BMJ Open

Screening and early warning system for chronic obstructive pulmonary disease with obstructive sleep apnoea based on the medical Internet of Things in three levels of healthcare: protocol for a prospective, multicentre, observational cohort study

Zihan Pan ,[1,2] Sha Liao,[1] Wanlu Sun,[3] Haoyi Zhou,[4] Shuo Lin,[5] Dian Chen,[1] Simin Jiang,[1] Huanyu Long,[1] Jing Fan,[1] Furong Deng,[6] Wenlou Zhang,[6] Baiqi Chen,[6] Junyi Wang,[1,6] Yongwei Huang,[1,7] Jianxin Li,[8] Yahong Chen[1]

To cite: Pan Z, Liao S, Sun W, *et al*. Screening and early warning system for chronic obstructive pulmonary disease with obstructive sleep apnoea based on the medical Internet of Things in three levels of healthcare: protocol for a prospective, multicentre, observational cohort study. *BMJ Open* 2024;**14**:e075257. doi:10.1136/bmjopen-2023-075257

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2023-075257).

ZP, SL and WS contributed equally.

Received 02 May 2023
Accepted 12 February 2024

For numbered affiliations see end of article.

Correspondence to
Dr Yahong Chen; chenyahong@vip.sina.com and Jianxin Li; lijx@buaa.edu.cn

ABSTRACT

Introduction Chronic obstructive pulmonary disease (COPD) and obstructive sleep apnoea (OSA) are prevalent respiratory diseases in China and impose significant burdens on the healthcare system. Moreover, the co-occurrence of COPD and OSA exacerbates clinical outcomes significantly. However, comprehensive epidemiological investigations in China remain scarce, and the defining characteristics of the population affected by COPD and OSA, alongside their intrinsic relationship, remain ambiguous.

Methods and analysis We present a protocol for a prospective, multicentre, observational cohort study based on a digital health management platform across three different healthcare tiers in five sites among Chinese patients with COPD. The study aims to establish predicative models to identify OSA among patients with COPD and to predict the prognosis of overlap syndrome (OS) and acute exacerbations of COPD through the Internet of Things (IoT). Moreover, it aims to evaluate the feasibility, effectiveness and cost-effectiveness of IoT in managing chronic diseases within clinical settings. Participants will undergo baseline assessment, physical examination and nocturnal oxygen saturation measuring. Specific questionnaires screening for OSA will also be administered. Diagnostic lung function tests and polysomnography will be performed to confirm COPD and OSA, respectively. All patients will undergo scheduled follow-ups for 12 months to record the changes in symptoms, lung functions and quality of life. Primary outcomes include the prevalence and characteristics of OS, while secondary outcomes encompass OS prognosis and the feasibility of the management model in clinical contexts. A total of 682 patients with COPD will be recruited over 12–24 months.

Ethics and dissemination The study has been approved by Peking University Third Hospital, and all study participants will provide written informed consent. Study results will be published in an appropriate journal and presented at national and international conferences, as well as relevant social media and various stakeholder engagement activities.

Trial registration number NCT04833725.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ In this study, the prevalence and characteristics of obstructive sleep apnoea (OSA) among patients with chronic obstructive pulmonary disease (COPD) in China are investigated.
⇒ The Internet of Things (IoT) is applied in the management of COPD and OSA, covering a wide range of patients attending three different levels of care and community populations in China.
⇒ The feasibility, effectiveness and cost–benefit of IoT are measured in a real-world context, which enhances the generalisability of the findings.
⇒ Due to COVID-19, people may have limited access to healthcare, lung function and polysomnography, which may affect the study results.
⇒ The study may be less representative of people who do not use smartphones or live in rural areas as they may not have access to IoT technology.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a common chronic disease with characteristics of persistent respiratory symptoms and airflow limitation.[1] As the third leading cause of global mortality,[2] it affects approximately 100 million individuals in China, with a prevalence of 13.7% among those aged 40 years or older.[3] The association of COPD with comorbidities

amplifies morbidity and mortality rates. Obstructive sleep apnoea (OSA), the most prevalent sleep breathing disorder, commonly complicates COPD.[4 5] Marked by daytime sleepiness and nocturnal snoring accompanied by apnoea, OSA results in nocturnal hypoxaemia and hypercapnia, substantially diminishing quality of life and escalating the risk of cardiovascular and cerebrovascular disorders, consequently elevating mortality rates.[4 5] Globally, OSA affects over 20% of the population, with an annual increase in incidence.[6 7] In China particularly, the situation is dire, with an estimated 176 million individuals afflicted by OSA, ranking the country foremost in OSA prevalence worldwide.[8]

OSA is diagnosed by polysomnography (PSG), which is mainly implemented in tertiary hospitals in China. However, the number of patients with OSA who actually receive diagnosis and treatment is limited due to low awareness and limited resources. This shortfall impedes active prevention strategies and fails to meet the comprehensive needs of patients beyond tertiary hospital settings. Thus, moving the threshold of OSA diagnosis and treatment to primary care is essential, where appropriate screening can be conducted and provide opportunities for early intervention. In China, the promotion of OSA screening in primary care settings has gained traction. In 2022, expert consensus on screening and management of a high-risk population of adults with OSA was published to support and guide the screening for high-risk populations with OSA.[9] Questionnaires such as STOP-Bang, the Epworth Sleepiness Scale (ESS) and the Berlin Questionnaire (BQ) have been recommended for screening.[9]

Both COPD and OSA are prevalent respiratory diseases with concerning increasing trends and well-defined impacts on quality of life. Research indicates a substantial proportion of patients with COPD concurrently experience Obstructive Sleep Apnea Syndrome (OSAS),[4 10–13] yet the specific correlation between the two conditions remains elusive. The concept of overlap syndrome (OS), which refers to individuals suffering from both COPD and OSA, has attracted great attention due to its association with a higher risk of mortality, more frequent cardiovascular events, poorer quality of life, increased risk of COPD exacerbation and higher medical costs.[4 14–17] Global studies reported that the prevalence of OS ranges from 1.0% to 3.6% in the population aged 40–89 years old.[4 5] The prevalence of OSA among patients with COPD is between 56.45% and 78%, while the coexistence of COPD in patients with OSA leads to a prevalence of 11.9%–23.2%.[14] Given the large populations of COPD and OSA, it is estimated that there is also a huge potential population of OS in China; however, the specific prevalence or epidemiology of OSA among patients with COPD in China is unknown.

Despite substantial variation in reported prevalence estimates for OS between epidemiological studies thus far, few studies have been conducted in China. Existing studies predominantly feature small sample sizes, limiting their capacity to comprehensively portray OS prevalence and characteristics in both the COPD and general populations. Conducting large-scale studies on OS in China is imperative. Such studies hold pivotal significance in unravelling the natural history, clinical ramifications and prognosis of this syndrome. Additionally, they aid in patient identification and facilitate the administration of appropriate therapies. Notably, screening assumes crucial importance, given that improved clinical outcomes have been observed in patients with COPD–OSA overlap on receiving treatment.[15] Although studies have demonstrated the feasibility of questionnaires or portable devices to screen for COPD or OSA,[14 18 19] there has been no effective or appropriate method to identify patients with the combination of both COPD and OSA.

Although COPD and OSA are common chronic respiratory diseases, ideally the best management of COPD and OSA occurs in primary care. Regrettably, the current capacity of primary care facilities in China remains inadequate. As a consequence, there exists a notable trend among patients to seek care in larger hospitals, leading to a dearth of COPD or OSA management within primary care settings. In recent years, China has implemented a hierarchical diagnosis and treatment policy in the hope that these diseases can be well treated within the health system; however, there is a lack of effective referral mechanisms between different medical institutions.

The Internet of Things (IoT) is a network of devices and objects equipped with sensors, software, electronics and network connectivity that communicate with each other wirelessly and transmit data to a cloud platform.[20 21] Over the past few years, IoT has experienced rapid development and its usage has extremely expanded in responding to COVID-19 pandemic.[20 22–24] Leveraging the advantages of IoT prompts us to contemplate its application in the management of COPD and OSA. This study endeavours to explore a novel management model using IoT technology to effectively identify OSA among patients with COPD and revolutionise the clinical approach to these chronic respiratory conditions.

Aims

The aim of the study is to establish a screening and early warning system for COPD with OSA based on IoT.

Objectives

- To evaluate the prevalence and describe the characteristics of OSA among patients with COPD.
- To assess the feasibility, effectiveness and cost-effectiveness of IoT-based long-term management for COPD and OSA in clinical settings.
- To establish a two-way referral channel between primary care and superior hospitals for COPD and OSA based on IoT.

METHODS/DESIGN

Study design

A prospective, multicentre, observational cohort study will be conducted. The study is registered at https://clinicaltrials.gov (NCT04833725).

The Strengthening the Reporting of Observational Studies in Epidemiology[25] checklist is used to inform the content of the protocol and will also be used to report the results of the study.

Study setting

Participants will be recruited from different levels of healthcare. The general tertiary hospital is Peking University Third Hospital (PUTH), the secondary hospitals are Haidian Hospital and Zhongguancun Hospital, and the primary care facilities are Beixiaguan Community Health Service Center and Huayuan Road Community Health Service Center.

Study population

Inclusion criteria

- Aged 40–80 years.
- Residing in Beijing.
- Patients with stable COPD registered at the study sites.

Exclusion criteria

- Contraindicated for spirometry (chest infection in the last 3 weeks, coughing up blood in the last month, severe angina, uncontrolled high blood pressure, pneumothorax or history in the last 3 months of tuberculosis, heart attack, detached retina or surgery on the chest/abdomen/brain/ears/eyes, or previous adverse reaction to salbutamol).
- Unable to perform spirometry (eg, dementia or lack of teeth—cannot make a good seal).
- Unable to perform sleep monitoring.
- Cannot or will not apply the mobile app operation.
- Unable to provide informed consent.
- Judged by the physician as not able to participate.

Recruitment

WeChat, a prominent social media application in China, assumes an active role in scientific research endeavours.[26–28] Leveraging its substantial social influence, this study aims to use WeChat for patient recruitment purposes. The five research sites and their satellite offices will employ WeChat as a platform to advertise the study. E-posters will be displayed on their WeChat platforms, accompanied by targeted messages dispatched to relevant WeChat groups, extending invitations to residents interested in participating. Potentially eligible patients visiting the research sites will be given a brief study introduction by healthcare professionals and invited to attend a baseline assessment, referring to demographic characteristics, questionnaires and tests.

The uncertainty surrounding patients' acceptance of the disease management model and their willingness to participate in the study indeed presents a potential challenge to recruitment. Moreover, the ongoing impact of COVID-19 further complicates matters, potentially limiting access to healthcare services, lung function tests and PSG, potentially causing delays in recruitment. To ensure the study's quality and strict adherence to the protocol, an initial trial phase will occur exclusively at the five designated research sites during the first month of recruitment. This trial period aims for a thorough assessment and potential adjustments to optimise study procedures as needed. On completion of this comprehensive trial phase, the study will proceed according to the refined and optimised protocols. The study flow diagram is shown in figure 1.

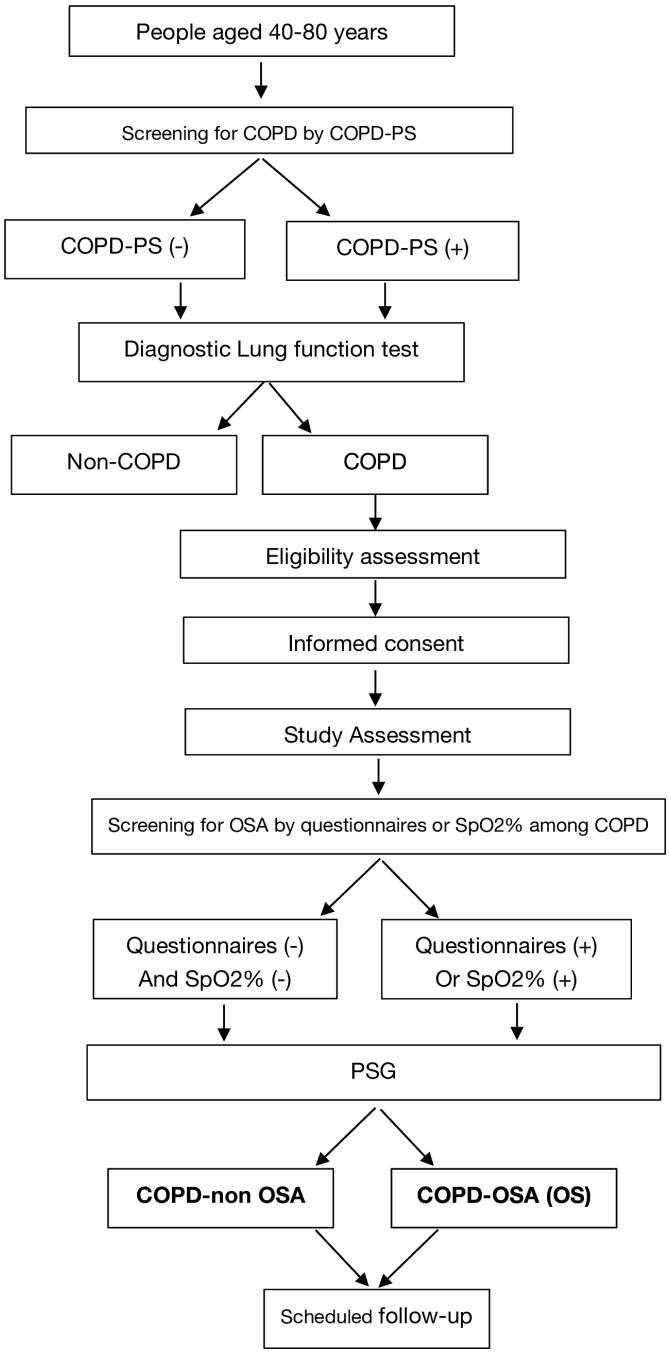

Figure 1 Study flow diagram. COPD, chronic obstructive pulmonary disease; OS, overlap syndrome; OSA, obstructive sleep apnoea; PSG, polysomnography; SpO_2, oxygen saturation; COPD-PS, the Self Scored COPD Population Screener Questionnaire.

Data collection

The data collection process for this study is bifurcated into two phases aligning with the study's objectives. The

initial phase involves identifying patients with COPD and establishing a COPD cohort. Subsequently, screening tools including STOP-Bang,[29] BQ,[30] ESS[31] and nocturnal oxygen saturation (SpO_2%) will be employed to detect OSA among patients diagnosed with COPD. All patients will undergo PSG, thereby enabling the establishment of an OS cohort. Using these data and machine learning techniques, a model will be developed to effectively screen for OSA in patients with COPD. The study's second phase entails a long-term follow-up, using IoT technology to observe and document the natural prognosis of OS and explore the interplay between COPD and OSA. This phase will culminate in the development of an OS prognosis model. Furthermore, the feasibility of an IoT-based management will be comprehensively evaluated. Eligible participants will be registered on a secure IoT platform named BOE (https://copd.boe.com.cn), and data will be entered into the platform.

Baseline assessment

All eligible participants enrolled in the study will undergo a comprehensive baseline assessment covering demographic characteristics such as height, weight, waist and neck circumference, blood pressure, smoking history, comorbidities, exposures, supplemental oxygen usage and medications. Additionally, their health status will be evaluated using the St George's Quality of Life Questionnaire,[32] while respiratory symptoms will be assessed through the CAT (COPD Assessment Test)[33] and mMRC (Modified British Medical Research Council) Dyspnea Scale.[34] These evaluations will be periodically updated during follow-up. Furthermore, the baseline assessment will include laboratory tests, lung function assessments, ECG, chest radiographs and nocturnal SpO_2% measurements using a fingertip pulse oximeter. Additionally, the cost per visit for health-related issues will be diligently recorded. For individuals with a history of COPD, information regarding the frequency of exacerbations within the last 12 months will also be collected. If patients diagnosed with COPD or OSA require treatments that are unavailable at the two community health service centres (CHSCs), they will be appropriately referred to secondary or tertiary hospitals. Standard treatments such as inhalers, continuous positive airway pressure or supplemental oxygen not accessible at the CHSCs will be provided at these higher-level healthcare facilities. After patients are registered on the BOE platform, they will receive labels based on assessment results, and these labels will dynamically change in response to variations in deterministic diagnostic outcomes. The anticipated labels include 'low risk with OSA', 'high risk with OSA', 'COPD', 'OSA' and 'COPD-OSA (OS)'. At any given point, a patient may carry multiple labels, and the platform will diligently track and display the evolution of label changes for each patient. Sleep monitoring recording and lung function test reviewers will be blinded to the above evaluation results to avoid review bias.

Follow-up and outcomes

After the initial baseline evaluation, regular follow-ups will occur every 3 months for all patients following recruitment. Patients who become lost to follow-up (having no response after three reminders), experience severe adverse events, withdraw consent or meet the study endpoints will be considered as having withdrawn from the study.

The follow-up process concludes if any of the following endpoints occur: (1) patient deceases; (2) non-response to assessment after three telephone reminders; and (3) inability to tolerate the required tests. The outlined follow-up schedule is detailed in table 1.

For the long-term disease monitoring, the following indicators will be observed: incidence of acute exacerbation of COPD (AECOPD); visits to healthcare facilities or hospitalisations for AECOPD per year; changes in lung function (forced expiratory volume in 1 s, forced expiratory volume in 1 s:forced vital capacity) and sleep monitoring indicators (ODI (Oxygen Desaturation Index), average nocturnal SpO_2%, minimum blood oxygen saturation, SpO_2% <90% accounted for the percentage of night monitoring time); changes in CAT, mMRC and quality of life assessment; new comorbidities; mortality; and medical cost.

AECOPD is defined as the acute worsening of respiratory symptoms, resulting in additional therapy according to the 2020 Global Initiative for Chronic Obstructive Lung Disease (GOLD).[1]

Screening for OSA

STOP-Bang (≥3),[29] BQ (>2),[30] ESS (>10),[31] nocturnal SpO_2% and heart rate measuring with a finger pulse oxygen instrument (BM2000A, BERRY, China) for one (up to three) night at home are administered to screen for OSA.

COPD diagnosis

At the baseline assessment, all recruited patients will undergo postbronchodilator diagnostic lung function tests (20–60 min after administration of 400 µg salbutamol) by a proficient healthcare professional with lung function certification, and a respiratory physician will diagnose COPD according to the 2020 GOLD.[1] As diagnostic spirometries are readily available at the five designated research sites, lung function tests will be conducted individually at each site. Therefore, standardised diagnostic spirometries across all sites are not mandated for this study. For the research sites where diagnostic lung function tests are not available, participants will be referred to PUTH by the BOE platform for a final diagnosis.

OSA diagnosis

All patients diagnosed with COPD will be referred to the sleep centre at PUTH to perform PSG (Apnealink Air, RESMED, Australia) to diagnose OSA following the American Academy of Sleep Medicine[35 36] and the criteria of the Chinese Sleep Society.[37 38]

Table 1 Follow-up schedule

Item/time	Baseline assessment	Third month	Sixth month	Ninth month	Twelfth month
Follow-up approach	Field investigation	Field investigation or telephone	Field investigation or telephone	Field investigation or telephone	Field investigation
COPD-PS	√				
STOP-Bang	√				
Berlin Questionnaire	√				
Epworth Sleepiness Scale	√				
CAT	√	√	√	√	√
mMRC	√	√	√	√	√
St George's Quality of Life Questionnaire	√	√	√	√	√
Combinations	√	√	√	√	√
Medications or therapy	√	√	√	√	√
Oxygen therapy	√	√	√	√	√
Lung function	√	√	√	√	√
Sleep monitoring indicators	√	√	√	√	√
Events of AECOPD during the last 3 months	√	√	√	√	√
Incidence of AECOPD during the last 3 months	√	√	√	√	√
Visits to healthcare or hospitalisations for AECOPD	√	√	√	√	√
Medical cost related to COPD or sleep breathing disorders	√	√	√	√	√
Referral		√	√	√	√
Withdrawal		√	√	√	√

AECOPD, acute exacerbation of COPD; CAT, COPD Assessment Test mMRC: Modified British Medical Research Council; COPD, chronic obstructive pulmonary disease; COPD-PS, the Self-Scored COPD Population Screener Questionnaire; STOP-Bang, Snoring, Tired, Observed, Pressure, BMI, Age, Neck, Gender.

Resource utilization

To assess the healthcare costs associated with this disease management model, we will conduct a comprehensive analysis of the expenses involved, including equipment and medical professional workers' type and grade. In addition, healthcare costs for patients' hospital admission, costs for IoT medical equipment (like finger pulse oxygen instrument and app on a mobile phone), and IoT platform establishment, maintenance and support will also be evaluated. Additional costs such as the time caregivers spend with the patient addressing health issues (calculated based on local wages) and the expenses incurred by patients during each hospital or CHSC visit will also be meticulously documented.

Statistical analysis plan

Sample size

Given that this study revolves around the construction of a machine learning-based model, we combined conventional sample size calculation methods and machine learning sample size algorithms to confirm the final sample size.

In terms of machine learning, we referred to the previous Time-Aware Long-Short Term Memory (T-LSTM) study,[39] which was a patient subtyping model for analysing sequential and longitudinal patient records. The T-LSTM model was trained and evaluated on the PPMI (Parkinson's Progression Markers Initiative) data set, comprising 654 patients. The COPD and OSA diagnosing and subtyping task and the target deep learning-based diagnostic model to be developed in this study were closely related to the reference research. Therefore, we took the sample size calculation of T-LSTM study as a reference, and finally 654 patients would be recruited in the data collection process to ensure accuracy.

In terms of conventional sample size calculations for clinical studies, the sample size was calculated by the

following formula: $N = \frac{Z_{\alpha}^2 p(1-p)}{d^2}$, where p was the prevalence of OSA among patients with COPD and was given the value of 52.8% based on findings from our previous study.[40] We proposed a confidence level of α=0.05 with a two-sided value in the standard normal distribution Zα=1.96. The relative error was proposed as 0.1 to account for the allowable error, d=0.1×p. We estimated a response rate of 80%, which led to an enrolment target of 430 patients with COPD. In order to do the power analysis for comparing the ability to screen for OSA between sleep assessment questionnaires, nocturnal SpO_2% and PSG, we proposed a sample size of 682 (which was larger than the sample based on machine learning calculation), a prevalence estimated by PSG of 52.8% and a significance level of 0.05. The power to find a difference of 10% in the prevalence of OSA between either of sleep assessment questionnaires and nocturnal SpO_2% and PSG was 96% (pwr package in R), which was acceptable for conducting this study. Based on the above, 682 patients with COPD will be recruited in this study.

Analysis plan

Data will be analysed using Stata V.15.

Descriptive statistics are made for general demographic information. Normally distributed continuous variables will be presented as mean±SD, while non-normally distributed continuous variables will be represented by median and IQR. Categorical variables will be expressed as absolute numbers and percentages (n, %). The differences among the groups are compared using the χ^2 test for categorical variables and t-tests or Wilcoxon rank-sum tests for continuous variables depending on the distribution. Missing data will be analysed using the 'last observation carried forward' method. Differences are considered significant at p<0.05 for all statistical analyses.

The performance of COPD-PS (the Self-Scored COPD Population Screener Questionnaire) to screen for COPD, sleep assessment questionnaires and nocturnal SpO_2% used to screen for OSA will be investigated by presenting 2×2 tables and calculating the sensitivity, specificity, and positive and negative predictive values, along with 95% CI. For the test with a continuous score, a receiver operator curve analysis with the area under the curve (with 95% CI) will be produced.

The primary outcomes are the prevalence and characteristic of OS, hospitalisations for COPD or OSA, incidences of AECOPD, morbidity and mortality.

The secondary outcomes are changes in respiratory symptoms, lung function, sleep assessment, as well as the quality of life, and the cost per true OS detected, the cost per hospitalisation or visit to healthcare avoided.

BOE health digital platform construction

The system contains four functional units: data collection, data storage, data processing, and early warning and message releasing. There are three components: a wearable device (a finger pulse oxygen), disease management platform (BOE) and an app on smartphones. Data collected by wearable devices will be transferred to the BOE platform and the app via Bluetooth and transforming protocol. Lung function tests will also be uploaded to the platform in the form of picture or file. Both patients and medical professionals can conveniently review this information using the mobile app installed on their smartphones or mobile devices. Disease assessment tools and forms to record therapy, medical cost and comorbidities, as well as referral forms are embedded in the platform. Administrators can edit modules according to the needs or requirements of medical care providers. The platform will be updated iteratively on a regular basis. All data are encrypted to protect privacy. What sets this disease management platform apart is its ability to break down information barriers not only between care providers and patients but also among the three levels of care, enabling seamless information sharing. Logical management was set up and the diagnostic criteria for COPD and OSA were embedded in the platform. In this way, the platform can automatically identify patients with OSA among patients with COPD through logical relationships between various data. Another article we are writing on medical engineering would detail the construction of the platform and the operating system, the algorithms applied in the system, the functions of each module, the establishment and implementation of screening and prediction models, and possible application scenarios for the whole system.

Patients are registered on the BOE platform by scanning a QR (quick response) code with their smartphones to connect to the app. Assessment can then be done by filling in relevant information in corresponding modules. When information suggesting changes in disease status is emerging, the platform will automatically integrate the information to form and issue alerts to medical professions, simultaneously reminding patients to consult physicians. In addition, a prediction model of AECOPD will be established based on the instant evaluation of patients' diseases through machine learning to achieve prediction of AECOPD to provide early warnings. (Continual assessment of patients' symptoms and disease conditions during follow-ups enables the use of updated data for timely prediction of potential acute exacerbations. These predictions evolve based on extensive data, allowing for real-time adjustments to the prediction model using any newly imported data into the BOE platform). This feature is being continuously applied and iterated to improve the predictive model's accuracy. The structure of the BOE platform is shown in figure 2.

For the warning model of OSA in patients with COPD, different core data are selected as indicators of disease diagnosis and status. The changes in each indicator over time have different weights to the analysis of the patients' conditions. For example, blood oxygen saturation mainly reflects the severity of apnoea, and it is a priority reference in screening for OSA. Another article we are writing on medical engineering will detail the

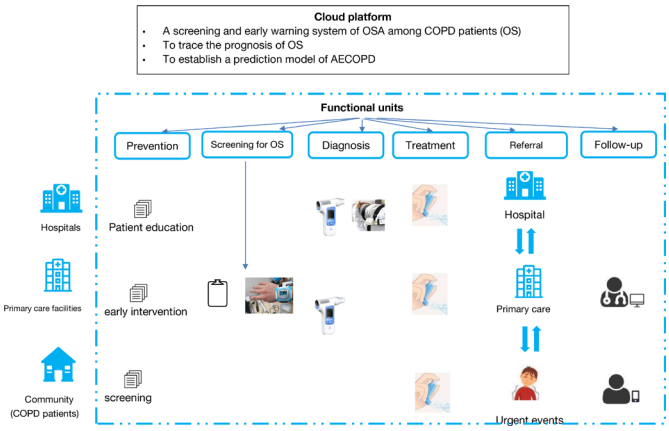

Figure 2 Structure of the BOE platform. AECOPD, acute exacerbation of COPD; COPD, chronic obstructive pulmonary disease; OS, overlap syndrome; OSA, obstructive sleep apnoea.

construction of the platform and the whole operation system.

Data management and quality control

All researchers involved in the study are medical professionals affiliated with the five research sites. A comprehensive 1-week training session will be conducted to ensure adherence to standardised study processes. This training will encompass various facets, including study protocols, assessment methodologies, respiratory and sleep physiology knowledge, as well as proficiency in conducting PSG and spirometry lung function tests. An expert will over-read spirometry traces to ensure sufficient quality before recruitment commences. ZP will over-read all spirometry tests during the study period to ensure quality is maintained. PSG will be conducted at PUTH by a professionally certified technician (YH) with 10 years of experience in sleep monitoring. A scheduled regular monitoring site visit plan is set up to ensure researchers adhere to the study protocol. Researchers will visit the sites monthly or quarterly based on the implementation quality. In every visit, especially during site initiation visits, the study team will observe a complete study assessment. The study will conduct monitoring site visits throughout the study period (from the recruitment of the first patient to the end of the last follow-up of the last patient, which will be from March 2021 to December 2023).

Patient and public involvement

No patient or public will be involved in the study design and implementation, reporting or dissemination plans of our research.

ETHICS AND DISSEMINATION

Ethics and informed consent

The study has been approved by the Ethics Review Committee of Peking University Third Hospital (2020-R-235-01) (online supplemental file 1). Medical ethics committee approvals have also been obtained from the other four research sites (Ethics Review Committee of Haidian Hospital, Ethics Review Committee of Zhongguancun Hospital, Ethics Review Group of Beixiaguan Community Health Service Center and Ethics Review Group of Huayuan Road Community Health Service Center) before the initiation of recruitment. Written informed consent will be obtained from all participants (online supplemental file 2) before the assessment.

Dissemination and publication policy

Study results will be published in peer-reviewed journals and presented at conferences and relevant stakeholder engagement activities. There will be no information that can identify participants in any publication. Participants who explicitly express a wish to be informed about the research outcome will be contacted and offered to receive an article or poster with a lay summary of the study.

DISCUSSION

This study aims to establish a screening and early warning system for COPD with OSA based on IoT, covering primary care facilities and secondary and tertiary hospitals.

Considering the large population of patients with COPD and OSA in China, it is reasonable to estimate that there is a great potential population of COPD patients with OSA, despite the lack of accurate epidemiological data on the prevalence of OS. To address knowledge gaps in the prevalence and characteristics of OSA in patients with COPD in China, our study will provide robust evidence on the profile of the combination and the association between COPD and OSA. As far as we know, this is the first study with a large sample size focused on OSA among patients with COPD in China. Previous studies primarily concentrated on patients within tertiary hospitals, with only a limited representation of the community population. This is also the first study to leverage IoT for COPD and OSA management during the COVID-19 epidemic, which covers a wide range of patients, including those presenting to three distinct levels of care and community populations.

In the last two decades, we have seen IoT grow enormously, especially in medicine.[41–43] Studies investigating the application of IoT in COPD and OSA have been documented.[44–50] However, minimal attention has been given to OS. While these studies have highlighted the explicit performances of devices or technologies in research settings, their practical functionality in clinical practice settings remains largely unexplored. Meanwhile, there is lack of economic evaluation of IoT. In the study, we will evaluate the system's performance in clinical settings, including a detailed economic analysis, which will objectively and comprehensively evaluate the feasibility, effectiveness and cost-effectiveness of IoT in clinical settings. Moreover, the study duration covers the COVID-19 pandemic, effectively providing practical evidence for IoT management of COPD and OSA in terms of feasibility and patients' acceptance of the management

model. Over the past decades, numerous health management platforms have emerged, yet their clinical application often falls short of anticipated effectiveness. Many of these platforms have been abandoned post scientific research tasks due to issues such as poor data quality and low utilisation, resulting in significant resource wastage. Our study aims to conduct a comprehensive investigation to validate the long-term efficacy of IoT in reducing costs and enhancing the quality of life for individuals affected by COPD, OSA and OS. Presently, studies concerning IoT in medical care are predominantly conducted in high-income countries, creating a notable gap in IoT research within low-resource settings.[42] By filling this gap, our study will offer critical evidence regarding the practical application of IoT in resource-limited areas.

Since the health system in China is different from that of Western countries, people can choose medical institutions according to their own wishes without requirements for referral. Generally, individuals tend to favour tertiary hospitals, consequently undermining the significance of primary care. While primary care has been an integral part of China's healthcare system since its inception, it took decades for people to truly recognise its significance.[51] Recently, hierarchical diagnosis and treatment is a public health issue with great concern in the management of common chronic diseases (like COPD). However, in reality, the implementation is not ideal, primarily attributed to the lack of available and effective referral mechanisms or referral channels, resulting in a poor interface between primary care facilities and hospitals. In this study, a two-way referral system is integrated in the BOE platform, making it possible to refer patients to hospitals and back to primary care facilities and pushing the implementation of hierarchical diagnosis and treatment for COPD and OSA.

In regular clinical practice in primary care in China, COPD-PS is recommended to screen for COPD,[52] but there is lack of validation of the questionnaire. Although screening for COPD is not the main purpose of this study, COPD-PS is embedded in the platform to further assess the accuracy in clinical settings. Research has indicated that the Oxygen Decrease Index can serve as a screening tool for OSA.[53 54] In China, the use of sleep monitoring tools is recommended for OSA screening, provided the availability of resources permits.[55] However, the performance of such tools in clinical practice is unclear. Moreover, even though STOP-Bang, BQ and the ESS have been widely validated in different countries,[56] there is a lack of validation in Chinese population. In the study, we systematically evaluated the performance of questionnaires and sleep monitoring device for screening, which will provide persuasive evidence for the effectiveness of these tools in different clinical settings.

Predicting AECOPD remains critical and challenging in COPD management. Meanwhile, patients with OS are at higher risk of AECOPD. Previous studies have developed IoT-based AECOPD prediction models, yet these investigations either relied on small sample sizes or exclusively involved hospitalised patients.[44 57 58] The external validation of these models remains inadequate, particularly in primary care settings. In this study, AECOPD prediction models applicable to three different levels of medical care will be established and validated generally and will provide practical evidence for early detection of AECOPD.

Similar to other studies in this domain, this research encounters common challenges prevalent in IoT investigations, including technical hurdles, social disruptions and regulatory considerations.[41 42] In anticipation of potential challenges, we have devised corresponding countermeasures. These include comprehensive training for research staff, detailed participant explanations, an efficient communication system enabling patients to promptly contact researchers if system issues arise, and continuous and vigilant data monitoring throughout the study to uphold data integrity and accessibility. During the study, the devices and the system will be iterated to ensure accuracy in measurements and technical issues. These limitations are speculative and subject to change based on the actual research process. A timely feedback mechanism has been put in place to respond to potential challenges that may arise during the implementation of the study. Lastly, the study may be less representative of people who do not use smartphones or live in rural areas as they may not have access to IoT technology.

In conclusion, this study will provide detailed OS epidemiological data, build disease prediction models and referral channels, and perform economic evaluation of IoT to provide rich evidence for IoT-based clinical practice.

Author affiliations
[1]Pulmonary and Critical Care Medicine, Peking University Third Hospital, Beijing, China
[2]General Practice Medicine, Peking University First Hospital, Beijing, China
[3]Department of Pulmonary and Critical Care Medicine, Beijing Institute of Respiratory Medicine and Beijing Chao-Yang Hospital, Beijing, China
[4]School of Software, Beihang University, Beijing, China
[5]Air Liquide Healthcare (Beijing), Beijing, China
[6]Department of Occupational and Environmental Health Sciences, School of Public Health, Peking University, Beijing, China
[7]Sleep Monitoring Center, Peking University Third Hospital, Beijing, China
[8]School of Computer Science and Engineering, Beihang University, Beijing, China

Acknowledgements We gratefully acknowledge the research centres and patients involved in the study and the support from BOE Technology Group and Air Liquide's VitalAire (Beijing). The funders did not have a role in the design, data collection and analysis, decision to publish, or manuscript preparation.

Contributors ZP and SL drafted the protocol paper with input from all other authors. YC and JL led the design of the trial, with contributions and advice from all other investigators. HZ and JL designed the framework and wrote the algorithm of the platform. FD, SJ, WZ, BC, JW, HL, WS, DC, JF and YH contributed to decisions on outcome measures. ZP advised on lung function testing. WS and YH advised on sleep monitoring. ZP designed the analysis plan and economic evaluation. SL was responsible for the management of the program. DC provided a sense-check in English and improved the quality of the writing throughout the manuscript. All authors have read and approved the final manuscript.

Funding The study was funded by the Capital Health Development Research Project (2020-2Z-40917), Beijing Science and Technology New Star Program (20220484157), Proof of Concept Program of Zhongguancun Science City and Peking University Third Hospital (HDCXZHKC2021206), and Clinical Cohort Construction Program of Peking University Third Hospital (BYSYDL2021013).

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.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD

Zihan Pan http://orcid.org/0000-0003-4502-1107

REFERENCES

1 Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. 2020. Available: https://goldcopd.org/
2 World health Statistics 2017-monitoring health for the SDGs [EB/OL]. n.d. Available: http://www.indiaenvironmentportal.org.in/content/442747/world-health-statistics-2017-monitoring-health-for-the-sdgs/
3 Wang C, Xu J, Yang L, *et al*. Prevalence and risk factors of chronic obstructive pulmonary disease in China (the China pulmonary health [CPH] study): a national cross-sectional study. *Lancet* 2018;391:1706–17.
4 Shawon MSR, Perret JL, Senaratna CV, *et al*. Current evidence on prevalence and clinical outcomes of co-morbid obstructive sleep apnea and chronic obstructive pulmonary disease: a systematic review. *Sleep Med Rev* 2017;32:58–68.
5 Azuma M, Chin K, Yoshimura C, *et al*. Associations among chronic obstructive pulmonary disease and sleep-disordered breathing in an urban male working population in Japan. *Respiration* 2014;88:234–43.
6 Young T, Peppard PE, Gottlieb DJ. Epidemiology of obstructive sleep apnea: a population health perspective. *Am J Respir Crit Care Med* 2002;165:1217–39.
7 Tishler PV, Larkin EK, Schluchter MD, *et al*. Incidence of sleep-disordered breathing in an urban adult population: the relative importance of risk factors in the development of sleep-disordered breathing. *JAMA* 2003;289:2230–7.
8 Benjafield AV, Ayas NT, Eastwood PR, *et al*. Estimation of the global prevalence and burden of obstructive sleep apnoea a literature-based. *Lancet Respir Med* 2019;7:687–98.
9 Sleep Disorder Group of Chinese Thoracic Society, Group of Sleep Disordered Breathing, Committee of Respiratory Diseases of China Association of Medical Equipment. Expert consensus on screening and management of high-risk population with obstructive sleep apnea in adults. *Chin J Health Manage* 2022;16:520–8.
10 Guilleminault C, Cummiskey J, Motta J. Chronic obstructive airflow disease and sleep studies. *Am Rev Respir Dis* 1980;122:397–406.
11 Chaouat A, Weitzenblum E, Krieger J, *et al*. Association of chronic obstructive pulmonary disease and sleep apnea syndrome. *Am J Respir Crit Care Med* 1995;151:82–6.
12 Soler X, Gaio E, Powell FL, *et al*. High prevalence of obstructive sleep apnea in patients with moderate to severe chronic obstructive pulmonary disease. *Ann Am Thorac Soc* 2015;12:1219–25.
13 Turcani P, Skrickova J, Pavlik T, *et al*. The prevalence of obstructive sleep apnea in patients hospitalized for COPD exacerbation. *Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub* 2015;159:422–8.
14 Czerwaty K, Dżaman K, Sobczyk KM, *et al*. The overlap syndrome of obstructive sleep apnea and chronic obstructive pulmonary disease: a systematic review. *Biomedicines* 2022;11:16.
15 Marin JM, Soriano JB, Carrizo SJ, *et al*. Outcomes in patients with chronic obstructive pulmonary disease and obstructive sleep apnea: the overlap syndrome. *Am J Respir Crit Care Med* 2010;182:325–31.
16 Lavie P, Herer P, Lavie L. Mortality risk factors in sleep apnoea: a matched case-control study. *J Sleep Res* 2007;16:128–34.
17 McNicholas WT. Chronic obstructive pulmonary disease and obstructive sleep apnea: overlaps in pathophysiology, systemic inflammation, and cardiovascular disease. *Am J Respir Crit Care Med* 2009;180:692–700.
18 Baty F, Boesch M, Widmer S, *et al*. Classification of sleep apnea severity by electrocardiogram monitoring using a novel wearable device. *Sensors (Basel)* 2020;20:286.
19 Pan Z, Dickens AP, Chi C, *et al*. Accuracy and cost-effectiveness of different screening strategies for identifying undiagnosed COPD among primary care patients (≥40 years) in China: a cross-sectional screening test accuracy study: findings from the breathe well group. *BMJ Open* 2021;11:e051811.
20 Dimitrov DV. Medical Internet of things and big data in healthcare. *Healthc Inform Res* 2016;22:156–63.
21 Fortino G, Guerrieri A, Pace P, *et al*. Iot platforms and security: an analysis of the leading industrial/commercial solutions. *Sensors (Basel)* 2022;22:2196.
22 Jacobsen M, Dembek TA, Kobbe G, *et al*. Noninvasive continuous monitoring of vital signs with Wearables: fit for medical use *J Diabetes Sci Technol* 2021;15:34–43.
23 Roblyer D. Perspective on the increasing role of optical wearables and remote patient monitoring in the COVID-19 era and beyond. *J Biomed Opt* 2020;25:10.
24 Greiwe J, Nyenhuis SM. Wearable technology and how this can be implemented into clinical practice. *Curr Allergy Asthma Rep* 2020;20:36.
25 Elm E von, Altman DG, Egger M, *et al*. The strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 2007;335:806–8.
26 Pan Z, Dickens AP, Chi C, *et al*. Accuracy and cost-effectiveness of different screening strategies for identifying Undiagnosed COPD among primary care patients (≥40 years) in China: a cross-sectional screening test accuracy study: findings from the breathe well group. *BMJ Open* 2021;11:e051811.
27 Pan Z, Yang T, Chi C, *et al*. An online survey of primary care physicians' knowledge of common respiratory diseases in China. *NPJ Prim Care Respir Med* 2022;32:28.
28 Pan Z, Dickens AP, Chi C, *et al*. Study to evaluate the effectiveness and cost-effectiveness of different screening strategies for identifying Undiagnosed COPD among residents (≥40 years) in four cities in China: protocol for a Multicentre cross-sectional study on behalf of the breathe well group. *BMJ Open* 2020;10:e035738.
29 Chung F, Abdullah HR, Liao P. STOP-bang questionnaire: a practical approach to screen for obstructive sleep apnea. *Chest* 2016;149:631–8.
30 Senaratna CV, Perret JL, Matheson MC, *et al*. Validity of the Berlin questionnaire in detecting obstructive sleep apnea: a systematic review and meta-analysis. *Sleep Med Rev* 2017;36:116–24.
31 Johns MW. Daytime Sleepiness, snoring, and obstructive sleep apnea: the Epworth Sleepiness scale. *Chest* 1993;103:30–6.
32 Jones PW, Quirk FH, Baveystock CM. The St George's respiratory questionnaire. *Respir Med* 1991;85 Suppl B:25–31;
33 Jones PW, Harding G, Berry P, *et al*. Development and first validation of the COPD assessment test. *Eur Respir J* 2009;34:648–54.
34 Ferris BG. Epidemiology standardization project (American Thoracic Society). *Am Rev Respir Dis* 1978;118:1–120.
35 Berry RB, Budhiraja R, Gottlieb DJ, *et al*. Rules for scoring respiratory events in sleep: update of the 2007 AASM manual for the scoring of sleep and associated events. deliberations of the sleep apnea definitions task force of the American Academy of Sleep Medicine. *J Clin Sleep Med* 2012;8:597–619.
36 Malhotra RK, Kirsch DB, Kristo DA, *et al*. Polysomnography for obstructive sleep apnea should include arousal-based scoring: an American Academy of Sleep Medicine position statement. *J Clin Sleep Med* 2018;14:1245–7.
37 Expert consensus on the application of the Internet of things in the diagnosis and treatment of sleep breathing disorders. *Chin J Asthma (Electronic Edition)* 2013;7:76–9.
38 Guidelines for diagnosis and treatment of obstructive sleep apnea hypopnea syndrome. *Chin J Respir Crit Care Med* 2015;14:398–405.
39 Baytas IM, Xiao C, Zhang X, *et al*. Patient Subtyping via time-aware Lstm Networks. Proceedings of the 23rd ACM SIGKDD International Conference on Knowledge Discovery and Data Mining; ACM, 2017:65–74
40 Sun W-L, Wang J-L, Jia G-H, *et al*. Impact of obstructive sleep apnea on pulmonary hypertension in patients with chronic obstructive pulmonary disease. *Chin Med J (Engl)* 2019;132:1272–82.

41 Channa A, Popescu N, Skibinska J, *et al*. The rise of Wearable devices during the COVID-19 pandemic: a systematic review. *Sensors (Basel)* 2021;21:5787.
42 Huhn S, Axt M, Gunga H-C, *et al*. The impact of wearable technologies in health research: Scoping review. *JMIR Mhealth Uhealth* 2022;10:e34384.
43 van der Kamp MR, Klaver EC, Thio BJ, *et al*. WEARCON: Wearable home monitoring in children with asthma reveals a strong association with hospital based assessment of asthma control. *BMC Med Inform Decis Mak* 2020;20:192.
44 Zhang J, Song YL, Bai CX. MIOTIC study: a prospective, multicenter, randomized study to evaluate the long-term efficacy of mobile phone-based Internet of things in the management of patients with stable COPD. *Int J Chron Obstruct Pulmon Dis* 2013;8:433–8.
45 Lao X, Zhang J, Bai C. The implication of telehealthcare in COPD management of China. *Expert Rev Respir Med* 2013;7:459–63.
46 Honkoop P, Usmani O, Bonini M. The current and future role of technology in respiratory care. *Pulm Ther* 2022;8:167–79.
47 Ma B, Wu Z, Li S, *et al*. Development of a support vector machine learning and smart phone Internet of things-based architecture for real-time sleep apnea diagnosis. *BMC Med Inform Decis Mak* 2020;20:298.
48 Hwang D, Chang JW, Benjafield AV, *et al*. Effect of telemedicine education and telemonitoring on continuous positive airway pressure adherence. *Am J Respir Crit Care Med* 2018;197:117–26.
49 Iwasaki A, Nakayama C, Fujiwara K, *et al*. Screening of sleep apnea based on heart rate variability and long short-term memory. *Sleep Breath* 2021;25:1821–9.
50 Yeo M, Byun H, Lee J, *et al*. Respiratory event detection during sleep using electrocardiogram and respiratory related signals: using polysomnogram and patch-type wearable device data. *IEEE J Biomed Health Inform* 2022;26:550–60.
51 Li X, Lu J, Hu S, *et al*. The primary health-care system in China. *Lancet* 2017;390:2584–94.
52 Chinese Medical Association, Chinese Medical Journal Publishing House, Chinese Society of General Practice, Chronic Obstructive Pulmonary Disease Group of Chinese Thoracic Society, Expert Group of Guidelines for Respiratory System Disease. Guideline for primary care of chronic obstructive pulmonary disease: practice version (2018). *Chin J Gen Pract* 2018;17:871–7.
53 Mashaqi S, Staebler D, Mehra R. Combined nocturnal pulse oximetry and questionnaire-based obstructive sleep apnea screening - a cohort study. *Sleep Med* 2020;72:157–63.
54 Bibbins-Domingo K, Grossman DC, Curry SJ, *et al*. Screening for obstructive sleep apnea in adults: US preventive services task force recommendation statement. *JAMA* 2017;317:407–14.
55 Sleep Disorder Group of Chinese Thoracic Society, Group of Sleep Disordered Breathing, Committee of Respiratory Diseases of China Association of Medical Equipment. Expert consensus on screening and management of high - risk population with obstructive sleep apnea in adults. *Chin J Health Manage* 2022;16:520–8.
56 Pivetta B, Chen L, Nagappa M, *et al*. Use and performance of the STOP-bang questionnaire for obstructive sleep apnea screening across geographic regions: a systematic review and meta-analysis. *JAMA Netw Open* 2021;4:e211009.
57 Wu C-T, Li G-H, Huang C-T, *et al*. Acute exacerbation of a chronic obstructive pulmonary disease prediction system using wearable device data, machine learning, and deep learning: development and cohort study. *JMIR Mhealth Uhealth* 2021;9:e22591.
58 Adibi A, Sin DD, Safari A, *et al*. The acute COPD exacerbation prediction tool (ACCEPT): a modelling study. *Lancet Respir Med* 2020;8:1013–21.

北京大学第三医院医学科学研究伦理委员会

Peking University Third Hospital Medical Science Research Ethics Committee

伦理审查批件

Ethical Review Approval Notice

（2020）医伦审第（235-01）号

项目编号	IRB00006761-M2020253	
项目名称	基于物联网医疗平台对慢阻肺合并睡眠呼吸疾病的筛查和预警	
项目来源	在研课题	
试验类型	流调类	
产品名称	通用名：无	商品名：无
药物注册分类		
CFDA药物临床试验批件号		
申办者/资助企业	无	
CRO公司	无	
临床试验单位及专业 /科室	呼吸内科	
主要研究者及职称	陈亚红 主任医师	
组长单位	北京大学第三医院	
其他参加研究/合作单位（必要可附表）		
会议审查地址及时间	长城电脑大厦七层第一会议室 2020-07-02	
审查文件（必要可附表）	2-知情同意书-版本号v1，版本日期20-6-6 3-质量管理方案-版本号v1，版本日期20-6-6 4-项目风险预评估及处置预案-版本号v1，版本日期20-6-6 5-经费保障说明-版本号v1，版本日期20-6-6 7-主要研究者GCP证书 8-主要研究者简历 1-研究方案-版本号v2，版本日期20-6-9 6-病例报告表-版本号v2，版本日期20-6-9 9-2020年首都卫生发展科研专项项目申请书-6.16-陈亚红 10-2020首发专项立项通知 12-研究用量表-版本号v1，版本日期20-6-9 13-方案签字页 14-贝瑞BM系列血氧仪2000A说明书 15-贝瑞BM系列血氧仪注册证	

（2020）医伦审第（235-01）号

投票结果	同意11票	作必要修改后重审0票	作必要修改后同意3票
	不同意0票	终止或暂停已批准的试验 0票	回避 0票
会议审查决定	同意		
审查意见	1. 经会议讨论，同意开展研究。 2. 如有措辞修改可报送修正案审查或备案。		
跟踪审查频率	12 个月		
伦理审查批件有效期	2020-07-03到2021-07-02 （请在有效期内启动实施，过期应重新申请审批）		
说明	1. 本批件将在各研究中心及其伦理委员会备案。如果对方案在本机构的可行性（包括研究者的资格与经验、设备与条件等）有不同意见，请及时与本伦理委员会联系。 2. 如对临床试验方案、知情同意书的任何修改，主要研究者更换，应及时通知伦理委员会，重新审查，获得批准后执行。 3. 如发生严重不良事件以及影响研究风险受益比的非预期不良事件，研究者应在获知24小时内报告本伦理委员会。 4. 暂停/提前终止/完成临床试验，请及时通知伦理委员会。 5. 发现严重违反方案情况应及时报告伦理委员会。 6. 完成临床试验后，请提交结题报告。 7. 请按照批件要求的跟踪审查频率及时向伦理委员会递交跟踪审查报告。		
主任委员（签字）：	签发日期： 2020年 07月 02日	北京大学第三医院 医学科学研究伦理委员会（章）	

基于物联网医疗平台对慢阻肺合并睡眠呼吸疾病的筛查和预警

知情同意书

亲爱的病友（及家属）：

您好！

您（的亲人）被邀请参加一项北京大学第三医院呼吸与危重症医学科陈亚红教授牵头开展的首都卫生发展科研专项资助的临床研究——基于物联网医疗平台对慢阻肺合并睡眠呼吸疾病的筛查和预警。参加单位包括北京大学第三医院、北京市中关村医院、北京市海淀医院、花园路社区卫生服务中心、北下关社区卫生服务中心 5 家单位。它将历时 3 年的时间。因为您具备“慢性阻塞性肺疾病”的研究入组条件而被邀请加入此项研究。

请仔细阅读本知情同意书并慎重做出是否参加研究的决定。当您的研究医生或者研究人员和您讨论知情同意书的时候，您可以让他/她给您解释您看不明白的地方。我们鼓励您在做出参与此项研究的决定之前，和您的家人及朋友进行充分讨论。本研究的内容/性质、风险、不便或不适及其他重要信息如下：

一、研究背景

慢性阻塞性肺疾病（简称慢阻肺），是一种常见的、以持续呼吸症状和气流受限为特征的慢性呼吸道疾病，导致患者的生活质量下降和较高的死亡率。睡眠呼吸暂停临床表现为夜间睡眠打鼾伴呼吸暂停和白天嗜睡，夜间可反复发生低氧血症和高碳酸血症，可导致多种心脑血管疾病。当慢阻肺和睡眠呼吸暂停这两种疾病共同发生时，称为重叠综合征，可以促进慢阻肺患者心血管疾病发生，增加住院率和死亡率。慢阻肺患者的睡眠呼吸疾病误诊漏诊率高和疾病负担重，是我国现阶段慢阻肺疾病管理忽略的问题之一。

基层医院在慢阻和睡眠呼吸疾病肺的诊疗中扮演着重要角色，而我国基层医疗卫生机构中基层医护队伍薄弱，慢阻肺相关诊疗与康复能力不足，对睡眠呼吸疾病的认知程度较低，接受疾病相关教育较少，疾病筛查和诊治不足。目前，国外已开展基于相对健全的基层医疗卫生管理体系，在慢阻肺的筛查、诊断、管理等方面都具有丰富的管理经验。运用家庭数据监测设备对慢阻肺患者进行管理，

为进一步改进慢阻肺管理策略提供了新的思路。现如今我国在区域中心医院和基层医院双向转诊制度方面尚未制定完善的机制，物联网医疗尚处于初级起步阶段，导致患者与医生之间的信息交接也存在一定的问题，需要进一步研究和完善。

二、研究目的

本研究拟开发慢阻肺合并睡眠呼吸疾病移动医疗辅助系统，实现多源信息整合，通过将已有的信息技术与医学研究成果相交叉融合，形成针对慢阻肺患者的睡眠呼吸疾病的筛查辅助医疗工具和筛查系统，并建立适用基层医护人员的简易操作的筛查和预警平台，增加慢阻肺患者和基层医院医生使用的可行性，满足我国从大量患者中快速识别睡眠呼吸疾病的医疗需求，促进以基层出发的针对慢阻肺患者的睡眠呼吸疾病的筛查和管理，探索社区患者家庭-基层医院-上级医院双向沟通渠道，探索慢阻肺分级诊疗新模式。

三、研究过程与方法

如果您同意参与本项研究，我们将和您预约，在您时间合适的时候，到我院入组研究。需要记录您的年龄、身高、体重、吸烟史、职业接触史、症状评分等基本资料。您需要完成数份关于您目前健康状态的问卷，如：慢阻肺评估量表、改良英国医学研究学会呼吸困难指数量表、圣乔治生活质量问卷、睡眠呼吸暂停临床评分、艾普沃斯嗜睡量表等。当然，您可以将这些问卷拿回家中完成，当您完成之后可于下次检查之时交给我们，或者选择以邮寄的方式发给我们，由我们承担邮资。此外，需要您通过可穿戴设备收集夜间的睡眠监测信息。我们会对您定期进行随访，记录您的急性加重住院次数及其他次要观察指标。

第一部分采用横断面观察研究：

① 入选标准：于北京大学第三医院、北京市海淀医院、北京市中关村医院、北下关社区卫生服务中心和花园路社区卫生服务中心登记的慢阻肺稳定期患者，慢阻肺诊断标准符合我国慢阻肺诊断指南，年龄 40-80 岁。

② 排除标准：除外不能或不会应用移动 APP 平台操作、无法配合完成睡眠监测和随访的患者。

第二部分采用前瞻性队列研究:

① 入选标准：于北京大学第三医院、北京市海淀医院、北京市中关村医院、北下关社区卫生服务中心和花园路社区卫生服务中心登记的慢阻肺稳定期患者，经可穿戴设备收集睡眠监测信息，同时符合睡眠呼吸疾病诊断标准的慢阻肺患者（氧减指数 ODI≥4 次/h）。

②排除标准：除外不能或不会应用移动 APP 平台操作、无法配合随访的患者。

随访方式及随访时点

随访时间	监测指标	随访方式
0 月	肺功能（FEV_1、FEV_1/FVC），生活质量评估（圣乔治生活质量问卷），合并症情况	现场调查
3 月	生活质量评估（圣乔治生活质量问卷）	电话随访
6 月	生活质量评估（圣乔治生活质量问卷）	电话随访
9 月	生活质量评估（圣乔治生活质量问卷）	电话随访
12 月	慢阻肺急性加重次数、急性加重发生率，肺功能（FEV_1、FEV_1/FVC）改变，病死率、医疗花费等	现场随访和电话随访

四、研究时间及人数

整个研究的时间为 3 年。

本项研究计划纳入患者 682 例。自 2020 年 1 月开始，截止为 2022 年 12 月。

五、研究风险、不适及处理

本研究需要患者使用可穿戴设备监测夜间睡眠信息，不会影响医生给患者的任何诊断和治疗。尽管如此，我们仍将严密监护，及时评估风险。

本研究可能存在信息安全方面的风险。我们会尽全力保护您提供的信息不被泄露。在研究中任何时刻，您都可以退出本研究。

北京大学第三医院呼吸科的陈亚红教授及各分中心负责人将负责医疗监督及整个研究过程中受试者的安全。

六、研究受益

您没有直接个人医疗受益。研究结果可能为今后更多的患者的诊断与治疗及推动医疗发展具有重要意义。

七、隐私问题

在研究期间收集到的所有信息都将是保密的，并由研究者保管。研究人员、伦理委员会成员及相关管理部门在法律允许的范围内，有权审阅您的信息记录。在任何有关本项目的研究报告和出版物中，您的个人信息不会被公开。

八、费用和补偿

本研究按照临床常规进行检查和治疗，除参加本研究进行的可穿戴睡眠监测免费外，不会给受试者增加常规治疗/检查/操作之外的额外费用。本研究没有额外补偿。

九、损伤赔偿

如果您因参加研究而导致损伤，北京大学第三医院会立刻提供必要的医疗护理，并遵照相应的法律法规，承担治疗的费用及相应的经济补偿。请联系研究者陈亚红教授，电话 13910232918。

十、自由退出

参加本研究以自愿为原则。您可以拒绝参加或随时退出研究，您不会因此而受到歧视、不公正对待或报复，您的医疗待遇与权益不会受到任何影响。受试者中途退出后，今后将不收集与其有关的新数据，之前收集的研究数据也将予以保密。

十一、联系方式

如果您有与本研究有关的问题，您可以与 陈亚红 教授联系，电话13910232918。她的通讯地址是 北京市海淀区花园北路 49 号北京大学第三医院呼吸与危重症医学科。

如果您有与自身权利/权益相关的任何问题，或者您想反映参与本研究过程中遭遇的困难、不满和忧虑，或者想提供与本研究有关的意见和建议，请联系北京大学第三医院科研伦理综合办公室（联系电话：010-82265571）。

告知声明

我已告知该受试者“基于物联网医疗平台对慢阻肺合并睡眠呼吸疾病的筛查和预警”的研究背景、目的、步骤、风险及获益情况，给予他/她足够的时间阅读知情同意书、与他人讨论，并解答了其有关研究的问题；我已告知该受试者当遇到与研究相关的问题时可随时与 陈亚红 医生联系，遇到与自身权利/权益相关问题时随时与北京大学第三医院医学科学研究伦理委员会联系，并提供了准确的联系方式；我已告知该受试者他/她可以退出本研究；我已告知该受试者他/她将得到这份知情同意书的副本，上面包含我和他/她的签名。

获得知情同意的研究人员签名	联系电话	日期

知情同意声明

我已被告知“基于物联网医疗平台对慢阻肺合并睡眠呼吸疾病的筛查和预警”研究背景、目的、步骤、风险及获益情况。我有足够的时间和机会进行提问，问题的答复我很满意。我也被告知，当我有问题、想反映困难、顾虑、对研究的建议，或想进一步获得信息，或为研究提供帮助时，应当与谁联系。我已经阅读这份知情同意书，并且同意参加本研究。我知道我可以在研究期间的任何时候无需任何理由退出本研究。我被告知我将得到这份知情同意书的副本，上面包含我和研究者的签名。

受试者签字	联系电话	日期

【当受试者不能签字时被允许以下方式:】

法定代理人与受试者的关系：

法定代理人签字	联系电话	日期