

Pursed Lip Breathing (PLB) and its role in the management of breathlessness in stable chronic obstructive pulmonary disease (COPD)

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/09/2012	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0277185567

Study information

Scientific Title

Study objectives

Does pursed lip breathing improve quality of life in patients with stable Chronic Obstructive Pulmonary Disease, in whom activities of daily living are limited by breathlessness?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added July 2008:

Moorfields and Whittington Local Research Ethics Committee, 05/Q0504/93, favourable opinion granted 08/02/06.

Study design

Randomised, controlled, single blind study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Respiratory: Chronic obstructive pulmonary disease (COPD)

Interventions

Pursed Lip Breathing (PLB) vs control

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Added July 2008:

1. Chronic Respiratory Disease Questionnaire
2. Endurance Shuttle Walk Test

Secondary outcome measures

Added July 2008:

1. Borg Dyspnoea Scale
2. Respiratory rate and inspiratory capacity pre and post exercise
3. Hospital Anxiety and Depression scale

Overall study start date

01/03/2006

Completion date

01/03/2009

Eligibility

Key inclusion criteria

Prior to July 2008:

1. Non smoking patients that have been diagnosed with COPD who are in a stable condition.
2. 86 participants, broken down as approximately 4/5th will be recruited from The Whittington NHS and 1/5th from Islington PCT.

Modified July 2008:

1. Diagnosis of COPD ($FEV1 < 80\%$ and $FEV1/FVC < 70\%$ predicted)
2. Medical intervention optimised according to NICE guidelines
3. MRC 3 or more; as a minimum walks slower than contemporaries on level ground or has to stop for breathing when walking at own pace
4. 4/52 since last exacerbation and 6/52 since last admission
5. Informed consent obtained and signed after provision of information sheet
6. Able to comply with study procedure

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Prior to July 2008: 86. As of July 2008: 46

Key exclusion criteria

Added July 2008:

1. Subject requires an interpreter for consent form
2. Mini-mental test score < 24 (performed in English)

3. Subject has no fixed abode or does not consent to home visits
4. Hospital Lone Practitioner Policy precludes home visits to this subject
5. Previously taught PLB
6. On long term oxygen therapy (LTOT)
7. Medical history preventing ability to walk (other than COPD)
8. Ex-smoker of < 3 months
9. Unstable Angina
10. Uncontrolled hypertension
11. Uncontrolled congestive cardiac failure
12. Uncontrolled cardiac arrhythmias
13. Myocardial infarct within 6 weeks

Date of first enrolment

01/03/2006

Date of final enrolment

01/03/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Whittington Hospital NHS Trust

London

United Kingdom

N19 5NF

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)**Funder type**

Government

Funder Name

Whittington Hospital NHS Trust (UK)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2011		Yes	No