

A single blind randomised controlled trial to determine the effectiveness and cost utility of manual chest physiotherapy techniques in the management of infective exacerbations of Chronic Obstructive Pulmonary Disease

Submission date 14/03/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/03/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/10/2012	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol

<http://www.hta.ac.uk/1416>

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

HTA 03/13/06

Study information

Scientific Title

Acronym

MATREX

Study objectives

This study proposes to look exclusively at COPD and compare a group of patients who do receive a chest physiotherapy intervention of manual techniques with a group of patients who receive no manual intervention but are given an information sheet, and to follow up all patients for one year.

Please note that, as of 11/05/2009, the anticipated start and end dates have been updated from 01/12/2004 and 31/08/2008 to 01/03/2005 and 30/04/2009, respectively.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic Obstructive Pulmonary Disease (COPD)

Interventions

Please note that, as of 10 January 2008, the anticipated start and end dates of this trial have been updated from 1 December 2004 and 31 August 2008 to 1 March 2005 and 30 April 2009, respectively.

Interventions:

Intervention arm:

Participants will receive the respiratory manual techniques of percussion, vibrations and chest shaking. A standard treatment protocol manual will be followed by all the participating hospitals. This manual will be developed with the clinical staff involved in order to represent current practice and optimise compliance. Treatment will be applied with the patient positioned according to an agreed protocol for optimal drainage of secretions. The chest will be percussed whilst the patient performs thoracic expansion exercises and vibrations and shaking will be applied on expiration. Treatment will be interspersed with periods of relaxed abdominal

breathing, breathing control. Participants will also be given an information sheet giving advice on positioning, managing cough and mobilisation. The content, number and duration of treatments will be at the discretion of the physiotherapist applying treatment, within the bounds set by the manual and will be varied according to clinical need. This information will be recorded. Oxygen saturation will be monitored and recorded during treatment. Once the patient has returned to his/her normal stable saturation, monitoring will stop. Sputum produced in each 24 hour period will be collected and its volume measured throughout each hospital admission.

Control arm:

Participants will receive no manual chest physiotherapy. They will be given the same information sheet giving advice on positioning, managing coughing and mobilisation by a physiotherapist. 24 hour sputum volumes will be measured as for the intervention group. For patients in the control arm who show severe deterioration due to sputum retention, additional physiotherapy including manual techniques will be permitted. Such movement between trial arms will be monitored closely. Movement between arms will occur where there is clear clinical evidence of sputum retention (Auscultation/chest x-ray [CXR] evidence) in conjunction with a pH of less than 7.26, a rising CO₂ in patients already receiving supportive treatment and controlled oxygen therapy. The primary analysis will be intention to treat. A per protocol analysis will be performed as a secondary analysis, with adjustment for baseline differences.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Quality of Life (St Georges Respiratory Questionnaire) at baseline, six weeks, three months, six months and one year post intervention.

Key secondary outcome(s)

Quality of life, breathlessness and exercise tolerance:

1. Breathlessness, Cough and Sputum Scale (QOL)
2. EuroQol five dimensional instrument (EQ-5D)
3. Sputum volume and oxygen saturation during hospitalisation
4. Total number of days spent in hospital during 12 months period
5. Marginal cost-utility ratio for manual versus no manual chest physiotherapy

Completion date

30/04/2009

Eligibility

Key inclusion criteria

Patients admitted to participating hospitals with infective exacerbations of COPD.

Inclusion Criteria:

1. Diagnosis of COPD as defined by the British Thoracic Society; namely
 - a. A forced expiratory volume in the first second (FEV₁) of <80% of the predicted value, which is

predominantly irreversible

b. Signs and symptoms of cough, breathlessness and +/- wheeze

c. In more severe disease there may be cyanosis and peripheral oedema

2. An infective exacerbation as set out by the British Thoracic Society; namely

a. A worsening of previous stable condition, a new respiratory event or complication imposed upon established COPD

b. Signs and symptoms of increased wheeze, dyspnoea, sputum volume and purulence, chest tightness and fluid retention

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Cognitive impairment, rendering patients unable to give fully informed consent

2. Contraindications to the use of manual techniques; namely

a. Osteoporosis

b. Frank haemoptysis

c. Bronchial hyper-reactivity

d. Known respiratory system malignancy

3. No evidence of excess sputum production after examination (i.e. the patient does not report excess secretions and no signs of excess secretions on auscultation)

Date of first enrolment

01/03/2005

Date of final enrolment

30/04/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

School of Allied Health Professions
Norwich
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Sponsor information

Organisation

University of East Anglia (UK)

ROR

<https://ror.org/026k5mg93>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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	01/05/2010		Yes	No
Results article	results	02/07/2012		Yes	No