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

Submission date 21/11/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/12/2006	**Overall study status** Completed	
Last Edited 14/11/2022	**Condition category** Respiratory	

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)

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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?
Results article		01/12/2007		Yes	No