ISRCTN30501538 https://doi.org/10.1186/ISRCTN30501538

Inspiratory muscle training and exercise goal setting to improve functional ability and relieve the symptoms of dyspnoea in advanced cancer patients

Submission date 18/12/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 11/04/2014	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/04/2017	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-breathing-exercises-relieve-breathlessness-caused-by-advanced-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
EHSDYSPNOEA

Study information

Scientific Title
A pilot study to investigate whether inspiratory muscle training and exercise goal setting can improve functional ability and relieve the symptoms of dyspnoea in advanced cancer patients

Study objectives
Inspiratory muscle training alongside exercise goal setting will relieve symptoms of dyspnoea for advanced cancer patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Pilot randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Cancer/dyspnoea

Interventions
Participants are randomised to two groups:
1. Inspiratory muscle training (IMT) and goal setting diary:
An 8 week course of self-directed IMT and exercise. Measurements at weeks 1 and 8: 6MWT, inspiratory muscle pressure, spirometry and a questionnaire relating to dyspnoea symptoms.
2. Control group: Do not receive IMT. Offered breathing control techniques and goal setting advice after they have completed their 8 week measurements.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Functional ability as assessed by the 6-minute walk test (6MWT)
2. Relief of dyspnea symptoms and health-related quality of life (HRQoL) as assessed by the St. Georges Respiratory questionnaire (SGRQ)

These are measured at week 1 and week 8.

Key secondary outcome(s)
1. Change in spirometry measurements
2. Maximal inspiratory mouth pressure (MIP) can be assessed using the IMT devices or using a

handheld respiratory pressure meter
3. Feasibility of the intervention will be assessed by monitoring compliance with the self-directed IMT/exercise logged in the weekly diaries and from any pertinent qualitative data gathered from focus groups

These are measured at week 1 and week 8.

Completion date
01/07/2014

Eligibility

Key inclusion criteria
1. Aged 16 or above
2. Diagnosed with any type of cancer for which they are having palliative treatment or have ended treatment
3. Showing symptoms of dyspnea (including exertional) as assessed by their physician
4. Ability to engage in gentle exercise

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients who have had recent thoracic surgery
2. Patients with mental incapacity unable to give informed consent
3. Patients unable to understand verbal and written information in English
4. Patients who have co-existing moderate or severe chronic obstructive pulmonary disease (COPD)
5. Patients on active treatment for cancer
6. Patients undergoing radical treatment with curative intent

Date of first enrolment
01/03/2014

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
EHS Faculty
Derby
United Kingdom
DE221GB

Sponsor information

Organisation
University of Derby (UK)

ROR
https://ror.org/02yhrrk59

Funder(s)

Funder type
University/education

Funder Name
University of Derby (UK)

Funder Name
Royal Derby Hospital (UK) - Lung cancer and mesothelioma Derby account

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration