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

Submission date	Recruitment status	[_] Prospectively registered
13/02/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/03/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/03/2020	Cancer	

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
United Kingdom
YO12 5RE

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

Sponsor details
Research and Development Department
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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?
Results article	results	01/12/2010		Yes	No