A randomised controlled study of the effectiveness of breathing retraining exercises taught by a physiotherapist either by instructional DVD or in face-to-face sessions in the management of asthma in adults

Mike Thomas,1* Anne Bruton,2 Paul Little,1 Stephen Holgate,1 Amanda Lee,3 Lucy Yardley,4 Steve George,1 James Raftery,1 Jennifer Versnel,5 David Price,3 Ian Pavord,6 Ratko Djukanovic,1 Michael Moore,1 Sarah Kirby,4 Guiqing Yao,1 Shihua Zhu,1 Emily Arden-Close,7 Manimekalai Thiruvothiyur,3 Frances Webley,8 Mark Stafford-Watson,9 Elizabeth Dixon8 and Lynda Taylor8

1Faculty of Medicine, University of Southampton, Southampton, UK
2Faculty of Health Sciences, University of Southampton, Southampton, UK
3Institute of Applied Health Sciences, University of Aberdeen, Aberdeen, UK
4School of Psychology, University of Southampton, Southampton, UK
5Asthma UK, London, UK
6Nuffield Department of Medicine, University of Oxford, Oxford, UK
7Department of Psychology, Bournemouth University, Bournemouth, UK
8Southampton Clinical Trials Unit, University of Southampton, Southampton, UK
9Patient and public involvement representative

*Corresponding author D.M.Thomas@soton.ac.uk

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Library Board. Lucy Yardley is a member of the Public Health Research journal Research Funding Board and a member of the HTA Efficient Study Designs Board and reports grants from the NIHR during the conduct of the study. James Raftery is a member of the NIHR Journals Library Editorial Group and the HTA and EME Editorial Board and was previously Director of the Wessex Institute and head of the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC). He is also a former member of the NIHR HSDR Research Led Board. Ian Pavord has received speaker’s honoraria for speaking at sponsored meetings in the last 5 years from AstraZeneca, Boehringer Ingelheim, Aerocrine, Almirall Ltd, Novartis and GSK. He has received honoraria for attending advisory panels with Almirall, AstraZeneca, Boehringer Ingelheim, GSK, MSD, Schering-Plough, Novartis, Dey Pharma, Napp Pharmaceuticals and RespiVert Ltd. He has received sponsorship to attend international scientific meetings from Boehringer Ingelheim, GSK, AstraZeneca and Napp. He is Chief Medical Advisor to Asthma UK, a member of the UK Department of Health Asthma Strategy Group, a member of the BTS/SIGN Asthma Guideline Group and joint Editor-in-Chief of Thorax. Neither Ian Pavord nor any member of his family has any shares in pharmaceutical companies. David Price reports other Board Membership (fees paid to Research in Real Life Ltd) from Aerocrine, Almirall, Amgen Inc., AstraZeneca, Boehringer Ingelheim, Chiesi Ltd, Meda, Mundipharma, Napp, Novartis and Teva Pharmaceutical Industries Ltd; consultancy (fees paid to Research in Real Life Ltd) from Almirall, Amgen, AstraZeneca, Boehringer Ingelheim, Chiesi, GSK, Meda, Mundipharma, Napp, Novartis, Pfizer Inc. and Teva; grants from the UK NHS, British Lung Foundation, Aerocrine, AKL Ltd, Almirall, AstraZeneca, Boehringer Ingelheim, Chiesi, Eli Lilly and Co., GSK, Meda, Merck & Co., Inc., Mundipharma, Napp, Novartis, Orion, Pfizer, Respiratory Effectiveness Group, Takeda, Teva and Zentiva; lectures/speaking engagement fees (paid to Research in Real Life Ltd) from Almirall, AstraZeneca, Boehringer Ingelheim, Chiesi, Cipla Ltd, GSK, Kyorin Pharmaceutical Co., Inc., Meda, Merck, Mundipharma, Novartis, Pfizer, Skyepharma, Takeda and Teva; manuscript preparation fees (paid to Research in Real Life Ltd) from Mundipharma and Teva; payment for travel/accommodation/meeting expenses (paid to Research in Real Life Ltd) from Aerocrine, Boehringer Ingelheim, Mundipharma, Napp, Novartis and Teva; funding for patient enrolment or completion of research (paid to Research in Real Life Ltd) from Almirall, Chiesi, Teva and Zentiva; and payment for the development of educational materials (paid to Research in Real Life Ltd) from GSK and Novartis, outside the submitted work. In addition, David Price has an AKL Ltd patent pending and owns shares in AKL Ltd, which produces phytopharmaceuticals. He owns 80% of Research in Real Life Ltd (which is subcontracted by Observational and Pragmatic Research Institute Pte Ltd), 75% of the social enterprise Optimum Patient Care Ltd and 75% of the Observational and Pragmatic Research Institute Pte Ltd. Ratko Djukanovic has received fees for lectures at symposia organised by Novartis and Teva and for consultation for these two companies as a member of advisory boards. He is a co-founder and current consultant, and has shares in, Synairgen, a University of Southampton spin-out company.

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Scientific summary

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Scientific summary

Background

Asthma affects > 5 million people in the UK, with costs in excess of £1B annually. Although pharmacotherapy is effective and can provide full control for some, surveys repeatedly show that outcomes remain suboptimal, with persisting symptoms and quality of life (QoL) impairment for the majority. Symptoms attributed to dysfunctional breathing overlap with those of asthma and have been reported to be more frequent in people with asthma, providing a rationale for using breathing retraining to improve asthma control. Randomised controlled trials (RCTs) have reported beneficial outcomes from breathing retraining in asthma, particularly from physiotherapist-administered breathing exercises, which are now advocated in guidelines as adjuvant treatment for those who remain uncontrolled on pharmacological treatment. Previous research from members of this study group provided evidence supporting this recommendation, with two positive RCTs supporting physiotherapist-delivered breathing retraining. However, the cost-effectiveness of this intervention was not addressed and resource constraints mean that the majority of people with asthma who could benefit are not able to access a suitably trained respiratory physiotherapist. Two preliminary studies have investigated the use of breathing retraining delivered by videotape or digital versatile disc (DVD), with some evidence of effectiveness. Such self-guided programmes have the potential to be accessed easily, conveniently and inexpensively by large numbers of people. No studies have compared the clinical effectiveness and cost-effectiveness of a self-guided programme with those of face-to-face breathing retraining interventions.

We hypothesised that breathing retraining exercises taught as a self-guided programme would improve asthma-related QoL above ‘usual care’ and would be equivalent to ‘face-to-face’ physiotherapist instruction.

Objectives

- To use an iterative patient-focused approach to transfer the contents of a three-session physiotherapist-delivered breathing retraining programme, previously shown to improve asthma control, to a self-guided format that is acceptable to patients.
- To perform a RCT in adults with impaired asthma control, comparing the effectiveness of breathing retraining delivered by the self-guided programme with the effectiveness of a face-to-face breathing retraining programme delivered by a respiratory physiotherapist and with usual care, for asthma-related QoL and other asthma control measures.
- To perform quantitative and qualitative process evaluations.
- To perform a health economic assessment using data collected from the trial and from general practice clinical records.

Methods

Trial design

We carried out a pragmatic, observer-blinded, three-arm, parallel-group RCT comparing a breathing retraining programme delivered in DVD format with a breathing retraining programme delivered face-to-face by a physiotherapist and with a control of usual care for adults with asthma and impaired health status.

Participants

In total, 655 adult patients with diagnosed and currently treated asthma were recruited from 34 primary UK NHS general practices in the Wessex region.
Inclusion criteria

- Full practice registration for 12 months prior to enrolment.
- Age 16–70 years.
- Physician-diagnosed asthma in medical records.
- One or more anti-asthma medication prescriptions in the previous year.
- Impaired asthma-related health status [Asthma Quality of Life Questionnaire (AQLQ) score of < 5.5].
- Able to give informed consent.

Exclusion criteria

- Asthma dangerously unstable and in need of urgent medical review at baseline.
- Concomitant chronic obstructive pulmonary disease if forced expiratory volume in 1 second (FEV1) is < 60% predicted.

Broad entry criteria were pragmatically used (with the inclusion of smokers and not insisting on physiological demonstration of reversible airflow obstruction) to allow the generalisability of the research findings to mild-to-moderate UK asthma populations treated in primary care NHS practice.

Outcome measures

Primary outcome
The primary outcome was the between-group [intention-to-treat (ITT)] 12-month asthma-specific health status (AQLQ score), adjusted for prespecified covariates.

Secondary outcomes

- Prespecified sensitivity analyses on the main outcome [unadjusted analysis of between-group ITT AQLQ score changes, per-protocol (PP) between-group AQLQ score changes, sensitivity analysis including patients without full AQLQ data].
- Analysis of the between-group ITT and PP changes in:
  - Asthma Control Questionnaire (ACQ) scores
  - Lung function [FEV1, FEV1-to-forced expiratory volume in 1 second (FEV1/FEV)] ratio, peak expiratory flow rate (PEFR)]
  - Fraction of exhaled nitric oxide (FeNO)
  - Generic health status [EuroQol-5 Dimensions (EQ-5D)]
  - Anxiety and depression scores [Hospital Anxiety and Depression Scale (HADS)]
  - Hyperventilation (Nijmegen) questionnaire scores
  - Asthma exacerbations (oral corticosteroid courses)
  - Bronchodilator use
  - Asthma-related health resource use
  - Cost-effectiveness/utility
  - Patient-reported process evaluations (qualitative assessments and questionnaires)
  - Patient engagement in breathing retraining programmes.

Study procedures

Development phase
We transferred an existing ‘face-to-face’ programme of breathing retraining taught by physiotherapists to patients with dysfunctional breathing to a self-guided programme format delivered through a DVD with printed supportive materials, and undertook qualitative piloting of these materials to optimise acceptability and effectiveness. Patient educational materials were developed by a team including physicians, physiotherapists,
health psychologists, communications technology specialists and patient representatives. The DVD and accompanying booklet were created iteratively with extensive patient input. The DVD content included:

- detailed explanations and illustrations of how to carry out the exercises, with footage showing a physiotherapist teaching the exercises to patients
- motivational components explaining the rationale for the exercises and addressing common doubts and concerns.

The materials were piloted with a panel of 29 members of the target population, purposively sampled for diversity in terms of age, sex, education and symptom profile. In audio-recorded face-to-face and telephone interviews we used open-ended questions to explore attitudes to the proposed treatment method in the context of health beliefs and then used ‘think-aloud’ methods to elicit reactions to the proposed materials, with modification of the scripts based on this feedback. Professional production of the DVD and booklet were undertaken and the materials were reviewed by the panel, who provided final feedback in face-to-face and telephone interviews.

Randomised controlled trial
Potentially eligible patients were identified by computer searches of general practice clinical and prescribing records. These patients were mailed the study information and an invitation letter, and were asked to complete the AQLQ and return it by post. Those with an AQLQ score of < 5.5 were recruited. Patients were seen at their general practice by a research nurse for a baseline assessment, consenting and randomisation. The baseline assessment consisted of assessment of clinical data (smoking status, asthma history, comorbidities, medication use), questionnaire data [disease-specific health status (AQLQ), Nijmegen hyperventilation questionnaire, ACQ, generic health status (EQ-5D), anxiety and depression (HADS)] and physiological data [spirometry (FEV1, FEV1-to-FVC ratio, PEFR), measured with a standardised calibrated portable spirometer; FeNO, measured with a NIOX MINO® portable monitor (Circassia Ltd, Oxford, UK)]. Randomisation was achieved by the study nurse telephoning the Southampton Clinical Trials Unit (SCTU) telephone randomisation service. Follow-up appointments were also arranged.

All consenting participants received postal questionnaires at 3 and 6 months and a final assessment visit at 12 months post randomisation. Those randomised to usual care received no other additional attention. Those randomised to the DVD were also provided with the booklet. Those randomised to face-to-face physiotherapy received three sessions (30–40 minutes each) with a respiratory physiotherapist at their general practice, at 2-weekly intervals following randomisation, and also received the instructional booklet. The final 12-month assessment was performed by a different study nurse blinded to randomisation group. The assessment consisted of the same clinical, questionnaire and physiological measurements performed at baseline, plus a short questionnaire exploring participants’ perceptions and experiences of being in the trial and adherence and collection of routine clinical data.

A group of participants in the active arms selected by purposive sampling underwent qualitative interviews to assess their experiences of the interventions, until data saturation was achieved.

Statistical methods
The primary statistical analysis consisted of a repeated-measures mixed model using the 12-month AQLQ score across the three arms with adjustments for prespecified covariates [baseline AQLQ score, general practice, age, sex, smoking status, British Thoracic Society (BTS) treatment step, baseline HADS score and baseline Nijmegen questionnaire score], with pairwise comparisons between the DVD group and the control group, the physiotherapy group and the control group (superiority study) and the DVD group and the physiotherapy group (equivalence study, equivalence margin 0.3).
Results

Recruitment, retention and missing data
The recruitment target of 585 was increased to 655 by the Data Monitoring and Ethics Committee as an early unblinded analysis suggested a slightly higher dropout rate in the DVD arm. We successfully randomised 655 patients from 34 primary care sites. A total of 15,203 invitation letters were mailed, with 1481 responses received (response rate 9.7%). In total, 680 (45.9%) respondents were ineligible and 655 (81.8% of eligible respondents) were randomised, 261 (39.8%) to the DVD group, 262 (40.0%) to the control (usual care) group and 132 (20.2%) to the physiotherapy group. All 655 randomised participants were included in the ITT population. The PP population included 556 participants (DVD, n = 215; physiotherapy, n = 110; control, n = 231; 84.9% of the randomised population). A very low proportion of data were missing for all other questionnaires (< 2%). Spirometry data (FEV1, FEV1-to-FVC ratio) were missing for 4% of participants and FeNO values were missing for 7.5% of participants; missing data values were similar between treatment arms. Only 21 patients withdrew (3.2%), with similar rates of withdrawal between arms. The AQLQ was returned at 12 months by 556 participants and at one or more follow-up points by all 655 participants.

Primary outcome
In the primary efficacy analysis, the between-group comparison of 12-month AQLQ scores in the ITT population adjusted for prespecified covariates, we observed a statistically significant improvement in mean AQLQ score in the DVD arm compared with the control arm [adjusted mean difference 0.28, 95% confidence interval (CI) 0.11 to 0.44] and in the physiotherapy arm compared with the control arm (adjusted mean difference 0.24, 95% CI 0.04 to 0.44), confirming the superiority of both active arms over usual care. The adjusted mean difference between the DVD arm and the physiotherapy arm was 0.04 (95% CI –0.16 to 0.24), confirming equivalence of the active arms. In subdomain analysis, the largest improvements in the active arms compared with usual care were in the emotions domain (DVD vs. control: adjusted mean difference 0.38, 95% CI 0.16 to 0.60; physiotherapy vs. control: adjusted mean difference 0.43, 95% CI 0.16 to 0.71); significant improvements were also seen for symptoms, activities and environment in the DVD arm compared with usual care and for symptoms for the physiotherapy arm compared with usual care, with no significant differences between the active arms. The statistically significant differences were largely unchanged in the sensitivity analyses, with minor changes in magnitude. Analysis of the 3-month and 6-month AQLQ changes showed improvements in both active arms compared with the control arm by the first assessment, which were maintained or increased over 12 months. In the DVD arm, the improvements in mean total AQLQ score from baseline in the ITT population were 0.9 at 3 months, 1.0 at 6 months and 1.1 at 12 months; in the physiotherapy arm the equivalent figures were 1.0, 1.1 and 1.1 respectively. In the control arm, improvements in mean total AQLQ score from baseline were 0.6, 0.6 and 0.8 respectively.

An analysis in the ITT population of individual patient data using a cut-off point of 0.5 to define a clinically important change showed that 62% of participants in the DVD group improved over 12 months, compared with 64% in the physiotherapy group and 56% in the control group. The figures for deterioration were 5%, 4% and 8% respectively. The proportions improving in the PP population were slightly higher. A number needed to treat (NNT) analysis showed a NNT of eight for the DVD group compared with usual care, seven for the physiotherapy arm compared with usual care and 41 for the physiotherapy arm compared with the DVD arm.

Secondary outcomes

Physiology
significant between-group differences when adjusted for covariates. These data indicate that breathing retraining by either modality did not significantly affect airway physiology or inflammation and so did not affect the pathophysiology of asthma.

**Questionnaires**

We found no significant between-group changes in asthma symptom control (ACQ), anxiety scores or hyperventilation symptom scores in either the ITT population or the PP population, although there were modest within-group changes from baseline in all within-group analyses and consistent trends favouring the intervention groups above the control group. There was a small but statistically significant improvement in depression scores in the DVD group compared with the control group.

**Asthma attacks**

Only 12% of the ITT population had one or more asthma attack over the 12-month period. The proportion of patients in the three randomisation groups (DVD, physiotherapy, control) having one or more asthma attack was 9%, 11% and 15% respectively. There was no statistically significant difference in exacerbation rate between the DVD group and the physiotherapy group ($p = 0.6$) or between the physiotherapy group and the control group ($p = 0.4$). The DVD group showed a marginal statistically significant reduction in exacerbations compared with the control group ($p = 0.06$). In a negative binomial regression model, the adjusted risk ratio for DVD compared with the control was $0.68$ (95% CI 0.39 to 1.20) and for physiotherapy compared with the control was $0.85$ (95% CI 0.43 to 1.67).

**Short-acting bronchodilator use**

A between-group analysis of rescue medication use in the 12 months post randomisation showed trends for lower bronchodilator use in the DVD group compared with the control group [incidence rate ratio (IRR) $0.83$, 95% CI 0.68 to 1.03] and in the physiotherapy group compared with the control group (IRR $0.81$, 95% CI 0.63 to 1.04).

**Patient engagement and experience**

In total, 95% of participants attended at least one of the three face-to-face physiotherapy sessions and 93% attended all three. Patient experience of the different intervention components was favourable, with most devoting time to practising techniques, the main hindrance being finding time to practise. Engagement was also good in the DVD group, although with lower engagement scores and practice times than in the physiotherapy group. Qualitative analysis revealed that both interventions were valued, although some in the DVD arm would have liked to be able to receive instruction from a practitioner.

**Adverse events**

The adverse event profile was as expected in the recruited population, with fewer events in the active arms than in the control group. There was no indication of treatment-related adverse effects from either the DVD programme or the physiotherapy programme, with both appearing to be well tolerated.

**Economic evaluation**

Costs were lower in both active treatment arms than in the control group, with the increased intervention costs offset by reductions in total costs, indicating a dominant health economic strategy favouring the DVD intervention. The quality-adjusted life-year changes were in the same direction as the primary outcome but were smaller. The DVD programme dominated the physiotherapy programme, having equivalent outcomes at a lower cost.

**Conclusions**

Using a rigorous patient-focused iterative development process, we produced a self-guided version of a face-to-face physiotherapy-based breathing retraining programme to improve QoL in people with asthma and performed a pragmatic RCT in primary care asthma patients to test the clinical effectiveness and
cost-effectiveness and patient acceptability of the programme. We showed that the self-guided intervention is superior to usual care and equivalent to face-to-face physiotherapy in improving asthma-related QoL in this patient group, and constitutes a dominant economic strategy. However, lung function and airway inflammation were not significantly affected, with the intervention helping people to cope better and suffer less despite not modifying the underlying pathophysiology of asthma. The exacerbation risk was one-third lower in the DVD group than in the usual-care group, but the study was underpowered to provide statistical significance for this outcome.

In conclusion, this intervention is potentially of benefit to large numbers of asthma patients and may save the NHS money.

**Recommendations for future research**

Larger studies to investigate a possible effect of the intervention on exacerbations, implementation studies and extensions to paediatric populations are needed.

**Trial registration**

This trial is registered as ISRCTN88318003.

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