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

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| **Submission date**<br>01/06/2007 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>25/06/2007 | **Overall study status**<br>Completed | |
| **Last Edited**<br>17/08/2012 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## 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 Resarch 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

## Study type(s)
Quality of life

## 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(s)
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

## Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex
Not Specified

### 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
United Kingdom

Northern Ireland

### Study participating centre

**Epidemiology and Public Health**
Belfast
United Kingdom
BT12 6BJ

# Sponsor information

**Organisation**
Queen's University Belfast (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

## 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? |
|---|---|---|---|---|---|
| Results article | feasibility results | 01/12/2008 | | Yes | No |
| Results article | results | 01/01/2009 | | Yes | No |