

# A randomised controlled trial of a patient-held quality of life record in patients with inoperable lung and oesophageal cancer

<b>Submission date</b> 01/06/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/06/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/08/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

### Study objectives

To determine if patient held Quality of Life (QoL) tools improve the quality of care and patient quality of life.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Office of Research Ethics Committees Northern Ireland (ORECNI) on 30/11/2004 (ref: 04/NIR01/77)

### Study design

A multi-centred randomised controlled trial.

### Primary study design

Interventional

### Secondary study design

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

Lung and oesophageal cancer

### Interventions

Patients receive a QoL diary which consists of a core questionnaire (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients [EORTC QLQ C-30]) with a Lung (LC-13) or Oesophageal (OES-18) cancer module, in the form of an A5 booklet, which they complete weekly. Patients are encouraged to share their diary with health professionals involved in their care.

The duration of treatment was four months, and at the end of this period outcomes were collected for both arms of the treatment, therefore there is no additional follow-up period for this trial.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

The primary outcome is QoL, measured through two questionnaires:

1. Functional Assessment of Cancer Therapy - General questionnaire (FACT-G) with lung and oesophageal modules, measured at the end of month two and month four following recruitment
2. Palliative care quality of life index, measured at the end of month two and month four following recruitment

**Secondary outcome measures**

Secondary outcomes include:

1. Indices of patient satisfaction, measured at the end of month two and month four following recruitment
2. Impact on carers, measured at the end of month two and month four following recruitment
3. Measures of communication, measured at the end of month two and month four following recruitment
4. Multi-disciplinary nature of patient management, measured at the end of month two and month four following recruitment

**Overall study start date**

01/01/2005

**Completion date**

01/01/2007

## Eligibility

**Key inclusion criteria**

1. Inoperable lung and oesophageal cancer
2. World Health Organisation (WHO) performance status of zero to two
3. No cognitive impairment

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

150

**Key exclusion criteria**

1. Surgically resectable patients
2. WHO performance status of 3+
3. Cognitively impaired patients

**Date of first enrolment**

01/01/2005

**Date of final enrolment**

01/01/2007

**Locations****Countries of recruitment**

Northern Ireland

United Kingdom

**Study participating centre**

Epidemiology and Public Health

Belfast

United Kingdom

BT12 6BJ

**Sponsor information****Organisation**

Queen's University Belfast (UK)

**Sponsor details**

University Road

Belfast

Northern Ireland

United Kingdom

BT7 1NN

+44 (0)28 90272568

rrs@qub.ac.uk

**Sponsor type**

University/education

**Website**

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

**ROR**

<https://ror.org/00hswnk62>

## Funder(s)

**Funder type**

Government

**Funder Name**

Research and Development Office of Northern Ireland (UK) (ref: EAT/2551/03)

## 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	feasibility results	01/12/2008		Yes	No
<a href="#">Results article</a>	results	01/01/2009		Yes	No