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Looking at the bright side: developing and testing a new intervention to target negative bias in people with eating disorders

Submission date
09/09/2013

Recruitment status
No longer recruiting

Registration date
08/11/2013

Overall study status
Completed

Last Edited
15/10/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
People with Eating Disorders (EDs) have socio-emotional difficulties. In particular, they show a bias towards negative information about the self and others attitudes. Previous studies from our unit found an attentional bias towards critical and angry faces, and lower implicit self-esteem and self-compassion in EDs than healthy subjects. A computerized training programme has been developed that aims to modify negative cognitive bias to social and self-relevant stimuli. The aim of this study is to test the acceptability and impact of this programme on clinical symptoms, interpersonal functioning (between self and others), and self-evaluation in patients with EDs.

Who can participate?
Patients with an eating disorder

What does the study involve?
Participants meet the researcher four times, on four different days, over the course of 7-10 days. During the first day (baseline; 60 min), participants complete a set of questionnaires. Then, participants are randomly allocated to one of four groups:
1. Attentional Bias intervention (experimental) group
2. Attentional Bias control group
3. Self-Esteem intervention (experimental) group
4. Self-Esteem control group.
The experimental groups receive computerized training (training session 1 - day 2; training session 2 - day 3; training session 3 - day 4) to develop a bias towards others (module 1) and self-related positive information (module 2). Participants in the control groups receive a different version of the training, where both positive and negative information are presented. At the end of the last training session (day 4), all participants complete follow-up measures of clinical symptoms, implicit and explicit self-esteem, interpersonal functioning, vigilance to social stimuli and interpretation of social situations (45 min). Participants in the control group are offered the intervention at this stage.

What are the possible benefits and risks of participating?
It is hoped that this intervention will be associated with a reduction of negative bias towards self- and others-related information and with improved self-esteem and social functioning in people with eating disorders. It is also hoped this intervention will be associated with a reduction of the eating disorders symptoms. The study will be testing participants with eating disorders who may be considered as at risk. They may experience mild distress or discomfort in completing some of the questionnaires because of the topics investigated (i.e., symptoms associated with the eating disorder). Also, participants may find it somewhat stressful to be involved in the study for a relatively long period of time (about 1 month). Throughout the study, precautions will be made to ensure that the participants are as protected as possible. If interested in taking part in the study, participants will be able to contact the researcher directly by email or telephone, to schedule an appointment with them. Otherwise, they could choose to let their consultant or primary nurse on the site know so that they contact the researcher by email or phone for the patient to schedule an appointment with them. During the face-to-face meeting with the researcher, the patient will be able to discuss the details of the project. Before agreeing to sign the consent form, the researcher will review the information sheet with the participant, offering them the opportunity to ask questions, and will remind the participant that they are free to withdraw at any time without having to specify a reason. During the screening phase, participants will be interviewed to understand whether they are eligible to take part. While completing the questionnaire materials, participants will be invited to take breaks as needed. Participants will also be invited to express the reasons for their distress so that they can be provided with additional guidance and support to address these issues. They will be reassured and reminded that they can withdraw from the study at any point. In case this reassurance is not sufficient to alleviate participant distress, they will then be asked to speak with Prof. Treasure, who has several years of experience working with people with Eating Disorders.

Where is the study run from?
The study sessions with volunteers from the local community will take place at King's College London. The study sessions with outpatients and inpatients will take place at South London and Maudsley NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
October 2013 to October 2015

Who is funding the study?
The Psychiatry Research Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Cognitive bias modification training in eating disorders: a pilot study

Study objectives
The computerised training developed will reduce the cognitive bias towards negative social and self-relevant stimuli.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Camberwell and St Giles Research Ethics Committee (London), approved 22/11/2013, amendment approved 02/05/2014, REC ref: 13/LO/1492

Study design
Pilot feasibility multicentre study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Eating Disorders

Interventions
Participants will be randomly allocated to one of four groups. Each of the four modules will entail four sessions (about 30 min/each).
1. Attentional Bias intervention (experimental) group
2. Attentional Bias control group

3. Self-Esteem intervention (experimental) group
4. Self-Esteem control group.
They will meet the researcher four times, on four different occasions (in 1 week/10 day-time). Together, the two modules comprise a full cognitive bias modification programme; they are divided into two modules to minimise the burden on patients and to keep the experimental sessions brief for the purpose of this pilot study.
During the first session (session 1; 40 min) participants will complete the baseline questionnaires and computerized tasks. During sessions 2 and 3 they will receive two training or placebo sessions (30 min in study 1; 15 min in study 2). During session 4 participants will receive the last session of training or placebo and will complete the follow-up questionnaires and computerized tasks (45 min). At the end of the study participants in the placebo group will be offered the intervention.
A follow-up will be conducted 30 days after the end of the project. Participants will receive some questionnaires and a brief structured phone interview to evaluate eating disorders and mood symptoms, interpersonal functioning, and self-esteem.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Acceptability and feasibility of the computerised training developed (qualitative feedback to be collected during the last study session)
2. Reduction of the negative bias towards social and self-related information (computerised tasks to be completed during the last study session)

Key secondary outcome(s))
An improvement of socio-emotional functioning and reduction of eating disorders symptoms (questionnaires to be completed during the last study session)

Completion date
01/10/2015

Eligibility

Key inclusion criteria
1. Diagnosis of eating disorders (anorexia nervosa, bulimia nervosa, subclinical anorexia nervosa or bulimia nervosa; binge eating disorder)
2. Fluency in English
3. No visual impairment
4. No cognitive impairment
5. No drugs or alcohol abuse

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
28

Key exclusion criteria
1. No English language fluency
2. Visual impairment
3. Drug or alcohol abuse
4. Cognitive impairment

Date of first enrolment
01/10/2013

Date of final enrolment
01/10/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Basement
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research organisation

Funder Name
Psychiatry Research Trust (UK)

Results and Publications

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?
Results article	results	01/12/2015	11/08/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes