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Singing and COPD: a pilot randomised controlled trial

Submission date
04/12/2018

Recruitment status
No longer recruiting

Registration date
08/05/2019

Overall study status
Completed

Last Edited
15/08/2022

Condition category
Respiratory

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

Plain English summary of protocol
Background and study aims
Chronic obstructive pulmonary disease (COPD) is a long-term and progressive respiratory disease which negatively affects people's health and wellbeing. The condition deteriorates over time, and there is no cure. However, there is evidence that activities like regular exercise and singing can improve breathlessness and general health and wellbeing. Previous research has shown positive benefits of singing for respiratory illness, but two recent reviews of the evidence highlights the limitations of previous research and the need for further larger-scale controlled studies with follow-up. The aim of this study is to build on previous research and undertake a larger-scale controlled study of the effects of regular group singing for people with COPD. A new feature of the study will be the direct assessment of patients' patterns of breathing to investigate whether regular singing serves to encourage stronger and more consistent use of the diaphragm to support breathing.

Who can participate?
Adult patients with moderate to very severe COPD

What does the study involve?
Participants are assessed using a number of short questionnaires to assess health status and psychological wellbeing. In addition, lung function is assessed. The focus of interest is on the extent to which patients engage in shallow upper chest breathing, or engage their diaphragm is deeper abdominal breathing. Following the assessment, half of the participants are selected at random to participate in a singing programme and half receive usual care. The singing programme takes place over ten 90-minute sessions. The programme involves breathing exercises and songs which encourage controlled breathing and progressive extension of the time taken to breathe out. Following the end of the singing programme, participants are assessed for a second time. There is then a follow-up period of three months during which no singing activity takes place, and the participants are assessed for a third time to see whether any changes observed immediately following the intervention are maintained.

What are the possible benefits and risks of participating?
On the basis of previous research, participants are expected to gain an increased sense of personal and social wellbeing from participating in an enjoyable and stimulating group activity. If

this is the case, we should see this reflected in answers given on the structured questionnaires that will be employed in the study. They may also find that regular singing teaches techniques of breathing which can help them manage their breathing difficulties more effectively. This potential outcome will be assessed using a validated COPD health questionnaire and direct assessments of lung function. A further benefit for all participants, whether in the intervention or control group, is the satisfaction of taking part in a scientific study aimed at improving the treatment of COPD. Previous research indicates that there are no risks associated with regular singing for people with COPD, and no side effects.

Where is the study run from?
The study is a collaboration between Canterbury Christ Church University, the University of Kent and Medway Community Healthcare who provide secondary support services for people with COPD. Patients will be recruited through Medway Community Healthcare Respiratory Team. The intervention will take place in a community venue in Medway UK, with singing sessions taking place weekly for ten weeks. Assessments will take place in the Sport Sciences laboratory of the University of Kent at Medway Park Sports Centre.

When is the study starting and how long is it expected to run for?
March 2018 to March 2020

Who is funding the study?
The study is being funded by Oak Foundation and supported by Canterbury Christ Church University and the University of Kent (UK)

Who is the main contact?
Prof. Persephone Sextou, persephone.sextou@canterbury.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
Protocol 1

Study information

Scientific Title
Singing and COPD: a pilot randomised controlled trial to assess the effects of a structured 10-week programme of singing on the health-related quality of life of patients with COPD, compared with usual treatment, six-months post-baseline assessment

Acronym
Singing and COPD

Study objectives
No change occurs in COPD-specific health status, following ten weeks of regular, weekly singing at the primary end point for the trial six months post-baseline

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/02/2019, London – Queens Square ethics committee (Friends Meeting House, Euston, NW1 2BJ; 0207 104 8061; NRESCommittee.London-QueenSquare@nhs.net), ref: 19/LO/0159

Study design
Single-blinded randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

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

Interventions
Randomisation will be conducted by a secure remote randomisation service independent of the research team. Randomisation will employ random permuted blocks of variable length with stratification by sex and COPD severity.

Intervention: a structured and progressive programme of group singing for participants with COPD delivered over 10 weeks in sessions lasting 90 minutes, supplemented by home practice between sessions supported by printed and audio-visual material.

The participants in the control condition will receive treatment as usual (TAU).

Participants will be assessed at baseline using a number of validated, short questionnaires to assess health status and psychological wellbeing. In addition, lung function will be assessed using standardised spirometry and a new technique which assesses patterns of breathing. The focus of interest is on the extent to which patients engage in shallow upper chest breathing, or engage their diaphragm is deeper abdominal breathing. Following baseline assessment, half of the participants will be selected at random to participate in a singing programme and half will receive usual care. The singing programme will be implemented over 10 90-minute sessions. The programme will involve breathing exercises and songs which will encourage controlled breathing and progressive extension of the time taken to breathe out. Following the end of the singing programme, participants will be assessed for a second time. There will then be a follow up period of 3 months during which no singing activity will take place, and the participants will be assessed for a third time to see whether any changes observed immediately following the intervention are maintained.

Intervention Type
Behavioural

Primary outcome(s)
Quality of life assessed with the COPD Assessment Test (CAT) at baseline, three months following the ten-week intervention, and then after a further three months.

Key secondary outcome(s))
Measured at baseline, three months following the ten-week intervention, and then after a further three months:
1. Breathlessness assessed using mMRC self-completion questionnaire
2. Physical health related quality of life and mental health related quality of life assessed using SF-36 v2 self-completion questionnaire
3. Generalised anxiety disorder assessed by GAD-7 (self-completion questionnaire)
4. Depression assessed by PHQ-9 (self-completion questionnaire)
5. Lung function and patterns of breathing assessed by standardised spirometry and structured light plethysmography
6. Functional exercise measured by the standardised six-minute walk test

Completion date
31/03/2020

Eligibility

Key inclusion criteria
The trial will be open to patients:
1. With a diagnosis of COPD who have received pulmonary rehabilitation (or in receipt during the recruitment period)
2. Willing to undergo the collection of assessments planned
3. Willing to be randomised to either the intervention or control group
4. Able to attend one of the two groups planned (given the proposed day and time)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
36

Key exclusion criteria
1. Are unable to give informed consent
2. Have comorbid conditions that make participation difficult
3. Are unable to travel independently to the venues
4. Are not sufficiently fluent in English to complete the questionnaires employed

Date of first enrolment
18/03/2019

Date of final enrolment
09/03/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Medway Community Healthcare
Bailey Drive
Gillingham
United Kingdom
ME8 0PZ

Sponsor information

Organisation
Canterbury Christ Church University

ROR
https://ror.org/0489ggv38

Funder(s)

Funder type
Charity

Funder Name
Oak Foundation

Alternative Name(s)
Oak Foundation USA, Oak Philanthropy (US) Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
Canterbury Christ Church University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Following publication of the trial results, all anonymised participant level data will be available to university researchers for secondary analysis. Participant consent given. Requests should be made in writing to the Head of Research, Faculty of Health and Wellbeing, Canterbury Christ Church University, North Holmes Road, Canterbury, Kent CT1 1QE, UK. Data will be available as an SPSS file for one year post-publication of the trial.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2022	15/08/2022	Yes	No
Results article	Implementation and evaluation	01/05/2022	15/08/2022	Yes	No
Results article	Participant experiences	01/05/2022	15/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 1	18/12/2018	15/08/2022	No	No