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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	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/10/2019	**Overall study status** Completed	
Last Edited 30/07/2024	**Condition category** Respiratory	

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

EudraCT/CTIS number

Nil known

IRAS number
268185

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design
Randomised controlled feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
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 measure
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

Secondary outcome measures

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

Overall study start date
01/12/2017

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

Age group
Adult

Sex
Both

Target number of participants
60

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
England

United Kingdom

Study participating centre
King's College London & King's College Hospital NHS Foundation Trust
Denmark Hill
London
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SE5 9RS

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Great Maze Pond
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Study participating centre
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Study participating centre
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Sponsor information

Organisation

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Sponsor type
University/education

Website
https://www.kcl.ac.uk/

Organisation
King's College Hospital NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.kch.nhs.uk/research/setting-up/contact-research-office

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

Publication and dissemination plan
The researchers will use a broad strategy to disseminate their findings. This will include:
1. A plain English summary for participants who opt to receive this on their consent form
2. Sharing of scientific findings via open-access publications in journals and presentation at international meetings
3. Plain English summaries of findings for public bodies and websites (e.g. Applied Research Collaborative, British Lung Foundation)
4. Online pages about the project on our website (www.csi.kcl.ac.uk)
5. Use of social media (e.g. Twitter, YouTube, blogs)
6. Public engagement via talks and open public events at the Cicely Saunders Institute and our collaborating sites
7. Additional documents (e.g. protocol, participant information sheet, consent form) are available on reasonable request to the chief investigator

Intention to publish date
01/04/2024

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?
Protocol article		29/03/2021	06/04/2021	Yes	No
HRA research summary			28/06/2023	No	No
Results article		29/07/2024	30/07/2024	Yes	No