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The PEOPLE-HULL Study: improving help-seeking for lung symptoms in Hull

Submission date
27/01/2020

Recruitment status
No longer recruiting

Registration date
09/03/2021

Overall study status
Completed

Last Edited
19/02/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
More people are diagnosed with and die from lung cancer in Hull than any other place in Yorkshire. The main reason for this is related to lung cancers being diagnosed at a time when they are too advanced to be eligible for curative treatment. The aim of this study is to improve earlier diagnosis of lung cancer by encouraging people to see their doctor if they get lung symptoms and supporting GPs to refer people sooner.

Who can participate?
Community events: All members of the public over 18 years old who are interested in participating in the study
All patients who have agreed to participate in the study and have consulted for respiratory symptoms during the study period at the recruited practices.
All healthcare professionals and practice staff at the recruited practices.

What does the study involve?
The researchers are developing a public media campaign and will also work in the communities via Roadshow type events to engage with the public about lung symptoms and how and when to seek help. They will support the public who attend the Roadshows who have potential cancer symptoms to see their GPs. They will recruit GP practices in Hull and engage with them about lung cancer symptoms and referral via educational events and quality improvement work. The practice activities will involve educational activities for healthcare professionals, raising lung health awareness within the recruited practices via a practice-specific media campaign, fast track appointments for symptomatic patients with respiratory symptoms, interviews for those symptomatic patients who agree to participate in the study, observations, interviews and focus group discussions for healthcare professionals and practice staff and data collection. The researchers will evaluate these public and practice level interventions by looking at referral rates, emergency presentation rates, stage of cancer at diagnosis, and by asking people subsequently diagnosed with lung cancer about their experiences of their pathway to diagnosis. They have already collected data from lung cancer patients about their pathway to diagnosis in a previous study so will have before and after data to analyse the benefit of the intervention.

What are the possible benefits and risks of participating?
There is no expected benefit to participants other than the potential of getting an early diagnosis of lung cancer and possibly early treatment leading to possibly better lung cancer outcomes-should they subsequently get lung cancer. This will not apply to most of them. There are in general minimal risks for the community events. The participant might become anxious when they complete the symptoms questionnaire or when they receive what they may perceive as lung health test results. The community support workers will be trained to deal with this and will facilitate a GP appointment for review and advice. There are in general minimal risks for the lung health checks. Some of the participants might be anxious when they complete the symptoms questionnaire or about the test findings. Any anxiety is not likely to be enhanced by taking part in the study (which in previous studies patients have found helpful).

Where is the study run from?
University of Hull (UK)

When is the study starting and how long is it expected to run for?
April 2019 to August 2023

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
241021

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

CPMS 41530, IRAS 241021

Study information

Scientific Title
PEOPLE-HULL: Primary care and community Engagement to Optimise time to Presentation with Lung cancEr symptoms in HULL

Acronym
PEOPLE-HULL

Study objectives
The aim of this study is to improve earlier diagnosis of lung cancer by encouraging people to see their doctor if they get lung symptoms and supporting GPs to refer people sooner.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/04/2019, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 1048091; nrescommittee.yorkandhumber-southyorks@nhs.net), REC ref: 19/YH/0088

Study design
Non-randomized; Both; Design type: Diagnosis, Prevention, Process of Care, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Management of Care, Cross-sectional

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Lung cancer

Interventions
PEOPLE-Hull is a programme of research incorporating two interlinked phases. The first involves community groups and the general public and has been the subject of University ethics

application and approval. This application relates to the second phase of the PEOPLE-HULL study. During this Phase the following activities will take place:

Community-based activities
The researchers will engage with members of the public regarding lung symptoms. This will include:
- Inviting them to complete the community symptoms questionnaire
- Opportunity to undertake a carbon monoxide test (optional)
- Referral to GPs for appointments of participants with potential lung cancer symptoms
- Observations and informal discussions about the event and lung health with some members of the public engaging in the event
- Support workers' focus group discussions

The primary care activities include:
- Educational activities for health professionals
- Raising lung health awareness in GP practices
- Focused ethnography, which includes observations, interviews and focus group discussions for health professionals and interviews for the patients
- Consensus development exercise
- Data collection/record-keeping

Community events
Roadshow type activities will be held at suitable locations throughout Hull. Members of the public, aged over 18 years old, will be invited by the community support workers to participate in the study. The interested person will be given the participant information sheet and if they want to join the study, they will complete the consent form. Once consent is given, the community health worker will assist the participant in completing a symptoms questionnaire and will offer them the carbon monoxide test which is optional. The rationale for this test is not diagnostic – these will merely give the participant an indication of lung fitness and are a means to engage in a conversation about lung health and lung symptoms.

If the participant reports experiencing one or more potential cancer symptoms (these are the NICE referral symptoms) the participant will be given a results card with a record of the reported symptoms and the test results and advised to schedule an appointment at their doctor's surgery within 7 days. The support worker will offer to ring the participant's practice for an appointment during the session if the participant consents to it and wishes this support. The participants without reported symptoms will receive a card with a list of symptoms to look out for, advice to see their doctor if they experience the symptoms on the list and their lung health test results. They will also be given a lung health pack which will comprise two booklets 'Lung health' and 'Keeping your lungs healthy' and a smoking cessation leaflet.

A field researcher will observe and hold informal discussions about the event and lung health with the members of the public who engage in the event.

Focus group discussions with the support workers: The support workers will be invited by the study researcher to participate in focus group discussions, which will be conducted by the study researcher.

Primary care
The number of practices to be recruited is 12 or the equivalent of 80,000 patient population. Recruited practices will be provided with opportunities to engage with educational activities related to lung cancer. These practice-based (or locality-based depending on practice

preference) sessions will cover the implementation of the NICE lung cancer referral guidelines, safety-netting for lung cancer based on our previous research on lessons learned by practices undertaking lung cancer significant event audits, and action plan development (some sessions at meetings to be delivered by/to include secondary care consultants).

Raising lung health awareness: The researchers will conduct practice specific media activity to encourage patients to contact the GP when symptomatic, highlighting the means to get a speedy appointment.

Consensus development exercise: The researchers will conduct a consensus development exercise regarding best practice-based triage pathway for new chest symptoms including cough in each recruited practice.

Focused ethnography: The researchers will conduct observations, interviews and focus group discussions. They will also interview patients who have consulted with respiratory symptoms recruited by the practice.

Data collection/record-keeping: The researchers will collect data pre-, during-and post-intervention (community and practice interventions).

Intervention Type
Mixed

Primary outcome measure
1. The number of early-stage lung cancers diagnosed and lung resections, measured using hospital Trust records (MDT records and LUCADA audit data) at the following timepoints: community intervention: 2 years pre-intervention March 2020 (March 2018) and 18 months post-intervention (September 2021); practice intervention (March/April 2021-December 2021-February/March 2022): pre-intervention (March/April 2019) and post-intervention (September 2023)
2. The number of advanced-stage lung cancers diagnosed, measured using MDT records and LUCADA audit data at the following timepoints: community intervention: 2 years pre-intervention March 2020 (March 2018) and 18 months post-intervention (September 2021); practice intervention (March/April 2021-December 2021-February/March 2022): pre-intervention (March/April 2019) and post-intervention (September 2023)

Secondary outcome measures
1. The number of monthly consultations of smokers or ex-smokers during the study period measured using GP records at 2 years pre-practice intervention (March 2019) and 18 months post-practice intervention (September 2023)
2. The number of monthly consultations for respiratory symptoms by smokers or ex-smokers during the study period measured using GP records at 2 years pre-practice intervention (March 2019) and 18 months post-practice intervention (September 2023)
3. The number of monthly consultations for lung symptoms by lung cancer patients measured using GP records at 1 year or 3 months pre-referral or emergency presentation and 18 months post-referral pr emergency presentation
4. The number of chest x-rays conducted, measured using GP records at 2 years pre-practice intervention, during the practice intervention and 18 months post-practice intervention
5. The number of GP referrals (both urgent and non-urgent) measured using GP records at 2 years pre-practice intervention and 18 months post-practice intervention

Overall study start date
29/04/2019

Completion date
31/08/2023

Eligibility

Key inclusion criteria
Community events:
All members of the public over 18 years old who are interested in participating in the study and able to give informed consent

Practice activities:
All patients who have agreed to participate in the study and have consulted for respiratory symptoms during the study period at the recruited practices

All healthcare professionals and practice staff at the recruited practices

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60 (about 10 patients per practice)

Key exclusion criteria
Community events:
1. All members of the public over 18 years old who are not interested in participating in the study
2. Members of the public less than 18 years old
3. Those unable to give informed consent

Practice activities:
Patients consulting for non-respiratory symptoms at the recruited practices

Healthcare professionals and practice staff at practices not participating in the study

Date of first enrolment
01/09/2019

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NIHR CRN: Yorkshire and Humber
United Kingdom
S10 2SB

Study participating centre
Hull and East Yorkshire Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
NHS Hull CCG
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Sponsor type
University/education

Website
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ROR
https://ror.org/04nkhwh30

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Cancer Research; Grant Codes: H404

Alternative Name(s)
YCR

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Other publication
6. Submission to regulatory authorities
7. Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No