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# Cough therapy for interstitial lung disease

**Submission date**
03/11/2025

**Recruitment status**
Recruiting

**Registration date**
05/11/2025

**Overall study status**
Ongoing

**Last Edited**
05/11/2025

**Condition category**
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Chronic cough is one of the most common problems experienced by people with fibrotic Interstitial Lung Disease (ILD) and affects their everyday life. ILD is a chronic, progressive disease that causes stiffening of the lungs. Cough can be a distressing symptom making sufferers feel embarrassed, low in mood, anxious, affects their sleep and affects their everyday activities. Current treatments to help chronic cough for people with ILD are limited clinically and there are a few medication trials ongoing. However, for people with chronic cough due to another condition called refractory chronic cough, studies have found Cough Control Therapy (CCT); a non-medication based treatment, can help to reduce how much people cough and improve their quality of life. CCT includes a combination of treatments including, education, techniques to reduce coughing, and exercises to improve breathing. This study is a feasibility study to explore what the feasibility of using CCT for patients with ILD is.

Who can participate?
Patients aged 18 years and over with a diagnosis of interstitial lung disease (ILD) at Manchester Foundation Trust (MFT) or Guys and St Thomas' (GSST) who meet all the inclusion criteria

What does the study involve?
Those who agree to take part will receive CCT in addition to their usual treatments for ILD. They will attend four treatment sessions in groups of three over a 7-week period with a physiotherapist. The first session will be 1.5 hours and the other sessions will all be 1 hour long. These will be a mix of face-to-face and online treatment sessions. There will also be a 2-month follow up.
During the study information on the number of people who did and didn't finish the study, their satisfaction, and the effect on their cough and quality of life will be recorded. Some of those taking part will also be asked to take part in an interview to talk about why they took part, their satisfaction with CCT and for those who did not finish the study why they didn't.

What are the possible benefits and risks of participating?
Improvements in cough following physiotherapy

Where is the study run from?
Manchester Foundation Trust (MFT) and Guys and St Thomas' (GSST) (UK)

When is the study starting and how long is it expected to run for?
April 2025 to August 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Conal Hayton, conal.hayton@mft.nhs.uk

# Contact information

### Type(s)

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
339244

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
CPMS 70534; Grant Code: NIHR203571

# Study information

### Scientific Title
Cough control therapy for fibrotic interstitial lung disease related chronic cough: feasibility study

### Acronym

COTHILD

## Study objectives
Aims of the study:
1. To assess the feasibility of a future, substantive, multi-centre trial to explore the clinical and cost-effectiveness of CCT for fibrotic-ILD chronic cough.
2. To understand the acceptability of CCT as well as barriers and enablers to adherence of the intervention.

Objectives of the study:
The overall objectives of this study are:
1. To assess the feasibility of a future, substantive, multi-centre trial to explore cough control therapy for fibrotic Interstitial Lung Disease chronic cough.
2. Understand the acceptability of cough control therapy as well as barriers and enablers to adherence of the intervention.

This will be explored through the following objectives:
1. To assess the rate of recruitment and retention of participants.
2. To identify the treatment fidelity (the extent to which the treatment was implemented as intended) of cough control therapy for fibrotic ILD patients including the variation and frequency of the different treatment components of cough control therapy used. Treatment will be patient centred so protocol will allow for some variation, this variation will be assessed and frequency of the different components used will be recorded.
3. To explore patient adherence and compliance with cough control therapy
4. To assess the rate of response to and completion of clinical outcome measures.
5. To determine the number and nature of adverse events.
6. To identify the potential primary outcome measures to use for the future main trial.
7. To assess the feasibility of collecting health-care resource use and cost-effectiveness information.
8. To explore participants' motivation to participate, reasons for adherence and non-adherence, enablers and barriers to cough control therapy via interviews.
9. To explore patients' acceptability of cough control therapy and reasons for non-completion via interviews.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 29/10/2025, West Midlands – Solihull Research Ethics Committee (Equinox House, City Link , Nottingham, NG2 4LA , United Kingdom; +44 (0)207 104 8191, +44 (0)207 104 8124, +44 (0) 207 1048 170; Solihull.rec@hra.nhs.uk), ref: 25/WM/0210

## Study design
Non-randomized; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Physical

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Interstitial lung disease

## Interventions
This is a feasibility multi-centre study to assess the feasibility of CCT for people with ILD and chronic cough. The study will recruit 50 participants with a diagnosis of fibrotic ILD and chronic cough (cough ≥8 weeks duration) across Manchester Foundation NHS Trust (MFT) and Guy's and St Thomas' NHS Foundation Trust (GSTT) over a 9-month period.

Participants will be recruited by their clinical care ILD teams at MFT and GSTT which consists of Respiratory Consultants, Respiratory Nurses and Research Respiratory Nurses and provided written information regarding the study.

Informed consent will be obtained by the study Research Nurse, midwife or Allied Health professional (NMAHP) at each site. Once consented participants will attend a baseline assessment visit (Visit 1) at their recruiting site (either Guy's and St Thomas' or Manchester Foundation Trust). During this visit they will be asked to complete the following questionnaires and patient reported assessments:
1. Leicester Cough Questionnaire (LCQ), a 19 question cough related quality of life questionnaire, Likert scale.
2. King's Brief ILD Questionnaire (KBILD), a 15 question ILD related quality of life questionnaire, Likert scale.
3. Cough severity Visual Analogue scale (VAS)
4. Generalised Anxiety Disorder Assessment (GAD-7), 7 question questionnaire, Likert scale.
5. Patient Health Questionnaire (PHQ-9), 9 question questionnaire, Likert scale.
6. Dyspnoea-12 (D-12), 12 question breathlessness questionnaire, Likert scale.
7. EuroQoL-5D (EQ-5D), 5 question cost effectiveness questionnaire, Likert scale.

The study NMAHP who will not be involved in delivering the cough control therapy but will be available at the baseline visit (V1) to assist the participants with completing these as necessary.

One of the study team will also fit participants with a VitaloJAK cough monitor at this visit. The VitaloJak is a digital cough monitor which is an objective digital cough monitor which consists of a portable sound recording device, which is worn in a pouch or pocket. The device will be worn for 24 hours, recording all sound via two microphones, one attached to the subject's chest wall and one attached to the subject's clothing (their collar or lapel, as close as possible to the anterior neck. The device will automatically stop recording when the 24 hours has passed. Participants will be required to return the VitaloJAK to the research NMAHP prior to starting CCT.

Cough recordings made by the VitaloJAK are configured and analysed within the Vitalograph online portal, a central system managed by Vitalograph, designed for this purpose. During the consent process, participants will be asked if they agree to donating their cough recording(s) collected during the study into the RaDAR database. RaDAR is an ethically approved repository of anonymised cough recordings from different groups of patients that is primarily used to develop cough detection algorithms. Participation in RaDAR is completely voluntary and will not affect main study inclusion.

Participants will then attend four CCT therapy sessions (Visit 2 to 5) in groups of ideally three with a physiotherapist either at GSTT or MFT depending on where they were recruited.

Visit 2 (1st treatment session) will be face to face and will include:
1. A general Respiratory Physiotherapy assessment – recording details covering participant's symptoms, cough triggers, breathlessness, respiratory breathing pattern assessment including the Breathing Pattern Assessment Tool (BPAT), a 7 part assessment for breathing pattern (takes 2-3 minutes to complete).
2. Education on cough in ILD and the goals of cough control therapy.
3. Introduction to breathing pattern retraining.

Visit 3 and 4 will be virtual. Visit 3 will be a week later than visit 2 and visit 4 will be 3 weeks later than visit 3. Visit 3 and 4 treatment sessions will include:
1. Further breathing pattern retraining and pursed lip breathing.
2. Cough control techniques. Participants will be encouraged to identify when they feel an urge to cough. A strategy is then prescribed to suppress the urge and control cough using distraction (drinking water, chewing gum or sucking non-medicinal hard boiled sweets) and substituting the cough with a swallow and relaxed throat breathing.
3. Airway clearance techniques (active cycle of breathing technique) will be taught if deemed necessary if participants are assessed as having a productive cough. If so, advice will be given on when to use their airway clearance techniques and cough suppression techniques. To reduce their cough but ensure good airway clearance.
4. Vocal hygiene and hydration techniques will be explained to participants – avoidance of factors that cause/increase vocal dehydration (e.g. excessive consumption of alcohol, caffeine) and encouragement to increase non-caffeinated and non-alcoholic fluid intake.
5. Psycho-educational counselling will also be included which covers explaining to patients the negative effects of anxiety regarding their cough and over-awareness of symptoms related to their cough. Advise on managing anxiety and stress in relation to their cough will be discussed such as advising them to try to rethink their thoughts on cough, distraction techniques and balanced awareness.

Visit 5 will be a face to face treatment session and will include:
1. Reinforcement and checking of previously taught techniques to check patients technique and understanding and strategies to control cough in the future.
2. A repeat of the general Respiratory Physiotherapy breathing pattern assessment will be conducted including BPAT.

During the study we will record information on the number of people who did and didn't finish the study, their satisfaction, and the effect on their cough and quality of life.

At each visit any adverse events will be recorded by the treating Physiotherapist at each treatment visit using the Trusts' non-CTIMPs adverse events SOPs.

Study participants will also be asked to complete a brief patient diary to assess their adherence to cough control therapy.

End of treatment assessments will be completed after the last CCT session at Visit 5:
1. LCQ
2. KBILD
3. Cough severity VAS
4. GAD-7
5. PHQ-9
6. Dyspnoea-12
7. EQ-5D
8. Modular Resource-use Measure (ModRum), 11 question questionnaire.

One of the study team will again be available at Visit 5 to assist the participants with completing these as necessary. One of the study team at this visit will fit participants with a VitaloJAK cough monitor at this visit. The device will be worn for 24 hours, and participants will be required to return the VitaloJAK to the research NMAHP afterwards.

Two months following the end of CCT participants will attend a two month follow up (Visit 6) at either Guy's and St Thomas' or Manchester University NHS Foundation Trust depending on where they were recruited and received their treatment. Participants will repeat the questionnaires and patient reported assessments taken at baseline and end of treatment:
1. LCQ
2. KBILD
3. Cough severity VAS
4. GAD-7
5. PHQ-9
6. Dyspnoea-12
7. EQ-5D
8. Modular Resource-use Measure (ModRum), 11 question questionnaire.

One of the study team will again be available at this visit (Visit 6) to assist the participants with completing these as necessary. There will be no VitaloJak cough monitor assessments at this visit.

Participants who consented at recruitment to be contacted regarding taking part in an interview following their CCT will be purposively recruited to reflect a diverse range of experiences, gender, ethnic background, age and socio-economic status. As the study is over two geographical sites to ensure we achieve data saturation, 12 to 14 participants per site will be interviewed. However, we will continue until data saturation has been achieved. Participants will be invited to attend an online (via MS teams) or telephone (depending on participants' preference) semi-structured interview following their 2 months follow-up with a Researcher based at Manchester University NHS Foundation Trust (MFT).

Interviews will explore participants' motivation to take part in the study, their satisfaction, reasons for adherence and non-adherence, enablers and barriers to intervention. Additionally, for participants who do not complete the trial, their motivation to participate in the trial and reasons for withdrawal will be explored. Interviews will be conducted by a researcher trained in qualitative interviews, unknown to the participants. Interviews will use a topic guide to guide the interview but will allow flexibility to explore new and unanticipated issues. The topic guide will be developed in further detail with further collaboration with our PPI group and piloted with a representative sample population to ensure its appropriateness. Interviews will last up to 60 min.

All interviews will be recorded via a digital voice recorder and saved on the MFT server again with only their study ID number and not their participant name. All interviews will be transcribed verbatim by a professional transcription company to ensure accuracy. Recorded interviews will be sent to the professional transcription company again with only the study ID number and not the participants' name, although it is possible to identify participants from their voice on the Dictaphone recordings for the telephone interviews and via their image on MS Teams. The transcription company used will be an established company for transcription services with MFT necessary contracts and data protection agreements will be sought prior to sharing any data. Recording will be shared via the professional transcription secure server. The recordings and

transcripts will only be accessible by the CI and members of the research team who are involved in the data analysis of these. Once transcribed and checked participants' interview recordings will be deleted from the server.

On enrolment to the study, participants will also be asked if they are willing to complete an NIHR equality, diversity and inclusion questionnaire. This will include questions about personal information including age, sex, gender, ethnicity, religion, disabilities and living arrangements. The purpose of this questionnaire is to allow the NIHR to monitor characteristics of study participants and understand if under-represented groups of society are being included in research. The questionnaire is optional and will be completed anonymously.

Primary Analysis:
Feasibility will be defined as the ability to recruit the target sample size in a timely manner and to retain at least 70% of participants in the trial over the follow-up period. Participant acceptability of cough control therapy will be assessed by the percentage of participants who engage and complete cough control therapy and more contextual and detailed data will be collected from semi-structured qualitative interviews focusing on the experience of cough control therapy.

Secondary Analysis:
We will report descriptive data on study 'processes' and 'outcomes'. Recruitment and attrition rates will be calculated and reasons for non-completion will be recorded where possible. Data on adherence to- and acceptability of the intervention will be summarised descriptively. We will assess rates of missing data (including which elements of specific questionnaires) at different stages of follow-up. We will also assess whether any of the measures display floor and/or ceiling effects. We will summarise, as appropriate (e.g. mean/ standard deviation; median/ inter-quartile range; proportion/ 95% confidence interval; data range), data for all potential outcome measures at baseline and at completion of the intervention. We will then summarise the change from baseline, including reporting confidence intervals as a potential way of investigating the 'promise' of cough control therapy. If possible, intra-group correlation in these outcomes will be explored. Data on 'change' will be used to help inform power calculations for a definitive trial.

Analysis of interviews:
Interview data will be analysed thematically. Inductive analysis of transcripts will be supported by NVIVO software, generating latent themes from a post-positivist theoretical position. Respondent validation will be employed by sharing the preliminary analysis with participants. Critical discussions amongst the research team and our PPI group, will take place to verify, modify and refine the themes.

There will be no interim analysis.

## Intervention Type
Behavioural

## Primary outcome(s)
Feasibility and acceptability assessed using:
1. Number of eligible patients and number recruited (target recruitment is 6 participants per month (3 per site) over 9-month recruitment period (Objective 1)
2. Rate of retention in the trial measured at end of study
3. Intervention fidelity and adherence assessed using physiotherapist-completed case report forms and patient-completed diaries for the interventions, measured at end of study
4. Response rates to questionnaires and outcome measures measured at beginning and end of

study
5. Rate of completion of health-care resource use via patient diaries (appointments with healthcare clinicians, medication use) measured at end of study
6. Participants' acceptability, views about the intervention and reasons for non-completion via qualitative interviews, measured at end of study

### Key secondary outcome(s))
1. Cough-related quality of life assessed using Leicester cough questionnaire (LCQ) at baseline, end of treatment and follow up (Objective 6)
2. ILD health-related quality of life assessed using the King's Brief Interstitial Lung Disease (KBILD) at baseline, end of treatment and follow up (Objective 6)
3. Cough frequency assessed using the VitaloJak Cough monitor (a cough recording device worn for 24 hours) at baseline and end of treatment (Objective 6)
4. Cough severity assessed using the visual analogue scale (VAS) at baseline, end of treatment and follow up (Objective 6)
5. Anxiety/depression assessed using the generalised anxiety disorder assessment (GAD-7) and Patient Health Questionnaire (PHQ-9) at baseline, end of treatment and follow up (Objective 6)
6. Dyspnoea assessed using Dyspnea-12 (D-12) at baseline, end of treatment and follow up (Objective 6)
7. Breathing pattern assessed using the Breathing Pattern Assessment Tool (BPAT) by the treating physiotherapists at participant's first treatment session (Visit 2) and last treatment session (Visit 5) (Objective 6)
8. Cost-effectiveness measured using the EuroQoL-5D (EQ-5D) at baseline, end of treatment and follow up (Objective 7)
9. Healthcare resource use measured using the Modular Resource-use Measure (ModRum) at end of treatment and follow up (Objective 7)
10. Number and type of adverse events recorded at every treatment session (Objective 5)

### Completion date
31/08/2026

## Eligibility

### Key inclusion criteria
1. Adults (>=18 years old) with a confirmed diagnosis of Fibrotic Interstitial Lung Disease on high resolution CT 3, defined as reticular abnormality with traction bronchiectasis, with or without honeycombing, with symptomatic fibrotic disease) and chronic cough lasting >=8 weeks.
2. Patients with signs or symptoms for co-morbidities associated known to be associated with chronic cough should be treated prior to the inclusion of the study.
3. Participants able to access and use technology required for the virtual sessions.
4. Patients on a stable dose of MST for at least a month and still have a patient reported troublesome cough to warrant treatment.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Upper or lower respiratory tract infection in past 2 months.
2. Currently taking or a history of ACE-inhibitor medications in the past 3 months (which can cause chronic cough).
3. Current smokers (cigarettes or e-cigarettes, self-reported).
4. Respiratory disease other than fibrotic interstitial lung disease e.g. COPD or bronchiectasis.
5. Currently or due to participate in pulmonary rehabilitation or receiving Physiotherapy/speech and language therapy for chronic cough or breathing pattern dysfunction in the next four months (as there is cross over of some of the breathing techniques taught in pulmonary rehabilitation and cough control therapy which may affect results).
6. Patients who have started new antifibrotic medication for their ILD <8 weeks duration.
7. Unable to provide informed consent.

### Date of first enrolment
30/11/2025

### Date of final enrolment
31/08/2026

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Manchester University NHS Foundation Trust**
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

### Study participating centre
**Guy's and St Thomas' NHS Foundation Trust**
St Thomas' Hospital
Westminster Bridge Road

London
United Kingdom
SE1 7EH

# Sponsor information

**Organisation**
Manchester University NHS Foundation Trust

**ROR**
https://ror.org/00he80998

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health and Care Research

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**
The data-sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**
Data sharing statement to be made available at a later date