Assessing the impact of different types of masks on COPD patients: a randomised controlled trial

Jingchun Fan [1,7], Tiantian Feng[1,7], Xiaomei Jiang[2], Caihong Wei[3], Xuhui Zhang[4], Caiyun Li[1], Feiyan Yue[1], Hong Yang[5,8], Shisan Bao[1,8] and Xuwen Chen[1,6,8]

[1]School of Public Health, Center for Evidence-Based Medicine, Gansu University of Chinese Medicine, Lanzhou, China. [2]Department of Psychosomatic and Sleep Medicine, Lanzhou Petrochemical General Hospital, Lanzhou, China. [3]Pulmonary and Critical Care Medicine, Lanzhou Petrochemical General Hospital, Lanzhou, China. [4]Respiratory Center, the 1st People's Hospital of Baiyin, Baiyin, China. [5]Department of Rehabilitation Medicine, Affiliated Hospital of Gansu University of Chinese Medicine, Lanzhou, China. [6]Health Management Center, Sichuan Gem Flower Hospital. North Sichuan Medical College, Chengdu, China. [7]J. Fan and T. Feng contributed equally to this article as first authors. [8]H. Yang, S. Bao and X. Chen contributed equally to this article as lead authors and supervised the work.

Corresponding author: Hong Yang (404978482@qq.com)

Shareable abstract (@ERSpublications)
The wearing of masks by COPD patients during short-term and low-intensity activities affected the patients' subjective perception scores but did not affect their common physiological variables
https://bit.ly/3zL8mqf

Cite this article as: Fan J, Feng T, Jiang X, *et al*. Assessing the impact of different types of masks on COPD patients: a randomised controlled trial. *ERJ Open Res* 2025; 11: 00806-2024 [DOI: 10.1183/23120541.00806-2024].

Received: 13 Aug 2024
Accepted: 25 Sept 2024

Abstract

Background Wearing masks imposes an additional respiratory burden on COPD patients. This study aimed to investigate the impact of various mask types on physiological parameters and subjective feelings in COPD patients.

Methods This randomised, open-label, parallel-controlled trial randomly assigned 129 COPD patients from two Chinese hospitals to the N95 mask group, the surgical mask group and the no mask group, who were required to complete a 6-min rest (6MR) and a 6-min walking test (6MWT) while wearing their designated masks, and were assessed for blood pressure, oxygen saturation, pulse rate, Borg score, rating of perceived exertion (RPE) score, 6-min walk distance (6MWD) and subjective feeling score. Data were analysed using intention-to-treat analysis and per-protocol analysis.

Results No significant differences were observed in blood pressure, oxygen saturation, pulse rate or the 6MWD among the three groups following a 6MR or 6MWT. Wearing N95 masks and surgical masks during the 6MWT significantly elevated perceived dyspnoea ($p<0.001$) and exertion scores ($p<0.001$) in COPD patients. The differences in the two scores between the highest and lowest groups were 2 and 4 points, respectively.

Conclusion Wearing surgical masks or N95 masks for 6MR or 6MWT did not adversely affect physiological parameters in COPD patients. However, it significantly increased perceived dyspnoea and exertion.

Introduction

COPD is a prevalent chronic airway condition characterised by persistent respiratory symptoms and airflow limitation [1]. It is predicted that the incidence of COPD will continue to climb each year for the next 40 years, and that according to the World Health Organization (WHO) by 2060, >5.4 million individuals may succumb to COPD or its related illnesses annually [2]. Factors contributing to death in COPD patients include acute exacerbations of COPD, which are often associated with pathogenic infections [3]. Therefore, implementing effective strategies to help COPD patients reduce exposure to pathogens could potentially lower the frequency of acute exacerbations [1].

Masks are often used to reduce the inhalation of various common and uncommon pathogens [4]. Although the pros and cons of wearing masks are controversial [5–7], the risk of infection by various respiratory

pathogens can be effectively minimised provided masks are worn correctly [8]. Common types of masks include cloth, N95 and surgical masks [9]. Among them, N95 masks are those certified by the National Institute for Occupational Safety and Health (NIOSH) as having a filtration efficiency of 95% for non-oily particulate matter [9]. Studies have found that wearing masks is an important factor in reducing the risk of acute exacerbation of COPD [10, 11]. However, the airflow resistance generated by mask wearing should not be ignored, and it is necessary to explore the potential adverse effects of masks on COPD patients at the level of respiration and subjective feelings, so as to guide the appropriate use of masks in COPD patients in special situations.

Currently, the research on masks for COPD patients is at the rather early stage, focusing on a single type of mask and utilising low-quality trial designs [12, 13]. In order to verify the validity of the existing hypothesis and improve the level of study in this field, this study used a randomised controlled trial design to explore the possible adverse effects of wearing surgical masks and N95 masks on COPD patients, so as to enrich the study on the impacts of masks on cardiopulmonary function of COPD patients and offer guidance on the safe use of masks during specific periods.

Methods

Study design

This trial employed a randomised, controlled, multicentre design to investigate the impact of N95 and surgical masks on common physiological indicators and subjective feelings in COPD patients during both a 6-min rest (6MR) and a 6-min walking test (6MWT). The trial was conducted at the Affiliated Hospital of Gansu University of Chinese Medicine and Lanzhou Petrochemical General Hospital. All aspects of the study adhered to the ethical principles outlined in the Declaration of Helsinki and received approval from the Ethics Committee of the Affiliated Hospital of Gansu University of Chinese Medicine (approval number: 202335). The reporting of this trial adhered to the CONSORT 2010 checklist criteria [14]. The protocol for this trial was previously published and available online [15].

Participants

In accordance with the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria [1], a pulmonary function criterion of forced expiratory volume in 1 s (FEV_1)/forced vital capacity (FVC) <70% post inhaled bronchodilators confirmed persistent airflow limitation and COPD diagnosis. Clinicians established definitive diagnoses by considering clinical presentations, exposure history to risk factors and laboratory test data.

Eligible participants were COPD patients with stable symptoms and no medication changes in the preceding 4 weeks, devoid of concurrent motor or neurological disorders. Evaluation by a specialised clinician was a prerequisite for trial participation. Exclusion criteria encompassed pregnancy, allergies, absolute contraindications to the 6MWT, learning or cognitive disabilities hindering communication, and abnormal heart rate or blood pressure.

Before participating in the study, all participants were informed of the trial process by reading the informed consent form or communicating with the study staff. The study staff would start the trial once the participants had signed the informed consent form.

Randomisation and masking

Prior to the initiation of the trial, a randomised grouping scheme was generated using SPSS 25.0 software by study staff uninvolved in any other trial aspects. This scheme randomly assigned all participants to the no mask, surgical mask or N95 mask groups at a ratio of 1:1:1. The outcomes of this randomisation process for each study participant were sealed in opaque envelopes and remained undisclosed until the completion of baseline data measurement.

Given the specificity of the intervention, during the whole study period, this study did not blind the study staff and participants but only blinded the statistical staff.

Procedures

Participants were interviewed to collect comprehensive sociodemographic variables through a structured questionnaire. Height and weight measurements were also taken during the interview, and the body mass index was calculated afterwards.

In the current study, COPD diagnoses remained consistent without redefinition or reassessment, with disease information extracted from prior medical records. However, lung functions of all participants were

reevaluated before the trial to assess disease severity. All assessments adhered to the guidelines set out by the American Thoracic Society (ATS) and European Respiratory Society (ERS) [16]. Lung function parameters were measured using a spirometer (MasterScreen SeS, Jaeger, Germany). Furthermore, disease-specific details were captured through questionnaires.

Prior to the trial, all participants were instructed to sit still for 10 min without a mask, breathing normally. This initial phase was labelled as the rest phase. According to the randomised grouping scheme, each participant performed two protocols without a mask, with a surgical mask, or with an N95 mask, including: 1) sitting quietly for 6 min; and 2) performing a 6MWT. Between the two phases, there was a 10-min rest period, and participants in the masked group were instructed to remove their masks during the rest period.

Outcomes

Physiological variables were evaluated both before and immediately after the completion of the 6MR. These variables included systolic blood pressure, diastolic blood pressure, pulse rate and oxygen saturation. Systolic and diastolic blood pressure were measured using an electronic sphygmomanometer, while pulse rate and oxygen saturation were measured using a finger-clamp pulse oximeter.

Similarly, the above physiological variables were evaluated immediately both before and after the completion of the 6MWT. In addition, according to the recommendations of the ATS, the participants' Borg score [17] and rating of perceived exertion (RPE) score [18] were evaluated, and the participants' 6-min walking distance (6MWD) was obtained after the 6MWT.

The subjective feelings of wearing masks were evaluated after the 6MR and 6MWT, respectively. The subjective feelings of wearing masks were mainly quantified by the questionnaire designed as Li *et al.* [19] described.

The safety assessment involved monitoring any adverse events associated with mask usage during seated rest or the 6MWT. These events included lower limb muscle cramps, chest pain, intolerable dyspnoea, profuse sweating, gait instability, pale complexion and other relevant indicators. Additionally, the trial was stopped immediately if a participant's systolic blood pressure dropped by 20 mmHg or more during the trial.

Statistical analysis

The calculation of the sample size was rooted in the difference in Borg scores between the masked and non-masked groups post the 6MWT. Referring to a prior study reporting a difference of 0.91 points and a standard deviation of 1.40 [20], the sample size was determined using the formula:

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

With a two-sided alpha of 0.05 and a power of 80%, computations using PASS 15 software yielded a minimum sample size of 39 cases per group. To account for a shedding rate of no more than 10%, a total of 129 participants were recruited.

Statistical analyses were conducted using SPSS 25.0 statistical software based on the full analysis set and the per-protocol set. Intention-to-treat analysis (ITT) and per-protocol analysis (PP) were used to evaluate the impact of masks on COPD patients. Quantitative data were presented as n (%) with group comparisons facilitated through the chi-square test or Fisher's exact test. Continuous variables, when conforming to normal distribution, were expressed as mean±SD, and inter-group comparisons were performed using analysis of variance. In cases where normal distribution criteria were not met, data were expressed as median (interquartile range), and nonparametric tests were employed. The Mann–Whitney U-test was used for comparison between two groups and the Kruskal–Wallis H test was used for comparison between multiple groups. A significance level of $p \leqslant 0.05$ was considered indicative of statistical significance.

Results

Between October 2023 and December 2023, this study enrolled 129 COPD patients through targeted recruitment efforts using posters and social media platforms at Gansu University of Chinese Medicine and Lanzhou Petrochemical General Hospital. After randomisation, all participants completed the 6MR phase and took a 10-min sitting rest, with five participants not completing the following 6MWT, as shown in figure 1.

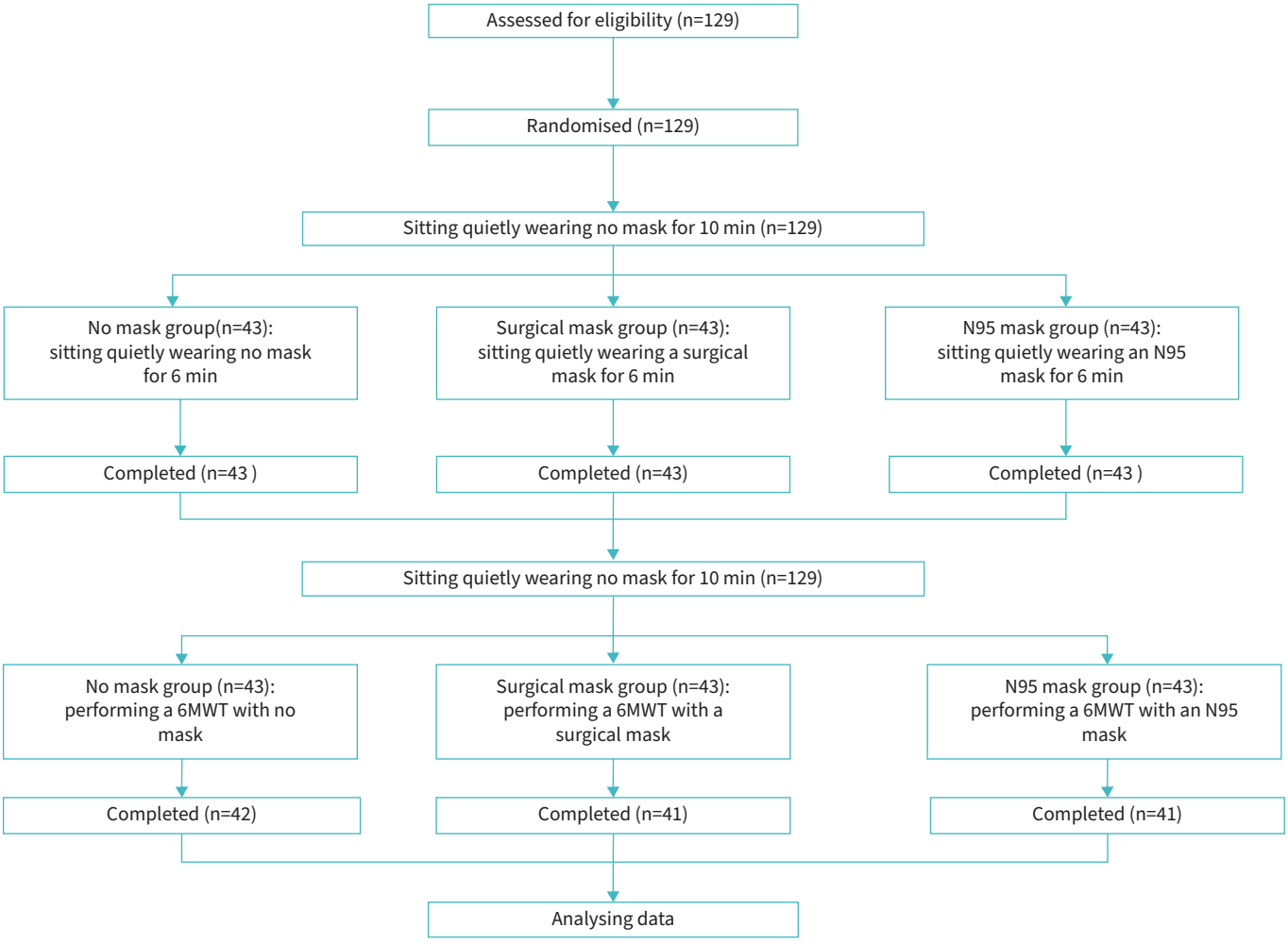

FIGURE 1 Patient disposition and population. 6MWT: 6-min walking test.

Baseline characteristics demonstrated equilibrium across the three groups, as depicted in table 1. Among the 129 participants, 106 were male, constituting 82.17% of the cohort. The age range spanned from 48 to 86 years. Notably, the mean FEV_1/FVC surpassed 50% in all three groups. The majority of participants had a respiratory disease history of <5 years, with 66 individuals (51.16%) having only COPD without any other concurrent diseases. No difference in demographic and clinical characteristics were observed among the three groups of participants at baseline.

Physiological variables of the participants were measured before both the 6MR and the 6MWT, and there were no significant differences in systolic blood pressure, diastolic blood pressure, blood oxygen saturation and pulse rate among the three groups (table 2). Similarly, in terms of subjective variables, there was no statistically significant difference in Borg scores and RPE scores among the participants in the three groups before the 6MWT (table 2).

Following the 6MR, no significant differences were observed in systolic blood pressure, diastolic blood pressure, blood oxygen saturation and pulse rate among the three groups (table 3). Consequently, the utilisation of N95 masks and surgical masks during the 6MR period in COPD patients did not have adverse effects on the aforementioned physiological indicators.

Systolic blood pressure, diastolic blood pressure and pulse rate were noticeably increased in all three groups of participants after the 6MWT compared to before the 6MWT, accompanied by a slight decrease in blood oxygen saturation (table 2 and table 4). Despite these changes, there remained no significant differences in the above variables between the three groups after the end of the 6MWT (table 4 and figure 2).

TABLE 1 Baseline characteristics

	No mask	Surgical mask	N95 mask
Patients, n	43	43	43
Age years	64.35±7.83	67.26±6.37	66.40±7.88
Sex			
Male	38 (88.4)	35 (81.4)	33 (76.7)
Female	5 (11.6)	8 (18.6)	10 (23.3)
BMI kg·m^{-2}			
<18.5	1 (2.3)	3 (7.0)	1 (2.3)
18.5–23.9	25 (58.2)	21 (48.8)	21 (48.9)
24.0–27.9	13 (30.2)	18 (41.9)	16 (37.2)
⩾28.0	4 (9.3)	1 (2.3)	5 (11.6)
Course of respiratory disease years			
<5	23 (53.5)	22 (51.2)	25 (58.1)
5–10	5 (11.6)	4 (9.3)	7 (16.3)
>10	15 (34.9)	17 (39.5)	11 (25.6)
Smoking status			
Nonsmoker	11 (25.6)	14 (32.6)	10 (23.3)
Current smoker	17 (39.5)	9 (20.9)	13 (30.2)
Former smoker who has quit	15 (34.9)	20 (46.5)	20 (46.5)
Exercise h per week			
<0.5	15 (34.9)	9 (20.9)	11 (25.6)
0.5–2	7 (16.3)	10 (23.3)	9 (20.9)
>2	21 (48.8)	24 (55.8)	23 (53.5)
Complications			
0	24 (55.8)	20 (46.5)	22 (51.2)
1	15 (34.9)	21 (48.8)	18 (41.8)
⩾2	4 (9.3)	2 (4.7)	3 (7.0)
FEV_1 L	1.45 (0.88–1.90)	1.52 (1.13–2.03)	1.29 (1.03–1.76)
FEV_1/FVC %	50.38±12.32	52.97±10.45	53.62±11.17
Grade			
GOLD 1	6 (14.0)	8 (18.6)	3 (7.0)
GOLD 2	14 (32.6)	18 (41.9)	20 (46.5)
GOLD 3	16 (37.2)	14 (32.6)	17 (39.5)
GOLD 4	7 (16.3)	3 (7.0)	3 (7.0)
mMRC score			
0	8 (18.6)	8 (18.6)	5 (11.6)
1	17 (39.5)	19 (44.2)	24 (55.8)
2	16 (37.2)	12 (27.9)	11 (25.6)
⩾3	2 (4.7)	4 (9.3)	3 (7.0)
CAT score			
<10	9 (20.9)	7 (16.3)	5 (11.6)
10–21	31 (72.1)	26 (60.5)	31 (72.1)
>21	3(7.0)	10 (23.2)	7 (16.3)

Data are presented as n (%), median (interquartile range) or mean±SD. BMI: body mass index; FEV_1: forced expiratory volume in 1 s; FVC: forced vital capacity; GOLD: Global Initiative for Chronic Obstructive Lung Disease; mMRC: modified Medical Research Council; CAT: COPD Assessment Test.

Furthermore, while the 6MWD was greater in the no mask group compared to the mask-wearing groups, this difference did not attain significance (ITT: p>0.05, PP: p>0.05; table 4). Importantly, a significant difference was observed in both Borg score (ITT: p<0.001, PP: p<0.001; table 4 and figure 3) and RPE score (ITT: p<0.001, PP: p<0.001; table 4 and figure 3). Specifically, the N95 mask group had a 2-point higher Borg score and a 4-point higher RPE score than the no mask group.

During both the 6MR and 6MWT, the N95 mask group exhibited higher scores than the surgical mask group listed in tables 5 and 6, in the categories of heat (6MR: p=0.001, 6MWT: p<0.001), breath resistance (6MR: p<0.001, 6MWT: p<0.001), tightness (6MR: p<0.001, 6MWT: p<0.001), fatigue (6MR: p<0.001, 6MWT: p<0.001) and overall discomfort (6MR: p<0.001, 6MWT: p<0.001). Additionally, following the 6MWT, the N95 mask group exhibited higher scores in humidity (ITT: p<0.001, PP:

TABLE 2 Effects of masks on physiological variables before 6MR or 6MWT

	No mask	Surgical mask	N95 mask	p-value
Patients, n	43	43	43	
SBP mmHg				
Pre-6MR	127.49±16.02	127.14±15.47	123.67±15.50	0.461
Pre-6MWT	128.47±16.59	129.49±14.93	126.30±15.22	0.627
DBP mmHg				
Pre-6MR	84.02±10.04	82.84±9.77	82.09±11.16	0.684
Pre-6MWT	84.02±8.31	82.91±9.89	80.47±9.66	0.198
S_{pO_2} %				
Pre-6MR	92.00 (90.00–94.00)	93.00 (91.00–94.00)	92.00 (90.00–94.00)	0.267
Pre-6MWT	93.00 (91.00–94.00)	93.00 (91.00–94.00)	93.00 (91.00–94.00)	0.861
PR bpm				
Pre-6MR	80.00±10.47	79.00±14.10	78.79±11.01	0.882
Pre-6MWT	80.95±10.13	79.16±12.84	78.49±10.43	0.575
Borg score				
Pre-6MWT	0.00 (0.00–0.50)	0.00 (0.00–0.50)	0.00 (0.00–0.50)	0.714
RPE score				
Pre-6MWT	6.00 (6.00–7.00)	6.00 (6.00–7.00)	6.00 (6.00–8.00)	0.242

Data are presented as median (interquartile range) or mean±SD. The Borg score ranges from 0 to 10. The RPE score ranges from 6 to 20. 6MR: 6-min rest; 6MWT: 6-min walking test; SBP: systolic blood pressure; DBP: diastolic blood pressure; S_{pO_2}: oxygen saturation; PR: pulse rate; bpm: beats per minute; RPE: rating of perceived exertion.

p<0.001; table 6) and salty (ITT: p<0.001, PP: p=0.001; table 6) compared to the surgical mask group. In terms of overall discomfort scores, the N95 mask group was 1 and 2 points higher than the surgical mask group after the 6MR and 6MWT, respectively.

No adverse events were observed throughout the study.

Discussion

Consistent with the systematic review and meta-analysis of the same topic carried out by our research team before [21], the results of this study showed that masks did not have a negative impact on the physiological indices of COPD patients after 6MR or 6MWT. Nevertheless, wearing masks did lead to adverse subjective feelings in COPD patients, with the negative effects being more pronounced with the N95 mask compared to the surgical mask. To our knowledge, this study is the first study in China to investigate the impact of different types of masks on physiological indices and subjective feelings in COPD patients after a 6MR or 6MWT.

The study results indicated that wearing a mask during a 6MR did not have a significant impact on blood pressure, oxygen saturation and pulse rate in patients with COPD. Notably, a Korean study involving COPD patients resting while wearing an N95 mask for 10 min showed a slight change in oxygen saturation compared to baseline, which was statistically significant but not clinically significant [22]. Similarly, Samannan *et al.* [12] demonstrated no clinically relevant physiological changes in oxygen saturation in COPD patients who rested with a surgical mask for 5 or 30 min, aligning with our own findings.

Similarly, our current study also found that patients wearing a mask for the 6MWT only affected the patients' Borg score and RPE score, and did not affect their systolic blood pressure, diastolic blood

TABLE 3 Effects of masks on physiological variables after 6MR

	No mask	Surgical mask	N95 mask	p-value
Patients, n	43	43	43	
SBP mmHg	128.84±16.11	129.12±14.89	123.40±15.07	0.155
DBP mmHg	83.58±9.27	83.14±8.70	82.63±9.64	0.891
S_{pO_2} %	92.00 (89.00–93.00)	92.00 (90.00–94.00)	92.00 (90.00–93.00)	0.563
PR bpm	79.88±10.11	79.19±13.40	78.74±10.50	0.897

Data are presented as median (interquartile range) or mean±SD. 6MR: 6-min rest; SBP: systolic blood pressure; DBP: diastolic blood pressure; S_{pO_2}: oxygen saturation; PR: pulse rate; bpm: beats per minute.

TABLE 4 Effects of masks on physiological variables after 6MWT

	No mask	Surgical mask	N95 mask	p-value
SBP mmHg				
ITT	138.21±17.38	138.44±14.55	132.41±14.46	0.129
PP	138.21±17.60	138.44±14.91	132.41±14.82	0.152
DBP mmHg				
ITT	87.55±8.63	88.76±8.53	86.15±8.00	0.356
PP	87.55±8.74	88.76±8.74	86.15±8.19	0.388
S_{pO_2} %				
ITT	88.00 (85.00–91.00)	88.00 (85.00–90.00)	86.00 (84.00–88.00)	0.084
PP	88.00 (85.00–91.00)	88.00 (84.50–90.00)	86.00 (84.00–88.50)	0.110
PR bpm				
ITT	99.98±11.01	100.56±14.53	104.83±11.46	0.146
PP	99.98±11.14	100.56±14.89	104.83±11.74	0.170
Borg score				
ITT	1.00 (0.50–2.00)	2.00 (2.00–3.00)[#]	3.00 (3.00–4.00)[#¶]	<0.001
PP	1.00 (0.50–2.25)	2.00 (2.00–3.00)[#]	3.00 (3.00–4.00)[#¶]	<0.001
RPE score				
ITT	7.00 (7.00–9.00)	10.00 (8.00–11.00)[#]	11.00 (11.00–13.00)[#¶]	<0.001
PP	7.00 (7.00–9.00)	10.00 (8.00–11.00)[#]	11.00 (11.00–13.00)[#¶]	<0.001
6MWD m				
ITT	340.90±56.66	335.73±68.82	326.44±71.94	0.591
PP	340.90±57.34	335.73±70.52	326.44±73.71	0.615

Data are presented as median (interquartile range) or mean±SD. The Borg score ranges from 0 to 10. The RPE score ranges from 6 to 20. 6MWT: 6-min walking test; SBP: systolic blood pressure; ITT: intention-to-treat analysis; PP: per-protocol analysis; DBP: diastolic blood pressure; S_{pO_2}: oxygen saturation; PR: pulse rate; bpm: beats per minute; RPE: rating of perceived exertion; 6MWD: 6-min walking distance. [#]: compared with non-mask group, p<0.05; [¶]: compared with the surgical mask group, p<0.05.

pressure, oxygen saturation or pulse rate, as compared to the 6MWT without a mask. Differences in Borg score and RPE score may be attributed to the fact that wearing a mask during exercise rebreathes a small amount of exhaled gas, which is minimally oxygenated and rich in carbon dioxide [23]. It has been found that carbon dioxide rebreathing causes subthreshold increases in the carbon dioxide partial pressure (P_{aCO_2}) in the blood in most healthy individuals, but some pathological increases in patients. These changes reflexively cause an increase in respiratory rate and depth, an increase in the work of the respiratory muscles, and the resulting additional oxygen demand and oxygen consumption [24]. Furthermore, patients' work of breathing increases during exercise, and the addition of a mask introduces a slight resistance to both inhalation and exhalation, potentially exacerbating perceived dyspnoea [23, 25]. Finally, SORIANO *et al.* [26] highlighted that while mask use heightens respiratory resistance, emotional factors may play a role in the discomfort experienced by some patients.

It is worth noting that fewer patients with very severe COPD were included in the current study, and the conclusions may not be generalisable to patients with all grades of COPD. It is possible that masks could have a more negative impact on the cardiopulmonary function of very severe patients, who already have varying levels of high carbon dioxide tension (P_{CO_2}) and low oxygen tension (P_{O_2}).

In addition, our current study, following similar research in Japan that focused on the impact of surgical masks on the 6MWD [20], demonstrated that the use of either N95 or surgical masks did not influence the 6MWD in COPD patients. Conversely, a study by JUST *et al.* [13], which required COPD patients to wear disposable medical surgical masks during a 6MWT, found a significant difference in the 6MWD between the masked and non-masked groups. Notably, this divergence in findings could be attributed to the higher severity of the study population, specifically patients with end-stage lung disease [13].

In the current study, the subjective feeling of participants wearing masks was assessed by subjective feeling scores. Consistent with previous studies [19, 27], this study revealed that heat, breath resistance, tightness, fatigue and overall discomfort scores were different between the N95 mask group and the surgical mask group after a 6MR trial. This may be due to the fact that surgical masks are thinner and more breathable compared to N95 masks, creating a less humid and hot environment in the additional dead space of the masks [28].

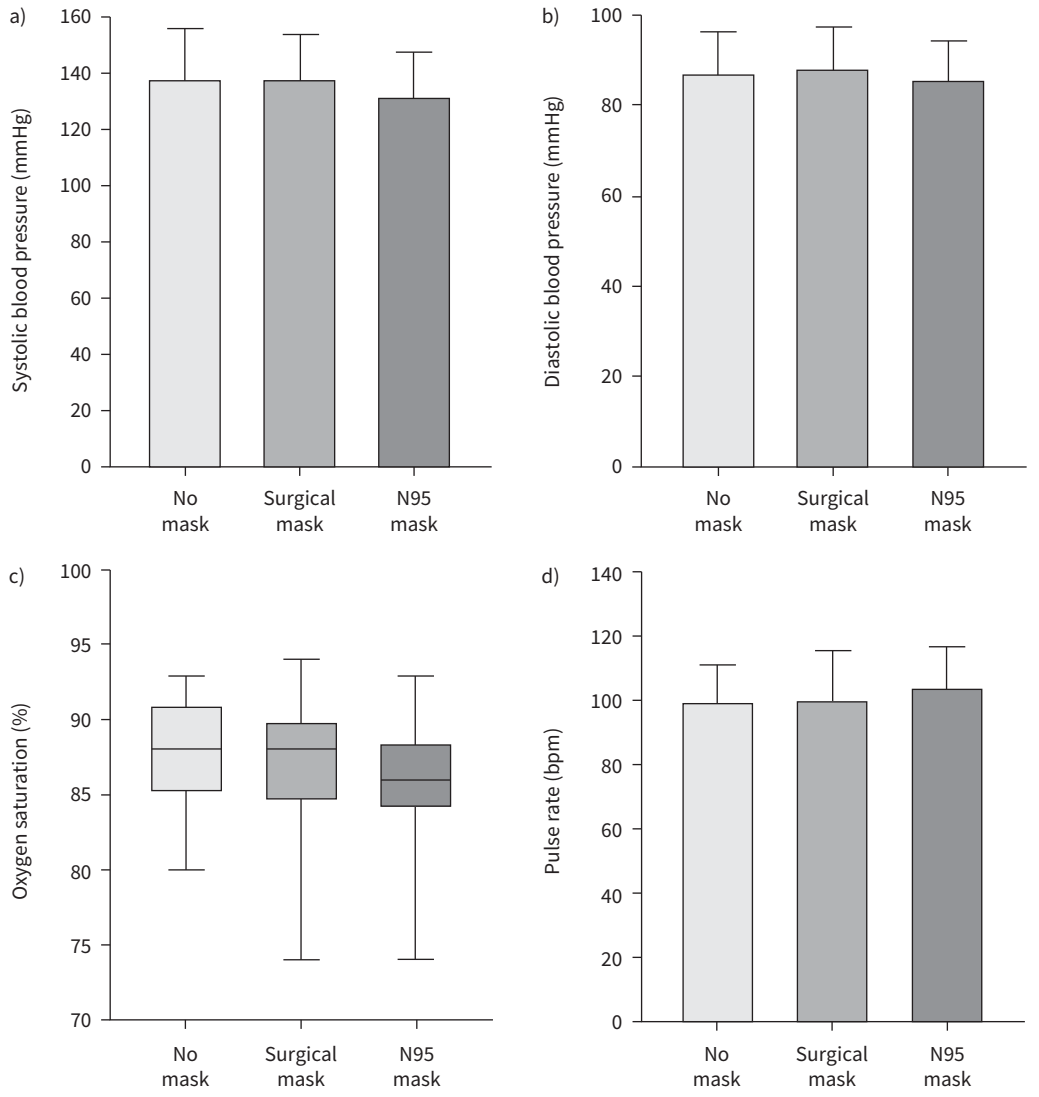

FIGURE 2 Impact of no mask, surgical mask and N95 mask on systolic blood pressure, diastolic blood pressure, oxygen saturation and pulse rate after 6-min walking test (6MWT). a) Comparison of systolic blood pressure among the three groups after 6MWT (per-protocol analysis (PP)). The data are expressed as the mean±SD. b) Comparison of diastolic blood pressure among the three groups after 6MWT (PP). The data are expressed as the mean±SD. c) Comparison of oxygen saturation among the three groups after 6MWT (PP). The data are expressed as median (interquartile range). d) Comparison of pulse rate among the three groups after 6MWT (PP). The data are expressed as the mean±SD. bpm: beats per minute.

Additionally, our current study found that the N95 mask group exhibited higher humidity and salty scores compared to the surgical mask group after a 6MWT. A potential explanation for these findings could be that subjective feeling scores gradually increase with time and workload [14].

The protective performance of N95 masks is known to be superior to that of surgical masks. In addition to differences in composition [29], another key factor influencing this performance is the fit of the N95 masks, which improves the facial seal [30]. Our current study further confirms this, as patients perceived N95 masks to be tighter than surgical masks both during periods of inactivity and while walking.

In addition, the occurrence of subjective fatigue in the current study may be related to the increased respiratory amplitude, abdominal muscle activity and fatigue, and the fatigue of scalene caused by wearing the mask [31]. In terms of potential metabolic effects, Sukul *et al*. [32] noted that mask-induced rebreathing increases the systematic effects of most volatile organic compounds as CO_2 exhalation and respiratory humidity accumulate. As an example, isoprene, which may mediate lipolysis in skeletal muscle,

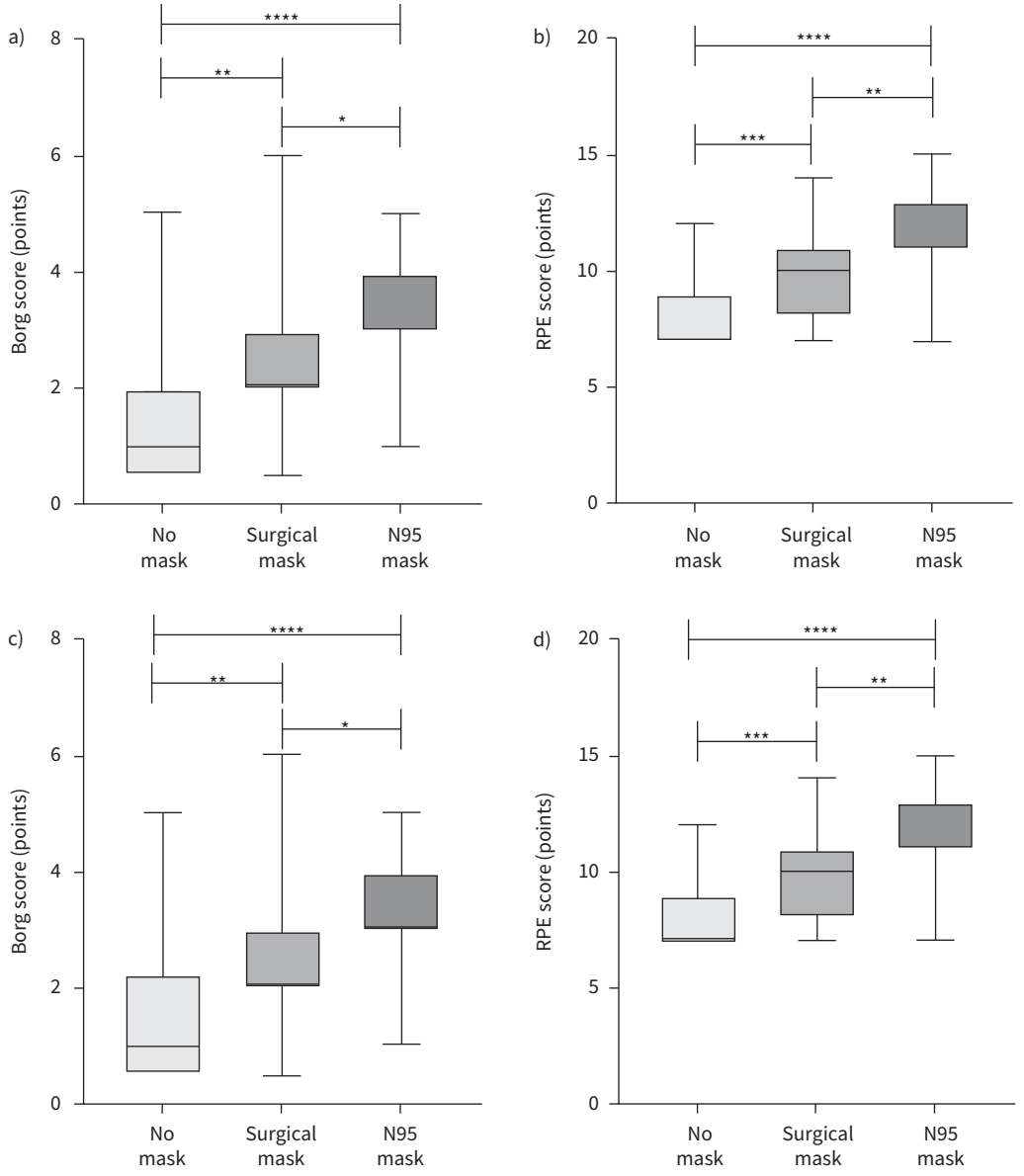

FIGURE 3 Impact of no mask, surgical mask and N95 mask on Borg score and rating of perceived exertion (RPE) score after 6-min walking test (6MWT). a) Comparison of Borg score among the three groups after 6MWT (intention-to-treat analysis (ITT)). b) Comparison of RPE score among the three groups after 6MWT (ITT). c) Comparison of Borg score among the three groups after 6MWT (per-protocol analysis (PP)). d) Comparison of RPE score among the three groups after 6MWT (PP). The data are expressed as median (interquartile range). Statistical significance levels are denoted as follows: *p⩽0.05; **p⩽0.01; ***p⩽0.001; ****p⩽0.0001.

is generally positively correlated with cardiac output, but mask-wearing-induced hypoxia causes sympathetic vasoconstriction of intermuscular compartments resulting in a decrease in isoprene concentration and an increase in cardiac output [33]. All the above-mentioned subjective feelings, including fatigue, contributed to the patients' overall discomfort after wearing the mask. Alleviating this discomfort is crucial for improving adherence [34].

Strengths and limitations

One of the strengths of this study is that before the study began, the study leader invited relevant clinical and epidemiological experts to discuss the study protocol and submitted it to the Chinese Clinical Trial Registry for review. This means that the study can protect the safety and rights of the subjects as well as ensure the scientific and rigour of the clinical trial. Secondly, compared with studies on the same topic,

TABLE 5 Perceived discomfort of wearing masks after 6MR

	Surgical mask	N95 mask	p-value
Humid	0.50 (0.50–0.50)	0.50 (0.50–0.50)	0.062
Hot	0.50 (0.50–1.00)	1.00 (1.00–1.00)	0.001
Breath resistance	1.50 (1.00–2.50)	2.50 (2.50–3.50)	<0.001
Itchy	0.50 (0.50–0.50)	0.50 (0.50–0.50)	0.090
Tight	0.50 (0.50–0.50)	1.50 (0.50–2.50)	<0.001
Salty	0.50 (0.50–0.50)	0.50 (0.50–0.50)	0.811
Unfit	0.50 (0.50–0.50)	0.50 (0.50–0.50)	0.595
Odour	0.50 (0.50–0.50)	0.50 (0.50–0.50)	0.167
Fatigue	0.50 (0.50–1.50)	1.50 (1.00–1.50)	<0.001
Overall discomfort	1.50 (1.00–2.00)	2.50 (2.00–2.50)	<0.001

Data are presented as median (interquartile range). All perceived discomfort scores range from 0 to 10. 6MR: 6-min rest.

this study calculated the sample size, used a high-quality randomised controlled study design, enriched the mask types in the study, and measured multiple subjective feeling scores of COPD patients after wearing masks in addition to objective indicators.

We acknowledge several limitations inherent in this study. Firstly, the small sample size of this study and the fact that only basic physiological variables were assessed may limit our interpretation of the results. Secondly, this study did not blind patients with COPD and did not assess their psychological status.

TABLE 6 Perceived discomfort of wearing masks after 6MWT

	Surgical mask	N95 mask	p-value
Humid			
ITT	0.50 (0.50–0.62)	1.00 (0.50–1.50)	<0.001
PP	0.50 (0.50–0.50)	1.00 (0.50–1.50)	<0.001
Hot			
ITT	1.00 (0.50–1.50)	1.50 (1.50–2.50)	<0.001
PP	1.00 (0.50–1.50)	1.50 (1.50–2.50)	<0.001
Breath resistance			
ITT	3.00 (2.25–3.50)	5.00 (4.50–5.50)	<0.001
PP	3.00 (2.25–3.50)	5.00 (4.25–5.75)	<0.001
Itchy			
ITT	0.50 (0.50–0.50)	0.50 (0.50–1.00)	0.128
PP	0.50 (0.50–0.50)	0.50 (0.50–1.00)	0.120
Tight			
ITT	0.50 (0.50–0.70)	1.50 (0.50–2.50)	<0.001
PP	0.50 (0.50–0.50)	1.50 (0.50–2.50)	<0.001
Salty			
ITT	0.80 (0.50–1.00)	1.00 (1.00–1.50)	<0.001
PP	0.50 (0.50–1.00)	1.00 (1.00–1.50)	0.001
Unfit			
ITT	0.50 (0.50–0.50)	0.50 (0.50–0.50)	0.160
PP	0.50 (0.50–0.50)	0.50 (0.50–0.50)	0.098
Odour			
ITT	0.50 (0.50–0.50)	0.50 (0.50–0.50)	0.961
PP	0.50 (0.50–0.50)	0.50 (0.50–0.50)	0.986
Fatigue			
ITT	1.50 (1.50–2.50)	3.50 (2.50–4.50)	<0.001
PP	1.50 (1.25–2.50)	3.50 (2.50–4.50)	<0.001
Overall discomfort			
ITT	2.50 (2.00–3.00)	4.50 (3.50–5.50)	<0.001
PP	2.50 (2.00–3.25)	4.50 (3.50–5.50)	<0.001

Data are presented as median (interquartile range). All perceived discomfort scores range from 0 to 10. 6MWT: 6-min walking test; ITT: intention-to-treat analysis; PP: per-protocol analysis.

Knowing mask grouping and negative psychological status may affect the subjective experience of wearing masks [26]. Thirdly, participants' health conditions prevented us from requiring prolonged mask usage or involving them in high-intensity exercises. Conclusions may be different in patients with COPD when they wear a mask for extended periods of time or when they participate in high-intensity exercise.

Conclusions

In conclusion, this randomised controlled trial revealed that the short-term use of N95 or surgical masks by COPD patients affected subjective feelings like dyspnoea and exertion. However, there were no significant impacts on objective indicators such as blood pressure, oxygen saturation and pulse rate. We conclude that wearing a mask for short periods, whether at rest or during activity, does not have negative effects on COPD patients. It is recommended that COPD patients use masks reasonably in special situations.

Provenance: Submitted article, peer reviewed.

Acknowledgements: We would like to thank the Department of Pulmonary Diseases of Affiliated Hospital of Gansu University of Chinese Medicine and the Pulmonary and Critical Care Medicine of Lanzhou Petrochemical General Hospital for supporting our study. We would also like to thank all the healthcare workers who participated in the recruitment, investigation and intervention. Finally, we would like to thank all the patients who volunteered to participate in this study and supported this work.

Data availability: The study protocol and statistical analysis plan are available online. 6 months after publication of the trial results, de-identified individual participant data will be made available to researchers in need upon reasonable requests by contacting the corresponding author.

This clinical trial is prospectively registered with Chinese Clinical Trial Registry as ChiCTR2300074554.

Ethics statement: This study has received approval from the Ethics Committee of the Affiliated Hospital of Gansu University of Chinese Medicine (approval number: 202335).

Author contributions: J. Fan, H. Yang and S. Bao conceptualised and designed the study, and X. Jiang and C. Wei provided methodological advice and revised and improved the study protocol. C. Li and F. Yue were responsible for recruiting volunteers. X. Zhang randomly assigned participants. T. Feng and H. Yang were responsible for implementing the intervention and collecting data. X. Chen and X. Jiang were responsible for statistical analysis. X. Chen and T. Feng wrote the original draft. S. Bao and J. Fan revised and polished the manuscript. J. Fan was responsible for the revision of the manuscript. All authors have read and approved the publication of the final manuscript. All authors can fully access and verify the complete data and are ultimately responsible for the decision to submit for publication.

Conflict of interest: The authors have no conflicts of interest to declare.

Support statement: This work was funded by Natural Science Foundation Project of Gansu Province (grant number 22JR5RA589); Gansu Provincial Science and Technology Plan (Joint Research Fund) Project (grant number 23JRRA1528); the Universities' Teacher Innovation Fund Project in Gansu Province (grant number 2024A-084); 2023 Lanzhou Science and Technology Development Guidance Plan (grant number 2023-ZD-2); 2022 Gansu Province Education Science and Technology Innovation Project (grant number 2022B-125); and Lanzhou Science and Technology Plan Project (grant number 2023-2-118). Funding information for this article has been deposited with the Crossref Funder Registry.

References

1 Global Initiative for Chronic Obstructive Lung Disease. Global strategy for prevention, diagnosis and management of COPD: 2023 report. https://goldcopd.org/2023-gold-report-2/
2 BMJ Best Practice. Chronic obstructive pulmonary disease (COPD). 2024. https://bestpractice.bmj.com/topics/zh-cn/7/epidemiology
3 Hartl S, Lopez-Campos JL, Pozo-Rodriguez F, *et al.* Risk of death and readmission of hospital-admitted COPD exacerbations: European COPD Audit. *Eur Respir J* 2016; 47: 113–121.
4 Tran TQ, Mostafa EM, Tawfik GM, *et al.* Efficacy of face masks against respiratory infectious diseases: a systematic review and network analysis of randomised-controlled trials. *J Breath Res* 2021; 15: 047102.
5 Spira B. Correlation between mask compliance and COVID-19 outcomes in Europe. *Cureus* 2022; 14: e24268.
6 Elgersma IH, Fretheim A, Elstrøm P, *et al.* Association between face mask use and risk of SARS-CoV-2 infection: cross-sectional study. *Epidemiol Infect* 2023; 151: e194.

7 Fögen Z. The Foegen effect: a mechanism by which facemasks contribute to the COVID-19 case fatality rate. *Medicine (Baltimore)* 2022; 101: e28924.
8 Jefferson T, Dooley L, Ferroni E, *et al.* Physical interventions to interrupt or reduce the spread of respiratory viruses. *Cochrane Database Syst Rev* 2023; 1: CD006207.
9 De Silva AP, Niriella MA, de Silva HJ. Masks in COVID-19: let's unmask the evidence. *Expert Rev Respir Med* 2021; 15: 293–299.
10 Faria N, Costa MI, Gomes J, *et al.* Reduction of severe exacerbations of COPD during COVID-19 pandemic in Portugal: a protective role of face masks? *COPD* 2021; 18: 226–230.
11 Zeng Y, Zhou Z, Chen P. Policy during coronavirus disease 2019 (COVID-19) pandemic: a protector for acute exacerbation of COPD (AECOPD) patients? *J Thorac Dis* 2021; 13: 3188–3190.
12 Samannan R, Holt G, Calderon-Candelario R, *et al.* Effect of face masks on gas exchange in healthy persons and patients with chronic obstructive pulmonary disease. *Ann Am Thorac Soc* 2021; 18: 541–544.
13 Just IA, Schoenrath F, Passinger P, *et al.* Validity of the 6-minute walk test in patients with end-stage lung diseases wearing an oronasal surgical mask in times of the COVID-19 pandemic. *Respiration* 2021; 100: 594–599.
14 Moher D, Hopewell S, Schulz KF, *et al.* CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *Int J Surg* 2012; 10: 28–55.
15 Chen X, Jiang X, Zhang X, *et al.* Assessing the impact of diverse mask types on COPD patients: a randomised controlled trial study protocol. *BMJ Open* 2024; 14: e080721.
16 Stanojevic S, Kaminsky DA, Miller MR, *et al.* ERS/ATS technical standard on interpretive strategies for routine lung function tests. *Eur Respir J* 2022; 60: 2101499.
17 ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. ATS statement: guidelines for the six-minute walk test. *Am J Respir Crit Care Med* 2002; 166: 111–117.
18 Borg GA. Psychophysical bases of perceived exertion. *Med Sci Sports Exerc* 1982; 14: 377–381.
19 Li Y, Tokura H, Guo YP, *et al.* Effects of wearing N95 and surgical facemasks on heart rate, thermal stress and subjective sensations. *Int Arch Occup Environ Health* 2005; 78: 501–509.
20 Hirai K, Tanaka A, Sato H, *et al.* Effect of surgical mask on exercise capacity in COPD: a randomised crossover trial. *Eur Respir J* 2021; 58: 2102041.
21 Chen X, Zhang C, Ibrahim S, *et al.* The impact of facemask on patients with COPD: a systematic review and meta-analysis. *Front Public Health* 2022; 10: 1027521.
22 Kyung SY, Kim Y, Hwang H, *et al.* Risks of N95 face mask use in subjects with COPD. *Respir Care* 2020; 65: 658–664.
23 Hopkins SR, Dominelli PB, Davis CK, *et al.* Face masks and the cardiorespiratory response to physical activity in health and disease. *Ann Am Thorac Soc* 2021; 18: 399–407.
24 Kisielinski K, Giboni P, Prescher A, *et al.* Is a mask that covers the mouth and nose free from undesirable side effects in everyday use and free of potential hazards? *Int J Environ Res Public Health* 2021; 18: 4344.
25 Balestracci B, La Regina M, Di Sessa D, *et al.* Patient safety implications of wearing a face mask for prevention in the era of COVID-19 pandemic: a systematic review and consensus recommendations. *Intern Emerg Med* 2023; 18: 275–296.
26 Soriano JB, Anzueto A, Bosnic Anticevich S, *et al.* Face masks, respiratory patients and COVID-19. *Eur Respir J* 2020; 56: 2003325.
27 Fikenzer S, Uhe T, Lavall D, *et al.* Effects of surgical and FFP2/N95 face masks on cardiopulmonary exercise capacity. *Clin Res Cardiol* 2020; 109: 1522–1530.
28 Gericke A, Militký J, Venkataraman M, *et al.* The effect of mask style and fabric selection on the comfort properties of fabric masks. *Materials (Basel)* 2022; 15: 2559.
29 Wang AB, Zhang X, Gao LJ, *et al.* A review of filtration performance of protective masks. *Int J Environ Res Public Health* 2023; 20: 2346.
30 Karuppasamy K, Obuchowski N. Comparison of fit for sealed and loose-fitting surgical masks and N95 filtering facepiece respirators. *Ann Work Expo Health* 2021; 65: 463–474.
31 Chen Y, Yang Z, Wang J, *et al.* Physiological and subjective responses to breathing resistance of N95 filtering facepiece respirators in still-sitting and walking. *Int J Ind Ergon* 2016; 53: 93–101.
32 Sukul P, Bartels J, Fuchs P, *et al.* Effects of COVID-19 protective face masks and wearing durations on respiratory haemodynamic physiology and exhaled breath constituents. *Eur Respir J* 2022; 60: 2200009.
33 Sukul P, Richter A, Junghanss C, *et al.* Origin of breath isoprene in humans is revealed via multi-omic investigations. *Commun Biol* 2023; 6: 999.
34 Bakhit M, Krzyzaniak N, Scott AM, *et al.* Downsides of face masks and possible mitigation strategies: a systematic review and meta-analysis. *BMJ Open* 2021; 11: e044364.