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Training to improve dyspnoea

Submission date 15/02/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 19/10/2017	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 12/02/2025	**Condition category** Respiratory	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a group of lung conditions that cause breathing difficulties. Breathlessness is a common symptom in COPD and can impact on a person' s exercise capacity and quality of life. A new device has been developed to improve patients' respiratory (breathing) muscle strength and in turn reduce breathlessness. The aim of this study is to find out whether this device can manage the symptoms of breathlessness and as a result impact on exercise capacity and health-related quality of life.

This study also includes two sub-studies. One explores the benefits of pulmonary rehabilitation for patients with lung disease (named ExPORt) and one explores the rehabilitation needs of patients that had an admission following Coronavirus (CORe).

Who can participate?
Patients aged 40 or above with COPD

What does the study involve?
Participants attend three hospital visits in total. The first visit involves checking their eligibility for the study and performing some breathing tests, exercise tests and questionnaires. The second visit is one week later after the participant has worn an activity monitor for 1 week. Participants are randomly allocated to use either the device or a sham (not working) device. Participants do not know which device they have until the end of the study. The device is used for 8 weeks three times per day. A daily diary of adherence is kept. On week 7 an activity monitor is worn for the final week. After 8 weeks the final visit repeats the previous tests. Those on the sham treatment are offered the working device.

What are the possible benefits and risks of participating?
Participants have the opportunity to discuss their condition with a trained healthcare professional. They receive a free device to keep once the study has ended. If allocated to the sham device they are offered the working device at the end of the study. There are no anticipated risks to taking part and the research team are happy to reimburse travel costs.

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

When is the study starting and how long is it expected to run for?
June 2017 to September 2021

Who is funding the study?
Actegy Ltd

Who is the main contact?
Miss Enya Daynes
enya.daynes@uhl-tr.nhs.uk

Contact information

Type(s)
Public

Contact name
Miss Enya Daynes

ORCID ID
http://orcid.org/0000-0003-0127-1649

Contact details
Respiratory Biomedical Research Unit
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP
+44 (0)116 250 2758
enya.daynes@uhl-tr.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number
220947

ClinicalTrials.gov number

Secondary identifying numbers
IRAS 220947

Study information

Scientific Title
A randomised controlled trial to investigate the use of high frequency airway oscillations as training to improve dyspnoea in COPD (TIDe)

Acronym

TIDe

Study objectives
1. Patients training with a HFAO device for 8 weeks will have a reduction in dyspnoea and an improvement in health status compared to baseline.
2. Patients training with a HFAO device for 8 weeks will show improvements in exercise capacity, cough frequency and intensity and dyspnoea at rest and upon exertion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicester South Research Ethics Committee, 12/06/2017, ref: 17/EM/0156

Study design
Single-centre randomised control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files, ISRCTN45695543_PIS_ExPORt_23May20 and ISRCTN45695543_PIS_CORE_23May20 (added 23/05/2020)

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

Interventions
Current interventions as of 23/05/2020:
For the main TIDe study participants are randomised by a computer-generated system to one of two groups:
1. Aerosure device
2. Sham device
This will be a blinded study therefore participants will not know which device they will receive until the end of the study. The assessor will also be unaware of this.

The Aerosure Device is a high-frequency oscillating device that requires maximal breathing in and out. It does not deliver any medicine but adds resistance to breathing and oscillates the air for training benefits.

For the sub-studies ExPORt and CORe the interventions will be rehabilitation, which includes exercise and education.

Participants will require 3 visits to the hospital in total. The first will ensure eligibility and perform some breathing tests, exercise tests and questionnaires. The second visit will be one week later after they have worn an activity monitor for 1 week and will randomise them to a device. The device will be used for 8 weeks 3 times per day. A daily diary of adherence will be kept. On week 7 an activity monitor will be worn for the final week. After 8 weeks the final visit will repeat the previous measures and this will conclude the visit schedule. Those on the sham treatment will be offered the active device.

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Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

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

Primary outcome measure
Dyspnoea is measured using the Dyspnoea domain of the Chronic Respiratory Questionnaire and the COPD assessment test at baseline and after 8 weeks of the intervention (typically 9 weeks later)

Secondary outcome measures
Current secondary outcome measures as of 13/02/2019:
All outcome measures are performed at baseline and after 8 weeks of the intervention (typically 9 weeks later):
1. Respiratory muscle strength is measured via maximal mouth inspiratory muscle strength test and maximal mouth expiratory muscle strength test

2. Exercise capacity is measured via the incremental shuttle walking test and the endurance shuttle walking test
3. Health-related quality of life is measured via the Chronic Respiratory Questionnaire, COPD assessment test, Leicester Cough Questionnaire, London Activity of Daily Living Questionnaire and the Hospital Anxiety and Depression Score
4. Activity is measured using an activity monitor prior to the intervention and on week 7 of the intervention
5. Lung Clearance Index measured via a Multiple Breath Washout.

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2. Exercise capacity is measured via the incremental shuttle walking test and the endurance shuttle walking test
3. Health-related quality of life is measured via the Chronic Respiratory Questionnaire, COPD assessment test, Leicester Cough Questionnaire, London Activity of Daily Living Questionnaire and the Hospital Anxiety and Depression Score
4. Activity is measured using an activity monitor prior to the intervention and on week 7 of the intervention

Overall study start date
12/06/2017

Completion date
30/09/2021

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 40 years or above
3. Confirmed diagnosed of COPD
4. MRC Score of 2 or more on the conventional 1-5 scale. (walk slower than people of the same age on the level or stops for breath when walking at own pace on the level)
5. Able to read and write in English
For the sub studies ExPORt and CORe (added 23/05/2020):
1. Participant is willing and able to give informed consent for participation in the study
2. Referred to the study through a clinical service (pulmonary rehabilitation or admission with COVID-19)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
105

Total final enrolment
104

Key exclusion criteria
1. Significant disease (other than COPD) that could cause dyspnoea or exercise limitation
2. Contraindications for exercise (unstable cardiovascular disease; hypertension etc, a full list is described by the American College of Sports Medicine and is routine deployed)
3. Inability/unwillingness to use the device
4. Contraindications to using HFAO device (including severe right heart failure with hypotension), current severe haemoptysis, ineffective cough, rib fractures, pregnancy, current or recent pneumothorax, epilepsy, current pulmonary embolism, oesophageal varices, recent thoracic, upper gastro-intestinal tract or facial surgery).
5. Previously engaged in exercised based research or pulmonary rehab in the last 6 months
6. Inability to secure informed consent
7. Those unable to communicate in full English will be excluded as the user manual is only available in English
8. Currently involved in exercise based research

Date of first enrolment
27/06/2017

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
University Hospitals of Leicester

Sponsor details
Gwendolen Road
Leicester
England
United Kingdom
LE5 4PW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Industry

Funder Name
Actegy Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer review journal and disseminated at conferences in 2020 (updated 05/03/2020, previously: 2019). The results of the study will be shared with the patient once recruitment has completed.

Intention to publish date
01/06/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current 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?
Participant information sheet	version V1		19/10/2017	No	Yes
Protocol article	protocol	29/07/2019	02/08/2019	Yes	No
Participant		23/05	23/05		

information sheet		/2020	/2020	No	Yes
Participant information sheet		23/05 /2020	23/05 /2020	No	Yes
Results article		27/10 /2021	13/12 /2021	Yes	No
HRA research summary			28/06 /2023	No	No
Other publications	Cohort sub study of early experiences and feasibility	06/05 /2021	12/02 /2025	Yes	No
Other publications	Exploratory qualitative analysis, a satisfaction survey and focus group	13/06 /2024	12/02 /2025	Yes	No
Other publications	Substudy under same ethics looking at changes in fatigue symptoms during the rehabilitation programme	22/07 /2025	12/02 /2025	Yes	No