

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

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

### Contact name

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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

**Study design**

Pilot randomised controlled trial

**Primary study design**

Interventional

**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