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Shortness Of Breath in Lung Cancer

Submission date 25/08/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 25/01/2011	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 25/10/2022	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-2-training-programmes-manage-breathlessness-people-with-cancer-affecting-lungs-sob-lc2

Contact information

Type(s)
Scientific

Contact name
Dr Miriam Johnson

Contact details
St. Catherine's Hospice
Throxenby Lane
North Yorkshire
Scarborough
United Kingdom
YO12 5RE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2

Study information

Scientific Title

A randomised trial of high versus low intensity training in breathing techniques for breathlessness in patients with malignant lung disease: early intervention

Acronym
SOB-LC II

Study objectives
Three breathing training sessions at weekly intervals are more effective than a single session in reducing the breathlessness severity of patients with intra-thoracic malignancy and refractory breathlessness.

Please note that this record is related to a previously registered trial entitled "Breathlessness training: comparison of two programmes for Shortness Of Breath in Lung Cancer" (ISRCTN62865905), and can be found at http://www.isrctn.com/ISRCTN62865905.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sheffield Research Ethics Committee, 15/12/2010, ref: 10/H1308/66

Study design
Multicentre randomised controlled non-blinded parallel-group study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Intrathoracic cancer

Interventions
Patients randomised to the single session training arm will be taught the four techniques of management of breathlessness (breathing control, pacing, anxiety management and relaxation) at a single session in a clinical setting appropriate to the needs of the patient by the therapist.

Patients randomised to the three session training arm will be taught the same four techniques of the management of breathlessness at a 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.

Both groups will receive written reinforcement in the form of information booklets plus verbal reinforcement in the format of the patients choice (CD, 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.

The primary analysis point is a 4 weeks, but participants will be followed up until 8 weeks.

Intervention Type
Behavioural

Primary outcome measure
Worst severity of breathlessness over past 24 hours measured by NRS

Secondary outcome measures
1. Breathlessness score on NRS (severity: average over last 24 hours)
2. NRS distress from breathlessness
3. NRS satisfaction with care of breathlessness
4. Global impression of changes of breathlessness
5. CRQ-SAS
6. HADS
7. Brief COPE/NRS cope
8. EQ5D
9. CIEQ-Chr
10. Number of other interventions for breathlessness during study period
11. Number of hospital admissions during study period
12. Costs associated with both comparators
13. Correlation with baseline BFI, MTQ, CIEQ-Chr scores
14. Correlation with patient programme preference

The following are measured at all time points: breathlessness severity (average over past 24 hours); distress due to, coping with, and satisfaction with the management of breathlessness; EQ5D. All secondary endpoints are measured at weeks 4 and 8 except for the global impression of change of breathlessness which is only measured at week 4.

Overall study start date
01/04/2011

Completion date
31/03/2013

Eligibility

Key inclusion criteria
1. Primary or secondary malignant lung disease
2. Aged over 18 years

3. Willingness to engage with breathlessness training
4. Ability to give informed consent
5. Sufficient understanding of the English language to complete the study questionnaires
6. Severity average breathlessness (Numeric Rating Scale [NRS]) greater than 3
7. All identified reversible causes of the breathlessness have been treated if appropriate to do so, in the opinion of the attending clinician
8. Verbal confirmation of consent
9. Estimated prognosis (in the investigator's opinion) of greater than 3 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
146

Total final enrolment
156

Key exclusion criteria
1. Inability to give informed consent
2. Intercurrent illness or co-morbidities making completion of the study unlikely
3. Rapidly worsening breathlessness requiring urgent medical intervention
4. Insufficient understanding of the English language to complete the study questionnaires
5. Verbal withdrawal of consent
6. Unable to complete study assessments

Date of first enrolment
25/05/2011

Date of final enrolment
31/03/2013

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 (HEYHT) (UK)

Sponsor details
Research and Development Department
Daisy Build 2nd Floor
Castle Hill Hospital
Cottingham
Hull
England
United Kingdom
HU16 5JQ

Sponsor type
Hospital/treatment centre

Website
http://www.hey.nhs.uk

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	cost-effectiveness results	01/11/2014		Yes	No
Results article	results	07/09/2015		Yes	No
Plain English results			25/10/2022	No	Yes