

Breathe Plus: a trial to test the feasibility of including a comprehensive assessment at the start of lung rehabilitation for people living with chronic obstructive pulmonary disease and frailty

Submission date 04/10/2019	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 08/10/2019	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/07/2024	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Part of standard care for people with chronic obstructive pulmonary disease (COPD) is pulmonary rehabilitation: an exercise and education-focused intervention. People with COPD also living with frailty (1 in 5) who complete pulmonary rehabilitation experience significant improvements in health outcomes. However, they also have twice the odds of not completing this intervention compared to non-frail people with COPD. Integrating a comprehensive geriatric assessment at the start of pulmonary rehabilitation may better support people living with COPD and frailty to complete their rehabilitation and get connected with other services relevant to their needs. However, before testing this intervention in an effectiveness trial, the researchers need to address uncertainties around the intervention and trial delivery. The aim of this study is to determine the feasibility of conducting a randomised controlled trial of a comprehensive geriatric assessment for people with COPD and frailty starting pulmonary rehabilitation.

Who can participate?

Patients aged 50 or older with COPD and frailty who have been referred for outpatient pulmonary rehabilitation

What does the study involve?

Participants are randomly allocated to a control group (usual care) or intervention group (usual care plus comprehensive geriatric assessment). In addition to usual care, people in the intervention group receive a geriatrician-led multidimensional assessment of their needs, to develop individual recommendations and a care plan. This plan is actioned between the geriatrics and rehabilitation teams, in collaboration with local services. This may include, for example, a medication review, nutritional support, cognitive assessment, and/or an occupational

therapy home assessment. All participants will complete a short physical assessment and questionnaires at baseline, 3 months post-randomisation and 6 months post-randomisation. Interviews will also be conducted with 10-15 patients and 5-10 staff.

What are the possible benefits and risks of participating?

This is a very low-risk study. Having an extra appointment and completing the questionnaires and the short physical test may be tiring for some. It is not known whether participants will benefit directly from participating. However, participants will be able to share their views and experiences in a way that will help to improve future care and research.

Where is the study run from?

1. King's College London & King's College Hospital NHS Foundation Trust (UK)
2. Guy's and St Thomas' NHS Foundation Trust (UK)
3. Royal Brompton and Harefield NHS Foundation Trust (UK)
4. Hillingdon Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2017 to February 2023

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Lisa Brighton

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Integrated Research Application System (IRAS)

268185

Protocol serial number

CPMS: 43111; IRAS: 268185

Study information

Scientific Title

Breathe Plus: Feasibility trial of a comprehensive geriatric assessment for people with chronic obstructive pulmonary disease and frailty starting pulmonary rehabilitation

Acronym

Breathe Plus

Study objectives

The study aim is to determine the feasibility of conducting a randomised controlled trial of an integrated comprehensive geriatric assessment for people with chronic obstructive pulmonary disease (COPD) and frailty starting pulmonary rehabilitation.

Objectives are as follows:

For people with COPD and frailty starting pulmonary rehabilitation:

1. To further define and understand the fidelity of implementation of a comprehensive geriatric assessment, including how it differs from and impacts on usual care
2. To explore the acceptability of the intervention for patients and staff
3. To refine the programme theory around the integration of a comprehensive geriatric assessment for this population
4. To estimate the appropriateness of the proposed eligibility criteria and recruitment processes in successfully retaining participants in the trial
5. To estimate the risk of contamination and unblinding in the trial
6. To explore the appropriateness and acceptability of proposed outcome measures and trial processes to patients and staff

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 26/09/2019, London City and East Research Ethics Committee (Bristol Research Ethics Committee Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, UK; Tel: +44 (0) 2071048033/53; Email: nrescommittee.london-cityandeast@nhs.net), ref: 19/LO/1402

Primary study design

Interventional

Study design

Randomised controlled feasibility trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

People living with chronic obstructive pulmonary disease and frailty

Interventions

Participants will be randomly allocated (1:1) to a control group (usual care) or an intervention group (usual care + comprehensive geriatric assessment). Participants will be randomised by minimisation (a hybrid system with a 20% simple randomisation element) using an independent web-based system created by the King's College London Clinical Trial Unit.

Intervention group: In addition to usual care, people in the intervention group will receive a geriatrician-led multidimensional assessment of their needs, in order to develop individual recommendations and a care plan. This will take place as a single appointment as soon as possible after the participant's pre-pulmonary rehabilitation assessment. This plan will be actioned between the geriatrics and pulmonary rehabilitation teams, in collaboration with local services. This may include, for example, a medication review, nutritional support, cognitive assessment, and/or an occupational therapy home assessment.

Follow-up data-collection timepoints will be at 3 months and 6 months post-randomisation.

Intervention Type

Other

Primary outcome(s)

Feasibility outcomes include:

1. Percentage of comprehensive geriatric assessment recommendations that are implemented at 6 months
2. Acceptability of the intervention to patients and staff based on qualitative interviews
3. Percentage screened eligible, and percentage eligible recruited at trial completion
4. Percentage of participants retained at 3 months and at 6 months
5. Percentage of participants where contamination occurs (i.e. control group participants receiving a comprehensive geriatric assessment) at 6 months
6. Percentage of participants where data collection blinding is maintained at 6 months
7. Level of missing data on patient outcome questionnaires at baseline, 3 and 6 months

Key secondary outcome(s)

The following outcomes will be measured at baseline, 3 and 6 months:

1. Physical frailty assessed using short physical performance battery
2. Activities of daily living assessed using Manchester Respiratory Activities of Daily Living questionnaire
3. Health-related quality of life assessed using Chronic Respiratory Questionnaire
4. Health Status assessed using Euro-Qol 5D-5L
5. Anxiety and depression assessed using Hospital Anxiety and Depression Scale
6. Loneliness assessed using De Jong Gierveld Loneliness Scale
7. Service use assessed using Client Service Receipt Inventory

Completion date

28/02/2023

Eligibility

Key inclusion criteria

1. Adults aged 50 years or older
2. Physician diagnosis of chronic obstructive pulmonary disease (in line with GOLD criteria)
3. Referred for outpatient pulmonary rehabilitation (in line with BTS guidelines)
4. Rockwood Clinical Frailty Scale score of 5 or more

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

31

Key exclusion criteria

1. Lacking mental capacity to provide informed consent
2. Unable to communicate verbally and respond to questions in written English (or unavailability of interpreters to enable this)
3. Currently receiving specialist geriatric services, or has in previous month, or due to in coming month

Date of first enrolment

01/11/2019

Date of final enrolment

30/04/2022

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

King's College London & King's College Hospital NHS Foundation Trust

Denmark Hill

London

United Kingdom

SE5 9RS

Study participating centre

Guy's and St Thomas' NHS Foundation Trust

Great Maze Pond

London

United Kingdom

SE1 9RT

Study participating centre

Royal Brompton and Harefield NHS Foundation Trust

Uxbridge

London

United Kingdom

UB9 6JH

Study participating centre

Hillingdon Hospitals NHS Foundation Trust

Uxbridge

London

United Kingdom

UB8 3NN

Sponsor information

Organisation

King's College London

Organisation

King's College Hospital NHS Foundation Trust

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 data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/07/2024	30/07/2024	Yes	No
Protocol article		29/03/2021	06/04/2021	Yes	No
HRA research summary			28/06/2023	No	No