# 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	<b>Recruitment status</b> No longer recruiting	Prospectively registered
		☐ Protocol
Registration date	Overall study status	Statistical analysis plan
11/04/2014	Completed	Results
Last Edited	Condition category	Individual participant data
13/04/2017	Cancer	<ul><li>Record updated in last year</li></ul>

# 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

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

# Secondary identifying numbers

**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

# Study design

Pilot randomised controlled trial

# Primary study design

Interventional

# Secondary study design

Non randomised controlled trial

# Study setting(s)

Other

# Study type(s)

Quality of life

# 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

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 measure

- 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.

# Secondary outcome measures

- 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.

# Overall study start date

01/03/2014

# 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

# Age group

Adult

### Sex

Both

# Target number of participants

40

# 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

England

United Kingdom

# Study participating centre EHS Faculty

Derby United Kingdom DE221GB

# Sponsor information

# Organisation

University of Derby (UK)

# Sponsor details

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# Sponsor type

Not defined

### **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**

# 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