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**Sing Your Lungs Out- A community singing group for chronic obstructive pulmonary
disease: a one-year pilot study**

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ABSTRACT

Objective Singing group participation may benefit patients with chronic obstructive pulmonary disease (COPD). Previous studies are limited by small numbers of participants and short duration of hospital-based singing group intervention. This study examined the feasibility of long-term participation in a community singing group for patients with COPD who had completed pulmonary rehabilitation (PR).

Methods This was a mixed methods pilot study. Patients with COPD who had completed PR were recruited to a new community-based singing group which met weekly for over one year. Measurements at baseline, four months and one year comprised comprehensive pulmonary function tests including lung volumes, six minute walk tests (6MWT), Clinical COPD Questionnaire (CCQ), Hospital Anxiety and Depression Scale (HADS), and hospital admission days for acute exacerbation of COPD (AECOPD) for one year before and after joining singing group. Individual interviews and a focus group provided data for the qualitative assessment which is reported separately.

Findings Of 28 initial participants, 21 completed four-month, and 18 completed one-year assessments. The mean attendance was 85.4%. The 6MWT at one year improved by 62.2 (95% CI 26.9 to 97.5) m compared to baseline $P=0.002$. There was an important reduction in residual volume after four months; 130 (95% CI 3 to 250) ml, $P=0.046$, and a reduction in the HADS Anxiety Score after one year of 1.1 (95% CI 0.3 to 1.9) points, $P=0.009$. Mean (SD) hospital admission days for AECOPD were 3.6 (7.9) before, and 2.7 (7.3) after joining the singing group, $p=0.40$ for the difference.

Conclusions Our findings support the feasibility of long-term participation in a community singing group for breathless adults with COPD and provide evidence of improved exercise capacity and lung function, and a reduction in anxiety.

Strengths and limitations of this study:

- The mixed-methods design of this study provides a broad perspective on a novel intervention.
- The inclusion of an unselected cohort of COPD patients, and the real-world community setting of the singing group supports generalisability of the findings.
- High retention rates with one-year follow-up support the feasibility of this intervention.
- This is the first report of serial lung volume measurements in COPD patients attending a singing group over one year.
- This is a relatively small cohort study.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD), characterised by persistent airflow limitation that is usually progressive, is an increasingly common syndrome.[1] Common symptoms include progressive breathlessness, cough and sputum production as well as anxiety and depression.[2,3] The chronic breathlessness in COPD is physically limiting and socially isolating, adding further to depression and anxiety.[4] Current pharmacological options have limited benefits and significant adverse effects driving the need for cost-effective, non-pharmacological, person-centred, community-based interventions.[5–8] Pulmonary Rehabilitation (PR) is one of the most effective therapies for COPD, improving quality of life, exercise tolerance, and breathlessness.[9] An important research question is how the benefits of PR can be sustained and augmented.[10]

There is a growing interest in the therapeutic potential of singing for COPD. Singing involves inspiratory expansion (using the diaphragm, external intercostal, and accessory muscles), active exhalation (incremental recruitment of abdominal and internal intercostal muscles) and optimal posture.[11] Singing, therefore, has the potential to improve breathing control and posture, and theoretically to reduce residual volume (RV), which is a manifestation of lung hyperinflation. Improvement in psychological wellbeing has been reported in healthy subjects and people with a variety of chronic conditions participating in singing groups.[12–14]

Two randomised controlled trials of singing group interventions in COPD report improvements in quality of life and reduction in anxiety, although not in lung function.[15,16], One study examining the effects of adding therapeutic singing to PR programme showed no benefit in quality of life or exercise tolerance,[17] whilst two studies have reported improvement in maximal expiratory pressure.[18,19] The limitations of these studies include small sample sizes and short duration, hospital-based intervention.[15–19] Combined with the heterogeneity of disease severity, phenotypes, comorbidities and treatment regimens of COPD, the clinical and physiological benefits of singing group interventions are likely to have been underestimated. What remains unknown is whether singing group participation as an intervention, is acceptable and sustainable longer term, to an unselected group of COPD patients

and whether the benefits can be achieved in real-world conditions. The effects of singing group participation on hyperinflation and lung function in COPD patients also remain unclear.

We are interested in the potential of singing group participation for patients with COPD as a means to sustain the benefits of PR. We wished to study this in real world conditions (amateur singing group facilitator leading free, weekly, sessions in a community hall), particularly looking at lung function including lung volumes, exercise capacity, and wellbeing. The purpose of this mixed methods cohort study was to assess the feasibility of community singing group participation for one year, for breathless patients with COPD who have completed PR. We report here the quantitative results of the study, the qualitative results are reported separately.[20]

METHODS

This was a prospective cohort study. Patients with COPD or another chronic lung disease, who had completed an eight-week, hospital-based PR programme, and were attending a weekly maintenance community PR exercise class, were invited by the PR nurse to join a new community-based singing group for the purposes of this study. The group was based in Wellington New Zealand. In our institution, patients are enrolled in PR programmes if they have chronic lung disease and a Modified Medical Research Council dyspnoea scale of at least grade 2. We report on those participants with physician-diagnosed COPD based on GOLD criteria.[21] There were no further recruitment restrictions based on age, severity of disease, cognition, singing ability, or co-morbidities. The study was approved by the Wellington Hospital Research Governance Group, and all patients gave written informed consent. The trial was prospectively registered at www.anzctr.org.au, registry number ACTRN12615000736549.

Data collection

Patient demographics, pulmonary function tests, six-minute walk test (6MWT), Hospital Anxiety and Depression Scale (HADS)[22] and the Clinical COPD Questionnaire (CCQ)[23] were measured at baseline, four months and one year after enrolment. Spirometry and lung volumes including forced expiratory volume in 1 s (FEV1), forced vital capacity (FVC), total lung capacity (TLC), residual volume (RV), functional residual capacity (FRC) and inspiratory capacity (IC) were measured according to ATS/ERS standards (body volume constant plethysmography Masterlab, Erich-Jaeger, Wurzburg, Germany). Reference values were those of the European Community for Coal and Steel (ECCS). Short-acting bronchodilator therapy was withheld for four hours prior to testing, and patients were tested when clinically stable, and not within two weeks of an exacerbation. Six-minute walk test (6MWT) was performed according to international guidelines [24]

The respiratory scientist performing the pulmonary function tests was blind to the results of previous assessments. Questionnaires were self-completed. Each patient's electronic health record was searched for admissions where the primary discharge code was an acute exacerbation of COPD.

Hospital admission data for acute exacerbation of COPD were recorded for the 12 months before and 12 months after, enrolment.

Singing group intervention

The singing group (Sing Your Lungs Out) met for one hour, weekly, in an urban community hall, continuously throughout the study period. An amateur singing group facilitator (SGF) led the group and a PR nurse attended all sessions. Each rehearsal comprised a five minute warm up session, 35 minutes singing, a five minute warm down and 15 minutes social morning-tea time. It was run free of charge to patients. The SGF and the group chose the singing repertoire together, including a wide mix of genres (eg pop, musicals, traditional Maori songs, folk songs, rounds) with attention to the group’s voice range and capacity for phrase lengths. The SGF also discussed breathing for singing techniques as the year progressed and as the group gained confidence. No music reading ability was required. We made CD recordings of songs to allow practice at home. Collaboration with a local boys’ high school developed from student piano accompaniment to working with the senior boys’ chorale including some joint performances. Over the year, the participants delivered six public performances, supported by the senior chorale from the local school on four occasions.

Analysis

Continuous variables were compared using paired t-tests for most variables. Hospital admission days were right skew and were compared with a paired Wilcoxon test and Hodges-Lehmann estimator of the difference. No adjustment has been made for multiple statistical testing. SAS version 9.4 was used.

RESULTS

Twenty-eight participants enrolled in the singing group in five months: October 2014 to February 2015. Five participants withdrew within one month of enrolment due to disinterest or recruitment to another study. Twenty-three (82%) participants attended the singing group for at least one year and had measurements at enrolment and after four months. Twenty participants were reassessed after 12 months: one had undergone lung transplant and two had such frequent exacerbations that stable follow-up testing was not possible. At baseline assessment, twenty-one participants had COPD as defined by GOLD criteria[21] but two participants had normal FEV1/FVC ratio on spirometry with a clinical diagnosis of interstitial lung disease. They continued to attend singing group but are excluded from this analysis. Figure 1 shows the study overview.

The participants with COPD had a wide range of disease severity and comorbidities. Mean (SD) FEV1% at baseline was 60.3 (21.1), median 57.1, range 14.6-110. Six patients (29%) had an FEV1 at baseline of less than one litre. Common comorbidities were bronchiectasis, congestive cardiac failure, diabetes, and obesity. Six of 21 (29%) were Māori, consistent with the higher prevalence of COPD in Māori in New Zealand who constitute only 6% of the total population over 50 years.[25] The mean (SD) attendance rate for the 12 months was 85.4% (12.1). Table 1 shows characteristics of the study population at baseline.

Table 1 Characteristics of the study population

	N=21	
Age years mean (SD)*	68.8 (9.8) range 51 to 91	
Sex n (%)		
Men	8 (38)	
Women	13 (62)	
Ethnicity n (%)		
European	14 (67)	
Maori	6 (29)	
Asian	1 (5)	
Smoking history n (%)		
Current smoker	1 (5)	
Ex-smoker	18 (86)	
Never smoker	2 (10)	
COPD severity ^a n (%)		
BODE score: 0-2	4 (19)	
3-4	8 (38)	
5-6	6 (29)	
7-10	3 (14)	
Continuous long term domiciliary oxygen therapy n (%)	2 (10)	
Comorbidities ^b n (%)		
Bronchiectasis	3 (14)	
Heart failure	6 (29)	
Diabetes	7 (33)	
Anxiety on treatment	5 (24)	
Atrial fibrillation	8 (38)	
Ischaemic Heart Disease	5 (24)	
Clinical characteristics *	Mean (SD)	Range
FEV1 (L)	1.3(0.5)	0.6-2.6
FEV1 (% predicted)	60.3 (21.1)	14.6-110.3
FVC (L)	2.85 (0.9)	1.8-4.9
FVC (%predicted)	103.5 (26.9)	53.4-160.4
FEV1/FVC	0.47 (0.14)	0.22-0.68
TLC (L)	6.38 (1.99)	3.57-11.3
RV (L)	3.39 (1.52)	1.67-8.52
SpO2 at rest (%)	95.4 (2.3)	89-99
6MWT (m)	299.6 (110.1)	132-508
BMI (kg/m ²)	29.1 (7.6)	20.1-53.0
Questionnaires*		
CCQ	2.11 (0.83)	0.4-3.3
HADS anxiety	5.8 (2.8)	1-11
HADS depression	4.1 (2.3)	1-10
HADS total	9.9 (4.6)	2-21

a:BODE score- The body-mass index, airflow obstruction, dyspnoea and exercise capacity index in COPD [26] **b** Some participants had multiple comorbidities.

FEV1- forced expiratory volume in one second, FVC- forced vital capacity, TLC- total lung capacity RV- residual volume, SpO2-oxygen saturation measured by a pulse oximeter, 6MWT- six-minute walk test, BMI- body mass index, CCQ- clinical COPD questionnaire, HADS- hospital anxiety and depression score.

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3 There was strong evidence for an increase in 6MWT after four months, with a mean increase of 28.4m,
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5 increasing further to 62.2m at one year. HADS Anxiety scores were lower at one year with a mean
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7 change from baseline of -1.1. Lung function tests showed a reduction in RV, mean decrease 130 ml,
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9 and total lung capacity, mean decrease 150 ml, after four months, but no significant differences at 12
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11 months compared to baseline. The questionnaire and clinical measurements, and their changes are
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13 shown in Table 2.
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Table 2: Changes from baseline in lung function, questionnaires and hospital admission days.

Variable	Mean (SD)			Difference from baseline (95% CI)	
	Baseline N=21	Four months N=21	One year N=18	Four months	One year
FEV1 (L)	1.32 (0.5)	1.34 (0.5)	1.44 (0.5)	0.02 (-0.01 to 0.06) P=0.21	0.04 (-0.04 to 0.12) P=0.32
FEV1%	60.3 (21.1)	61.9 (22.3)	64.5 (20.2)	1.6 (-0.1 to 3.4) P=0.065	2.4 (-1.5 to 6.3) P=0.22
FVC (L)	2.85 (0.9)	2.81 (0.92)	2.91 (0.97)	-0.04 (-0.15 to 0.06) P=0.38	-0.03 (-0.16 to 0.10) P=0.65
FVC%	103.5 (26.9)	103.1 (30.4)	107.0 (24.8)	-0.5 (-4.5 to 3.6) P=0.81	-0.3 (-5.0 to 4.4) P=0.90
FEV1/FVC	0.47 (0.14)	0.48 (0.13)	0.50 (0.12)	0.01 (-0.004 to 0.03) P=0.13	0.01 (-0.003 to 0.03) P=0.10
TLC (L)	6.38 (1.99)	6.22 (1.86)	6.23 (1.7)	-0.15 (-0.29 to -0.02) P=0.023	-0.04 (-0.21 to 0.13) P=0.63
TLC%	117.8 (20.9)	115.2 (20.2)	116.4 (20.8)	-2.6 (-4.8 to -0.4) P=0.021	-0.7 (-3.6 to 2.2) P=0.62
RV (L)	3.39 (1.52)	3.27 (1.44)	3.22 (1.18)	-0.13 (-0.25 to -0.003) P=0.046	0.03 (-0.18 to 0.24) P=0.78
RV%	156.1 (59.9)	150.2 (57.1)	145.7 (44.1)	-5.9 (-11.5 to -0.3) P=0.04	-0.1 (-8.9 to 8.8) P=0.99
IC (L)	2.29 (0.86)	2.35 (0.83)	2.33 (0.87)	0.06 (-0.03 to 0.15) P=0.18	-0.07 (-0.18 to 0.04) P=0.19
IC%	107.2 (27.2)	110.1 (25.7)	108.6 (24.3)	3.0 (-1.8 to 7.7) P=0.21	-2.9 (-9.3 to 3.4) P=0.35
IC/TLC	0.37 (0.09)	0.39 (0.09)	0.38 (0.09)	0.02 (0.001 to 0.03) P=0.037	-0.01 (-0.03 to 0.01) P=0.49
RV/TLC	0.52 (0.09)	0.52 (0.09)	0.52 (0.09)	-0.01 (-0.02 to 0.01) P=0.45	0.01 (-0.02 to 0.03) P=0.61
6MWT (m)	299.6 (110.1)	328.0 (118.4)	376.5 (103.6)	28.4 (5.1 to 51.7) P=0.019	62.2 (26.9 to 97.5) P=0.002
CCQ	2.11 (0.83)	2.08 (0.86)	2.31 (1.04)	-0.03 (-0.31 to 0.26) P=0.84	0.27 (-0.04 to 0.57) P=0.09
HADS Anxiety	5.8 (2.8)	5.81 (3.52)	4.67 (3.2)	0 (-1.2 to 1.2) P=0.99	-1.1 (-1.9 to -0.3) P=0.009
HADS Depression	4.1 (2.3)	3.19 (2.56)	4.0 (3.91)	-0.9 (-2.1 to 0.2) P=0.11	-0.1 (-1.5 to 1.4) P=0.93

HADS Total	9.9 (4.6)	9.0 (5.7)	8.7 (6.4)	-0.9 (-3.0 to 1.2) P=0.37	-1.2 (-2.9 to 0.5) P=0.17
		12 months prior to enrolment	12 months after enrolment	HL estimator (95% CI)	
Hospital admission days for AECOPD N=20* Mean (SD)		3.6 (7.9)	2.7 (7.3)	-1.0 (-8.5 to 3.0) P=0.40	

FEV1, Forced expiratory volume in 1 s; FVC, forced vital capacity; TLC, total lung capacity; RV, residual volume; FRC, functional residual capacity; IC, inspiratory capacity. Spirometric reference values from European Community for Coal and Steel (ECCS). Short-acting bronchodilator therapy withheld for four hours before testing, patients were tested when clinically stable, and not within two weeks of an exacerbation. Six-minute walk test (6MWT) performed according to international guidelines.[24] AECOPD, Acute exacerbation of COPD. * Excluding one patient who had lung transplant between 4 months and 1-year follow-up assessments.

Figure 2 displays individual patient line plots of 6 minute walk test distance of each participant at baseline, 4 months and one year.

DISCUSSION

The results of this study show that participation in a weekly community-based singing group for one year is associated with increased exercise capacity, reduced anxiety, and improved lung function in patients with COPD. The high attendance rate over one year, (mean 85.4%), supports the acceptability, feasibility, and enjoyment of this intervention. Factors favouring generalisability of these findings are the broad inclusion criteria, COPD patients recruited from typical public hospital pulmonary rehabilitation service and singing group intervention requiring no special training.

We were surprised by the high long-term attendance rate (mean 85.4%) for this cohort of patients with significant respiratory disease and comorbidities. The qualitative data from this mixed methods study showed that most participants had not been previously interested in singing and considered the singing group a fun social activity more than music practice.[20] The reduction in HADS anxiety scores confirms previous research [15] but this is the first report of statistically and clinically significant improvements in respiratory function and 6MWT with this type of intervention. The mean reduction in HADS anxiety of -1.1 at one year, did not exceed minimal clinically important difference (MCID) of 1.32.[27] The mean increase in 6MWT of 62.2m at one year was greater than the MCID of

30m.[28] The small reduction in RV after four months supports the findings of a previous small study.[19] This is the first report of serial RV measurement in COPD patients attending a singing group over one year. Although the reduction in hospital admission days for AECOPD was not statistically significant, the point estimate was almost one day less per participant in the year attending singing group, compared to the year before starting (excluding the patient who has a lung transplant during the year). If this is a genuine reduction then, at a daily hospital bed day rate of approximately \$NZ800 (GBP400), this represents a saving of \$14080 for this group of 20 patients. The actual cost of running the singing group for 12 months was approximately \$NZ4000. Therefore this low-cost intervention could potentially be very cost effective.

Strengths of this study, are the inclusion of an unselected cohort of patients with COPD, high retention rates with one-year follow-up, comprehensive pulmonary function tests, and mixed-method design in a real world community context. Previously reported studies of singing intervention for COPD have generally been of short duration, none longer than 24 weeks, mostly 6-10 weeks.[15,16,18,19] In contrast to studies using professional singing teachers and physiotherapists, we used amateur singing group facilitators, with musical experience and strong group facilitation skills. Limitations of the study include that the 6MWT was only performed once at each visit, but participants had all done at least two 6MWT as part of their recent PR programmes so any learning effect is likely to have been minimised.[29] All participants received usual medical care; so therapeutic changes may have affected some, but not all, of the participants. This is a relatively small cohort study without a control group so both type I and type II errors are possible.

Our findings are also relevant to the question of sustaining the benefits of pulmonary rehabilitation. All our participants had completed a PR programme- the improvements described here are additional. A possible mechanism for singing group effectiveness is the promotion of physical activity which is considered to be a critical component of PR.[30] Our qualitative data showed that for many patients, attending the weekly singing group was a most enjoyable highlight of their week and often their only outing.[20] Our finding of a reduction in RV after four months, but not 12 months, may

reflect a positive effect of singing on respiratory muscles and expiratory airways pressure that is subsequently overtaken by the natural history of the decline in lung function in COPD. In contrast to other studies[15–18] our singing group intervention focussed on fun group singing with no specific breathing exercises. The impact of breathing exercises alone or in addition to singing remains uncertain.[31] Our group met weekly with singing duration of 35 minutes, and no explicit practice at home. It is possible that there is a dose-response relationship, with increased benefit with more frequent singing group classes and singing practice at home. From our experience, longer classes would not be well tolerated by COPD patients.

Our qualitative analysis showed singing group participation was associated with an increased sense of social connection, purpose and meaningful participation which may, in turn, have ameliorated anxiety.[20] Although there seems to be an association between anxiety in COPD patients, and their health status, the frequency of AECOPD and hospitalisation, it is complex.[32][32][32] However, the reduction in anxiety and increased exercise capacity observed in this study points to the potential for reducing readmissions and supports the use of exercise capacity and readmission for AECOPD, as primary outcome measures for a future randomised controlled trial (RCT).

We believe our results are generalizable because of our broad inclusion criteria, recruitment from a typical hospital PR programme and the use of amateurs for singing group facilitation. We have made available on-line our “10 practical top tips” document for setting up and running a community singing group for people living with COPD. We have been able to sustain this intervention long term, free to patients, as it was set up and financed by a charitable trust. The singing group is still going strong after twenty-two months with high attendance including almost all of the founding members, avoiding the ethical issue of withdrawing the intervention at study completion.

CONCLUSIONS

Our findings support the feasibility of long-term participation in a community singing group for breathless adults with COPD and provide evidence of improvement in lung function and

exercise capacity, and reduction in anxiety. These results can inform sample size and selection of outcome measures for a future RCT. A study of community singing group participation as an alternative to PR for those who decline PR is underway: ACTRN12616000584437. We provide links to two short videos of this singing group and a “10 practical top tips” document for setting up a community singing group for people living with COPD which we hope will inform, motivate and encourage others to set up singing groups.

https://www.dropbox.com/sc/boc5sr7hkcibi6tz/AAAibUQqOWyvDeJGTnoXVcg-a?preview=NO_Graphics_02.mp4

<https://www.youtube.com/watch?v=fduau0jV09o>

http://www.mrinz.ac.nz/pdfs/How_to_set_up_SYLO.pdf

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Contributors AM conceived the idea of the study, designed the protocol, wrote the first and final drafts of the manuscript, was the senior investigator, and will act as guarantor. SA, HM, MWi, GW, MWe, RB helped design and plan the study and helped write the first and final drafts of the manuscript. GW, AM recruited patients to the study. MWi, AM collected data. MWe was responsible for the analysis.

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Competing interests None

Ethics approval This study was approved by the Wellington Hospital Research Governance Group on 23 September 2014

Data sharing No additional data are available

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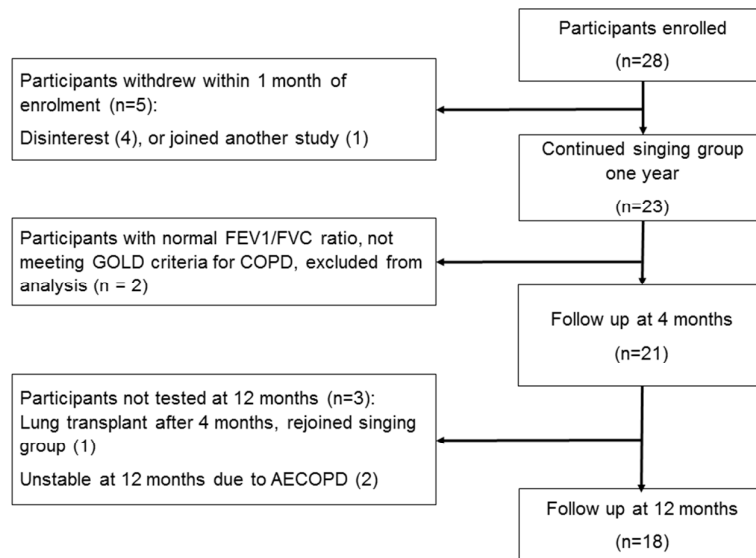
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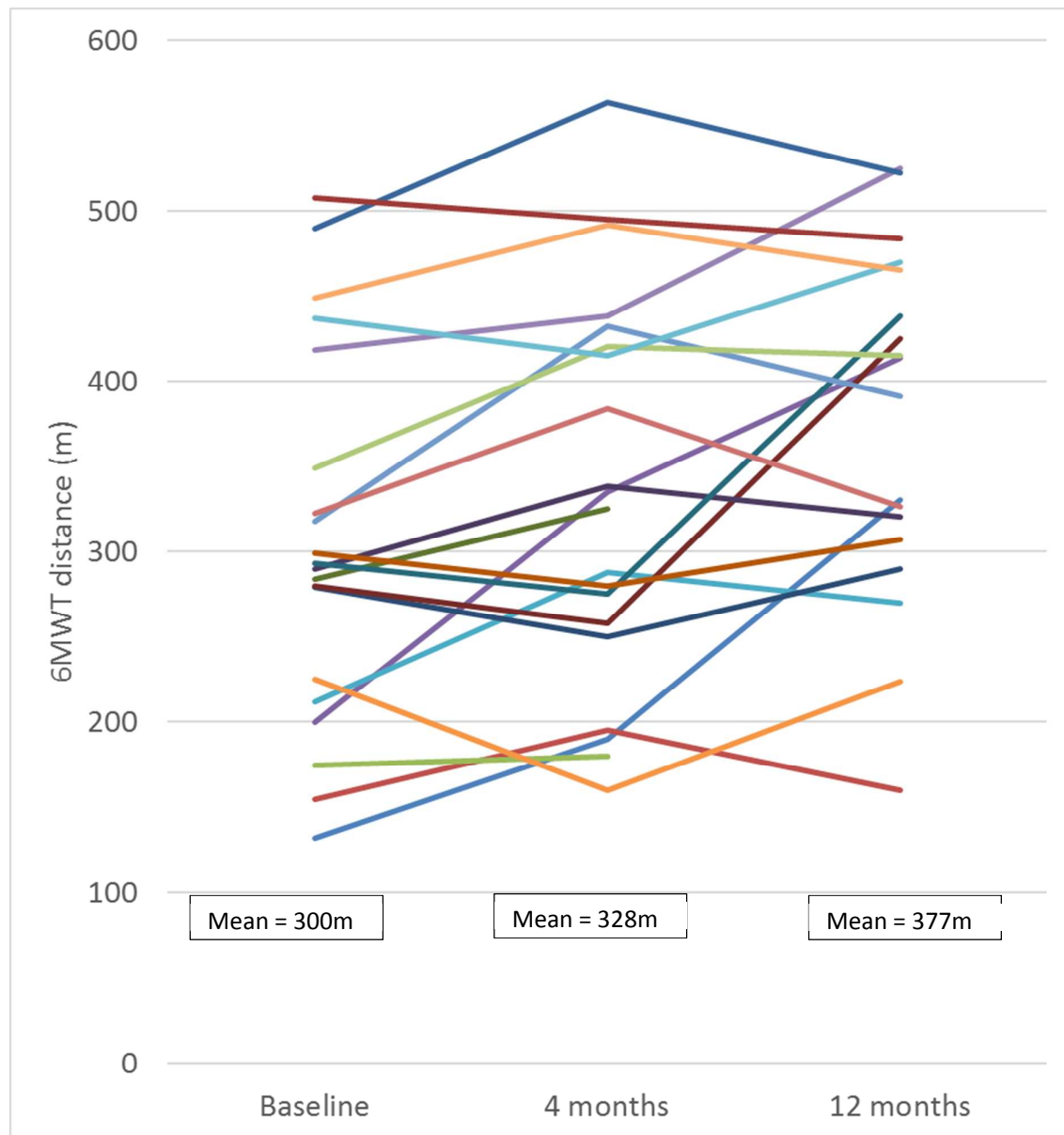
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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	Pilot in study title.
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes Introduction para 1-3, pg3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes Introduction para 4, pg 4. No hypotheses, this was a feasibility study.
Methods			
Study design	4	Present key elements of study design early in the paper	Methods, para 1, pg 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Methods, para 1, pg 5 and under ‘Singing Group Intervention’ pg 6. Specific dates are in first line of Results, pg 7
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	Methods, para 1, pg 5
		(b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed Case-control study—For matched studies, give matching criteria and the number of controls per case	No matched control group
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Methods, ‘data collection’, pg 5
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Methods, ‘Data collection’, pg 5

Bias	9	Describe any efforts to address potential sources of bias	Objective lung function tests measured by scientist blinded to previous results. Self reported questionnaires
Study size	10	Explain how the study size was arrived at	Convenience sample, twice the size of previous studies.
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Methods, 'Analysis', pg 6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Methods, 'Analysis', pg 6
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	N/A
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed	Results, para 1, pg 7 and Figure 1 Study overview
		<i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	
		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Results, para 1, pg 7 and Study overview Figure 1
		(b) Give reasons for non-participation at each stage	Results, para 1 and figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Results, para 2, pg 7 and Table 1
		(b) Indicate number of participants with missing data for each variable of interest	Table 1
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	Result, para 1,pg 7
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	Results, para 3, pg 9 and Table 2 and Figure 2
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	
Main results	16	(a) Give unadjusted estimates and, if	Admission days adjusted. Other

		applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	results unadjusted. Table 2
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A feasibility study
Discussion			
Key results	18	Summarise key results with reference to study objectives	Discussion para 1
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Discussion para 3, pg 12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Discussion para 4 and 5, pg 12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	Discussion para 6, pg 13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Funding statement pg 14

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Sing Your Lungs Out- A community singing group for chronic obstructive pulmonary disease: a one-year pilot study

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Sing Your Lungs Out- A community singing group for chronic obstructive pulmonary disease: a one-year pilot study

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ABSTRACT

Objective Singing group participation may benefit patients with chronic obstructive pulmonary disease (COPD). Previous studies are limited by small numbers of participants and short duration of generally, hospital-based singing group intervention. This study examines the feasibility of long-term participation in a community singing group for patients with COPD who had completed pulmonary rehabilitation (PR).

Methods This was a non-experimental cohort study. Patients with COPD who had completed PR were recruited to a new community-based singing group which met weekly for over one year. Measurements at baseline, four months and one year comprised comprehensive pulmonary function tests including lung volumes, six minute walk tests (6MWT), Clinical COPD Questionnaire (CCQ), Hospital Anxiety and Depression Scale (HADS), and hospital admission days for acute exacerbation of COPD (AECOPD) for one year before and after the first singing group session.

Findings There were 28 participants with chronic lung disease recruited initially. Five withdrew in the first month. Twenty-one participants meeting GOLD criteria for COPD completed four-month, and 18 completed one-year assessments. The mean attendance was 85%. The 6MWT at one year improved by 65 (95% CI 35 to 99) m compared to baseline $P<0.001$. There was a reduction in residual volume after four months of 130 (95% CI 3 to 250) ml, $P=0.046$, and a reduction in the HADS Anxiety Score after one year of 0.9 (95% CI 0.1 to 1.8) points, $P=0.038$. Mean (SD) hospital admission days for AECOPD were 3.6 (7.9) before, and 2.7 (7.3) after joining the singing group, $p=0.40$ for the difference.

Conclusions Our findings support the feasibility of long-term participation in a community singing group for breathless adults with COPD who have completed PR and provide evidence of improved exercise capacity and a reduction in anxiety.

Strengths and limitations of this study:

- Broad inclusion criteria and community setting of the singing group supports generalisability of the findings.
- High retention rates with one-year follow-up support the feasibility of this intervention.
- This is the first report of serial lung volume measurements in COPD patients attending a singing group over one year.
- This is a relatively small cohort study.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD), characterised by persistent airflow limitation that is usually progressive, is an increasingly common syndrome.[1] Common symptoms include progressive breathlessness, cough and sputum production as well as anxiety and depression.[2,3] The chronic breathlessness in COPD is physically limiting and socially isolating, adding further to depression and anxiety.[4] Current pharmacological options have limited benefits and significant adverse effects driving the need for cost-effective, non-pharmacological, person-centred, community-based interventions.[5–8] Pulmonary Rehabilitation (PR) is one of the most effective therapies for COPD, improving quality of life, exercise tolerance, and breathlessness.[9] An important research question is how the benefits of PR can be sustained and augmented.[10]

There is a growing interest in the therapeutic potential of singing for COPD. Singing involves inspiratory expansion (using the diaphragm, external intercostal, and accessory muscles), active exhalation (incremental recruitment of abdominal and internal intercostal muscles) and optimal posture.[11] Singing, therefore, has the potential to improve breathing control and posture, and theoretically to reduce residual volume (RV), which is a manifestation of lung hyperinflation. Improvement in psychological wellbeing has been reported in healthy subjects and people with a variety of chronic conditions participating in singing groups.[12–14]

Two randomised controlled trials of singing group interventions in COPD report improvements in quality of life and reduction in anxiety, although not in lung function.[15,16], One study examining the effects of adding therapeutic singing to PR programme showed no benefit in quality of life or exercise tolerance,[17] whilst two studies have reported improvement in maximal expiratory pressure.[18,19] The limitations of these studies include small sample sizes and short duration, hospital-based intervention.[15–19] A non-experimental feasibility study of singing group intervention for people with COPD in the United Kingdom recruited 106 people into 6 singing groups, and followed the group for ten months. [20] In that report it was unclear if the participants had participated in PR before the singing intervention. That study reported a 34% attrition rate and small statistically significant differences in St

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3 86 Georges Respiratory Questionnaire as well as spirometry parameters measured by a portable
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5 87 spirometry device. We wished to explore whether singing group participation as an intervention, is
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7 88 acceptable and sustainable for a longer time period with adequate retention rates, to a broad group of
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10 89 COPD patients who had completed PR and whether the benefits can be achieved in a community
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12 90 setting taking a low-cost, pragmatic approach that might be easily reproducible in other centres
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14 91 comprising amateur singing group facilitator leading free weekly sessions in a community hall. We are
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16 92 interested in the potential of singing group participation for patients with COPD as a means to sustain
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18 93 the benefits of PR. The effects of singing group participation on hyperinflation and lung function in
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20 94 COPD patients remain unclear and we wished to measure both spirometry and lung volumes over a
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22 95 significant time period in singing group participants, looking for any effect on residual volume as well as
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24 96 airflow.
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27 97 The purpose of this cohort study was to assess the feasibility of community singing group
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29 98 participation for one year, for breathless patients with COPD who have completed PR. We report here
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31 99 the quantitative results of the study, the qualitative results are reported separately.[21]
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METHODS

This was a prospective cohort study. Patients with COPD or another chronic lung disease, who had completed an eight-week, hospital-based PR programme, and were attending a weekly maintenance community PR exercise class, were invited by the PR nurse to join a new community-based singing group for the purposes of this study. The group was based in Wellington, New Zealand. In our institution, patients are enrolled in PR programmes if they have chronic lung disease and a Modified Medical Research Council dyspnoea scale of at least grade 2. We report on those participants with physician-diagnosed COPD based on GOLD criteria.[22] There were no further recruitment restrictions based on age, severity of disease, cognition, singing ability, or co-morbidities. The study was approved by the Wellington Hospital Research Governance Group, and all patients gave written informed consent. The trial was registered at www.anzctr.org.au, registry number ACTRN12615000736549.

Data collection

Patient demographics, pulmonary function tests, six-minute walk test (6MWT), Hospital Anxiety and Depression Scale (HADS)[23] and the Clinical COPD Questionnaire (CCQ)[24] were measured at baseline, four months and one year after enrolment. Spirometry and lung volumes including forced expiratory volume in 1s (FEV1), forced vital capacity (FVC), total lung capacity (TLC), residual volume (RV), functional residual capacity (FRC) and inspiratory capacity (IC) were measured according to ATS/ERS standards (body volume constant plethysmography Masterlab, Erich-Jaeger, Wurzburg, Germany) using the reference values of the European Community for Coal and Steel (ECCS).[25] Short-acting bronchodilator therapy was withheld for four hours prior to testing, and patients were tested when clinically stable, and not within two weeks of an exacerbation. Six-minute walk test (6MWT) was performed according to international guidelines [26] except that only one test was performed at each measurement point, rather than the recommended two. All participants had performed at least one, and mostly two, 6MWT previously as part of their PR programme. The respiratory scientist performing the pulmonary function tests was masked to the results of previous assessments. Questionnaires were self-completed. Each patient's electronic health record was

searched for admissions where the primary discharge code was an acute exacerbation of COPD. Hospital admission data for acute exacerbation of COPD were recorded for the 12 months before enrolment and 12 months starting from the date of enrolment. PR programme information, the date, sessions attended, and 6MWT results at entry and completion, were obtained from the PR nurse who runs the programme.

Singing group intervention

The singing group (Sing Your Lungs Out) met for one hour, weekly, in an urban community hall, continuously throughout the study period. An amateur singing group facilitator (SGF) led the group and a PR nurse attended all sessions. Each rehearsal comprised a five minute warm up session, 35 minutes singing, a five minute warm down and 15 minutes social morning-tea time. It was run free of charge to patients. The SGF and the group chose the singing repertoire together, including a wide mix of genres (eg pop, musicals, traditional Māori songs, folk songs, rounds) with attention to the group's voice range and capacity for phrase lengths. The SGF also discussed breathing for singing techniques as the year progressed and as the group gained confidence. No music reading ability was required. We made recordings of songs to allow practice at home although this was optional. Collaboration with a local boys' high school developed from student piano accompaniment to working with the senior boys' chorale including some joint performances. Over the year, the participants delivered six public performances, supported by the senior chorale from the local school on four occasions. Singing group members continued to attend maintenance exercise classes as well as singing group.

Analysis

Continuous variables were compared using a mixed linear model for most variables with an unstructured variance-covariance correlation structure. Hospital admission days were right skew and

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3 153 were compared with a paired Wilcoxon test and Hodges-Lehmann estimator of the difference. Although
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5 154 individual comparisons are presented with 95% confidence intervals a large number of statistical tests
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7 155 have been carried out and this will inflate the Type I error rate. SAS version 9.4 was used.
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RESULTS

Twenty-eight participants with chronic lung disease were enrolled in the singing group in five months: October 2014 to February 2015. The mean (SD) time from completion of past PR was 1.2 (1.2) years. Response to past PR by the change in 6MWT was available for 14 participants and for these participants the distance had improved from a mean (SD) of 316 (126) m to 356 (148) m. Five participants withdrew within one month of enrolment as they did not wish to continue (n=4) or were recruited into another study (n=1). At baseline assessment, twenty-one participants had COPD as defined by GOLD criteria[22] but two participants had normal FEV1/FVC ratio on spirometry with a clinical diagnosis of interstitial lung disease. They continued to attend singing group but were excluded from this analysis. The 21 participants with COPD attended the singing group for at least one year and had measurements at enrolment and after four months. Eighteen participants were reassessed after 12 months: one had undergone lung transplant and two had such frequent exacerbations that stable follow-up testing was not possible. Figure 1 shows the study overview.

The participants with COPD had a wide range of disease severity and comorbidities. Mean (SD) FEV1% at baseline was 60.3 (21.1), median 57.1, range 14.6-110. The majority (66%) of participants had moderate COPD by GOLD criteria but 20% had severe or very severe COPD, similar to the proportions of COPD severity in the NZ community.[27] Six patients (29%) had an FEV1 at baseline of less than one litre. Common comorbidities were bronchiectasis, congestive cardiac failure, diabetes, and obesity. Six of 21 (29%) were Māori, consistent with the higher prevalence of COPD in Māori in New Zealand who constitute only 6% of the total population over 50 years.[28] The mean (SD) attendance rate for the 12 months was 85% (12.1). Table 1 shows characteristics of the study population at baseline.

181 Table 1 Characteristics of the study population

	N=21		
Age (years) mean (SD) [range]	68.8 (9.8) [51 to 91]		
Sex	N/21 (%)		
Men	8 (38)		
Women	13 (62)		
Ethnicity			
European	14 (67)		
Maori	6 (29)		
Asian	1 (5)		
Smoking history			
Current smoker	1 (5)		
Ex-smoker	18 (86)		
Never smoker	2 (10)		
COPD severity (FEV1% predicted)			
≥80% (mild)	3 (14)		
50-79% (moderate)	14 (66)		
30-49% (severe)	2 (10)		
<30% (very severe)	2 (10)		
COPD mortality risk ^a			
BODE score: 0-2	4 (19)		
3-4	8 (38)		
5-6	6 (29)		
7-10	3 (14)		
Continuous long term domiciliary oxygen therapy	2 (10)		
Comorbidities ^b			
Bronchiectasis	3 (14)		
Heart failure	6 (29)		
Diabetes	7 (33)		
Anxiety on treatment	5 (24)		
Atrial fibrillation	8 (38)		
Ischaemic Heart Disease	5 (24)		
Clinical characteristics	Mean (SD)	Median (IQR)	Min to max
FEV1 (L)	1.3(0.5)	1.3 (0.9 to 1.6)	0.6 to 2.6
FEV1 (% predicted)	60.3 (21.1)	57.1 (50 to 72.4)	14.6 to 110.3
FVC (L)	2.85 (0.9)	2.75 (2.2 to 3.0)	1.8 to 4.9
FVC (%predicted)	103.5 (26.9)	102.5 (85.3 to 126.7)	53.4 to 160.4
FEV1/FVC	0.47 (0.14)	0.47 (0.36 to 0.56)	0.22 to 0.68
TLC (L)	6.38 (1.99)	5.68 (5.2 to 7.0)	3.57 to 11.3
RV (L)	3.39 (1.52)	3.06 (2.6 to 3.4)	1.67 to 8.52
SpO2 at rest (%)	95.4 (2.3)	96 (93 to 97)	89 to 99
6MWT (m)	300 (110)	290 (212 to 349)	132 to 508
BMI (kg/m ²)	29.1 (7.6)	28.0 (23.9 to 32.5)	20.1 to 53.0
Questionnaires			
CCQ	2.11 (0.83)	1.9 (1.7 to 2.8)	0.4 to 3.3
HADS anxiety	5.8 (2.8)	6 (4 to 7)	1 to 11
HADS depression	4.1 (2.3)	3 (3 to 6)	1 to 10
HADS total	9.9 (4.6)	9 (7 to 12)	2 to 21

182 a:BODE score- The body-mass index, airflow obstruction, dyspnoea and exercise capacity index in
 183 COPD [29] b Some participants had multiple comorbidities.

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184 FEV1- forced expiratory volume in one second, FVC- forced vital capacity, TLC- total lung capacity RV-
185 residual volume, SpO2-oxygen saturation measured by a pulse oximeter, 6MWT- six-minute walk test,
186 BMI- body mass index, CCQ- clinical COPD questionnaire, HADS- hospital anxiety and depression score.
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188 There was strong evidence for an increase in 6MWT after four months, with a mean increase of 28
189 (95%CI 5 to 52) m, $p = 0.019$, increasing further to 65 (95%CI 35 to 99) m, $p < 0.001$ at one year. HADS
190 Anxiety scores were lower at one year with a mean change from baseline of -0.9 (95%CI -1.8 to -0.1) p
191 $= 0.038$. Lung function tests showed a reduction in RV, mean decrease 130 (95%CI -250 to -3) ml, p
192 $= 0.046$ and total lung capacity, mean decrease 150 (95%CI -290 to -20) ml, $p = 0.023$ after four
193 months, but no significant differences at 12 months compared to baseline. The questionnaire and
194 clinical measurements, and their changes are shown in Table 2.

196 Table 2: Changes from baseline in lung function, questionnaires and hospital admission days.

Variable	Mean (SD)			Difference from baseline (95% CI)	
	Baseline N=21	Four months N=21	One year N=18	Four months	One year
FEV1 (L)	1.32 (0.5)	1.34 (0.5)	1.44 (0.5)	0.02 (-0.01 to 0.06) P=0.21	0.04 (-0.05 to 0.12) P=0.44
FEV1%	60.3 (21.1)	61.9 (22.3)	64.5 (20.2)	1.6 (-0.1 to 3.4) P=0.065	2.4 (-1.4 to 6.1) P=0.21
FVC (L)	2.85 (0.9)	2.81 (0.92)	2.91 (0.97)	-0.04 (-0.15 to 0.06) P=0.38	-0.04 (-0.17 to 0.09) P=0.50
FVC%	103.5 (26.9)	103.1 (30.4)	107.0 (24.8)	-0.5 (-4.5 to 3.6) P=0.81	-0.02 (-4.5 to 4.4) P=0.99
FEV1/FVC	0.47 (0.14)	0.48 (0.13)	0.50 (0.12)	0.01 (-0.004 to 0.03) P=0.13	0.02 (-0.002 to 0.03) P=0.08
TLC (L)	6.38 (1.99)	6.22 (1.86)	6.23 (1.7)	-0.15 (-0.29 to -0.02) P=0.023	-0.04 (-0.21 to 0.13) P=0.61
TLC%	117.8 (20.9)	115.2 (20.2)	116.4 (20.8)	-2.6 (-4.8 to -0.4) P=0.021	-0.7 (-3.7 to 2.3) P=0.61
RV (L)	3.39 (1.52)	3.27 (1.44)	3.22 (1.18)	-0.13 (-0.25 to -0.003) P=0.046	0.06 (-0.16 to 0.27) P=0.58
RV%	156.1 (59.9)	150.2 (57.1)	145.7 (44.1)	-5.9 (-11.5 to -0.3) P=0.04	1.3 (-7.8 to 10.3) P=0.77
IC (L)	2.29 (0.86)	2.35 (0.83)	2.33 (0.87)	0.06 (-0.03 to 0.15) P=0.18	-0.07 (-0.18 to 0.04) P=0.21
IC%	107.2 (27.2)	110.1 (25.7)	108.6 (24.3)	3.0 (-1.8 to 7.7) P=0.21	-2.9 (-9.3 to 3.5) P=0.35
IC/TLC	0.37 (0.09)	0.39 (0.09)	0.38 (0.09)	0.02 (0.001 to 0.03) P=0.037	-0.01 (-0.03 to 0.01) P=0.36
RV/TLC	0.52 (0.09)	0.52 (0.09)	0.52 (0.09)	-0.01 (-0.02 to 0.01) P=0.45	0.01 (-0.01 to 0.03) P=0.35
6MWT (m)	300 (110)	328 (118)	377 (104)	28 (5 to 52) P=0.019	65 (35 to 99) P<0.001
CCQ	2.11 (0.83)	2.08 (0.86)	2.31 (1.04)	-0.03 (-0.31 to 0.26) P=0.84	0.26 (-0.04 to 0.57) P=0.08
HADS Anxiety	5.8 (2.8)	5.81 (3.52)	4.67 (3.2)	0 (-1.2 to 1.2) P=0.99	-0.9 (-1.8 to -0.1) P=0.038
HADS Depression	4.1 (2.3)	3.19 (2.56)	4.0 (3.91)	-0.9 (-2.1 to 0.2) P=0.11	0.1 (-1.3 to 1.6) P=0.85

HADS Total	9.9 (4.6)	9.0 (5.7)	8.7 (6.4)	-0.9 (-3.0 to 1.2) P=0.37	-0.8 (-2.6 to 1.0) P=0.35
		12 months prior to enrolment	12 months after enrolment	HL estimator (95% CI)	
Hospital admission days for AECOPD N=20* Mean (SD)		3.6 (7.9)	2.7 (7.3)	-1.0 (-8.5 to 3.0) P=0.40	

FEV1, Forced expiratory volume in 1 s; FVC, forced vital capacity; TLC, total lung capacity; RV, residual volume; FRC, functional residual capacity; IC, inspiratory capacity. Spirometric reference values from European Community for Coal and Steel (ECCS). Short-acting bronchodilator therapy withheld for four hours before testing, patients were tested when clinically stable, and not within two weeks of an exacerbation. Six-minute walk test (6MWT) performed according to international guidelines.[24] AECOPD, Acute exacerbation of COPD. * Excluding one patient who had lung transplant between 4 months and 1-year follow-up assessments.

DISCUSSION

In this study participation in a weekly community-based singing group for one year is associated with increased exercise capacity, reduced anxiety, and improved lung function in patients with COPD who have completed PR. The high attendance rate over one year, (mean 85%), supports the acceptability and feasibility of this intervention. Factors favouring generalisability of these findings are the broad inclusion criteria, COPD patients recruited from typical public hospital pulmonary rehabilitation service and singing group intervention requiring no special training.

We were surprised by the high long-term attendance rate, mean 85%, for this cohort of patients with significant respiratory disease and comorbidities, including two participants with very severe COPD, one of whom had a lung transplant four months after joining the singing group. The qualitative data from this project, reported separately, showed that most participants had not been previously interested in singing and considered the singing group a fun social activity more than a musical endeavour.[21] The reduction in HADS anxiety scores confirms previous research [15] but this is the first report of statistically and clinically significant improvements in 6MWT and lung volumes, albeit that the latter were modest and short-term, with this type of intervention.. The mean reduction in HADS anxiety score of 0.9 units at one year, did not exceed the minimal clinically important difference (MCID) of 1.32.[30] The mean increase in 6MWT of 65m at one year was greater than the MCID of 30m.[31]

This is the first report of serial RV measurement in COPD patients attending a singing group over one year. The small reduction in RV after four months supports the findings of a previous small COPD study although in that study lung volumes were measured immediately after singing.[19] Although the reduction in hospital admission days for AECOPD was not statistically significant, the point estimate was almost one day less per participant in the year attending singing group, compared to the year before starting (excluding the patient who has a lung transplant during the year). If this is a genuine reduction then, at a daily hospital bed day rate of approximately \$NZ800 (GBP460), this represents a saving of \$14080 for this group of 20 patients. The actual cost of running the singing group for 12 months was approximately \$NZ4000. Therefore this low-cost intervention could potentially be cost effective.

Strengths of this study are the broad inclusion criteria, high retention rates with one-year follow-up, comprehensive pulmonary function tests, and pragmatic community context. Previously reported studies of singing intervention for COPD have generally been of short duration, mostly 6-10 weeks.[15,16,18,19] In contrast to studies using professional singing teachers and physiotherapists, we used amateur singing group facilitators, with musical experience and strong group facilitation skills. Our findings confirm those of Morrison and colleagues who showed medium-term (ten months) feasibility for community singing groups for people with COPD in the UK but with a significantly higher attrition rate than we achieved. A significant component of our study was that participants had both completed a PR programme and were enrolled in a weekly maintenance exercise programme. These are likely to be people more motivated to manage their own health and who had already demonstrated an ability to attend weekly sessions. Thus these results can't be readily generalised to a population of people with COPD who have declined or not been offered PR. We believe there may be a role for SG participation for people with COPD who decline PR and have started a controlled study testing this hypothesis (www.anzctr.org.au registry number ACTRN12616000584437). Limitations of our study include that the 6MWT was only performed once at each visit, but participants had all done at least one 6MWT as part of their recent PR programmes so any learning effect is likely to have been minimised.[32] Singing

group members continued to attend maintenance exercise classes which could explain some of the improvement in exercise capacity. However, on average, the participants had been attending exercise classes for approximately one year prior to singing group enrolment and mean 6MWT distance at commencement of singing group was lower than the 6MWT distance at the end of the PR programme for the 14 participants with complete data from the preceding PR programme. The presence of a PR nurse at the singing sessions may have been important. Her role was in 'meeting and greeting' participants, general encouragement to attend, supervising refreshments and organising transport for performances. There was no formal or informal exercise advice provided. In the interviews that formed the qualitative component of this project [21], a key theme was being cared for in a safe environment and the PR nurse presence contributed to this. All participants received usual medical care so therapeutic changes may have affected some, but not all, of the participants. This is a relatively small cohort study without a control group so both type I and type II errors are possible. This analysis also includes a large number of hypothesis tests which inflate the type 1 error rate.

Our findings are relevant to the question of sustaining the benefits of pulmonary rehabilitation.. A possible mechanism for singing group effectiveness is the promotion of physical activity which is considered to be a critical component of PR.[33] Our qualitative data showed that for many patients, attending the weekly singing group was a most enjoyable highlight of their week and worth the extra physical activity it took to get there.[21] Our finding of a reduction in RV after four months, but not 12 months, may reflect type I error rate inflation, and so be due to the play of chance. However, if this is a real result it could reflect a positive effect of singing on respiratory muscles and expiratory airways pressure that is subsequently overtaken by the natural history of the decline in lung function in COPD. In contrast to other studies[15–18] our singing group intervention focussed on fun group singing with no specific breathing exercises. The impact of breathing exercises alone or in addition to singing remains uncertain.[34] Our group met weekly with singing duration of 35 minutes, and no explicit practice at home. It is possible that there is a dose-response relationship, with increased benefit with more frequent singing group classes and singing practice at home. With the very high attendance rate we

274 were not able to attempt an analysis for a dose-response relationship between attendance and
275 outcomes. From our experience, longer classes would not be well tolerated by COPD patients.

276 Our qualitative analysis showed singing group participation was associated with an increased
277 sense of social connection, purpose and meaningful participation which may explain the reduction in
278 anxiety.[21] Although there seems to be an association between anxiety in COPD patients, their health
279 status, and the frequency of AECOPD and hospitalisation, it is complex.[35] However, the reduction in
280 anxiety and increased exercise capacity observed in this study points to the potential for reducing
281 readmissions and supports the use of exercise capacity and readmission for AECOPD, as primary
282 outcome measures for a future randomised controlled trial (RCT).

283 We believe our results are generalisable because of our broad inclusion criteria, recruitment
284 from a typical hospital PR programme and the use of amateurs for singing group facilitation. We have
285 made available on-line our “10 practical top tips” document for setting up and running a community
286 singing group for people living with COPD (see online supplement). We have been able to sustain this
287 intervention long term, free to patients, as it was set up and financed by a charitable trust. The singing
288 group is still going strong after twenty-two months with high attendance including almost all of the
289 founding members, avoiding the ethical issue of withdrawing the intervention at study completion.

291 **CONCLUSIONS**

292 Our findings support the feasibility of long-term participation in a community singing group for
293 breathless adults with COPD and provide evidence of improvement in exercise capacity and
294 reduction in anxiety. These results can inform sample size and selection of outcome measures
295 for a future RCT.

297 **Figure legend:**

298 Figure 1: Study overview

COPD = chronic obstructive pulmonary disease, PR= pulmonary rehabilitation, AECOPD = acute exacerbation of COPD, FEV1 = forced expiratory volume in 1 second, FVC = forced vital capacity, GOLD = Global Initiative for Chronic Obstructive Lung Disease

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Contributors AM conceived the idea of the study, designed the protocol, wrote the first and final drafts of the manuscript, was the senior investigator, and will act as guarantor. SA, HM, MWi, GW, MWe, RB helped design and plan the study and helped write the first and final drafts of the manuscript. GW, AM recruited patients to the study. MWi, AM collected data. MWe was responsible for the analysis.

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Competing interests None

Ethics approval This study was approved by the Wellington Hospital Research Governance Group on 23 September 2014

Data sharing No additional data are available

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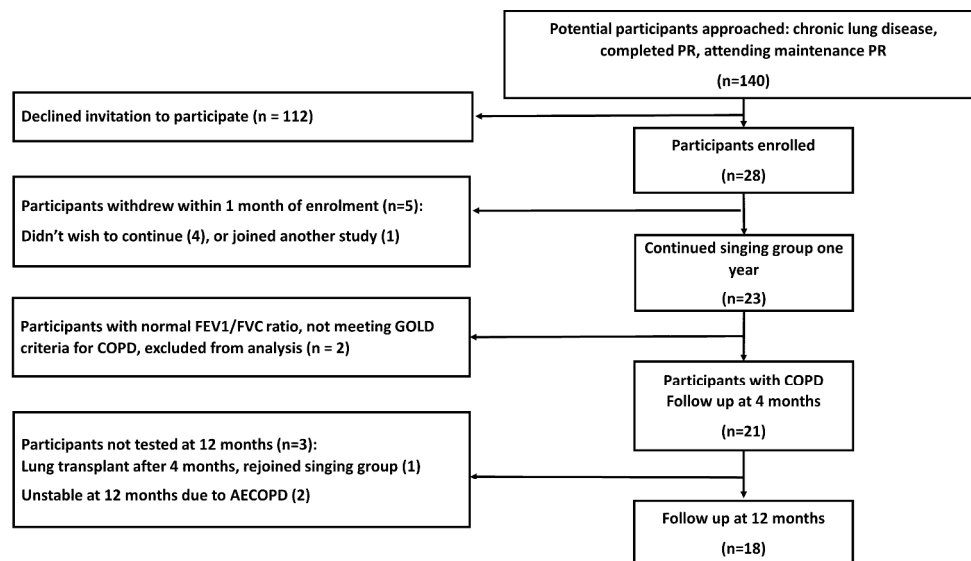


Figure 1: Study overview.

COPD = chronic obstructive pulmonary disease, PR= pulmonary rehabilitation, AECOPD = acute exacerbation of COPD, FEV1 = forced expiratory volume in 1 second, FVC = forced vital capacity, GOLD = Global Initiative for Chronic Obstructive Lung Disease

Figure 1 shows the study overv
338x190mm (300 x 300 DPI)

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Setting up a singing group like Sing Your Lungs Out

We provide links below to two short videos of this singing group and a "10 practical top tips" document for setting up a community singing group for people living with COPD which we hope will inform, motivate and encourage others to set up singing groups.

https://www.dropbox.com/sc/boc5sr7hkcbi6tz/AAAlbUQqOWyvDeJGTnoXVcg-a?preview=NO_Graphics_02.mp4

<https://www.youtube.com/watch?v=fduau0jV09o>

http://www.mrinz.ac.nz/pdfs/How_to_set_up_SYLO.pdf

BMJ Open: first published as 10.1136/bmjopen-2016-014151 on 24 January 2017. Downloaded from <http://bmjopen.bmj.com/> on June 1, 2025 at Department GEZ-LTA
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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Pilot in study title.
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes Introduction para 1-3, pg3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes Introduction para 4, pg 4. No hypotheses, this was a feasibility study.
Methods			
Study design	4	Present key elements of study design early in the paper	Methods, para 1, pg 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Methods, para 1, pg 5 and under 'Singing Group Intervention' pg 6. Specific dates are in first line of Results, pg 7
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	Methods, para 1, pg 5
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	No matched control group
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Methods, 'data collection', pg 5
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Methods, 'Data collection', pg 5

Bias	9	Describe any efforts to address potential sources of bias	Objective lung function tests measured by scientist blinded to previous results. Self reported questionnaires
Study size	10	Explain how the study size was arrived at	Convenience sample, twice the size of previous studies.
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Methods, ‘Analysis’, pg 6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Methods, ‘Analysis’, pg 6
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	N/A
		(d) Cohort study—If applicable, explain how loss to follow-up was addressed	Results, para 1, pg 7 and Figure 1 Study overview
		Case-control study—If applicable, explain how matching of cases and controls was addressed	
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Results, para 1, pg 7 and Study overview Figure 1
		(b) Give reasons for non-participation at each stage	Results, para 1 and figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Results, para 2, pg 7 and Table 1
		(b) Indicate number of participants with missing data for each variable of interest	Table 1
		(c) Cohort study—Summarise follow-up time (eg, average and total amount)	Result, para 1,pg 7
Outcome data	15*	Cohort study—Report numbers of outcome events or summary measures over time	Results, para 3, pg 9 and Table 2 and Figure 2
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(a) Give unadjusted estimates and, if	Admission days adjusted. Other

		applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	results unadjusted. Table 2
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A feasibility study
Discussion			
Key results	18	Summarise key results with reference to study objectives	Discussion para 1
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Discussion para 3, pg 12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Discussion para 4 and 5, pg 12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	Discussion para 6, pg 13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Funding statement pg 14

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Sing Your Lungs Out- A community singing group for chronic obstructive pulmonary disease: a one-year pilot study

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Primary Subject Heading:	Respiratory medicine
Secondary Subject Heading:	Patient-centred medicine
Keywords:	Chronic Obstructive Pulmonary Disease, Pulmonary Rehabilitation, Singing

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ABSTRACT

Objective Singing group participation may benefit patients with chronic obstructive pulmonary disease (COPD). Previous studies are limited by small numbers of participants and short duration of generally, hospital-based singing group intervention. This study examines the feasibility of long-term participation in a community singing group for patients with COPD who had completed pulmonary rehabilitation (PR).

Methods This was a feasibility cohort study. Patients with COPD who had completed PR and were enrolled in a weekly community exercise group, were recruited to a new community-based singing group which met weekly for over one year. Measurements at baseline, four months and one year comprised comprehensive pulmonary function tests including lung volumes, six minute walk tests (6MWT), Clinical COPD Questionnaire (CCQ), Hospital Anxiety and Depression Scale (HADS), and hospital admission days for acute exacerbation of COPD (AECOPD) for one year before and after the first singing group session.

Findings There were 28 participants with chronic lung disease recruited from 140 people approached. Five withdrew in the first month. Twenty-one participants meeting GOLD criteria for COPD completed four-month, and 18 completed one-year assessments. The mean attendance was 85%. For the pre-specified primary outcome measure, total HADS score, difference between baseline and 12 months was -0.9, 95% CI -3.0 to 1.2, $p = 0.37$. Of the secondary measures, a significant reduction was observed for HADS Anxiety Score after one year of -0.9 (95% CI -1.8 to -0.1) points, $P=0.038$ and an increase in the 6MWT at one year, of 65 (95% CI 35 to 99) m compared to baseline $P<0.001$.

Conclusions Our findings support the feasibility of long-term participation in a community singing group for breathless adults with COPD who have completed PR and are enrolled in a

weekly community exercise group and provide evidence of improved exercise capacity and a reduction in anxiety.

Strengths and limitations of this study:

- High attendance and retention rates over one-year follow-up support the feasibility of this intervention.
- Recruitment from a typical hospital PR programme and low cost community setting of the singing group supports the practicality and reproducibility of the intervention
- This is the first report of serial lung volume measurements in COPD patients attending a singing group over one year.
- This is a relatively small cohort study.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD), characterised by persistent airflow limitation that is usually progressive, is an increasingly common syndrome.[1] Common symptoms include progressive breathlessness, cough and sputum production as well as anxiety and depression.[2,3] The chronic breathlessness in COPD is physically limiting and socially isolating, adding further to depression and anxiety.[4] Current pharmacological options have limited benefits and significant adverse effects driving the need for cost-effective, non-pharmacological, person-centred, community-based interventions.[5–8] Pulmonary Rehabilitation (PR) is one of the most effective therapies for COPD, improving quality of life, exercise tolerance, and breathlessness.[9] An important research question is how the benefits of PR can be sustained and augmented.[10]

There is a growing interest in the therapeutic potential of singing for COPD. Singing involves inspiratory expansion (using the diaphragm, external intercostal, and accessory muscles), active exhalation (incremental recruitment of abdominal and internal intercostal muscles) and optimal posture.[11] Singing, therefore, has the potential to improve breathing control and posture, and theoretically to reduce residual volume (RV), which is a manifestation of lung hyperinflation. Improvement in psychological wellbeing has been reported in healthy subjects and people with a variety of chronic conditions participating in singing groups.[12–14]

Two randomised controlled trials of singing group interventions in COPD report improvements in quality of life and reduction in anxiety, although not in lung function.[15,16], One study examining the effects of adding therapeutic singing to PR programme showed no benefit in quality of life or exercise tolerance,[17] whilst two studies have reported improvement in maximal expiratory pressure.[18,19] The limitations of these studies include small sample sizes and short duration.[15–19] A non-experimental feasibility study of singing group intervention for people with COPD in the United Kingdom recruited 106 people into 6 singing groups, and followed the group for ten months. [20] In that report it was unclear if the participants had participated in PR before the singing intervention. That study reported a 34% attrition rate and small statistically significant differences in St Georges Respiratory

Questionnaire as well as spirometry parameters measured by a portable spirometry device. We wished to explore whether singing group participation as an intervention, is acceptable and sustainable for a longer time period with adequate retention rates, to a broad group of COPD patients who had completed PR and whether the benefits can be achieved in a community setting taking a low-cost, pragmatic approach that might be easily reproducible in other centres. We are interested in the potential of singing group participation for patients with COPD as a means to sustain the benefits of PR. We are also interested in identifying measures sensitive to change during the intervention period and the feasibility of this measurement. The effects of singing group participation on hyperinflation and lung function in COPD patients remain unclear and we wished to measure both spirometry and lung volumes over a significant time period in singing group participants, looking for any effect on residual volume as well as airflow.

The purpose of this cohort study was to assess the feasibility of community singing group participation for one year, for breathless patients with COPD who had completed PR. We report here the quantitative results of the study, the qualitative results are reported separately.[21]

METHODS

This was a prospective feasibility study. Patients with COPD or another chronic lung disease, who had completed an eight-week, hospital-based PR programme, and were enrolled in a weekly community exercise class, were invited by the PR nurse to join a new community-based singing group for the purposes of this study. The group was based in Wellington, New Zealand. In our institution, patients are enrolled in PR programmes if they have chronic lung disease and a Modified Medical Research Council dyspnoea scale of at least grade 2. All patients completing a PR programme are encouraged to enrol in a weekly community exercise class. We report on those participants with physician-diagnosed COPD based on GOLD criteria.[22] There were no further recruitment restrictions based on age, severity of disease, cognition, singing ability, or co-morbidities. The study was approved by the Wellington Hospital Research Governance Group, and all patients gave written informed consent. The trial was registered at www.anzctr.org.au, registry number ACTRN12615000736549.

Data collection

Patient demographics, pulmonary function tests, six-minute walk test (6MWT), Hospital Anxiety and Depression Scale (HADS)[23] and the Clinical COPD Questionnaire (CCQ)[24] were measured at baseline, four months and one year after enrolment. Spirometry and lung volumes including forced expiratory volume in 1s (FEV1), forced vital capacity (FVC), total lung capacity (TLC), residual volume (RV), functional residual capacity (FRC) and inspiratory capacity (IC) were measured according to ATS/ERS standards (body volume constant plethysmography Masterlab, Erich-Jaeger, Wurzburg, Germany) using the reference values of the European Community for Coal and Steel (ECCS).[25] Short-acting bronchodilator therapy was withheld for four hours prior to testing, and patients were tested when clinically stable, and not within two weeks of an exacerbation. Six-minute walk test (6MWT) was performed according to international guidelines [26] except that only one test was performed at each measurement point, rather than the recommended two. All participants had performed at least one, and mostly two, 6MWT previously as part of their PR programme.

The respiratory scientist performing the pulmonary function tests was masked to the results of previous assessments. Questionnaires were self-completed. Each patient's electronic health record was searched for diagnosis, comorbidities and admissions where the primary discharge code was an acute exacerbation of COPD. Hospital admission data for acute exacerbation of COPD were recorded for the 12 months before enrolment and 12 months starting from the date of enrolment. PR programme information, the date, sessions attended, and 6MWT results at entry and completion, were obtained from the PR nurse who runs the programme.

Singing group intervention

The singing group (Sing Your Lungs Out) met for one hour, weekly, in an urban community hall, continuously throughout the study period. An amateur singing group facilitator (SGF) led the group and a PR nurse attended all sessions. Each rehearsal comprised a five minute warm up session, 35 minutes singing, a five minute warm down and 15 minutes social morning-tea time. It was run free of charge to patients. The SGF and the group chose the singing repertoire together, including a wide mix of genres (eg pop, musicals, traditional Māori songs, folk songs, rounds) with attention to the group's voice range and capacity for phrase lengths. The SGF also discussed breathing for singing techniques as the year progressed and as the group gained confidence. No music reading ability was required. We made recordings of songs to allow practice at home although this was optional. Collaboration with a local boys' high school developed from student piano accompaniment to working with the senior boys' chorale including some joint performances. Over the year, the participants delivered six public performances, supported by the senior chorale from the local school on four occasions. Singing group members remained enrolled in the community exercise classes, as well as singing group.

Analysis

Continuous variables were compared using a mixed linear model for most variables with an unstructured variance-covariance correlation structure. Hospital admission days were right skew and were compared with a paired Wilcoxon test and Hodges-Lehmann estimator of the difference. Although individual comparisons are presented with 95% confidence intervals a large number of statistical tests have been carried out and this will inflate the Type I error rate. SAS version 9.4 was used.

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RESULTS

Out of 140 people with chronic lung disease approached, 28 participants (20%) were enrolled in the singing group in five months: October 2014 to February 2015. The mean (SD) time from completion of past PR was 1.2 (1.2) years. Response to past PR by the change in 6MWT was available for 14 participants and for these participants the distance had improved from a mean (SD) of 316 (126) m to 356 (148) m. Five participants withdrew within one month of enrolment as they did not wish to continue (n=4) or were recruited into another study (n=1). At baseline assessment, twenty-one participants had COPD as defined by GOLD criteria[22] but two participants had normal FEV1/FVC ratio on spirometry with a clinical diagnosis of interstitial lung disease. They continued to attend singing group but were excluded from this analysis. The 21 participants with COPD attended the singing group for at least one year and had measurements at enrolment and after four months. Eighteen participants were reassessed after 12 months: one had undergone lung transplant and two had such frequent exacerbations that stable follow-up testing was not possible. Figure 1 shows the study overview.

The participants with COPD had a wide range of disease severity and comorbidities. Mean (SD) FEV1% at baseline was 60.3 (21.1), median 57.1, range 14.6-110. The majority (66%) of participants had moderate COPD by GOLD criteria but 20% had severe or very severe COPD, similar to the proportions of COPD severity in the NZ community.[27] Six patients (29%) had an FEV1 at baseline of less than one litre. Common comorbidities were bronchiectasis, congestive cardiac failure, diabetes, and obesity. Six of 21 (29%) were Māori, consistent with the higher prevalence of COPD in Māori in New Zealand who constitute only 6% of the total population over 50 years.[28] The mean (SD) attendance rate for the 12 months was 85% (12.1). Table 1 shows characteristics of the study population at baseline.

184 Table 1 Characteristics of the study population

	N=21		
Age (years) mean (SD) [range]	68.8 (9.8) [51 to 91]		
Sex	N/21 (%)		
Men	8 (38)		
Women	13 (62)		
Ethnicity			
European	14 (67)		
Maori	6 (29)		
Asian	1 (5)		
Smoking history			
Current smoker	1 (5)		
Ex-smoker	18 (86)		
Never smoker	2 (10)		
COPD severity (FEV1% predicted)			
≥80% (mild)	3 (14)		
50-79% (moderate)	14 (66)		
30-49% (severe)	2 (10)		
<30% (very severe)	2 (10)		
COPD mortality risk ^a			
BODE score: 0-2	4 (19)		
3-4	8 (38)		
5-6	6 (29)		
7-10	3 (14)		
Continuous long term domiciliary oxygen therapy	2 (10)		
Comorbidities ^b			
Bronchiectasis	3 (14)		
Heart failure	6 (29)		
Diabetes	7 (33)		
Anxiety on treatment	5 (24)		
Atrial fibrillation	8 (38)		
Ischaemic Heart Disease	5 (24)		
Clinical characteristics	Mean (SD)	Median (IQR)	Min to max
FEV1 (L)	1.3(0.5)	1.3 (0.9 to 1.6)	0.6 to 2.6
FEV1 (% predicted)	60.3 (21.1)	57.1 (50 to 72.4)	14.6 to 110.3
FVC (L)	2.85 (0.9)	2.75 (2.2 to 3.0)	1.8 to 4.9
FVC (%predicted)	103.5 (26.9)	102.5 (85.3 to 126.7)	53.4 to 160.4
FEV1/FVC	0.47 (0.14)	0.47 (0.36 to 0.56)	0.22 to 0.68
TLC (L)	6.38 (1.99)	5.68 (5.2 to 7.0)	3.57 to 11.3
RV (L)	3.39 (1.52)	3.06 (2.6 to 3.4)	1.67 to 8.52
SpO2 at rest (%)	95.4 (2.3)	96 (93 to 97)	89 to 99
6MWT (m)	300 (110)	290 (212 to 349)	132 to 508
BMI (kg/m ²)	29.1 (7.6)	28.0 (23.9 to 32.5)	20.1 to 53.0
Questionnaires			
CCQ	2.11 (0.83)	1.9 (1.7 to 2.8)	0.4 to 3.3
HADS anxiety	5.8 (2.8)	6 (4 to 7)	1 to 11
HADS depression	4.1 (2.3)	3 (3 to 6)	1 to 10
HADS total	9.9 (4.6)	9 (7 to 12)	2 to 21

185 a:BODE score- The body-mass index, airflow obstruction, dyspnoea and exercise capacity index in
 186 COPD [29] b Some participants had multiple comorbidities.

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187 FEV1- forced expiratory volume in one second, FVC- forced vital capacity, TLC- total lung capacity RV-
188 residual volume, SpO2-oxygen saturation measured by a pulse oximeter, 6MWT- six-minute walk test,
189 BMI- body mass index, CCQ- clinical COPD questionnaire, HADS- hospital anxiety and depression score.
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191 There was strong evidence for an increase in 6MWT after four months, with a mean increase of 28
192 (95%CI 5 to 52) m, $p = 0.019$, increasing further to 65 (95%CI 35 to 99) m, $p < 0.001$ at one year. HADS
193 Anxiety scores were lower at one year with a mean change from baseline of -0.9 (95%CI -1.8 to -0.1) p
194 = 0.038. Lung function tests showed a reduction in RV, mean decrease 130 (95%CI -250 to -3) ml, p
195 = 0.046 and total lung capacity, mean decrease 150 (95%CI -290 to -20) ml, $p = 0.023$ after four
196 months, but no significant differences at 12 months compared to baseline. The questionnaire and
197 clinical measurements, and their changes are shown in Table 2.

199 Table 2: Changes from baseline in lung function, questionnaires and hospital admission days.

Variable	Mean (SD)			Difference from baseline (95% CI)	
	Baseline N=21	Four months N=21	One year N=18	Four months	One year
FEV1 (L)	1.32 (0.5)	1.34 (0.5)	1.44 (0.5)	0.02 (-0.01 to 0.06) P=0.21	0.04 (-0.05 to 0.12) P=0.44
FEV1%	60.3 (21.1)	61.9 (22.3)	64.5 (20.2)	1.6 (-0.1 to 3.4) P=0.065	2.4 (-1.4 to 6.1) P=0.21
FVC (L)	2.85 (0.9)	2.81 (0.92)	2.91 (0.97)	-0.04 (-0.15 to 0.06) P=0.38	-0.04 (-0.17 to 0.09) P=0.50
FVC%	103.5 (26.9)	103.1 (30.4)	107.0 (24.8)	-0.5 (-4.5 to 3.6) P=0.81	-0.02 (-4.5 to 4.4) P=0.99
FEV1/FVC	0.47 (0.14)	0.48 (0.13)	0.50 (0.12)	0.01 (-0.004 to 0.03) P=0.13	0.02 (-0.002 to 0.03) P=0.08
TLC (L)	6.38 (1.99)	6.22 (1.86)	6.23 (1.7)	-0.15 (-0.29 to -0.02) P=0.023	-0.04 (-0.21 to 0.13) P=0.61
TLC%	117.8 (20.9)	115.2 (20.2)	116.4 (20.8)	-2.6 (-4.8 to -0.4) P=0.021	-0.7 (-3.7 to 2.3) P=0.61
RV (L)	3.39 (1.52)	3.27 (1.44)	3.22 (1.18)	-0.13 (-0.25 to -0.003) P=0.046	0.06 (-0.16 to 0.27) P=0.58
RV%	156.1 (59.9)	150.2 (57.1)	145.7 (44.1)	-5.9 (-11.5 to -0.3) P=0.04	1.3 (-7.8 to 10.3) P=0.77
IC (L)	2.29 (0.86)	2.35 (0.83)	2.33 (0.87)	0.06 (-0.03 to 0.15) P=0.18	-0.07 (-0.18 to 0.04) P=0.21
IC%	107.2 (27.2)	110.1 (25.7)	108.6 (24.3)	3.0 (-1.8 to 7.7) P=0.21	-2.9 (-9.3 to 3.5) P=0.35
IC/TLC	0.37 (0.09)	0.39 (0.09)	0.38 (0.09)	0.02 (0.001 to 0.03) P=0.037	-0.01 (-0.03 to 0.01) P=0.36
RV/TLC	0.52 (0.09)	0.52 (0.09)	0.52 (0.09)	-0.01 (-0.02 to 0.01) P=0.45	0.01 (-0.01 to 0.03) P=0.35
6MWT (m)	300 (110)	328 (118)	377 (104)	28 (5 to 52) P=0.019	65 (35 to 99) P<0.001
CCQ	2.11 (0.83)	2.08 (0.86)	2.31 (1.04)	-0.03 (-0.31 to 0.26) P=0.84	0.26 (-0.04 to 0.57) P=0.08
HADS Anxiety	5.8 (2.8)	5.81 (3.52)	4.67 (3.2)	0 (-1.2 to 1.2) P=0.99	-0.9 (-1.8 to -0.1) P=0.038
HADS Depression	4.1 (2.3)	3.19 (2.56)	4.0 (3.91)	-0.9 (-2.1 to 0.2) P=0.11	0.1 (-1.3 to 1.6) P=0.85

HADS Total	9.9 (4.6)	9.0 (5.7)	8.7 (6.4)	-0.9 (-3.0 to 1.2) P=0.37	-0.8 (-2.6 to 1.0) P=0.35
		12 months prior to enrolment	12 months after enrolment	HL estimator (95% CI)	
Hospital admission days for AECOPD N=20* Mean (SD)		3.6 (7.9)	2.7 (7.3)	-1.0 (-8.5 to 3.0) P=0.40	

FEV1, Forced expiratory volume in 1 s; FVC, forced vital capacity; TLC, total lung capacity; RV, residual volume; FRC, functional residual capacity; IC, inspiratory capacity. AECOPD, Acute exacerbation of COPD. * Excluding one patient who had lung transplant between 4 months and 1-year follow-up assessments.

DISCUSSION

This study has shown that recruitment and retention of patients with COPD to a community singing group (SG) is feasible. The high attendance rate over one year, mean 85%, supports the acceptability and feasibility of this intervention. In this study, participation in a weekly community-based singing group for one year is associated with increased exercise capacity and reduced anxiety in patients with COPD who have completed PR and are attending a community exercise group.

We were surprised by the high long-term attendance rate, for this cohort of patients with significant respiratory disease and comorbidities, including two participants with very severe COPD, one of whom had a lung transplant four months after joining the singing group. The qualitative data from this project, reported separately, showed that most participants had not been previously interested in singing and considered the singing group a fun social activity more than a musical endeavour.[21] The reduction in HADS anxiety scores confirms previous research [15] but this is the first report of statistically and clinically significant improvement in 6MWT with this type of intervention. The mean reduction in HADS anxiety score of 0.9 units at one year did not exceed the minimal clinically important difference (MCID) of 1.32.[30] The mean increase in 6MWT of 65m at one year was greater than the MCID of 30m.[31] This is the first report of serial RV measurement in COPD patients attending a singing group over one year. The small (130ml) statistically significant reduction in RV after four months but not 12 months may reflect type I error rate inflation, and so be due to the play of chance. A

223 previous small COPD study showed a median fall in RV of 270ml in four patients after 10 weeks of
224 singing classes.[19] On the other hand, Bonilha and colleagues did not find any significant change in
225 RV in 15 participants after 24 weeks of singing classes.[18] They did report a small but statistically
226 significant difference in RV two minutes after a short singing session in subjects from the singing group
227 (where RV reduced) and a control group (where RV increased) but no difference between the groups at
228 30 minutes.[18] Although the reduction in hospital admission days for AECOPD per year was not
229 statistically significant, the point estimate was almost one day less per participant in the year attending
230 singing group, compared to the year before starting (excluding the patient who had a lung transplant
231 during the year). The actual cost of running the singing group for 12 months was approximately
232 \$NZ4,000 (GBP 2,363). Any significant reduction in hospital bed days, even one day per patient per
233 year, as a result of the intervention would likely make this low cost intervention cost effective.

234 Strengths of this study are the one year duration, high retention rates, comprehensive
235 pulmonary function tests and low-cost community setting. Previously reported studies of singing
236 intervention for COPD have generally been of short duration, mostly 6-10 weeks.[15,16,18,19] In
237 contrast to studies using professional singing teachers and physiotherapists, we used amateur singing
238 group facilitators, with musical experience and strong group facilitation skills. Our findings confirm those
239 of Morrison and colleagues who showed medium-term (ten months) feasibility for community singing
240 groups for people with COPD in the UK but they had a significantly higher attrition rate.[20] A
241 significant component of our study was that participants had both completed a PR programme and
242 were enrolled in a weekly maintenance exercise programme. These are likely to be people more
243 motivated to manage their own health and who had already demonstrated an ability to attend weekly
244 sessions. It is possible that some of the benefit in reduced hospital admissions could be explained by
245 recent completion of PR.[32] These results can't be readily generalised to a population of people with
246 COPD who have declined or not been offered PR. We believe there may be a role for SG participation
247 for people with COPD who decline PR and have started a controlled study testing this hypothesis
248 (www.anzctr.org.au registry number ACTRN12616000584437). Limitations of our study include that the

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6MWT was only performed once at each visit, but participants had all done at least one 6MWT as part of their recent PR programmes so any learning effect is likely to have been minimised.[33] Singing group members remained enrolled in maintenance exercise classes after PR, as recommended by international guidelines [32]. There is conflicting evidence as to whether maintenance exercise classes preserve the benefits on exercise capacity of PR, but no evidence that maintenance exercise classes improve exercise capacity in people who have completed PR [32]. On average, our participants had been attending exercise classes for approximately one year prior to singing group enrolment and mean 6MWT distance at commencement of singing group was substantially lower than the 6MWT distance at the end of the PR programme for the 14 participants with complete data from the preceding PR programme. This suggests a low likelihood that the substantial improvement in 6MWT distance during 12 months of SG participation could be explained by exercise class attendance alone. The presence of a PR nurse at the singing sessions may have been important. Her role was in 'meeting and greeting' participants, general encouragement to attend, supervising refreshments and organising transport for performances. There was no formal or informal exercise advice provided. In the interviews that formed the qualitative component of this project [21], a key theme was being cared for in a safe environment and the PR nurse presence contributed to this. All participants received usual medical care so therapeutic changes may have affected some, but not all, of the participants. This is a relatively small cohort study without a control group so both type I and type II errors are possible. This analysis also includes a large number of hypothesis tests which inflate the type 1 error rate.

Our findings are relevant to the question of sustaining the benefits of pulmonary rehabilitation. A possible mechanism for singing group effectiveness is the promotion of physical activity which is considered to be a critical component of PR.[34] Our qualitative data showed that for many patients, attending the weekly singing group was a most enjoyable highlight of their week and worth the extra physical activity it took to get there.[21]. In contrast to other studies[15–18] our singing group intervention focussed on fun group singing with no specific breathing exercises. The impact of breathing exercises alone or in addition to singing remains uncertain.[35] Our group met weekly with

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3 275 singing duration of 35 minutes, and no explicit practice at home. It is possible that there is a dose-
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5 276 response relationship, with increased benefit with more frequent singing group classes and singing
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7 277 practice at home. With the very high attendance rate we were not able to attempt an analysis for a
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9 278 dose-response relationship between attendance and outcomes.
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11 279 Our qualitative analysis showed singing group participation was associated with an increased
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13 280 sense of social connection, purpose and meaningful participation which may explain the reduction in
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15 281 anxiety.[21] Although there seems to be an association between anxiety in COPD patients, their health
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17 282 status, and the frequency of AECOPD and hospitalisation, it is complex.[36] However, the reduction in
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19 283 anxiety and increased exercise capacity observed in this study points to the potential for reducing
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21 284 readmissions and supports the use of exercise capacity and readmission for AECOPD, as primary
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23 285 outcome measures for a future randomised controlled trial (RCT).
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27 286 We believe our results could be replicated by others given recruitment from a typical hospital PR
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29 287 programme and the practical, low cost approach to running the singing group, including community
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31 288 venue and the use of amateurs for singing group facilitation. We have made available on-line our “10
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33 289 practical top tips” document for setting up and running a community singing group for people living with
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35 290 COPD (see online supplement). We have been able to sustain this intervention long term, free to
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37 291 patients, as it was set up and financed by a charitable trust. The singing group is still going strong after
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39 292 twenty-four months with high attendance including almost all of the founding members, avoiding the
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41 293 ethical issue of withdrawing the intervention at study completion.
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46 295 **CONCLUSIONS**
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48 296 Our findings support the feasibility of long-term participation in a community singing group for
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50 297 breathless adults with COPD who have completed PR and are enrolled in a weekly community
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52 298 exercise group and provide evidence of improvement in exercise capacity and reduction in
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54 299 anxiety. These results can inform sample size and selection of outcome measures for a future
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56 300 RCT.
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Figure legend:

Figure 1: Study overview

COPD = chronic obstructive pulmonary disease, PR= pulmonary rehabilitation, AECOPD = acute exacerbation of COPD, FEV1 = forced expiratory volume in 1 second, FVC = forced vital capacity, GOLD = Global Initiative for Chronic Obstructive Lung Disease

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Contributors AM conceived the idea of the study, designed the protocol, wrote the first and final drafts of the manuscript, was the senior investigator, and will act as guarantor. SA, HM, MWi, GW, MWe, RB helped design and plan the study and helped write the first and final drafts of the manuscript. GW, AM recruited patients to the study. MWi, AM collected data. MWe was responsible for the analysis.

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Competing interests None

Ethics approval This study was approved by the Wellington Hospital Research Governance Group on 23 September 2014

Data sharing No additional data are available

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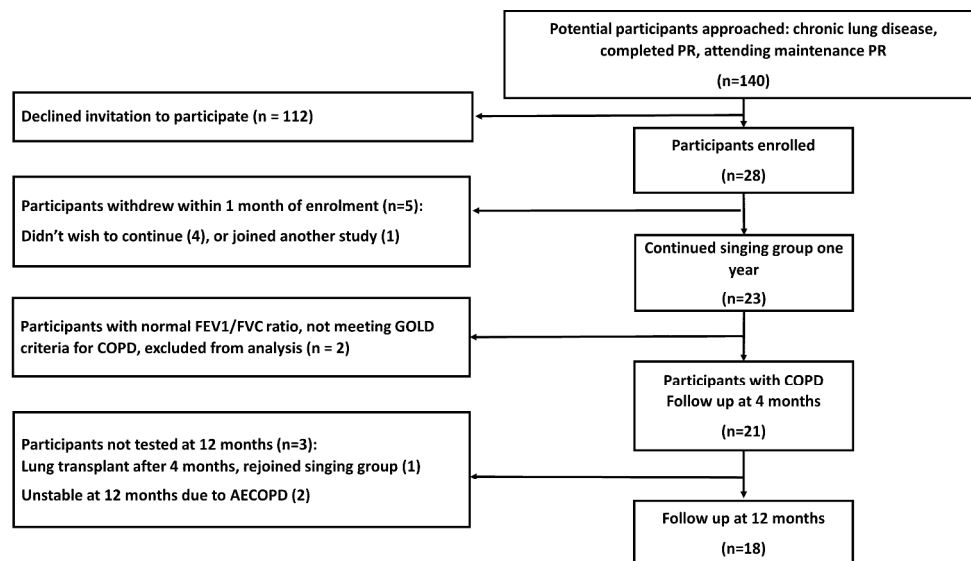


Figure 1: Study overview.

COPD = chronic obstructive pulmonary disease, PR= pulmonary rehabilitation, AECOPD = acute exacerbation of COPD, FEV1 = forced expiratory volume in 1 second, FVC = forced vital capacity, GOLD = Global Initiative for Chronic Obstructive Lung Disease

Figure 1 shows the study overv
338x190mm (300 x 300 DPI)

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Setting up a singing group like Sing Your Lungs Out

We provide links below to two short videos of this singing group and a "10 practical top tips" document for setting up a community singing group for people living with COPD which we hope will inform, motivate and encourage others to set up singing groups.

- https://www.dropbox.com/sc/boc5sr7hkcbi6tz/AAAlbUQqOWyvDeJGTnoXVcg-a?preview=NO_Graphics_02.mp4
- <https://www.youtube.com/watch?v=fduau0jV09o>
- http://www.mrinz.ac.nz/pdfs/How_to_set_up_SYLO.pdf

BMJ Open: first published as 10.1136/bmjopen-2016-014151 on 24 January 2017. Downloaded from <http://bmjopen.bmj.com/> on June 1, 2025 at Department GEZ-LTA
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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Pilot in study title.
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes Introduction para 1-3, pg3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes Introduction para 4, pg 4. No hypotheses, this was a feasibility study.
Methods			
Study design	4	Present key elements of study design early in the paper	Methods, para 1, pg 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Methods, para 1, pg 5 and under 'Singing Group Intervention' pg 6. Specific dates are in first line of Results, pg 7
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	Methods, para 1, pg 5
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	No matched control group
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Methods, 'data collection', pg 5
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Methods, 'Data collection', pg 5

Bias	9	Describe any efforts to address potential sources of bias	Objective lung function tests measured by scientist blinded to previous results. Self reported questionnaires
Study size	10	Explain how the study size was arrived at	Convenience sample, twice the size of previous studies.
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Methods, ‘Analysis’, pg 6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Methods, ‘Analysis’, pg 6
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	N/A
		(d) Cohort study—If applicable, explain how loss to follow-up was addressed	Results, para 1, pg 7 and Figure 1 Study overview
		Case-control study—If applicable, explain how matching of cases and controls was addressed	
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Results, para 1, pg 7 and Study overview Figure 1
		(b) Give reasons for non-participation at each stage	Results, para 1 and figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Results, para 2, pg 7 and Table 1
		(b) Indicate number of participants with missing data for each variable of interest	Table 1
		(c) Cohort study—Summarise follow-up time (eg, average and total amount)	Result, para 1,pg 7
Outcome data	15*	Cohort study—Report numbers of outcome events or summary measures over time	Results, para 3, pg 9 and Table 2 and Figure 2
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(a) Give unadjusted estimates and, if	Admission days adjusted. Other

		applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	results unadjusted. Table 2
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A feasibility study
Discussion			
Key results	18	Summarise key results with reference to study objectives	Discussion para 1
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Discussion para 3, pg 12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Discussion para 4 and 5, pg 12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	Discussion para 6, pg 13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Funding statement pg 14

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Sing Your Lungs Out- A community singing group for chronic obstructive pulmonary disease: a one-year pilot study

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ABSTRACT

Objective Singing group participation may benefit patients with chronic obstructive pulmonary disease (COPD). Previous studies are limited by small numbers of participants and short duration of generally, hospital-based singing group intervention. This study examines the feasibility of long-term participation in a community singing group for patients with COPD who had completed pulmonary rehabilitation (PR).

Methods This was a feasibility cohort study. Patients with COPD who had completed PR and were enrolled in a weekly community exercise group, were recruited to a new community-based singing group which met weekly for over one year. Measurements at baseline, four months and one year comprised comprehensive pulmonary function tests including lung volumes, six minute walk test (6MWT), Clinical COPD Questionnaire (CCQ), Hospital Anxiety and Depression Scale (HADS), and hospital admission days for acute exacerbation of COPD (AECOPD) for one year before and after the first singing group session.

Findings There were 28 participants with chronic lung disease recruited from 140 people approached. Five withdrew in the first month. Twenty-one participants meeting GOLD criteria for COPD completed four-month, and 18 completed one-year assessments. The mean attendance was 85%. For the pre-specified primary outcome measure, total HADS score, difference between baseline and 12 months was -0.9, 95% CI -3.0 to 1.2, $p = 0.37$. Of the secondary measures, a significant reduction was observed for HADS Anxiety Score after one year of -0.9 (95% CI -1.8 to -0.1) points, $P=0.038$ and an increase in the 6MWT at one year, of 65 (95% CI 35 to 99) m compared to baseline $P<0.001$.

Conclusions Our findings support the feasibility of long-term participation in a community singing group for adults with COPD who have completed PR and are enrolled in a weekly

community exercise group and provide evidence of improved exercise capacity and a reduction in anxiety.

Strengths and limitations of this study:

- High attendance and retention rates over one-year follow-up support the feasibility of this intervention.
- Recruitment from a typical hospital PR programme and low cost community setting of the singing group supports the practicality and reproducibility of the intervention
- This is the first report of serial lung volume measurements in COPD patients attending a singing group over one year.
- This is a relatively small cohort study.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD), characterised by persistent airflow limitation that is usually progressive, is an increasingly common syndrome.[1] Common symptoms include progressive breathlessness, cough and sputum production as well as anxiety and depression.[2,3] The chronic breathlessness in COPD is physically limiting and socially isolating, adding further to depression and anxiety.[4] Current pharmacological options have limited benefits and significant adverse effects driving the need for cost-effective, non-pharmacological, person-centred, community-based interventions.[5–8] Pulmonary Rehabilitation (PR) is one of the most effective therapies for COPD, improving quality of life, exercise tolerance, and breathlessness.[9] An important research question is how the benefits of PR can be sustained and augmented.[10]

There is a growing interest in the therapeutic potential of singing for COPD. Singing involves inspiratory expansion (using the diaphragm, external intercostal, and accessory muscles), active exhalation (incremental recruitment of abdominal and internal intercostal muscles) and optimal posture.[11] Singing, therefore, has the potential to improve breathing control and posture, and theoretically to reduce residual volume (RV), which is a manifestation of lung hyperinflation. Improvement in psychological wellbeing has been reported in healthy subjects and people with a variety of chronic conditions participating in singing groups.[12–14]

Two randomised controlled trials of singing group interventions in COPD report improvements in quality of life and reduction in anxiety, although not in lung function.[15,16], One study examining the effects of adding therapeutic singing to PR programme showed no benefit in quality of life or exercise tolerance,[17] whilst two studies have reported improvement in maximal expiratory pressure.[18,19] The limitations of these studies include small sample sizes and short duration.[15–19] A non-experimental feasibility study of singing group intervention for people with COPD in the United Kingdom recruited 106 people into 6 singing groups, and followed the group for ten months. [20] In that report it was unclear if the participants had participated in PR before the singing intervention. That study reported a 34% attrition rate and small statistically significant differences in St Georges Respiratory

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3 88 Questionnaire as well as spirometry parameters measured by a portable spirometry device. We wished
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5 89 to explore whether singing group participation as an intervention, is acceptable and sustainable for a
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7 90 longer time period with adequate retention rates, to a broad group of COPD patients who had
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9 91 completed PR and whether the benefits can be achieved in a community setting taking a low-cost,
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11 92 pragmatic approach that might be easily reproducible in other centres. We are interested in the
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13 93 potential of singing group participation for patients with COPD as a means to sustain the benefits of PR.
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15 94 We are also interested in identifying measures sensitive to change during the intervention period and
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17 95 the feasibility of this measurement. The effects of singing group participation on hyperinflation and lung
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27 99 The purpose of this cohort study was to assess the feasibility of community singing group
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29 100 participation for one year, for breathless patients with COPD who had completed PR. We report here
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31 101 the quantitative results of the study, the qualitative results are reported separately.[21]
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METHODS

This was a prospective feasibility study. Patients with COPD or another chronic lung disease, who had completed an eight-week, hospital-based PR programme, and were enrolled in a weekly community exercise class, were invited by the PR nurse to join a new community-based singing group for the purposes of this study. The invitation was to the group as a whole and no individual approach was made. The group was based in Wellington, New Zealand. In our institution, patients are enrolled in PR programmes if they have chronic lung disease and a Modified Medical Research Council dyspnoea scale of at least grade 2. All patients completing a PR programme are encouraged to enrol in a weekly community exercise class. We report on those participants with physician-diagnosed COPD based on GOLD criteria.[22] There were no further recruitment restrictions based on age, severity of disease, cognition, singing ability, or co-morbidities. The study was approved by the Wellington Hospital Research Governance Group, and all patients gave written informed consent. The trial was registered at www.anzctr.org.au, registry number ACTRN12615000736549.

Data collection

Patient demographics, pulmonary function tests, six-minute walk test (6MWT), Hospital Anxiety and Depression Scale (HADS)[23] and the Clinical COPD Questionnaire (CCQ)[24] were measured at baseline, four months and one year after enrolment. Spirometry and lung volumes including forced expiratory volume in 1s (FEV1), forced vital capacity (FVC), total lung capacity (TLC), residual volume (RV), functional residual capacity (FRC) and inspiratory capacity (IC) were measured according to ATS/ERS standards (body volume constant plethysmography Masterlab, Erich-Jaeger, Wurzburg, Germany) using the reference values of the European Community for Coal and Steel (ECCS).[25] Short-acting bronchodilator therapy was withheld for four hours prior to testing, and patients were tested when clinically stable, and not within two weeks of an exacerbation. Six-minute walk test (6MWT) was performed according to international guidelines [26] except that only one test was performed at each measurement point, rather than the recommended two. All participants had performed at least one, and mostly two, 6MWT previously as part of their PR programme.

The respiratory scientist performing the pulmonary function tests was masked to the results of previous assessments. Questionnaires were self-completed. Each patient's electronic health record was searched for diagnosis, comorbidities and admissions where the primary discharge code was an acute exacerbation of COPD. Hospital admission data for acute exacerbation of COPD were recorded for the 12 months before enrolment and 12 months starting from the date of enrolment. PR programme information, the date, sessions attended, and 6MWT results at entry and completion, were obtained from the PR nurse who runs the programme.

Singing group intervention

The singing group (Sing Your Lungs Out) met for one hour, weekly, in an urban community hall, continuously throughout the study period. An amateur singing group facilitator (SGF) led the group and a PR nurse attended all sessions. Each rehearsal comprised a five minute warm up session, 35 minutes singing, a five minute warm down and 15 minutes social morning-tea time. It was run free of charge to patients. The SGF and the group chose the singing repertoire together, including a wide mix of genres (eg pop, musicals, traditional Māori songs, folk songs, rounds) with attention to the group's voice range and capacity for phrase lengths. The SGF also discussed breathing for singing techniques as the year progressed and as the group gained confidence. No music reading ability was required. We made recordings of songs to allow practice at home although this was optional. Collaboration with a local boys' high school developed from student piano accompaniment to working with the senior boys' chorale including some joint performances. Over the year, the participants delivered six public performances, supported by the senior chorale from the local school on four occasions. Singing group members remained enrolled in the community exercise classes, as well as singing group.

Analysis

Continuous variables were compared using a mixed linear model for most variables with an unstructured variance-covariance correlation structure. Hospital admission days were right skew and were compared with a paired Wilcoxon test and Hodges-Lehmann estimator of the difference. Although individual comparisons are presented with 95% confidence intervals a large number of statistical tests have been carried out and this will inflate the Type I error rate. SAS version 9.4 was used.

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RESULTS

Out of 140 people with chronic lung disease approached, 28 participants (20%) were enrolled in the singing group in five months: October 2014 to February 2015. The mean (SD) time from completion of past PR was 1.2 (1.2) years. Response to past PR by the change in 6MWT was available for 14 participants and for these participants the distance had improved from a mean (SD) of 316 (126) m to 356 (148) m. Five participants withdrew within one month of enrolment as they did not wish to continue (n=4) or were recruited into another study (n=1). At baseline assessment, twenty-one participants had COPD as defined by GOLD criteria[22] but two participants had normal FEV1/FVC ratio on spirometry with a clinical diagnosis of interstitial lung disease. They continued to attend singing group but were excluded from this analysis. The 21 participants with COPD attended the singing group for at least one year and had measurements at enrolment and after four months. Eighteen participants were reassessed after 12 months: one had undergone lung transplant and two had such frequent exacerbations that stable follow-up testing was not possible. Figure 1 shows the study overview.

The participants with COPD had a wide range of disease severity and comorbidities. Mean (SD) FEV1% at baseline was 60.3 (21.1), median 57.1, range 14.6-110. The majority (66%) of participants had moderate COPD by GOLD criteria but 20% had severe or very severe COPD, similar to the proportions of COPD severity in the NZ community.[27] Six patients (29%) had an FEV1 at baseline of less than one litre. Common comorbidities were bronchiectasis, congestive cardiac failure, diabetes, and obesity. Six of 21 (29%) were Māori, consistent with the higher prevalence of COPD in Māori in New Zealand who constitute only 6% of the total population over 50 years.[28] The mean (SD) attendance rate for the 12 months was 85% (12.1). Table 1 shows characteristics of the study population at baseline.

185 Table 1 Characteristics of the study population

	N=21		
Age (years) mean (SD) [range]	68.8 (9.8) [51 to 91]		
Sex	N/21 (%)		
Men	8 (38)		
Women	13 (62)		
Ethnicity			
European	14 (67)		
Maori	6 (29)		
Asian	1 (5)		
Smoking history			
Current smoker	1 (5)		
Ex-smoker	18 (86)		
Never smoker	2 (10)		
COPD severity (FEV1% predicted)			
≥80% (mild)	3 (14)		
50-79% (moderate)	14 (66)		
30-49% (severe)	2 (10)		
<30% (very severe)	2 (10)		
COPD mortality risk ^a			
BODE score: 0-2	4 (19)		
3-4	8 (38)		
5-6	6 (29)		
7-10	3 (14)		
Continuous long term domiciliary oxygen therapy	2 (10)		
Comorbidities ^b			
Bronchiectasis	3 (14)		
Heart failure	6 (29)		
Diabetes	7 (33)		
Anxiety on treatment	5 (24)		
Atrial fibrillation	8 (38)		
Ischaemic Heart Disease	5 (24)		
Clinical characteristics	Mean (SD)	Median (IQR)	Min to max
FEV1 (L)	1.3(0.5)	1.3 (0.9 to 1.6)	0.6 to 2.6
FEV1 (% predicted)	60.3 (21.1)	57.1 (50 to 72.4)	14.6 to 110.3
FVC (L)	2.85 (0.9)	2.75 (2.2 to 3.0)	1.8 to 4.9
FVC (%predicted)	103.5 (26.9)	102.5 (85.3 to 126.7)	53.4 to 160.4
FEV1/FVC	0.47 (0.14)	0.47 (0.36 to 0.56)	0.22 to 0.68
TLC (L)	6.38 (1.99)	5.68 (5.2 to 7.0)	3.57 to 11.3
RV (L)	3.39 (1.52)	3.06 (2.6 to 3.4)	1.67 to 8.52
SpO2 at rest (%)	95.4 (2.3)	96 (93 to 97)	89 to 99
6MWT (m)	300 (110)	290 (212 to 349)	132 to 508
BMI (kg/m ²)	29.1 (7.6)	28.0 (23.9 to 32.5)	20.1 to 53.0
Questionnaires			
CCQ	2.11 (0.83)	1.9 (1.7 to 2.8)	0.4 to 3.3
HADS anxiety	5.8 (2.8)	6 (4 to 7)	1 to 11
HADS depression	4.1 (2.3)	3 (3 to 6)	1 to 10
HADS total	9.9 (4.6)	9 (7 to 12)	2 to 21

186 a:BODE score- The body-mass index, airflow obstruction, dyspnoea and exercise capacity index in
 187 COPD [29] b Some participants had multiple comorbidities.

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188 FEV1- forced expiratory volume in one second, FVC- forced vital capacity, TLC- total lung capacity RV-
189 residual volume, SpO2-oxygen saturation measured by a pulse oximeter, 6MWT- six-minute walk test,
190 BMI- body mass index, CCQ- clinical COPD questionnaire, HADS- hospital anxiety and depression score.
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3 192 There was strong evidence for an increase in 6MWT after four months, with a mean increase of 28
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5 193 (95%CI 5 to 52) m, $p = 0.019$, increasing further to 65 (95%CI 35 to 99) m, $p < 0.001$ at one year. HADS
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7 194 Anxiety scores were lower at one year with a mean change from baseline of -0.9 (95%CI -1.8 to -0.1) p
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9 195 = 0.038. Lung function tests showed a reduction in RV, mean decrease 130 (95%CI -250 to -3) ml, p
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11 196 = 0.046 and total lung capacity, mean decrease 150 (95%CI -290 to -20) ml, $p = 0.023$ after four
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13 197 months, but no significant differences at 12 months compared to baseline. The questionnaire and
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15 198 clinical measurements, and their changes are shown in Table 2.
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Table 2: Changes from baseline in lung function, questionnaires and hospital admission days.

Variable	Mean (SD)			Difference from baseline (95% CI)	
	Baseline N=21	Four months N=21	One year N=18	Four months	One year
FEV1 (L)	1.32 (0.5)	1.34 (0.5)	1.44 (0.5)	0.02 (-0.01 to 0.06) P=0.21	0.04 (-0.05 to 0.12) P=0.44
FEV1%	60.3 (21.1)	61.9 (22.3)	64.5 (20.2)	1.6 (-0.1 to 3.4) P=0.065	2.4 (-1.4 to 6.1) P=0.21
FVC (L)	2.85 (0.9)	2.81 (0.92)	2.91 (0.97)	-0.04 (-0.15 to 0.06) P=0.38	-0.04 (-0.17 to 0.09) P=0.50
FVC%	103.5 (26.9)	103.1 (30.4)	107.0 (24.8)	-0.5 (-4.5 to 3.6) P=0.81	-0.02 (-4.5 to 4.4) P=0.99
FEV1/FVC	0.47 (0.14)	0.48 (0.13)	0.50 (0.12)	0.01 (-0.004 to 0.03) P=0.13	0.02 (-0.002 to 0.03) P=0.08
TLC (L)	6.38 (1.99)	6.22 (1.86)	6.23 (1.7)	-0.15 (-0.29 to -0.02) P=0.023	-0.04 (-0.21 to 0.13) P=0.61
TLC%	117.8 (20.9)	115.2 (20.2)	116.4 (20.8)	-2.6 (-4.8 to -0.4) P=0.021	-0.7 (-3.7 to 2.3) P=0.61
RV (L)	3.39 (1.52)	3.27 (1.44)	3.22 (1.18)	-0.13 (-0.25 to -0.003) P=0.046	0.06 (-0.16 to 0.27) P=0.58
RV%	156.1 (59.9)	150.2 (57.1)	145.7 (44.1)	-5.9 (-11.5 to -0.3) P=0.04	1.3 (-7.8 to 10.3) P=0.77
IC (L)	2.29 (0.86)	2.35 (0.83)	2.33 (0.87)	0.06 (-0.03 to 0.15) P=0.18	-0.07 (-0.18 to 0.04) P=0.21
IC%	107.2 (27.2)	110.1 (25.7)	108.6 (24.3)	3.0 (-1.8 to 7.7) P=0.21	-2.9 (-9.3 to 3.5) P=0.35
IC/TLC	0.37 (0.09)	0.39 (0.09)	0.38 (0.09)	0.02 (0.001 to 0.03) P=0.037	-0.01 (-0.03 to 0.01) P=0.36
RV/TLC	0.52 (0.09)	0.52 (0.09)	0.52 (0.09)	-0.01 (-0.02 to 0.01) P=0.45	0.01 (-0.01 to 0.03) P=0.35
6MWT (m)	300 (110)	328 (118)	377 (104)	28 (5 to 52) P=0.019	65 (35 to 99) P<0.001
CCQ	2.11 (0.83)	2.08 (0.86)	2.31 (1.04)	-0.03 (-0.31 to 0.26) P=0.84	0.26 (-0.04 to 0.57) P=0.08
HADS Anxiety	5.8 (2.8)	5.81 (3.52)	4.67 (3.2)	0 (-1.2 to 1.2) P=0.99	-0.9 (-1.8 to -0.1) P=0.04
HADS Depression	4.1 (2.3)	3.19 (2.56)	4.0 (3.91)	-0.9 (-2.1 to 0.2) P=0.11	0.1 (-1.3 to 1.6) P=0.85

HADS Total	9.9 (4.6)	9.0 (5.7)	8.7 (6.4)	-0.9 (-3.0 to 1.2) P=0.37	-0.8 (-2.6 to 1.0) P=0.35
		12 months prior to enrolment	12 months after enrolment	HL estimator (95% CI)	
Hospital admission days for AECOPD N=20* Mean (SD)		3.6 (7.9)	2.7 (7.3)	-1.0 (-8.5 to 3.0) P=0.40	

FEV1, Forced expiratory volume in 1 s; FVC, forced vital capacity; TLC, total lung capacity; RV, residual volume; IC, inspiratory capacity; 6MWT- six-minute walk test, CCQ- clinical COPD questionnaire, HADS- hospital anxiety and depression score. AECOPD, Acute exacerbation of COPD. * Excluding one patient who had lung transplant between 4 months and 1-year follow-up assessments.

DISCUSSION

This study has shown that recruitment and retention of patients with COPD to a community singing group (SG) is feasible. Approximately 20% of people attending a maintenance exercise class following PR accepted the invitation to participate in a new singing group. Recruitment could be increased by individual approaches, repeat approaches and feedback by current participants in the singing group which now has a significant profile in the community. The high attendance rate over one year, mean 85%, supports the acceptability and feasibility of this intervention. In this study, participation in a weekly community-based singing group for one year was associated with increased exercise capacity and reduced anxiety in patients with COPD who have completed PR and were attending a community exercise group.

We were surprised by the high long-term attendance rate, for this cohort of patients with significant respiratory disease and comorbidities, including two participants with very severe COPD, one of whom had a lung transplant four months after joining the singing group. The qualitative data from this project, reported separately, showed that most participants had not been previously interested in singing and considered the singing group a fun social activity more than a musical endeavour.[21] The reduction in HADS anxiety scores confirms previous research [15] but this is the first report of statistically and clinically significant improvement in 6MWT with this type of intervention. The mean

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3 224 reduction in HADS anxiety score of 0.9 units at one year did not exceed the minimal clinically important
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5 225 difference (MCID) of 1.32.[30] The mean increase in 6MWT of 65m at one year was greater than the
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7 226 MCID of 30m.[31] This is the first report of serial RV measurement in COPD patients attending a
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10 227 singing group over one year. The small (130ml) statistically significant reduction in RV after four months
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12 228 but not 12 months may reflect type I error rate inflation, and so be due to the play of chance. A
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14 229 previous small COPD study showed a median fall in RV of 270ml in the four patients able to be tested,
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16 230 out of eight patients originally recruited, after 10 weeks of singing classes.[19] On the other hand,
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18 231 Bonilha and colleagues did not find any significant change in RV in 15 participants after 24 weeks of
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20 232 singing classes.[18] They did report a small but statistically significant difference in RV two minutes
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22 233 after a short singing session in subjects from the singing group (where RV reduced) and a control group
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24 234 (where RV increased) but no difference between the groups at 30 minutes.[18] The reduction in
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26 235 hospital admission days for AECOPD per year was not statistically significant, with a point estimate of
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28 236 approximately one day less per participant in the year attending singing group, compared to the year
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30 237 before starting (excluding the patient who had a lung transplant during the year). The actual cost of
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32 238 running the singing group for 12 months was approximately \$NZ4,000 (GBP 2,363). A future study of
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34 239 singing group intervention could include a health economic analysis to assess cost-effectiveness.
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36
37 240 Strengths of this study are the one year duration, comprehensive pulmonary function tests and
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39 241 low-cost community setting. Previously reported studies of singing intervention for COPD have
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41 242 generally been of short duration, mostly 6-10 weeks.[15-19] In contrast to studies using professional
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43 243 singing teachers and physiotherapists, we used amateur singing group facilitators, with musical
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45 244 experience and strong group facilitation skills. Limitations of our study include that the 6MWT was only
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47 245 performed once at each visit, but participants had all done at least one 6MWT as part of their recent PR
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49 246 programmes so any learning effect is likely to have been minimised.[32] This is a relatively small
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51 247 cohort study without a control group so both type I and type II errors are possible. This analysis also
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53 248 includes a large number of hypothesis tests which inflate the type 1 error rate.
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Our findings confirm those of Morrison and colleagues who showed medium-term (ten months) feasibility for community singing groups for people with COPD in the UK but they had a significantly higher attrition rate.[20] A significant component of our study was that participants had both completed a PR programme and were enrolled in a weekly maintenance exercise programme. These are likely to be people more motivated to manage their own health and who had already demonstrated an ability to attend weekly sessions. It is possible that some of the benefit in reduced hospital admissions could be explained by recent completion of PR.[33] These results can't be readily generalised to a population of people with COPD who have declined or not been offered PR. We believe there may be a role for SG participation for people with COPD who decline PR and have started a controlled study testing this hypothesis (www.anzctr.org.au registry number ACTRN12616000584437). Singing group members remained enrolled in maintenance exercise classes after PR, as recommended by international guidelines.[33] There is conflicting evidence as to whether maintenance exercise classes preserve the benefits on exercise capacity of PR, but no evidence that maintenance exercise classes improve exercise capacity in people who have completed PR.[33] On average, our participants had been attending exercise classes for approximately one year prior to singing group enrolment and mean 6MWT distance at commencement of singing group was substantially lower than the 6MWT distance at the end of the PR programme for the 14 participants with complete data from the preceding PR programme. This suggests a low likelihood that the substantial improvement in 6MWT distance during 12 months of SG participation could be explained by exercise class attendance alone. The presence of a PR nurse at the singing sessions may have been important. Her role was in 'meeting and greeting' participants, general encouragement to attend, supervising refreshments and organising transport for performances. There was no formal or informal exercise advice provided. In the interviews that formed the qualitative component of this project [21], a key theme was being cared for in a safe environment and the PR nurse presence contributed to this. All participants received usual medical care so therapeutic changes may have affected some of the participants.

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3 274 Our findings are relevant to the question of sustaining the benefits of pulmonary rehabilitation. A
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5 275 possible mechanism for singing group effectiveness is the promotion of physical activity which is
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7 276 considered to be a critical component of PR.[34] Our qualitative data showed that for many patients,
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10 277 attending the weekly singing group was a most enjoyable highlight of their week and worth the extra
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12 278 physical activity it took to get there.[21]. In contrast to other studies[15–18] our singing group
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14 279 intervention focussed on fun group singing with no specific breathing exercises. The impact of
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16 280 breathing exercises alone or in addition to singing remains uncertain.[35] Our group met weekly with
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18 281 singing duration of 35 minutes, and no explicit practice at home. It is possible that there is a dose-
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20 282 response relationship, with increased benefit with more frequent singing group classes and singing
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22 283 practice at home. With the very high attendance rate we were not able to attempt an analysis for a
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24 284 dose-response relationship between attendance and outcomes.
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27 285 Our qualitative analysis showed singing group participation was associated with an increased
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29 286 sense of social connection, purpose and meaningful participation which may explain the reduction in
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31 287 anxiety.[21] Although there seems to be an association between anxiety in COPD patients, their health
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33 288 status, and the frequency of AECOPD and hospitalisation, it is complex.[36] However, the reduction in
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35 289 anxiety and increased exercise capacity observed in this study points to the potential for reducing
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37 290 readmissions and supports the use of exercise capacity and readmission for AECOPD, as primary
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39 291 outcome measures for a future randomised controlled trial (RCT).
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42 292 We believe our results could be replicated by others given recruitment from a typical hospital PR
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44 293 programme and the practical, low cost approach to running the singing group, including community
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46 294 venue and the use of amateurs for singing group facilitation. We have made available on-line our “10
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48 295 practical top tips” document for setting up and running a community singing group for people living with
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50 296 COPD (see online supplement). We have been able to sustain this intervention long term, free to
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52 297 patients, as it was set up and financed by a charitable trust. The singing group is still going strong after
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54 298 twenty-four months with high attendance including almost all of the founding members, avoiding the
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56 299 ethical issue of withdrawing the intervention at study completion.
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CONCLUSIONS

Our findings support the feasibility of long-term participation in a community singing group for adults with COPD who have completed PR and are enrolled in a weekly community exercise group and provide evidence of improvement in exercise capacity and reduction in anxiety. These results can inform sample size and selection of outcome measures for a future RCT.

Figure legend:

Figure 1: Study overview

COPD = chronic obstructive pulmonary disease, PR= pulmonary rehabilitation, AECOPD = acute exacerbation of COPD, FEV1 = forced expiratory volume in 1 second, FVC = forced vital capacity, GOLD = Global Initiative for Chronic Obstructive Lung Disease

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Contributors AM conceived the idea of the study, designed the protocol, wrote the first and final drafts of the manuscript, was the senior investigator, and will act as guarantor. SA, HM, MWi, GW, MWe, RB helped design and plan the study and helped write the first and final drafts of the manuscript. GW, AM recruited patients to the study. MWi, AM collected data. MWe was responsible for the analysis.

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Competing interests None

Ethics approval This study was approved by the Wellington Hospital Research Governance Group on 23 September 2014

Data sharing No additional data are available

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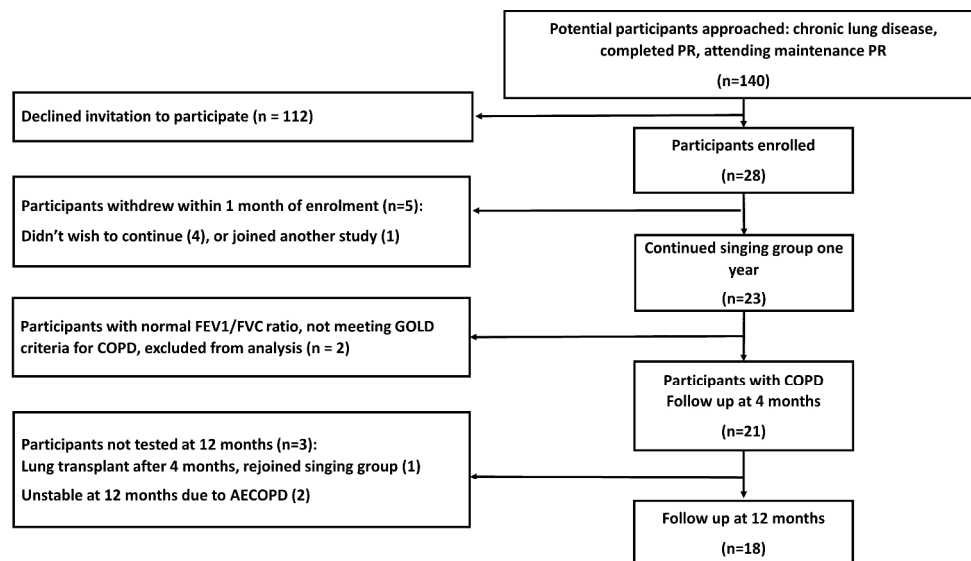


Figure 1: Study overview.

COPD = chronic obstructive pulmonary disease, PR= pulmonary rehabilitation, AECOPD = acute exacerbation of COPD, FEV1 = forced expiratory volume in 1 second, FVC = forced vital capacity, GOLD = Global Initiative for Chronic Obstructive Lung Disease

Figure 1 shows the study overv
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Setting up a singing group like Sing Your Lungs Out

We provide links below to two short videos of this singing group and a "10 practical top tips" document for setting up a community singing group for people living with COPD which we hope will inform, motivate and encourage others to set up singing groups.

- https://www.dropbox.com/sc/boc5sr7hkcbi6tz/AAAlbUQqOWyvDeJGTnoXVcg-a?preview=NO_Graphics_02.mp4
- <https://www.youtube.com/watch?v=fduau0jV09o>
- http://www.mrinz.ac.nz/pdfs/How_to_set_up_SYLO.pdf

BMJ Open: first published as 10.1136/bmjopen-2016-014151 on 24 January 2017. Downloaded from <http://bmjopen.bmj.com/> on June 1, 2025 at Department GEZ-LTA
Erasmus Hogeschool
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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Pilot in study title.
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes Introduction para 1-3, pg3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes Introduction para 4, pg 4. No hypotheses, this was a feasibility study.
Methods			
Study design	4	Present key elements of study design early in the paper	Methods, para 1, pg 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Methods, para 1, pg 5 and under 'Singing Group Intervention' pg 6. Specific dates are in first line of Results, pg 7
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	Methods, para 1, pg 5
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	No matched control group
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Methods, 'data collection', pg 5
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Methods, 'Data collection', pg 5

Bias	9	Describe any efforts to address potential sources of bias	Objective lung function tests measured by scientist blinded to previous results. Self reported questionnaires
Study size	10	Explain how the study size was arrived at	Convenience sample, twice the size of previous studies.
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Methods, ‘Analysis’, pg 6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Methods, ‘Analysis’, pg 6
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	N/A
		(d) Cohort study—If applicable, explain how loss to follow-up was addressed	Results, para 1, pg 7 and Figure 1 Study overview
		Case-control study—If applicable, explain how matching of cases and controls was addressed	
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Results, para 1, pg 7 and Study overview Figure 1
		(b) Give reasons for non-participation at each stage	Results, para 1 and figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Results, para 2, pg 7 and Table 1
		(b) Indicate number of participants with missing data for each variable of interest	Table 1
		(c) Cohort study—Summarise follow-up time (eg, average and total amount)	Result, para 1,pg 7
Outcome data	15*	Cohort study—Report numbers of outcome events or summary measures over time	Results, para 3, pg 9 and Table 2 and Figure 2
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(a) Give unadjusted estimates and, if	Admission days adjusted. Other

		applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	results unadjusted. Table 2
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A feasibility study
Discussion			
Key results	18	Summarise key results with reference to study objectives	Discussion para 1
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Discussion para 3, pg 12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Discussion para 4 and 5, pg 12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	Discussion para 6, pg 13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Funding statement pg 14

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.