

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

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| <b>Submission date</b><br>30/09/2004   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>30/09/2004 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>06/05/2015       | <b>Condition category</b><br>Respiratory          | <input type="checkbox"/> 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)  
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## Contact information

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## Additional identifiers

**Protocol serial number**

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

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**Study type(s)**

Treatment

**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(s)**

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.

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

45 Years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

Brighton & Sussex Medical School  
Brighton

United Kingdom  
BN1 9PH

## Sponsor information

**Organisation**  
Department of Health

## 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)**  
asthmalunguk, Asthma + Lung UK, Asthma UK

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Research institutes and centers

**Location**  
United Kingdom

## Results and Publications

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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/05/2015   |            | Yes            | No              |