

# Breathlessness training: comparison of two programmes for Shortness Of Breath in Lung Cancer

<b>Submission date</b> 13/02/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/03/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/03/2020	<b>Condition category</b> Cancer	<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**  
Version 2

# Study information

## Scientific Title

Non-pharmacological management of breathlessness: a randomised controlled trial of different intensity training

## Acronym

SOB-LC

## Study objectives

Training in breathlessness techniques in a programme of three sessions is more beneficial than training in a single session.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Hull and East Riding Local Ethics Research Ethics Committee gave approval in January 2008 (ref: 07/Q1104/2)

## Study design

Single centre randomised controlled non-blinded parallel group feasibility study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## 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

Breathlessness in patients with intrathoracic malignancy

## Interventions

Low intensity training programme:

Patients randomised to the low intensity arm will be taught four techniques of management of breathlessness at a single hour long session in a clinical setting appropriate to the needs of the patient by the therapist. They will be taught diaphragmatic breathing and pacing which require face-to-face demonstration. In addition, a brief introduction will be given to techniques to

promote relaxation and manage anxiety. Written reinforcement in the form of information booklets plus verbal reinforcement in the format of the patients choice (tape, video or DVD) will be given to remind the patient of the techniques they have been taught.

One week later, the therapist will ring the patient to see if they have remembered to practise the techniques and if they have managed to watch/listen to the reinforcement information.

High intensity training programme:

Patients randomised to the high intensity arm will be taught the same four techniques of the management of breathlessness at a hour long single session in a clinical setting appropriate to the needs of the patient by the therapist. This will be followed by practice and reinforcement face-to-face with the therapist on two further occasions at weekly intervals.

Written reinforcement in the form of information booklets plus verbal reinforcement in the format of the patients choice (tape, video or DVD) will be given to remind the patient of the techniques they have been taught. One week after the final visit, the therapist will ring the patient to see if they have remembered to practise the techniques and if they have managed to watch/listen to the reinforcement information.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Recruitment, retention and variability of breathlessness severity (Numerical Rating Scale [NRS] worst breathlessness over last 24 hours)

### **Secondary outcome measures**

1. NRS average breathlessness over last 24 hours
2. NRS breathlessness "now"
3. NRS distress due to breathlessness
4. NRS coping with breathlessness
5. NRS satisfaction of care
6. Brief COPE
7. Hospital Anxiety and Depression scale (HAD)
8. Euroqol EQ-5D (EQ-5D)
9. Visual Analogue Scale (VAS)

### **Overall study start date**

01/09/2007

### **Completion date**

30/09/2008

## **Eligibility**

### **Key inclusion criteria**

1. Intractable breathlessness resulting from primary or secondary malignant lung disease in the palliative setting where the underlying cause has been maximally treated

2. All identified reversible causes of the breathlessness have been treated if appropriate to do so, in the opinion of the attending clinician
3. Karnofsky Performance Status (KPS) greater than 40%
4. Aged greater than 18 years, either sex
5. Willingness to attend for breathlessness training
6. Ability to give informed consent
7. Expected prognosis of at least 3 months in the opinion of the attending clinician

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

1. Inability to give informed consent
2. Intercurrent illness or co-morbidities making completion of the physiotherapy breathlessness course (PBC) course unlikely
3. Rapidly worsening breathlessness requiring urgent medical intervention
4. Palliative radiotherapy to chest in previous 4 weeks
5. Radical radiotherapy in previous 6 months
6. Chemotherapy or change in anti-cancer hormone treatment in previous 2 weeks

**Date of first enrolment**

01/09/2007

**Date of final enrolment**

30/09/2008

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**St. Catherine's Hospice**  
Scarborough  
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YO12 5RE

## **Sponsor information**

### **Organisation**

Hull and East Yorkshire Hospitals NHS Trust (UK)

### **Sponsor details**

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### **Sponsor type**

Hospital/treatment centre

### **Website**

<http://www.hey.nhs.uk/>

### **ROR**

<https://ror.org/01b11x021>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

National Cancer Research Institute (NCRI) Supportive and Palliative Care (SuPaC) Research Collaboration (UK) (ref: SuPaC CBG 15; awarded October 2006)

## **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?
<a href="#">Results article</a>	results	01/12/2010		Yes	No