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Singing for adults with chronic obstructive pulmonary disease (COPD) (Protocol)

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[Intervention Protocol]

Singing for adults with chronic obstructive pulmonary disease (COPD)

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To determine the effect of singing on health-related quality of life and dyspnoea in people with COPD.

BACKGROUND

Description of the condition

Chronic obstructive pulmonary disease (COPD) is a progressive lung disease characterised by airflow limitation that is not fully reversible and is associated with an abnormal inflammatory response of the lungs to noxious particles or gases (GOLD 2013). The prevalence of COPD has been reported as ranging from 0.2% to 37%, and varies widely across countries and populations (Rycroft 2012). Prevalence and incidence is greatest in men and those aged 75 years and over (Rycroft 2012). COPD is a major cause of morbidity and is the third most common cause of death globally (Lozano 2012). Symptoms of COPD include dyspnoea, cough and fatigue. Reduced functional capacity and physical inactivity are common features (Troosters 2010; Singer 2011), which significantly increase the risk for hospitalisation and mortality (Garcia-Aymerich 2006). Pulmonary rehabilitation is an important component in the management of COPD and is beneficial in relieving dyspnoea and fatigue, and improving health-related quality of life and exercise capacity (McCarthy 2015).

Description of the intervention

Singing is the production of musical words or sounds with the voice (Oxford 2016). Singing can be performed individually or in a group (choir), and can be arranged or improvised. Singing is a much more complex physical activity than speaking due to the greater length of phrases and greater range of pitch required (Irons 2010). Singing is dependent on the use of the lungs for air supply. During normal tidal breathing, the diaphragm contracts for inhalation, while exhalation occurs passively. During singing, air flow must be regulated and large lung volumes are required, thus exhalation is active and aided by the abdominal, internal inter-

costal and pelvic muscles. Singing requires a high degree of muscle coordination by highly developed muscle reflexes. There are four stages of breathing with singing: inhalation, suspension, controlled exhalation (when phonation occurs) and recovery. A singer controls these stages consciously until they become conditioned reflexes (Mathis 2009).

Diaphragmatic breathing is the method employed by singers, as the diaphragm can generate the greatest inspiratory muscle force to increase lung volumes and change sub-glottal pressures necessary for singing (Sundberg 1993). The sub-glottal air pressure requirements are much greater for singing tasks than for speaking tasks (Leanderson 1987; Leanderson 1988), as higher sub-glottal pressures are required for loudness and higher pitch (Sundberg 1993). Audible speech can be produced with sub-glottal pressures as low as 2 cmH_2O with ordinary speech ranging from 7 cmH_2O to 10 cmH_2O; however, singing can vary from 5 cmH_2O to 40 cmH_2O for soft to loud tones (Proctor 1980). An increase in sub-glottal pressure is achieved by decreasing the volume of the rib cage using muscular forces, elasticity forces and gravity (Sundberg 1993).

Posture can greatly affect the quantity of air, the capacity of the lungs and the ability to move air in and out when singing. Good posture facilitates an efficient breathing pattern and can influence the voice (Bunch 1995; Staes 2011). Trained singers have greater breathing efficiency and greater use of their lung capacity than non-trained singers (Gould 1973; Salomoni 2016).

Mastery of diaphragmatic breathing is vital for singing. Data from Engen 2005 suggests a minimum of two half-hour sessions could be sufficient for people with emphysema to learn the diaphragmatic breathing technique correctly. Singing needs to be performed at a sufficient intensity and for a sufficient duration in order to ensure an effective stimulus for learning this technique and for potentially having an effect on important health outcomes. The precise 'dosage' will likely vary for each person (Irons 2010).

How the intervention might work

Singing is an activity that has the potential to improve health outcomes, such as relieving dyspnoea and enhancing quality of life, in people with COPD. Qualitative studies of singing and health report that singing can enhance mood, provide social support and friendship, help develop self esteem and self confidence, relieve stress, promote good posture and distract attention from personal worries (MacDonald 2012). Singing in people with COPD has the potential to demonstrate similar effects due to the enjoyable and low-risk nature of the activity (Engen 2005), and may have a positive impact on the distressing effects of COPD such as breathlessness, reduced quality of life and fatigue. The perceptions of people with COPD following a group singing programme support this (Morrison 2013; Skingley 2014).

Therapies that incorporate breathing manoeuvres, such as controlled breathing techniques including active expiration (as performed during singing), have been shown to improve lung function (Esteve 1996), alleviate dyspnoea and improve quality of life (Gosselink 2003; Gosselink 2004), and improve functional exercise capacity (Holland 2012) in people with COPD. Singing requires great control to ensure a smooth and sustained exhalation. This exhalation is similar to that of pursed lip breathing and controlled breathing that have been shown to reduce breathlessness in people with COPD (Gosselink 2003; Bianchi 2004).

Education on breathing and air support is fundamental in learning to sing, and knowledge of the physical processes that make up the act of singing and how those processes function (Mathis 2009) may improve breathing awareness and efficiency in people with COPD.

Poor posture (hyperkyphosis), which is common in people with COPD, can restrict the expansion of the rib cage and movement of the diaphragm. Singing requires the development of skills in controlling posture that may be transferable to activities in daily life in people with COPD (Lord 2010).

Why it is important to do this review

Singing may have the potential to improve health outcomes in people with COPD. Systematic reviews of research literature have been completed for singing in other chronic respiratory diseases such as bronchiectasis (Irons 2010), and cystic fibrosis (Irons 2014), and found an absence of randomised controlled trials (RCTs) to support or refute the benefits of singing. However, the authors of these reviews found studies that reported an improvement in quality of life in people with COPD, and a systematic review of singing for COPD has not yet been carried out.

OBJECTIVES

To determine the effect of singing on health-related quality of life and dyspnoea in people with COPD.

METHODS

Criteria for considering studies for this review

Types of studies

We will include RCTs reported as full-text, published as abstract only and unpublished data. We will use data from studies published as abstract only where authors can provide study data. Where the data are not available, we will record the studies as awaiting classification.

Types of participants

We will include studies that involve adults with COPD, diagnosed according to the investigators' definition, of any age or disease severity. The COPD should be stable (i.e. optimal and stable respiratory medications with no exacerbation or hospitalisation within the previous month). We will allow participants using supplemental oxygen. We will include participants with and without a history of singing training, and record the singing training history wherever possible.

Types of interventions

We will include studies examining structured supervised singing training of at least four weeks' duration with a minimum of four sessions. Studies will be included that compare:

1. singing versus no intervention (usual care) or a control group;
2. singing plus pulmonary rehabilitation versus pulmonary rehabilitation alone.

The singing may be performed individually or as part of a group (choir) facilitated by a singing teacher or instructor, and will include inpatient and outpatient programmes. We will record the precise nature of the singing facilitators' professional backgrounds, singing training and any pulmonary rehabilitation programme (frequency, duration, type, intensity) wherever possible.

Types of outcome measures

Primary outcomes

1. Health-related quality of life measured using total scores from either generic or respiratory-specific quality-of-life questionnaires.
2. Dyspnoea measured using a dyspnoea scale (e.g. Medical Research Council (MRC) dyspnoea scale) or dyspnoea scores from a respiratory-specific quality-of-life questionnaire (e.g. dyspnoea from the Chronic Respiratory Disease Questionnaire), or both.

Secondary outcomes

1. Respiratory muscle strength measured from a pressure gauge (e.g. maximal inspiratory and expiratory mouth pressures or maximal sniff nasal inspiratory pressure).
2. Pulmonary function measured by spirometry or plethysmography (e.g. forced expiratory volume in one second (FEV_1) measured in litres or as per cent of predicted, forced vital capacity (FVC), FEV_1/FVC, total lung capacity (TLC), residual capacity (RC), functional residual capacity (FRC)).
3. Psychological status measured from generic psychological questionnaires or scales (e.g. Hospital Anxiety and Depression Scale).
4. Functional exercise capacity measured from a functional exercise test.
5. Peak exercise capacity measured from a peak exercise test.
6. Endurance exercise capacity measured from an endurance exercise test.
7. Healthcare utilisation recorded as hospitalisation or length of hospital stay, or both.
8. Physical activity level from objective measurement tools (e.g. pedometers, accelerometers, multi-sensor devices).
9. Adverse events/side effects.

Reporting one or more of the outcomes listed here in the study will not be an inclusion criterion for the review. Primary and secondary outcomes will be reviewed at baseline and immediately following the intervention period. If outcomes are also measured in the long-term (e.g. six or 12 months after completion of intervention), this will also be reviewed at each time point in addition to immediately following the intervention period. The selected primary outcome measures are important to patients and clinicians, and all outcome measures are clinically relevant and may potentially be altered by a singing intervention.

Search methods for identification of studies

Electronic searches

We will identify trials from the Cochrane Airways Group's Specialised Register (CAGR), which is maintained by the Information Specialist for the Group. The Register contains trial reports identified through systematic searches of bibliographic databases including the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, CINAHL, AMED and PsycINFO, and handsearching of respiratory journals and meeting abstracts (see Appendix 1 for further details). We will search all records in the CAGR using the search strategy in Appendix 2. We will also conduct a search of ClinicalTrials.gov (www.ClinicalTrials.gov) and the World Health Organization (WHO) trials portal (www.who.int/ictrp/en/) and PEDro (www.pedro.org.au/). We will search all databases from their inception to the present, and we will impose no restriction on language of publication.

Searching other resources

We will check reference lists of all primary studies and review articles for additional references. We will search for errata or retractions from included studies published in full-text on PubMed (www.ncbi.nlm.nih.gov/pubmed) and report the date this was done within the review.

Data collection and analysis

Selection of studies

Two review authors (RJM, CE) will independently screen titles and abstracts for inclusion of all the potential studies we identify as a result of the search and code them as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. We will retrieve the full text study reports/publication and two review authors (RJM, CE) will independently screen the full text and identify studies for inclusion, and identify and record reasons for exclusion of the ineligible studies. We will resolve any disagreement through discussion or, if required, we will consult a third review author (ZJM). We will identify and exclude duplicates and collate multiple reports of the same study so that each study rather than each report is the unit of interest in the review. We will record the selection process in sufficient detail to complete a PRISMA flow diagram and 'Characteristics of excluded studies' table (Moher 2009).

Data extraction and management

We will use a data collection form for study characteristics and outcome data that has been piloted on at least one study in the review. One review author (RJM) will extract study characteristics from included studies. We will extract the following study characteristics:

1. methods: study design, total duration of study, details of any 'run-in' period, number of study centres and location, study setting, withdrawals and date of study;
2. participants: number, mean age, age range, gender, severity of condition, diagnostic criteria, baseline lung function, smoking history, inclusion criteria and exclusion criteria;
3. interventions: intervention, comparison, concomitant medications and excluded medications;
4. outcomes: primary and secondary outcomes specified and collected, and time points reported;
5. notes: funding for trial and notable conflicts of interest of trial authors.

Two review authors (RJM, CE) will independently extract outcome data from included studies. We will note in the 'Characteristics of included studies' table if outcome data were not reported in a usable way. We will resolve disagreements by consensus or by involving a third review author (ZJM). One review author (RJM) will transfer data into Review Manager 5 (RevMan 2014). We will double-check that data are entered correctly by comparing the data presented in the systematic review with the study reports. A second review author (EC) will spot-check study characteristics for accuracy against the trial report.

Assessment of risk of bias in included studies

Two review authors (RJM, CE) will independently assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will resolve any disagreements by discussion or by involving another review author (ZJM). We will assess the risk of bias according to the following domains:

1. random sequence generation;
2. allocation concealment;
3. blinding of participants and personnel;
4. blinding of outcome assessment;
5. incomplete outcome data;
6. selective outcome reporting;
7. other bias.

We will grade each potential source of bias as high, low or unclear and provide a quote from the study report together with a justification for our judgement in the 'Risk of bias' table. We will summarise the 'Risk of bias' judgements across different studies for each of the domains listed. We will consider blinding separately for different key outcomes where necessary (e.g. for unblinded outcome assessment). Where information on risk of bias relates to unpublished data or correspondence with a trialist, we will note this in the 'Risk of bias' table.

When considering treatment effects, we will take into account the risk of bias for the studies that contribute to that outcome.

Assessment of bias in conducting the systematic review

We will conduct the review according to this published protocol and report any deviations from it in the 'Differences between protocol and review' section of the systematic review.

Measures of treatment effect

We will analyse dichotomous data as odds ratios (OR) and continuous data as mean difference (MD) or standardised mean difference (SMD). We will enter data presented as a scale with a consistent direction of effect.

We will undertake meta-analyses only where this is meaningful, that is, if the treatments, participants and the underlying clinical question are similar enough for pooling to make sense.

We will describe skewed data reported as medians and interquartile ranges narratively.

Where multiple trial arms are reported in a single trial, we will include only the relevant arms. If two comparisons are combined in the same meta-analysis, we will halve the control group to avoid double-counting.

Unit of analysis issues

We will not include cross-over trials. If the search identifies cluster randomised trials, we will consult the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Dealing with missing data

We will contact investigators or study sponsors in order to verify key study characteristics and obtain missing numerical outcome data where possible (e.g. when a study is identified as abstract only). Where this is not possible, and the missing data are thought to introduce serious bias, we will explore the impact of including such studies in the overall assessment of results by conducting a sensitivity analysis**.**

Assessment of heterogeneity

We will use the I^2 statistic to measure heterogeneity among the studies in each analysis. If we identify substantial heterogeneity, we will report it and explore possible causes by prespecified subgroup analysis.

Assessment of reporting biases

If we are able to pool more than 10 studies, we will create and examine a funnel plot to explore possible small-study and publication biases.

Data synthesis

We will use a random-effects model and perform a sensitivity analysis with a fixed-effect model using Review Manager 5 (RevMan 2014). If the outcomes are reported using adjusted analyses (such as ANOVA or ANCOVA), we will use the generic inverse variance method to combine the results with other studies; if adjusted analyses are not available, we will prefer change from baseline results to final scores.

'Summary of findings' table

We will create a 'Summary of findings' table using the following outcomes: health-related quality of life, dyspnoea, respiratory muscle strength and adverse events. We will use the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of a body of evidence as it relates to the studies that contribute data to the meta-analyses for the prespecified outcomes. We will use methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) using GRADEpro software (GRADEpro GDT). We will justify all decisions to down- or upgrade the quality of studies using footnotes and we will make comments to aid the reader's understanding of the review where necessary.

Subgroup analysis and investigation of heterogeneity

We plan to carry out the following subgroup analyses if sufficient studies are retrieved:

1. severity of lung disease - severe (FEV_1 % predicted less than 40%) versus not severe (FEV_1 % predicted 40% predicted or greater).
2. mode of singing intervention - individual versus group (choir);
3. participant's experience with singing training - no previous history with singing training versus prior history of singing training;
4. singing facilitator's professional background - formally trained music or singing professional versus health or lay professional.

We will use the following outcomes in subgroup analyses:

1. health-related quality of life;
2. dyspnoea.

We will use the formal test for subgroup interactions in Review Manager 5 (RevMan 2014).

Sensitivity analysis

We plan to carry out the following sensitivity analysis:

1. Studies with a low risk of bias (to examine the effects of removing studies with a high risk of bias).

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Sources and search methods for the Cochrane Airways Group Specialised Register (CAGR)

Electronic searches: core databases

Database	Frequency of search
CENTRAL (*the Cochrane Library*)	Monthly
MEDLINE (Ovid)	Weekly

(*Continued*)

Embase (Ovid)	Weekly
PsycINFO (Ovid)	Monthly
CINAHL (EBSCO)	Monthly
AMED (EBSCO)	Monthly

Handsearches: core respiratory conference abstracts

Conference	Years searched
American Academy of Allergy, Asthma and Immunology (AAAAI)	2001 onwards
American Thoracic Society (ATS)	2001 onwards
Asia Pacific Society of Respirology (APSR)	2004 onwards
British Thoracic Society Winter Meeting (BTS)	2000 onwards
Chest Meeting	2003 onwards
European Respiratory Society (ERS)	1992, 1994, 2000 onwards
International Primary Care Respiratory Group Congress (IPCRG)	2002 onwards
Thoracic Society of Australia and New Zealand (TSANZ)	1999 onwards

MEDLINE search strategy used to identify trials for the CAGR

COPD search

1. Lung Diseases, Obstructive/
2. exp Pulmonary Disease, Chronic Obstructive/
3. emphysema$.mp.
4. (chronic$ adj3 bronchiti$).mp.
5. (obstruct$ adj3 (pulmonary or lung$ or airway$ or airflow$ or bronch$ or respirat$)).mp.
6. COPD.mp.
7. COAD.mp.
8. COBD.mp.
9. AECB.mp.
10. or/1-9

Filter to identify RCTs

1. exp "clinical trial [publication type]"/
2. (randomized or randomised).ab,ti.
3. placebo.ab,ti.
4. dt.fs.
5. randomly.ab,ti.
6. trial.ab,ti.
7. groups.ab,ti.
8. or/1-7
9. Animals/
10. Humans/
11. 9 not (9 and 10)
12. 8 not 11

We will adapt the MEDLINE strategy and RCT filter to identify trials in other electronic databases.

Appendix 2. Search strategy to identify relevant trials from the CAGR

#1 MeSH DESCRIPTOR Pulmonary Disease, Chronic Obstructive Explode All
#2 MeSH DESCRIPTOR Bronchitis, Chronic
#3 (obstruct*) near3 (pulmonary or lung* or airway* or airflow* or bronch* or respirat*)
#4 COPD:MISC1
#5 (COPD OR COAD OR COBD OR AECOPD):TI,AB,KW
#6 #1 OR #2 OR #3 OR #4 OR #5
#7 (sing or singing or singer* or song*):ti,ab,kw
#8 (voice* or vocal*) NEAR (exercis* or train*)
#9 diaphragm* NEAR2 breath*
#10 MeSH DESCRIPTOR Music Therapy
#11 choir*:ti,ab,kw
#12 #7 or #8 or #9 or #10 or #11
#13 #6 AND #12

[in search line #4, MISC1 denotes the field in the record where the reference has been coded for condition, in this case, COPD]

CONTRIBUTIONS OF AUTHORS

Initiation of protocol: RJM.

Protocol development: RJM, CE, EC, ZJM.

DECLARATIONS OF INTEREST

RJM, CE, EC, ZJM: none known.

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