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A web-based Enhanced Relapse Prevention (ERP-online) intervention for bipolar disorder

Submission date
26/03/2013

Recruitment status
No longer recruiting

Registration date
26/03/2013

Overall study status
Completed

Last Edited
26/10/2017

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Individuals with bipolar disorder (BD) typically experience periods of extreme high and low mood (mania and depression). BD is treated with medication, yet many people continue to experience relapses. Enhanced Relapse Prevention (ERP) is a psychological approach developed by members of our research team and found effective in reducing relapse and improving functioning in BD. Limited NHS resources restrict the availability of face-to-face ERP. This study will translate ERP into an interactive web resource (ERP online), which has the potential to increase accessibility. The main purpose of this study is to assess the feasibility and acceptability of ERP online.

Who can participate?
We will ask 125 individuals with BD (who have had 3 relapses in their lifetime, with 1 falling in the past 2 years and access to the internet) to take part.

What does the study involve?
Half of the individuals with bipolar disorder will use ERP online for 12 months alongside current treatment, and we will compare their outcome with the other half, who will receive current treatment only. Individuals that experience crisis may access support services in their usual way via their care team/GP. National crisis support services will also be signposted on ERP online. Outcome measures include observer-rated mood (assessed using telephone interviews at 12 week intervals for a total of 48 weeks) and self-report questionnaires on functioning, quality of life, medication adherence and use of health services (delivered online every 24 weeks for a total of 48 weeks). Twenty participants who have used ERP online will be invited to an interview to provide feedback on whether ERP online is an acceptable intervention they want to use. We may also interview friends or health professionals who participants have chosen to involve in the intervention as a way of understanding their experiences of this process.

What are the possible benefits and risks of participating?
Participants who are allocated to the intervention arm of the trial will receive ERP Online which we hope will be helpful in reducing relapse and improving functioning and quality of life for individuals with bipolar disorder. In addition to this, all participants will have regular appointments with the research team to talk about their own mood experiences. In our

experience of conducting similar research, participants valued sharing their personal experiences. All individuals taking part in this study will be making a valuable contribution to understanding the experiences of bipolar disorder and this knowledge will then be used to help design specific and appropriate treatment interventions for people with bipolar disorder. Participants will be paid £10 in vouchers (Amazon.co.uk) per assessment as a token of appreciation for their time and effort (at the beginning of the study and again at 12, 24, 36 and 48 weeks).
It is possible that talking about personal experiences may cause distress. The researcher will be sensitive to this. Participants will have the opportunity to discuss any concerns at the end of the assessments and will be free to stop the process at any point. Following each assessment appointment the researcher will also offer the opportunity for a follow-up phone call the next day to ensure participants are feeling okay and to check whether there are any issues relating to the research which the participant wishes to discuss.

Where is the study run from?
The project is led by the Spectrum Centre for Mental Health Research at Lancaster University in collaboration with Cumbria Partnership NHS Foundation Trust and the University of Nottingham.

When is the study starting and how long is it expected to run for?
The study started in October 2012 and will be completed by September 2015.

Who is funding the study?
This study is funded by the National Institute for Health Research and a collaboration between Lancaster University, Cumbria Partnership NHS Foundation Trust, and the University of Nottingham.

Who is the main contact?
Adam Sawczuk, ERP Research Assistant
a.sawczuk@lancaster.ac.uk

Study website
http://www.erponline.co.uk/

Contact information

Type(s)
Scientific

Contact name
Prof Fiona Lobban

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13957

Study information

Scientific Title
A pilot study to assess the feasibility of a web-based intervention for prevention of relapse in bipolar disorder (ERP-Online)

Acronym
ERP-online

Study objectives
ERP Online will be feasible, acceptable and effective for individuals with bipolar disorder.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lancaster NHS Research Ethics Committee and Lancaster University Research Ethics Committee, First MREC approval date 14/08/2012, ref: 12/NW/0594

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at http://www.erponline.co.uk/participant_information

Health condition(s) or problem(s) studied

Topic: Mental Health Research Network; Subtopic: Bipolar affective disorder; Disease: Bipolar affective disorder

Interventions
1. ERP Online, Web-based Psychological Intervention
2. Current treatment only

Follow Up Length: 12 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
From 10/10/2017:
Feasibility and acceptability (recruitment, retention, data completion, ERPonline website usage, adverse events, participant feedback).

Prior to 10/10/2017:
Weeks well; Timepoint(s): 12, 24, 36, 48 weeks

Secondary outcome measures
From 10/10/2017:
Estimates of impact on participant outcomes [weeks well (time spent euthymic), relapse, depression, mania, quality of life, functioning, personal recovery) and potential mechanisms of change (medication adherence, illness perceptions, early warning signs monitoring)].

Prior to 10/10/2017:
No secondary outcome measures.

Overall study start date
01/10/2012

Completion date
30/09/2015

Eligibility

Key inclusion criteria
1. Male and female, over 18 years of age
2. Access to a computer and the internet. ERP-online will only be accessible via the internet, so computer and internet access is necessary. However, it is up to individual participants where they wish to access the intervention, so we have not stipulated that they must own a computer, in order to allow those who access computers in public areas or at the homes of friends/family to take part.
3. Meet SCID research diagnostic criteria for bipolar disorder type 1 or 2. ERP in face-to-face form has been evaluated among individuals with this diagnosis, and it was specifically developed to help service users to identify the triggers and early warning signs of mania/depression

(symptoms of bipolar disorder), and how to manage these.
4. Have had 3 relapses in their lifetime, with 1 falling in the preceding 2 years. This is to ensure we have a sample considered high risk for relapse for which this kind of intervention is most appropriate.
5. Unfortunately our budget is not sufficient to cover the costs of a translating the online intervention content and some of the questionnaire measures used in this study are not validated in other languages. For this reason we have made one of our inclusion criteria the ability to understand spoken and written English.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 125; UK Sample Size: 125; Description: The sample size may increase if there is a high rate of attrition.

Key exclusion criteria
1. An organic cause for the disorder
2. Primary diagnosis of alcohol or substance misuse
3. Unable/unwilling to give informed consent
4. In current episode (or in episode within previous 4 weeks) this is because the intervention focuses on the identification and management of early warning signs of relapse and therefore is not intended for those currently in episode who would benefit from a different kind of approach.
5 Currently taking part in another intervention study (or follow-up period). This is to reduce burden of research participation on any one individual and to control for the effects of involvement in another intervention study at the same time.
6. Currently being treated under a section of the mental health act.

Date of first enrolment
12/04/2013

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lancaster University
Lancaster
United Kingdom
LA1 4YG

Sponsor information

Organisation
Lancaster University (UK)

Sponsor details
Clinical Anatomy Learning Centre
Lancaster
England
United Kingdom
LA1 4YT

Sponsor type
University/education

Website
http://www.lancs.ac.uk/

ROR
https://ror.org/04f2nsd36

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0211-10001

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Fiona Lobban, email: f.lobban@lancaster.ac.uk. The type of data available is anonymised quantitative datasets only, as participants gave consent for publication of anonymised data. Any requests will be reviewed by the ERPonline team and independent Trial Steering Committee.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/03/2017		Yes	No