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

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/09/2012	Respiratory	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2000

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
80

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

England

United Kingdom

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

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

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.doh.gov.uk

Funder(s)

Funder type
Government

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