Singing and COPD: A pilot randomised controlled trial in association with Medway Community Healthcare 2019-2020

Study Protocol (Version 1)

Trial will be registered in: http://www.isrctn.com/

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Contents

Lay Summary

Chronic obstructive pulmonary disease (COPD) is a long-term and progressive respiratory disease which negatively affects people's health and wellbeing. The condition deteriorates over time, and there is no cure. However, there is evidence that activities like regular exercise and singing can improve breathlessness and general health and wellbeing.

Previous research has shown positive benefits of singing for respiratory illness, but two recent reviews of the evidence highlights the need for further larger-scale controlled studies with follow-up.

We plan to set up a randomised controlled trial to assess the potential benefits of singing for COPD patients in Medway. A total of 100 patients with moderate to very severe COPD, as assessed by spirometry, will be recruited, assessed and then randomised into two arms of the trial. Half will participate in a singing programme and half will receive usual care. The singing programme will be implemented over 10 ninety minute sessions. The programme will involve breathing exercises and songs which will encourage controlled breathing and progressive extension of the time taken to breathe out.

Participants who are NOT in the singing groups will be offered the opportunity to join a singing group after the final data gathering session.

For all participants, assessments of lung function, breathing patterns and exercise will be gathered before and after ten weeks of weekly singing and then at follow-up after a further three months. Participants will also complete questionnaires about their breathing, quality of life, personal and mental wellbeing and use of medication and health services.

This information will help us assess in a controlled and rigorous way whether singing for people with COPD helps them to manage their breathing difficulties more effectively and contributes to feelings of improved quality of life and wellbeing. It will also enable us to evaluate the potential economic impacts of the initiative for the NHS.

1. Introduction

1.1 Background and rationale

New, innovative initiatives are needed to help people with COPD engage in physical and social activity in order to support independence and quality of life. Recently there has been some interest in the value of singing in promoting wellbeing, including its ability to improve breathing. Currently this is an under-researched, though growing field, and has mixed findings (McNamara et al., 2018). Although surveys have shown that choral singers believe that singing improves their breathing and enhances lung function (Clift & Hancox, 2001; Clift et al, 2009), direct assessment of lung function in professional singers compared with wind and percussion players, has failed to show differences in spirometric parameters (Clift et al, 2008).

Chronic obstructive pulmonary disease (COPD) is an umbrella term that includes a number of specific airway conditions including bronchitis and emphysema. Diagnosis relies on a combination of history, physical examination and spirometry (GOLD, 2017). Dyspnoea (breathlessness) is a cardinal symptom and major cause of disability and anxiety associated with the disease (GOLD, 2017). COPD is associated with other serious health conditions including cardiovascular disease, osteoporosis and depression (Fletcher et al 2010).

Smoking tobacco is the main risk factor for COPD, but other environmental factors can contribute such as exposure to smoke or dust in different occupations, and atmospheric pollution may be important determinants. COPD is progressive over time, especially if individuals continue to smoke or continue to be affected by environmental factors, but individuals may periodically experience episodes of acute worsening of respiratory symptoms or exacerbations, commonly due to infections, or periods of stress.

COPD is a widely prevalent chronic illness throughout the world, and represents a major public health challenge internationally. Gold (2017) states that COPD is currently the fourth leading cause of death in the world but is expected to be the third leading cause of death by 2020. Currently, in the UK, 1.2 million people are estimated to have a diagnosis of COPD (BLF, 2016) which makes COPD the second most common lung disease after asthma. Approximately, 2% of the British population are living with COPD and prevalence increased by 9% between 2008 and 2012.

Currently, 115,000 people are newly diagnosed annually and it is the second biggest cause of death in the UK, with approximately 30,000 deaths due to the condition every year.

COPD makes a big impact on hospital services, and currently accounts annually for over 140,000 hospital admissions and over a million bed days across the UK. This is 1.7% of all hospital admissions and bed days. Exacerbation of COPD is the most common cause of readmissions to hospitals in the UK (Royal College of Physicians, 2017). The direct cost of COPD to the UK National Health Service has been estimated at £810-930 million per year and these costs are expected to rise (DH, 2010). Up to 40% of people with COPD are forced to retire from work prematurely because of the disease (Fletcher et al, 2011).

Since smoking remains the primary cause of COPD, smoking cessation is the intervention with the greatest capacity to influence the natural history of the disease (GOLD, 2017). COPD is not curable, however progress may be slowed down and symptoms reduced through pharmacological management using a stepped approach to inhaled therapies (bronchodilators, steroids and combination therapies), based on the severity of the disease (DH, 2010). In addition, pulmonary rehabilitation can significantly improve exercise capacity, dyspnoea and psychological wellbeing and a minimum of 12 supervised sessions is recommended with patients being encouraged to continue exercise beyond the programme (BTS, 2013).

1.2 Singing and COPD – current state of evidence

Research specific to singing and COPD can be divided into:

- controlled trials
- quantitative studies without controls; and
- qualitative studies (mostly reflecting participant perceptions recorded via written comments or interviews and focus group discussions).

In addition, a number of reviews of related literature exist.

Controlled trials

Four controlled trials have been identified (see Table 1), three of which are randomised. All reported interventions of 1 hour either weekly or twice weekly and duration ranged from 6 weeks to 24 weeks. Participant numbers were limited to 13-15 in the intervention groups and equal or fewer numbers in controls. Two of the studies involved the control groups engaging in alternative group

work, the remaining two involved usual care. A variety of measures were used in these studies, making comparisons difficult, however, both of the Lord et al (2010,2012) studies reported a significant increase in physical wellbeing assessed by the SF-36.

Quantitative studies without controls

Studies without controls (Table 2) are predominantly single cohort studies with pulmonary function and other measures taken at baseline, endpoint and often midpoint. Numbers of participants completing range from 7 to 228. With the exception of an early study (Engen 2005), these studies tend to run for longer than the controlled trials above. Only one study, which had both long term follow-up and a large cohort (Morrison et al 2013) showed significant improvement in pulmonary function. A reduction in anxiety was demonstrated in two studies and there was further support for the need for large controlled trials.

Qualitative studies

A number of studies included embedded qualitative evaluations (Table 3) through either inviting written comments on questionnaires or (more commonly) through conducting interviews. Numbers interviewed vary between 5 and 37, however responses are almost universally favourable and themes are common across studies.

Reviews

Four reviews which included singing for people with COPD have been conducted between 2015 and 2018, though only one (McNamara et al.'s Cochrane Review) focused solely on this group and was limited to randomised controlled trials (Table 4). All these reviews commented on the limited or conflicting evidence for the impact of singing on respiratory function. Where evidence does exist the quality is low due to small sample numbers and other features such as attrition rates.
Gick & Nicol (2015) conducted a review of singing for respiratory health, including studies pertaining to COPD. Those considered are Engen (2015), Morrison et al. (2013), Lord et al. (2010, 2012), Goodridge et al. (2013) and Bonilha et al. (2009). They raise a number of challenges in conducting such studies, including: attrition; length of intervention; conducting non-medical interventions for medical conditions (and therefore working in partnership with health professionals); and the finite length of the intervention (and what happens when the research ends). They conclude that the results from the studies reviewed suggest promising but inconclusive findings overall.

Lewis et al (2016) conclude their review with a consensus statement covering seven statements on the current status of knowledge together with pointers for research and practice:

- Singing for Lung health has the potential to deliver benefits for respiratory conditions.
- Qualitative data is strongly positive.
- Small trials have been positive but evidence for functional status and economic evaluation is needed.
- A distinction needs to be made between singing specifically for lung health and more generic community singing groups.
- There is a need to define competencies and training pathways for group facilitators.
- Appropriate outcome measures need to be identified which are meaningful to participants. CAT is one such possible measure.
- There is a need for robustly designed and powered trials before singing for lung health can be recommended for routine management of conditions.

Daykin et al (2016) found only two studies met their criteria in looking at wellbeing outcomes where singing was compared to a comparator or where a qualitative study was undertaken, focusing on COPD. Evidence pointed to outcomes including reduced stress and improved wellbeing but was of a low quality.

McNamara et al (2018) used the Cochrane guidelines and templates for a review of RCTs only (being the highest quality evidence) and only three studies met the criteria with limited opportunity for meta-analysis. A number of omissions and limitations in the reporting of studies were noted including the recording of compliance with home practice, which facilitators in all three studies requested.

1.3 Psychological and social impacts of COPD

In addition to the physical consequences associated with lung damage, people with COPD are at heightened risk of additional threats to their wellbeing and health, including social isolation, anxiety and depression. In some case, the mental health consequences can be clinically significant and prompt further intervention.

In the current study a measure of mental health related quality of life and clinical measures of generalised anxiety disorder and depression will be used as secondary outcome measures to assess the extent to which singing as an intervention is beneficial for the mental health and wellbeing of people with COPD.

1.4 Structured Light Plethysmography

The relevance of measuring tidal breathing to detect differences between those with respiratory diseases such as Chronic Obstructive Pulmonary Disease (COPD) and healthy subjects has been well established (Cain and Otis, 1949; Kostianev, Hristova and Lluchev, 1999; Yamauchi et al., 2012; Yamada et al., 2017). There are a number of approaches to measuring tidal breathing including respiratory inductance plethysmography and optoelectronic plethysmography (Mehra and Strohl, 2009). The current more common method used is pneumotachography (PNT) which is considered gold standard (Iles et al., 2015). PNT however, involves COPD patients wearing a mouthpiece potentially causing unease which may change the patients' respiratory pattern leading to inaccurate results (Laveneziana et al., 2015). Consequently, the need for a technique with minimal patient cooperation and high levels of accuracy is present.

Structured Light Plethysmography (SLP) is a relatively new non-contact technique which measures tidal breathing requiring minimal patient cooperation (de Boer, 2010). Subjects have a light grid projected onto their chest and two cameras record the movement of the thoraco-abdominal (TA) wall allowing tidal breathing parameters to be calculated (Alimohamed, 2011; Motamedi-Fakhr, Wilson and Iles, 2016b). Respiratory rate, which is a tidal breathing parameter derived from SLP, has been validated against the gold standard clinician over-scored capnography (Motamedi-Fakhr, Wilson and Iles, 2016b). Iles et al. (2015) and Motamedi-Fakhr et al. (2017) tested the accuracy and repeatability of SLP against PNT, concluding SLP to be of equal gold standard. This research provides promising results for SLP to be introduced as a non-invasive method for measuring tidal breathing.

The use of SLP as a clinical tool to measure tidal breathing specifically among COPD patients has been evaluated (Motamedi-Fakhr, Wilson and Iles, 2016; Nierat et al., 2017). Motamedi-Fakhr, Wilson and Iles (2016) used thirty-one COPD patients and thirty-one healthy subjects to investigate whether SLP can recognise differences in tidal breathing. The results show that SLP does recognise differences between the two groups and that it may also have potential as a method to

detect COPD. These results compliment the findings from Nierat's et al. (2017) research which used thirty COPD and thirty healthy subjects, differences in breathing patterns were observed. SLP also provides more precise measurements of TA movements which allow for a greater analysis (Nierat et al., 2017). Conclusive observations highlight SLP as an appropriate method to assess tidal breathing among COPD patients, both Motamedi-Fakhr, Wilson and Iles (2016) and Nierat et al. (2017) empathise the need for more research.

SLP may also have potential use in measuring the effectiveness of COPD treatments (Laveneziana et al., 2014; Hmeidi et al., 2016; Hmeidi et al., 2017). Laveneziana et al. (2014) tested sixteen COPD patients before and after bronchodilators (BD), SLP showed differences in some of the tidal breathing parameters highlighting a response to BD. Although not among COPD patients, Hmeidi et al. (2016) and Hmeidi et al. (2017) conducted research using thirty children with asthma and thirty without, SLP showed breathing differences between the two groups and observed a positive response to BD. These results show promise for health professionals to use SLP as a tool to measure the effectiveness of COPD treatments.

1.5 Feasibility studies in Medway

Singing for Better Breathing

As a basis for assessing the feasibility of setting up and running a randomised controlled trial in Medway and in association with Medway Community Healthcare Respiratory Team, two 'singing for better breathing' groups were established in Medway in May, 2017. Participants were recruited through visits to pulmonary rehabilitation classes (PR) run by the respiratory team in two community venues. Members of the De Haan Centre spoke about the idea of 'singing for better breathing' and ran taster exercises. Interest levels were high with approximately half of PR participants expressing a willingness to participate in singing groups. Two groups were set up in Gillingham and St. Mary's Island, and of the people expressing interests at PR, approximately half were able to join one of the groups (i.e. 25% of those contacted initially). This suggests that in recruitment for a further study, at least four times the required sample would need to be reached through direct contact.

The two groups ran weekly over three months, and participants were guided through a structured progressive programme of exercises and singing in line with the approach adopted in previous

studies conducted by the De Haan Centre. In addition, participants were given a printed resource and access to video of exercises and singing to support individual practice at home between sessions.

The singing programme was evaluated by Charlotte Epsley as part of her PhD research within the De Haan Centre, and three measures were employed in a simple baseline-follow up design: the COPD Assessment Test (CAT), the Asthma Control Questionnaire (ACQ) and the Warwick Edinburgh Mental Wellbeing Scale (WEMWBS). The table below gives the means on these questionnaires at baseline and after the programme, and show clearly that significant improvements took place on the CAT and WEMWBS with a marginally significant improvement on the Asthma Control Questionnaire.

Table 5: Changes observed in the Medway Singing for Better Breathing feasibility study

Scale	Sample	Baseline	Follow-up	t	p
CAT	21	25	20	2.75	0.01
WEMWBS	21	49	55	-2.61	<0.02
ACQ	20	12	10	2.01	<0.10

The results from the CAT questionnaire were especially encouraging, as the improvement of five points on the scale is clearly greater than the established 'minimal clinically important' change score of two points (Kon et al., 2014).

A film based on the project also supports the findings from the questionnaires, with participants giving positive testimonies of the positive benefits they experienced from regular singing. See: https://vimeo.com/245825761 (Password s4bbMedway).

Trial of Structured Light Plethysmography

As we propose to make use of Structured Light Plethysmography to assess potential changes in breathing patterns as a result of singing, a trial of the technique was also undertaken with volunteers from the Medway Singing for Better Breathing group. As a comparison, members of the Rochester Choral Society were also invited to participate to provide a comparison with people with healthy lungs in April, 2018. In the course of the assessment participants were asked to sing a short extract from *My Bonnie Lies over the Ocean* and also a simple counting song (I can sing to one, two, three etc. up to 8, then to 12, then to 16). The songs were used to assess the potential value of examining breathing patterns during singing, especially when the demands on the out-

breath increase as the numbers counted in the second song increase. This worked well, but on reflection for the trial, it was clear that a simple assessment of breathing at rest, and an assessment of breathing following a period of structured exercise, would be easier to undertake and of greater relevance to the aims of the trial.

A film of the assessments together with testimonies from participants with COPD and those with healthy lungs can be viewed here:

https://www.youtube.com/watch?v=P1KJYPWm2Hs&feature=youtu.be

1.6 Rationale and hypotheses for the current study

The conclusion of reviews of research supports the need for further research in the form of randomised controlled trials, as do the recommendations from the studies cited above. The proposed study will be larger than previous studies and include assessment of change on the primary outcome measure of COPD specific health status (the COPD Assessment Test, CAT), immediately after a three-month programme of regular singing, and on further three month follow up. The primary research null hypothesis will be that: 'No change occurs in COPD-specific health status, following ten weeks of regular, weekly singing at the primary end point for the trial six months post-baseline.'

A particular challenge is establishing real-time records of patterns of respiratory function to test a secondary hypothesis that regular singing leads to change towards deeper breathing supported by the diaphragm. One technique which may do this is structured light plethysmography (SLP) where movements of the chest wall and abdomen can be recorded for individuals as participants' breath. A small, feasibility exercise assessing the value of this technique for the current study has been undertaken (see above). The supplementary null hypothesis will be that: 'No changes occur in key parameters (specified below) derived from structured light plethysmography reflecting movement of the chest and abdomen during breathing, following three months of regular singing, at the primary end point of the trial six months post-baseline.'

Further secondary hypotheses will be tested for potential changes three months post-baseline at the conclusion of the singing programme.

As, following randomisation, participants will inevitably be fully aware of their allocation to singing group or control, the trial cannot be double-blinded. However, in follow-up assessments, the staff conducting the measurement procedures will be blind to trial allocation.

1.7 Public and patient involvement

Considerable care has been taken in the design of the current study to consult with patients affected by COPD and interested members of the public (including family members of people with COPD), drawing on participants of singing for better breathing groups previously established by the De Haan Centre and which have continued to meet. A member of the research team has a diagnosis of COPD. In addition, people with COPD and other members of the lay public were formally invited to review the protocol in the course of its development. The Trial Management Committee will also include patients affected by COPD and lay members.

Table 1. Research with controls

Reference	Number of participants (intervention vs control)	Intervention	Control	Measures	Findings	Conclusions
Bonilha et al 2009	Randomised 15:15	1 hr weekly singing for 24 weeks. Relaxation, respiratory & vocal exercises then Brazilian folks songs. Enc home practice	Handcraft work 1 hour weekly over 24 weeks. Relaxation exercises. Including home practice	Pulmonary function, SGRQ, QoL and Borg scale	Intervention group showed small improvement in maximal expiratory pressure, control group declined. Both groups increased their scores on SGRQ	Regular singing may improve QoL and improve maximal expiratory pressure. Additional studies recommended to define role of singing as potential to assist PR
Lord et al 2010	Randomised 15:13	1 hr sessions for 6 weeks of twice weekly singing.	Usual care	SF36, HADS, single breath counting, breath hold, walk test	Significant improvements in anxiety (HADS) and physical component of SF36 in intervention group	Singing classes can improve QoL and anxiety but did not improve measures of breath control or functional capacity. Further work needed to quantify magnitude and duration of improvement
Lord et al 2012	Randomised 13:11	1 hr sessions twice weekly for 8 weeks. Includes vocal exercises, posture and relaxation training. Homework CD.	Weekly Film club for 8 weeks followed by group discussion	HADS, CAT, SF36, walk test, Borg scale, single breath holding	Significant improvements in the physical component of SF36 in intervention group.	Participation in singing lessons may be a useful activity for people with COPD
Goodridge et al 2013	Consecutive assignment 14:5	1 hr weekly sessions post PR for 8 weeks led by music therapist. Plus relaxation, resp. & vocal exercises. Request to practice at home.	Usual care (PR)	SGRQ, walk test, Illness perception questionnaire	No significant changes on SGRQ or walk test.	Ongoing work is needed to establish whether longer duration and intensity of singing demonstrates improvement

Table 2. Quantitative studies without controls

Reference	Number completing	Design	Intervention	Measures	Findings	Conclusions
Engen 2005	7	Cohort pre-test-post-test	45 min sessions twice a week for 6 weeks. Inc warm-up exercises	Physical health, functional outcomes and QoL	No sig difference in physical or functional outcomes. Breath control and voice intensity showed sig improvement. QoL results mixed. Breathing mode changed to diaphragmatic.	Vocal instruction + breathing exercises may help improve QoL of senior citizens with emphysema. Further investigation of the treatment method is warranted.
Morrison et al 2013	72	Cohort pre-test-post-test plus midpoint testing	6 singing groups set up. 90 min sessions over 36 weeks. Inc relaxation, posture, breathing and vocal exercises.	SCRQ, MRC scale, EQ-5D, York SF-12 at baseline, midpoint and end. Pulmonary function at base and end	QoL (SGRQ) showed sig. improvement. Improvement in spirometry measures.	Community singing can have an exercise training effect on ling function of people with mild to very severe COPD. Need for a larger-scale controlled study.
Waugh et al 2015 (unpublished)	8	Cohort pre-test-post-test	1.5hr singing twice a month plus breathing exercises	AQ20 (QoL measure)	5 of 8 improved score but no significant differences	Singing is a low-cost, enjoyable way to improve health of pts with respiratory conditions
McNaughton et al 2017	21	Feasibility cohort pre-test-post-test plus midpoint testing	1 hr a week for a year, including warm-up and cooling down. Home practice encouraged with recording.	Pulmonary function, Clinical COPD questionnaire, HADS and walk test	Significant reduction on HADS anxiety score at 1 yr. Walk distance increased at 4 mo. & 1 yr. No improvement or deterioration in pulmonary measures.	Findings support feasibility of long-term participation in a community singing group for adults with COPD who have completed PR. Results can inform sample size and choice of measures for RCT
Clift et al 2017	44 (questionnaire) 42 (lung assessment)	Feasibility, 2 cohort pre-test-post-test	4 groups set up. 90 min weekly sessions over 38-40 weeks. Included relaxation, posture, breathing and vocal exercises	SGRQ, MRC scale, EQ-5D, pulmonary function, walk test, Borg scale.	No sig. improvement in respiratory function (except for one measure, which may be incidental). Sig reduction in SGRQ symptom scale	As a feasibility study, project ran successfully. Larger trials need to establish impact of singing for lung health.
Lewis et al 2018	113 (47% had COPD) from 26 BLF groups	Baseline & 3 months.	60-90 min weekly singing + breathing, posture & vocal ex.	CAT, EQ-5D-3L (VAS only), MRC scale, GAD-7, Patient activation score	Sig improvement in CAT score and GAD-7 anxiety	Endpoints should be evaluated with large-scale RCTs.

Table 3 Qualitative studies

Reference	Data collection	Number of participants	Summary findings across studies
Lord et al 2010	Interviews	8	• Physical: Control of breathing, understanding and managing condition day to day, posture improvement, increase in energy. • Mental: Mental wellbeing, improved mood, including pleasure, distraction, safe space, sense of achievement and purpose, confidence, generalise into life outside group. • Social: Support, part of a community, connections
Lord et al 2012	Interviews	5	
Skingley et al 2014 (included in Morrison et al 2013)	Written comments	97	
McNaughton et al 2016 (included in McNaughton et al 2017)	Interviews, focus group	12 and 11	
Skingley et al 2018 (included in Clift et al 2017)	Interviews	37	

Table 4 Reviews

Reference	COPD studies included	Conclusions	Recommendations
Gick & Nicol 2016	Bonilha et al 2009; Engen 2015; Goodridge et al 2013; Lord et al 2010, 2012; Morrison et al 2013.	Limited or inconsistent improvements in COPD symptoms or objective breathing measures. Benefits may be due to enjoyment.	Need for longer term outcomes. Emphasise possible psych and social benefits to increase recruitment and collect data on beliefs about value of singing.
Lewis et al 2016	Bonilha et al 2009; Lord et al 2010, 2012; Morrison et al 2013.	Singing for lung health may improve physical health status and quality of life in COPD.	Larger and longer studies are needed with economic outcomes.
McNamara et al 2018	Bonilha et al 2009; Lord et al 2010, 2012.	Low to very low evidence that singing improves physical health on SF-36. Small samples. Few studies of singing in conjunction with PR.	More RCTs and larger samples are needed.
Daykin et al, 2016	Lord et al 2012; Skingley et al, 2014	Low quality evidence points to wellbeing outcomes for people with COPD	There are challenges to establish evidence due to the diversity of research approaches and measures used.

2 Methodology

2.1 Design, questions, aim and objectives

Design

The planned study is a single-blinded randomised controlled trial which will compare participation in a structured singing programme over 10 weekly sessions, with a usual treatment control. A 3 by 2 mixed anova design will be adopted with time as the within subjects factor at 3 levels (baseline, end of intervention and follow-up) and Condition as the between subjects factor with 2 levels (singing vs. control).

Questions

The study seeks to answer the following questions:

1. Is a ten-week progressively structured programme with recommended weekly practice between sessions acceptable, manageable and enjoyable for participants in the trial?
2. Does regular singing help to improve the perceived health and quality of life of patients with COPD over and above the provision of usual treatment?
3. Does regular singing result in a changed pattern of breathing in COPD patients with a shift towards breathing supported by the diaphragm, and a longer, slower controlled out-breath?
4. Does regular singing help patients with COPD manage the demands of daily living more effectively?
5. Does regular singing compared with usual treatment lead to a reduction in the use of medication and health services that will result reduced in care costs?

Aim and objectives

The overall aim is to conduct a pilot single-blinded randomised controlled trial, to evaluate the health benefits of a community singing group for patients with COPD in Medway, Kent. We are interested in finding out whether participating in community singing helps to improve the quality of life of patients with COPD.

Principal objectives are formulated around the primary outcome measure for the study, and a number of secondary outcomes. Service use will be assessed. There will also be an embedded qualitative study of patients' experiences of the singing programme, and the extent to which they follow guidance on practising breathing exercises and singing between group sessions.

Primary Outcome

- Impact on quality of life and management of breathing difficulties (as assessed by CAT) (Jones, et al., 2009; Kon, et al., 2014; Jones, et al., 2014; CAT, 2016)

Secondary Outcomes

- nMRC breathlessness scale (see: https://mrc.ukri.org/research/facilities-and-resources-for-researchers/mrc-scales/mrc-dyspnoea-scale-mrc-breathlessness-scale/%EF%BB%BF Williams, 2017; Fletcher et al., 1959)
- SF-36 v2, Physical health related quality of life and Mental health related quality of life (Jenkinson et al., 1999) (Available from Optum: http://campaign.optum.com/optum-outcomes/what-we-do/health-surveys/sf-36v2-health-survey.html)
- Generalised anxiety disorder (as assessed by GAD-7) (Spitzer, et al., 2006)
- Depression (as assessed by PHQ-9) (Kroenke, et al., 2001)
- Anxiety (as assessed by GAD-7) (Kroenke, et al., 2002)
- Lung function and patterns of breathing (as assessed by spirometry and SLP – for further details see below)
  Functional exercise (as measured by the 6MWT – further details below)
  Use of inhalers, consultations with health professionals and hospital admissions

The standardised measures employed in this trial have been chosen based on previous research on singing and COPD, the outcome of recent systematic reviews (Lewis et al., 2016; McNamara et al., 2017, and the latest guidance on the assessment and diagnosis of COPD (NICE, 2018). All questionnaires have been screened and assessed for suitability as 'patient reported outcome' measures using the checklist devised by Francis et al. (2016) (see Appendix 7.10).

We are using CAT, GAD-7 and PHQ-9 as these measures are routinely used by the Medway Community Healthcare Respiratory team in the monitoring of responses to pulmonary rehabilitation.

CAT serves as a COPD-specific quality of life measure and is especially suited to being the primary outcome measure for the study. There is also an established 'minimum clinically importance' change score of two points (Kon et al., 2014), and this will provide an important criterion against which to judge the outcome of the trial for clinical purposes.

Both GAD-7 and PHQ-9 have established cut-off points for increasing grades of severity on mental health condition, and will serve to assess the extent to which participants in the trial can be regarded as experiencing clinically significant levels of mental health challenge, and whether this changes over the course of the trial for the intervention group relative to the control. It is recognised also that the two mental health scales can be combined to form a single measure of anxiety-depression.

The SF-36 will also be used as this measure was employed in both Brompton studies (Lord et al., 2010, 2012), and revealed significant changes on the physical health related quality of life scale, with a large effect of approximately 1. The current study will employ the current version 2 of the SF-36 as opposed to the earlier version used in the previous Brompton studies. This is justified as V2 is the most recent version and we will have the benefit of technical support from Optum, the owners of the scale, together with access to the most recently available and appropriate norms for scoring. We assume that scores arising from the earlier and current version would be virtually identical.

The MRC breathlessness scale (nMRC, see Williams, 2017) will be employed as a score of 3 (out of a score range of 0-4) is often used as a criterion for recommending pulmonary rehabilitation (PR). As this trial will target recruitment towards patients who have undergone or who are receiving PR, it is expected that all participants will have an nMRC score of 3 or 4.

Details of spirometry, SLP assessments and the 6MWT parameters are given in section 2.6 below

2.2 Participants

In this study, the participant population will come from the population of COPD patients supported by the Respiratory Service of Medway Community Healthcare. Participants will be recruited from patients who have received PR and those who are currently undergoing PR. The study will seek to achieve a final sample of 80 patients at the second follow-up – 40 in the intervention arm and 40 in the control arm. The intention is to recruit 100 patients who consent to allow for 20% attrition. It is expected that we will need to secure initial expressions of interest from at least 120 people to allow for drop out even prior to consenting.

The number of participants is based on the resources available to run the trial, and no formal power calculation has been used to determine the sample size to be recruited. There is an important ethical issue raised by running a trial that is potentially under-powered. As Freedman et al. (2001:401) put it:

> Sample size and power must be addressed before the start of a randomised, controlled trial. It is necessary to know in advance the likelihood of finding valid conclusions from the population assessed. It may be acceptable to subject a patient to a chance of a less than ideal treatment, or to the psychological stress of being a 'subject', if there is a chance of a valid scientific outcome, but it is not ethical to conduct a study the design of which cannot make valid conclusions.

However, relevant considerations are:

- There is no reason to think that participation in the trial will pose any risks to the participants, nor subject them to 'less than ideal treatment' or undue psychological stress. All of our experience with running previous studies in East Kent and Lambeth and Southwark, and the feasibility study in Medway is that participants will find the singing intervention enjoyable and personally and socially beneficial.
- The Brompton trials (Lord, 2010, 2012), involved 28 and 24 participants respectively, and reported significant changes in the physical component of the SF-36. The proposed study will be three times larger.
- The Medway feasibility study (see above) showed an improvement on the CAT questionnaire of five points, more than twice the minimum clinical difference score of two. A change of five points represents a moderate effect size of approximately 0.5. If such a difference arises between the intervention and control groups in the proposed trial, where data is paired from pre-test and follow up, a sample size of 40 per group will be more than sufficient to give 90% power at a p-value of 5% (two-tailed) (Chan, 2003).
- The proposed study will assess participants immediately following the intervention and then after a further three months. No such follow-up has taken place in previous trials.

- The current study is a pilot and if the findings are encouraging the results could be subsumed into a larger multi-centre trial conducted in the same way.

2.3 Inclusion and exclusion criteria

The trial will be open to patients:

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

Excluded from the trial will be patients who:

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

2.4 Circumstances under which participants might leave the trial

We have no reason to anticipate that participants would have any adverse reaction to the intervention, but our experience of running singing and COPD projects suggests that individuals may decide to leave the singing group for the following reasons:

- Health problems associated with COPD or other conditions
- Health problems of spouse or partner or other family members
- Changes to other commitments which means that the day/time of the group no longer convenient
- Finding that the singing group is not what they expected

2.5 Intervention and control

Following baseline assessments, participants will be randomly allocated to the control arm, which will be treatment as usual (TAU) following PR, or the intervention group, which will be TAU plus group singing.

There will be two intervention groups in the same community venue in the Medway district meeting on different days. Each group will consist initially of approximately 25 participants at the outset. The groups will be conducted by two experienced and skilled singing facilitators who are trained in facilitating breathing and singing techniques specifically for people with a respiratory disease. A total of 10 sessions will occur over the period of the study, with the expectation that most participants will attend a minimum of 5 sessions. Each session will be run for 90 mins with breathing exercises and singing occurring for one hour. The additional time will allow for the groups to socialise. Details of the programme are given in Appendix 7.12 together with a goals framework with details the links between activities and expected outcomes.

To complement the group singing, intervention participants will also be expected to practise the taught techniques away from the group. This home practice will be supported by a guide and video resources developed specifically for people with COPD. Choir facilitators will encourage use of the resources each week and ask participants to keep a diary of their use of the home programme.

2.6 Data Collection

Participants will be invited to attend for assessments three times over the course of the project (baseline, end of intervention, further three months follow-up). It is expected that one hour to an hour and a half, will be needed for the physical assessments and completion of questionnaires. Participants will arrive at the baseline assessment session and informed consent taken, and a safety check will be made regarding their suitability for the physical assessments (health screening questionnaire, resting heart rate and oxygen saturation, and blood pressure). They will then complete the written questionnaires before undertaking the physical assessments in a structured sequence:

The following demographic details and information on health service use will be collected for all participants as the first part of an assessment questionnaire:

- Gender
- Age
- Ethnicity
- Marital status
- Employment/volunteer status

- Smoking status
- COPD diagnosis (date and severity)
- Details of PR attendance
- Co-morbid conditions
- Medication and health service use (use of inhalers and home oxygen, primary care consultations and hospital admission over the previous three months)
- Frequency and severity of exacerbations (over the previous three months)

Questionnaires

The quantitative data will be collected from both the singing group and the participants at baseline, and conclusion of the programme at three months, and on follow-up at six months. Participants will be asked to complete the following collection of questionnaires:

- COPD Assessment Test (CAT)
- MRC breathlessness scale (MRC)
- SF-36v2 (physical and mental health related quality of life)
- GAD-7
- PHQ-9

All of these questionnaires are simple, short and straightforward. It is anticipated that they will take 20 minutes to complete. Support will be available if participants need help in completing the questionnaires.

Exercise assessment and Spirometry

The following measures will be taken on the basis of physical examination:

- Weight and height (to allow for BMI)
- FEV1 (plus percentage)
- FVC (plus percentage)
- Expiratory pressure
- Chronic hypoxia and/or cor pulmonale
- Transfer factor for carbon monoxide (TLCO)

- Breathing patterns assessed with Structured Light Plethysmography (SLP) before and after the 6-minute walk test
- Exercise capacity assessed by 6-minute walk test (6MWT)

Procedure

On arrival participants will have a resting heart rate and oxygen saturation measurement using finger pulse oximetry and resting blood pressure to ensure good health to undertake the exercise test. On successful completion of this initial screening participants will then complete an initial SLP assessment followed by the a 6-minute walk test following published ERS / ATS guidelines, and then further assessment with SLP.

Six Minute Walk Test (6MWT)

The Six Minute Walk Test will be administered according to published guidelines (Holland, A.E. et al. (2014). This will be conducted indoors to reduce the impact of weather and environmental conditions in a room with a level, non-slip surface. A shuttle walking course 10-metres in length will be measured out and marked with cones and masking tape. Distances walked (6MWD) will be measured to the nearest completed metre, with Borg breathlessness scores (0-10) and oxygen saturation and heart rate recorded at test termination using finger pulse oximetry and monitored for a minimum of 5-minutes post-exercise to ensure sufficient recovery. A number of parameters will be measured to reflect participant performance in this test (Table 6).

Table 6. Measurements derived from 6MWT

Parameter	**Description**
Resting heart rate	beats per min^{-1} (bpm^{-1})
Resting oxygen saturation	SaO_{2rest} (%)
Resting blood pressure	mmHg
6-minute walk distance (6MWD)	metres (m)
Terminal exercise heart rate	bpm^{-1}
Terminal exercise oxygen saturation	$SaO_{2exercise}$ (%)
Exertional breathlessness	Borg breathlessness score (0-10)

Structured Light Plethysmography (SLP)

Participants will be assessed using SLP in a standardised (Hmeidi *et al*., 2017) way before and after the 6MWT. In short, the participants will be asked to wear a tight white top and sit in front of the SLP device (Pneumacare Ltd. Cambridge UK). A chess board of light will be projected onto the participant's chest and abdomen. The participant will be instructed to sit still for 5 minutes. The measures in table 5 will be recorded and analysed are considered of potential interest to reflect patterns of breathing that may be affected by singing training. Consideration of such a large number of parameters is necessary and justified given the newness of this technique and the limited research so far conducted with COPD participants.

Table 7: Measurements derived from Structured Light Plethysmography assessment	
Parameter	**Description**
*mTi	Median inspiratory time (Ti) in seconds
*vTi	Interquartile range (IQR) of inspiratory time (Ti) in seconds
*mTi/Te	Median inspiratory time to expiratory ratio (Ti/Te)
*vTi/Te	Interquartile range (IQR) of inspiratory time to expiratory ratio (Ti/Te)
*mTi/Ttot	Median duty cycle (Ti/Ttot)
*vTi/Ttot	Interquartile range (IQR) of duty cycle (Ti/Ttot)
*mBreathPhase_RC2AB	Median asynchrony between ribcage and abdomen (also known as thoraco-abdominal asynchrony [TAA]) in degrees
vBreathPhase_RC2AB	Interquartile range (IQR) of asynchrony between ribcage and abdomen (also known as thoraco-abdominal asynchrony) in degrees
*mIE50	Median inspiratory flow divided by expiratory flow at 50% tidal volume (displacement)
*vIE50	Interquartile range (IQR) of inspiratory flow divided by expiratory flow at 50% tidal volume (displacement)
*mTPTEF_TE	Median time to reach peak tidal expiratory flow divided by expiratory time (tPTEF/tE)
*vTPTEF_TE	Interquartile range (IQR) of time to reach peak tidal expiratory flow divided by expiratory time (tPTEF/tE)

However, given the theoretical assumption that singing encourages a change in pattern of breathing towards greater engagement of the diaphragm in the production of longer, controlled out-breaths, the most discriminatory measure is considered to be a change in the 'mBreathPhase_RC2AB' parameter. An improvement on this measure would indicate better initiation of breathing utilising the diaphragm and a smoother breath cycle.

The key null hypothesis to be tested is that no change will be seen on the 'mBreathPhase_RC2AB' parameter as a result of regular singing at six months post-baseline assessment.

Qualitative Data

Participants in the singing groups will be asked to keep a weekly diary to record their use of the home programme of breathing and singing exercises. A representative sample of participants in both intervention and control arms of the trial will also be interviewed on completion of the final period of data collection.

Photography and filming

A photographic and film record will be made of the project as it progresses, and a representative sample of participants (including those in the control condition) will be interviewed on camera following the completion of data collection.

2.7 Randomisation

Following the assessments of the total sample at baseline, randomisation will be undertaken immediately, with stratification by sex and severity of COPD, and participants informed of their allocation. Use will be made of the 'Sealed Envelopes' professional randomisation service: https://www.sealedenvelope.com/

2.8 Data Analysis

The design of the trial is a 3 by 2 mixed anova design with time as the within subjects factor at 3 levels (baseline, end of intervention and follow-up) and Condition as the between subjects factor with 2 levels (singing vs. control). The primary outcome variable for the trial will be the COPD Assessment Test score. Additional secondary analyses will consider a range of additional health measures, together with spirometry, exercise and SLP parameters. We will also examine differences between the intervention and control groups on indicators of service use to determine potential cost-savings associated with reduced inhaler usage, consultations with health professionals and hospital admissions. Embedded within the trial will be a qualitative assessment of the participant experience and perceived benefits, together with an evaluation of the resources to support practice between singing sessions.

Quantitative data

Quantitative data will be analysed using IBM SPSS 24. Comparative analysis will take place to examine composition of the intervention and control groups at baseline to assess equivalence. Comparisons will be made between the intervention and control groups at two follow up points to

determine whether the intervention has resulted in significant change on the primary and secondary outcome measures, which allow for rejection of the null hypothesis that singing results in no change in functional status, health related quality of life, mental wellbeing and patterns of breathing. Appendix 7.11 provides a plan for the statistical analysis to be undertaken, and considerations of effect size and power, provided by the project statistical consultant Dr. Sabina Hulbert.)

Qualitative data

For the qualitative data obtained from individual interviews, thematic analysis (Braun and Clarke, 2006) will be used to identify any consistent themes. The qualitative data will be analysed using QSR International's NVivo 11 software. Within NVivo, queries will be run to determine word frequencies within respondents' qualitative comments.

For the thematic analysis, this process has six phases:

- Familiarising yourself with your data: Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas.
- Generating initial codes: Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
- Searching for themes: Collating codes into potential themes, gathering all data relevant to each potential theme.
- Reviewing themes: Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis.
- Defining and naming themes: Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme.
- Producing the report: The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis.

2.9 Gantt chart for the trial

A Gantt chart for the trial can be found in Appendix 7.1

3 Ethics

Ethical approval will be sought through the NHS IRAS, following proportionate review.

3.1 Informed consent and the right to withdraw

Participants will be provided with a detailed information sheet describing the study and what will be required of them. They will have at least a week to read the information sheet before consenting to participate and will have the opportunity to speak with a member of the research team if they have any questions or concerns.

3.2 Risk and adverse events

Group singing is a popular and frequently occurring activity and we have come across no documented instances of harm arising from this. Our previous research into the benefits and effects of singing for various groups of people, including people with COPD, mental health problems and older people, has found that the activity of singing in a group has often offered support in times of physical and emotional distress. However, we also acknowledge that people with COPD constitute a group liable to experience health problems which may be exacerbated at any time and due to outside causes. Therefore, we will ensue that all those responsible for running the groups, and especially facilitators, are trained in how to prevent, be alert to and respond to the potential for health issues within this group. For example, they will suggest that participants only engage in activities which they feel comfortable with and reassure them that nothing is compulsory. At least one individual trained in first aid will be present. The venues selected will comply with health and safety legislation and will be disability compliant. There are some contraindications to some of the tests to be administered and these will be addressed through screening participants prior to undertaking the tests (see above section 2.6).

3.3 Vulnerability

We will only be recruiting those who are able to provide informed consent and so will ensure that all recruiters are able to assess capacity as set out in the Mental Capacity Act 2005 and Good Clinical Practice guidelines. We will ensure that explanations of the nature of the project are made clear and are understood. No pressure will be placed on individuals to participate nor will inducements be used. GPs will be involved in identifying and writing to patients for whom the intervention is suitable, which will provide confidence for participants that those involved can be trusted. No indication will be given that the singing intervention will lead to improvements in COPD. Care will be taken to ensure that respondents do not feel overburdened by the demands of the research in terms of data collection.

3.4 Anonymity and confidentiality

We will collect personal data in order to link these to outcomes. We will ensure that all such information is stored safely during the course of the project in accordance with data protection legislation, and that it is destroyed following completion of the project. We will ensure that only researchers have access to the data and that questionnaires are anonymised through the use of coding. No individually identifiable information will be used in any reports resulting from the research.

3.5 Demoralisation of the control group

One issue that may arise in the trial given the nature of the intervention, is that participants randomised to the control arm may feel disappointed having hope to take part in singing. We will ensure at recruitment that all participants are aware of this possibility, understand the need for a control group in the study and consent given those conditions. We will however provide participants in the control group with the opportunity to take part in group singing after the end of the final data gathering session in the trial. In our experience, people who have engaged in a number of singing for health and wellbeing research projects run by the De Haan Centre have generally wanted singing groups to continue after the research phase, and have found a variety of ways to sustain the group, through raising funds or making personal contributions to the cost. We anticipate that this will happen with this study too, and that the existing groups will be able to welcome new members from the control group after the trial.

4. Project Timetable

4.1 Monthly activities on the project

- June onwards 2018 – Formulate study protocol & develop database
- October 2018 onwards – pre-recruitment publicity – target 120 expressions of interest, with the aim of 100 participants formally consenting.
- December 2018 – Ethics application submitted
- March 2019 – Ethics approved
- April 2019-June 2019 – Recruitment to project
- May-June 2019 – Taster sessions
- July 2019 – Consenting and baseline assessments
- August 2019 – Randomisation and letters to participants
- September - November 2019 – Ten weeks singing intervention
- November - December 2019 – Post-intervention assessments
- December - February 2020 – Post-intervention period
- February - March 2020 – Follow-up assessments and interviews
- April - May 2020 – Data analysis
- May - July 2020 – Writing of papers for peer-reviewed journals
- July 2020 – Publication/Dissemination

4.2 Detailed timetable for assessments and the singing intervention

PLEASE NOTE: Sessions are proposed to start at the beginning of September 2019, to ensure that 10 sessions can be run before the middle of November. This will allow the post-intervention assessments to happen in November-December 2019. Easter 2020 is April 12.

May 2019

6 May bank holiday

13 Taster session
20 Taster session
27 May bank holiday

June 2019
3 Taster session
10 Taster session
17 Taster session
24 Taster session

July 2019
1 Consent and baseline assessments
8 Baseline assessments
15 Baseline assessments
22 Baseline assessments

August 2019
Randomisation and letters out to participants

September 2019
2 Session 1
9 Session 2
16 Session 3
23 Session 4
30 Session 5

October 2019
7 Session 6
14 Session 7
21 Session 8
28 Session 9

November 2019
4 Session 10
11 Start of follow-up assessments / and three-month break until mid-February

18 Follow-up assessments
25 Follow-up assessments

December
2 Follow-up assessments
9 End of follow-up assessments
16 Christmas break
23
30

January 2020
6
13
20
27

February 2020
3
10
17 Start of follow-up assessments
24 Follow-up assessments

March 2020
2 Follow-up assessments
9 Follow-up assessments
16 End of follow-up assessments
23 Data inputting and cleaning
30 Data inputting and cleaning

April-November 2020
Analysis, report writing, feedback to participants, publications

5. Project Finance

Core funding is provided by Oak Foundation and will be used as outlined below. Further support through staffing is provided by Canterbury Christ Church University, University of Kent and Medway Community Healthcare. The total cost of the trial is estimated to be £75K including contributions in kind (research staff, administration, university services etc.).

A letter from the funder confirming funds is attached to the IRAS application

Research support (e.g. £300 trial registration, Additional support for assessments)	2,000
Delivery of the intervention 14 sessions x 2 = 28 @ £250	7,000
Assessments (University of Kent) 100 participants x 3 assessments @ £50 each	15,000
Travel/subsistence/meetings	2,000
Materials/publicity	2,000
Contingencies	2,000
Total	30,000

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7. Appendices

7.1 Project Gantt chart

	Singing for COPD: A pilot randomised controlled trial																							
	Month by month (20 months) from gaining ethical approval																							
Activities	November	December	January	February	March	1 April	2 May	3 June	4 July	5 August	6 September	7 October	8 November	9 December	10 January	11 February	12 March	13 April	14 May	15 June	16 July	17 August	18 September	19 October	20 November
Ethics / R&D	x	x	x	x	x																			
Recruitment						x	x	x																
Assessment 1								x	x															
Randomisation										x														
Intervention											x	x	x											
Assessment 2													x	x										
Follow up														x	x	x								
Assessment 3																x	x							
Interviews																	x							
Data Analysis, writing up																		x	x	x	x	x	x	x

7.2 Text for recruitment publicity

This will be the basis for professionally designed posters, flyers and advertisements

Do you have difficulties with breathing due to COPD (chronic obstructive pulmonary disease)?

Have you already taken part in Pulmonary Rehabilitation?

Would you be willing to participate in a new research trial to study whether group singing can help to improve breathing?

Medway Community Healthcare Respiratory Team is collaborating with researchers at Canterbury and Christ Church University and the University of Kent in an important new project.

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

The study will be a controlled trial, and we are looking for 100 participants, half of whom would join a weekly singing group for ten weeks and half would act as a comparison and not be involved in singing. After the project finishes, participants in the comparison condition will be offered the opportunity to join a singing group.

The singing groups will start in the autumn of 2019 and run for ten weeks.

For further details and to register your interest in taking part, please ring Di White, Sidney De Haan Research Centre for Arts and Health on 01303 220870 or email her on di.white@canterbury.ac.uk

For further details of the De Haan Centre's work on singing and health, please visit:

https://www.canterbury.ac.uk/health-and-wellbeing/sidney-de-haan-research-centre/sidney-de-haan-research-centre.aspx

7.3 Patient Information Sheet - Version 1, 7 December 2018

PARTICIPANT INFORMATION SHEET

Study title: Singing and COPD: A pilot randomised controlled trial in Medway

The above study is being conducted by Prof Stephen Clift from the Sidney De Haan Research Centre for Arts and Health at Canterbury Christ Church University (CCCU) together with the following partners: University of Kent and Medway Community Healthcare, Respiratory Team. Before you decide to take part in the study it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully before making a decision to take part in the study.

Background
A number of recent research studies have shown that regular group singing can be beneficial for people with lung conditions that make breathing difficult, lead to problems of breathlessness, and limit physical activity. Previous studies are small-scale and more research is needed. This study aims to set up and evaluate weekly singing groups for patients with chronic obstructive pulmonary disease (COPD) supported by Medway Community Healthcare, to further research this idea.

The aim is to test whether regular community singing is helpful for people with COPD to manage their breathing difficulties better. It is important in order to robustly test the potential value of singing to undertake what is known as a randomised controlled trial. This means that if you participate, you could be selected completely at random to join a singing group (the intervention arm) or to be part of the comparison arm of the trial (sometimes called a control group). The random selection process is like taking numbers out of a hat, and whether you are in the singing group or the comparison group is entirely a matter of chance. If you are in the comparison arm, you will not be offered any activity, and your support or treatment for COPD will just continue as usual from your GP, nurse or Medway Community Healthcare.

PLEASE NOTE: If you are randomly assigned to the comparison condition you will have the opportunity to take part in a singing group once the research is completed following the final assessments.

What will you be required to do?

Everyone who is part of the study, whether in the singing group or control condition, will be asked to participate in assessment sessions before the project starts, at the end of the intervention period and then after a further three months. To help us assess the benefits of this activity, you will be asked to complete tests of your lung function and exercise capacity (more details are given at the end of this information sheet). You will also be asked to complete questionnaires about health and wellbeing and your use of health services. You have the right to leave blank any questions you would rather not answer. Details of the assessments are given below.

If you are randomly selected to be in the singing condition, you will have the opportunity to attend a singing group meeting every week at VENUE TO BE CONFIRMED, for TEN WEEKS starting at the beginning of September 2019. We would like you to attend every week if this is possible for you, but understand that your health and other commitments may mean you have to miss occasional sessions.

If you are part of the comparison arm, you will not engage in any new activity, but will continue to receive any treatment required to help you with your breathing.

Towards the end of the project we may invite members of the intervention groups and the control condition to take part in a recorded interview with a member of the research team.

During the study we will also make a documentary record of the singing groups using photography and filming. You will be asked at every stage for your permission to be involved in any photography or filming that happens during the project. You can take part in the project but refuse to be photographed or filmed without giving any reason for your decision.

To participate in this research you must

- Be aged 18 or over
- Be willing to be allocated at random to either the singing activity or a control group, with no activity provided during the trial
- Be able to attend a local venue where a singing group is taking place weekly over the study period
- Be willing to undertake assessments of your lung function and how much physical activity you can comfortably do
- Be able to complete questionnaires in English (help will be provided)

Confidentiality and Data Protection
On the legal basis of your informed consent all data and personal information will be stored securely within CCCU premises in accordance with the General Data Protection Regulation (GDPR) and the University's own data protection policies. No unrelated or unnecessary personal data will be collected or stored. The following categories of personal data will be processed: sex. age, lung function measurements, answers given on questionnaires and statements made in personal interviews. Personal data will be anonymised and used purely for research purposes as the basis for published scientific reports. Data can only be accessed by members of the research team under the direction of Professor Stephen Clift. After completion of the study, all data will be made anonymous (i.e. all personal information associated with the data will be removed) and held for a period of 5 years, after which it will be destroyed.

Dissemination of results
We will write up the results of the study in a report. There will also be a summary of the results which will be available for people who have taken part. We will also publish the results in health journals. A film documentary of the project will also be produced which will be available through the internet. You will be asked for your permission to be involved at every stage of filming and you will have the opportunity to see the film before it is made public to ensure that you are happy to be included.

Deciding whether to participate

If you have any questions or concerns about the nature, procedures or requirements for participation do not hesitate to contact us. If you decide to participate that doesn't mean that you have to continue with the project. You can decide to stop coming to the singing groups and being part of the research project at any time without having to give a reason.

Any questions?
If you have any questions or concerns about the nature, procedures or requirements for participation do not hesitate to contact:

Professor Stephen Clift
Sidney De Haan Research Centre for Arts and Health
Canterbury Christ Church University
60 69 Tontine Street, Folkestone
Kent, CT20 1JR
Email: stephen.clift@canterbury.ac.uk
Tel: 01303 220870

Thank you very much for taking the time to consider being involved in this study

Details of lung function and exercise assessments

The procedures to test your lung function will involve the following tests:

Spirometry: *a test to assess the maximum amount of air that can be inhaled and exhaled from your lungs in one breath.*
From a stable, seated position, you will breathe in until you feel that your lungs are full. Then you will purse your lips tightly around a mouthpiece and breathe out as hard and as fast as you possibly can until your lungs are empty (which takes approximately 6 seconds). You will have an opportunity for three tests with one minute rest between each, and the maximum measurement will be recorded.

Mouth Inspiratory Pressure: *a test to measure the strength of the diaphragm and other inspiratory muscles.*
This test will require you to breathe out slowly and completely through a mouthpiece and then breathe in as hard and fast as you can until your lungs are full. You will repeat this process up to 10 times. The maximum pressure you create in your mouth will be recorded.

SLP: *A test to assess chest and abdominal wall synchrony.*
You will wear a tight fitting, white T-shirt. From a seated position we will project a grid of normal light onto your chest and abdomen. You will be asked to sit still for few minutes and breathe normally throughout the test. We will be able to measure the movements of your chest and abdomen during this test. We will then ask you to perform a standardised 30 second piece of singing sat whilst we measure the movement of your chest and abdomen.

Carbon Monoxide Monitoring: this measures the level of carbon monoxide in the air you breathe out and will provide an indication of exposure to tobacco smoke.

6-minute walk test: The procedure to test walking ability is designed to replicate the physical challenges of everyday life and functional performance. The walk test is self-paced, which means that you determine the level of effort and exertion, so there is low risk of any discomfort.

You will perform a shuttle walking test lasting 6 minutes and we will measure the total distance you cover. You should aim to walk as fast as you can over the 6-minutes, but you can take a break if needed. This will be performed indoors on a flat surface.

To promote comfort and accuracy of test results please ensure you prepare for the lung function and exercise tests by adhering to the following:

- Comfortable clothing should be worn.
- Appropriate shoes for walking should be worn.
- Patients should use their usual walking aids during the test (cane, walker, etc.).
- Patient’s usual medication regimen should be followed
- Avoid heavy meals 2 hours before testing.

7.4 Patient Consent Forms - Version 1, 7 December 2018

CONSENT FORM

Title of Project: **Singing and COPD: A pilot randomised controlled trial in Medway**

Name of Researcher: Professor Stephen Clift (Chief Investigator)

Contact details:

Address:	Sidney De Haan Research Centre for Arts and Health, Canterbury Christ Church University, 69 Tontine Street, Folkestone, Kent, CT20 1JR
Tel:	01303 220870
Email:	stephen.clift@canterbury.ac.uk

Please initial box

1.	I confirm that I have read and understand the information sheet for the above study (Version 1, 7 December 2018) and have had the opportunity to ask questions.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.	
3.	I understand that any personal information that I provide to the researchers will be kept strictly confidential and will not be shared with anyone else	
4.	I agree to my GP being informed about my involvement in this study	

Name of Participant	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

Copies: 1 for participant, 1 for researcher

CONSENT FORM

Title of Project: **Singing and COPD: A pilot randomised controlled trial in Medway**

Name of Researcher: Professor Stephen Clift (Chief Investigator)

Contact details:

Address:	Sidney De Haan Research Centre for Arts and Health, Canterbury Christ Church University, 69 Tontine Street, Folkestone, Kent, CT20 1JR
Tel:	01303 220870
Email:	stephen.clift@canterbury.ac.uk

	Please initial box
1. I confirm that I have previously given my consent to participate in this study and understand that my participation is voluntary and that any personal information I provide will be kept confidential	
2. I agree to photography and filming during group singing sessions and combined performance events	
3. I understand that I will have the opportunity to view any images before they are used in reports and presentations on the project and for purposes of disseminating findings from the project	

Name of Participant	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

Copies: 1 for participant, 1 for researcher

7.5 Letter to participant GP

Sidney De Haan Research Centre for Arts and Health
65-69 Tontine Street
Folkestone
Kent CT20 1JG

Dear Dr. _____

Singing and COPD: A pilot randomised controlled trial

I am writing with the permission of your patient _____ to inform you that he/she is participating in a randomised trial to assess the effects of regular group singing for people with chronic obstructive pulmonary disease.

Recruitment for this trial took place through the Respiratory Team at Medway Community Healthcare.

I attach the patient information sheet for this project, for your information.

If you have any questions regarding this trial, I should be very pleased to hear from you.

Yours sincerely

Prof. Stephen Clift
Chief Investigator
stephen.clift@canterbury .ac.uk
Tel: 01303 220870

7.6 Participant personal information questionnaire

Participant personal information questionnaire

Name _____

Age _____

Address

_____

Name and address of your GP _____

1. What is your sex? Please circle: Male Female

2. What is your marital status? Please circle:

Single/Unmarried

Married

Same-sex civil partnership

Separated but still legally married or legally in civil partnership

Divorced

Widow/widower (including from civil partnerships)

3. How would you describe your national identity? Please circle:

British

English

Northern Irish

Scottish

Welsh

Another Nationality – Please describe here: _____

4. What is your ethnic group?

Choose one section from A to E, then circle one to best describe your ethic group or background

A. White

English/Welsh/Scottish/Northern Irish/British

Irish

Gypsy or Irish Traveller

Another white background

B. Mixed/multiple ethnic groups

White and Black Caribbean

White and Black African

White and Asian

Another mixed/multiple ethnic group

C. Asian/Asian British

Indian

Pakistani

Bangladeshi

Chinese

Another Asian background

D. Black/African/Caribbean/ Black British

African

Caribbean

Another Black/African/Caribbean/ Black British

E. Another ethnic group

Arab

Another ethnic background

5. Have you received a formal diagnosis of COPD? Yes No

6. Have you undertaken pulmonary rehabilitation in the last THREE months? Yes No

7. If yes, how many sessions did you attend? _____ sessions

8. How would you describe your level of COPD currently?

Mild

Moderate

Severe

Very severe

9. Have you experienced any significant worsening of your COPD over the last THREE months? Yes No

10. Are you affected by other health conditions? Yes No

9. If yes, please describe here:

7.7 MRC Breathlessness Scale

Grade	Description of breathlessness
Grade 0	I only get breathless with strenuous exercise
Grade 1	I get short of breath when hurrying on level ground or walking up a slight hill
Grade 2	On level ground, I walk slower than people of the same age because of breathlessness, or I have to stop for breath when walking at my own pace on the level
Grade 3	I stop for breath after walking about 100 yards or after a few minutes on level ground
Grade 4	I am too breathless to leave the house or I am breathless when dressing

7.8 COPD Assessment Test

The COPD Assessment Test (CAT)

http://www.catestonline.org/

This questionnaire is designed to measure the impact COPD (Chronic Obstructive Pulmonary Disease) has on wellbeing and daily life. It can also identify difficulties experienced due to other lung conditions like asthma.

For each item below, circle the number that best describes you currently. Be sure to only select one response for each question.

	I never cough	0	1	2	3	4	5	6	I cough all the time
1	I have no phelgm (mucus) in my chest at all	0	1	2	3	4	5	6	My chest is completely full of phelgm (mucus)
2	My chest does not feel tight at all	0	1	2	3	4	5	6	My chest feels very tight
3	When I walk up a hill or one flight of stairs I am not breathless	0	1	2	3	4	5	6	When I walk up a hill or one flight of stairs I am very breathless
4	I am not limited doing any activities at home	0	1	2	3	4	5	6	I am very limited doing activities at home
5	I am confident leaving my home despite my lung condition	0	1	2	3	4	5	6	I am not at all confident leaving my home because of my lung condition
6	I sleep soundly	0	1	2	3	4	5	6	I don't sleep soundly because of my lung condition
7	I have lots of energy	0	1	2	3	4	5	6	I have no energy at all

7.9 PHQ-9

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1 Little interest or pleasure in doing things	0	1	2	3
2 Feeling down, depressed, or hopeless	0	1	2	3
3 Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4 Feeling tired or having little energy	0	1	2	3
5 Poor appetite or overeating	0	1	2	3
6 Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7 Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8 Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9 Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

7.10 GAD-7

	Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1	Feeling nervous, anxious or on edge	0	1	2	3
2	Not being able to stop or control worrying	0	1	2	3
3	Worrying too much about different things	0	1	2	3
4	Trouble relaxing	0	1	2	3
5	Being so restless that it is hard to sit still	0	1	2	3
6	Becoming easily annoyed or irritable	0	1	2	3
7	Feeling afraid as if something awful might happen	0	1	2	3

A12 – GAD7 total score

7.11 SF-36 v2

This survey asks for your views about your health, how you feel and how well you are able to do your usual activities. Answer every question by checking the appropriate response. There are no right or wrong answers. If you are unsure about how to answer a question, please give the best answer you can.

Your Health in General

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor

2. Compared to one year ago, how would you rate your health in general now?

Much better than one year ago	Somewhat better than one year ago	About the same as a year ago	Somewhat worse than a year ago	Much worse now than a year ago

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Vigorous activities, such as running, lifting heavy objects, participating in vigorous sports			
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf			
Lifting or carrying groceries			
Climbing several flights of stairs			
Bending, kneeling or stooping			
Walking more than a mile			
Walking several hundred yards			
Walking one hundred yards			
Bathing or dressing yourself			

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Cut down on the amount of time you spend on work or other activities					
Accomplished less than you would like					

Were limited in the kind of work or other activities					
Had difficult performing the work or other activities (for example, it took extra effort)					

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Cut down on the amount of time you spend on work or other activities					
Accomplished less than you would like					
Did work or other activities less carefully than usual.					

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely

7. How much bodily pain have you had during the **past 4 weeks**?

None	Very mild	Mild	Moderate	Severe	Very severe

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely

9. These questions are about how you feel and how things have been with you with the **past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past 4 weeks…**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Did you feel full of life?					
Have you been very nervous?					
Have you felt so down in the dumps that nothing could cheer you up?					
Have you felt calm and peaceful?					

Did you have a lot of energy?					
Have you felt downhearted and depressed?					
Did you feel worn out?					
Have you been happy?					
Did you feel tired?					

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
I seem to get sick a little easier than other people					
I am as healthy as anybody I know					
I expect my health to get worse					
My health is excellent					

THANK YOU FOR COMPLETING THESE QUESTIONS!

7.12 Service utilisation questionnaire

Service utilisation questionnaire

1. **Have you been prescribed oxygen therapy?**

   □ Yes □ No

2. **Over the last THREE months how often have you used oxygen on average while at home?**

   □ 4 times a day or more
   □ 2 or 3 times a day
   □ Once a day
   □ Less than daily

3. **Over the last THREE months have you carried portable oxygen with you when leaving your home?**

   □ Yes □ No

4. **In the last THREE months have you used a rescue (blue) inhaler to help with your breathing?**

   □ Yes □ No

5. **If YES, in the last THREE months how often have you used your rescue inhaler (blue inhaler) on average? Tick one box and give details of how often you use the inhaler.**

   □ Every day

   Please specify how many times a day you typically use your inhaler _____

   □ Less than daily

   Please specify how many times a week you typically use your inhaler _____

---

6. **In the last THREE months how many times have you been admitted to hospital?**

   _____ times

Please give further information on each of your TWO longest hospital stays in this period starting with the longest stay

a. What was the reason for your longest hospital stay?

b. How long did you spend in hospital? _____ nights

c. What was the reason for your second longest hospital stay?

d. How long did you spend in hospital? _____ nights

7. **In the last THREE months have you used the following health and social care services?**

If yes please provide the following information.

Service	*Tick box if service used*	*How many contacts / visits in the last THREE months?*
a. Visits to a Hospital A & E Department		
b. Visits to a Hospital Outpatient Department		
c. Visits to General Practitioner at GP Practice		
d. Visit to Nurse at GP Practice		

8. **In the last THREE months have you attended pulmonary rehabilitation classes?**

□ Yes □ No

7.13 Checklist for the suitability of patient-reported outcome measures (Francis et al., 2016)

CONCEPTUAL MODEL
1. Has the PRO construct to be measured been specifically defined?
2. Has the intended respondent population been described?
3. Does the conceptual model address whether a single construct/scale or multiple subscales are expected?
CONTENT VALIDITY
4. Is there evidence that members of the intended respondent population were involved in the PRO measure's development?
5. Is there evidence that content experts were involved in the PRO measures's development?
6. Is there a description of the methodology by which items/questions were determined (e.g. focus groups, interviews)?
RELIABILITY
7. Is there evidence that the PRO measure's reliability was tested (e.g. test-retest, internal consistency)?
8. Are reported indices of reliability adequate (e.g. ideal: $r \geq 0.80$; adequate: $r \geq 0.7$; or otherwise justified)?
CONSTRUCT VALIDITY
9. Is there reported quantitative justification that single scale or multiple subscales exist in the PRO measure (e.g. factor analysis, item-response theory)?
10. Are there findings supporting expected associations with existing PRO measure or with other relevant data?
11. Are there findings supporting expected differences in scores between relevant known groups?
12. Is the PRO measure intended to measure change over time? If YES, is there evidence of test-retest reliability and responsiveness to change?
SCORING AND INTERPRETATION
13. Is there documentation how to score the PRO measure (e.g. scoring method
14. Has a plan for managing and/or interpreting missing responses been described (i.e. how to score incomplete surveys)?
15. Is information provided about how to interpret the PRO measure scores (e.g. scaling/anchors (what high and low scores represent), normative data and/or a definition of severity (mild to severe))?
RESPONDENT BURDEN AND PRESENTATION
16. Is the time to complete reported and reasonable?
17. Is there a description of the literacy level of the PRO measure?
18. Is the entire PRO measure available for public viewing (e.g. published with the citation, or information provided about how to access a copy)

7.14 – Statistical Analysis Plan

Design	3x2 mixed anova				
factors	levels	measurement			
Time	3 (T1, T2, T3)	within subject/repeated measures			
Condition	2 (Intervention, TaU)	between subjects			
effect/analyses	**expected difference**	**Notes**	**required N for minimum .80 power and alpha at .05 with moderate effect size d=.5**		
anova - main effect of time	not relevant		34		
anova - main effect of condition	not relevant		86		
anova - interaction	significant		36		
anova - main effect of condition within T1	non significant		146	Bonferroni corrections included	sensitivity power analyses releaved that the minimum effect size detectable with power of .80 and sample sive of 40 in each group is d=.68
anova- main effect of condition within T2	significant	the effect sizes of these two effects can be compared to test for prolonged effects of the intervention	146	Bonferroni corrections included	
anova - main effect of condition within T3	significant (but smaller than above)		146	Bonferroni corrections included	
anova - main effect of Time within Intervention Condition	significant		28		
anova - main effect of Time within TaU Condition	non significant		28		
anova - post hoc on main effect of Time within Intervantion Condition	significant between T1 and T2 but possibly disappearing between T2 and T3		39	Bonferroni corrections included	
anova - post hoc on main effect of Time within TaU Condition	not relevant		39	Bonferroni corrections included	

7.15 – Medway Singing and COPD Programme

The design of the singing programme is based on facilitator experience and participant feedback from singing for health projects conducted by the Sidney De Haan Research Centre over the past ten years. Each session will commence with physical and vocal warm-ups to prepare and protect the voice. These range in intensity and demand and are designed to provide a common focus, as well as encourage participants to learn to gain control of their breathing prior to singing.

Participants will be guided through a variety of songs, which gradually demand greater breath control and vocal production during the course of the singing sessions. Repertoire will include songs with short and long phrases, and a blended approach in each session will encourage confidence and breath-control. In addition, material will be utilised which encourages strong diction and vocal projection, both of which require consideration of breath control and management. Potential limitation in vocal range will be carefully addressed, with consideration given to the key and notation range in each song.

Singing is often a trigger for emotional release, and consideration will be given to the focus of songs chosen, with avoidance of highly emotive subject matter. The range of songs will incorporate popular, national and world music, including those likely to be at least partly familiar participants as well as new material. The use of well-known material encourages greater confidence with singing and avoids spending much time learning new melodies. However, if appropriate, harmonies and creative performance will be encouraged.

Participants will also be encouraged to use the Singing for Better Breathing Resource, which will enable them to practise additional songs in between sessions. Use of the resource gradually demands greater breath control and vocal strength and supports the development of the individual singer during the course of the project.

Issues targeted in the programme	**Symptoms / issues**	**Musical intervention**	**Activity or songs**
Phonation	Breathy voice quality Weakened vocal anatomy Side-effects of inhaler use (hoarseness)	Breathing technique, velum exercises (e.g. tongue tip to soft pallet, sound ka, ga), group chanting, use of crescendo	*Banaha, Swing Low, When All the Saints, She'll Be Coming 'Round the Mountain* medley
Articulation	Weak articulatory muscles	Steady rhythmic pieces	*Swing Low*, *When All the Saints, She'll Be Coming 'Round the Mountain* medley
Breathlessness and the fear of breathlessness	Breathlessness on exertion and/or at rest	Breath-control warm-up exercises. Exercises to encourage deep breathing with controlled exhalation. Songs which encourage full	Fizz and Blow exercise. Counting on exhalation. Full inhalation followed by upper and lower tone laughter. *Pick A Bale A Cotton, Whip Jamboree*

		exhalation followed by quick 'muscular' inhalation.	
Coughing	Cough on inhalation and exhalation	Encourage nasal inhalation to warm air and avoid trigger of cold air on cough reflex	
Generalised muscle weakness	Immobility, falls, loss of intercostal muscle strength	Core strength, rhythmic stepping	Songs with a marching beat or strong rhythm e.g. *I'd Like To Teach The World To Sing*
Attention	Lethargy, withdrawal	Motivation, energising accessible material with appropriate challenge	Energizing songs, e.g. *I Got Rhythm*
Depression	Misery, poor motivation, lethargy, carer stress	As above	Depending on mood, either uplifting, energizing or thoughtful songs e.g. *Lean on Me*
Anxiety	Acute distress, hyperventilating, rapid pulse rate, carer stress	Group security, bonding, relaxation	Songs which focus on community, friendship and welcome e.g. *Senwa De Dende, Consider Yourself*
Social isolation	Loneliness, withdrawal, carer stress	Social bonding, motivation, group security	Songs which focus on community, friendship and welcome e.g. *Senwa De Dende, Consider Yourself*

7.16 Interview Schedules

Singing Group Participant Interview Schedule

Introduce yourself and thank the participant for agreeing to be interviewed. Check that they are happy to be recorded. Double check that the recorder is working!

Are you happy for this interview to be recorded? It will be completely confidential and the recording will be deleted at the end of the project. If yes:

Could you please give your name and the group you are attending for the purposes of this recording? If no:

Would you mind if I took a few brief notes as we talk? I will type these up later and let you check that you are happy with them as a record of our conversation.

1. Looking back, could you tell me how you got to hear about the project and why you were interested to join? **Card: Joining the project**

2. You were randomly allocated to the singing condition in the trial. Could you tell me how you felt about that? **Card: Singing condition**

3. More generally, could you tell me about your lung problem – how it started and what effects it has had on your life? **Card: Your lungs**

4. What help have you received in managing your condition? Card: **Help with your lungs**

5. Going back to this project, in terms of your physical health and your lungs, has being part of the singing group made any difference to you?
    a. Has it made a difference for your breathing? **Card: Difference breathing?**
    b. Has it made a difference to how active you are? **Card: Difference activity?**
    c. Has it affected the support you have needed from your GP, the surgery and other health services? **Card: Difference support?**
    d. Has it affected your use of medication? **Card: Difference medication?**

    With each of these aspects prompt the participant to give more information if appropriate

6. Has the group made any difference to your mental and social wellbeing and health? In what ways? **Card: Mental and social wellbeing**

7. Have there been any aspects of the group and the singing activities that you haven't enjoyed or could have been improved? **Card: Improvements?**

8. Could you tell me how you got on with using the singing resource to practise at home between sessions, and the diary? **Card: Singing resource and diary**

9. We have evaluated this project by asking participants to complete lung function and exercise tasks and also complete questionnaires. Do you have any views on how we have tried to assess the project? **Card: Evaluation of project**

10. Do you have anything else you would like to add about your involvement in this project or any questions for me?

    Thank the participant again for their help. Say that following the completion of the project a report will be prepared and they will receive a copy.

Control Group Participant Interview Schedule

Introduce yourself and thank the participant for agreeing to be interviewed. Check that they are happy to be recorded. Double check that the recorder is working!

Are you happy for this interview to be recorded? It will be completely confidential and the recording will be deleted at the end of the project. If yes:

Could you please give your name and the group you are attending for the purposes of this recording? If no:

Would you mind if I took a few brief notes as we talk? I will type these up later and let you check that you are happy with them as a record of our conversation.

1. Looking back, could you tell me how you got to hear about this project and why you were interested to join? **Card: Joining the project**

2. Could you tell me how you felt about being allocated to the control condition in the trial rather than the singing group? **Card: Being in the control condition**

3. More generally, could you tell me about your lung problem – how it started and what effects it has had on your life? **Card: Your lungs**

4. What help have you received in managing your condition? Card: **Help with your lungs**

5. Going back to the study, over the course of the project, have you noticed any differences in your health and wellbeing
    a. Have you noticed a difference for your breathing? **Card: Difference breathing?**
    b. Has there been a change in how active you are? **Card: Difference activity?**
    c. Has there been a change in the support you have needed from your GP, the surgery and other health services? **Card: Difference support?**
    d. Has there been a change in your use of medication? **Card: Difference medication?**

    With each of these aspects prompt the participant to give more information if appropriate

6. We have evaluated this project by asking participants to complete lung function and exercise tasks and also complete questionnaires. Do you have any views on how we have tried to assess the project? **Card: Evaluation of project**

7. Do you have anything else you would like to add about your involvement in this project or any questions for me?

   Thank the participant again for their help. Remind them that they will shortly have the opportunity to join a singing group. Say that following the completion of the project a report will be prepared and they will receive a copy.

7.17 Diary for recording of practice of singing at home

Diary for recording of practice of singing at home

Text and layout of a diary for participants to use is given below. This will be designed to form an attractive A5 booklet with one page per session.

Name _____

We would like you to keep a simple record of the practice you have done at home between sessions, and comment on the singing programme.

Please record whether you attended the session indicated, followed the practice video after the session and which songs you sang along to, plus any other activities you engaged in related to the singing programme.

	Did you attend this session?	Did you practise after the session as recommended?	What songs did you sing at home after the session?	How much time did you spend at home on exercises and singing?	Any other comments?
Session 1					
Session 2					
Session 3					
Session 4					
Session 5					
Session 6					
Session 7					
Session 8					
Session 9					
Session 10					