

Study of the effectiveness of breathing training exercises taught by a physiotherapist by either instructional videos/DVDs/internet download or by face to face sessions in the management of asthma in adults

| | | |
|--|---|--|
| Submission date 30/09/2011 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 05/10/2011 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 13/12/2018 | Condition category Respiratory | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Asthma is a common long-term condition that can cause breathing difficulties. Although effective drug treatment exists for asthma, many people continue to have distressing symptoms and impaired quality of life. Recent surveys show that over half of all adults with asthma in the UK are not properly controlled on their current treatment, resulting in impaired quality of life and increased costs to the community. Many people with asthma are interested in non-drug asthma treatments, particularly breathing exercises. Several recent studies have shown benefits from undergoing a short breathing exercises course taught by a respiratory physiotherapist for people who still had asthma symptoms despite usual treatment. There is currently not enough access to suitable trained physiotherapists to provide such a service to most people with asthma in the UK. The aim of this study is to evaluate a physiotherapy breathing training programme, already shown to be effective in face-to-face contact, delivered in a new video/DVD/download format. If effective, this could be used in routine NHS asthma care. The video/DVD/download breathing instruction programme will be developed in phase 1 of the project. In phase 2, we will assess the effectiveness of this video/DVD/download as treatment for adults with asthma. We will see whether this type of instruction is better than the 'usual care' that is currently provided, and whether it is as good as the 'face to face' physiotherapist instruction (which is more expensive and less convenient for patients).

Who can participate?

Patients age 16-70 with asthma

What does the study involve?

Participants are randomly allocated to one of three groups. The first group receives the video /DVD/download (plus supporting written material, according to preference). The second group attends three sessions (arranged at fortnightly intervals) of face to face physiotherapy

breathing instruction. The third group receives usual care. Follow up assessments for each groups are carried out 3, 6 and 12 months later. We assess the effects of the video and face to face breathing training programmes on asthma control, quality of life, anxiety and depression, how 'in control' of their condition the patient feels ('enablement') as well as assessing lung function and airway inflammation. We ask patients whether they like the video intervention, feel it helped them and could help others. We assess the costs and benefits of the two ways of delivering the breathing intervention, to see which is most useful for investment of NHS resources. Patients not receiving breathing training are offered it at the end of the study, and continue to receive the 'usual care' from their GP.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Aberdeen (UK)

When is the study starting and how long is it expected to run for?
November 2011 to October 2015

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Dr Mike Thomas

Contact information

Type(s)
Scientific

Contact name
Dr Mike Thomas

Contact details
General Practice and Primary Care
University of Aberdeen
Centre of Academic and Primary Care
Foresterhill Health Centre
Westburn Road
Aberdeen
United Kingdom
AB25 2AY

Additional identifiers

Protocol serial number
HTA 09/104/19

Study information

Scientific Title

A controlled study of the effectiveness of breathing training exercises taught by a physiotherapist by either instructional videos/DVDs/internet download or by face to face sessions in the management of asthma in adults

Acronym

BREATHE

Study objectives

BREATHE - Breathing REtraining for Asthma - Treatment at Home Evaluation

We hypothesise that breathing training exercises taught by an audio-visual educational package consisting of a video / DVD / download instructional programme and supporting written information will result in clinically important improvements in asthma-related quality of life and in asthma control above 'usual care' and of a similar magnitude to those resulting from 'face to face' physiotherapist instruction.

Further details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/0910419>

Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0015/81600/PRO-09-104-19.pdf

Ethics approval required

Old ethics approval format

Ethics approval(s)

Plan to submit to Southampton and South West Hampshire - early 2012

Study design

Pragmatic observer blinded three-arm parallel-group randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Asthma

Interventions

We propose a prospective evaluation of a physiotherapy breathing training programme (already shown to be effective in face-to-face contact) delivered in a new video / DVD / download format. If effective, this could be used in routine NHS asthma care. The video / DVD / download breathing instruction programme will be developed in phase 1 of the project. In the subsequent randomised controlled trial (phase 2), we will assess the effectiveness of this video / DVD / download as adjuvant treatment for asthmatic adults with asthma-related health status impairment (AQLQ <5.5) despite pharmacotherapy. Consenting subjects will be randomly assigned to

1. Receipt of the DVD, the video or the internet download (plus supporting written material, according to preference)
2. Three sessions (arranged at fortnightly intervals) of face to face physiotherapy breathing

instruction

3. Usual care

In all 3 arms, no attempt will be made to change the standard asthma care provided in the practice.

Follow up assessments for each group are at 3, 6 and 12 months

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Analysis of the between-group (Intention-To-Treat (ITT)) change in asthma-specific health status [AQLQ (short version) score]. Outcome measures will be between-group and within-group changes from baseline to the end of the study (12 months).

Key secondary outcome(s)

1. Asthma Control Questionnaire score
2. Lung function [Forced expiratory volume in one second (FEV1), ratio of the forced expiratory volume in the first one second to the forced vital capacity of the lungs (FEV1/FVC ratio), peak expiratory flow rate (PEFR)]
3. Fraction of exhaled nitric oxide
4. Health status (EuroQOL)
5. Anxiety and depression scores (HAD questionnaire)
6. Hyperventilation (Nijmegen questionnaire)
6. Oral corticosteroid courses
7. Bronchodilator use
8. Asthma related health resource use
9. Smoking status
10. Cost effectiveness/utility
11. Patient reported process evaluations (questionnaires) and estimates of adherence (use of exercises)

Completion date

30/10/2015

Eligibility

Key inclusion criteria

1. Full practice registration for a minimum of 12 months prior to enrolment
2. Age 16-70 years
3. Physician diagnosed asthma in medical records
4. One or more anti-asthma medication prescription in the previous year (determined from the physician prescribing records)
5. Impaired asthma-related health status (Asthma Quality of Life Questionnaire score of < 5.5)
6. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Asthma judged at the baseline assessment not to be dangerously unstable and in need of urgent medical review (if unstable asthma is found, the patient will be referred back to usual primary care clinician for review)

2. Documented diagnosis of Chronic Obstructive Pulmonary Disease (COPD)

We aim to allow broad entry criteria (with inclusion of smokers, and not insisting on physiological demonstration of reversible airflow obstruction) in order to allow generalisability of research findings to mild-to-moderate UK asthma populations treated in primary care National Health Service (NHS) practice.

Date of first enrolment

01/11/2011

Date of final enrolment

30/10/2015

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

University of Aberdeen

Aberdeen

United Kingdom

AB25 2AY

Sponsor information

Organisation

University of Aberdeen (UK)

ROR

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme (09/104/19)

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| Results article | results | 01/09/2017 | | Yes | No |
| Results article | results | 01/01/2018 | | Yes | No |
| Protocol article | protocol | 01/06/2013 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |