

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

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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

St. Catherine's Hospice

Scarborough

United Kingdom

YO12 5RE

Sponsor information

Organisation

Hull and East Yorkshire Hospitals NHS Trust (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

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	01/12/2010		Yes	No