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Investigating attention in people with asthma

Submission date 25/04/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 29/04/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/10/2017	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Asthma is a common long-term health condition caused by inflammation of the small tubes (bronchi) that carry air in and out of the lungs. Symptoms vary in severity and include coughing, wheezing, a tightness in the chest and feeling breathless. It occurs when the sufferer comes in contact with something that irritates their lungs – a trigger - causing their airways to narrow and an increase in the production of phlegm in their airways. Common triggers include house dust mites, animal fur, pollen, cigarette smoke, exercise and viral infections (such as a cold). The focus of asthma treatment is on medication, usually with inhalers, and the response to poorly controlled asthma (PCA) is often to increase medication. However, asthma affects people in many ways, including effects on emotions, concentration and self-management behaviour. Having attacks of breathlessness can be frightening, and some may become anxious or depressed. Significant anxiety is six times as common in people with asthma, particularly when control is poor. Those with anxiety are more likely to have asthma attacks, have more frequent attacks, worse symptoms and have a lower quality of life. Anxiety is often not talked about with doctors, so can be untreated. The Department of Health has recently made studies of psychological treatments in asthma a research priority. Notably, there is a relatively poor association between the symptoms of asthma (e.g. physiological measurement of lung function) and how bad patients themselves consider their asthma to be. However, there is a stronger relationship between how anxious patients feel and how severe they think their asthma is. Currently, there is a lot of research examining thought-processing biases in anxiety (for example, people with anxiety more quickly notice negative stimuli in the environment). However, the corresponding research has not been conducted in asthma. This area of research will therefore benefit greatly from research that reconciles findings from both anxiety and asthma.

Who can participate?
Adults diagnosed with asthma

What does the study involve?
Participants take a bronchial challenge test (or methacholine challenge), which is a medical test that helps is diagnosing asthma. It involves the patient breathing in methacholine, a drug that causes the airways to narrow (bronchoconstriction). They will be asked complete some short and simple computer tasks and questionnaires before and after the methacholine challenge. These computer tasks and questionnaires will be used to understand participants' thought processes, and how they are affected by asthma.

What are the possible benefits and risks of participating?
Participants do not benefit directly from taking part in this study. However, the results may increase researchers understanding of asthma and lead to improved diagnosis and treatment in the future. They may also benefit from gaining a more thorough understanding of their condition and how it affects them. Possible side effects include a feeling of being tight chested or coughing during the methacholine challenge, however this is a likely to be very mild.

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

When is the study starting and how long is it expected to run for?
April 2016 to April 2017

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

Who is the main contact?
1. Dr Ben Ainsworth (scientific)
2. Mrs Megan Liddiard (public)

Contact information

Type(s)
Scientific

Contact name
Dr Ben Ainsworth

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MED1286

Study information

Scientific Title
Investigating maladaptive cognitive biases in patients with asthma using a bronchial hyperreactivity challenge.

Acronym
BROCOG

Study objectives
The trialists predict an association between subjective symptoms of asthma and anxiety-related thought processes. Specifically, they hypothesize that increased anxiety will be related to increased perception of breathlessness/asthma severity (regardless of actual measures of physiological lung function).

Ethics approval required
Old ethics approval format

Ethics approval(s)
City Road and Hampstead Research Ethics Committee, 13/01/2016, ref: 15/LO/1898

Study design
Within-subjects design using standardised cognitive and behavioural measures

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Participants will complete some baseline measures of lung function and psychological measures. They will then complete the key outcome measures (computer tasks, and anxiety-related questionnaires) DURING a bronchial challenge.

The bronchial challenge is known as a methacholine challenge. Patients will be asked to inhale a drug called Methacholine to assess how reactive to 'twitch' the muscles in the airways are. They start with a very low inhaled amount, and measure whether patients' airways tighten at all by repeating the blowing test (spirometry). If they don't, or do so very little, a slightly higher dose inhalation will be given and the spirometry will be repeated. This will continue for up to 7 inhalations, stopping if patients start to feel bad or when the blowing test has reduced to 4/5 of the original level. Inhaling this agent may make patients wheeze or cough a bit. At the end of the test we will ask patients to do the computer tasks, and then we will give you some salbutamol (reliever inhaler medication) to reverse the effects of methacholine.

They will complete the same measures after the bronchial challenge, and results will be compared.

Intervention Type
Other

Primary outcome measure
1. Attentional functioning, measured using the computerized Attention network test
2. Attention biases towards threatening stimuli, measured using a dot-probe task
3. Severity of anxiety, measured using the spielberger state-trait anxiety inventory

Measured during vs. after methacholine challenge

Secondary outcome measures
1. Mindfulness and attention questionnaires, measured using the MAAS and ACS
2. Asthma control/quality of life, measured using the ACQ and AQLQ

Measured at baseline

Overall study start date
26/04/2016

Completion date
26/04/2017

Eligibility

Key inclusion criteria
1. Adult (over 18 years)
2. Confirmed diagnosis of asthma. Asthma severity will be clinically diagnosed according to BTS guidelines from Step 1 [mild intermittent asthma] to Step 4 [persistent poor control], have an FEV1 of 60% or more in order to undergo methacholine challenge

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Patients under 18 years of age
2. Comorbid psychological disorders other than anxiety/depression (measured using the MINI 3. neuropsychiatric interview questionnaire)
4. Currently participating in an active asthma intervention study
5. Have had acute exacerbation of asthma (needing a course of oral steroid of increased dose of maintenance steroid) with 28 days of the first intervention study

Asthma severity is characterised according to BTS guidelines as Step 5 (continuous or frequent use of oral steroids)

Date of first enrolment
30/04/2016

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Southampton
Tremona Rd
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University of Southampton

Sponsor details
Tremona Rd
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SO17 1BJ

Sponsor type
University/education

Website
www.soton.ac.uk

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
Publications will be submitted to peer-reviewed internation journals and presented at conferences

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No