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Sputum clearance devices to improve symptoms in chronic obstructive pulmonary disease

Submission date
29/10/2019

Recruitment status
No longer recruiting

Registration date
30/10/2019

Overall study status
Completed

Last Edited
19/07/2023

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There are 1.3 million people with a diagnosis of chronic obstructive pulmonary disease (COPD) in the UK. COPD is a combination of chronic bronchitis and emphysema. Cough with sputum is a common feature of the condition, even in people on optimum medical therapy. The amount of sputum production varies between individuals. Coughing can be tiring and embarrassing for patients. If sputum isn't cleared, infections can arise. Sputum can also block small airways, meaning that the lungs can't work effectively. The Acapella is a handheld device that patients can breathe into when they want to help clear sputum from their chest. It generates positive pressure which helps keep airways open and also produces vibrations which helps free sputum and makes it easier to cough up. It is about the size of a small plastic water bottle and has a dial at the end to adjust the amount of resistance when the person breathes through it. There have been only a few short-term trials so far. These have been encouraging but do not provide enough evidence to recommend widespread use of the devices. The aim of this study is to see if people with COPD who produce sputum on at least most days of the week benefit from using the Acapella to help them to clear sputum from their chest. This will involve measuring quality of life and also in some patients measuring how often they cough using a recording device.

Who can participate?
Adult patients with COPD who frequently produce sputum

What does the study involve?
Participants are randomly allocated to an Acapella group or to usual care. The Acapella group receive teaching on how to use the device then take it home (asked to use it at least 3 times daily). Both groups have measures of quality of life and severity of cough symptoms compared using well-established questionnaires at the beginning and after 3 months. A subset of patients also wears a cough monitor and an activity monitor for 3 days.

What are the possible benefits and risks of participating?
Participants will be helping to advance understanding of processes involved in lung disease. The sputum clearance device is already used in routine clinical practice, so apart from the inconvenience involved no risks are expected.

Where is the study run from?
1. Royal Brompton and Harefield NHS Foundation Trust (UK)
2. Taunton and Somerset NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2019 to January 2022

Who is funding the study?
Saudi Arabia Cultural Bureau in London (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
269494

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
19IC5363; IRAS 269494

Study information

Scientific Title
The O-COPD trial: oscillatory positive expiratory pressure (OPEP) devices to improve outcome in patients with chronic obstructive pulmonary disease (COPD)

Acronym
O-COPD

Study objectives
In patients with chronic obstructive pulmonary disease (COPD), who produce sputum frequently (daily or most days in the preceding month), does providing an oscillatory positive expiratory pressure (OPEP) device (the Acapella®) improve health status and reduce exacerbation frequency compared to usual care over 3 months?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/11/2019, London-Chelsea Research Ethics Committee NRES (Research Ethics Committee (REC) London Centre, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0) 207 104 8029; nrescommittee.london-chelsea@nhs.net), ref: 19/LO/1427

Study design
Multi-centre single-blind controlled parallel-group study

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 conmtact details to request a participant information sheet.

Health condition(s) or problem(s) studied
COPD patients who produce sputum regularly

Interventions
Participants will be randomised to OPEP device (the AcapellaTM) with usual care or usual care alone. Allocation will be by computer-generated list.

Active: Taught active cycle of breathing. Acapella device used at least three times per day
Control: Taught active cycle of breathing

The Acapella group will receive teaching on how to use the device then take it home (asked to use it at least three times daily). Both groups will have measures of quality of life (the main research outcome) and severity of cough symptoms compared using well-established questionnaires at the beginning and after 3 months. A subset of patients will also wear a cough monitor and an activity monitor for 3 days.

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
Cough symptoms measured using the Leicester cough questionnaire (LCQ) at baseline and 12 weeks

Secondary outcome measures
1. Cough severity measured by Visual Analog Scale (VAS) at baseline and 12 weeks
2. Health status measured by CAT score at baseline and 12 weeks
3. Health status measured using EQ-5D-5L at baseline and 12 weeks
4. Fatigue measured using FACIT score at baseline and 12 weeks
5. Exacerbation rate (number of exacerbations during the 12 weeks of the study) measured using patient diaries at 12 weeks

A subset of 32 participants will undergo measurement of cough frequency and sleep movements to determine whether the OPEP device influences cough frequency and sleep efficiency. This will use the Leicester Cough Monitor and the McRoberts MoveMonitor at baseline and 12 weeks

Overall study start date
13/01/2019

Completion date
14/01/2022

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 02/03/2020:
1. Adult patients with COPD who frequently produce sputum defined as: (i) every or most days in the last month and a score of >=5/8 on the two CAT cough items
2. Stable treatment for the preceding four weeks

Previous participant inclusion criteria:
1. Adult patients with COPD who frequently produce sputum defined as: (i) every or most days in the last month and a score of >=6/8 on the two CAT cough items
2. Stable treatment for the preceding four weeks

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
102

Total final enrolment
103

Key exclusion criteria
1. Unable to provide informed consent
2. Major condition limiting life expectancy for <3 months
3. Referral for chest physiotherapy in the preceding year
4. Already using an adjunct device for sputum clearance
5. Within 1 month of pulmonary exacerbation
6. Within 1 month of COPD medication change
7. Within 1 month of a pneumothorax

Date of first enrolment
27/02/2020

Date of final enrolment
01/06/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Brompton and Harefield NHS Foundation Trust
Fulham Rd
London
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SW3 6NP

Study participating centre
Taunton and Somerset NHS Foundation Trust
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Sponsor information

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Sponsor type
University/education

Website
https://www.imperial.ac.uk/research-and-innovation/support-for-staff/joint-research-office/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Other

Funder Name
Saudi Arabia Cultural Bureau in London

Alternative Name(s)
Royal Embassy of Saudi Arabia Cultural Bureau in London, Royal Embassy of Saudi Arabia - Cultural Bureau in London, Royal Embassy of Saudi Arabia Cultural Bureau, SACB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results will be used to guide treatment guidelines for people with COPD and shared through presentation at conferences and publication in medical journals. No additional documents will be available.

Intention to publish date
30/09/2022

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?
Results article		10/08/2022	12/08/2022	Yes	No
HRA research summary			28/06/2023	No	No