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Assessing the impact of diverse mask types on COPD patients: a randomised controlled trial study protocol

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ABSTRACT

Introduction Wearing masks has proven beneficial in preventing respiratory pathogen infections in individuals with chronic obstructive pulmonary disease (COPD). However, the impact of different mask types on physiological indicators and daily physical activity in COPD patients remains uncertain. This study aims to assess the immediate effects of various mask types on cardiopulmonary function indicators, subjective perceptions and the 6-minute walking distance (6MWD) in individuals with COPD.

Methods and analysis This randomised controlled trial will enrol 129 stable COPD patients. Participants will be randomly divided into three groups: control, N95 mask and surgical mask groups. Each group will undergo both a 6-minute seated test and a 6-minute walk test (6MWT), without or with their respective masks. A 10-minute interval will be provided between the two phases. The primary indicators of the study include the 6MWD and blood oxygen saturation. Secondary outcomes encompass blood pressure, pulse rate, Borg score, Rate of Perceived Exertion (RPE) score and subjective perception score. Oxygen saturation, pulse rate and blood pressure will be recorded four times during the trial, while Borg and RPE scores will be compared before and after the 6MWT. Additionally, subjective perception scores will be collected after each mask-wearing stage.

Ethics and dissemination This study has received approval from the Ethics Committee of the Affiliated Hospital of Gansu University of Chinese Medicine (approval number: 202335). We plan to disseminate research results through publication in a peer-reviewed journal or presentation at a conference.

Trial registration number ChiCTR2300074554.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ To mitigate potential bias, this study adopts a randomised controlled trial design to investigate the short-term effects of mask-wearing on chronic obstructive pulmonary disease (COPD) patients.
⇒ The collaboration between epidemiologists and clinical respiratory specialists in designing the study contributes to its scientific validity. Additionally, conducting the trial at two healthcare facilities enhances its safety.
⇒ The primary focus of the outcome variables in this study lies in assessing the impact of masks on the subjective perception of COPD patients, with relatively fewer objective measures incorporated.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) stands as a prevalent, preventable and treatable chronic airway ailment marked by persistent airflow limitation and associated respiratory symptoms. The pathology primarily involves airway or alveolar abnormalities.[1] Despite the complex and not fully elucidated pathogenesis, environmental factors such as tobacco, fuel smoke and air pollution constitute common risk factors for the disease.[2] According to the Global Burden of Diseases, Injuries and Risk Factors Study (GBD), estimates for 2019 revealed 212.3 million (200.4–225.1) prevalent cases and 16.2 million (15.2–17.2) new cases.[3] COPD, ranking third among the leading global causes of death, imposes substantial economical and social burdens.[1 4] A predictive study further underscores the anticipated increase in new cases, prevalence, deaths and disability-adjusted life years, projecting a sustained and severe impact over the next 25 years.[5]

The efficacy of masks in mitigating the transmission of respiratory pathogens has been unequivocally demonstrated.[6] Particularly for individuals grappling with COPD, the act of wearing a mask holds the potential to effectively impede respiratory infections and reduce the frequency of acute COPD exacerbations.[7 8] However, it is acknowledged that COPD patients harbour concerns regarding potential adversities associated with mask usage, including breathing challenges, headaches and facial irritation.[9] The unique physiological attributes of COPD patients, encompassing airflow limitations,

gas retention and perturbed gas exchange,[10] might render them more susceptible to the effects of masks compared with the general populace. Hence, a comprehensive inquiry into the potential negative repercussions of mask-wearing on COPD patients assumes considerable significance.

Currently, researchers from diverse nations have conducted several pertinent investigations probing the impact of various mask types on cardiopulmonary function and exercise prowess in individuals afflicted by COPD. Kyung *et al* observed that the utilisation of N95 masks among COPD patients influenced both their oxygen saturation and end-tidal carbon dioxide levels, irrespective of whether they were at rest or engaged in a 6-minute walk test (6MWT).[11] In a study involving 15 COPD patients, it was revealed that the utilisation of surgical masks did not exert a significant effect on gas exchange within the COPD population.[12] A separate study conducted by Just *et al* demonstrated that the utilisation of disposable medical masks did not impart any discernible impact on the 6MWD among patients in advanced stages of COPD.[13] An inquiry necessitating COPD patients to partake in cardiopulmonary exercise tests uncovered that masks wielded a notable influence on the patients' blood lactate levels.[14] Exploring the longitudinal aspect, a study involving 100 COPD patients tracked over a span of 4-6 weeks found that mask usage did not trigger alterations in the patients' CAT (COPD Assessment Test) scores.[15] Hirai *et al.*, in their investigation wherein COPD patients were tasked with a 6-minute walk test, concluded that donning a surgical mask did not appreciably impact their physiological indicators or exercise capacity. However, it did exacerbate subjective perceptions of dyspnea when contrasted with instances where a surgical mask was not worn.[16]

In the broader context, a significant portion of existing investigations in the current thematic domain tends to favour non-randomised controlled trial designs. However, there exists a compelling need to enhance the methodological framework to facilitate more robust inquiries. Consequently, building on the COPD patient cohort, this study aims to delve into the ramifications of various mask types on COPD patients' physiological indicators, exercise performance and subjective perceptions. This ambitious goal is to be achieved through the implementation of a meticulously crafted, high calibre randomised controlled trial design, thereby fostering an enriched understanding among COPD patients regarding the implications of mask usage. Moreover, the insights garnered from this endeavour are anticipated to extend beyond the research realm and contribute as a guiding compass for endeavours within the clinical domain.

METHODS AND ANALYSIS

Objectives

The primary objective of the current study is to meticulously examine the impact of various mask variants on respiratory function, cardiovascular performance and the results of the 6MWT among COPD patients. The findings of this investigation are envisioned to furnish valuable insights, guiding COPD patients towards a judicious approach to mask utilisation.

Trial design

A meticulously devised randomised parallel controlled trial has been structured to comprehensively assess both the subjective and objective repercussions of distinct mask varieties on individuals afflicted by COPD.

Study setting

This research will be conducted across two major hospitals in Lanzhou, Gansu Province, China. If circumstances are favourable, there is a prospect of expanding the trial's scope to encompass additional regions within the province.

Eligibility criteria

Inclusion criteria

1. Inclusion of patients with clinically confirmed COPD diagnosed according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria. Diagnosis requires pulmonary function testing to demonstrate persistent airflow limitation, defined as $FEV_1/FVC<70\%$ after inhaled bronchodilators.[1]
2. Inclusion of COPD patients who have experienced no change in symptoms or medications in the 4 weeks preceding the commencement of the intervention.
3. No related motor or nervous system diseases.
4. Patients who can participate in this trial after evaluation by relevant professional clinicians.
5. Informed consent.

Exclusion criteria

1. Resting heart rate >120 beats per minute.
2. Systolic blood pressure >180 mm Hg and diastolic blood pressure >110 mm Hg.
3. Patients with inconvenient movement.
4. Special groups such as pregnant women.
5. Have learning and cognitive impairment and have been diagnosed with Alzheimer's disease and depression.
6. Patients with absolute contraindications for a 6MWT, such as cardiovascular disease, including acute myocardial infarction (3–5 days), and other related conditions.[17]
7. Patients with allergic constitution.
8. Declared unwilling to participate in the research.

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Sample size

This research constitutes a randomised controlled trial, wherein the experimental group encompasses participants wearing masks, while the control group comprises

those without masks. Among the observed outcome indicators, the participant's Borg score assumes significance. The following formula is employed to compute the requisite sample size:

$$n = \frac{2(Z_\alpha + Z_\beta)^2 \sigma^2}{\delta^2}$$

In this equation, 'n' denotes the sample size, 'δ' signifies the discrepancy between the means of the two groups (literature value of 0.91) and 'σ' represents the SD, estimated at approximately 1.40 based on literature analysis.[16] Employing a two-sided alpha of 0.05 and an 80% power, the sample size calculation is executed using PASS 15 software, indicating a minimum of 39 samples for each group. Considering a dropout rate not exceeding 10%, the sample size requirement for each group becomes 43 cases. As the study is divided into three groups, the cumulative sample size stands at 129.

Recruitment

This study will enrol COPD patients meeting the inclusion and exclusion criteria from two hospitals, utilising posters and social media for recruitment. The recruited patient pool will encompass both hospitalised patients and COPD patients attending outpatient clinics for follow-up visits.

Randomisation

Sequence generation

Each patient will be assigned a number based on their entry sequence into the study, totalling 129 numbers. Utilising SPSS V.25.0 software, random number seeds will be set, and random grouping schemes will be generated in a 1:1:1 ratio corresponding to the total number of assigned numbers. Each patient's number will be linked to a specific intervention programme within this programme.

Concealment mechanism

The grouping scheme must be securely saved. To prevent the inadvertent disclosure of group information, the random grouping scheme will be documented in an opaque envelope, distinctly marked with the corresponding number.

Implementation

The initiation of the random number seed is conducted by a researcher with no role in the recruitment or intervention of participants by the research team, ensuring an unbiased commencement of the study. Subsequently, throughout the trial, other researchers implement participant interventions based on the pre-established scheme enclosed within envelopes corresponding to each participant.

Interventions

The explanation for the choice of comparators

In the intervention aspect, the control group will engage in activities identical to the experimental group, with the exception of not wearing masks.

Intervention description

The investigation will take place within hospital corridors. Before initiating the study, all researchers must undergo training for the 6MWT and obtain cardiopulmonary resuscitation (CPR) proficiency. To ensure the well-being of participants, respiratory care specialists will be periodically engaged, aligning with the participants' medical needs. The specified interventions are outlined as follows.

6-minute walk test (6MWT)

In accordance with the guidelines outlined by the American Thoracic Society,[18] a meticulous 6MWT will be conducted. The designated corridor for this purpose spans a length of 30 metres and ensures limited foot traffic. Strategically placed chairs at both ends and a midpoint will serve as markers, providing participants with opportunities to pause and rest, if necessary. To optimise test outcomes, participants are advised to refrain from strenuous physical activity and familiarise themselves with the test protocol and environment within a 2-hour timeframe preceding the test. Initiating the 6MWT, participants are encouraged to exert their utmost effort in traversing the corridor repeatedly, aiming to minimise external disruptions. The test will conclude precisely at the 6-minute mark, during which researchers will meticulously measure and document the 6MWD, along with other relevant test data.

Standards and mask application

Surgical masks comply with the specifications outlined in the 'Medical Surgical Masks' standard (YY 0469–2011).[19] N95 masks adhere to the prescribed 'Technical Requirements for Medical Protective Masks' (GB 19083–2010).[20] Participants opting for N95 masks must conduct an initial self-assessment of airtightness. This involves employing a positive pressure assessment method by exhaling rapidly with both hands covering the mask or adopting a negative pressure evaluation by inhaling. In either case, the participant should perceive a slight expansion or contraction of the mask. If a participant detects any gas leakage around the nasal bridge, prompt adjustments to the nasal clip are recommended. Similarly, if gas leakage is noted along both sides of the mask, fine-tuning of the headband's positioning is advised.

Specific intervention methods for different groups

N95 mask group: Participants will initiate with a 10-minute resting period without the mask (T1). Subsequently, a 6-minute seated session wearing the N95 mask (T2) will follow. This will be succeeded by mask removal and another 10-minute rest (T3). Finally, participants will proceed to don the mask again for a 6MWT (T4).

Surgical mask group: The protocol for this group mirrors that of the N95 mask group, with the only alteration being the substitution of the mask type with a surgical mask.

Control group: Identical procedures will be executed in the control group as observed in the N95 mask and surgical mask groups, with the exception that participants in this group will undergo all activities without wearing a mask.

Criteria for discontinuation or modification of allocated interventions

Instances mandating immediate termination of the trial for a participant encompass the following scenarios:

1. Participants encountering severe adverse events or reactions during the intervention.
2. Participants experiencing pronounced complications or a discernible deterioration in their condition during the intervention.
3. Aberrations arising during the 6MWT, including but not limited to chest pain, a systolic blood pressure reduction of 20 mm Hg or more, muscular spasms in the lower extremities or any other symptomatic manifestations necessitating the abrupt cessation of the test.[18 21]

Strategies to enhance adherence to interventions

Throughout the trial, researchers will provide verbal and emotional support to participants to enhance compliance and minimise dropout rates.

Relevant concomitant care permitted or prohibited during the trial

During the trial, participants who do not require oxygen are advised to refrain from its use.

Provisions for post-trial care

Following the conclusion of the trial, clinicians will conduct nursing care and follow-up investigations on participants who discontinue intervention due to adverse reactions. Detailed information will be recorded until the adverse reactions subside.

Demographic and clinical characteristics

The demographical data for this study will encompass age, height, weight, gender, marital status and education level, among other factors.

Prior to the commencement of the trial, lung function measurements, including FEV_1, FVC and FEV_1/FVC, will be obtained for all participants. Participants will be classified into GOLD 1, GOLD 2, GOLD 3 and GOLD 4 categories based on FEV_1 (% pred). Additionally, the investigators will inquire about patients' smoking status and other disease-related details using questionnaires, including comorbidities, the British modified Medical Research Council dyspnoea scale (mMRC) and COPD Assessment Test (CAT) score, among other parameters.

Outcomes

Primary outcomes

Main outcome measures include venous oxygen saturation and the 6MWD. The necessary measuring tools are a finger-clamp oximeter and a tape measure. Venous oxygen saturation needs to be measured immediately at the end of T_1, T_2, T_3 and T_4, while the 6MWD is measured at the end of T_4.

Secondary outcomes

Secondary outcome measures include pulse, systolic blood pressure, diastolic blood pressure, Borg score, RPE score and subjective feeling score. Pulse is measured using a finger-clamp oximeter, blood pressure is assessed with an electronic sphygmomanometer and the remaining indicators are evaluated using score tables. Measurements are taken at specific time points: pulse and systolic and diastolic blood pressure are measured immediately at the end of T_1, T_2, T_3 and T_4. Borg score and RPE score are measured at the end of T_3 and T_4, while the subjective feeling score is assessed at the end of T_2 and T_4.

Participant timeline

This study is scheduled to commence participant recruitment in October 2023. As there is no follow-up involved, and the total intervention time per participant is relatively short, no specific cut-off time has been established for the study. Once the required sample size is attained, the researchers will conclude participant recruitment and bring the study to a close. The participant timeline is illustrated in figure 1.

Blinding

Due to the specific nature of the intervention (wearing masks), it proves challenging to implement blinding for participants, researchers and data collectors.

Data collection and management

Plans for assessment and collection of outcomes

Researchers will employ self-designed questionnaires to gather demographical and basic data from participants through face-to-face interviews.

Three scales—Borg scale,[18] RPE scale[22] and the subjective perception scale—are utilised in this study. Notably, the subjective perception scale was introduced in the study by Li Y *et al*,[23] and it has also been employed by Fikenzer S *et al* and Driver S *et al* in comparable investigations.[24 25]

All researchers participating in the study will undergo training to ensure the use of standardised guidance and accurate methods for collecting and recording participant outcomes and safety indicators.

Strategies for enhancing participant retention and ensuring full follow-up

The study does not involve follow-up. If participants have no adverse reactions, researchers should actively encourage them to complete the entire trial. When participants are unable to complete the entire trial, researchers should record the reasons for their withdrawal.

Data management and safety

The data will be entered by two individuals to minimise entry errors caused by subjective factors. Specialised researchers within the research team are responsible for managing and collating all study-related data. All collected data will be strictly confidential and stored securely with restricted access.

Participant records will be treated confidentially, with only researchers and ethics committees having authorised access to their medical information. Any public reports

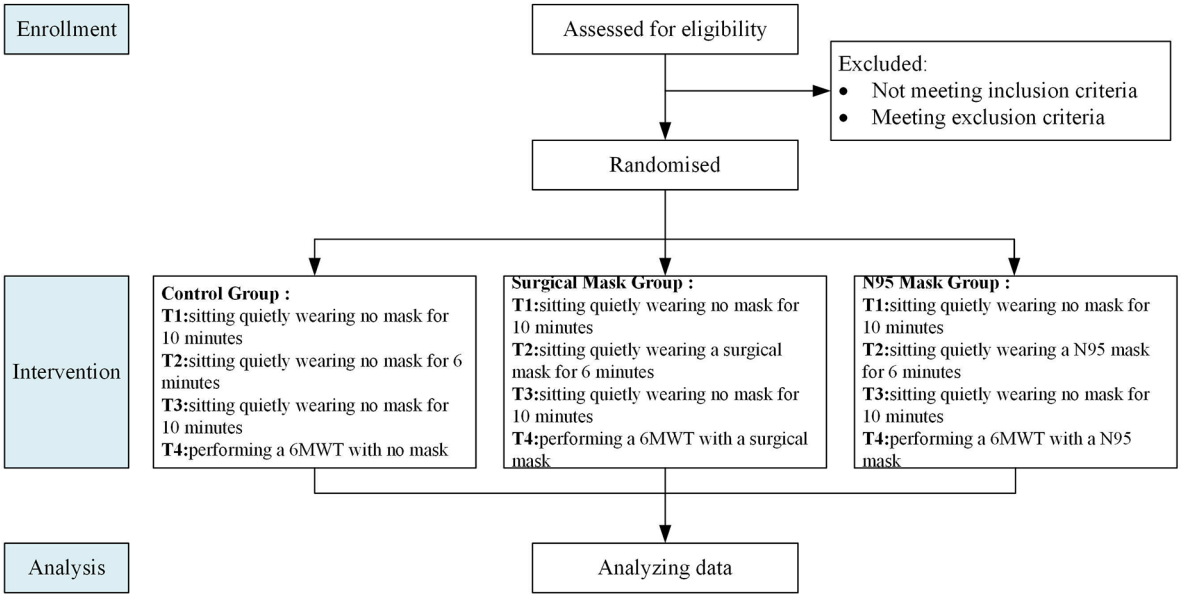

Figure 1 Participant timeline.

on the study results will not reveal the personal identities of the participants. Researchers will make every effort to safeguard the privacy of participants' medical data within the bounds permitted by law.

Statistical methods

Statistical methods for primary and secondary outcomes

For dichotomous or categorical data, counts (n) and percentage (%) will be presented, and the difference between groups will be compared using the Fisher's exact test or the χ^2 test. Variables meeting the criteria of normal distribution and homogeneity of variance will be presented using mean and SD values. To compare means across multiple groups, analysis of variance (ANOVA) will be employed, followed by the application of the SNK (Student-Newman-Keuls) method for pairwise comparisons between any two groups. In cases where variables deviate from the normal distribution, data will be presented using the median and IQR, and non-parametric tests will be applied for intergroup comparisons. All data analyses will be conducted exclusively on participants who have successfully completed this particular phase of the trial. The statistical assessments will follow a two-sided testing approach, where $p \leq 0.05$ will be considered statistically significant.

The demographical and clinical characteristics specific to each group of variables will be presented in summary. Overall, the provided data exhibit a balance and comparability across groups. In the event of any imbalances detected among the data sets, regression analyses will be employed to mitigate potential confounding biases. This strategic approach aims to investigate factors influencing outcome metrics, such as the 6MWD. Noteworthy confounding indicators to be considered in these analyses include FEV_1, CAT score and mMRC score.

Strategies for handling protocol non-adherence and addressing missing data in the analysis

This study will adhere to the basic principles of per-protocol (PP) analysis and will solely analyse the outcome indicators of participants who completed the intervention.

Adverse event reporting and harms

Throughout the entire study duration, the researchers will diligently monitor and document any occurrences of adverse events. In cases where adverse reactions manifest during the study, the timing, severity, duration and corresponding treatment procedures shall be meticulously recorded in the adverse reaction record table. Furthermore, a comprehensive assessment of their correlation with the trial will be conducted.

While we anticipate that participants will encounter no adverse reactions, it is essential to note that patients with COPD may experience significant decreases in oxygen saturation during the 6MWT, necessitating continuous monitoring of changes in patient oxygen saturation during the study.[26]

Adverse events in this study are primarily associated with the mask and the 6MWT. Adverse events related to the mask that may lead to trial termination include headache, dizziness and dyspnoea.[11] According to the American Thoracic Society (AST) statement, potential adverse reactions during the 6MWT encompass chest pain, intolerable dyspnoea, leg cramps, staggering, sweating and a pale or pallid appearance.[18] In such instances, researchers are mandated to promptly assess the situation, administer appropriate corrective actions and facilitate the participant's transition to a seated or supine position. Continuous monitoring of vital signs and subsequent medical interventions must

be executed, with all pertinent details comprehensively documented until the adverse reactions have abated.

In instances where adverse events transpire during the course of the trial, it is incumbent on the researchers to expeditiously implement protective measures and promptly relay the incident to the study's designated authority.

Ethics and dissemination

Ethics approval

This study will involve the participation of human subjects and has received approval from the Ethics Committee of the Affiliated Hospital of Gansu University of Chinese Medicine (approval number: 202335). Once the protocol has been modified, we will notify the Ethics Committee of the Affiliated Hospital of the Gansu University of Chinese Medicine.

The researcher will draft the informed consent form before commencing the study. The informed consent content will encompass an overview of the trial, its objectives, the intervention procedures and the potential random allocation to specific groups. Participants will receive comprehensive information about the research process either by reviewing the informed consent form or through direct communication with the researcher before deciding to participate in the study. The intervention will only commence after the participant has signed the informed consent form.

Dissemination plans

Researchers plan to disseminate the study findings through presentations at scientific conferences and by publishing the trial results and conclusions in peer-reviewed journals. For access to the trial results after its completion, interested parties can contact the corresponding author.

DISCUSSION

This study represents a randomised parallel controlled trial, marking a pioneering effort in China to investigate the impact of mask use among specific populations. The primary aim is to determine whether the use of different mask types has discernible effects on key physiological indicators and subjective sensations in individuals with COPD. In contrast to the study by Hirai *et al*, this investigation incorporates a larger sample size,[16] providing a more robust and comprehensive understanding of the influence of masks on COPD patients.

Drawing on insights from the non-randomised controlled trials conducted by Kyung *et al*,[11] the design paradigm of this study skillfully minimises potential biases that could arise during the conception and execution of clinical trials. By effectively balancing confounding variables, this study aims to provide COPD patients with a well-informed framework for the selection and utilisation of masks.

This study presents several noteworthy strengths. Initially, the research team conducted a systematic review and meta-analysis on the impacts of mask utilisation on COPD patients, establishing a robust theoretical foundation for the study (identifier, CRD420223262650).[27] Moreover, the trial design benefits from the expertise of epidemiology and clinical respiratory specialists who have contributed to its meticulous formulation. Furthermore, the execution of the trial within medical institutions contributes significantly to ensuring the trial's safety and methodological integrity.

However, it is important to acknowledge the inherent limitations of this study. For instance, while employing scales to assess participants' subjective sensations offers valuable insights, it fails to encompass the potential influence of participants' psychological states on their reported feelings. Moreover, given the distinctive nature of the participants, this study exclusively examines the short-term effects of mask usage on COPD patients, focusing on scenarios characterised by low exercise intensity.

Furthermore, a 2020 study identified N95 masks and surgical masks as the predominant types used in China.[28] Given the disparate standards for cloth masks and the considerable variability in their filtration efficacy,[29 30] our study excludes cloth masks, focusing solely on surgical masks and N95 masks. These two mask types will serve as the foundation for future investigations into the potential adverse effects of other masks with superior filtration capabilities on individuals with COPD.

Moving forward, it is imperative for researchers to delve deeper into these facets. Subsequent investigations could explore the optimal duration for mask usage among COPD patients, evaluating the varying impacts of masks across different exercise intensities. Furthermore, there exists a compelling need for a more comprehensive exploration of the underlying biological mechanisms through which masks exert their influence on COPD patients.

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Contributors CW, XZ, DR, HY and JS conceived and designed the study. XC and XJ drafted the protocol manuscript. SB and JF substantially revised the manuscript. AX, RB, FY and CL have been responsible for the execution of the study procedures. All authors read and approved the final manuscript.

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Competing interests None declared.

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