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Cardiac Control of Fear in Brain: relationship to anxiety symptoms

Submission date
21/08/2014

Recruitment status
No longer recruiting

Registration date
16/12/2014

Overall study status
Completed

Last Edited
20/05/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
We have found that heartbeat timing (heart rate) affects the way the brain processes fear. This is called Cardiac Control of Fear in the Brain (CCFIB). This effect is present in 75% of the population and its possible that it is linked to mental health problems. We want to find out whether more people with anxiety disorder display CCFIB compared to other type of patients. In a follow-up study, we will also find out whether CCFIB can predict how well treatments will work.

Who can participate?
Adults who currently use mental health services.

What does the study involve?
Participants are asked to complete questionnaires that gather information on their symptoms of mood and anxiety, how severe their disorder is, their quality of life, medical history, and how they see their own body (body perception). Participants also complete some computerised tasks that measure their interoceptive awareness (awareness of, for example, heartbeat, “butterflies in the stomach” or being aware of face flush) while using a finger sensor to measure their pulse.

What are the possible benefits and risks of participating?
There are no immediate benefits from taking part in this study. Although this research may not directly benefit participants, it could result in new ways of treating anxiety and other mental health symptoms in the future. There are no risks in participating in the study. Information from the study will be protected and anonymous so that people will not have access to the information about who took part or find out results of any one individual.

Where is the study run from?
1. Assessment and Treatment Centre East, East Brighton Community Mental Health Centre, Brighton General Hospital, Brighton (UK)
2. Assessment and Treatment Centre West, Mill View Hospital, Hove (UK)
3. The University of Sussex, Falmer, Brighton (UK)

When is the study starting and how long is it expected to run for?
July 2014 to May 2017.

Who is funding the study?
European Research Council (Belgium)

Who is the main contact?
Dr Cassandra Gould
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16309

Study information

Scientific Title
Cardiac Control of Fear in Brain: relationship to anxiety symptoms: an observational study

Acronym
CCFIB

Study objectives
Primary objectives are to determine whether the cardiac control of fear in the brain (CCFIB) is linked to anxiety disorder (i.e. whether a greater proportion of anxiety patients express CCFIB than other patient groups and control groups).

Ethics approval required

Old ethics approval format

Ethics approval(s)
13/LO/1866MHRNA; First MREC approval date 22/01/2014

Study design
Non-randomised; Observational; Design type: Qualitative

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Other

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: Mental Health; Subtopic: Anxiety; Disease: Anxiety

Interventions
Participants will first give informed consent and will then perform computerized measures of interoceptive awareness and CCFIB. CCFIB is a clinical screening tool. The usefulness of CCFIB as a clinical screening tool will be evaluated against symptom expression within a clinical population. We will examine whether CCFIB predicts treatment effectiveness. Physiological equipment is applied with participant seated, including application of finger sensors for heartbeat measurements using a pulse oximeter.

The second component of the study is a follow up study. Patients assessed within the survey, and assigned to a cognitive behavioural therapy (CBT) programme or a course of SSRI medication, will be followed up.

Updated 17/07/2015: All patients assessed within the survey will be followed up.

Follow Up Length: 6 month(s)

Intervention Type
Other

Primary outcome measure
Patient survey: Is CCFIB linked to anxiety disorder?

Secondary outcome measures
Patient survey: Does CCFIB predict treatment effectiveness?

Overall study start date
14/07/2014

Completion date
31/05/2017

Eligibility

Key inclusion criteria
Previous inclusion criteria:
1. Service User (GP surgeries, Well-being services, Health in Mind, and Assessment and Treatment Services, Brighton and Hove)
2. Diagnosed with any mental health problem
3. Target Gender: Male & Female ; Lower Age Limit 18 years

Current inclusion criteria as of 17/07/2015:
1. Service User (GP surgeries, Well-being services, Health in Mind, and Assessment and Treatment Services, Brighton and Hove)
2. Diagnosed with anxiety disorder
3. Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 300; UK Sample Size: 300

Key exclusion criteria
1. A significant history of cognitive impairment or a neurological condition
2. History of substance abuse
3. Alcohol intake during that day

Date of first enrolment
14/07/2014

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Imaging Sciences Centre
University of Sussex
Brighton
United Kingdom
BN1 9RR

Study participating centre
Assessment and Treatment Centre East
East Brighton Community Mental Health Centre
Brighton General Hospital
Brighton
United Kingdom
BN2 3EW

Study participating centre
Assessment and Treatment Centre West
Mill View Hospital
Hove
United Kingdom
BN3 7HY

Sponsor information

Organisation
Sussex Partnership NHS Foundation Trust (UK)

Sponsor details
Sussex Education Centre
Nevill View Hospital
Hove
England
United Kingdom
BN3 7HZ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05fmrjg27

Funder(s)

Funder type
Government

Funder Name
European Research Council; Grant Codes: 324150CCFIB

Alternative Name(s)
ERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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

Study outputs

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