ISRCTN13097622 https://doi.org/10.1186/ISRCTN13097622

Influence of the Vitabreath on exercise tolerance in COPD

Submission date
21/02/2017

Recruitment status
No longer recruiting

Registration date
28/03/2017

Overall study status
Completed

Last Edited
26/08/2020

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is the name given to a collection of diseases which affect the lungs. It is characterised by breathlessness, cough and excess mucus production and is usually caused by smoking. When people with COPD exercise, breathing can be more difficult as they often are unable to breath out fully before they need to take another breath. Pulmonary rehabilitation (PR) is a program of exercise, education and support that is used in patients with COPD to help them improve their physical condition. There are breathing devices that are used in combination with PR that can provide breathing assistance, such as non-invasive positive pressure ventilators (a face mask mask attached to a machine which provide a strong flow of air into the lungs). Previous research has shown that when people with COPD use non-invasive ventilation, they are able to exercise for longer and breathe easier. A new portable non-invasive ventilation device, called the VitaBreath, can be helpful for patients during exercising as it is small, handheld and battery powered. The aim of this study is to assess whether the VitaBreath can help people recover from breathlessness during exercise breaks more quickly and allow them to be able to exercise for longer overall.

Who can participate?
Adults aged 40 years or older with confirmed and stable COPD

What does the study involve?
Participants attend three study visits within a ten day period. After an initial visit in which participants are tested to see measure their exercise and breathing levels, participants are randomly allocated (based on the measurements taken in the first visit) to one of two groups. Those in the first group have two more visits in which they undergo continuous exercise. This involves participants using the VitaBreath device or the pursed lip breathing technique in the first minute of each two minute rest interval between the six minute exercise periods. Those in the second group attend two more visits in which they undergo interval exercise. This involves participants using the VitaBreath device or the pursed lip breathing technique in the first minute of each two minute rest interval between the two minute exercise periods. For participants in both groups, their overall exercise time, breathlessness, and oxygen levels are measured in order to compare between the using the VitaBreath and using pursed–lip breathing.

What are the possible benefits and risks of participating?
Participants may benefit from using the device to recover more quickly after exercise. There small but unlikely risks associated to exercise such as abnormal blood pressure, fainting, problems with heart rate and heart attacks. Also, participants may feel breathless and/or muscle discomfort during and after exercising.

Where is the study run from?
North Tyneside General Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2016 to April 2018

Who is funding the study?
Philips (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HRC-GRA-17030-VBREATH-SH

Study information

Scientific Title
Influence of the VitaBreath device on exercise tolerance in patients with chronic obstructive pulmonary disease

Acronym
VitaBreath

Study objectives
Using the VitaBreath device will increase exercise tolerance and decrease the intensity of breathlessness (dyspnoea) during rehabilitative exercise training in patients with COPD, when compared to normal breathing (pursed lip breathing technique) in two separate groups of patients undergoing different exercise regime, either a constant-load (continuous exercise) or interval exercise.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tyne & Wear South Research Ethics Committee, 06/04/2017, ref: 17/NE/0085

Study design
Single-centre randomised cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)

Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease (COPD)

Interventions
Participants in this study attend three visits to the study centre over a ten day period. The total duration of each visit is expected to last for approximately one hour. Patients perform the three tests during the visits within a period of ten days with at least 48 hours resting periods in between each visit.

Visit 1: Cardiopulmonary exercise testing to define peak work capacity
Participants undergo an incremental symptom-limited exercise test to the limit of tolerance with gas exchange analysis on a cycle ergometer to assess their peak exercise capacity. Minute ventilation (VE), oxygen consumption (VO2), breathing pattern such as inspiratory time (Ti), expiratory time (Te) and total breathing cycle time (Ttot) is recorded breath-by-breath via a portable gas exchange analyzer (K4b2, Cosmed) throughout the test. Inspiratory capacity (IC) maneuvers are performed at predefined time points during exercise and at peak exercise, in order to evaluate the rate of dynamic hyperinflation (DH). In addition, oxygen saturation and blood pressure are be recorded during the test at predefined time points.

After the initial visit, participants are randomly allocated to one of two groups. Group A undergo continuous exercise and group B undergo interval exercise. Stratified randomisation is used to balance the two groups in terms of baseline lung function (FEV1 % predicted) and exercise capacity (PWR). Within each group the two exercise protocols are delivered in a balanced ordering sequence. During the visits, participants undergo two different exercise trials (either with VitaBreath device or with pursed lip breathing technique) during two different exercise modalities (continuous or interval). Patients use the VitaBreath device or the pursed lip breathing technique in the first minute of each interval between the six minute exercise bouts during continuous exercise and in the first minute of each interval between the two minute exercise periods during interval exercise.

Visit 2 and 3:
Continuous exercise (Group A)
Patients undergo a constant load exercise protocol with gas exchange analysis on a cycle ergometer. The exercise protocol consists of repeated six minute exercise bouts, separated by two minute rest periods in between in order to allow the application of the vitabreath device. During the first minute of each resting period participants breathe either via the Vitabreath device or normally adopting the pursed lip breathing technique. During the second minute of each resting period participants breathe normally and perform an inspiratory capacity (IC) maneuver to assess the magnitude of dynamic hyperinflation and score the intensity of their perceived breathlessness using the Borg 1-10 scale. Cardiac output and stroke volume are measured non-invasively using a cardio-impedance method (physio-flow) throughout the exercise and resting periods. From measurements of oxygen uptake and cardiac output, arteriovenous oxygen difference content is calculated using the Fick equation. Inspiratory capacity (IC) maneuvers and scoring on the dyspnoea scale are additionally performed on the second, fourth and sixth minute of each exercise bout, and on the second, fourth and fifth

minute of recovery following completion of the exercise test in order to evaluate the rate of dynamic hyperinflation (DH). In addition, oxygen saturation is recorded throughout the exercise and resting periods

Interval exercise (Group 2)
Patients undergo an interval exercise protocol with gas exchange analysis on a cycle ergometer. The exercise protocol consists of repeated two minute exercise bouts, separated by two minute resting periods in between in order to allow the application of the VitaBreath device. During the first minute of each resting period participants breathe either via the VitaBreath device or normally adopting the pursed lip breathing technique. During the second minute of each rest period participants breathe normally and perform an IC maneuver, to assess the magnitude of dynamic hyperinflation and they score the intensity of their perceived breathlessness using the Borg 1-10 scale. Cardiac output and stroke volume are measured non-invasively using a cardio-impedance method (physio-flow) throughout the exercise and resting periods. From measurements of oxygen uptake and cardiac output, arteriovenous oxygen difference content are calculated using the Fick equation. Inspiratory capacity (IC) maneuvers and scoring on the dyspnoea scale are additionally performed on the second minute of each exercise bout, and on the second, fourth and fifth minute of recovery following completion of the exercise test in order to evaluate the rate of dynamic hyperinflation (DH). In addition, oxygen saturation is recorded throughout the exercise and resting periods.

The two exercise modalities are separately assessed in different groups of patients, but within each group the intervention (VitaBreath) is compared to control (pursed-lip breathing) within patients.

Intervention Type
Device

Primary outcome measure
Exercise tolerance (total exercise time in minutes) is measured using two different exercise modalities (i.e. continuous or interval) and two different interventions for each modality (i.e.: the VitaBreath device or normal breathing asking the patients to perform the pursed lip breathing technique) at baseline visit, visit 2 and visit 3 (over a ten day period)

Secondary outcome measures
1. Breathlessness is assessed using the Borg 1-10 scale during exercise of different exercise modalities at baseline visit, visit 2 and visit 3 (over a ten day period)
2. Dynamic hyperinflation (DH) is assessed by the inspiratory capacity maneuvers (IC) at baseline visit, visit 2 and visit 3 (over a ten day period)
3. Oxygen uptake (VO2) is measured using a portable gas analyzer (K4b2Cardiac output) at baseline visit, visit 2 and visit 3 (over a ten day period)
4. Cardiac Output (CO) is measured using the noninvasive bioelectrical conductance method, namely PhysioFlow during exercise of different exercise modalities at baseline visit, visit 2 and visit 3 (over a ten day period)
5. Heart rate (HR) is measured using the noninvasive bioelectrical conductance method, namely PhysioFlow during exercise of different exercise modalities at baseline visit, visit 2 and visit 3 (over a ten day period)
7. Stroke volume (SV) is measured using the noninvasive bioelectrical conductance method, namely PhysioFlow during exercise of different exercise modalities at baseline visit, visit 2 and visit 3 (over a ten day period)
7. Arteriovenous oxygen difference content (a-vO2) is calculated using the Fick equation during

exercise of different exercise modalities at baseline visit, visit 2 and visit 3 (over a ten day period)
8. Arterial oxygen saturation (SpO2) is measured using an oximeter during exercise of different exercise modalities at baseline visit, visit 2 and visit 3 (over a ten day period)
9. Minute ventilation (VE) is measured using a portable gas analyzer (K4b2) during exercise of different exercise modalities at baseline visit, visit 2 and visit 3 (over a ten day period)
10. Inspiratory time (Ti) is measured using a portable gas analyzer (K4b2) during exercise of different exercise modalities at baseline visit, visit 2 and visit 3 (over a ten day period)
11. Expiratory time (Te) is measured using a portable gas analyzer (K4b2) during exercise of different exercise modalities at baseline visit, visit 2 and visit 3 (over a ten day period)
12. Total breathing cycle (Ttot) is measured using a portable gas analyzer (K4b2 during exercise of different exercise modalities at baseline visit, visit 2 and visit 3 (over a ten day period)
13. Leg discomfort is measured using the 1-10 Borg scale during exercise of different exercise modalities at baseline visit, visit 2 and visit 3 (over a ten day period)

Overall study start date
01/10/2016

Completion date
30/04/2018

Eligibility

Key inclusion criteria
1. Male or female aged 40 years or older
2. Current or previous smoking history, 10 or more pack years
3. Spirometry confirmed stable COPD (GOLD stages II-IV) under optimal medical therapy
4. Exhibit substantial exercise-induced dynamic hyperinflation (ΔIC baseline > 0,2 L)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
24

Total final enrolment
24

Key exclusion criteria
1. Orthopaedic, neurological or other concomitant diseases that significantly impair normal biomechanical movement patterns, as judged by the investigator
2. Moderate or severe COPD exacerbation within 6 weeks
3. Unstable cardiac arrhythmia
4. Unstable ischaemic heart disease, including myocardial infarction within 6 weeks
5. Moderate or severe aortic stenosis or hypertrophic obstructive cardiomyopathy

6. Uncontrolled hypertension
7. Uncontrolled hypotension (SBP<85mmHg)
8. Uncontrolled diabetes
9. Intolerance of the VitaBreath device

Date of first enrolment
01/05/2017

Date of final enrolment
31/05/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Tyneside General Hospital
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Sponsor information

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Sponsor type
Industry

ROR
https://ror.org/04ktqp584

Funder(s)

Funder type
Industry

Funder Name
Philips Respironics

Results and Publications

Publication and dissemination plan
The data will be presented in British Thoracic Society conference and planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ioannis Vogiatzis ioannis.vogiatzis@northumbria.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/01/2019	26/08/2020	Yes	No
HRA research summary			28/06/2023	No	No