

The SYMPTOM Study: factors influencing patient appraisal of symptoms

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| Submission date 22/11/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 03/03/2011 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 17/01/2019 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
9223

Study information

Scientific Title

Factors influencing patient appraisal of symptoms and associations with cancer diagnosis: an observational cohort study with an interview component

Acronym

SYMPTOM

Study objectives

The DISCOVERY Programme has the overall aim of optimising the diagnosis of symptomatic cancer, and comprises 6 projects which contribute to three themes, addressing the issues at patient level (Theme 1, The SYMPTOM Study), primary care level (Theme 2), and the primary /secondary care interface (Theme 3).

The SYMPTOM Study will identify features of later presentation of cancer to inform consumer awareness and general practice based interventions. It is a cohort study with an interview component, to characterise factors affecting symptom appraisal and associations with cancer in people referred with symptoms suspicious of lung, colorectal or pancreatic cancer.

The objectives are:

1. To identify symptoms associated with later presentation
2. To identify symptoms associated with later stage at diagnosis
3. To identify other patient factors (e.g. age, gender, comorbidities, living alone) associated with later presentation or later stage at diagnosis
4. To understand the way in which symptoms suggestive of these cancers are recognised, interpreted and acted upon by patients

Patients referred by their GP to hospital for further investigation of symptoms suggestive of lung, colorectal or pancreatic cancer will be invited to participate in the study. They will be asked to complete a questionnaire about their symptoms and their decision to consult their doctor about them. We will conduct in-depth, face-to-face interviews with some participants to better understand their views and experiences of their symptoms.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridgeshire 3 REC, 14/09/2010, ref: 10/H0306/50

Study design

Multicentre observational cohort study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network, Primary Care Research Network for England;
Subtopic: Colorectal Cancer, Upper Gastro-Intestinal Cancer, Lung Cancer, Not Assigned;
Disease: Colon, Lung (small cell), Lung (non-small cell), Pancreas, Rectum, All Diseases

Interventions

1. Participant interviews: in-depth semi-structured interviews with approximately 120 participants
2. Questionnaires: questionnaires for self-completion will be mailed to the participants

Follow-up length: 0 months

Study entry: registration only

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Identification of patient and symptom factors associated with later presentation to health care, measured at 24 months (end of study)

Key secondary outcome(s)

1. Association of delay in presentation of symptoms with stage at diagnosis, measured at 24 months (end of study)
2. Understanding patient interpretation of symptoms and the language used by patients, measured at 24 months (end of study)

Completion date

31/12/2012

Eligibility

Key inclusion criteria

Respiratory symptoms:

1. Aged over 40 years, either sex
2. Persistent or changed cough
3. Change of breathlessness
4. Chest pain (intermittent, worse when breathing or coughing)
5. Coughing up blood-stained phlegm (haemoptysis)
6. GP expressed concern about possibility of cancer

Gastrointestinal symptoms:

1. Aged over 40 years, either sex
2. Change in bowel habit
3. Blood in stool
4. Abdominal pain with weight loss
5. Abdominal mass
6. Anaemia
7. GP expressed concern about possibility of cancer

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Respiratory symptoms:

1. Review of established diagnosis where there is no cancer concern
2. Previous lung or ENT cancer

Gastrointestinal symptoms:

1. Review of established diagnosis where there is no cancer concern
2. Previous gastrointestinal (GI) cancer
3. Chronic alcohol abuse (to exclude chronic pancreatitis)
4. Known infective diarrhoea (e.g., after recent foreign travel)
5. Abdominal pain in the absence of weight loss
6. Dyspepsia
7. Upper abdominal pain where dyspepsia is a significant symptom

Date of first enrolment

22/11/2010

Date of final enrolment

31/12/2012

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

University of Cambridge

Cambridge

United Kingdom

CB2 0SR

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust and University of Cambridge (UK)

ROR

<https://ror.org/04v54gj93>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Central Commissioning Facility (CCF)

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request until end of 2019.

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 11/12/2014 | | Yes | No |
| Results article | results | 31/03/2015 | | Yes | No |
| Results article | results | 09/10/2015 | | Yes | No |
| Results article | results | 23/08/2016 | | Yes | No |
| Results article | results | 01/12/2016 | | Yes | No |

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|---|-------------------------------|------------|------------|----|-----|
| Results article | results | 03/09/2017 | Yes | No | |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |