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# Feasibility trial of a respiratory symptom intervention

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 10/10/2012 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 11/10/2012 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 26/08/2016 | Cancer | [_] 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

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## Additional identifiers

**Protocol serial number**
13253

## 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

## Study type(s)
Treatment

## 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(s)
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

## Key secondary outcome(s))
No secondary outcome measures

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### 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
United Kingdom

England

**Study participating centre**
**The University of Manchester**
Manchester
United Kingdom
M13 9PL

# Sponsor information

**Organisation**
University of Manchester (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, MarieCurieUK

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**

# IPD sharing plan summary