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Physio and Speech Therapy management of chronic cough

Submission date	Recruitment status	[X] Prospectively registered
29/07/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/07/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/09/2016	Respiratory	

Plain English summary of protocol

Background and study aims
Cough is the most common reason that patients seek medical advice. Cough medicine and drugs preventing cough are ineffective and chronic cough can cause considerable long-term distress. However, there are strategies that may be beneficial. One recent study showed a positive effect on the perception of cough after treatment delivered by speech language therapists. Treatment that combines speech and language techniques (such as helping patients suppress cough and relaxing the mouth/neck area) with physiotherapy techniques (such as optimising breathing patterns, teaching about cough triggers and helping patients clear any airway secretions) may maximise the benefits. This study will test the effectiveness of a Physiotherapy, Speech and Language Therapy Intervention (PSALTI) for chronic cough.

Who can participate?
Anyone with a persistent, troubling cough in which all other causes have been excluded.

What does the study involve?
Prior to taking part in the study our hospital consultant at King's College Hospital will perform a number of routine tests to rule out other causes of your cough. The tests will include a chest x-ray, spirometry testing (lung function testing by blowing into a machine), and laryngeal scoping (a small tube down the nose to look at the back of the throat). If all these are tests are normal you will be suitable for the study. You will then be randomly allocated to receive either PSALTI treatment or health education delivered by a health professional. This will allow us to test the effects of the treatment over that of general health advice. Both groups will attend four forty minute long sessions, once weekly at King's College Hospital. You would also need to attend for a one hour long assessment before and after the 4-week treatment period. We will be measuring three things throughout this study. We will measure quality of life using simple questionnaires and the intensity and frequency of your cough. We will monitor the frequency of your cough using a small device that you wear on your arm for 24 hours that will record the number of coughs. We will measure the intensity of your cough by performing a capsaicin cough sensitivity challenge. During this test, we will use a nebuliser device containing an extract of chilli called capsaicin of varying strengths to induce you to cough. The capsaicin can cause a tickly

burning sensation in the throat, but this usually only lasts a few minutes. The test will take about 40 minutes. We will provide you with expenses for your travel/parking to and from the hospital. At the end of the study, we will send a letter to all participants with the results of the study.

What are the possible benefits and risks of participating?
Your cough may reduce in severity, and you will have a greater understanding about cough and its relevance to you. This study may lead benefit others if the treatment proves to be successful. We would not perceive there to be any disadvantages to taking part in the study. Capsaicin may cause a burning or tingling feeling in the throat. This is meant to induce a cough, and will wear off after one to two minutes. There are no known long-term lasting ill effects from this test and it is a very common procedure.

Where is the study run from?
The study will take place at King's College Hospital (UK).

When is the study starting and how long is it expected to run for?
We hope to begin recruiting patients to the study in October 2011. The study will take place over 24 months.

Who is funding the study?
The research is funded by the Physiotherapy Research Foundation UK and organised by Dr Garrod and Dr Birring of King's College NHS Foundation Trust.

Who is the main contact?
1. Dr Rachel Garrod
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Contact information

Type(s)
Scientific

Contact name
Dr Rachel Garrod

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Additional identifiers

Protocol serial number
10678

Study information

Scientific Title
Efficacy of a Physiotherapy, Speech and Language Therapy Intervention (PSALTI) for patients with chronic cough: a randomised controlled trial

Acronym
PSALTI

Study objectives
The purpose of this randomised placebo controlled study is to investigate, using valid and reliable subjective and objective outcome measures, the effectiveness of an out-patient based multi disciplinary, Physiotherapy, Speech and Language Therapy Intervention (PSALTI) on frequency and severity of cough in patients with chronic cough refractory to medical therapy.

Research aims:
1.To assess the impact of PSALTI on quality of life (QOL) and subjective cough severity.
2.To assess the effect of PSALTI on frequency, severity and intensity of cough
3. To determine cost effectiveness of PSALTI using Health Related Quality of Life Years (QALYS)

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Chelsea, 08/06/2011, ref: 11-LO-0504

Primary study design
Interventional

Study design
Randomised interventional trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Respiratory diseases

Interventions
1. At power 80% and $p < 0.05$ and based on a clinically relevant change of 2.7 (seen in our pilot study) we require 33 patients in each group. Allowing for a 25% drop out we require 88 patients, 44 in each group.
2. Placebo group (equal attention group): therapist will provide information regarding healthy lifestyle, advice about exercise, nutrition and stress management in 4 weekly sessions
3. The patients will not be told of group allocation until the end of the study
4. The same therapist will deliver all aspects of treatment and placebo control attention group.
5. PSALTI Treatment: A multidisciplinary intervention that involves the assessment of patients to identify triggers of cough, evaluate breathing patterns, adequacy of sputum clearance, voice disorders and effort of coughing
6. Therapy is individualised; patients are given advice and education on trigger avoidance and

taught cough suppression exercises such as swallowing, re-hydration and breathing control
7. Further management addresses, voice disorders, impaired airway clearance (if relevant)
8. Follow Up Length: 24 months

Intervention Type
Behavioural

Primary outcome(s)
Cough-related quality of life: Leicester Cough Questionnaire (QOL) assessed at start of study and at each PSALTI session and at 3 months post PSALTI treatment

Key secondary outcome(s)
1. Cost effectiveness
2. Short Form 36 will be completed pre, post and at 3 months post intervention
3. Cough frequency
4. The Leicester Cough Monitor is a validated, objective, 24-hour ambulatory cough monitoring device
5. Cough Intensity: Capsaicin Cough Challenge measured before and at end of treatment period
6. Cough symptom severity
7. Visual analogue scale (VAS, 0-100mm). This simple VAS will be completed at each visit

Completion date
01/07/2013

Eligibility

Key inclusion criteria
1. Patients with an isolated stable chronic cough >2 months in duration, normal chest X-ray and spirometry
2. Persistent cough despite negative investigations and/or failed treatment trials for asthma, reflux and rhinitis
3. Chronic cough >2 months
4. Cough is the major respiratory symptom
5. Sputum production absent or minimal (less than tablespoon/10ml a day)
6. Patients with chronic asthma and Chronic Obstructive Pulmonary Disease (COPD) may be included in the study where their principle problem is cough (as felt by the patient)
7. Male or female
8. Upper Age Limit 100 years; Lower Age Limit 17 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Upper respiratory tract infection in past 4 weeks
2. Taking angiotensin converting enzyme inhibitor medication
3. Current smokers
4. Patients with the following diagnoses of known respiratory disease will be excluded:
4.1. Lung cancer
4.2. Pneumonia
4.3. Pulmonary fibrosis
4.4. Sarcoidosis
4.5. Pleural effusion
4.6. Bronchiectasis and upper airway aspiration
5. Patients with chronic/ acute asthma / COPD will be excluded from the study where their primary problem is not felt to be cough, ie primary problem may be breathlessness, excess sputum production or fatigue
6. Patients with suspicious throat or laryngeal mass, or with evidence of active aspiration (observed via Fibreoptic Endoscopic Evaluation of Swallowing (FEES) will be excluded

Date of first enrolment
03/10/2011

Date of final enrolment
01/07/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Dulwich Community Hospital
London
United Kingdom
SE22 8PT

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Research organisation

Funder Name
Physiotherapy Research Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2017		Yes	No