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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

Registration date
11/04/2014

Overall study status
Completed

Last Edited
13/04/2017

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

Contact name
Dr Heidi Sowter

Contact details
EHS Faculty
University of Derby
Derby
United Kingdom
DE221GB
+44 1332 590500
h.sowter@derby.ac.uk

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
Kedleston Road
Derby
United Kingdom
DE221GB
+44 1332 590500
h.sowter@derby.ac.uk

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