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The SYMPTOM Study: factors influencing patient appraisal of symptoms

Submission date 22/11/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/03/2011	**Overall study status** Completed	
Last Edited 17/01/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)

GP practice

Study type(s)
Diagnostic

Participant information sheet
Can be found at http://www.medschl.cam.ac.uk/gppcru/userfiles/ProjectDocs/Symptom/the%20symptom%20study%20pis%20version%203%2015sept10%20adh.pdf

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

Secondary outcome measures
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)

Overall study start date
22/11/2010

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

Age group
Adult

Sex
Both

Target number of participants
Planned sample size: 7000; UK sample size: 7000

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
England

United Kingdom

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)

Sponsor details
Addenbrooke's Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/addenbrookes/addenbrookes_index.html

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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
Results article	results	03/09/2017		Yes	No