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Effects of tele-exercise rehabilitation intervention on women at high risk of osteoporotic fractures: study protocol for a randomised controlled trial

Simin Li,[1] Yi Li ,[2,3] Qiu Liang,[2] Wen-Jie Yang,[4] Rui Zi,[2] Xuyi Wu,[2] Chunping Du,[2,3] Yan Jiang [5]

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For numbered affiliations see end of article.

Correspondence to
Professor Yan Jiang; hxhljy2018@163.com and Professor Chunping Du; ducp118@163.com

ABSTRACT

Introduction Premenopausal and postmenopausal osteoporosis and associated fragility fractures are major public health problems. Exercise, especially moderate-to-high-intensity impact exercise, has been recommended as an effective, low-cost non-pharmacological strategy for bone strength improvement; however, evidence on fracture risk is limited. In addition, maintaining regular training is currently a problem. Therefore, this study aims to conduct a randomised controlled trial of moderate-to-high-intensity tele-exercise intervention using a tele-rehabilitation app and quantify its effects on vertical fracture and fall prevention in women at high risk of osteoporotic fractures.

Methods and analysis In this multicentre, randomised controlled trial, 794 women at high risk of osteoporotic fractures will be recruited and randomised into either the tele-exercise rehabilitation or control group. Participants in the control group will receive routine remote rehabilitation, while those in the intervention group will be provided with a 6-month tele-exercise rehabilitation. The primary outcomes are the percentage of participants with one or more new vertebral fractures and incidence of falls. Intention-to-treat, full analysis set and per-protocol approaches will be used for outcome analyses.

Ethics and dissemination The study was approved by the biomedical research ethics committee of the West China Hospital of Sichuan University (2021-579). Written informed consent will be obtained from each participant after agreeing to participate in the study. The study findings will be presented at national and international scientific conferences and published in peer-reviewed journals. Results are propagated regardless of the magnitude or direction of the impact. Authorship is assigned according to authorship guidelines as defined by the International Board of Medical Journal Editors, and each author's role is based on journal requirements for publication.

Trial registration number The study was registered with the Chinese Clinical Trial Registry (ChiCTR2200058780) prior to recruitment (May 2022).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a randomised, multicentre, large sample size study with good representation of regions and populations and strong outreach.
⇒ The set exercise intensity in this study is higher than that in other studies for participants under many protective precautions.
⇒ The settings of the intervention methods ensure the comparability between groups.
⇒ Although this is a multicentre study, we do not use traditional epidemiological sampling methods, which may potentially affect the representativeness of the population.
⇒ Rehabilitation app may exclude the participants who have no access to the internet or who have a device that connects to the internet but have difficulty using it.

INTRODUCTION

Premenopausal and postmenopausal osteoporosis (OP) and associated fragility fractures are major global public health problems.[1–3] In China, 20.6% of women and 5.0% of men aged 40 years or older suffer from OP.[4] Fractures, particularly vertebral fractures, are the most serious complications and common consequences of OP.[5] Every year, approximately 9 million people suffer from OP fractures worldwide, more than 60% of whom are women.[6] Moreover, one in five women with a vertebral fracture will suffer from another vertebral fracture within a year, and the risk of death is 2.7 times higher in them than in those without fracture.[7] Osteoporotic fracture is the fourth most burdensome chronic disease[8]; it results in pain, depression and functional impairment and is a substantial burden on health systems.

Many OP-related fractures are preventable and treatable.[6 9 10] Exercise has been recommended as a low-cost and effective non-pharmacological strategy for improving bone strength.[11–13] There is considerable evidence suggesting that moderate-to-high-intensity impact and muscle strengthening exercises are more effective than low-impact exercises

in maintaining improvements in measures such as bone mineral density (BMD)[14–17]; however, evidence on fracture risk is limited.[18 19] Moreover, regular, long-term moderate-to-high-intensity exercises can positively influence bone metabolism and are more likely to reduce the risk of osteoporotic fracture.[10] However, due to the differences in medical accessibility,[20] most patients at high risk of osteoporotic fracture cannot be identified and receive few regular and professional exercises. Hence, the long-term efficacy of exercise interventions is difficult to assess in women at high risk of fracture.

To allow more patients to receive professional rehabilitation guidance, many studies have begun to explore tele-rehabilitation, which is considered a potential innovative treatment approach and has been confirmed to achieve physical and functional outcomes.[21 22] Nevertheless, there is insufficient literature and data available on the effectiveness of tele-rehabilitation for patients with OP. Therefore, we aim to conduct a randomised controlled trial of moderate-to-high-intensity tele-exercise intervention on women at high risk of fracture. The primary objective of this study is to assess the effect of a 6-month supervised tele-exercise rehabilitation (tele-e rehab) programme on the incidence of fractures and falls in women at high risk of osteoporotic fractures.

METHODS AND ANALYSIS

Study design

The trial is a parallel-group, multicentre, assessor-blinded, superiority randomised controlled clinical trial. The overall flowchart is shown in figure 1. It is designed to allocate participants in an intended 1:1 allocation ratio to compare the efficacies of supervised moderate-to-high-intensity tele-e rehab intervention and routine remote rehabilitation in reducing the incidence of fractures and falls in 794 women at high risk of osteoporotic fractures. The study protocol was developed according to the Standard Protocol Items: Recommendations for Interventional Trials.

Participants

Participants will be recruited from the rehabilitation department of seven hospitals separately selected from the seven geographical regions in China: northeast, north, east, central, south, southwest and northwest China. Study recruitment will commence in May 2022 and it is anticipated to be completed in October 2022. The number of enrolled participants is allocated according to the proportion of OP hospitalised at each site in the previous year. Patients will be included or excluded based on the following inclusion and exclusion criteria.

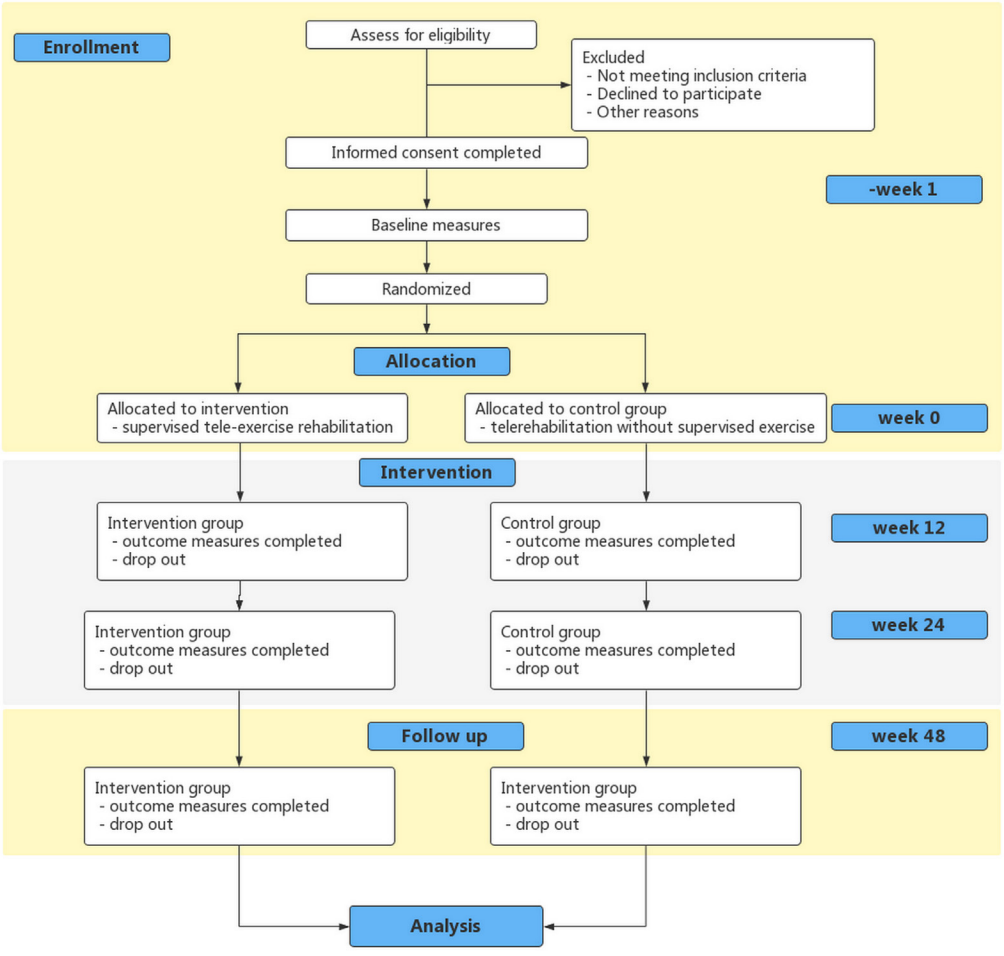

Figure 1 Flow chart of the study.

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Inclusion criteria

Participants will be included in the study if they:

1. Are women aged between 40 and 70 years.
2. Are at high risk of fracture: participants are recognised as having a high risk of fracture if the 10-year probability of a hip fracture is ≥3% or that of a major OP-related fracture (clinical spine, forearm, hip or shoulder fracture) is ≥20%[23] using the Fracture Risk Factor Assessment Tool.[24]
3. Clearly understand the content and purpose of the research, volunteer to participate in the study, cooperate to complete the programme and sign the informed consent form.
4. Have mobile phones (that can download the rehab app) and are skilled in using them.

Exclusion criteria

Potential participants will be excluded if they:

1. Have had a lower limb joint injury or surgery.
2. Have had a fracture or circumscribed back pain within the last 1 year.
3. Are current smokers.
4. Have a malignancy.
5. Have an uncontrolled cardiovascular disease.
6. Have a cognitive impairment or disorder.
7. Have contraindications for heavy physical activity.
8. Have participated in any type of progressive resistance training or weight-bearing/impact exercise more than once a week in the past 3 months.
9. Have conditions known to influence bone health (eg, thyrotoxicosis or hyperparathyroidism, Paget's disease, diabetes, renal disease or immobility).
10. Are taking drugs (other than OP medications) known to influence bone health (eg, prolonged use of corticosteroids, thyroxine, thiazides or antiretroviral agents).

Termination criteria

The study will be stopped if:

1. Fragility fractures occur during the study.
2. Malignancy, cardiovascular disease, and other diseases affecting bone health, such as thyrotoxicosis or hyperparathyroidism, Paget's disease, renal disease or diabetes, are observed during the study.
3. Life-threatening accidents occur during the study.

Randomisation, concealment and blinding

The random scheme was produced by the central research group and grouped by the subcentre research group. An independent statistician from the central research group (who is not on the research team) used R software (V.3.5.1; R Foundation for Statistical Computing) to generate random numbers, which were placed into opaque envelopes by an independent researcher (not involved in the study) to avoid selection bias. The envelopes will be delivered to each research centre and kept in a double-locked cabinet. The practitioners at each research centre will open the envelopes and allocate participants who meet the eligibility criteria according to the contents of the envelopes. Patients will be randomised into either a 6-month tele-e rehab group or a control group.

Given the nature of the intervention, it is impossible to blind the participants and researchers in the study. However, both groups are allowed to receive a tele-rehabilitation intervention through the same app to maintain blinding. The interventionists will be informed of the results of the randomised grouping before the intervention. However, outcome assessment and data analysis will be carried out by two independent investigators from each hospital and a statistician from the central research group, respectively, all of whom are blinded to allocation, baseline measurements and intervention. All information and the number of participants will be encrypted using specific coding. All participants will be informed of the group they may be divided into orderly before the research commences, but the specific intervention content of each group will not be disclosed to them, and they will not be able to discuss groupings and interventions with the researchers.

Intervention

Control group

Participants in the control group will receive tele-education guidance about OP once a week via the tele-rehabilitation app and be reviewed by doctors and nurses as outpatients at follow-up. The control group will not receive a tele-exercise programme. All participants in the two groups will be advised to take two calcium supplements (calcium carbonate and vitamin D_3 tablets, Jiang Su, China, 600 mg elemental calcium as calcium carbonate, 1200 mg total; 125 IU vitamin D_3, 250 mg total) and one vitamin D supplement (Vitamin D_2 Soft Capsules, Nanjing, China, 400 IU/day) daily throughout the study period. This is to ensure that these patients who are already at high risk of OP fractures are protected as much as possible.

Intervention group

The intervention group will be provided a tele-e rehab programme through the tele-rehabilitation app. The exercise rehabilitation plans will be formulated according to guidelines, expert consensus statement, systematic review of physical activity and exercise for OP,[11 18 19 25–28] and subsequently, 10 domestic experts will be invited for Delphi expert consultation.

The tele-e rehab intervention (table 1) is set at three sessions per week and a progressive intensity of four distinct 6-week phases for 6 months; it will be provided by an interdisciplinary team of doctors, therapists and nurses who are not involved in the outcome assessment.

The first phase is mainly for familiarisation and adaptation to exercise; it is mainly set at low intensity. As the participants improve, they will progress to phases III, IV and be maintained at moderate-to-high-intensity training. The specific type of exercise will be prescribed by the therapists according to each participant's functional ability, which will be assessed at baseline. The sequence

Table 1 Tele-exercise rehabilitation programme and training doses for 6 months

Phase	Week	RPE	Balance training		Muscle-strengthening exercise			Weight-bearing impact exercise		
			Sets	Reps per set	Sets	Reps per set	%HR_{max}	Sets	Reps per set	%HR_{max}
1	1–6	9–11	3	6–12	3	8–12	40–60	3	10–12	40–60
2	7–12	12–13	4–6	6–12	3–5	8–12	61–70	3–5	10–12	61–70
3	13–18	14–17	>6	6–12	>5	8–12	>70	>5	10–12	>70
4	19–24	14–17	>6	6–12	>5	8–12	>70	>5	10–12	>70

RPE, Rating of Perceived Exertion.

of the exercise phase can be warm-up (5 min), main exercise (30–50 min) and cool-down (5 min). Walking or light stretching is recommended for warm-up and cool-down. The main exercise training comprises of balance training, muscle strengthening exercise and weight-bearing impact exercise. In total, one to two balance trainings and muscle-strengthening and weight-bearing impact exercises will be included in each training session and the type of exercise will be adjusted to the participants' condition. A 1 min rest between the sets will be given throughout the exercise.

Balance training

Balance training in this study will be limited to a highly challenging form, which includes standing weight shifting, sit-to-stand, tandem walking heel-to-toe, heel walk, toe walk, alternating front kick, single-leg hop forward and single-leg stance with hip abduction. Individualised selection will be performed by the therapist based on each participant's condition. In the first phase, for each session, 3 sets of each balance exercise will be performed using 6–12 repetitions per set. The intensity can then be gradually increased to six or more sets. Each balance exercise is to last for at least 10 s, increasing to a longer duration as tolerated.

Muscle-strengthening exercise

The muscle-strengthening exercise plan will consist of a series of exercises that enhance the strength of the muscle of the spine and lower limbs including forward reverse lunge, long sitting straight leg raise, four-kneeling straight hip extension, knee plate support, wall push-ups, leg hip bridge and squats. In the first phase, the intensity ensuring good technique will be set at a light intensity of 40%–60% maximal heart rate and 3 sets of 8–12 repetitions per set for each muscle-strengthening exercise, with every action sustained for 5–10 s. In the next phase, the intensity will gradually increase to 70% or more after 5 or more sets of 8–12 repetitions per set for each muscle-strengthening exercise, and this level will be maintained until the end of the study.

Weight-bearing impact exercise

Weight-bearing impact exercises will include jumping squats in and out, ski jumping back and forth, alternating lunge jump, jump and hold, jumping forward and backward, crossed jump and high knee running. The initial intensity will be set at 40%–60% maximal heart rate and gradually increased to 70% or more maximal heart rate by increasing the number of sets from 3–5 sets or more of 10–12 repetitions per set for each weight-bearing impact exercise. Each weight-bearing impact exercise is to last for 20–30 s.

During the intervention, a chest-worn heart rate band (Recovery Plus Inc.) will be used to connect wirelessly with the tele-rehabilitation app to measure exercise frequency, intensity, time and volume. In addition, the Rating of Perceived Exertion (RPE) Scale[29] will be used to measure the level of exertion or fatigue and a combination of fairly light (RPE 9–11), somewhat hard (RPE 12–13) and very hard (RPE 14–17) intensity exercise is used according to the the American College of Sports Medicine's guidelines.[30] The data obtained from the chest-worn heart rate band and RPE level will provide feedback to the therapists' platforms. Once the patient's heart rate and exercise volume exceed the target value or an abnormality occurs, the app will alert the patient to stop the training. After each exercise, the therapist of the project team will call to check the patient's condition and adjust the training plan accordingly.

Tele-rehabilitation app

Patients and medical staff will need to log in through their own ports using mobile phone numbers and passwords and bind the main caregiver to the patient's own account. Patients and their main caregivers can view the patient's personal information and contact the medical staff. Doctors, nurses and therapists involved in this study can log in to the app to view and input the information of patients. The app mainly includes six modules: the health education guidance, exercise guidance, doctor–patient interaction, case information, questionnaires and data analysis modules. The health education guidance module provides knowledge related to OP diseases, such as diet, nutrition, drugs, daily life behaviour and fall prevention. The exercise module shows the specific content of the exercise training plan for patients in the form of a video according to the intervention time of the research plan, mainly for the intervention group. In the doctor–patient interaction module, patients can communicate and consult with the medical staff through text,

voice messages, pictures and videos. The case information module provides an avenue where medical records and examination results can be uploaded for the patients and medical staff. The questionnaire module presents all the assessment questionnaires used in the study. The data analysis module provides a preliminary analysis of the basic data of the participants.

Implementation procedure

All patients will be screened and enrolled 1 week before discharge, since the patients' hospitalisation time is generally fixed. Three nurses from each hospital in the seven regions of China will screen eligible patients according to the inclusion and exclusion criteria from Monday to Sunday each week, depending on the patients' discharge time. Patients will sign the consent form if they agree to participate after the study nurses have introduced the aims and significance of the entire programme. Baseline and home safety assessments will be conducted for the enrolled patients by the three study nurses.

Following enrolment, the patients will be randomised into groups, as described above. All participants will be asked to download the tele-rehabilitation app and given nearly 1 week to familiarise themselves with it. During this familiarisation period, all participants will receive one-on-one guidance from the study nurses. The intervention group will receive additional instruction from study therapists regarding exercise training in the app and the usage of the chest-worn heart rate band before discharge; afterwards, they will be set for the initial exercise intensity, followed by a transition to home-based tele-rehabilitation programme.

The patients will receive one-on-one tele-exercise monitoring to ensure movement safety during the tele-e rehab. A day before the start of each exercise training session, a remote reminder will be sent through the app regarding the time and content of the exercise. After receiving the training task, the participants will click and reply whether they can participate at the time or not; if not, they will fill in the reason. After daily exercise training is completed, the system will automatically push the RPE Scale to measure the level of exertion or fatigue and the therapist will conduct real-time intensity adjustments based on the feedback. One-on-one therapists will give a weekly telephone return call to assess exercise safety and adjust parameters such as intensity, tolerance and adverse effects.

Outcome assessment

The primary outcomes will be the percentage of participants with one or more new vertebral fractures and incidence of falls. The secondary outcomes will include the following: percentage of participants with non-vertebral fractures, including fractures of the hip, sternum, bone, toes, fingers and skull; (2) BMD of the femoral neck, 3rd–5th lumbar spines and hip, which will be examined using the GE Lunar double-energy x line; (3) pain improvement (assessed using the Numeric Rating Scale[31]); (4) improvement in balance function (evaluated using the Berg Balance Scale[32]); (5) changes in the risk of falls (evaluated using the Morse Fall Scale[33]); (6) improvement in activities of daily living (assessed using the Barthel Index[34] and Instrumental Activities of Daily Living Scale[35]); (7) changes in mental function (assessed using the Self-Rating Anxiety Scale[36] and the Self-Rating Depression Scale[37]); (8) improvement in quality of life (assessed using the 36-Item Short Form Survey (SF-36 Scale[38]) ; and (9) qualitative evaluation of patient adherence to the programme. The project team will inform the participants about follow-up at the outpatient clinic, and outcome measures will be assessed at weeks 12, 24 and 48.

Statistical plan

Sample size

The sample size was calculated using PASS V.11 software (NCSS Statistical Software, Kaysville, Utah, USA). According to the Consolidated Standards of Reporting Trials guidelines, the sample size was estimated mainly based on the primary outcome measure and the rate of vertebral fracture. The sample size would achieve 90% power to detect a between-group difference of −0.1 in the proportion of patients with vertebral fracture. The calculation is based on the assumption that the proportion of patients with incident vertebral fracture is 0.3 under the null hypothesis for both groups and 0.2 for the intervention group under the alternative hypothesis. The test statistic used is a one-sided Z-test (unpooled) with a type I error of 0.05. By allowing 20% attrition, the total sample size was estimated to be 794.

Statistical analysis

Data analyses will be performed by a central research group at West China Hospital of Sichuan University, Chengdu, China. An independent statistician blinded to allocation as described above will conduct all statistical analyses using R software (V. 3.5.1; R Foundation for Statistical Computing) with one-tailed tests as appropriate and one-sided $p<0.05$ will be considered statistically significant.

Intention-to-treat analyses will mainly be used for the primary and secondary outcomes, including all available randomised participants in the analysis. Full analysis set (FAS) analyses will be defined as all participants who received the intervention and provided the assessment data. For per-protocol (PP) analyses, all participants who withdraw or become lost to follow-up will be excluded. We will conduct a sensitivity analysis to compare the results from the FAS and PP sets. The multiple imputation method will be adopted to handle missing data in incomplete datasets.

For categorical variables, the χ^2 or Fisher's exact test will be used to evaluate differences between the two groups. For all repeated measures data, we will use a repeated measures analysis of variance or generalised estimated equation. The effect of time will be considered during the analysis. Both the time and group-by-time interaction

Table 2 The timetable of the study period

	Enrolment	Baseline measures	Allocation	Intervention		Follow-up
Time point	$-T_1$		T_0	T_1	T_2	T_3
Enrolment						
Eligibility screen	×					
Informed consent	×					
Baseline assessment		×				
Randomisation allocation			×			
Intervention						
Tele-e rehab			×	×	×	
Usual tele-rehabilitation			×	×	×	
Assessment						
Demographic data		×				
Physical examination		×		×	×	×
Home safety assessment		×		×	×	×
Concomitant medication	×			×	×	×
FRAX	×					×
Vertebral fracture	×			×	×	×
Non-vertebral fractures	×			×	×	×
BMD		×		×	×	×
Incidence of falls		×		×	×	×
Morse Fall Scale		×		×	×	×
NRS		×		×	×	×
BI		×		×	×	×
IADL		×		×	×	×
BBS		×		×	×	×
SAS		×		×	×	×
SDS		×		×	×	×
SF-36		×		×	×	×
Adherence				×	×	×
Adverse event				×	×	×
Complications				×	×	×

BBS, Berg Balance Scale; BI, Barthel Index; BMD, bone mineral density; FRAX, Fracture Risk Factor Assessment Tool; IADL, Instrumental Activities of Daily Living; NRS, Numeric Rating Scale; SAS, Self-Rating Anxiety Scale; SDS, Self-Rating Depression Scale; *SF-36, 36-Item Short Form Survey .

models will be used. Subgroup analyses will be conducted to check whether there are significant differences in the responses to tele-e rehab depending on the participant's age and different hospitals measured at baseline.

Data management and monitoring

The time points for enrolment, intervention and assessment are described in table 2.

Two independent researchers from each hospital, blinded to allocation as described previously, will conduct outcome assessments and data management. To ensure the quality of the assessment, the study team will perform central (online) and on-site training on data collection for three courses, each lasting 60–90 min. We will use paper for raw data collection, and all data will remain confidential. EpiData will be used for data entry, and two researchers will input the data independently to ensure data accuracy.

An investigator at each hospital in the seven regions of China will regularly monitor the quality of the study, including recruitment, intervention procedures and assessment. To ensure consistency of the procedures among the seven hospitals, a detailed implementation manual will be provided to all researchers and quality improvement team meetings will be held once a month among site investigators to provide feedback on problems encountered during the research and discuss solutions.

Adverse event and monitoring

After each training session, the tele-rehabilitation app will send a questionnaire to provide feedback on adverse events. Every week, one-on-one therapists will give telephone calls to assess for adverse effects. Once an adverse event occurs during the 6-month intervention period, it will be reported through the app, which will automatically alert the researchers. Thereafter, the intervention will be terminated immediately, and a report will be promptly sent to site investigators to confirm whether it is related to the intervention or not or review the grading. All adverse effects will be recorded promptly and reported in the final paper, including the start and end times of the adverse events, patient symptoms/signs, corresponding measures taken and results of adverse events. All serious and unanticipated adverse events will be reported to the appropriate institutional review board.

Ethics and dissemination

The study was approved by the biomedical research ethics committee of West China Hospital of Sichuan University (2021-579) and registered with the Chinese Clinical Trial Registry (ChiCTR2200058780) prior to recruitment (May 2022). This study will follow the principles of the Declaration of Helsinki, and written informed consent will be obtained from each participant after agreeing to participate in the study. The study findings will be presented at national and international scientific conferences and published in peer-reviewed journals. Results are propagated regardless of the magnitude or direction of the impact. Authorship is assigned according to authorship guidelines as defined by the International Board of Medical Journal Editors, and each author's role is based on journal requirements for publication.

DISCUSSION

Since there is insufficient evidence for the effect of exercise intervention, especially tele-e rehab intervention, on fracture incidence after OP, this study will lay the foundation for evidence formation.

This study has several strengths. To our knowledge, this is the first study to evaluate the impact of tele-e rehab on women at high risk of fracture. This is a well-designed, randomised, multicentre study with a large sample size. The application of tele-rehabilitation to patients with OP will be beneficial in overcoming the barriers of participation in exercise observed in patients with OP and broadening access to exercise intervention. The intensity of tele-exercise is set to moderate to high according to guidelines and expert opinion, higher than the low or moderate intensity used in the vast majority of studies. Meanwhile, to ensure the safety of the participants during the exercise, the following safety precautions will be taken: (1) setting strict inclusion and exclusion criteria as described above, and based on the incidence of OP and the safety of exercise, we will include women aged between 40 and 70 years; (2) signing an informed consent form for exercise rehabilitation; (3) evaluating each participant's home environment at baseline assessment and at 12, 24 and 48 weeks. If there is a risk, the participants and caregivers will be instructed to transform the home environment to ensure safety; (4) after enrolment, each participant has a period to familiarise with the rehabilitation app after the research team has guided them on how to use it; (5) the study therapists will give face-to-face guidance for exercise training to ensure the exercise methods correct and safety of participants; (6) the chest-worn heart rate band is connected to the tele-rehabilitation app to ensure exercise safety, and dynamic adjustment of exercise intensity and time will be conducted during the whole period; and (7) each participant will be provided with medical insurance in case of accidents. This study also has several limitations. Using the rehabilitation app to deliver exercise rehabilitation intervention may exclude participants who either do not have access to the internet or have a device that connects to the internet but have difficulty using it. Moreover, this form of long-lasting intervention and tele-exercise interventions may influence participants' adherence.

Author affiliations
[1]West China School of Nursing, Sichuan University/ Department of Rehabilitation, West China Hospital, Sichuan University, Chengdu, Sichuan, China
[2]Department of Rehabilitation, West China Hospital, Sichuan University, Chengdu, Sichuan, China
[3]Key Laboratory of Rehabilitation Medicine in Sichuan Province, West China Hospital, Sichuan University, Chengdu, Sichuan, China
[4]Center of Biostatistics, Design, Measurement and Evaluation (CBDME), West China Hospital, Sichuan University, Chengdu, Sichuan, China
[5]Department of Nursing/Evidence-based Nursing Center, West China Hospital, Sichuan University, Chengdu, Sichuan, China

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Contributors SL and YL contributed to the study design. SL drafted the study protocol. SL and QL formulated a tele-exercise program. W-JY planned the statistical strategy and was actively involved in the sample size calculations and random allocation. RZ and XW were responsible for the osteoporosis health education program. CD and YJ conceived the study and had final responsibility for publication. All authors were involved in editing the protocol for critically important contexts and have approved the final version of the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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ORCID iDs
Yi Li http://orcid.org/0000-0002-6714-3028
Yan Jiang http://orcid.org/0000-0002-9813-3738

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