Emotion recognition training and brain responses

Submission date 19/10/2012	Recruitment status No longer recruiting	Prospectively registered	
		[] Protocol	
Registration date	Overall study status	Statistical analysis plan	
21/01/2013	Completed	[X] Results	
Last Edited 21/02/2020	Condition category Mental and Behavioural Disorders	Individual participant data	

Plain English summary of protocol

Background and study aims

Faces play a key role in everyday life, and the accurate recognition of emotional content in faces is critical to social functioning. This is disrupted in a range of psychiatric disorders for example, people with depression show a negative bias whereby they fail to identify happiness in faces. We have developed a new concept which targets the recognition of facial expression of emotions by initially assessing the threshold for detecting one emotion over another in an ambiguous (unclear) expression (e.g., a blend of happiness and sadness), and then providing feedback to shift this threshold (e.g., to favour identification of happiness over sadness). Preliminary results from adults recruited from the general population on the basis of high levels of depressive symptoms show that this manipulation of the perception of emotion in ambiguous facial expressions, designed to promote the perception of positive emotion over negative emotion, may have therapeutic (remedial) benefit which persists for at least two weeks. The present project aims to investigate brain responses during the emotion recognition training procedure in individuals with low mood.

Who can participate?

The study will recruit adults aged 18 and 40 years, either sex, from the general population who report high levels of depressive symptoms (defined as a score of 14 or more on the Beck Depression Inventory; BDI-ii).

What does the study involve?

The study will evaluate a computer-based training programme that is designed to modify recognition of ambiguous facial expressions, from seeing them as expressing sadness to seeing them as expressing happiness. This training is designed to promote the perception of positive emotion over negative emotion. The participants will be randomly allocated to either a treatment group, which will receive feedback designed to shift their recognition of ambiguous faces as displaying happiness rather than sadness, or a control group which will receive feedback not designed to shift their recognition.

What are the potential benefits and risks of participating? Participants would not directly benefit from taking part in this research study. However, the information we get from this study may help us to understand the influence of emotion perception on low mood. There are no expected risks of taking part in this study.

Where is the study run from?

The study will be run in the School of Experimental Psychology, 12a Priory Road, University of Bristol and CRIC Bristol, University of Bristol (UK)

When is the study starting and how long will it be expected to run for? November 2012 to May 2013

Who is funding the study? Medical Research Council (UK)

Who is the main contact? Dr Sally Adams sally.adams@bristol.ac.uk

Study website

http://www.bristol.ac.uk/expsych/research/brain/targ/participants/emotionbrain.html

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers UOB1700

Study information

Scientific Title

Identifying the neural substrates of emotion recognition and mood processing targets in an emotion recognition training procedure

Study objectives

Emotional recognition training will reduce amygdala responses to negative facial expressions. We also hypothesise that training will alter activity in the occipital cortex because it is highly connected to the amygdala and is sensitive to attentional change in response to emotional stimuli and the prefrontal cortex which exerts effects on circuitry implicated in pharmacological and psychological treatment for depression.

Ethics approval required

Old ethics approval format

Ethics approval(s) Faculty of Science Human Research Ethics Committee, 13t/09/2012, ref: 130912583

Study design Double-blind placebo controlled study

Primary study design

Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Patient information material can be found at http://www.bristol.ac.uk/expsych/research/brain /targ/participants/emotionbrain.html

Health condition(s) or problem(s) studied

Low mood / depression

Interventions

Emotion Recognition Training (ERT):

Session 1: The first session will involve a screening assessment to ensure that participants fit the requirements of the study and are in general good physical and psychological health. During this session participants will also complete questionnaire measures and will be required a computer-based emotion perception task. Participants will be randomised to one of 2

groups: treatment or control. This session would last approximately 60 minutes. Sessions 2-5: We will ask participants to attend four sessions on consecutive days (or as close as possible) to complete the computer-based emotion perception task and a series of questionnaires rating mood. These sessions should last approximately 25 minutes. Session 5: We will ask participants to undergo a MRI scan consisting of two parts. Participants will first undergo an anatomical MRI scan; this will last approximately 5 minutes and participants will just lie still. In the second part of the MRI scan participants will view images projected on a screen above their head. This session would last approximately 60 minutes.

Control:

The control arm procedure is identical to the intervention arm procedure, except that the cognitive bias modification task is designed to elicit no change in perception of emotional expression in the control condition. Participants will complete computerised training (or control) procedures repeated five times over consecutive days (Monday to Friday).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Neural response to emotional cues: Blood oxygen level dependent (BOLD) responses to emotional facial expression at baseline and one week.

Secondary outcome measures

Current secondary outcome measures as of 17/05/2013:

1. Depressive symptoms: Beck Depression Inventory-ii (BDI-ii) at baseline and one week

2. Depressive symptoms: Hamilton Rating Scale for Depression (HAM-D) at baseline and one week

- 3. Anxiety symptoms: Beck Anxiety Inventory (BAI) at baseline and one week
- 4. Positive affect: Positive and Negative Affect Schedule (PANAS) at one week
- 5. Negative affect: Positive and Negative Affect Schedule (PANAS) at one week
- 6. Emotion sensitivity: Emotion Recognition Task (ERT) at one week
- 7. Approach motivation and persistence: The Fishing Game at one week
- 8. Depressive interpretation bias: The Scrambled Sentences Test (SST) at one week

Previous secondary outcome measures until 17/05/2013:

- 1. Depressive symptoms: Hamilton Rating Scale for Depression (HAM-D)
- 2. Anxiety symptoms: Beck Anxiety Inventory (BAI) (rated over the past week)
- 3. Positive affect: Positive and Negative Affect Schedule (PANAS) (rated over the past day)
- 4. Negative affect: Positive and Negative Affect Schedule (PANAS) (rated over the past day)

Overall study start date

01/11/2012

Completion date 30/05/2013

Eligibility

Key inclusion criteria

1. Aged between 18 and 40 years

- 2. Participants who score 14 or higher on the Beck Depression Inventory (BDI)-II
- 3. English as first language or equivalent level of fluency
- 4. Right-handed (as assessed by Edinburgh Handedness Inventory)

5. Able to give informed consent as judged by lead researcher

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Total final enrolment

36

Key exclusion criteria

1. Primary anxiety disorder, psychosis, bipolar disorder or substance dependence [other than nicotine and caffeine] as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)

- 2. Current use of illicit drug (except cannabis)
- 3. Being at clinically significant risk for suicidal behaviour
- 4. Use of psychotropic medication in last 5 weeks prior to study

5. Major somatic or neurological disorders and concurrent medication which could alter emotional processing (including active treatment with counselling, cognitive behavioural therapy or other psychotherapies). We will allow intermittent use of medication, judged by the principal investigator.

7. Participants who have contra-indication for magnetic resonance imaging (MRI) imaging

8. Participants unable to tolerate the scanner environment

Date of first enrolment

01/11/2012

Date of final enrolment 30/05/2013

Locations

Countries of recruitment England United Kingdom

Study participating centre School of Experimental Psychology 12a Priory Road Bristol United Kingdom BS8 1TU

Sponsor information

Organisation University of Bristol (UK)

Sponsor details Research and Enterprise Development 3rd Floor, Senate House Tyndall Avenue Bristol England United Kingdom BS8 1TH

Sponsor type University/education

Website http://www.bris.ac.uk/red/

ROR https://ror.org/0524sp257

Funder(s)

Funder type Research council

Funder Name Medical Research Council (MRC) (UK) grant ref: MR/J011819/1

Results and Publications

Publication and dissemination plan

Planned publication of study results in a peer reviewed journal.

Intention to publish date 31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/02/2020	21/02/2020	Yes	No