

# Singing and COPD: a pilot randomized controlled trial of wellbeing and respiratory outcomes

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Paper 1 of 3

Article Info.	Summary
<p><u>Date Submitted:</u> March 2021</p> <p><u>Date Accepted:</u> February 2022</p> <p><u>Date Published:</u> May 2022</p>	<p><b>Aims/objectives</b></p> <p>To test whether a ten-week regular weekly group singing programme, with guided home practice, leads to improvement in COPD-specific health status, as assessed by the COPD Assessment Test (CAT, primary outcome).</p> <p>To test whether the programme results in changes to health-related quality of life, mental health, breathlessness, lung function, functional exercise performance and breathing patterns (secondary outcomes).</p> <p><b>Rationale</b></p> <p>A number of randomized controlled trials (RCTs) exist which suggest that there are potential benefits to health and wellbeing of regular singing for people with COPD (Chronic Obstructive Pulmonary Disease). However, most rely on small samples, and findings across the different outcome measures are inconsistent, while interview studies tend to report consistent positive physical and psychological outcomes. Further research is therefore needed.</p> <p><b>Approach</b></p> <p>A single-blind, randomized controlled trial compared a structured, weekly group singing programme plus home practice between sessions over ten weeks, with a usual COPD treatment control. The sample was drawn from a local NHS population of people with COPD. Following baseline assessments, participants were allocated to a 10-week singing programme or a control.</p> <p><b>Findings</b></p> <p>Twenty-four individuals completed to follow-up. Measures at 12 weeks showed no significant differences between singing and control groups except for one item on the health status questionnaire (SF-36) which suggested the singers were less limited in their activities of daily living post-singing. Final follow-up, planned for 6 months post intervention, was aborted due to the COVID-19 pandemic.</p> <p><b>Discussion and conclusion</b></p> <p>The study failed to recruit to target. There remains a recruitment problem in RCTs of singing for COPD, resulting in inconclusive findings, which conflict with the positive qualitative evidence. A wide variety of research methods, as well as RCTs, are suggested to enable a better understanding of the impact of singing on COPD.</p>

Key words: Singing; Chronic Obstructive Pulmonary Disease (COPD); Randomized Controlled Trial; COPD Assessment Test; Structured Light Plethysmography

## 1. Introduction

Chronic obstructive pulmonary disease (COPD) is the name given to describe a number of lung conditions, including emphysema and chronic bronchitis (British Lung Foundation [BLF online]) where airways become narrower, making breathing difficult. Some 115, 000 people are diagnosed with the disease each year in the UK. COPD is not curable, however progress may be delayed and symptoms reduced through targeting known causes (such as smoking or work environment), by pharmacological management using a stepped approach to inhaled therapies (bronchodilators, steroids and combination therapies), based on the severity of the disease, and through pulmonary rehabilitation with an emphasis on maintaining physical activity (NICE, 2018).

There is an ongoing need for research to find ways of managing symptoms of COPD. Recently there has been serious interest in the UK spearheaded by the British Lung Foundation, in the value of singing in promoting wellbeing, including its ability to improve breathing (Lewis, Cave and Hopkinson, 2018). This is despite the fact that singing and COPD is an under-researched, though growing field, and has mixed findings (McNamara, Epsley, Coren and McKeogh, 2018). Lack of research on the specific value of singing for people with breathing difficulties reflects the fact that scientific interest in the value of singing for health has only developed from 2000 onwards.

Five recent reviews have been conducted of randomized controlled trials (RCTs) of singing for people with chronic respiratory diseases, including but not limited to COPD (McNamara, et al., 2018; Gick and Nicol, 2015; Lewis, Cave, Stern, Walsh, et al., 2016; Daykin, Julier, Tomlinson, Meads, et al., 2016; Ubolnuar, Tantisuwat, Thaveeratithan, Lertmaharit, et al., 2019). All these reviews commented on the limited or conflicting evidence for the impact of singing on respiratory function. Where evidence does exist, the quality is low due to small sample numbers and other features, such as attrition rates and limitations in reporting. Overall, reviews reported that singing has the potential to improve physical health status and wellbeing, that qualitative findings have been consistently positive but that there is a need for further research in the area, in particular for RCTs, as these are often considered the 'gold standard' for testing clinical interventions (Bondemark and Ruf, 2015).

A number of research studies relate singing specifically to COPD, including six previous controlled trials, five of which were randomized (Bonila, Onofre, Vieiri, Prado, et al., 2008; Lord, Cave, Hume, Flude, et al., 2010; Lord, Hume, Kelly, Cave, et al., 2012; Goodridge, Nicol, Horvey and Butcher, 2013; Liu, Song, Zhong-Hio, Shi, et al., 2019; Philip, Lewis, Jeffery, Buttery, et al., 2020). All interventions were of one hour either weekly or twice weekly and duration ranged from six weeks to 24 weeks. Participant numbers were generally limited to 13-15 in the intervention groups and equal or fewer numbers in controls. A variety of measures were used in these studies, making comparisons difficult, however, two of the studies (Lord, et al., 2010; Lord, et al., 2012) reported a significant increase in 'physical wellbeing' assessed by patients' self-report on the SF-36 questionnaire. The SF-36 is one of the most widely used self-report measures of health used in research studies world-wide, and measures eight aspects of physical and mental health on a scale of 0-100 with higher scores indicating better health. A significant improvement in the SF-36 'change of health' measure is also reported by Philip, et al. (2020), but no change was found on the COPD specific COPD Assessment Test (CAT).

A recent RCT on the potential value of group singing for older people average age 76 years (without respiratory illness), found that both intervention and usual activity control groups showed significant declines in three measures of respiratory function over 34 weeks of the trial (Galhina, Pinal, Lima, Luisa Lima et al. (2021). There was no evidence, in other words, that regular singing improved breathing and measures of lung function in the participants.

Seven studies without controls exist (Morrison, Clift, Page, Salisbury, et al., 2013; McNaughton, Weatherall, Williams, McNaughton, et al., 2017; Lewis, Cave and Hopkinson, 2018; Clift, Skingley, Page, Stephens, et al., 2017; Engen, 2005; Epsley, 2018; Cahalan, Green, Meade and Griffin, 2021).

These are predominantly single cohort studies with pulmonary function and other measures taken at baseline, endpoint and often midpoint. Only one study (Morrison, et al., 2013), which had both long-term follow-up and a large cohort, showed significant improvement in pulmonary function. This study also reported a statistically significant improvement on health-related quality of life assessed by the St George's Respiratory Questionnaire but the improvement of 3.3 points was less than the estimated minimum clinically important difference (MCID) for this scale of 4.0 points for this instrument (Jones, 2005). A reduction in anxiety was demonstrated in two studies (McNaughton, et al., 2017; Lewis, 2018). Some improvement in COPD symptoms and wellbeing was noted in a feasibility study conducted as a basis for the current trial, with an improvement of -5.0 in CAT scores (Epsley, 2018), in excess of the estimated MCID of 2.0 points (CAT, 2016). Cahalan et al. (2021) however, found no improvements on the CAT measure, but did find improvements on the Six Minute Walk Test. This result is confounded, however, by participants also attending COPD support groups that encourage physical exercise.

A number of studies included embedded qualitative evaluations through either inviting written comments on questionnaires or (more commonly) through conducting interviews (Lord, et al., 2010; Lord, et al., 2012; Skingley, Page, Clift, Morrison, et al., 2014; McNaughton, Aldington, Williams and Levack, 2016; Skingley, Clift, Hurley, Price, et al., 2018; Cahalan, et al., 2021). Numbers interviewed varied between 5 and 37, however responses were almost universally favourable and common themes (enjoyment, friendship and improved management of breathing) appeared across studies. A recent Danish study gathered qualitative feedback from leaders of singing for lung health choirs and identified observed psychological, social, physical and musical benefits for participants with respiratory illness (Kaasgaard, Andersen, Rasmussen, Hilgard, et al., 2020). An observational, feasibility study of singing and chronic lung disease in Uganda (Downes, Philip, Lewis, Katagira et al., 2019), also found that participants 'greatly enjoyed' the singing sessions.

Existing evidence suggests that there is a need for further research, particularly for randomized controlled trials with adequate sample sizes and using measures consistent with previous studies to allow for comparison. Randomized controlled trials are of particular importance in studies involving older people with long-term health conditions, as physical function generally declines over time. If singing helps to maintain function, this would only be apparent by means of a control group receiving usual treatment. Our aim was to test whether a ten-week regular weekly singing programme, with guided home practice, leads to improvement in COPD-specific health status, as assessed by the COPD Assessment Test (CAT), when compared to usual treatment. Additional measures of self-assessed breathing difficulties, and physical and mental health were taken to assess whether more general improvements in health-related quality of life took place. Participants also undertook standard spirometry and exercise assessments. In addition, we explored the use of Structured Light Plethysmography to assess breathing patterns through the measurement of chest wall movement.

## **2. Methods**

### **2.1. Design**

A single-blinded randomized controlled trial (with researchers blind), was designed in consultation with a steering group including people with COPD and health service stakeholders. The trial compared a structured singing programme once a week and home practice for at least an hour between sessions over ten weeks, with a usual COPD treatment control. At the protocol stage we aimed to recruit 120 participants and run the trial for approximately six months, with follow up immediately after the programme, and then after a further three months. Sample size was judged on the basis of previous research, and a feasibility study which involved recruitment via pulmonary rehabilitation and the CAT as an outcome measure (Epsley, 2018). A three-month programme of weekly singing improved CAT scores by 5.0 points. Based on this outcome, a sample size of 80 (40 in each arm of the trial) would give 90% power with a p-value of 5% (two-tailed) with CAT as the primary outcome measure (for a short film based on the feasibility study, reporting its results, and featuring testimonies from participants, see:

<https://vimeo.com/245825761>). The fact that the feasibility study demonstrated measurable benefits from a three-month programme of weekly singing, provided the justification for the length of the singing intervention in this trial. A further consideration for the length of the intervention is that the ten-week programme started in late summer, following baseline assessments and randomization, and was timed to allow for follow-up assessments before Christmas.

Recruitment and retention proved to be challenging (see below). In addition, the trial had to be abandoned at the start of the second follow-up in March 2020 due to the coronavirus pandemic and risks to participants.

## 2.2. Setting and participants

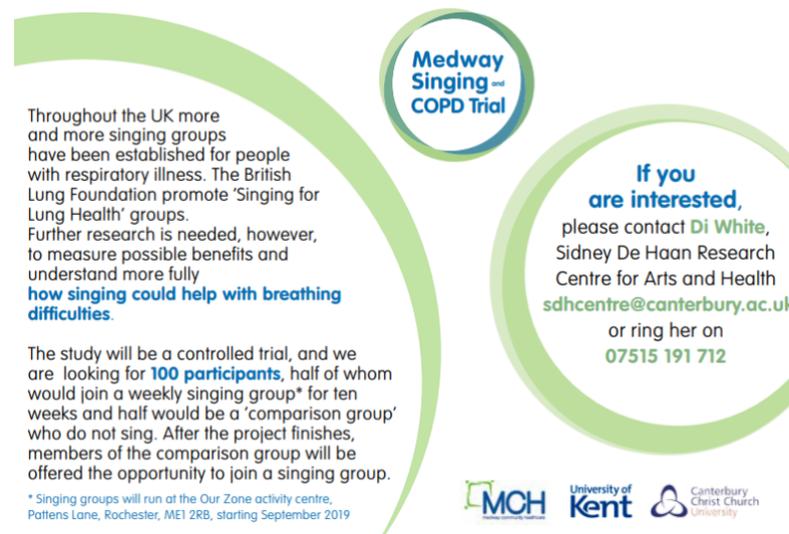
Participants came from the population of people with COPD supported by the respiratory service of Medway Community Healthcare organisation in Southeast England. Over six months, prior to the start of the trial, contact was made with groups during pulmonary rehabilitation classes run by the healthcare organisation to raise awareness of the trial. A letter and simple colourful flyer (Image 1) was sent to all individuals registered with the Respiratory Service to invite participation. The trial was also advertised via community events, through advertisements in a local newspaper and through social media.

## 2.3. Inclusion and exclusion criteria

The trial was open to participants with a diagnosis of COPD who were willing: to be assessed; randomized, and able to attend one of the two groups planned. Excluded from the trial were patients who: could not give informed consent; had comorbid conditions that precluded participation; were unable to travel to the trial sites; lacked sufficient English to complete questionnaires and were currently involved in a singing for health group.

**Image 1:** Trial recruitment flyer





Throughout the UK more and more singing groups have been established for people with respiratory illness. The British Lung Foundation promote 'Singing for Lung Health' groups. Further research is needed, however, to measure possible benefits and understand more fully **how singing could help with breathing difficulties.**

The study will be a controlled trial, and we are looking for **100 participants**, half of whom would join a weekly singing group\* for ten weeks and half would be a 'comparison group' who do not sing. After the project finishes, members of the comparison group will be offered the opportunity to join a singing group.

\* Singing groups will run at the Our Zone activity centre, Pattens Lane, Rochester, ME1 2RB, starting September 2019

**Medway Singing COPD Trial**

**If you are interested,** please contact **Di White**, Sidney De Haan Research Centre for Arts and Health [sdhcentre@canterbury.ac.uk](mailto:sdhcentre@canterbury.ac.uk) or ring her on **07515 191 712**

MCH University of Kent Canterbury Christ Church University

#### 2.4. Intervention and control

Following baseline assessments, participants were allocated to singing or control using an independent randomization service (<https://www.sealedenvelope.com/>). The control was treatment as usual (TAU i.e., medication, access to services provided by the secondary care team as required), and the intervention was TAU plus group singing once a week for ten weeks with home practice between sessions. There were two intervention groups in the same venue, meeting on different days. Groups were conducted by two skilled facilitators with prior experience of working with people with respiratory disease. A progressive programme of ten sessions involved increasingly challenging singing exercises and repertoire. Each session ran for 90 mins with breathing exercises and singing occurring for one hour. Singing participants were asked to practise the taught techniques and songs at home supported by a guide and video resource developed for people with COPD (for details see Price and Skingley, 2022).

#### 2.5. Outcomes and measures

The primary outcome measure was the COPD Assessment Test (CAT), which assesses impact on quality of life and management of breathing difficulties (Jones, Harding, Berry, Wiklund, et al., 2009; Kon, Canavan, Jones, Nolan, et al., 2014; CAT, 2016).

Secondary outcomes measures were:

The mMRC breathlessness scale (Williams, 2017; Fletcher, Elmes, Fairburn and Wood, 1959). The SF-36 v2, Physical health related quality of life and Mental health related quality of life (Jenkinson, Stewart-Brown, Perterson and Paice, 1999). The GAD-7 measure of Generalised Anxiety Disorder (Spitzer, Kroenke, Williams and Löwe, 2006). The PHQ-9 Patient Health Questionnaire, which provides a measure of depression (Kroenke, Spitzer and Williams, 2001).

In addition, the study involved the assessment of lung function and breathing patterns (as assessed by spirometry and Structured Light Plethysmography) and functional exercise performance (as measured by the Six Minute Walk Test)

#### 2.6. Ethics

Ethical approval was provided by a UK NHS Research Ethics Committee (REC Ref. 19/LO/0159). Participants were provided with an information sheet outlining details of the trial and

provided written informed consent. Electronic data were stored in password protected computers by the two universities involved and paper questionnaires were kept in a locked filing cabinet.

## 2.7. Procedure

Following ethical approval for the trial, in Spring 2019 all individuals with COPD registered with the Medway Community Healthcare organisation were invited by letter including full details of the trial, to attend a respiratory laboratory at the University of Kent for assessments at baseline and then at the end of the singing programme. Completion of the physical assessments and questionnaires took approximately an hour. Before the baseline assessment session an initial screening check was undertaken to ensure that it was safe to undertake the physical assessments. At follow-up assessments, participants were greeted on arrival by an administrator and reminded that the researchers did not know their group allocation and asked not to give any indication of whether they had participated in singing or were part of the control. An initial screening assessment was again made to ensure safety. We had planned for further (6 month) follow-up measures, however these had to be abandoned due to the onset of the Covid-19 pandemic.

## 2.8. Testing day overview

On arrival participants completed a brief health screening questionnaire and also had a resting heart rate and oxygen saturation measurement using finger pulse oximetry, along with resting blood pressure to ensure good health to undertake the exercise test. Height and weight were also measured. On successful completion of this, participants then completed a maximal lung function assessment, carbon monoxide check, and breathing pattern assessment via Structured Light Plethysmography (SLP) (Iles, Motamedi-Fakhr, Khalid and Wilson, 2015). Participants then completed a 6-minute walk test following published ERS / ATS guidelines (ATS, 2002 ; Holland, Spruit, Trosters, Puhan, et al., 2014), and then a second assessment with SLP.

## 2.9. Questionnaire

The following demographic details were collected for all participants: gender, age, ethnicity, marital status, employment, smoking status, COPD diagnosis, details of pulmonary rehabilitation attendance, co-morbid conditions, medication and health service use and experience of pulmonary exacerbations (over the previous three months).

Participants were also asked to complete the following questionnaires: the COPD Assessment Test (CAT) (the primary outcome measure), the mMRC breathless scale, the GAD-7, the PHQ-9 and the SF-36v2 (eight sub-scales).

## 2.10. Lung Function

Baseline maximal lung function was recorded using a spirometer and following European Respiratory Society and American Thoracic Society guidelines (Graham, Steenbruggen, Miller, Barjaktarevic, et al 2019). Maximal flow-volume measurements were recorded via a digital spirometer (MicroMedical Spiro USB Spirometer, Micro Medical, UK). Participants completed three maximal flow-volume manoeuvres with the best Forced Expiratory Volume in One Second (FEV1) and Forced Vital Capacity (FVC) recorded in accordance to ATS/ERS criteria (Graham et al 2019). Predicted lung function values were also recorded using the equations of Kuster, Kuster, Schlindler, Rochat, et al. (2008).

## 2.11. Six Minute Walk Test (6MWT)

The Six Minute Walk Test was administered according to published guidelines (ATS, 2002 ; Holland, et al, 2014). It was conducted indoors to reduce the impact of weather and environmental conditions in a corridor with a level, non-slip surface. A shuttle walking course 10-metres in length was

measured out and marked with cones and masking tape. Distances walked (6MWD) were measured to the nearest completed metre, with Borg breathlessness scores (0-10) (ATS, 2002), oxygen saturation and heart rate recorded at test termination using finger pulse oximetry. Participants were escorted back to the SLP machine as soon as they were able to and then recovery was monitored via pulse oximetry during the second SLP measurements. A number of parameters were measured to reflect participant performance in this test, including number and length of any rest periods.

## 2.12. Structured Light Plethysmography (SLP)

Participants were assessed using Structured Light Plethysmography (SLP) in a standardised way before and immediately after the 6MWT (Hmeidi, Motamedi-Fakhr, Chawick, Gilchrist, et al., 2017). The participants were asked to wear a figure hugging white top and sit in front of the SLP device (Pneumacare Ltd. Cambridge UK). A chess board of light was projected onto the participant's chest and abdomen. The participant was then instructed to sit still for 5 minutes. The measures in Table 1 were recorded and analysed as they were considered to be of potential interest to reflect patterns of breathing that may be affected by singing training (for a short video demonstration of Structured Light Plethysmography see: <https://www.youtube.com/watch?v=P1KJYPWm2Hs&t=5s>).

**Table 1.** Measurements derived from Structured Light Plethysmography assessment

Parameter	Description
*mTi	Median inspiratory time (Ti) in seconds
*vTi	Interquartile range (IQR) of inspiratory time (Ti) in seconds
*mTi/Te	Median inspiratory time to expiratory ratio (Ti/Te)
*vTi/Te	Interquartile range (IQR) of inspiratory time to expiratory ratio (Ti/Te)
*mTi/Ttot	Median duty cycle (Ti/Ttot)
*vTi/Ttot	Interquartile range (IQR) of duty cycle (Ti/Ttot)
*mBreathPhase_RC2AB	Median asynchrony between ribcage and abdomen (also known as thoraco-abdominal asynchrony [TAA]) in degrees
vBreathPhase_RC2AB	Interquartile range (IQR) of asynchrony between ribcage and abdomen (also known as thoraco-abdominal asynchrony) in degrees
*mIE50	Median inspiratory flow divided by expiratory flow at 50% tidal volume (displacement)
*vIE50	Interquartile range (IQR) of inspiratory flow divided by expiratory flow at 50% tidal volume (displacement)
*mTPTEF_TE	Median time to reach peak tidal expiratory flow divided by expiratory time (tPTEF/tE)
*vTPTEF_TE	Interquartile range (IQR) of time to reach peak tidal expiratory flow divided by expiratory time (tPTEF/tE)

## 2.13. Data analysis

The design of the trial is a 2 by 2 mixed ANOVA design with time as the within subjects factor at 2 levels (baseline and end of intervention) and condition as the between subjects factor with 2 levels (singing vs. control). The primary outcome variable for the trial was the COPD Assessment Test score. Additional secondary analyses considered a range of additional health measures, together with

spirometry, 6MWT and SLP parameters. Embedded within the trial was qualitative assessment of the participant experience and perceived benefits, together with an evaluation of the resources to support practice between singing sessions. Details are reported in companion papers (Lane, Cooke and Skingley, 2022 ; Price and Skingley, 2022).

Quantitative data were analysed using IBM SPSS version 24. Comparative analysis took place to examine composition of the intervention and control groups at baseline to assess equivalence. Comparisons were made between the intervention and control groups at the end of the intervention to determine whether the intervention had resulted in a significant change on the primary and secondary outcome measures. Examination of the interaction between group and time allowed for testing of the null hypothesis that singing results in no change in functional status, health related quality of life, mental wellbeing and patterns of breathing.

### 3. Results

#### 3.1. Sample

The trial commenced with baseline assessments in June 2019 and at this point, only 36 of the 84 who had expressed interest were available for assessment (see Figure 1 for details). Of these, 19 were randomized to the singing groups and 17 to the control. Letters were sent to participants in August 2019 confirming their allocation within the trial. One person in the singing arm withdrew before the start of their group. During the course of the trial, three participants in each arm withdrew on account of illness or personal circumstances, leaving 15 in the singing groups and 14 in the control. When followed up for post-testing, a further 2 from the singing groups and 3 from the control were unable to attend due to illness, leaving a total sample for analysis of 24 with no differences between groups by sex, age, ethnicity or experience of pulmonary rehabilitation (Table 2). Groups were also equivalent at baseline on all outcome measures (Tables 3-10). A CONSORT diagram is reported in Figure 1.

**Table 2.** Participant characteristics at baseline (frequencies, means  $\pm$  standard deviations)

Variable	Singing group (n=13)	Control group (n=11)	Comparison
Sex (female)	5/13	5/11	Chi-squared n.s.
Single	2/13	2/11	No difference
Non-white British	0/13	1/11	No difference
Current smoker	2/13	1/11	No difference
Co-morbid conditions	7/13	7/11	Chi-squared n.s.
Undertaken pulmonary rehabilitation	6/13	6/11	Chi-squared n.s.
Age (years)	69 $\pm$ 6.50	70 $\pm$ 8.20	t-test n.s.

#### 3.2. Outcomes following the singing programme

##### Self-reported psychological and health assessments

Table 3 reports the scores obtained for the participants on all health-status and psychological variables assessed at baseline and following the end of the ten-week singing programme. For all measures, no significant differences were apparent at baseline. Repeat measures ANOVA interaction outcomes are reported to assess whether any differences emerged between the two groups at follow up.

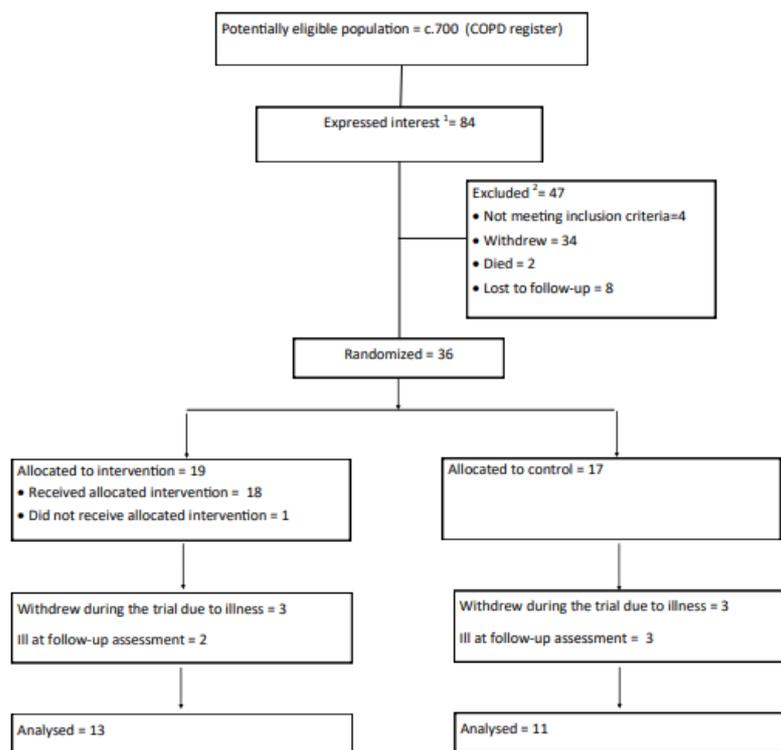
The primary outcome measure, the COPD Assessment Test (CAT) has a score range 0-48, with higher scores indicating greater impact from COPD. It also has an estimated minimum clinically important difference score (MCID) of two points (Kon, et al., 2014). The results show no difference between the singing and control groups on follow up. Far from showing a reduction in CAT scores, the singing group shows an increase on average of two points.

For the mMRC breathlessness scale similarly, no significant difference between the singing and control groups were seen on follow-up.

For the measure of depression (PHQ-9) scores of 5, 10, 15, and 20 represented mild, moderate, moderately severe, and severe depression, respectively. At baseline, both groups registered between 'mild' to 'moderate' depression, on average, but no changes were apparent for either group on follow-up. On the measure of generalised anxiety (GAD-7) scores of 5, 10, and 15 are taken as the cut-off points for mild, moderate and severe anxiety, respectively. At baseline the sample reported only 'mild' anxiety, with many giving a score of zero, and no significant changes occurred over the course of the trial.

For all of the SF-36 scales, scoring is 0-100, with higher scores indicating better health status. At baseline, the results for the physical health scales are at the mid-range on the scale, whereas scores on the mental health scales are higher. This indicates that this group of participants with COPD is relatively compromised with respect to physical function, but generally maintains positive mental health. At follow up, ANOVA with repeated measures revealed that there were no differences between the intervention and control groups on the SF-36 measures, with the exception of SF-36 'Role physical' subscale. This assesses the extent to which participants feel that their 'work and usual activities' are affected by physical difficulties. The singing group has higher scores at the end of the singing programme, indicating that they feel their activities are less limited, whereas scores for the control group have decreased. The observed difference is significant ( $p < 0.05$ , 2-tailed, Cohen's  $d = 0.6$  for the singing group).

**Figure 1.** CONSORT flow diagram for Singing and COPD trial



<sup>1</sup> Via: PR visits 47; MCH letter 24; Press advert 4; relative/friend 4; Our Zone 1; unknown/can't remember 4

<sup>2</sup> PR group: withdrew 24; excluded 1; died 1; lost to follow-up 8

MCH group: withdrew 6; excluded 1; died 1; lost to follow-up 0

Press group: excluded 1

Relative/friend group: excluded 1

Unknown group: withdrew 3

**Table 3.** Health status and psychological assessments at baseline and post intervention

Measure	Singing group (n=13)		Control group (n=11)		Group by time Interaction P values
	Baseline Mean ± SD	Post test Mean ± SD	Baseline Mean ± SD	Post test Mean ± SD	
CAT	18.85 ± 8.28	20.85 ± 9.33	21.82 ± 11.75	22.18 ± 10.22	P=0.59
MRC	2.38 ± 0.65	2.38 ± 0.65	2.18 ± 0.87	2.55 ± 1.04	P=0.17
PHQ9	7.00 ± 6.89	6.23 ± 6.85	7.18 ± 8.17	7.45 ± 7.79	P=0.62
GAD7	5.54 ± 6.11	4.69 ± 5.85	5.27 ± 7.28	5.36 ± 7.72	P=0.61
SF36 General health	45.77 ± 13.52	45.38 ± 17.26	43.18 ± 18.07	47.73 ± 22.62	P=0.40
SF36 Physical function	46.15 ± 21.33	41.54 ± 20.96	49.09 ± 23.86	48.64 ± 25.89	P=0.54
SF36 Mental health	64.62 ± 19.59	71.69 ± 22.36	69.45 ± 19.37	68.36 ± 27.68	P=0.39
SF36 Role physical	34.62 ± 41.51	59.62 ± 40.23	29.55 ± 35.03	27.27 ± 39.46	P= 0.05
SF36 Role emotional	61.54 ± 42.70	74.31 ± 36.49	63.64 ± 45.84	45.45 ± 42.93	P=0.12
SF36 Social function	45.19 ± 18.78	60.69 ± 26.33	54.55 ± 10.11	64.82 ± 31.07	P=0.67
SF36 Vitality	47.31 ± 16.28	52.69 ± 23.60	59.09 ± 18.68	54.09 ± 13.75	P=0.31
SF36 Pain	70.94 ± 25.47	66.69 ± 26.16	72.73 ± 27.38	66.55 ± 28.03	P=0.74

### 3.3. Physical assessments, lung function and 6MWT

Physical assessments, lung function, 6MWT data, heart rate recovery and oxygen saturation recovery of the participants from both groups pre and post singing intervention are presented in tables 4 with no differences on any measure apparent at baseline. The body mass and BMI ( $\text{kg.m}^2$ ) of the singing group increased slightly, whereas the control group's weight decreased by 5%, although the BMI ( $\text{kg.m}^2$ ) increased over the intervention period. Both groups had resting blood pressure values in the normal range (SBP < 140 mmHg; DBP < 90 mmHg), although the singing group had an increased SBP score post-intervention that was statistically significant ( $p = 0.02$ ). Resting oxygen saturation ( $\text{SaO}_2$ ) improved in the singing group by 2% and this was statistically significant ( $p=0.01$ ) with the control group levels remaining relatively stable. Neither the singing or control group had a significant change in lung function over the 3 month period. Both groups experienced an increase in distance walked in the 6-minute walk test (6MWT). The singing group improved by 1% whereas the control group experienced a 2.5% improvement. Neither was statistically significant.

The data from the breathing pattern assessments via SLP are presented in tables 5 and 6. There were no significant differences in breathing pattern parameters between groups at baseline or post singing intervention either before or after the 6MWT.

**Table 4.** Physical assessments, lung function, Six Minute Walk Test (6MWT), heart rate recovery from 6MWT, and oxygen saturation recovery for the singing and control groups pre and post intervention

	Singing Group		Control		Group / time interaction P Value
	Baseline (Mean ± SD)	Post test (Mean ± SD)	Baseline (Mean ± SD)	Post test (Mean ± SD)	
<b>Physical assessments</b>					
Body Mass (Kg)	86.5 ± 15.6	87.8 ± 16.4	77.8 ± 13.6	73.6 ± 13.4	0.73
BMI	31.3 ± 5.2	31.9 ± 6.0	26.8 ± 5.7	27.2 ± 5.8	0.52
Systolic BP (mmHg)	125.5 ± 14.2	138.6 ± 10.6	132.0 ± 17.5	131.8 ± 18.1	0.02
Diastolic BP (mmHg)	73.1 ± 12.1	77.1 ± 10.7	73.3 ± 13.3	75.5 ± 12.2	0.63
Resting HR (b.min <sup>-1</sup> )	75.5 ± 11.6	73.5 ± 11.1	78.9 ± 10.6	79.4 ± 8.4	0.41
Resting SaO <sub>2</sub>	94.7 ± 2.2	96.9 ± 2.0*	96.5 ± 1.8	96.1 ± 3.2	0.01
Resting breath CO (ppm)	5.1 ± 4.4	3.3 ± 4.1	3.0 ± 1.6	1.5 ± 0.6	0.74
<b>Lung function measures</b>					
FEV <sub>1</sub> (L)	1.55 ± 0.62	1.48 ± 0.55	1.72 ± 0.64	1.70 ± 0.65	0.31
Predicted FEV <sub>1</sub> (%)	64.6 ± 24.1	62.8 ± 22.9	71.3 ± 23.9	72.5 ± 22.5	0.48
FVC (L)	2.75 ± 0.70	2.56 ± 0.66	3.18 ± 0.83	3.12 ± 0.81	0.06
FEV <sub>1</sub> /FVC (%)	53.5 ± 13.5	53.7 ± 11.7	53.5 ± 13.4	54.3 ± 12.7	0.76
PEF (L.min <sup>-1</sup> )	293.1 ± 95.6	285.5 ± 90.4	274.3 ± 99.0	269.5 ± 123.9	0.86
<b>Six Minute Walk Test</b>					
6MWT (m)	398.8 ± 100.2	402.6 ± 99.7	409.1 ± 107.1	420.0 ± 112.8	0.61
BORG end of 6MWT	3.5 ± 1.0	3.4 ± 1.0	3.8 ± 1.5	3.8 ± 1.9	0.95
HR end of 6 MWT	109.3 ± 13.2	104.8 ± 16.6	105.5 ± 16.6	107.3 ± 13.2	0.15
SaO <sub>2</sub> end of 6MWT	91.9 ± 5.8	91.0 ± 6.1	93.0 ± 5.9	92.4 ± 7.8	0.87
<b>Heart rate recovery</b>					
HR recovery 1 min	85.1 ± 14.7	81.1 ± 15.8	83.4 ± 12.8	86.5 ± 10.2	0.15
HR recovery 2 min	81.7 ± 14.3	79.8 ± 15.3	82.7 ± 12.6	84.9 ± 10.1	0.39
HR recovery 3 min	81.0 ± 12.9	76.5 ± 14.0	80.5 ± 12.5	84.5 ± 9.6	0.06
HR recovery 4 min	79.3 ± 13.0	76.4 ± 14.3	80.4 ± 12.2	84.8 ± 10.5	0.14
HR recovery 5 min	80.2 ± 13.2	74.0 ± 14.6	79.6 ± 14.4	84.2 ± 10.1	0.09
<b>Oxygen saturation recovery</b>					
SaO <sub>2</sub> 1 min	95.7 ± 3.2	94.1 ± 4.4	95.8 ± 1.7	94.9 ± 3.2	0.43
SaO <sub>2</sub> 2 min	96.5 ± 2.2	95.8 ± 2.2	96.3 ± 2.1	95.5 ± 2.9	0.50
SaO <sub>2</sub> 3 min	96.3 ± 2.7	96.2 ± 1.5	96.3 ± 1.7	94.9 ± 2.0	0.09
SaO <sub>2</sub> 4 min	95.7 ± 2.5	95.8 ± 2.0	95.2 ± 2.4	95.0 ± 2.0	0.79
SaO <sub>2</sub> 5 min	95.8 ± 2.4	95.5 ± 2.0	94.6 ± 2.9	94.6 ± 2.0	0.77

**Table 5.** Comparison SLP measures between baseline and post intervention pre 6MWT between singing and control groups

Variable	Singing Group		Control Group		Group by time Interaction
	Baseline (Mean ± SD)	Post Singing (Mean ± SD)	Baseline (Mean ± SD)	Post Singing (Mean ± SD)	
RR	17.55 ± 5.68	18.05 ± 4.54	14.92 ± 4.52	14.46 ± 3.98	P = 0.30
Ti	1.46 ± 0.46	1.36 ± 0.22	1.60 ± 0.44	1.68 ± 0.57	P = 0.08
Te	2.26 ± 1.01	2.16 ± 0.78	2.71 ± 0.76	2.82 ± 0.98	P = 0.30
Ttot	3.73 ± 1.42	3.52 ± 0.98	4.32 ± 1.16	4.54 ± 1.58	P = 0.13
Ti/Te	0.66 ± 0.11	0.67 ± 0.13	0.60 ± 0.11	0.60 ± 0.08	P = 0.95
Ti/Ttot	0.40 ± 0.00	0.40 ± 0.01	0.37 ± 0.04	0.37 ± 0.03	P = 0.94
UL2TotCont(%)	28.17 ± 6.62	25.88 ± 6.27	28.04 ± 4.65	28.15 ± 3.85	P = 0.83
UR2TotCont(%)	26.58 ± 7.65	27.20 ± 6.32	29.95 ± 5.70	31.06 ± 4.20	P = 0.83
InspRC2TotCont(%)	52.61 ± 14.03	52.99 ± 12.45	57.88 ± 9.62	58.89 ± 7.39	P = 0.87
ExpRC2TotCont(%)	52.60 ± 14.03	53.05 ± 12.64	57.85 ± 9.76	59.00 ± 7.55	P = 0.86
AvgRC2TotCont(%)	52.65 ± 14.07	53.03 ± 12.70	57.95 ± 9.69	58.88 ± 7.48	P = 0.80
BreathPhase-UL2UR(deg)	3.96 ± 3.46	2.32 ± 1.88	1.90 ± 1.19	1.74 ± 1.25	P = 0.08
BreathPhase-RC2AB(deg)	7.43 ± 3.66	6.55 ± 4.16	6.52 ± 4.58	5.79 ± 3.18	P = 0.93
InspPhase-UL2UR(%)	0.12 ± 4.12	0.46 ± 2.56	0.52 ± 1.60	1.48 ± 2.09	P = 0.55
InspPhase-RC2AB(%)	-0.37 ± 5.3	-1.19 ± 2.12	0.97 ± 4.55	0.40 ± 3.75	P = 0.87
ExpPhase-UL2UR(%)	0.10 ± 1.14	0.35 ± 0.98	-0.10 ± 0.67	0.25 ± 0.82	P = 0.80
ExpPhase-RC2AB(%)	-0.38 ± 2.23	-0.62 ± 2.95	-0.00 ± 1.46	-0.18 ± 1.52	P = 0.92
IE50	1.34 ± 0.35	1.39 ± 0.19	1.57 ± 0.32	1.66 ± 0.28	P = 0.57
Tptef/Te	0.21 ± 0.06	0.24 ± 0.08	0.18 ± 0.07	0.20 ± 0.06	P = 0.87
Tptif/Ti	0.53 ± 0.10	0.55 ± 0.06	0.57 ± 0.09	0.51 ± 0.11	P = 0.80

#### 4. Discussion

##### 4.1. Self-reported health and psychological measures

This study suggests that a ten-week group singing intervention with COPD patients did not result in significant improvement for the singing group on the CAT measure relative to the control group. The observed change was in the direction of some deterioration, and by two points on the scale, which corresponds to the minimum clinically important change score. The lack of significant improvement for the singing group on the CAT measure is in line with the findings reported by Philip et al. (2020), and Cahalan et al. (2021), and the reduced values may well reflect the fact that COPD is a progressive degenerative condition.

Although the study lacked power, the change observed on the CAT measure is actually contrary to the change we expected to see based on an earlier feasibility study using CAT, where a reduction in five points on the scale was observed (Epsley, 2018). Similarly, no significant changes were seen for the mMRC scale when comparing the two groups, although a post-hoc examination of the change for the control group suggested that they showed some increase in breathlessness ( $p < 0.05$ ). A lack of power is a potential factor here, and with a larger sample size, the changes seen may have achieved statistical significance.

**Table 6.** Comparison SLP measures between baseline and post intervention post 6MWT between singing and control groups

Variable	Singing Group		Control Group		Group by time Interaction P value
	Baseline (Mean ± SD)	Post test (Mean ± SD)	Baseline (Mean ± SD)	Post test (Mean ± SD)	
RR	19.81 ± 6.80	19.16 ± 6.20	17.49 ± 6.12	16.31 ± 5.74	P = 0.66
Ti	1.26 ± 0.35	1.23 ± 0.24	1.41 ± 0.46	1.52 ± 0.59	P = 0.32
Te	2.02 ± 0.72	2.11 ± 0.76	2.43 ± 0.82	2.65 ± 1.10	P = 0.56
Ttot	3.33 ± 1.08	3.38 ± 0.97	3.86 ± 1.27	4.19 ± 1.70	P = 0.43
Ti/Te	0.66 ± 0.12	0.63 ± 0.13	0.60 ± 0.11	0.60 ± 0.11	P = 0.14
Ti/Ttot	0.40 ± 0.04	0.38 ± 0.05	0.37 ± 0.04	0.37 ± 0.04	P = 0.22
UL2TotCont(%)	26.74 ± 7.41	26.31 ± 6.51	30.47 ± 5.00	28.60 ± 4.55	P = 0.42
UR2TotCont(%)	27.66 ± 7.93	28.00 ± 6.51	31.19 ± 5.10	31.83 ± 5.80	P = 0.90
InspRC2TotCont(%)	54.07 ± 15.40	54.10 ± 12.99	61.45 ± 9.83	60.48 ± 9.89	P = 0.79
ExpRC2TotCont(%)	54.06 ± 15.36	54.36 ± 12.99	61.41 ± 9.90	60.37 ± 9.86	P = 0.73
AvgRC2TotCont(%)	54.08 ± 15.40	54.20 ± 13.05	61.41 ± 9.84	60.50 ± 9.92	P = 0.79
BreathPhase-UL2UR(deg)	3.64 ± 2.76	2.54 ± 1.87	1.82 ± 0.74	1.53 ± 0.87	P = 0.31
BreathPhase-RC2AB(deg)	8.98 ± 5.29	6.82 ± 3.25	6.67 ± 5.15	6.49 ± 3.73	P = 0.29
InspPhase-UL2UR(%)	0.32 ± 3.45	0.69 ± 1.33	-0.35 ± 2.07	1.59 ± 1.96	P = 0.97
InspPhase-RC2AB(%)	-2.69 ± 5.63	-3.19 ± 5.53	-0.01 ± 5.30	-0.59 ± 3.71	P = 0.97
ExpPhase-UL2UR(%)	0.04 ± 1.64	0.85 ± 1.14	0.01 ± 0.91	0.39 ± 0.61	P = 0.38
ExpPhase-RC2AB(%)	-0.95 ± 2.35	-0.95 ± 2.07	-0.36 ± 1.65	-0.42 ± 0.80	P = 0.92
IE50	1.41 ± 0.27	1.40 ± 0.23	1.61 ± 0.31	1.56 ± 0.28	P = 0.74
Tptef/Te	0.21 ± 0.07	0.20 ± 0.08	0.17 ± 0.05	0.19 ± 0.07	P = 0.42
Tptif/Ti	0.55 ± 0.09	0.54 ± 0.09	0.61 ± 0.11	0.56 ± 0.09	P = 0.33

No significant changes occurred with respect to the mental health measures GAD-7 and PHQ-9. While previous studies have found beneficial effects of singing for mental wellbeing (Lewis, et al., 2016; Daykin, et al., 2016; Liu, et al., 2019) in this study, the lack of change may be accounted for by the fact that the participants overall did not report substantial issues of anxiety or depression at the outset (a few participants did have high scores on both scales, but the majority had very low scores with some scoring zero). There is some indication that some small improvements occurred for the singing group on both measures on these scales, relative to the control group, so again with a larger sample, including people experiencing greater challenges with their mental wellbeing, such a change may emerge as significant.

For the SF-36 measures, the same picture of no differences at follow-up for the seven sub-scales emerges, with the exception of the 'Role physical' subscale. This is an important finding, however, which makes sense given the fact that the patients taking part in the singing programme made the effort to attend weekly, and gained new skills. Participants also had the opportunity to socialise with other people with COPD, and it is clear that positive relationships, friendships and social wellbeing was fostered (Lane et al, 2022). The activity of engaging in singing may have demonstrated to the participants that their chronic breathing condition did not prevent them from taking up a new activity, and this is reflected in the change

of scores on this specific measure. The change here is also in line with improvements in overall physical health on the SF-36 reported from three small previous trials on singing and COPD (Lewis, 2016; Lord, et al., 2010; Lord, et al., 2012; Lewis et al., 2020). There is also some evidence of improvement for the singing group on the 'Role emotional' scale, and here again, the failure to achieve statistical significance may be due to the lack of power in the study.

#### 4.2. Physiological Findings

The body mass (kg) and BMI (kg.m<sup>2</sup>) of the singing group increased slightly, whereas the control group's weight decreased by 5%, although the BMI (kg.m<sup>2</sup>) increased over the intervention period. It is well-reported in the health literature that weight tends to increase with age, but an increase in BMI has been associated with increased incidence of disease and increases in cardiovascular and respiratory workload, particularly during ambulation. The BMI scores of the singing group were higher and classified as obese (>30 kg.m<sup>2</sup>). The BMI classification of the control group was overweight (>25 kg.m<sup>2</sup>).

Both groups had resting blood pressure (systolic [S] and diastolic [D]) values in the normal range (SBP < 140 mmHg; DBP < 90 mmHg), although the singing group had an increased SBP score post-intervention that was statistically significant ( $p = 0.02$ ). This SBP increase is not thought to be associated with the intervention, as singing has been associated with decreased resting blood pressure (SBP and DBP) scores (Bernardi, Snow, Peretz, Orozco Peretz, et al., 2017).

Resting oxygen saturation (SaO<sub>2</sub>) improved in the singing group by 2% and this was statistically significant ( $p=0.01$ ) with the control group levels remaining relatively stable. This improvement in the intervention group may also be considered to have some clinical significance in COPD patients, particularly with symptom experience / severity. Improved oxygen carrying capacity of the blood has been associated with reduced breathlessness and improved quality of life in a COPD population (Quershi, Sharafkhaneh and Hanania, 2014).

Both groups experienced a reduction in carbon monoxide levels (resting breath CO [ppm]) with significance level  $p<0.01$ . This reduction may have been due to reduced smoking activity immediately prior to testing, smoking cessation / abstinence, or improved air quality in the environment, particularly the vicinity of where testing was conducted. It is unlikely to have been caused by the latter as testing was conducted indoors at the same time of day on both occasions (accommodating for changes in traffic flow in and around the testing site).

We also reported non-significant reductions in most of the standard spirometry measures employed for both the singing and control groups. Galinha et al. (2021) reported significant reductions, in lung function measures in participants aged 76-77 without respiratory disease, who participated over approximately eight months, in a trial of weekly group singing. The fact that no significant reductions occurred in our study is perhaps due to the short length of the trial.

Both groups experienced an increase in distance walked in the 6-minute walk test (6MWT [m]). The singing group improved by 1% whereas the control group experienced a 2.5% improvement. Neither was statistically significant. However, in the context of COPD, any improvement in functional capacity as measured through this endurance walking test, would be considered beneficial. Some of this improvement could be explained by a learning effect between the baseline test and post singing intervention assessments.

The minimum clinically significant distance improvement (54 - 80 m, for COPD patients, Wise and Brown, 2005; 14 to 30.5 m, across multiple patient groups, Bohannon and Crouch, 2017), was not achieved by either group. However, the perceived effort experienced by participants in this test as measured by the BORG scale decreased slightly for the singing group, i.e. they perceived slightly less

effort for walking a bit further. The control group on the other hand, whilst they walked 11m further, found this extra effort made them just as breathless. The breathlessness ratings for the control group were higher on both measurements compared to the singing group. Subjective experience of breathlessness is considered an important indicator of disease state. Breathlessness experience can vary for COPD patients due to climatic and environmental conditions. However, when considering this subjective index with a reduction in physiological / cardiovascular load experienced with a 6MWT, this may indicate some adaptation or improvement in functional capacity. This reduced loading on the cardiopulmonary system is further evidenced by a 4% reduction in 6MWT terminal heart rate, compared to a nearly 2% increase in the control group.

Walking further in the 6MWT requires a faster walking speed, or quicker turning ability around the cones at each end of the 10m walking course. Whilst the singing group experienced a smaller increase in 6MWD, the distance walked was achieved with less subjective effort (reduced BORG score), even though their terminal SaO<sub>2</sub> was lower in this group (91% vs 92/93%) and a lower terminal heart rate. The lower SaO<sub>2</sub> may lead to increased perception of breathlessness. In physiological terms, this is indicative of an improved functional capacity. The control group walked further (10.90m or one additional length of the walking course) but experienced a higher state of breathlessness and terminal heart rate, even though their SaO<sub>2</sub> was higher than the singing group.

An indication of an improved functional capacity in the singing group could be evidenced by the recovery heart rate following the 6MWT. This was recorded for 5-minutes following completion of the 6MWT and for each minute (see Table 4) the singing group had a lower heart rate in the post-test and a lower rate than the control group. This indicates that the singing group recovered from the 6MWT faster than the control group – the latter's heart rate increased in the post-testing, suggesting that their recovery was much slower. Borg breathlessness score (0-10) were not measured during the 5-minute recovery period as participants could not talk or move due to the post-test SLP measurement at the same time. However, it would be interesting to know whether this increased physiological / cardiorespiratory loading was reflected in higher reported subjective breathlessness (i.e. higher BORG breathlessness scores). None of these reported HR post 6MWT measures were statistically significant between pre- and post-test or between the groups. However, due to the relatively short duration of the intervention and the nature of the COPD disease, only marginal improvements might be expected. These improvements might be experienced as slight changes in breathlessness or function, as reported here in 6MWT, heart rate and BORG scores.

There were no significant differences in SaO<sub>2</sub> in the 5-minutes recovery pre- or post-test, or between the groups. Both groups did achieve resting SaO<sub>2</sub> within the 1-minute recovery period. Interestingly, for each minute of the recovery SaO<sub>2</sub> following the 6MWT were all higher than the resting SaO<sub>2</sub> for both tests and in both groups, suggesting that a short bout of exercise, like a short walk, does not compromise oxygen levels (i.e. de-saturation) in a COPD population and are quickly recovered (within one minute). It should also be considered that in this 6MWT participants were required to walk as far as possible, which also implies that they were walking as fast as they could manage.

In our study we utilised a novel assessment of breathing pattern using SLP. This method provides specific detail related to the contribution of chest and abdominal wall movement and their synchronisation through the breath cycle to better describe an individual's breathing pattern. It has been previously demonstrated the breathing patterns in COPD patients are significantly different from healthy individuals (Iles, Motamedi-Fahkr, Khalid and Wilson, 2015). We adopted SLP into this study to investigate whether singing had an impact on COPD participants. Results suggest that COPD patients had similar breathing patterns to those previously reported (Iles, et al., 2015), however singing did not appear to change breathing pattern of our participants. It may be that singing does not change the breathing pattern of COPD patients, but this study did have some limitations that may have resulted in our observations. One of these limitations is that analysis of breathing pattern took place in a laboratory environment, asking

the participant to sit motionless, thus making the participant very aware we were measuring their breathing pattern, which may have impacted on the breathing pattern adopted. The SLP analysis is very sensitive to movement, and it is not possible to analyse breathing pattern if the participant is moving, which does not allow for analysing breathing pattern during physical activity. Another limitation is that we did not measure the participant's breathing pattern during singing, which may have changed. There are some standardised pieces of music that we could have asked the participants to perform, however, the research team felt it would have led to un-blinding of the groups had an SLP analysis during a singing piece been performed.

The debate around the value of RCTs is perhaps of relevance here. While historically regarded as the 'gold standard' in terms of rigour in clinical trials, this method has been criticized for being subject to bias, focusing on averages and ignoring individual idiosyncracies (Kabeer, 2018) and human agency such as choice and the 'Hawthorne Effect' (Bondemark & Ruff, 2015). This latter effect refers to situations where individuals modify their behaviour in response to their awareness of being observed and might help explain, for example, why both groups in our trial experienced an increase in distance walked in the 6MWT. However, while this is a possible explanation for lack of significant evidence of difference between groups in our self-report measures, it could not account for the findings in physiological measures which are not amenable to behavioural change. Jones and Podolsky (2015) have called for a more 'ecumenical' approach to research designs when testing clinical interventions, to include prospective cohort studies, which might result in larger samples, and qualitative studies, which can cope with individual perspectives (for further discussion see Lane et al, 2022). However there is clearly still a need for good RCTs for evaluating certain interventions such as the physiological measures in our study.

#### 4.3. Study strengths

The singing programme ran very effectively, with active and enthusiastic engagement from participants, none of whom had previous experience of being part of an organised community singing group. The groups were valued for the opportunities they provided for people with COPD to come together regularly and make friends and gain social support. An account of participants' experiences and experienced benefits are given by Lane et al (2022). These positive features were fully in line with observations on group atmosphere and subjective benefits reported in previous studies (Skingley, et al., 2014; Lewis et al., 2016; Skingley, et al., 2018; Downes, et al., 2019; Philip, et al., 2020; Kaasgaard et al., 2020).

#### 4.4. Study limitations

Recruitment to this trial proved challenging despite the active support of the Medway Community Healthcare respiratory team in providing access to contact details of COPD patients. We had the opportunity to make face-to-face contact with patients in the course of pulmonary rehabilitation classes, when singing taster sessions took place, and we were also able to write directly to all patients on the organisation's database to invite them to participate. We also had support from the local British Lung Foundation Breatheasy Group. In addition, we had excellent coverage in the local newspaper in the form of a feature article and advertising over several weeks during the recruitment phase, with details also on their website, and coverage on their local television channel. Active use was also made of social media, and this led to the MP for the local constituency inviting us to attend a district-wide 'healthy living' event for older people during which the project was promoted. An extended recruitment period was required in order to build up sufficient numbers for the singing group activity. Nevertheless, the study failed to reach its recruitment target, and in addition, substantial attrition was experienced in the lead up to the start of the trial for a wide variety of reasons, including illness, and the fact that the days, times and venues for the singing groups were not suitable. Feedback from patients with COPD over the period of recruitment indicated that the main reason for an unwillingness to participate was a lack of interest in singing, or a feeling that they were not able to sing given their breathing difficulties. Given that 36 participants were willing to participate in the study prior to commencement of baseline assessments, a decision was made

to proceed only to find that over the course of the study, a total of 12 participants were lost for follow-up, primarily due to illness. A major limitation of the pilot trial, therefore, was compromised power to detect possible changes on the measures used in response to the singing programme.

In future research based on RCTs, a number of strategies might be considered to enhance recruitment. It would be sensible, for example, to work with a number of health trusts, over a wider geographical area in order to access a larger potential population of people with COPD. In addition, researchers might consider linking a singing programme to follow directly on from pulmonary rehabilitation provision. A further strategy could be to establish a rolling trial in which participants were randomized to singing and control groups as soon as a suitable target number had been recruited. This would help to avoid the issue that arose in the current study of participants dropping out during the extended period of recruitment to achieve our target figure.

## 5. Conclusion

In this small-scale pilot randomized controlled trial, it was demonstrated that a ten-week singing programme for people with COPD resulted in a significant improvement in perceived activity as assessed by the SF-36. No changes were found on measures of direct physical impacts of COPD, however, as assessed by CAT and the mMCR scale of breathlessness. Participants' mental health was generally positive, and no changes in self-assessed anxiety or depression in the singing group relative to the control group were found. We also found no changes to lung function, breathing pattern or functional capacity (measured via 6MWT) in patients with a COPD diagnosis following the singing intervention.

In the light of inconclusive findings based primarily on pulmonary and physiological function in most trials of singing interventions, future research should include, in addition to RCTs, a greater variety of designs for self-report measures, and in-depth, theoretically informed accounts from participants. These may provide researchers with evidence for identifying more comprehensive sets of outcomes for research on singing for people with COPD and for interventions based on those findings. For further discussion, see Lane et al (2022).

## Notes

This is the first in a trio of papers. They present contrasting, but complementary, approaches to researching the effects of engaging in singing groups for people with chronic obstructive pulmonary disease (COPD). Previous research has suggested benefits may exist, but the variety of measures and designs adopted has meant conclusions remain tentative. We present a theoretically based sequence of studies to contribute to this evidence gap.

Firstly, Clift et al present a traditional randomised controlled trial (RCT), comparing a treatment as usual (TAU) group with a TAU plus group singing intervention programme using standardised outcome measures (lung function, exercise capacity and self-report health status). The singing programme followed a developmental model, previously tested, which included educative elements around managing the condition. We aimed to recruit to a target calculated from previous studies but found both recruitment and retention challenging. While few significant differences were found between the groups or the within-group measures, we offer a number of possible explanations for this. We also argue that, despite the challenges in undertaking RCTs in this area, the method remains a valuable contributor to knowledge when measuring certain outcomes. Recommendations for future research are suggested, including strategies to overcome under-recruitment within this design.

A second paper (Lane et al) builds on these findings and on previous qualitative studies on singing for COPD, which have, in contrast to the above, found that participants report benefits to wellbeing from group singing. This approach overcomes the problem of sample size and retention

inherent in RCTs. In-depth interviews, focusing on participants' explanations for any effects of singing in a group, were analysed using Interpretive Phenomenological Analysis (IPA), informed by the Common Sense Model of illness representation. The study identified five explanatory themes, with the overall finding that the experience of the singing group changed participants' largely negative response to COPD to a greater feeling of control over the disease and improved self-efficacy. These concepts are less amenable to detection in more quantitative approaches. In addition, the study contributes an equivalent to longitudinal follow-up, since the interviews indicated that participants recalled what they had been taught, and in some cases, continued to put learning into practice, some time after the intervention.

The third paper (Price and Skingley) further adds to these findings by describing the design, implementation and evaluation of a singing resource, based on the learning embedded in the singing programme, to encourage self-management of COPD. This approach puts into practice the theory proposed in the Common Sense Model that the ability to employ adaptive, coping strategies may be more important to the individual as an outcome than improvements in objective measures of respiratory function. The Singing for Better Breathing (SfBB) resource comprises a DVD of 13 films, and accompanying handbook. Participants were invited to complete diaries and attend interviews in order to evaluate the resource. A number of positive benefits were reported, and continued use of the resource, plus numbers accessing an online version, point to its effectiveness and support the guiding theory.

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### **Declaration of conflicting interests**

The authors have no competing interests

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