ISRCTN18345305 https://doi.org/10.1186/ISRCTN18345305

Sputum clearance devices to improve symptoms in chronic obstructive pulmonary disease

Submission date 01/02/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 03/02/2023	**Overall study status** Completed	
Last Edited 30/12/2024	**Condition category** Respiratory	

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 (airway inflammation) and emphysema (damaged air sacs). Cough with sputum (mucus) 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 help to free sputum and make 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 the widespread use of the devices. The aim of this study is to see if people with COPD who produce sputum daily 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 three 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 6 months. A subset of patients will also be asked to wear 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 the 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?
Royal Brompton Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2022 to December 2025

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

Who is the main contact?
Nick Hopkinson, COPD@rbht.nhs.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Nicholas Hopkinson

ORCID ID
https://orcid.org/0000-0003-3235-0454

Contact details
NHLI, Imperial College, London
Royal Brompton Hospital Campus
Fulham Road
London
United Kingdom
SW3 6NP
+44 (0)2073497775
n.hopkinson@ic.ac.uk

Type(s)
Public

Contact name
Mr Ahmed Alzahrani

ORCID ID
https://orcid.org/0000-0003-3200-5984

Contact details
NHLI, Imperial College London
Royal Brompton Hospital Campus
Fulham Rd
London
United Kingdom

SW3 6NP
+44 (0)2073518029
copd@rbht.nhs.uk

Type(s)
Scientific

Contact name
Prof Nicholas Hopkinson

Contact details
NHLI, Imperial College, London
Royal Brompton Hospital Campus
Fulham Road
London
United Kingdom
SW3 6NP
+44 (0)2073518029
n.hopkinson@ic.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
269494

Central Portfolio Management System (CPMS)
43088

Protocol serial number
V4

Study information

Scientific Title
The O-COPD2 trial: oscillatory positive expiratory pressure devices to improve outcome in patients with chronic obstructive pulmonary disease

Acronym
O-COPD2

Study objectives
In patients with chronic obstructive pulmonary disease (COPD), who produce sputum daily, does providing an oscillatory positive expiratory pressure (OPEP) device (the Acapella®) improve health status and reduce exacerbation frequency compared to usual care over 6 months?

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 09/08/2022, 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

Primary study design
Interventional

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
Participants are randomly allocated to an Acapella group or to usual care. The Acapella group receive teaching on how to use an oscillatory positive expiratory pressure device (Acapella) device then take it home (asked to use it at least three 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 6 months. A subset of patients will also be asked to wear a cough monitor and an activity monitor for 3 days.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Acapella device

Primary outcome(s)
Cough-related quality of life measured using the Leicester cough questionnaire (LCQ) at 6 months

Key secondary outcome(s)
1. Cough severity measured by Visual Analog Scale (VAS) at 6 months
2. Health status measured by COPD Assessment Test (CAT) score at 6 months
3. Generic health status measured using EQ-5D-5L at 6 months
4. Fatigue measured using Functional Assessment of Chronic Illness Therapy (FACIT) score at 6 months
5. Exacerbation rate based on self-report at 6 months

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.

Completion date

01/12/2025

Eligibility

Key inclusion criteria
Adult patients with COPD who report daily sputum production and with a score of >5/8 on the two COPD assessment test (CAT) score cough items

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
01/07/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Brompton Hospital
Sydney Street
London
United Kingdom
SW3 6NP

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Other

Funder Name
Saudi Arabia Cultural Bureau in London (UK)

Results and Publications

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
Published as a supplement to the results publication

Study outputs

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