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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

Primary study design
Interventional

Study design
Randomised interventional trial

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