

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/04/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 13/04/2017	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EHS DYS PNOEA

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