control and experiment patients to assess their insights of being in the trial.

3.2 | Study setting and recruitment

Patients will be recruited by trained nurses from the Department of Rheumatology in the hospital. More than 500 patients are admitted annually, ensuring that a sufficient number of clinical research cases can be incorporated in the trial.

We will organize a work team, including rheumatology specialists, specialist nurses and clinical researchers. The team members will be invited to learn trial details well with the help of workshops and group discussions. We will inform qualified patients of trial details before the study starts. When a patient consent to be informed about the study, the nurse will tell the researcher, and then, the researcher will provide patients with study detailed explanation and written informed consent. Participant recruitment time into the group will start in January 2021 and end in December 2021.

4 | PARTICIPANTS

4.1 | The inclusion criteria will be as follows

- Patients diagnosed with RA, according to the 1987 American Rheumatology Association (ARA) revised classification criteria for RA (Arnett et al., 1988) and 2010 American College of

	STUDY PERIOD						
	Enrollment	Allocation	Post-allocation				Final follow-up
TIMEPOINT**	-t₁	0	6-month				t_f
ENROLLMENT:							
Eligibility screen	X						
Informed consent	X						
Sample size calculation	X						
Allocation		X					
INTERVENTIONS:							
standard care+M-Health group			◆———————————◆				
standard care			◆———————————◆				
ASSESSMENTS:	Baseline		Week 4		Month 3		Month 6
Feasibility	X						X
SDAI	X		X		X		X
CDAI	X		X		X		X
DAS28	X		X		X		X
HAQ	X		X		X		X
SECD6	X		X		X		X

FIGURE 1　The schedules for patient enrolment, interventions and assessments
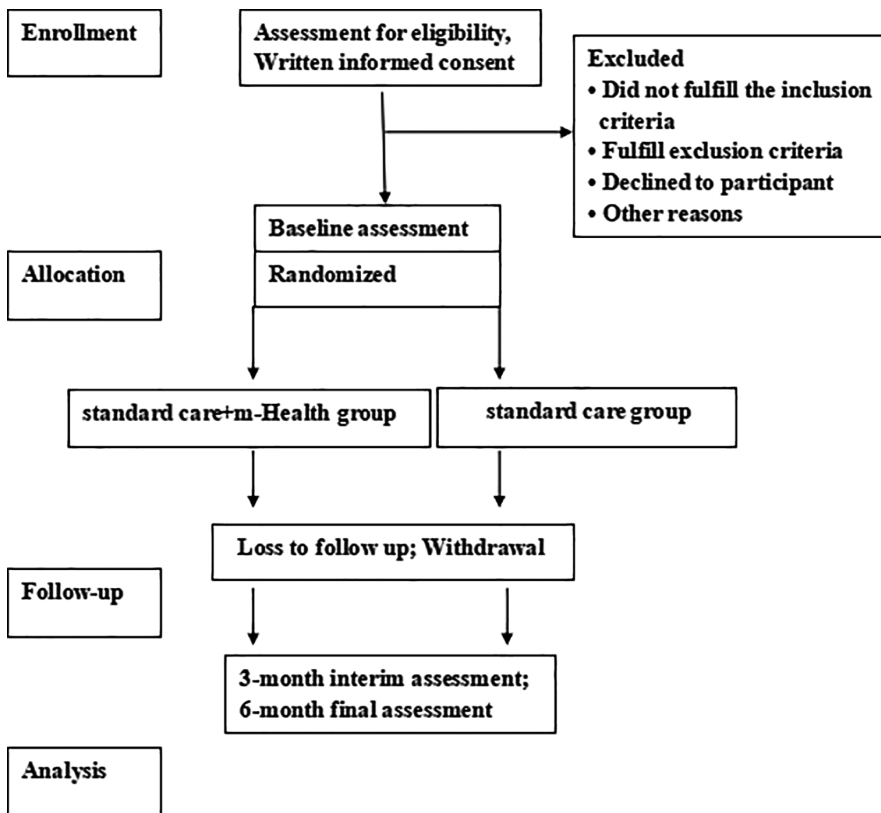
Rheumatology (ACR)/European League Against
- Rheumatism (EULAR) classification criteria for RA (Aletaha et al., 2010)
- Patients with a total score of less than or equal to 5.1 on the DAS score 28 (mild-to-moderate activity)
- Adults over 18 years of age who volunteer to participate in this study
- Patients who have good communication skills
- Patients who have access to the mobile app and can use it correctly.

4.2 | The exclusion criteria are as follows

- Patients with other coexisting diseases, including severe cardio-pulmonary disease, liver or kidney disease, coronary heart disease, diabetes, blood diseases or a malignant tumour
- Pregnant or lactating women
- Patients with dementia, severe cognitive disorders or psychiatric disorders that can make patients unlikely to complete the study.

4.3 | Withdrawal

The participants are informed to have the right to withdraw from the study at any time may due to personal reasons or the worsening of their health condition during treatment. We will make corresponding

records. If the patient is willing to inform, we will record the reasons for withdrawal in detail. If patients do not want to inform, we will not force patients, only record the number of withdrawals. In addition, if a subject suffers an adverse event at any time, measurement may be discontinued at any time, and adverse events will be recorded.

4.4 | Sample size

It fails to perform a formal sample size calculation, as the primary outcome is to evaluate the feasibility of the m-Health app in improving patients' self-management of RA. Considering a sample size of 12 per group based on a feasibility test (Julious, 2010), a sample size of 60 participants is estimated to be needed, which will provide us with adequate information about intervention feasibility. Therefore, we schedule to recruit 30 patients for each group.

4.5 | Randomization and blinding

We will randomly allocate RA hospitalized patients who achieve the inclusion criteria and consent to take part in this research to either the intervention group or the control group, with an allocation ratio of 1:1. A statistician (outside the research team) is responsible for generating a list of random numbers using a computer program. The group assignment of random numbers will be written on a piece of paper and inserted in a closed envelope. The participants will be

obtained an envelope based on the randomization sequence after the baseline assessment. Outcome assessors in the team are required to be blind to the randomized group assignments.

5 | INTERVENTIONS

5.1 | The experimental intervention

In addition to regular treatment and health guidance, patients will participate in short m-Health app disease management session once a month for a total of six sessions. M-Health app details are shown in Figures 3 and 4. The monthly disease management content includes (1) releasing health education knowledge through a mobile app health information column to help patients understand the pathogenesis of RA, risk factors, clinical manifestations, drug treatment and prognosis, diet, psychological care, functional exercise and other aspects of RA, with a specific topic being featured every month. (2) Through the treatment management column in the mobile app, the medication, adverse events and test reports of patients in the past month will be assessed. (3) Through the disease assessment and dynamic chart column of the mobile app, the patient's disease control status in the past month will be evaluated. (4) Through online communication with patients through the mobile app, the patients will be invited to express negative emotions. Moreover, on the basis of the above evaluation results, guidance will be provided regarding the subsequent treatment and nursing care of the patients. The patients will be monitored and evaluated at weeks 4, 12 and 24. The patients will receive further treatment at any time if their disease worsens.

5.2 | The control intervention

We will offer patients with routine treatments and health education. Routine treatments will include oral anti-rheumatic drugs such as celecoxib, leflunomide, methotrexate and other anti-rheumatic drugs. Health education topics will mainly include activities of daily living, diet, medications, psychology, sport, etc. The patients should take precautions to keep their joints warm and avoid cold stimuli to prevent discomfort. Daily, patients should adhere to a low-salt, low-fat, nutrient-rich diet, should not smoke or drink alcohol, should not eat fried fast food or spicy food and should maintain a balanced diet according to seasonal changes. Our nurses will introduce the patients to commonly used drugs, basic medications and the principal pharmacological effects of clinical drugs to improve patients' understanding of their daily medications and how to maintain a good mood and communicate with others. Each patient can decide to walk, walk briskly, square dance or participate in other types of physical activity, depending on their condition and preferences. In addition, the patients will be invited to attend regular follow-ups. The patients will be monitored and evaluated at weeks 4, 12 and 24. If the disease worsens, the patients can receive additional treatment at any time.

5.3 | Qualitative process evaluation

All patients from both groups will be invited to participate in qualitative interviews after completing six-month follow-up assessment. We will encourage patients from both groups to express their insights of being in the trial. The interview questions will focus on our approach to recruitment, the appropriateness of intervention measures and

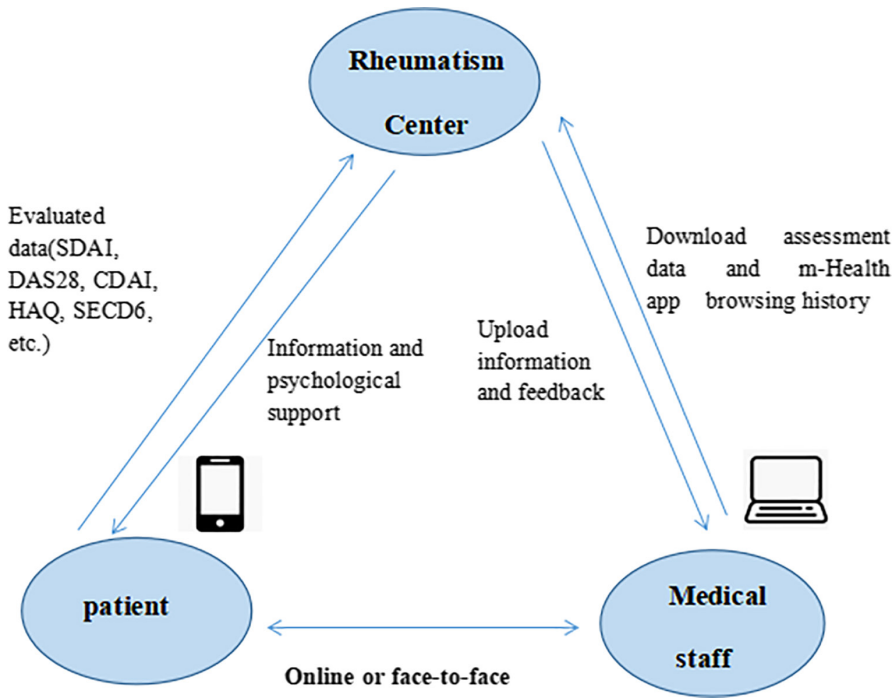| Main Module	Content
Self-diagnosis module	ACR1987 EULAR2010
Disease assessment module	There are some evaluation items, such as the RA evaluation, HAQ, and BMI, that patients can fill out before seeing a doctor to help the doctor evaluate the overall condition of the patient.
Treatment management module	Medication management,Medication reminder, Adverse event management,Inspection report management,Medical records management
Inspection report module	The patient can upload the test report, which truly reflects the current condition
Dynamic chart	Disease assessment dynamic trend, inspection report dynamic trend
Health Knowledge Module	Disease knowledge, health regimen, questionnaire survey, questions and answers, etc.
Health log module	Patients can record blood pressure, blood sugar, exercise, height and weight every day and generate dynamic charts
Online patient education module	Educational video on the disease recorded by experts
Doctor consultation module	The patient can consult the doctor at any time when there are concerns.

FIGURE 3 The "Rheumatism Center" m-Health app details 1

FIGURE 4 The "Rheumatism Center" m-Health app details 2

FIGURE 5 Task form for standard care plus the m-Health intervention group (above) and standard care group (below)

Name:_____ ID: _____

Task	Time	Date
Clinic visit 1 and assessment	Week 4	
M-Health app visit 1	Month 1	
M-Health app visit 2	Month 2	
M-Health app visit 3	Month 3	
Clinic visit 2 and assessment	Month 3	
M-Health app visit 4	Month 4	
M-Health app visit 5	Month 5	
M-Health app visit 6	Month 6	
Clinic visit 3 and assessment	Month 6	

Name:_____ ID: _____

Task	Time	Date
Clinic visit 1 and assessment	Week 4	
Clinic visit2 and assessment	Month 3	
Clinic visit3 and assessment	Month 6	

the acceptability of the intervention. We will explore an in-depth description of the participants' experience of app usage in the experiment group, including what type of support they like most and least, their views on the functionality they use, their views on the usefulness of m-Health intervention, the acceptability of the intervention and what they hope to improve. Besides, if the patient is willing to inform, we will try our best to understand the unique contexts in which patients are attempting to quit via qualitative interviews.

5.4 | Outcome assessment

The participants in the study will be tracked for 24 weeks and assessed at regular intervals, such as at baseline and 4 weeks, 12 weeks and 24 weeks after baseline. We will give them a detailed trial explanation and a task form (Figure 5). A researcher blinding to the group assignments will take all the measurements of the participants.

5.5 | Primary outcome measures

The information networks' rapid development brings about not only new opportunities for chronic disease management but also many challenges. To determine whether patients will accept the mobile app for chronic disease management is the fundamental purpose of this study. In some previous studies (Huang et al., 2018; Julious, 2010), the primary outcome was the feasibility of the study. The feasibility will be evaluated by recording RA patient proportion who achieves the eligibility criteria but refuses to participate, intervention group adherence level and withdrawal rate. In addition, we are about to collect patients' satisfaction during the "Rheumatism Center" m-Health app use among participants in the trial group (Figure 6).

5.6 | Secondary outcome measures

SDAI is the sum of traditional 5 core variables: 28 joint swelling index (SJC) and joint tenderness (TJC), the patient's overall assessment of disease activity (PGA), the evaluator's overall assessment of disease activity (EGA) and the CRP level. The formula is as follows (Aletaha et al., 2005): SDAI = SJC28 + TJC28 + EGA + PGA + CRP. The level of disease activity is following: high activity (>26), moderate activity (>11 and ≤26), low activity (>3.3 and ≤11) and remission (≤3.3). The same variables, except for the CRP level, are contained in the CDAI as in the SDAI. The formula is as follows (Aletaha & Smolen, 2006): CDAI = SJC28 + TJC28 + EGA + PGA. The level of disease activity is categorized as follows: high activity (>22), moderate activity (>10 and ≤22), low activity (>2.8 and ≤10) and remission (≤2.8).

For the DAS28, the general health (GH), the SJC and TJC, ESR and visual analog scale (VAS) score will be evaluated. 28 joints contain the knee joint, proximal interphalangeal joint, metacarpophalangeal joint, wrist joint, elbow joint and shoulder joint. The formula is as follows (Aletaha et al., 2005): DAS28-ESR = $0.56 \times \sqrt{(TJC28)} + 0.28 \times \sqrt{(SJC28)} + 0.70 \times \ln(ESR) + 0.014 \times GH$. The disease activity level is categorized as follows: high activity (>5.1), moderate activity (>3.2 and ≤5.1), low activity (>2.6 and ≤3.2) and remission (≤2.6).

The HAQ will be used to assess patients' physical function (Fries, 1991). The HAQ, widely used worldwide, is a 20-item questionnaire. Its dimensions are as follows: dressing, washing, standing up, walking and other aspects of daily life. The total score ranges between 0 and 60 points, with average score ranging between 1 and 3 points.

The SECD6 is commonly used to measure the level of patients' self-efficacy with chronic diseases (Lorig et al., 2001). It consists of two dimensions: symptom management self-efficacy and disease generic management self-efficacy with 6-item contents. Each item is scored on a scale from 1 to 10.

5.7 | Economic evaluation

Although patients do not have to bear additional costs, the intervention does have other costs, more human costs, such as health education data preparation, follow-up, monitoring, dynamic follow-up of patient indicators and online answers. Hence, in terms of costs of the intervention, we will estimate those associated with human costs. The service time required to complete the work task will be investigated. The cost-effectiveness ratio will be calculated to compare both costs and effectiveness of the experiment and control groups. A single-factor sensitivity analysis of human costs will be conducted to evaluate the robustness of the conclusions. These help to estimate the cost of this study, arrange human resources more reasonably in future research and maximize the benefit of research results.

5.8 | Data analysis

To examine the feasibility of this trial, we will determine enrolled patients' proportion with respect to all qualified patients, intervention adherence level and dropout rate. Data analysis will be done by SPSS software, version 23.0. Measurement data, such as patient age, SECD6 and HAQ scores, conforming to a normal distribution will be described as the mean ± standard deviation (SD). A t test will

Contents	Yes	Maybe	Not
It achieves disease management conveniently and quickly.			
The explanations of the doctors' or nurses' were easily understood.			
The service attitudes of the doctors and nurses were very friendly.			
Problems could be solved with this "Rheumatism Center" m-Health app in a timely manner.			
It was used for my disease recovery.			
My privacy was not compromised.			
I will keep using the "Rheumatism Center" m-Health app.			
I will recommend the app to my family and friends.			
I am satisfied with the use of this "Rheumatism Center" m-Health app in general.			

FIGURE 6 The satisfaction survey of "Rheumatism Center" m-Health app

be utilized to analyse normally distributed data. Data that are abnormally distributed will be described by the median and interquartile range. A nonparametric test (Mann–Whitney U) will be used to assess abnormally distributed data. The X^2 test or Fisher's exact test will be utilized to enumeration data, such as the level of intervention adherence and withdrawal rate. Categorical variables, such as sex and occupation, will be compared by a chi-square test. It considers $p < 0.05$ as a significant difference.

5.9 | Qualitative process evaluation data collection and analysis

Before the interview, the purpose, method and significance of the study, the voluntary and confidential nature of the interview will be introduced to the patients to establish a good trust relationship. The interview will be via phone, last approximately 30 min. Data saturation will be reached when patients no longer had additional perspectives to share. A smartphone (only used for this trial) will be used for audio recording interviews. Within 24 hr after the interview, the recordings will be transcribed into text materials in a timely manner (in Chinese), and the post-transcription data will be fed back to the interviewees to confirm and modify the doubts.

Data analysis will be conducted using Colaizzi 7-step analysis. Two trained nurses will read, summarize and analyse the interview data repeatedly and finally refine the relevant topics. Specifically, first carefully read all interviews, the description of the object of study to form a general understanding; extract meaningful statements consistent with research questions; summarize and refine meaningful statements and coding; sum up the encoded views, looking for common concepts or features, forming themes; link the theme to the research object for a detailed description; statement constitutes the essential structure of the phenomenon; the final analysis results are returned to the research object to verify the authenticity of the content.

5.10 | Ethics

This trial has been approved by Human Research Ethics Committees of the First Affiliated Hospital of Guangzhou University of Chinese Medicine (K2020-076). This trial has been registered at the Chinese Clinical Trials Registry: ChiCTR2000038561. All study participants will sign written consent prior to participation. All related study information will be protected securely at the study site.

6 | DISCUSSION

It is worth mentioning that long-term disease management plays an important role in the treatment of chronic diseases. The m-Health intervention has been proven to helpRA patients (Nishiguchi et al., 2014). Our research will report practical information via

"Rheumatism Center" m-Health app, which is specifically designed to enhance patient awareness on disease management and enhance life quality for RA patients in China. If this intervention is considered effective, the "Rheumatism Center" m-Health app will be beneficial to enhance the awareness of disease management and quality of life for RA patients. This m-Health interventions do not require expensive equipment or additional cost, it can easily be accepted by patients and, to a certain extent, reduce the resistance factors of implementation, thus, this research has a certain dissemination potential. In the future, we hope to carry out multi-centre and multi-regional cooperation in the form of point to area, so as to spread the influence of this study and benefit more patients with RA. In addition, this intervention model will be gradually extended to other patients with chronic diseases, helping more other chronic disease patients to improve their self-management ability.

This study, based on the Internet Plus action plan, is an exploratory trial in which disease management is provided via m-Health. The study strengths include the fact that it combines network technology, extends professional medical resources to communities and families and potentially improves the management of patients with RA. This intervention not only meets the health needs of patients and their families but also improves patients' self-management behaviours, thus reducing the incidence of complications and the economic burden on patients and their families, reducing the occurrence of dysfunction and improving patients' life quality. For family members of patients, this intervention will effectively reduce the amount of long-term care they need to provide and economic burden. For nursing, on the one hand, nursing staff can promote the growth of professional knowledge and teaching in the process of follow-up education and learn from the intervention protocol of this study to explore the most suitable local chronic disease management mode and make contributions to the improvement of chronic disease management. On the other hand, through m-Health interventions, the quality of life of patients is improved, and the disease outcome is developed in a favourable direction. To a certain extent, it will also improve the quality of nursing care and nursing satisfaction and increase the professional accomplishment of nursing staff, so as to stabilize the nursing professional team and reduce the turnover rate. In addition, although there are some studies on m-Health interventions with RA patients, due to regional cultural differences, the actual application is different, but it is also because of the collision and integration of multiculturalism, which is conducive to a more comprehensive development of more suitable for internationalization of patients with RA and even other chronic patients with self-management mode. Therefore, chronic disease management of RA with mobile apps has enormous potential regarding long-term care and is worthy of being studied in detail.

6.1 | Limitations

There are several minor limitations. First, the study includes a long-term intervention. Thus, some patients may drop out of this study

due to personal reasons or the worsening of their health condition during treatment. Therefore, we will distribute a task form interpreting the accurate time of their appointments to every participant. Second, the control group needs to learn to use m-Health, and this study is highly associated with network data transmission and access. Third, due to regional and cultural differences, the implementation of m-Health interventions for patients with RA will be different, and the specific implementation needs to be flexibly combined with the local culture of the country. Finally, missing data risk must be taken into account.

7 | CONCLUSION

This study will examine the feasibility and effect of RA patients using a m-Health app in the disease management. Even if null results are obtained, RA patients will grasp more comprehensive disease management knowledge that helps them deal with the disease. Supposing that online intervention is effective, it will be implemented in hospitals, and crucial nursing care can be provided in clinical practice during the process of RA patients' disease management.

CONFLICT OF INTEREST
The authors do not have any conflicts of interest.

AUTHOR CONTRIBUTIONS
HFL helped conceive the study, develop the overall study design and write the manuscript. XWY and GXC helped conceive the study and develop the overall study design. YS helped design the details of the study and revised the manuscript for critical content. QM, JTS and JP helped conceive the study and revised the manuscript for critical content. GXC, XWY and CSL performed this study. All authors were involved in drafting the manuscript and revising it critically for important intellectual content and have approved the final version to be published. All participants agreed to the publication of identifiable data.

DATA AVAILABILITY STATEMENT
As this is a protocol, there are no data to present.

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