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Inspiratory muscle training in patients with Chronic Obstructive Pulmonary Disease (COPD)

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
17/09/2012

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
RDC01621

Study information

Scientific Title

Study objectives
The aim of this study is to investigate the effects of the POWERbreathe on respiratory muscle strength and endurance in people with COPD and also to assess the effects of IMT on breathlessness, functional exercise capacity and quality of life. The results of this study will provide evidence to enable healthcare professionals to advise their patients about the value of this device and may support the introduction of this or similar devices as a therapy for people with COPD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease

Interventions
Not provided at time of registration

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Mean changes in respiratory muscle strength (cms H2O), respiratory muscle endurance (peak power [cms H2O] and duration [seconds]), shuttle walk distance (metres), Borg scores for breathlessness and CRDQ will be compared between groups using an unpaired t-test or analysis of covariance. Any changes in respiratory muscle strength and endurance will be compared with changes in shuttle walk distance and CRDQ scores using correlation.

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/03/2002

Eligibility

Key inclusion criteria
1. 80 non-hypercapnic patients with moderate (forced expiratory volume [FEV] <40%) will be recruited from consultant hospital and community chest clinics.
2. All patients will be receiving optimum medical management and will have been stable for at least 4 weeks prior to their initial assessment.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Hypercapnia (PaCO2 >45 mmHg)
2. Any patient who is unsuitable for magnetic stimulation (pacemakers, artificial heart valves, metal prosthesis).

Date of first enrolment
01/03/2000

Date of final enrolment
01/03/2002

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College Hospital Medical School
London
United Kingdom
W8 7AH

Sponsor information

Organisation

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (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?
Abstract results		01/12/2003		No	No