

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

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| Submission date 28/09/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 28/09/2007 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 07/07/2017 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

Measures of processing of emotional information

Key secondary outcome(s)

Subjective measures of anxiety and cardiovascular function

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

55 years

Sex

All

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

United Kingdom

England

Study participating centre

Bristol Royal Infirmary

Bristol

United Kingdom

BS2 8HW

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

United Bristol Healthcare NHS Trust

Funder Name

NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration