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Imagery based emotion regulation for bipolar disorder

Submission date	Recruitment status	[ ] Prospectively registered
08/10/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/10/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/06/2020	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Bipolar disorder (BD), formerly known as manic depression, is associated with episodes of extreme high and low mood. Relapse rates are high and there is considerable room for improvement in the treatment of BD. People diagnosed with BD tend to suffer from anxiety. Being anxious is linked to people being more likely to have extreme mood swings and to attempt suicide. However, there are no treatments for anxiety for people in this group. Researchers have been working on developing a new treatment for people diagnosed with BD and have discovered that the anxiety they experience is driven by having lots of emotional mental images that keep popping into their minds. On the back of this work, and together with service users diagnosed with BD, a new intervention has been developed called Imagery Based Emotion Regulation. It involves training people in skills to better manage their distressing mental images. An early version of this intervention was adapted based on feedback from those who received it and input from service-user focus groups. Imagery Based Emotion Regulation (IBER) involves up to 12 sessions within 4 months. It has been tested with 14 patients diagnosed with BD and has been found to reduce anxiety and improve mood stability. Patients reported that they found the skills easy to use. A full trial is planned to see whether IBER really works and is value for money. First, a smaller study needs to be conducted to check that a big study would be acceptable to patients and achievable within the planned time limits.

Who can participate?
People aged 18 or over with BD

What does the study involve?
Participants are randomly allocated to be offered IBER or to receive routine NHS care. IBER is delivered over 12 one-hour individual sessions to be completed within 4 months. Sessions are normally weekly, moving to fortnightly at session 8 (allowing flexibility for therapist and patient illness or annual leave). IBER involves training individuals to be able to modify and regulate their emotional reactions to intrusive mental images. Assessments are carried out over 8 months to help to decide if a big trial should be done.

What are the possible benefits and risks of participating?
Many patients have a positive experience of the research assessments conducted within

‘treatment as usual’, and this can provide important information for the NHS clinical team (e.g. previously unnoticed levels of depression and anxiety). Those who are allocated to receive IBER may become anxious as to what is involved. This will be dealt with during the random allocation outcome meeting and the first session of treatment, led by experienced clinicians.

Where is the study run from?
1. Berkshire Healthcare NHS Foundation Trust (UK)
2. Devon Partnership NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2018 to November 2020

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Craig Steel
craig.steel@hmc.ox.ac.uk

Contact information

Type(s)
Scientific

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Prof Craig Steel

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
37141; PB-PG-1216-20009

Study information

Scientific Title
Imagery Based Emotion Regulation (IBER) for bipolar disorder: a feasibility study

Acronym
IBER

Study objectives
The feasibility study will inform the recruitment and timeline of a full trial by establishing the number of participants identified, approached, consented and randomised within a fixed period along with the participant retention rates for followup assessment and completion of intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Berkshire B REC, 02/05/2018, ref: 18/SC/0164

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

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
Bipolar disorder

Interventions
Participants are randomised 1:1 stratified by site to either:
1. Imagery Based Emotion Regulation (IBER)
2. Standard NHS treatment as control

IBER is a structured intervention delivered via 12 one hour individual sessions to be completed within 4 months. Sessions are normally weekly, moving to fortnightly at session 8 (allowing flexibility for therapist and patient illness or annual leave). IBER involves training individuals to

be able to modify and regulate their emotional reactions to intrusive mental images, and is comprised of three stages:

Assessment: The assessment of current coping strategies and, where necessary, the development of a crises management plan. The therapist then assesses the occurrence of intrusive mental images, including how many different images occur, how often and with what emotional impact. A personalised treatment plan is then developed, in which the most significantly distressing images are identified for treatment.

Treatment: Four distinct theoretically informed modules have been developed as outlined below. Each distressing image is treated through training the patient in one or more of the following four techniques and strategies:
1. Imagery Rescripting (IR)
2. Visual Imagery Techniques (VIT)
3. Positive Imagery
4. Competing Tasks

Consolidation: A review of what has been achieved during the intervention, including the participant making a video blueprint for use in the future.

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment measured by number of referrals and number consenting and randomised; Timepoint: Baseline
2. Retention measured by percentage follow-up and questionnaire response rates; Timepoint(s): 4 and 8 months assessment points

Progression to a full trial will be based on the following criteria:
1. No serious negative consequences are associated with trial participation (criterion 1)
2. Any concerns over the feasibility and acceptability of a full trial can be rectified (criterion 2)
3. Overall recruitment at 80% or above within the 12-month recruitment period (criterion 3)
4. 8-month follow up data is obtained from at least 80% of participants (criterion 4)
5. At least 80% of participants allocated to the intervention group do not drop out (i.e. attend at least 50% of the possible sessions) (criterion 5)

Secondary outcome measures
1. Attendance at intervention sessions; Timepoint: 4 months
2. Qualitative interview exploring the personal experiences of involvement in the trial (including both arms); Timepoint: 4 months

Overall study start date
10/09/2018

Completion date
10/11/2020

Eligibility

Key inclusion criteria

1. DSM-V diagnosis of bipolar disorder (I, II or other specified) assessed using the Structured Clinical Interview for DSM-V (SCID)
2. Aged 16 or above; Updated 31/01/2019: Aged 18 or above
3. Score 5 or above on the Generalised Anxiety Disorder Assessment (GAD7)
4. Sufficient understanding of English in order to be able to engage in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Currently within an episode of depression or mania
2. Unable to provide informed consent
3. Acute suicide risk
4. DSM-V diagnosis of substance use disorder, moderate or severe assessed using SCID
5. A change in medication within 3 months prior to randomisation
6. Currently engaged in a psychological intervention

Date of first enrolment
15/09/2018

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Berkshire Healthcare NHS Foundation Trust
Fitzwilliam House
Skimped Hill Lane
Bracknell
United Kingdom
RG12 1BQ

Study participating centre
Devon Partnership NHS Trust
Wonford House
Dryden Rd
Exeter
United Kingdom
EX2 5AF

Sponsor information

Organisation
Berkshire Healthcare NHS Foundation Trust

Sponsor details
Skimped Hill Lane
Bracknell
England
United Kingdom
RG12 1BQ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t542436

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1216-20009

Results and Publications

Publication and dissemination plan
Planned publication of the study results in a peer reviewed journal at approximately end of 2020.

Intention to publish date
01/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Craig Steel (craig.steel@hmc.ox.ac.uk). The data will be mood and health economics questionnaires, and will be available for 5 years from late 2020 onwards. The data will be anonymised and consent will be taken.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/06/2020	19/06/2020	Yes	No
HRA research summary			28/06/2023	No	No