Study Protocol

Individualised monitoring programme for pulmonary rehabilitation of patients with chronic obstructive pulmonary disease—study protocol for a randomised controlled trial

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Background: Chronic obstructive pulmonary disease (COPD) is characterised mainly by exertional dyspnoea, which may lead to activity reduction. Pulmonary rehabilitation (PR) is considered capable of mitigating these impairments. However, access to PR is limited to specialised centres, especially during the coronavirus disease 2019 pandemic. Moreover, low-cost home rehabilitation programmes have non-individualised prescriptions, which might lead to inconsistent clinical effects in patients with COPD. Therefore, it is important to develop new, low-cost protocols involving individualised prescriptions and staff supervision.

Methods: This is a descriptive protocol for a randomised controlled study at the Grade III A Hospital in Tianjin. The sample size was calculated according to a described formula. Fifty-six participants will be selected and randomly allocated into two groups: (I) control (traditional PR training, medication, and nursing interventions); and (II) intervention [PR training in the hospital and at home by the Cardiopulmonary Rehabilitation System Management Platform (CSM)]. The protocol will be performed twice a week for 8 consecutive weeks in the outpatient clinic, and the training will be performed by the application of the CSM system in the final 6 months of the trial. The study will assess lung function and physical fitness and analyse the scores of the modified Medical Research Council Dyspnoea Scale, the COPD assessment test, the International Classification of Functioning, Disability, and Health, and the 6-minute walk test before and after the training protocol. Comparison of differences will be performed using repeated measures analysis of variance, a linear mixed effects analysis, or a non-parametric test, which will include only participants who completed all outcome measures and followed the intervention protocol. The study results will be disseminated through presentations at scientific conferences and publications in peer-reviewed journals.

Discussion: The new, low-cost supervised rehabilitation programmes are expected to present positive results, making PR programmes more accessible and effective for patients with COPD.

Trial Registration: The study was registered in the Chinese Clinical Trial Registry: ChiCTR2000040723.

Keywords: Chronic obstructive pulmonary disease (COPD); mobile health technology; pulmonary rehabilitation; randomised controlled trial

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Introduction

Chronic obstructive pulmonary disease (COPD) is defined by chronic respiratory symptoms and airflow limitation, and a major clinical COPD phenotype is emphysema, characterised mainly by exertional dyspnoea, which may lead to spontaneous bed rest or reduced activity (1). Pulmonary rehabilitation (PR) can improve the physical and mental status of patients with COPD by reducing symptoms, enhancing exercise ability, promoting autonomy, increasing participation in daily activities, improving quality of life, and realising long-term changes in health promotion behaviour, and it has recently attracted the attention of many researchers (2). However, a recent survey by the *British Medical Journal* (3) suggested that traditional PR, including exercise training, education, and self-management, is available to only a small fraction of patients with COPD (4). As the exercise prescription is not individualised, the empirical protocol may under- or over-estimate the patient's capacity, leading to muscle soreness, fatigue, and inconsistent clinical effects based on patient type. Owing to inconvenient transportation, poverty, and frailty (5), the results of current centre-based PR services do not apply to the current social environment. Furthermore, coronavirus disease 2019 (COVID-19) has greatly impacted pulmonary rehabilitation programmes (PRPs) owing to the fear of viral transmission and resultant outbreaks of COVID-19. The number of PRPs has been significantly reduced or, in some cases, completely shut down (6). To address this problem, some hospital- or clinic-centred PRPs have converted some or all of their learning content to home-based telerehabilitation during the pandemic (7-9). Patients with chronic diseases are willing to manage themselves with smartphones (10). However, medical staff cannot receive objective data feedback or monitor the training situation or the effects on patients with the rehabilitation. Furthermore, most patients with COPD are unaware of the variation in their condition, and few receive follow-ups from doctors, which may lead to the coexistence of multiple diseases over time (11). Telerehabilitation is characterised by home-based activities performed by patients under professional supervision using communication technologies such as mobile devices, the internet, and remote control and monitoring (4). Thus, no patient dislocation is needed, and a lack of programs, issues associated with travel and transport can all be solved (12). Nevertheless, the high cost prevents its feasibility for low-income patients. In China, most existing studies (13,14) use questionnaires, lacking objective indicators that reflect the health of patients, which makes the rehabilitation effect unconvincing. Therefore, considering the limited access to PR in specialised centres and other issues mentioned above, our study developed a rehabilitation programme called the Cardiopulmonary Rehabilitation System Management Platform (CSM), which uses the internet and monitoring devices to provide online education and collect data based on patients' rehabilitation exercises, enabling therapists to monitor patients in real time. Our study is based on a system suitable for patients with COPD, and it relies on the cooperation of the PR teams to provide remote respiratory rehabilitation services and to observe the impact of a remote, intelligent PR service system on the activity of the patients. We present this article in accordance with the SPIRIT reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-964/rc).

Methods

Study design

The present study is a randomised prospective clinical trial. Owing to the nature of the intervention programme, the study participants, clinical, and research staff who collect clinical outcome data will be aware of group allocation. However, the randomisation assignment will be concealed from the outcome adjudication committee members. The study will adhere to the Declaration of Helsinki (as revised in 2013). Ethical approval was obtained from the Ethics Committee of Tianjin Fourth Central Hospital (No. SZXLL-2020-KY0413), and the trial was retrospectively registered in the Chinese Clinical Trial Registry: ChiCTR2000040723. The trial status is the registration date, and the initial data is on 1 October 2020. The actual status is ongoing, and the prevision is for December 2023. The study will use a quantitative methodology study with a measurement protocol that utilizes clinical examination as

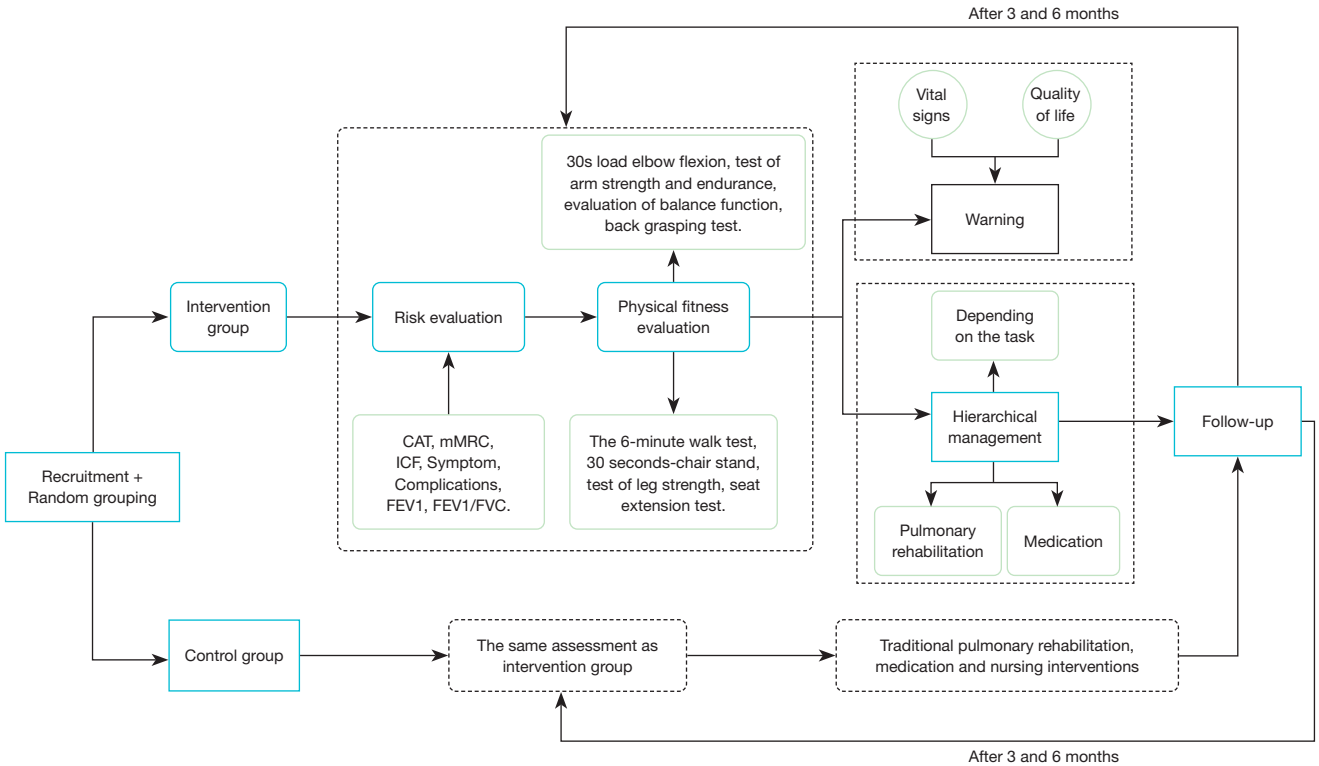

Figure 1 A diagram of the proposed care pathway. CAT, COPD assessment test; mMRC, modified Medical Research Council Dyspnoea Scale; ICF, International Classification of Functioning, Disability, and Health; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity; COPD, chronic obstructive pulmonary disease.

well as internationally accepted scales to effectively ensure the objectivity of the trial. After recruitment, participants will be invited to the outpatient clinic to perform an initial evaluation, and a secure web-based randomisation system will be used to allocate participants into two groups: the control group will be performed traditional PR training, medication, and nursing interventions; and the intervention group will be performed twice a week for 8 consecutive weeks in the outpatient department, and the last 6 months will include training in the application of the CSM system. Questionnaires and physical examinations will be conducted at baseline and at 1, 3 and 6 months of follow-up to check for changes in pulmonary function, dyspnoea, and health status. The details of the study are shown in *Figure 1* and *Table 1*.

Sample size

The sample size will be based on detection of a minimum difference of 54 m in the 6-minute walk test (6-MWT) (15) between the control and intervention groups and using a baseline standard deviation (SD) of 57 m (16). With a power of 90% and an alpha of 5% (two-sided) (17), the minimum sample size per group will be 23, for a total of 46 participants. Assuming a dropout rate of 20%, the minimum sample size will be 56 (28 participants per group).

Participants

According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD), individuals with a clinical diagnosis of COPD being treated in two general tertiary hospitals in Tianjin between October 2020 and December 2023 will be enrolled in the study. All participants will receive information regarding their participation in the study and will sign the informed consent form. All patients' information will be kept confidential during the study. The inclusion criteria are as follows: (I) aged between 40 and 80 years; (II) patients with GOLD 2023 spirometry stages B or E; (III) good communication and cooperation

Table 1 Clinical outcomes before and after the study for patients who completed the study

Outcomes	Enrolment (T_{-1})	Allocation	Post allocation		
		Baseline (T_0)	1 months (T_1)	3 months (T_2)	6 months (T_3)
Enrolment	–	–	–	–	–
Eligibility screen	×	–	–	–	–
Informed consent	×	–	–	–	–
Allocation	–	×	–	–	–
Assessment	–	–	–	–	–
Six-minute walk test	–	×	×	×	×
Back scratch (l)	–	×	×	×	×
Back scratch (r)	–	×	×	×	×
Chair sit and reach (l)	–	×	×	×	×
Chair sit and reach (r)	–	×	×	×	×
Arm curl (left) (rep.)	–	×	×	×	×
Arm curl (right) (rep.)	–	×	×	×	×
Chair stand (rep.)	–	×	×	×	×
ICF	–	×	×	×	×
CAT	–	×	×	×	×
mMRC	–	×	×	×	×

The table lists the time points for enrolment, interventions, and assessment. Baseline characteristics include pulmonary function assessed by spirometry, dyspnoea assessed by mMRC; ADL assessed by the CAT; and height and weight assessed by a body tester. ×, represents the data need to be filled in the future; –, represents these places do not need to be filled with data. l, left; r, right; rep., repeat; ICF, International Classification of Functioning, Disability, and Health; CAT, chronic obstructive pulmonary disease assessment test; mMRC, modified Medical Research Council Dyspnoea Scale; ADL, activities of daily life.

in completing the whole study; and (IV) proficiency in using smartphones. The exclusion criteria are as follows: (I) pneumonia, tuberculosis, and other respiratory inflammatory diseases; (II) severe comorbidities, including cardiovascular, liver, or kidney disease; and (III) other problems that make it impossible to walk or prevent the assessment of body composition. The cessation criteria are as follows: (I) those who have an aggravated condition or other emergencies in the study and need urgent medical treatment. (II) Those who have poor compliance, low participation, and cannot complete the project research.

Intervention

The PR protocol will be performed twice a week for 8 consecutive weeks in the outpatient department. The exercises will be performed as follows: (I) fitness exercises, coordination and balance exercises, and stretching exercises using elastic tape. Exercises will be performed in standing or sitting positions. (II) Respiratory exercises for 30 minutes: relaxation exercises for breathing muscles, exercises to increase costal or chest breathing, belly breathing, and "Eight Duan Jin" to improve cardiorespiratory function; and (III) relaxation training: 15 minutes at a time. All activities will be supervised by a previously trained respiratory therapist, a doctor, and two nurses in a room with a controlled temperature set between 23 and 26 ℃. Physical training will be interrupted whenever the heart rate (HR) exceeds 85% of the individual's maximum HR value (220–age) or the oxygen saturation level drops (SpO_2) <90%.

In addition, the last 6 months will include training in the application of the CSM system, which will remotely supervise and guide the exercise prescription for at least 1 hours a day, according to the recommendations of the guidelines on PR in adults (18). Participants will be oriented to fill in the unsupervised exercise diary on the CSM

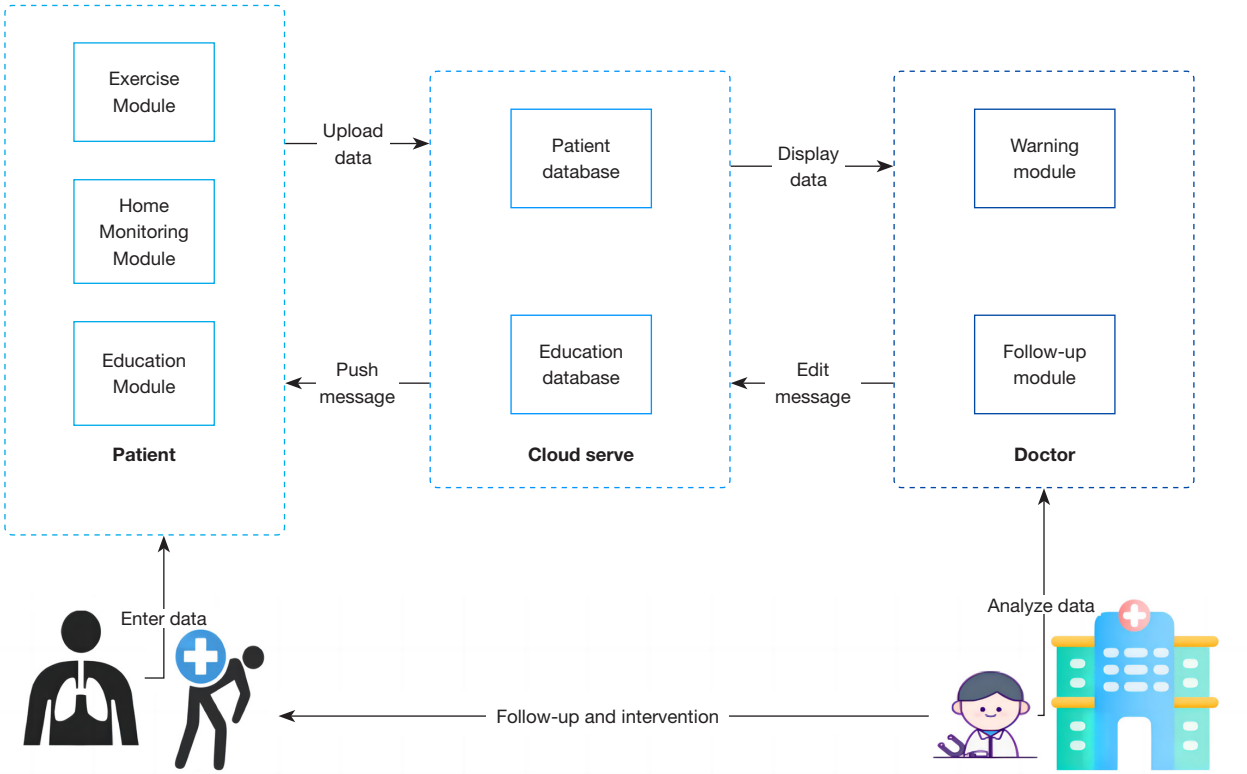

Figure 2 System architecture.

regarding the type of exercise, duration, and frequency, as well as for symptoms experienced during the activity. If any problems occur, we will contact the patient to change the prescription.

Control

Conventional medications and health education will be administered to the control group. At 1, 3, and 6 months, the therapist will provide appropriate health education and offer functional exercises appropriate to the patient's condition, such as breathing exercises or abdominal breathing. The nurse emphasises modifiable factors according to the patient's personal habits, such as doing an influenza vaccination each year or smoking cessation. Patients in the control group will also be able to go to the outpatient clinic for prescription medication to relieve their symptoms if needed.

The description of the CSM

Tele-PR management is implemented using the CSM system. As presented in *Figure 2*, the system involves three parts: the patient interface, cloud server, and doctor workstation. The patient interface will run on a smartphone and will have three modules: exercise, home monitoring, and education. The exercise module will guide the patients to record daily exercises and patients will be required to record their vital values through a home-monitoring module. The education module will include videos and texts on COPD-related educational materials. Patients will receive individual materials based on the rehabilitation assessment and all the data will be synchronised with the cloud.

The cloud server will store all data securely and an inference engine will provide decision support to patients, based on the uploaded vital signs, such as patient classification, follow-up scheduling, and warning generation. It can also recommend services, such as delivering educational materials via video and text.

The doctor's workstation will have a warning and a follow-up module. The warning module will alert rehabilitators as soon as the CSM detects abnormal data uploaded by the patients. The follow-up module will be

Figure 3 30-second chair stand. This image is published with the participants' consent.

convenient for rehabilitators to schedule patients and nurses for each follow-up. The system will provide complete patient information, including demographics, health assessments, and self-monitoring data history.

Outcomes

All participants will undergo assessments in the outpatient setting at enrolment, at baseline, and at the end of 3 and 6 months. The primary outcomes are pulmonary function tests, 6-MWT, and physical fitness, including strength, endurance, flexibility, balance, and motor coordination (19-24). The modified Medical Research Council Dyspnoea Scale (mMRC), COPD assessment test (CAT) scale, and International Classification of Functioning, Disability, and Health (ICF) questionnaires are used to measure secondary outcomes (25,26).

Assessments of basic characteristics

Assessments of basic characteristics will mainly assess pulmonary function, dyspnoea, and health status. Specialist personnel will perform the pulmonary function test. Participants will be instructed to breathe, and three reproducible measurements, such as forced expiratory volume in 1 second, forced vital capacity (FVC), and maximal mid-expiratory flow, will be obtained. The highest value will be recorded and used for analysis. The symptoms of dyspnoea will be assessed using the mMRC, a five-point scale (0–4) for the severity of dyspnoea, with a higher score indicating a higher severity. The CAT is simple for analysis, consisting of eight questions about general symptoms and limitations in activities of daily life. The score varies from 0 to 5 points for each item, with a maximum of 40 points. Lower scores correspond to a low impact of the disease on health status, and scores >10 correspond to patients with a poorer health status owing to COPD. In addition, body mass index will be calculated by measuring height and weight (27,28).

Peripheral muscle strength and flexibility

30-second chair stand: to assess lower body strength (23)
At least 5–10 minutes of rest will be allowed before performing this test. The patient will be encouraged to complete as many full stands as possible from the sitting position on a chair with a straight back without arm rests within 30 seconds. This test is illustrated in *Figure 3*.

Arm curl (24): to assess upper body strength, calculated as repetitions
The patient will be allowed to rest and will be instructed to sit on the chair, lean slightly against the side of the test arm, hold the dumbbell, and naturally droop, with the palm facing the inside to form a preparatory action. The patient will be asked to bend their elbows and lift the dumbbell to the highest point when they hear the command "Go", turning the palms upward during the process of lifting the dumbbell and inward during the return to the initial position; the upper arm will remain stationary during the test. The number of times the patient completes the action in 30 seconds will be noted. This test is illustrated in *Figure 4*.

Back-scratch (19): to assess upper body flexibility, calculated in centimetres
During the test, the patient's shoulders will be extended back and the hands touch or exceed each other along the spine as far as possible. When the movement is stable for >2 seconds, the distance between the middle fingers and the fingertips of both hands will be measured. This test is illustrated in *Figure 5*.

Chair sit and reach (20): to assess lower body flexibility, calculated in centimetres
During the test, the patient will be made to sit on a standard seat with a height of 43 cm. When the left leg is straightened, the forearm will be extended as far as possible, and the distance between the tip of the middle finger and the tip of the foot will be measured after 2 seconds. If the tip of the middle finger exceeds the tip of the foot, it will be recorded as a positive number; otherwise, it will be recorded as a negative number. The patient will be asked to repeat

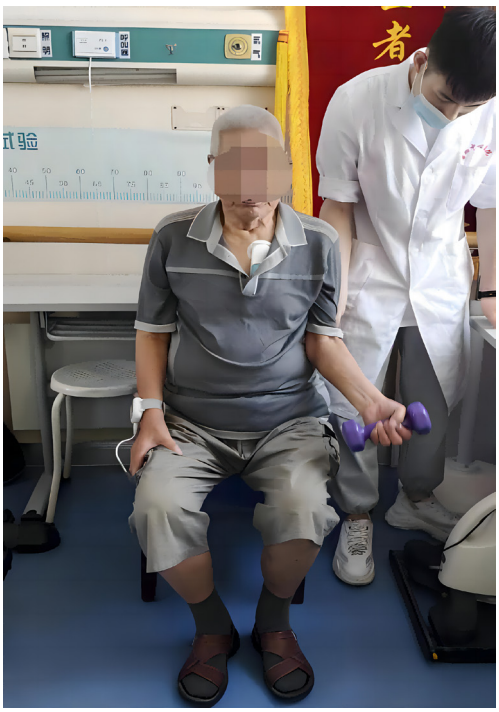

Figure 4 Arm curl. This image is published with the participants' consent.

Figure 5 Back-scratch. This image is published with the participants' consent.

the test on the right leg after rest. This test is illustrated in *Figure 6*.

The one-legged stance test (21): to assess agility and dynamic balance, calculated in seconds

The test will evaluate the patients' balance function reserve and fall risk, which is the basis for formulating a balance function training prescription for lung rehabilitation. This test is illustrated in *Figure 7*.

Figure 6 Chair sit and reach. This image is published with the participants' consent.

Figure 7 The one-legged stance test. This image is published with the participants' consent.

6-MWT (22)

6-MWT: to assess exercise performance calculated in metres.

The 6-MWT will be performed along a 30-metre corridor based on the CSM system. SpO_2 will be monitored continuously throughout the test, and the test will be terminated if SpO_2 falls <90%. SpO_2 will be recorded pre-exercise and at the lowest point during the test. The HR

Figure 8 Six-minute walking test. This image is published with the participants' consent.

will be continuously monitored throughout the test. This test is illustrated in *Figure 8*.

ICF (25)

The ICF (World Health Organization, 2001) is based on a biopsychosocial view of functioning, which is the outcome of the interaction between a health condition and contextual factors (environmental and personal factors). Based on this concept, the classification uses alphanumerical-coded ICF categories for the following components: body functions (b), body structures (s), activities and participation (d), and environmental factors (e). The ICF qualifiers will be applied to rate the degree of problems in each category of the body function and structure component and activity participation component on a five-point scale: 0, 1, 2, 3, and 4, which indicate no problems, mild, moderate, severe, and complete problems, respectively. Environmental factors will be graded on a nine-point scale: +4, +3, +2, +1, 0, 1, 2, 3, and 4, indicating complete, substantial, moderate, and mild facilitators, no barriers or facilitators, and mild, moderate, severe, and complete barriers, respectively (26). Moreover, eight and nine are also unspecified and not applicable in all categories. The internal consistency of the whole scale was 0.873, and the values for body function, structure, activity, and participation were 0.750, 0.640, and 0.843, respectively.

Statistical analysis

Microsoft Excel 2016 (Microsoft Corp., Redmond, WA, USA) and the R Foundation (http://www.r-project.org; version 4.2.1) will be used for pre-processing data, including the extraction of clinical outcomes from the database. For statistical analyses, R4.2.1, and IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA), will be used. A Kolmogorov-Smirnov test will be used to test for normality. Normal data will be expressed as mean ± SD, while non-normal data will be expressed as median and interquartile range (IQR). An intention-to-treat analysis will be used for the allocation. Missing outcome data will be handled using R.4.2.1. Comparisons of differences will be performed using repeated measures analysis of variance, a linear mixed effects analysis, or a non-parametric test, which will include only patients who completed all outcome measures and followed the intervention protocol. Statistical significance will be set at $P<0.05$.

Discussion

Current international guidelines recommend a minimum length of 6–12 weeks for a PRP, indicating a higher efficacy of programmes with a longer duration (29). During COVID-19, however, the number of PRPs was significantly reduced or, in some cases, completely shut down (6). The recent pandemic has raised interest in new services such as tele-rehabilitation. This may lead to some unanswered questions, such as the rehabilitation effects. Recent studies (30-33) have reported the effects of low-cost, home-based physical rehabilitation associated with educational and supervised programmes. In this study, we have designed and will implement a feasible method to manage patients with moderate and severe COPD undergoing PR and determine how to select the right home-based rehabilitation programme using an mHealth-based system over a 6-month

period, despite the challenges with physical function monitoring outside of the hospital. We believe that the protocols used in our study of combined outpatient and home training will guide healthcare providers and patients to implement the most effective PR. This study aims to investigate the effects of prescribed pulmonary exercise on lung function, exercise capacity, quality of life, and psychological function in patients with COPD and is expected to provide a comprehensive understanding of the effects of prescribed pulmonary exercise on patients with COPD by comparing usual care, pulmonary exercise, and education with tele-PR. We introduce an mHealth-based method for COPD management using CSM. The tailored closed-loop-care pathway will be feasible and effective in areas with limited medical resources. Moreover, despite the advanced age of the participants, proper education and simple interfaces may encourage their acceptance and use of smartphones to support COPD self-management.

In terms of the completion rate, a previous study (34) based on a 6-month intervention in patients with COPD had a dropout rate of 30%. Another study (20) in patients with COPD with a similar protocol had a dropout rate of 5%. The differences in the completion rates in previous studies may be attributed to various factors, including the duration of the intervention, content differences, and disease severity. Even though the dropout rates vary, a high completion rate for tele-PR intervention is predicted. For traditional PR in COPD patients, the dropout rates for intervention protocols are in the range of 15–25% (35,36). Hence, an assumed drop-out rate of 20% is feasible for this study.

Strengths and limitations of the study

The sedentary behaviour of most patients with COPD is difficult to reverse without the sustained effort of professionals trained in motivational techniques and the support of similarly afflicted patients in group sessions, the premises of which address an important problem in rehabilitation: how to motivate patients with COPD to perform regular physical fitness exercises at home? This problem develops when the patient is discharged from the hospital and no longer has regular supervision of health care. Our research addresses this through regular prescriptions from the rehab, clocking in to complete the daily content by patients, and regular outpatient follow-up monitoring. Meanwhile, during outpatient follow-up, patients will be able to compare their recovery results with those of fellow patients to motivate each other, which may avoid the above problems.

A limitation of this study is the inclusion of only GOLD stages B and D. Stable patients (A or C) have a low probability of hospitalisation, which may affect the extrapolation of findings. The study will present findings from 6 months of PRPs, and it may be assumed that the results might have been even better if the study lasts longer. In this study, we will not evaluate application satisfaction using standardised questionnaires.

Assessment of safety

The data monitoring committee (DMC) will be composed of at least two members from the Biomedical Ethics Committee of Tianjin Fourth Central Hospital, who have no conflicts of interest with our study. The DMC will conduct regular monitoring and review of the study, and will report the findings to the Ethics Committee. This process will operate independently of the primary investigators. If the DMC identifies deviations from the approved research protocol or unauthorized changes to the study procedures during the research process, they have the authority to suspend or terminate the study. Furthermore, adverse and serious adverse events will be recorded at the outpatient department in each assessment, such as readmission or other issues related to the research procedure and will be provided as a summary. Where an event requiring recording occurs, full details including the nature of the event, start and stop dates, severity, relationship to the research product or trial procedures, and the outcome of the event will be recorded in the participant's medical notes. These events will be monitored until satisfactory resolution and stabilisation are achieved (37). Each adverse event will be assessed to determine whether it is related to the study.

Protocol amendments

Any change in the study protocol will require an amendment. Any proposed protocol amendments will be initiated following a discussion by the project steering group.

Other important information about the study

We have verified the pre- and post-rehabilitation effects and also considered the minimum clinically important difference in the whole study to confirm the further effects

of the intervention. In addition, we will re-evaluate the patients after each intervention, observe the frequency of the exercises performed weekly, and ask about adherence to exercise, which will be recorded in the CSM system. All patients will receive medical support while participating in the study.

Contribution and clinical applicability

The main contributions will be a more accessible alternative and low-cost rehabilitation for patients with COPD, which also includes individualised prescriptions. Hence, it may be more effective than the alternatives described in previous studies. Moreover, more COPD patients can undergo PRP in an alternative location, such as at home or in the community. We expect that the protocol could be adapted and applied in different situations, such as in remote areas of China or in patients with low education.

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Footnote

Reporting Checklist: The authors have completed the SPIRIT reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-964/rc

Peer Review File: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-964/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-964/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study will adhere to the Declaration of Helsinki (as revised in 2013). The ethical approval was obtained from the Ethics Committee of Tianjin Fourth Central Hospital (No. SZXLL-2020-KY0413), and the trial was retrospectively registered in the Chinese Clinical Trial Registry: ChiCTR2000040723 (on 8 December 2020, https://www.chictr.org.cn/showproj.aspx?proj=65438). All participants will receive information regarding their participation in the study and will sign the informed consent form. All patients' information will be kept confidential during the study.

References

1. Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2022. Available online: https://goldcopd.org/2023-gold-report-2/
2. Dixit S, Borghi-Silva A, Bairapareddy KC. Revisiting pulmonary rehabilitation during COVID-19 pandemic: a narrative review. Rev Cardiovasc Med 2021;22:315-27.
3. Holland AE, Jones AW, Mahal A, et al. Implementing a choice of pulmonary rehabilitation models in chronic obstructive pulmonary disease (HomeBase2 trial): protocol for a cluster randomised controlled trial. BMJ Open 2022;12:e057311.
4. Shenoy MA, Paul V. Pulmonary Rehabilitation. Treasure Island, FL, USA: StatPearls Publishing; 2023.
5. Ji W, Kwon H, Lee S, et al. Mobile Health Management Platform-Based Pulmonary Rehabilitation for Patients With Non-Small Cell Lung Cancer: Prospective Clinical Trial. JMIR Mhealth Uhealth 2019;7:e12645.
6. Candy S, Reeve J, Dobson R, et al. Characteristics of pulmonary rehabilitation programmes in New Zealand: a survey of practice prior to and during COVID-19. N Z Med J 2022;135:13-25.
7. Hu J, Long Y. A commentary on "Efficacy of pulmonary rehabilitation in improving the quality of life for patients with chronic obstructive pulmonary disease: Evidence based on nineteen randomized controlled trials - A systematic review and meta-analysis" [Int. J. Surg. 73 (2020) 78-86]. Int J Surg 2021;89:105934.
8. Bernocchi P, Vitacca M, La Rovere MT, et al. Home-based telerehabilitation in older patients with chronic obstructive

pulmonary disease and heart failure: a randomised controlled trial. Age Ageing 2018;47:82-8.
9. Tsai LL, McNamara RJ, Moddel C, et al. Home-based telerehabilitation via real-time videoconferencing improves endurance exercise capacity in patients with COPD: The randomized controlled TeleR Study. Respirology 2017;22:699-707.
10. Dou K, Yu P, Deng N, et al. Patients' Acceptance of Smartphone Health Technology for Chronic Disease Management: A Theoretical Model and Empirical Test. JMIR Mhealth Uhealth 2017;5:e177.
11. da Silva MMC, Arcuri JF, Di Lorenzo VAP. Individualized, low-cost and accessible pulmonary rehabilitation program based on functional clinical tests for individuals with COPD-a study protocol of a randomized controlled trial. Trials 2021;22:367.
12. Cox NS, Dal Corso S, Hansen H, et al. Telerehabilitation for chronic respiratory disease. Cochrane Database Syst Rev 2021;1:CD013040.
13. Wang Y, Di R, Zhou J, et al. Effect of remote pulmonary rehabilitation management in patients with CPOD. Chin J Mod Nurs 2021;27:2073-8.
14. Zhang H, An K, Su Q, et al. Application status of telerehabilitation for chronic obstructive pulmonary disease under the epidemic of coronavirus disease 2019. West China Medical Journal 2022;37:1140-4.
15. Ng BH, Tsang HW, Jones AY, et al. Functional and psychosocial effects of health qigong in patients with COPD: a randomized controlled trial. J Altern Complement Med 2011;17:243-51.
16. Liu X, Li P, Xiao L, et al. Effects of home-based prescribed pulmonary exercise by patients with chronic obstructive pulmonary disease: study protocol for a randomized controlled trial. Trials 2019;20:41.
17. Neal B, Tian M, Li N, et al. Rationale, design, and baseline characteristics of the Salt Substitute and Stroke Study (SSaSS)-A large-scale cluster randomized controlled trial. Am Heart J 2017;188:109-17.
18. Spruit MA, Singh SJ, Garvey C, et al. An official American Thoracic Society/European Respiratory Society statement: key concepts and advances in pulmonary rehabilitation. Am J Respir Crit Care Med 2013;188:e13-64.
19. García-Garro PA, Hita-Contreras F, Martínez-Amat A, et al. Effectiveness of A Pilates Training Program on Cognitive and Functional Abilities in Postmenopausal Women. Int J Environ Res Public Health 2020;17:3580.
20. Rutkowski S, Rutkowska A, Kiper P, et al. Virtual Reality Rehabilitation in Patients with Chronic Obstructive Pulmonary Disease: A Randomized Controlled Trial. Int J Chron Obstruct Pulmon Dis 2020;15:117-24.
21. Araujo CG, de Souza E Silva CG, Laukkanen JA, et al. Successful 10-second one-legged stance performance predicts survival in middle-aged and older individuals. Br J Sports Med 2022;56:975-80.
22. Agarwala P, Salzman SH. Six-Minute Walk Test: Clinical Role, Technique, Coding, and Reimbursement. Chest 2020;157:603-11.
23. Wareńczak A, Lisiński P. Body balance a few years after total hip replacement. Acta Bioeng Biomech 2020;22:87-96.
24. Liu CJ, Marie D, Fredrick A, et al. Predicting hand function in older adults: evaluations of grip strength, arm curl strength, and manual dexterity. Aging Clin Exp Res 2017;29:753-60.
25. Abdi S, Spann A, Borilovic J, et al. Understanding the care and support needs of older people: a scoping review and categorisation using the WHO international classification of functioning, disability and health framework (ICF). BMC Geriatr 2019;19:195.
26. Zhang Y, Meng X, Shen Y, et al. The Reliability and Validity of the Brief ICF Core Set in Patients with Chronic Obstructive Pulmonary Disease. Int J Chron Obstruct Pulmon Dis 2021;16:2077-87.
27. Ge P, Li Q, Dong M, et al. Self-medication in Chinese residents and the related factors of whether or not they would take suggestions from medical staff as an important consideration during self-medication. Front Public Health 2022;10:1074559.
28. Hogg JC, Chu F, Utokaparch S, et al. The nature of small-airway obstruction in chronic obstructive pulmonary disease. N Engl J Med 2004;350:2645-53.
29. Nici L, Lareau S, ZuWallack R. Pulmonary rehabilitation in the treatment of chronic obstructive pulmonary disease. Am Fam Physician 2010;82:655-60.
30. Campo G, Tonet E, Chiaranda G, et al. Exercise intervention improves quality of life in older adults after myocardial infarction: randomised clinical trial. Heart 2020;106:1658-64.
31. Dor-Haim H, Katzburg S, Leibowitz D. A Novel Digital Platform for a Monitored Home-based Cardiac Rehabilitation Program. J Vis Exp 2019;(146):10.3791/59019.
32. Holtz B, Krein SL, Bentley DR, et al. Comparison of Veteran experiences of low-cost, home-based diet and exercise interventions. J Rehabil Res Dev 2014;51:149-60.

33. Burke L, Lee AH, Jancey J, et al. Physical activity and nutrition behavioural outcomes of a home-based intervention program for seniors: a randomized controlled trial. Int J Behav Nutr Phys Act 2013;10:14.
34. Deng N, Chen J, Liu Y, et al. Using Mobile Health Technology to Deliver a Community-Based Closed-Loop Management System for Chronic Obstructive Pulmonary Disease Patients in Remote Areas of China: Development and Prospective Observational Study. JMIR Mhealth Uhealth 2020;8:e15978.
35. Chen Y, Niu M, Zhang X, et al. Effects of home-based lower limb resistance training on muscle strength and functional status in stable Chronic obstructive pulmonary disease patients. J Clin Nurs 2018;27:e1022-37.
36. Nyberg A, Lindström B, Rickenlund A, et al. Low-load/high-repetition elastic band resistance training in patients with COPD: a randomized, controlled, multicenter trial. Clin Respir J 2015;9:278-88.
37. Taylor A, Lowe DJ, McDowell G, et al. Remote-Management of COPD: Evaluating the Implementation of Digital Innovation to Enable Routine Care (RECEIVER): the protocol for a feasibility and service adoption observational cohort study. BMJ Open Respir Res 2021;8:e000905.

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