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The GPIAG/Leicester asthma and dysfunctional breathing project: The GLAD study (RESUBMITTED - PLEASE SEE UHL 8567)

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 18/02/2014	**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

Secondary identifying numbers

N0123119545

Study information

Scientific Title

Study objectives
1. To investigate the effects of breathing retraining supervised by a respiratory physiotherapist on clinical and physiological measures of asthma control
2. To identify the characteristics of patients who may benefit from this intervention
3. To perform a health economical evaluation of the intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Asthma

Interventions
Breathing retraining supervised by a respiratory physiotherapist compared to an attention control of generic asthma education provided by a nurse.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Asthma related quality of life (Juniper AQLQ)
2. Generic quality of life (Euroquol)
3. Asthma control (Juniper ACQ)
4. Nijmegen Questionnaire
5. Hospital Anxiety and Depression
6. Bronchial hyper-responsiveness (methacholine PC20)
7. Sputum eosinophil counts
8. Exhaled nitric oxide concentrations
9. Capnography
10. Hyperventilation studies

Measured before and 1 month after the intervention and control procedures. The questionnaires will be re-administered 6 and 12 months following the completion of intervention.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/06/2002

Completion date
31/08/2004

Eligibility

Key inclusion criteria
1. Family practice patients aged 18 - 65 years
2. A diagnosis of asthma
3. Received at least one asthma prescription in the previous year
4. With and without symptoms of dysfunctional breathing

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
212

Key exclusion criteria
Does not comply with above inclusion criteria

Date of first enrolment
01/06/2002

Date of final enrolment
31/08/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester
Leicester
United Kingdom
LE1 4PW

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Charity

Funder Name
National Asthma Campaign (UK)

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?
Results article	results	01/01/2009		Yes	No