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Breathlessness - DiagnosE Early in Primary care (Breathe DEEP)

Submission date
25/10/2019

Recruitment status
No longer recruiting

Registration date
06/11/2019

Overall study status
Completed

Last Edited
20/08/2025

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Becoming short of breath doing everyday activities is a common problem. People often see their General Practitioner (GP). It can be difficult for a GP to know whether there is a serious problem and what the problem is. There are many reasons why people become more short of breath. Over half of cases are caused by five problems:
1. A heart condition called Chronic Heart Failure (CHF)
2. A lung condition called Chronic Obstructive Pulmonary Disease (COPD)
3. Obesity (being very overweight)
4. Anaemia (low red blood cells that carry oxygen around the body)
5. Anxiety
These conditions can be identified or ruled out using a simple panel of investigations which are all accessible in primary care. Many people wait a long time to find out what the problem is and to get the right treatment, in part because guidelines for GPs focus on specific diseases and specialist services are designed around ‘specialities’ such as cardiology (specialist heart services) not symptoms. The aim of this study is to understand what the practicalities are of running a larger trial. The larger trial will investigate a novel diagnostic pathway, including a panel of simple early investigations, for patients with breathlessness in primary care.

Who can participate?
Patients aged over 40 attending a GP consultation for breathlessness lasting longer than two months

What does the study involve?
This study will recruit GP practices from Leicester and Leicestershire who will be randomly allocated to an intervention group or a usual care group. The GPs in the intervention group will use a new diagnostic pathway including early investigations. The GPs in usual care will continue their normal practice and clinicians will be directed to the NICE Clinical Knowledge Summary on Breathlessness (2017). Time to diagnosis will be recorded. Participants will be asked to attend two research visits at the Biomedical Research Centre at Glenfield Hospital where walk tests, balance and strength, body composition, physical activity and health status (using questionnaires) will be collected. The participants will attend their first research visit soon after they have seen their GP with symptoms of breathlessness and again after 12 months. Patients,

GPs and relevant healthcare professionals will be invited for an interview to help understand their experiences of taking part in the study and help inform the larger trial. The interviews will also explore what is 'usual care' and how breathlessness as a symptom is currently addressed in primary care. Health care utilisation data will be recorded at 12 months, and data on hospital admissions and patient survival will be accessed from NHS digital at 12 months and 5 years.

What are the possible benefits and risks of participating?
As part of the study visits, the researchers will be carrying out tests not normally performed as part of routine NHS care, e.g. 7-day physical activity and sedentary behaviour monitoring. The study is considered to be low risk. Patients will be asked to complete several simple physical tests at the study visits. They may feel breathless at the end of the walking tests but this normally settles within a few minutes. It would be very unusual for symptoms to persist. However, in this unlikely situation medical staff are on hand at the hospital. After the thigh muscle strength tests, patients may experience a small amount of muscle soreness. This is unusual but would settle without any treatment. The measurements made are non-invasive except for the blood tests which can leave bruising and there is a small risk of pain by the needle. If any results from the tests undertaken as part of the study are clinically significant, the researchers will inform both the participant and their GP.

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

When is the study starting and how long is it expected to run for?
September 2019 to September 2025

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Rachael Evans
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
261499

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS: 42353; IRAS: 261499

Study information

Scientific Title
A feasibility study of a multi-centre cluster randomised controlled trial (RCT) to investigate whether a new diagnostic pathway is clinically and cost-effective for older adults presenting with chronic breathlessness compared to usual care

Acronym
Breathe DEEP

Study objectives
It is hypothesised that using a symptom-based approach for diagnosis in primary care will lead to earlier diagnosis for patients with chronic breathlessness.

The overarching aim of the programme of research is to improve the symptoms, quality of life and prognosis for sufferers of chronic breathlessness with an affordable approach for the healthcare system.

For this feasibility study, the specific aims are:
1. To assess feasibility by recruitment of GP practices, recruitment and retention rate of patients in the trial to enable calculation of number of GP practices, cluster sizes and duration of the ultimate RCT
2. To better understand ‘usual care’ through prospective observation and qualitative analysis, and to understand any influence of the trial design on usual care
3. To improve the estimate of the proposed primary outcome measure for the future trial (the difference in proportion of diagnoses at two months or the time to diagnosis between the intervention and usual care) and to increase understanding of what is an important and realistic difference whilst exploring potential of other outcome measures
4. Identify sources of data and how best to collect these in order to plan the economic evaluation that would accompany a full trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/08/2019, Nottingham 1 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; Tel: +44 (0)207 104 8056; Email: NRESCommittee.EastMidlands-Nottingham1@nhs.net), ref: 19/EM/0201

Study design
Feasibility study of a multi-centre cluster randomised controlled trial (RCT) including nested qualitative interviews

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Chronic breathlessness in adults over the age of 40

Interventions
Randomisation will be clustered by GP practice with 5 practices in the Diagnostic pathway (intervention) arm and 5 practices in the Usual care arm.

The intervention is a structured clinical diagnostic pathway for chronic breathlessness which includes early and standardised use of a ‘panel of investigations’. GPs will request a panel of investigations when the patient presents with chronic breathlessness and will review with the results. The investigations will be performed to quality assured standards.

Usual care - GPs and patients will be asked to continue their management and/or interaction with healthcare services, respectively, as usual. Usual care will be standardised by directing clinicians to the NICE Clinical Knowledge Summary on Breathlessness (2017).

Time to diagnosis will be recorded. Patients aged over 40 years old attending a GP consultation for breathlessness lasting longer than two months will be invited to take part in the study. Participants will be asked to attend two research visits at the Biomedical Research Centre at Glenfield Hospital where outcome measures such as walk tests, balance and strength, body composition, physical activity and health status (using questionnaires) will be collected. The participants will attend their first research visit soon after they have seen their GP with symptoms of breathlessness and then again after 12 months. There will also be patient and GP interviews to help understand their experiences of taking part in the study and help inform the larger trial. The interviews will also explore what is 'usual care' and how breathlessness as a symptom is currently addressed in primary care. Health care utilisation data will be recorded at twelve months and five years to provide information on hospital admissions, healthcare use and patient survival. This information will be collected from patient healthcare records and NHS digital.

Intervention Type
Other

Primary outcome(s)

Recruitment rate assessed by the number of participants recruited over 12 months to inform number of GP practices needed for the ultimate cluster RCT accounting for population size

Key secondary outcome(s))
Secondary outcome measures will be collected to help inform outcomes for the larger trial, to assess the impact of an earlier diagnosis.

Measured at a research visit within 1 month of the participant consenting to have their details passed to the study team, and at a further research visit 12 months later. There will also be an interim 6-month phone call and postal questionnaires.
1. Diagnoses made and time to diagnosis assessed using patient medical records at 3 months and 1 year
2. Exercise capacity assessed using the Incremental Shuttle Walk Test (ISWT)
3. Strength and balance assessed using quadriceps maximal voluntary contraction (QMVC), handgrip using dynamometer, Short Physical Performance Battery (SPPB) and Timed Up and Go (TUG)
4. Health-related quality of life assessed using:
4.1. Quality-Adjusted Life Years (QALYs) assessed using the Euroqol Five Dimension and Five Level questionnaire (EQ5D-5L)
4.2. The Chronic Heart Questionnaire Self-Report (CHQ-SR)
4.3. Dyspnoea-12 questionnaire
4.4. Multi-Dimensional Dyspnoea Profile
4.5. Baseline Dyspnoea Index and Transition Dyspnoea Index (BDI/TDI)
4.6. Hospital Anxiety and Depression (HAD)
4.7. Patient Activation Measure (PAM)
4.8. A Likert scale
5. Participant activity levels measured using activity monitors (GT3x Actigraph and GENEActiv)
6. Frailty measured using:
6.1. Fried's frailty definition
6.2. Rockwood Frailty Scale
6.3. Timed Up and Go test
6.4. Short Physical Performance Battery
6.5. Handgrip and quadriceps strength will be conducted as per the relevant SOPs

7. Identify sources of data and collect data to plan the economic evaluation
8. Healthcare utilisation at 12 months from patient healthcare records
9. Hospital admissions at 12 months and 5 years using NHS digital
10. Mortality at 12 months and 5 years using NHS digital

Semi-structured interviews with general practitioners, other relevant healthcare professionals and patients will be conducted to assess:
11. The acceptability of the research visits for participants and GPs
12. Understand usual care and any influence of the trial on usual care

Completion date
04/09/2025

Eligibility

Key inclusion criteria

1. Adults ≥ 40 years old
2. Within two presentations to a GP with persistent exertional breathlessness for over 2 months
3. Able and willing to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Presence of a known diagnosis for symptoms
2. A known active malignancy or other unrelated illness that is likely to result in a prognosis of less than 1 year
3. If patient requires immediate hospital admission

Date of first enrolment
05/11/2019

Date of final enrolment
28/02/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Leicester
Glenfield Hospital
Groby Road
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LE3 9QP

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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 the current study will be available on reasonable request to the CI - Prof Rachael Evans.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/11/2023	07/06/2023	Yes	No
HRA research summary			28/06/2023	No	No
Interim results article	Results of semi-structured qualitative interviews with participants	05/05/2021	07/06/2023	Yes	No
Interim	Results of semi-structured qualitative interviews with participants	25/05	07/06		

results article		/2023	/2023	Yes	No
Interim results article	Investigating a structured diagnostic approach for chronic breathlessness in primary care: a mixed-methods feasibility cluster randomised controlled trial	13/02 /2025	20/08 /2025	Yes	No
Other publications	Recruitment strategy	09/11 /2022	07/06 /2023	Yes	No
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes