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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 27/09/2012	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Suzanne E Roberts

Contact details
Whittington Hospital NHS Trust
Dept of Physiotherapy
The Whittingotn Hospital
Magdala Avenue
London
United Kingdom
N19 5NF
+44 020 7288 5660
suzanne.Roberts@whittington.nhs.uk

Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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(s)
Added July 2008:
1. Chronic Respiratory Disease Questionnaire
2. Endurance Shuttle Walk Test

Key secondary outcome(s))
Added July 2008:
1. Borg Dyspnoea Scale
2. Respiratory rate and inspiratory capacity pre and post exercise
3. Hospital Anxiety and Depression scale

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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 Practioner 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
United Kingdom

England

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

Funder(s)

Funder type
Government

Funder Name
Whittington Hospital NHS Trust (UK)

Results and Publications

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