

'Singing for Lung Health' group participation after pulmonary rehabilitation completion. A feasibility study

Submission date 13/09/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/09/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/05/2023	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Pulmonary Rehabilitation (PR) is an education and exercise programme recommended for people with lung conditions to improve the management of breathlessness, exercise capacity and quality of life. Improvements from PR are typically lost after a year without supervised 'maintenance' programmes which are not widely available. Without joining these programmes people increase their risk of getting chest infections, being hospitalised and dying. Singing for Lung Health (SLH) provide management of breathlessness and other symptoms. By improving singing techniques, individuals gain skills that help them to cope with their lung condition. People taking part in SLH groups find them enjoyable, sociable and useful managing their conditions. However, only small, short-term studies have been performed. Research has not yet shown benefit specifically for individuals with respiratory disease participating in singing groups after completing PR.

Who can participate?

Adults over 18 years who have recently completed PR.

What does the study involve?

Patients completing PR will be randomised to receive standard care home-exercise advice, or to attend local SLH groups once a week for 12 weeks, as well as receiving the home-exercise advice. All patients will complete diaries of their home practice sessions of singing and exercise. Patients will complete research assessments before starting their first SLH session and again after completing 12 weeks of singing. The research team will help develop working relationships between PR group leaders and SLH leaders.

Clinicians, singing leaders and participants will be interviewed about their experiences of working together, and participating in the research.

Participants will be paid to attend singing sessions and assessments.

What are the possible benefits and risks of participating?

Participating in a Singing for Lung Health programme, which will be allocated to half the

participants in this study, may improve participant health status, levels of physical activity and balance. There may be other impacts such as improving mood and increasing social interactions. However, these impacts are not yet proven, and part of why we are doing this research. Another possible benefit is knowing that participants will be helping to improve understanding of treatments for your lung condition.

Apart from the time and potential inconvenience, no risks are anticipated from this study. No side effects have been previously reported participating in singing. Exercise may cause some muscle soreness between two days and a week following exercise, but this is unlikely because participants will be used to performing such exercise for weeks as part of Pulmonary Rehabilitation. Exercise and singing may change how breathing feels, but this in itself is not harmful.

Where is the study run from?

Guy's and St Thomas' NHS Foundation Trust (UK)

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

June 2021 to March 2023

Who is funding the study?

National Institute for Health Research (NIHR) (UK).

Who is the main contact?

Dr Adam Lewis, adam.lewis@brunel.ac.uk

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

293580

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 49439, NIHR201539, IRAS 293580

Study information

Scientific Title

Randomised controlled feasibility study of maintaining the benefits of pulmonary rehabilitation with harmonies and melodies via singing for lung health. The WHAM study

Acronym

WHAM

Study objectives

The aim is to find out if individuals with lung disease, who have completed an exercise and disease education programme, can then attend 12 weeks of singing classes designed for individuals with lung conditions.

The primary objective of this study is to find out how many individuals with chronic respiratory disease who are taking part in pulmonary rehabilitation agree to take part in a trial of and then complete participation in a Singing for Lung Health (SLH) group for after completing pulmonary rehabilitation.

We hypothesise that 60% of individuals who complete PR will then complete SLH for at least 8 out of 12 sessions. This information will enable us to plan an appropriate estimated participant drop-out for a future definitive trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval pending, Hampshire REC B (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8140; hampshireb.rec@hra.nhs.uk), ref: not provided

Study design

Randomized; Both; Design type: Treatment, Process of Care, Complementary Therapy, Physical, Rehabilitation, Qualitative

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Rehabilitation from all lung conditions

Interventions

Intervention group – Home-exercise advice (standard care) + Singing for Lung Health (SLH) group participation

Individuals will participate in once-weekly SLH sessions for 12 weeks and receive routinely prescribed home exercise advice. Home exercise advice includes information based on principles of Frequency, Intensity, Time, Type and Progression, and UK age-dependent physical activity guidelines. Exercise advice will include progressive resistance and endurance training including exercises such as bicep curls, lateral shoulder raises, push ups against the wall, squats, sit-to-stands and step-ups. Physical activity advice will include information about progression of walking in time, distance or speed depending patient goals and any specific physical activity that participants enjoy. The frequency of home exercise sessions will be recorded using a participant completed paper diary.

Singing is a complex intervention, involving postural and breathing support, and vocal technique. SLH differs from participation in more generic singing activities by its focus on improving breath control and posture in relation to respiratory disease. A typical 60-minute class includes physical warm-ups, breathing exercises, vocal warm-ups, songs and a cool down/relaxation. Physical warm-ups use body mobilisation and simple exercises as well as using action songs and body percussion. Breathing exercises focus on awareness of supporting musculature during inhalation and exhalation. Vocal exercises include unvoiced and voiced fricatives to introduce vocal fold closure and to begin to move from passive to voiced exhale. Introducing 'primal sounds' such as Hey, Ho, Ha, etc., to engage vocal mechanism and support. A range of vocal sounds are used to warm up the voice, alternating different vocal qualities, range, dynamics, timbre, pitch and rhythm. These are taught in a call-and-response style. A variety of more formal singing exercises to set patterns are used to start to integrate melodic patterns with the length of exhalation. Participant choice is given from a balanced repertoire of appropriate songs that are fit for purpose in terms of phrase lengths, breath points, lyrics, and melodic challenge. A cool-down, guided relaxation focussing on body and breath awareness are included. Practice exercises at home will be performed using the 'Singing for Breathing' CD (available from <http://www.rbht.nhs.uk/about/arts/whats-on/singingfor-breathing/>) . We are providing these CDs as part of the Trial. The frequency of practice sessions will be recorded using a paper diary completed by the participant. Singing group sessions will follow on from Pulmonary Rehabilitation group sessions whereby groups of people will be allowed in a particular indoor space according to capacity numbers, aligned to social distancing restrictions, current mask wearing and ventilation guidelines in response to the COVID-19 pandemic.

Control Group – Home exercise advice only

This group will receive home-exercise advice according to the description above. The participants in the control group will be able to join their local SLH group once the trial has finished.

Intervention Type

Behavioural

Primary outcome measure

Proportion of patients who complete SLH after completing PR, defined as attending at least 8 out of 12 sessions of SLH measured using case report forms

Secondary outcome measures

Measured using case report forms unless otherwise noted:

1. Rates of PR completer participants commencing the trial
2. The number of eligible participants completing local PR programmes
3. The percentage of PR programmes who successfully implement the singing taster session within their PR
4. Recruitment rate per site in the RCT
5. The standard deviations of key outcome measures including the Dyspnoea-12 and Multidimensional Dyspnoea Profile in response to SLH after PR to be able to determine a sample size for a future trial (analysed following 12 weeks of intervention or control participation)
6. The feasibility of recording home practice SLH sessions in patient diaries. This will be calculated as a mean percentage recorded sessions
7. The number of patients in the control arm who continue in the trial to 24 weeks. This will be calculated as whether there is any significant difference in drop-out rates across the trial between intervention and control groups.
8. The feasibility of an economic evaluation. The aim is to develop and understand the accuracy, reliability and practicality of the data collection tools associated with resource use and quality of life data, and variability in this data. This will be analysed according to baseline data collected from the health service inventory and the questionnaire completed once again at 24 weeks.
9. The feasibility of collecting disease specific and general health related quality of life data according to completion rates of the COPD Assessment/Asthma Quality of Life Questionnaire /Kings Brief ILD questionnaire, Voice related QOL questionnaire, EQ-5D-5L (Collected at baseline, 12 weeks and 24 weeks).
10. The perspectives of stakeholders across sites (PR leaders, singing leaders and patients), regarding experiences and the design of the Trial. These will be obtained via qualitative interviews.
11. Change in exercise capacity within and between groups according to the differences in 6-minute walk distance between baseline and 12 week outcomes.
12. Changes in lung function parameters of inspiratory capacity, peak flow, forced expiratory volume in 1 second, forced vital capacity, within and between groups according to changes from baseline to 12 weeks.
13. Change in physical function according to the short physical performance battery (SPPB) score and physical activity according to activity monitor data. These data will be analysed according to differences within and between groups from baseline to 12 weeks
14. Change in maximum phonation time. These data will be analysed according to differences within and between groups from baseline to 12 weeks.

Overall study start date

01/06/2021

Completion date

31/03/2024

Eligibility

Key inclusion criteria

1. Aged 18 years or older
2. Received a full course of SARS-CoV-2 vaccine
3. Received an annual flu vaccine
4. Received a pneumonia vaccination
5. Clinician diagnosis of COPD, Asthma, Bronchiectasis or ILD
6. Stable respiratory health in the preceding 4 weeks without exacerbating
7. Completion of PR defined as completing at least 8 sessions.
8. Attend a baseline assessment within a month of completing PR
9. Informed consent provided by participant.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 64; UK Sample Size: 64

Key exclusion criteria

1. Previous attendance at Singing for Lung Health group sessions or regularly participating in any other singing group activity.
2. Have a life-limiting co-morbidity
3. Unable to consent

Date of first enrolment

01/12/2021

Date of final enrolment

31/07/2023

Locations

Countries of recruitment

England

United Kingdom

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

Sponsor information

Organisation

Guy's and St Thomas' NHS Foundation Trust

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.guysandstthomas.nhs.uk/Home.aspx>

ROR

<https://ror.org/00j161312>

Funder(s)

Funder type

Government

Funder Name

NIHR Central Commissioning Facility (CCF)

Funder Name

National Institute for Health Research (NIHR) (UK)

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

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/05/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Dr Adam Lewis (adam.lewis@brunel.ac.uk). The data will be made available following the publication of the study for 10 years in a controlled-access fashion. Those requesting use of the data set will need to confirm it is for research purposes, as covered in the patient consent form. Therefore, we will require the researcher's confirmation of employment at a recognised academic institution and proposed hypotheses in the use of data. A data sharing agreement will need to be signed between parties before release of a fully anonymised copy of the dataset.

IPD sharing plan summary

Available on request