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# Mindfulness for patients with difficult-to-manage asthma

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 13/01/2016 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 13/01/2016 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 19/05/2017 | Respiratory | |

## Plain English summary of protocol

Background and study aims
Asthma is a long-term condition which affects the airways. It can affect people of any age, however in usually is first spotted during childhood. When a person is suffering from asthma, the bronchi (tubes which carry air in and out of the lungs) can become narrowed or swollen (inflammation). This can cause a range of distressing symptoms such as wheezing, chest tightness and breathlessness. During episodes of breathlessness, many patients with asthma experience anxiety which puts their lungs under even more stress. It has been found that patients with severe and poorly controlled asthma (PCA) often experience more symptoms when compared to those with better controlled disease. It is likely that this is associated with higher levels of anxiety, which can make it very difficult to cope day-to-day. Mindfulness is a concept designed to help people to become more aware of their thoughts and feelings in order to become more self-aware and accepting of the current moment. Its use in the treatment of people suffering from mental health problems is steadily increasing, and new programs are being developed to help people with different medical problems. The aim of this study is to find out whether a short course of mindfulness-based training is an effective way of helping patients who are struggling to control their asthma to cope better.

Who can participate?
Adults who have asthma and attend the “Difficult Asthma Clinic” at Southampton General Hospital.

What does the study involve?
All participants attend four sessions of mindfulness-based training. The training is given in group sessions, once a week, lasting for around one hour. “Daily homework”, such as meditation exercises, is also given to participants to practice at home every day. Participants are also interviewed and complete a number of questionnaires in order to evaluate whether the mindfulness training is an effective treatment for patients suffering from poorly controlled asthma.

What are the possible benefits and risks of participating?
Participants may benefit from getting new ideas which could help them to better manage their asthma. There are no significant risks of taking part, however participating does involve a time commitment.

Where is the study run from?
Southampton General Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2015 to December 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Megan Liddiard

# Contact information

### Type(s)
Public

### Contact name
Mrs Megan Liddiard

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University of Southampton
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
20243

# Study information

### Scientific Title
Investigating the impact of a short-course MBSR-based mindfulness intervention on patients with difficult-to-manage asthma

### Study objectives

The aim of this study is to develop a short mindfulness meditation intervention for patients from the Southampton General Hospital 'difficult asthma' clinics, and to establish whether it can be successfully delivered (and is acceptable) to patients with poorly controlled asthma (PCA).

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
South Central - Berkshire B Research Ethics Committee, 12/10/2015, ref: 15/SC/0522

## Study design
Single-centre non-randomised study

## Primary study design
Interventional

## Secondary study design
Non randomised study

## Study setting(s)
Other

## 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
Topic: Primary Care, Respiratory disorders; Subtopic: Respiratory (all Subtopics), Respiratory disorders; Disease: Respiratory, All Diseases

## Interventions
At baseline, participants provide informed consent and complete a battery of self-report questionnaires and computerized measures and routinely-collected clinic data will be collected during routine patient clinic sessions in the UHS Difficult Asthma Clinic.

All participants then take part in a short mindfulness-based meditation course, involving 4 weekly 1.5 hour sessions with daily homework practice. The sessions will build experience progressing through attention training practices, to reconnecting the mind and body developing awareness of bodily signatures of stress, anxiety and low mood and learning practical techniques of how to deal with them. Session 1 explores the common stories and emotions that we get caught up with when our mind is wandering and causes distress. In this session participants learn how to calm a wandering mind with attention training using the breath as a focus, Session 2 reconnects the mind and body, providing a suitable mindfulness tool for these patients. In the 3rd session components of MBCT will be introduced exploring "thoughts are not facts" and how to deal with difficulties. The final session looks at how to establish and sustain a mindfulness practice and explores how to integrate mindfulness into daily life. Mindful movement such as gentle stretching and mindful walking is introduced. At the end of this course participants will have a tool box of mindfulness techniques to draw on and support them.

Participants are requested to do home practice for at least 6 days of the week for 10-20minutes a day if possible using recordings to pace and guide them. They will be requested to keep a homework diary to log their practice and experience, as well as facilitating engagement. The three formal mindfulness techniques of body scan, focusing on the breath and gentle stretching exercises are taught. Although a set curriculum is outlined for the intervention, as with all mindfulness programmes due to their experiential nature and variation in groups there is some flexibility.

After 3 months, participants will complete a second battery of self-report questionnaires, computerized measures and clinic data in the UHS Difficult Asthma Clinic Focus groups will be conducted 6 weeks after the intervention to elicit in depth discussion on the experiences of taking part and the acceptability of the intervention.

Throughout the study, the recruitment procedures, recruitment rates/uptake, adherence and attrition are monitored using descriptive statistics. A thematic analysis of focus group data will be conducted to ensure an inductive approach.

## Intervention Type
Other

## Primary outcome measure
Asthma-related quality of life is measured using the Asthma Quality of Life Questionnaire (AQLQ) at baseline and 3 months post-test.

## Secondary outcome measures
1. Asthma control is measured using The Asthma Control Test (ACT) at baseline and 3 months post-test
2. Anxiety and depression is measured using The Hospital Anxiety and Depression Scale (HADS) at baseline and 3 months post-test
3. Mindfulness is measured using the Mindful Attention Awareness Scale (MAAS) at baseline and 3 months post-test
4. Anxiety is measured using the Spielberger Anxiety Inventory (STAI) at baseline and 3 months post-test
5. Hyperventilation syndrome is determined using the Nijmegen Questionnaire (NQ) at baseline and 3 months post-test
6. Medication adherence is measured using the Medication Adherence Report Scale for Asthma (MARS-A) at baseline and 3 months post-test
7. Degree of airway inflammation and to confirm that psychological benefits are independent from lung-function improvement are determined by measuring the level of exhaled nitric oxide
8. Potential dose-response of mindfulness is measured using self-reporting in weekly diaries
9. Cognitive measures of attention including versions of the dot-probe task (8-minutes) and the attention network test (8 minutes) are completed at baseline and 3 months post test
10. Acceptability of the intervention is measured using in-depth discussions with focus groups 6 weeks post-test

## Overall study start date
01/09/2015

## Completion date
31/12/2016

# Eligibility

### Key inclusion criteria
1. Aged 18 years or over
2. Confirmed diagnosis of Asthma
3. Under the care of the Difficult Asthma Clinic at Southampton General Hospital (University Hospital Southampton NHS Foundation Trust)
4. Positive screening score for anxiety (greater than 8 on the HADS hospital anxiety and depression scale)

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 20; UK Sample Size: 20; Description:
There will be 2 Mindfulness courses each consisting of a maximum of 10 people run during the stud

### Key exclusion criteria
1. Under 18 years of age
2. Comorbid psychological disorders other than anxiety/depression measured using MINI Neuropsychiatric Interview questionaire
3. Acute exacerbation of asthma needing course of oral steroid or increased dose of maintenance steroid within 28 days of first intervention session
4. Current participation in an additional asthma intervention study

### Date of first enrolment
13/01/2015

### Date of final enrolment
29/02/2016

# Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre

**Southampton General Hospital**
University Hospital Southampton NHS Foundation Trust
Tremona Road
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SO16 6YD

# Sponsor information

**Organisation**
University of Southampton

**Sponsor details**
School of Psychology
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**Sponsor type**
University/education

**ROR**
https://ror.org/01ryk1543

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health Research

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

### Location
United Kingdom

# Results and Publications

### Publication and dissemination plan
Results of the pilot study will advise on future randomised controlled trials with a view to publish at a later stage.

### Intention to publish date
31/12/2017

### Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from M.E.Liddiard@soton.ac.uk

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Basic results | | 12/05/2017 | 16/05/2017 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |