

# Breathing and relaxation exercises for adult patients diagnosed with asthma in primary care: a randomised controlled trial

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>21/11/2006   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>06/12/2006 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>14/11/2022       | <b>Condition category</b><br>Respiratory          | <input type="checkbox"/> Individual participant data                                              |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**  
NCT00400270

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

Breathing and relaxation exercises for adult patients diagnosed with asthma in primary care: a randomised controlled trial

## Study objectives

Asthma is of global concern and prevalence, thus morbidity and expenditure are increasing. Orthodox medical treatment focuses primarily on pharmaceutical control and education concerning its administration; patients are reported as seeking complementary and alternative therapies wishing to self-manage their condition. The majority of patients are being managed in primary care settings.

Chartered physiotherapists, since the 1960s, have been referred patients with asthma and breathing dysfunction for treatment with the Papworth Method (PM). Patients report improved quality of life but there is little evidence, including from Cochrane reviews, to support the use of breathing and relaxation therapies.

Therefore hypotheses for this trial are that:

1. A specific physical therapy intervention, comprising integrated breathing and relaxation exercises, the Papworth Method (PM), will improve the quality of life for adult asthma patients, already receiving usual medical care, in a primary care population.
2. Anxiety and depression will reduce in this population of patients diagnosed with asthma when treated with the PM.
3. Symptoms from dysfunctional breathing will reduce in this population after treatment with the PM.
4. Respiratory measures will improve (although this study is powered for quality of life and not respiratory function outcomes).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Hertfordshire Local Research Ethics Committee. Approval granted September 2004 (reference number: EC03660)

## Study design

Randomised controlled trial with an intervention and control arm. Twelve month follow-up. Open label - as this is a therapy trial.

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## **Study type(s)**

Treatment

## **Participant information sheet**

## **Health condition(s) or problem(s) studied**

Asthma

## **Interventions**

Integrated breathing and relaxation exercises known as the Papworth Method (PM). These techniques originated and were developed by physiotherapists in the Respiratory Medicine Department of Papworth Hospital, Cambridgeshire, UK in the 1960s.

The five, 60 minute treatments were undertaken by a respiratory physiotherapist in the intervention group between the baseline and six month assessments.

Patients in the control and intervention groups received usual asthma care. The comparisons were between normal care only (the control group) and the intervention group receiving five PM treatments at six months (or post-treatment) and at 12 months post baseline.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

1. Health related quality of life, as measured by the validated St Georges Respiratory Questionnaire with three domains (symptoms, activities and impacts) and a total overall score.

## **Secondary outcome measures**

1. Anxiety and Depression as measured by the validated Hospital Anxiety and Depression Scale.
2. Symptoms from dysfunctional breathing as measured by the validated Nijmegen Questionnaire.
3. Respiratory measures as measured by spirometry and capnography.

## **Overall study start date**

01/10/2004

## **Completion date**

01/02/2006

# **Eligibility**

## **Key inclusion criteria**

1. Men and women between 16 and 70 years of age
2. 'Doctor' diagnosed asthma volunteers, recruited from the asthma database of one primary care practice

3. Able to understand, read and write English
4. Willing to give written informed consent
5. Willing and able to attend the local surgery for required number of attendances

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

56

**Total final enrolment**

85

**Key exclusion criteria**

Serious co-morbid conditions such as hemiplegia (we aimed to recruit patients typical of the caseload of any semi-rural population of primary care asthma patients in order that this study should be generalisable to similar practices. For the same reason we did not require confirmation of a diagnosis of asthma by reversibility etc.,)

**Date of first enrolment**

01/10/2004

**Date of final enrolment**

01/02/2006

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

University College London

London

United Kingdom

WC1E 6BT

**Sponsor information**

**Organisation**

University College London (UK)

**Sponsor details**

Department of Epidemiology and Public Health  
London  
England  
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**Sponsor type**

University/education

**Website**

<http://www.ucl.ac.uk/>

**ROR**

<https://ror.org/02jx3x895>

**Funder(s)****Funder type**

University/education

**Funder Name**

University College London

**Alternative Name(s)**

University College London in United Kingdom, Collegium Universitatis Londinensis, UCL

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**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

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 01/12/2007   |            | Yes            | No              |