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Writing about emotional experiences to reduce symptoms, improve quality of life and improve lung function in patients with asthma: a randomised controlled trial

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
06/05/2015

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Addressing the psychological needs of patients can produce improvements in both their mental and physical health. In the last decade several research studies have demonstrated that writing about emotionally traumatic experiences can improve how well people feel and reduce their use of health care services. More recently studies have begun to focus on people with particular chronic diseases and a study from North America suggested that in patients with asthma, expressive writing improved lung function by 12% for up to 4 months after the writing has stopped. In this study we will test whether writing about stressful experiences can improve lung function, decrease symptoms and improve quality of life in people with asthma in Britain. If improvements are observed, we will continue to follow study participants to determine for how long these improvements are sustained.

Who can participate?
Adult patients aged 18-45 with asthma.

What does the study involve?
We will allocate participants to one of two groups, to either write about stressful experiences or to write about time management. Participants in both groups will be asked to write for 20 minutes on 3 consecutive days in their own homes. We will assess participants' lung function, symptoms, quality of life and medication used at the start of the study, and after 1, 3, 6 and 12 months.

What are the possible benefits and risks of participating?
A great deal of research has shown a beneficial effect on physical health, social and emotional well-being following writing about stressful events. Specifically, asthma patients have shown an improvement in lung function after writing. Therefore we think that at least some of participants in the stressful writing group will benefit in terms of lung function, reduced symptoms and quality of life. Previous studies indicate that rarely, emotional disclosure can lead

to short-lived distress, but in over 20 years of research of this kind it is very rare that any participant has become seriously distressed.

Where is the study run from?
Brighton & Sussex Medical School (UK).

When is the study starting and how long is it expected to run for?
From May 2003 to June 2008.

Who is funding the study?
Brighton and Sussex University Hospitals NHS Trust, Asthma Research UK and Asthma UK.

Who is the main contact?
Prof Helen Smith (H.E.Smith@bsms.ac.uk)
Ms Alice Theadom (a.theadom@bsms.ac.uk)

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0051127195

Study information

Scientific Title
Writing about emotional experiences to reduce symptoms, improve quality of life and improve lung function in patients with asthma: a randomised controlled trial

Study objectives
1. Can writing about stressful experiences decrease symptoms, improve quality of life and improve lung function in patients with asthma?
2. For how long are these improvements sustained?

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)
Not specified

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
Respiratory: Asthma

Interventions

A pragmatic, randomised controlled trial of expressive writing for patients with asthma versus no writing.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Lung function (forced expiratory volume in one second [FEV1], peak expiratory flow [PEF]) (primary outcome). Symptom scores, quality of life, medication use and health service use will be used as secondary outcome measures.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2003

Completion date
30/06/2008

Eligibility

Key inclusion criteria
Adult patients (18-45) registered with participating general practices with a diagnosis of asthma and requiring regular inhaled medication (British Thoracic Society [BTS] steps 2-4). The upper age limit has been chosen to exclude people whose respiratory problems may be due to chronic obstructive pulmonary disease (COPD).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Both

Target number of participants
We aim to recruit 144 participants into the main study

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/2007

Date of final enrolment
01/05/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Brighton & Sussex Medical School
Brighton
United Kingdom
BN1 9PH

Sponsor information

Organisation
Department of Health

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

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Charity

Funder Name
Brighton and Sussex University Hospitals NHS Trust (UK)

Funder Name
Asthma Research UK (UK)

Funder Name
Asthma UK (UK)

Alternative Name(s)
Asthma UK, Asthma + Lung UK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trial is completed and the manuscript has been accepted for publication.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2015		Yes	No