

Feasibility trial of a respiratory symptom intervention

Submission date 10/10/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/10/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/08/2016	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-trial-test-self-help-techniques-help-control-symptoms-cancer-affecting-lungs>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Feasibility randomised trial of a novel non-pharmacological intervention for the management of the respiratory distress symptom cluster (breathlessness, cough, fatigue) in patients with advanced lung cancer

Study objectives

The overall purpose of this study is to assess a new intervention promoting effective coping and better management of common lung cancer associated symptoms (i.e. breathlessness, cough, fatigue) and obtain the patients' and carers' views about it.

More details can be found at: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=13253>

Ethics approval required

Old ethics approval format

Ethics approval(s)

First MREC, 14 March 2012, ref: 12/NW/0090

Study design

Randomised interventional trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

Lung Cancer; small cell and non-small cell

Interventions

Non-pharmacological, The core components of the non-pharmacological intervention would be teaching of:

1. Diaphragmatic breathing
2. Cough suppression techniques
3. Acupressure (chest points)

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. To explore the impact of a novel non-pharmacological supportive intervention on symptom distress
 2. To identify the most valid and sensitive primary outcome measures
- Measured at baseline, 2 weeks and 12 weeks

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/12/2012

Completion date

01/09/2013

Eligibility**Key inclusion criteria**

1. Diagnosed with primary or secondary lung cancer
2. Suffering from refractory breathlessness or cough or fatigue ie. not responding to current treatment for the past 2 weeks (presence of a minimum of two of the three symptoms)
3. In the presence of COPD, in stable condition
4. Karnofsky score >50% and Palliative Performance Scale [24] score of >60%
5. Expected prognosis of at least 3 months
6. 18+ years
7. Able to give informed consent
8. Patients are eligible even without the availability of a caregiver

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

UK Sample Size: 120

Key exclusion criteria

1. Unstable COPD or acute exacerbation of COPD
2. Rapidly worsening breathlessness requiring urgent medical intervention
3. Unstable cardiovascular, musculoskeletal or neuromuscular disease
4. Palliative radiotherapy to the chest < 4 weeks
5. Chemotherapy < 2 weeks

Date of first enrolment

01/12/2012

Date of final enrolment

01/09/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

The University of Manchester

Manchester

United Kingdom

M13 9PL

Sponsor information

Organisation

University of Manchester (UK)

Sponsor details

Oxford Road

Manchester

England

United Kingdom

M13 9PL

Sponsor type

University/education

Website

<http://www.manchester.ac.uk/>

ROR

<https://ror.org/027m9bs27>

Funder(s)

Funder type

Charity

Funder Name

Marie Curie Cancer Care (UK) ref: C16394/A14093

Alternative Name(s)

Marie Curie Cancer Care

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

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