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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

Registration date
05/10/2011

Overall study status
Completed

Last Edited
13/12/2018

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 grous are at 3, 6 and 12 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
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).

Secondary outcome measures
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)

Overall study start date

01/11/2011

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

Age group
Adult

Sex
Both

Target number of participants
585

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
Scotland

United Kingdom

Study participating centre
University of Aberdeen
Aberdeen
United Kingdom
AB25 2AY

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
Kings College
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United Kingdom
AB24 3FX

Sponsor type
University/education

Website
http://www.abdn.ac.uk

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme (09/104/19)

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	01/06/2013		Yes	No
Results article	results	01/09/2017		Yes	No
Results article	results	01/01/2018		Yes	No