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# Further development of a new model of generalised anxiety disorder: effects on processing of emotional material

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 28/09/2007 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 28/09/2007 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 07/07/2017 | Mental and Behavioural Disorders | [ ] Record updated in last year |

**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
N0264192826

# Study information

### Scientific Title
Further development of a new model of generalised anxiety disorder: effects on processing of emotional material

### Study objectives
This study will enable us to learn more about how the inhalation of carbon dioxide (CO2) produces anxiety. We can examine the psychological mechanisms of CO2-induced anxiety and see how these influence the processing of emotional material. These findings will aid our understanding of anxiety and validate the CO2 model for use in studies of potential new treatments. It is widely accepted that anxiety results in altered processing of emotional material. Anxiety is also associated with physical symptoms such as racing heart, raised blood pressure, and muscle tension. We aim to examine the relationship between heart rate and blood pressure and altered processing of emotional material (i.e., are changes in the physical response to CO2 related to changes in the psychological response?).

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Double-blind placebo-controlled randomised crossover study

### Primary study design
Interventional

### Secondary study design
Randomised cross over trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### 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
General anxiety disorder

### Interventions

Participants will complete a single test session, which will consist of the inhalation of air and the inhalation of 7.5% CO2, in counterbalanced order.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Measures of processing of emotional information

### Secondary outcome measures
Subjective measures of anxiety and cardiovascular function

### Overall study start date
01/01/2007

### Completion date
01/01/2008

## Eligibility

### Key inclusion criteria
1. Male and female participants
2. Aged 18-55
3. With a normal medical and psychiatric history, physical examination and ECG who give signed, fully-informed consent to participate

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
55 Years

### Sex
Both

### Target number of participants
20

### Key exclusion criteria

1. Females who are pregnant, breastfeeding, or not using adequate contraception
2. Presence of any pathological condition
3. Personal history of current or past psychiatric illness by psychiatric interview
4. Strong family history of mood disorder, including panic disorder
5. Personal history of cardiovascular or respiratory disease, including asthma
6. Personal history of migraine headaches requiring treatment
7. Cigarette smoking in the last 6 months
8. Drinking more than the recommended units of alcohol per week
9. Personal history of alcoholism or drug dependence
10. Drinking more than 8 caffeinated drinks per day
11. Medication use (except local treatment, or aspirin or paracetamol) within 8 weeks of testing
12. Potential, in the opinion of the investigator, to be non-compliant with study

### Date of first enrolment
01/01/2007

### Date of final enrolment
01/01/2008

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Bristol Royal Infirmary**
Bristol
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BS2 8HW

## Sponsor information

### Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

### Sponsor details
The Department of Health
Richmond House
79 Whitehall
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**Sponsor type**
Government

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

# Funder(s)

**Funder type**
Government

**Funder Name**
United Bristol Healthcare NHS Trust

**Funder Name**
NHS R&D Support Funding

# 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