


BMJ Open Digital gamification-based pursed lip breathing exercises driven by Behaviour Change Wheel in patients with COPD: a feasibility trial protocol using pre-post study design

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ABSTRACT

Introduction Effective chronic obstructive pulmonary disease (COPD) interventions require intensive and repetitive exercises, yet their monotonous nature can reduce adherence. Innovative rehabilitation devices that are safe, user-friendly, engaging and cost-effective are crucial. This study introduces a digital gamification-based approach to pursed lip breathing (PLB) exercises, guided by the Behaviour Change Wheel (BCW) framework. The digital platform transforms traditional PLB into an interactive and enjoyable experience, enhancing motivation and adherence. Using a pre-post study design, this feasibility trial aims to assess the safety, feasibility and acceptability of the digital gamification PLB intervention protocol driven by the BCW framework installed on WeChat (DT-PLB) for home-based COPD management.

Methods and analysis The methodology of this study is divided into two phases. Phase 1 refers to the development of the DT-PLB system based on research evidence, behavioural analysis from the insight of the BCW and stakeholders' perspectives, and phase 2 points to present the pre-post trial design for the DT-PLB system consisting of five smartphone-based software interface modules: Ranking, Report, Daily PLB Tasks, Social Community and Mine. Eligible patients with COPD will be recruited from a university hospital in Sichuan Province, Mainland China. The DT-PLB will be conducted in non-hospital settings for patients with COPD for 10 min per session, three times a day on a daily basis for 8 weeks. Data collection will be conducted at two time points: baseline and post-intervention.

Demographic data (eg, age, gender and marital status) will be collected only at baseline. The primary outcome measures in this study will be a series of feasibility outcomes involving participant recruitment and completion of the DT-PLB intervention. Additionally, several clinical outcomes in terms of the effects of the DT-PLB intervention on dyspnoea, exercise capability, quality of life, and pulmonary function index will be evaluated as secondary outcomes.

Ethics and dissemination This study has received Manchester Metropolitan University ethical approval (REC reference 56631) and the Affiliated Hospital of

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The trial will examine the feasibility, acceptability and safety of a novel digital gamification-based pursed lip breathing (PLB) exercises for patients with chronic obstructive pulmonary disease (COPD).
- ⇒ This study develops an innovative gamification-based digital platform grounded by the Behaviour Change Wheel framework, which transforms traditional PLB exercises into an engaging and interactive experience to enhance adherence among patients with COPD.
- ⇒ The absence of a control group in this study will undermine the capability to determine definitive conclusions on the real effects of the DT-PLB intervention.
- ⇒ The lack of benchmarks for evaluating feasibility and acceptability, along with the absence of measures for respiratory muscle strength, may limit insights into the effects of the DT-PLB intervention.

Southwest Medical University ethical approval (REC reference KY2023105). The findings from DT-PLB will be disseminated widely through peer-reviewed publications, scientific conferences and workshops. If successful, DT-PLB will be directly applied to the Affiliated Hospital of Southwest Medical University to manage PLB exercises.
Trial registration number [NCT06063733](https://www.clinicaltrials.gov/ct2/show/study?term=NCT06063733).

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) represents a significant and escalating global health challenge, characterised by persistent respiratory symptoms and airflow limitation.¹ Despite advancements in medical interventions, COPD remains a leading cause of morbidity and mortality, necessitating innovative approaches to enhance patient outcomes and quality of life (QoL).

Pulmonary rehabilitation, which incorporates various therapeutic exercises, is a

cornerstone of COPD management.² Among these, pursed lip breathing (PLB) is a promising intervention for alleviating dyspnoea, improving exercise capacity, enhancing quality of life (QoL) and supporting pulmonary function, and the detailed PLB procedures are outlined in the principal researcher's previously published article.³ However, its effectiveness relies on consistent practice.^{4,5}

PLB is an ideal home-based intervention for stable patients with COPD in China, as it is a simple, cost-effective and noninvasive breathing exercise particularly suitable for middle- and low-income individuals.³ Unlike pulmonary rehabilitation or high-intensity exercise, PLB is easy to learn, is safe to perform at home and does not require special equipment or hospital visits.³ Its simplicity makes it especially beneficial for older patients with COPD who may struggle with more complex interventions.

However, adherence to PLB exercises in China has been reported to be significantly low, with rates ranging from only 25% to 32%.⁶ Key factors contributing to this low adherence include a lack of knowledge and skills related to PLB, the absence of supportive systems such as reminders, monitoring or feedback and the monotonous nature of the exercise process.^{6,7} These challenges are particularly pronounced among patients with COPD discharged from hospitals, who often experience difficulty in maintaining engagement with traditional PLB methods. Therefore, strategies to improve adherence should focus on addressing these barriers by enhancing patient engagement and creating more interactive and supportive exercise environments.

The growing prevalence of internet and mobile phone usage^{8,9} means that digital interventions are within reach of most patients, offering information and support at their convenience. Digital gamification intervention has emerged as a promising strategy to address adherence issues by integrating game design elements such as point scoring, leader boards and challenges into non-game contexts to enhance user motivation and engagement.¹⁰ The incorporation of digital gamification into behavioural change fields uses the motivational power of gaming to transform patient experiences and outcomes.^{11,12}

Current evidence suggests that using digital gamification can lead to a better and more efficient result in improving adherence to physical exercise in patients with COPD.^{13,14} However, there still remains unknown regarding combining digital gamification with PLB exercise intervention for patients with COPD.¹⁴ Generally, it is essential to apply a behavioural change theory when developing a digital gamification intervention as this can improve transparency and replication in a more structured approach.

Behaviour Change Wheel (BCW), which provides a framework for designing and evaluating behavioural change strategies and helps understand how to motivate individuals to adopt and maintain new behaviours, underpins the design of these gamified interventions.¹⁵ Using BCW principles—such as action planning and clear missions—digital gamification can create an effective and

robust intervention that encourages sustained participation in therapeutic exercises.

Therefore, a digital gamification-based PLB programme has been developed by embedding PLB exercises within a gamified digital platform, WeChat mini-program as the most popular social media, guided by the BCW framework (DT-PLB) delivered in an acceptable and feasible online format. By integrating digital gamification techniques grounded in behavioural change principles, this novel intervention is hypothesised to enhance patient adherence, engagement and clinical outcomes, representing the initial phase of a larger clinical trial with an expanded sample size. This study protocol outlines a feasibility trial of the DT-PLB programme for patients with COPD using a pre-post study design.

Study aims and objectives

This study aims to determine the safety, feasibility and acceptability of a digital gamification PLB intervention protocol driven by the BCW framework installed on WeChat for managing PLB exercises in patients with COPD and to preliminarily evaluate the effects of the DT-PLB intervention via a pre-post study. The study objectives are:

1. To identify potential adverse effects associated with the DT-PLB intervention in patients with COPD.
2. To determine the recruitment rate, retention rate, attrition rate, as well as software usage adherence during the period of patient recruitment and intervention process.
3. To evaluate the usability and participants' satisfaction with the DT-PLB system.
4. To preliminarily evaluate the effects of the DT-PLB intervention in patients with COPD.

METHODS AND ANALYSIS

Study design

This DT-PLB intervention will be initially evaluated for recruitment and acceptability by assessing quantitative parameters, including participants' recruitment, retention and attrition rates. The preliminary endpoints for this complex intervention will be assessed using a pre- and post-test quasi-experimental design with a single arm. This pre-post study design without a control group is commonly accepted and used during the feasibility study phase in the healthcare context.¹⁵ This study will conduct two measurements at baseline and post-intervention.

Study setting

This study will be conducted only in a university hospital, situated in Luzhou, a city in southwest China with over 5 million population. All assessments will be performed at the hospital, and this complex intervention will be implemented in non-hospital settings, such as the participants' home environment.

Trial status

Data collection is ongoing at the time of submission of this study protocol.

Participants

Inclusion criteria

1. Diagnosed with COPD satisfying GOLD criteria¹⁶
2. Being Chinese
3. Able to understand, speak, and hear
4. Clinically stable for at least 3 months prior to enrolment¹⁷
5. The classification of GOLD grades for patients is mild, moderate and severe, which means FEV1/FVC <70%, FEV1 >30% predicted¹⁶
6. Participants who were mindful about the IT technology and know how to use a smartphone
7. Willing to participate in this study.

Exclusion criteria

1. Impaired hand function causing an inability to use the application
2. Have disorders in pleural effusion, pulmonary malignancy, heart diseases, stroke with sequels
3. Patients who have oral or nasal diseases cannot complete the exercise.

Sample size

It is widely accepted that sample size calculations are typically not required for feasibility studies.¹⁸ According to the rule of thumb, having 12 participants is generally considered sufficient for a feasibility or pilot study.¹⁹ However, considering a common participation refusal rate of around 20%, it is recommended to recruit a minimum of 16 participants for this feasibility study.

Recruitment

The hospital information system used to store all patients' information will be screened to identify potentially eligible participants according to the study's inclusion and exclusion criteria. A predetermined table will be formulated to record potential participants' data including telephone numbers and diagnoses. Afterwards, phone calls will be made to potential participants to invite them to the hospital to attend a research presentation by providing a concise overview of the research project. During the calls, potential participants will also be told that this project would offer complimentary transportation from their current locations to the hospital. On expressing interest in participating, potential participants will return to the hospital to attend the presentation, which will be held in the lecture hall of the hospital. Then, after receiving a participation information sheet, consent form and software usage booklet, each attendee will be thoroughly explained the study's objectives, procedures, potential risks, benefits and rights as a participant associated with their involvement. In addition, participants could ask any questions related to this study. More importantly, participants will be told that they have the right to withdraw at any time without any penalty, and the decision

to withdraw will not have any impact on their healthcare services. After agreeing to participate in this study, potential participants will immediately attend a free pulmonary function index test to determine if they meet the eligibility criteria. Participants who meet inclusion and exclusion criteria will be taught how to conduct PLB and operate the software after signing the consent form.

Intervention

Before developing the DT-PLB intervention, the principal researcher in this study had developed and published the home-based PLB protocol for stable patients with COPD, which is fully described elsewhere.³ The PLB protocol recommends that exercise parameters are as follows: 10 min per session, three times every day for 8 weeks and forming the basis of this digital gamification intervention.

Subsequently, as mentioned in the Introduction section, the BCW theory was chosen to connect identified behavioural targets with intervention functions that are most likely to achieve change.¹⁴ Specifically, the BCW framework in this research project played a core role in guiding the development of the DT-PLB intervention by systematically identifying and mapping intervention components. Based on this approach, the DT-PLB intervention was developed using theory-based, evidence-based and person-based approaches.²⁰ This method outlined the process of designing and creating the DT-PLB software, which consists of five smartphone interface modules: Ranking, Report, Daily PLB Tasks, Social Community and Mine. Brief usage steps are listed in table 1. Additionally, each of these modules is depicted below, guided by the Template for Intervention Description and Replication (TIDieR) checklist where possible.²¹

Ranking module

This module uses gamification techniques such as points and ranking to elicit target users' motivation for continuous use of this software. Participants can obtain health points by engaging in various operations (online supplemental figure 1). The software assesses and ranks patients based on these health points obtained. Within this module, patients can review the points they have earned on the current day, their ranking for the day and their overall cumulative points ranking. Comprehensive rules governing the points system can be accessed by clicking the button 'Today's points' in the 'Ranking' section of this software, where patients can also discover which operations contribute to their points for the day. Furthermore, patients can track their progress in participation over time. Brief information can be found in the accompanying screenshots (online supplemental figure 1).

Report module

This module employs several behavioural change techniques, such as feedback on behaviour, to enhance the motivation and self-efficacy of conducting PLB for patients with COPD. This module comprises three distinct sections: adverse events (eg, dizziness or lightheadedness

Table 1 Brief usage steps

Procedures	Contents
First step	Installing the DT-PLB software on the WeChat Mini-Program store: Participants install the DT-PLB software in WeChat by searching the WeChat Mini-Program store.
Second step	Participant registration: Researchers input the unique recruitment number (based on enrolment order) to complete the software system registration with the participants' consent.
Third step	Daily three PLB tasks: Three daily PLB exercise tasks (one in the morning, one in the afternoon and one at night) are listed separately. Each task consists of a 10min instructional animated video for PLB exercises. Participants can click on each task to access video instructions for the exercise. Furthermore, if a task is not accepted by a participant before the corresponding time (eg, 9 a.m.), a reminder phone message is automatically sent to the participant by the software.
Fourth step	PLB health education video: This video provides definitions, benefits and procedures of PLB exercises. Each participant can choose to watch the video to earn health points or select 'skip' during the study.
Fifth step	PLB exercise instructions: A PLB exercise animated video has been developed to guide participants on conducting PLB exercises, including 'inhale' and 'exhale' actions. The video includes a 10min countdown, voice exercise reminders and animated demonstrations of the exercises.
Sixth step	Results of PLB exercise: The earned health points and encouraging words to participants for this session are presented.
Seventh step	Participants are required to complete the Borg Scale survey and indicate whether they encounter adverse effects.
Eighth step	Updates in the social forum: The social forum has been developed for participants posting updates. Additionally, peer participants can give 'like' and leave 'comments'.
Ninth step	Ranking: Participant exercise data are presented in this section, including health points, medals earned based on health points, and daily and cumulative health point rankings.

PLB, pursed lip breathing.

in participants when practicing breathing, a data breach of confidentiality and risk of inappropriate comments on the peer support platform (see the Social Community module section)), medication record and message to medical staff. The adverse events and medication record sections feature predefined multiple-choice questions for the convenience of patients. The message to medical staff section enables patients to engage with healthcare professionals through voice or text messages, thereby ensuring effective receipt of feedback. Brief information can be identified in the screenshots (online supplemental figure 2).

Daily PLB Tasks module

These are the core components of the DT-PLB intervention, which tailors several behavioural change techniques, such as action planning, clear missions, instruction on how to perform a behaviour, restructuring the physical environment and prompts, to improve the motivation, opportunity and capability of carrying out PLB for patients with COPD at home. This study sets the daily PLB tasks at three times a day—morning, afternoon and evening—each lasting 10min. If the patient forgets to click to receive the task in the module, the system will automatically send an SMS message to remind the patient to carry out the exercise task. After accepting the animated exercise task, patients are provided with an educational video on PLB exercise, which they can choose whether to watch. Subsequently, they enter the animated video stage of each exercise task,

where each task is guided by a step-by-step animated video combining video and audio to instruct patients with COPD in PLB exercise. During the patient's exercise process, they can choose to 'End', 'Pause' or 'Continue' the animated guidance. Concurrently, patients can see the current implementation intervention time progress on the homepage of this module. Screenshots can be found for the Daily PLB Tasks module (online supplemental figure 3).

Social Community module

The module is well informed to be developed to provide enrolled participants with a platform for seeking peer support based on behavioural change techniques, such as social support and social engagement, to promote participants' motivation to use this software. Participants can post texts, images or both in the module, and their peers can 'like' and 'comment' on them. Detailed information can be identified in the screenshots (online supplemental figure 4).

Mine module

This module is designed for software management functions, such as resetting a password, updating an exercise record, obtaining health points and adjusting the font size. Detailed information can be identified in the screenshots (online supplemental figure 5).

Intervention fidelity

Intervention fidelity is to take actions in place to ensure that the intervention protocol is conducted as intended.²²

Table 2 Evaluation criteria for PLB exercises (Participant No.):

	Items	Assessment method	Points	Note (each criterion met earns 1 point, with a total possible score of 9 points)
Preparation before exercises	Sit or stand in a comfortable and safe environment, maintaining an upright, slightly forward-leaning posture	Observation, pose questions		
	Before beginning the exercises, place a chair or another supportive object next to the patient to provide support in case of an emergency	Observation, pose questions		
	Relax the muscles of the shoulders and neck	Observation		
Breathing techniques	Maintain an inhalation-to-exhalation ratio of 1:2	Pose questions		
	Keep the lips slightly closed and inhale through the nose for 2 s. The depth of inhalation should depend on the patient's tolerance	Observation, pose questions		
	Purse the lips and slowly exhale air from the lungs through the opening between the lips within 4 s	Observation, pose questions		
Breathing rate and duration	Each exercise session lasts for 10 min	Pose questions		
	Three times a day: once in the morning, once at noon and once in the evening	Pose questions		
	Exercise for a total of 8 weeks	Pose questions		
Each participant must achieve a score of 9 points to meet the requirements of the PLB exercises. If a participant does not pass on their first attempt, training will continue for that participant until they achieve a score of 9 points. PLB, pursed lip breathing.				

Several approaches will be used to guarantee the fidelity of the DT-PLB intervention when those participants consent to participate in this study in the hospital. As PLB is the core component of the DT-PLB intervention, the principal researcher for facilitating standard exercises of the PLB will only be responsible for delivering detailed procedures of PLB for all enrolled participants by playing slides to articulate each movement of the PLB after participants sign the consent form at the hospital and, at the same time, lead participants to correctly operate each movement. In addition, a predetermined standard PLB exercises evaluation form presented in [table 2](#) is formulated to assess participants' appearance of PLB learning at the enrolment phase, with only each participant being tested to obtain a score of 9 being considered 'pass'. Furthermore, an educational video covering the techniques of PLB was embedded in the DT-PLB software so that participants could learn how to undertake PLB when they returned home. In terms of how to operate DT-PLB software functions, several methods will be employed to

deliver the software functions: first, participants will be introduced to the detailed interfaces of the DT-PLB software by clicking through and explaining each section of the interface. Second, a handy manual booklet will be provided to deliver the software functions when participants return.

Patient and public involvement

Patients and public were not involved in the design and conduct of this research protocol, which was reported in this study.

Assessments

Participants will undergo assessments at the hospital before the intervention and 8 weeks after its commencement. If any participant requires hospitalisation due to an acute exacerbation or attends any other rehabilitation programme during the DT-PLB intervention period, their participation in the intervention will be terminated, and they will be counted as a withdrawal. However, all

exercise data collected up to the point of withdrawal will be retained and included in the final analysis. Additionally, participants who do not withdraw from this study during the intervention, including those who discontinue their usage of the DT-PLB software, will be asked to complete follow-up assessments and explain their reasons for withdrawal. The assessment to measure all outcomes will last approximately 1 hour, with regular breaks given to minimise fatigue and burden. Additionally, apart from the specified outcomes, demographic data will also be collected at baseline.

Outcomes

Several outcomes will be used as primary outcomes in this feasibility study, consisting of the safety of the DT-PLB intervention, the feasibility of participant recruitment and the intervention process, the acceptability of the DT-PLB intervention and the system utility evaluation as well as participants' satisfaction with the DT-PLB intervention. A log designed with the DT-PLB software will also be used to record any adverse event. All outcome measures comply with a standardised collection procedure.

Safety of the DT-PLB intervention

Safety will also be assessed in the feasibility study of DT-PLB intervention, as it indicates that any potential adverse events which are associated with a therapy or treatment should be well documented in clinical studies.²³ In this study, participants are responsible for recording and reporting any side effects associated with DT-PLB by using the software or making a phone call to the principal researcher if it is an emergency event during the intervention period (table 3). The possibility of causality between the DT-PLB intervention and the reported suspected adverse events will be determined by a discussion between an experienced respiratory physician and a nurse based on predetermined criteria by the adapted WHO-Uppsala Monitoring Centre (UMC) in this

study. Six categories of causality are employed to present the likelihood: 'certain', 'probable/likely', 'possible', 'unlikely', 'conditional/unclassified' and 'unassessable/unclassifiable' (WHO-UMC System for Standardized Case Causality Assessment) (table 4). However, it should be noted that the WHO-UMC system was initially formulated to evaluate medicine-related harm events, and the criteria employed in the feasibility study are slightly adapted given two recent systematic reviews that focused on the potential side effects related to the usage of digital intervention.^{24 25}

Feasibility of participant recruitment and intervention process

In terms of participant recruitment and the intervention process, the DT-PLB intervention feasibility will be assessed based on the following outcomes: (1) the eligibility rate, which refers to the number of subjects eligible for participation divided by the number of subjects screened for eligibility; (2) the recruitment rate, which is defined as the number of subjects who participated in the study divided by the number of subjects eligible for participation; (3) the retention rate, which refers to the number of subjects who completed the study divided by the number of subjects who participated in the study; (4) the attrition rate, which is the number of subjects who discontinue the intervention study after participation divided by the number of subjects who participate in the study²⁶ and (5) the participants' reasons for discontinuing the DT-PLB intervention after participation.

Acceptability of the DT-PLB intervention

The acceptability of the DT-PLB software intervention will be assessed based on participants' adherence to the following outcomes: (1) weekly acceptance rate of PLB exercise tasks, which is the percentage of the real amount of participation in PLB exercise sessions to the planned total times of PLB tasks per week. It should be noted that according to the developed PLB protocol, the PLB

Table 3 Adverse Events Assessment Form Participant No.:_____ Evaluator:_____ Date:_____

Adverse events	Time of occurrence	End time	Outcomes	Results of causal relationship analysis	Quitting research
			<input type="checkbox"/> Self-remission <input type="checkbox"/> Remission after treatment <input type="checkbox"/> Not remitted <input type="checkbox"/> Unclear	<input type="checkbox"/> Definitely related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Unlikely related <input type="checkbox"/> Conditional <input type="checkbox"/> Unable to assess	<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Self-remission <input type="checkbox"/> Remission after treatment <input type="checkbox"/> Not remitted <input type="checkbox"/> Unclear	<input type="checkbox"/> Definitely related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Unlikely related <input type="checkbox"/> Conditional <input type="checkbox"/> Unable to assess	<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Self-remission <input type="checkbox"/> Remission after treatment <input type="checkbox"/> Not remitted <input type="checkbox"/> Unclear	<input type="checkbox"/> Definitely related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Unlikely related <input type="checkbox"/> Conditional <input type="checkbox"/> Unable to assess	<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Self-remission <input type="checkbox"/> Remission after treatment <input type="checkbox"/> Not remitted <input type="checkbox"/> Unclear	<input type="checkbox"/> Definitely related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Unlikely related <input type="checkbox"/> Conditional <input type="checkbox"/> Unable to assess	<input type="checkbox"/> Yes <input type="checkbox"/> No

Table 4 Appendix III: WHO-UMC System for Standardized Case Causality Assessment (modified version for the safety assessment of SI)*

Causality term	Assessment criteria
Certain	There was a plausible time relationship between the occurrence of side reactions and the use of SI, and there was a plausible response to the withdrawal of SI; thus, it was impossible that these side reactions were attributed to health problems (diseases) or other therapeutic approaches.
Probable or likely	There was a reasonable time relationship between the occurrence of side reactions and the use of SI, and these side reactions were unlikely to be explained by health problems (diseases) or other therapeutic approaches.
Possible	There was a reasonable time relationship between the occurrence of side reactions and the use of SI, but these side reactions could also be attributed to health problems (diseases) or other therapeutic approaches, and there was no clear information on SI withdrawal.
Unlikely	An improbable time relationship was identified between the reported side reactions and the use of AT.
Conditional or unclassified	The side reactions were identified but more reliable information must be collected for an appropriate judgement of the causality between the side reactions and the use of AT.
Unclassifiable or unassessable	The side reactions were proposed but the causality could not be assessed because the available information was contradictory or insufficient.
*This tool has been modified for use in SI safety assessment based on two systematic reviews that focused on adverse events associated with the use of SI. ^{24 25} SI, software intervention.	

exercise tasks designed within this software intervention consisted of three tasks per day for each participant: one in the morning, one in the afternoon and one in the evening; therefore, each week for all enrolled participants can be figured out the total number of PLB tasks; (2) average individual weekly software usage time, which refers to average minutes per week for each participant using the software; (3) average individual weekly health video viewing time, which means average minutes per week for each participant for viewing the health video on the DT-PLB system and (4) average individual weekly exercise time, which refers to mean minutes per week for each participant using the PLB-animated exercise video among enrolled participants. It should be noted that participants may fail to accept all PLB tasks or complete PLB exercises according to the predetermined duration during the intervention period; therefore, the computation of their DT-PLB system usage time, task acceptance rate and average exercise duration of each PLB task will be based on the actual data recorded in the system.

System's usability with the intervention

The system usability scale (SUS) is a patient-administered instrument commonly used to evaluate the usability and user experience of digital intervention systems with high reliability and sensitivity outside China.²⁷ In this study, considering cross-cultural differences in mainland China, an adapted version of the SUS by Chinese researchers will be deployed, with formal permission granted, demonstrating a high Cronbach's alpha reliability of 0.84 and a sensitivity of 75.64.²⁸ This Chinese version of SUS holds 10 questions which are answered using a 5-point (1–5) Likert scale producing an overall score between 0 and 100, with higher scores indicating better usability and user experience.²⁸

Participants' satisfaction with the study intervention

Participants will be requested to rate their satisfaction with this DT-PLB intervention after completing the 8-week intervention. Only one question listed in the paper sheet will be asked about their satisfaction using a 10-point numeric rating scale, where '1' represents 'very dissatisfied' and '10' means 'very satisfied'.

Obtained health scores

Based on the assumption that proper competition mechanisms facilitate intervention implementation, health points will significantly motivate participants to use the DT-PLB software by establishing the basis for rankings and corresponding achievement badges. Therefore, health points rules are set based on a consensus among researchers in this developed DT-PLB software (table 5).

Clinical outcomes

This feasibility study will use clinical outcomes to measure the preliminary effects of this DT-PLB intervention.

Dyspnoea

Dyspnoea will be assessed using the Modified Medical Research Council (mMRC) Dyspnea Scale, which already holds the Medical Research Council's usage permission. This self-report instrument assesses the severity of breathlessness in patients with COPD. It comprises five categories, ranging from 0 to 4, with higher scores indicating more pronounced breathlessness.²⁹ Specifically, a score of 0 signifies the absence of breathlessness except during strenuous exercise. In contrast, a score of 4 indicates extreme breathlessness, significantly impeding the patient's ability to leave the house or dress themselves. The mMRC scale demonstrates high reliability, with a range of 0.84 to 0.99, and validity ranging from 0.76 to

Table 5 Health point rules

Operation	Earned health point rules
Log in	The system finds that participants earned 1 health point when they stayed on the software for more than 1 min. If participants exit the system midway, they must log back in and stay for more than 1 min to continue earning health points. A maximum of 3 health points can be earned per day.
Watch PLB health education video	Every minute participants stay on the video, they earn 1 health point. The maximum score for a single viewing was equal to the length of the video.
Accept PLB exercise task	Participants earn 1 health point on claiming an exercise task. For every minute spent on the training animated videos, patients earn 1 health point, with a maximum of up to 10 health points. Completing the Borg scale assessment and reporting/skipping adverse effects at the end of each exercise can grant 1 health point.
Social forum	Participants can post an update in an internal forum, earning them 1 health point. A maximum of 3 health points can be earned per day.
Reward health points of consecutive accepted tasks	Participants would receive an additional 50 health points for continuously claiming exercise tasks for nine consecutive times.
Rankings and corresponding achievement badges medal	Rankings will be in place based on daily obtained health points and cumulative health points in the ranking interface. Perseverer: >140 health points; Training Guru: >280 health points; Health Enthusiast: >560 health points.
PLB, pursed lip breathing.	

0.83, underscoring its robustness for assessing breathlessness in patients with COPD.³⁰ Currently, the mMRC Dyspnea Scale is widely applied in China.³¹ Therefore, this study will employ the mMRC Dyspnea Scale as an assessment tool for dyspnoea.

Exercise capability

The 6 min walking test (SMWT) will be used to measure exercise capability. The SMWT is a widely used method to evaluate the distance an individual can walk on a flat, hard surface within 6 min.^{32 33} This test will be conducted on a flat, straight track of 40 m in length at the hospital. Participants will be requested to wear comfortable clothing and shoes, use their usual walking aids, take regular medications and are instructed to walk as far as possible within 6 min, and verbal encouragement is provided to motivate them. During the test, the principal researcher and a healthcare professional monitor the participant's progress and record the total distance covered, ensuring safety and comfort. Additionally, patients should rest for at least 15 min in a chair near the starting point before beginning the test.^{32 33}

Quality of life

The assessment of QoL will be conducted using the COPD Assessment Test (CAT). This is a validated, concise and easily administered questionnaire completed by the patient and designed for routine clinical application in evaluating the health status of patients with COPD.^{34 35} It comprises eight questions that address various symptoms such as cough, sputum production, breathlessness, chest tightness and limitations in physical activity. Each question on the CAT is rated on a scale from 0 to 5, with a maximum cumulative score of 40. A higher score indicates a more pronounced deterioration in health

status.^{34 35} A Chinese version of the CAT scale followed by full linguistic and cultural validation was obtained,³⁶ with authorisation for use in this study from the official.

Pulmonary function index

The pulmonary function index is a critical parameter in pulmonary function tests, which is used to assess the airway obstruction status in patients with COPD and extensively in research.¹ FEV₁% predicted, or 'forced expiratory volume in one second predicted', evaluates lung function by indicating the maximum amount of air a person can forcefully exhale from their lungs in 1 s, considering age, height, sex and race. It is expressed as a percentage of the expected value for an individual with the same characteristics but without lung disease.³⁶ FEV₁/FVC is another lung function measure commonly employed in the diagnosis and management of respiratory conditions. It denotes the ratio of the air exhaled forcefully in 1 s (FEV₁) to the total amount of air exhaled (forced vital capacity (FVC)) during a complete exhalation. A low FEV₁/FVC ratio indicates obstructed or narrowed airways, which is a characteristic interface of COPD.³⁶

Time points for data collection

Data collection, including baseline, feasibility and clinical data, will be carried out at two points: baseline (T1) and post-intervention (T2). Eligible participants first sign the consent before performing baseline data collection, including demographic data, dyspnoea, QoL, exercise capability and pulmonary function in the hospital. Afterwards, participants will be requested to return to the hospital to perform the second data collection for system usability, satisfaction and clinical outcomes, including dyspnoea, QoL, exercise capability and pulmonary

function in the hospital at post-intervention. In addition, the principal researcher will retrieve acceptability data, such as participants' usage time of the DT-PLB and health points, from the software database after week 8.

Data analysis

The statistical analysis plan for this feasibility study will use both descriptive and inferential statistical methods, with a significance level set at $p < 0.05$ for two-tailed tests. Baseline data will be analysed using descriptive statistics, with categorical data presented as frequencies and percentages, and continuous data summarised as mean (SD) or median (IQR) depending on normality. Feasibility data will include the safety of the intervention (adverse events), recruitment and retention rates, software usage and task acceptance rates, system usability, participant satisfaction, and health scores, analysed using appropriate descriptive methods. Clinical outcomes, including mMRC, CAT, SMWD and pulmonary function indices, will be compared using paired t-tests or Wilcoxon signed-rank tests based on normality. The analysis will also assess data integrity and the prevalence of missing data, providing insights for future trial feasibility.

Data monitoring

Participants in this study face minimal anticipated risks, with very low occurrences (see online supplemental table 1). Consequently, there will be no Data Monitoring Committee, interim analyses or stopping rules.

Ethics and dissemination

Manchester Metropolitan University and the Affiliated Hospital of Southwest Medical University have separately approved this study, which will be conducted at the Affiliated Hospital of Southwest Medical University.

The strategy for sharing the trial findings will be developed at the outset and will encompass a wide range of channels, including social media, broadcast media, the internet and email, in addition to traditional outlets such as peer-reviewed journals and national and international conferences. The dissemination will follow the guidelines of Enhancing the Quality and Transparency of Health Research for reporting non-randomised studies. Authorship will adhere to international criteria, specifically those outlined by the International Committee of Medical Journal Editors. The research results will be communicated to all participants and to individuals who expressed interest in participating but did not meet the inclusion criteria, provided they consented to be contacted for research-related purposes.

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