

Feasibility trial of a respiratory symptom intervention

Submission date 10/10/2012	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 11/10/2012	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 26/08/2016	Condition category Cancer	☐ Individual participant data ☐ 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

Mrs June Warden

Contact details

The University of Manchester
School of Nursing, Midwifery and Social Work
Jean McFarlane Building
University Place
Manchester
United Kingdom
M13 9PL

-

june.warden@manchester.ac.uk

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