

# The use of a portable positive airway pressure device to relieve shortness of breath after exercise

<b>Submission date</b> 22/06/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/07/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/01/2017	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Chronic obstructive pulmonary disease (COPD) is the name used to refer to a number of progressive devastating and debilitating lung diseases, which includes chronic bronchitis, emphysema and chronic obstructive airways disease. People that have COPD typically feel breathless after physical activity, have a persistent cough with phlegm and suffer frequently from chest infections. Feeling short of breath can lead to inactivity and muscle deconditioning in patients with COPD. Positive airway pressure (PAP) can relieve shortness of breath and improve exercise tolerance (the amount of exercise that they are able to do). This study examines the effect of PAP delivered by a battery powered handheld device to COPD patients after exercise to relieve shortness of breath.

### Who can participate?

Aged at least 18 with diagnosed COPD but able to do mild exercise.

### What does the study involve?

Participants are randomly allocated into one of three groups. They are all then asked to do some mild exercise. Those in group 1 are then provided with the portable PAP device to use after the exercise to ease breathlessness. Those in group 2 are provided with what looks like a portable PAP device, but it is nonfunctional (a SHAM device) to use after the exercise. Those in group 3 are asked to perform lip breathing after exercise. The time it takes to return to the shortness of breath experienced prior to exercise for each participant is determined. We anticipate that the time after exercise to return to baseline shortness of breath using the hand held device is shorter than that while using a SHAM device and pursed-lip breathing (PLB) after exercise. As a secondary outcome, we will evaluate the distance walked during exercise.

### What are the possible benefits and risks of participating?

Other than possibly gaining a better understanding of their ability to exercise and contributing to general knowledge of strategies to address shortness of breath, participants will not benefit directly from enrolling in the study. Risks of study participation include breathing and general discomfort while exercising. Lung damage from the portable positive airway pressure device is a

remote possibility. Participants will be closely monitored during exercise and may request that the exercise activity be terminated. Patients with a history of lung damage from positive pressure devices are not eligible to participate.

Where is the study run from?  
Pittsburgh Pulmonary Associates Ltd (USA)

When is the study starting and how long is it expected to run for?  
April 2014 to October 2015

Who is funding the study?  
Philips Respironics (USA)

Who is the main contact?  
Mr William Hardy  
bill.hardy@philips.com

## Contact information

**Type(s)**  
Public

**Contact name**  
Mr William Hardy

**Contact details**  
Philips Respironics  
1740 Golden Mile Highway  
Monroeville  
United States of America  
PA 15146  
+ 724 387 4169  
bill.hardy@philips.com

## Additional identifiers

**Protocol serial number**  
HRC-1510-ENGVB-SS

## Study information

**Scientific Title**  
Effect of intermittent positive air pressure in relieve of shortness of breath in COPD patients after exertion.

**Study objectives**  
To determine whether intermittent positive airway pressure given after exercise to patients with COPD can shorten their shortness of breath recovery period

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Allendale Institutional Review Board (AIRB), 26/03/2015

**Study design**

Prospective, interventional trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Chronic obstructive pulmonary disease

**Interventions**

Participants are asked to undergo exercise session and then use one of the following to alleviate shortness of breath:

1. Portable battery powered positive airway pressure (PAP) device
2. Portable sham positive airway pressure device
3. Pursed lip breathing

**Intervention Type**

Device

**Primary outcome(s)**

Time to return to baseline shortness of breath rating after exercise

**Key secondary outcome(s)**

Distance walked during exercise

**Completion date**

30/10/2015

**Eligibility**

**Key inclusion criteria**

1. Age  $\geq 18$
2. Ability to provide consent
3. COPD diagnosis with FEV1  $< 55$  and  $> 25$  of predicted value
4. Perceived Shortness of Breath via the Modified Medical Research Council Dyspnea questionnaire (rating of 2 or greater)
5. Able to follow directions
6. Able to tolerate mild physical activity

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Subjects who are acutely ill, medically complicated or who are medically unstable as determined by the investigator
2. Suffering from COPD Exacerbation at time of data collection

**Date of first enrolment**

06/04/2015

**Date of final enrolment**

30/10/2015

**Locations****Countries of recruitment**

United States of America

**Study participating centre**

Pittsburgh Pulmonary Associates, Ltd

United States of America

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**Sponsor information****Organisation**

Philips Respironics

**ROR**

<https://ror.org/03kw6wr76>

**Funder(s)**

**Funder type**

Industry

**Funder Name**

Philips Respiroics (USA)

**Results and Publications****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration