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Bipolar Interactive PsychoEDucation trial

Submission date	Recruitment status	[X] Prospectively registered
21/10/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/11/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/12/2017	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SPON611-08

Study information

Scientific Title
An exploratory (phase II) trial of a novel interactive psychoeducational intervention for bipolar disorder

Acronym
BIPED

Study objectives
The aim of this study is to conduct an exploratory (phase II) trial of a novel interactive psychoeducational intervention for bipolar disorder. The objective of the trial is to assess the efficacy of the intervention in terms of impact on quality of life, levels of psychosocial functioning and experiences of both depressive and manic symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Application submitted to South East Wales Research Ethics Committee on 16/10/2008.

Study design
Single site exploratory randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

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
Bipolar disorder

Interventions
BEATING BIPOLAR is a novel interactive psychoeducational intervention. It involves a blending of different delivery mechanisms, with initial face-to-face delivery to focus on engagement, followed by written and web-based interactive delivery of factual content. The online content requires the reader to be engaged in a number of interactive exercises which maximise long-term retention of the material.

The key areas covered in the package are:
1. The accurate diagnosis of bipolar disorder
2. The causes of bipolar disorder

3. The role of medication
4. The role of lifestyle changes
5. Relapse prevention and early intervention
6. Psychological approaches
7. Gender-specific considerations
8. Advice for family and carers

The eight modules are delivered online on a fortnightly basis over a four-month period. There is an initial face-to-face introductory meeting with participants and each module is discussed within an online discussion forum for participants. This forum will facilitate peer support and will allow us to provide clarification of module content, answer questions from participants and provide on-going support with engagement. The online forum will also be important in terms of assessing the acceptability of the intervention.

The control group will received treatment as usual. The intervention will begin within 2 weeks of randomisation and treatment will last for 4 months. Outcome assessments for this study will occur 6 months after the end of the intervention.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Quality of life, assessed using the World Health Organization Quality of Life Questionnaire (WHOQOL-Bref). Outcome assessments will occur 6 months after the end of the intervention.

Secondary outcome measures
1. Global Assessment of Functioning (GAF) scores
2. Functioning Assessment Short Test (FAST) scores
3. Schedule of Assessment of Insight (SAI) scores
4. Current depressive symptoms according to the Montgomery-Asberg Depression Rating Scale (MADRS) and current manic symptoms according to the Young Mania Rating Scale (YMRS) scale
5. All participants will be re-assessed using the Mini International Neuropsychiatric Interview (MINI) applied to the 6 month follow-up period in order to obtain information about the number and severity of depressive and manic symptoms and number of episodes of depression and mania or hypomania experienced during this follow-up period
6. Cost-effectiveness analysis of the intervention

Outcome assessments will occur 6 months after the end of the intervention.

Overall study start date
01/04/2009

Completion date
31/03/2011

Eligibility

Key inclusion criteria

1. Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) criteria of bipolar disorder (including type I and type II)
2. Male and female
3. Aged between 18 - 65 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
Inability to engage fully in the psychoeducational programme (for example, because of cognitive impairment or not having English language of sufficient ability).

Date of first enrolment
01/04/2009

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Department of Psychological Medicine
Cardiff
United Kingdom
CF14 4DW

Sponsor information

Organisation
Cardiff University (UK)

Sponsor details
c/o Dr Kathryn Pittard Davies
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Sponsor type
University/education

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

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) (UK) - postdoctoral fellowship funded by the Welsh Assembly Govenment (ref: CRES4050)

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?

Protocol article	protocol	12/08/2009	Yes	No
Results article	results of exploratory trial	01/08/2011	Yes	No
Results article	results	08/07/2015	Yes	No