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Living With Bipolar: a web-based self management intervention

Submission date
12/08/2011

Recruitment status
No longer recruiting

Registration date
12/09/2011

Overall study status
Completed

Last Edited
19/01/2018

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
Bipolar disorder is a condition that affects your moods, which can swing from one extreme to another. Medication is the main treatment offered but its effectiveness is limited and there is increasing evidence that people with bipolar disorder respond well to psychological therapy. The aim of this study is to test a website that helps patients to manage their bipolar disorder.

Who can participate?
Patients aged over 18 with bipolar disorder.

What does the study involve?
Participants are randomly allocated to one of two groups. One group uses the 'Living with Bipolar' website while the other group receives normal treatment and is given access to the website at the end of the study. Participants in both groups complete questionnaires about their quality of life, mood symptoms, coping, recovery and illness beliefs.

What are the possible benefits and risks of participating?
The results of this study will be used to develop a larger study to test the use of the website within the National Health Service (NHS).

Where is the study run from?
Lancaster University (UK).

When is the study starting and how long is it expected to run for?
September 2011 to February 2012.

Who is funding the study?
Mersey Care NHS Trust (UK).

Who is the main contact?
Nicholas Todd
n.todd@lancaster.ac.uk

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

Contact information

Type(s)
Scientific

Contact name
Mr Nicholas Todd

Contact details
Spectrum Centre for Mental Health Research
Division of Health Research
Faculty of Health and Medicine
Lancaster University
Lancaster
United Kingdom
LA1 4YT
+44 (0)152 459 2768
n.todd@lancaster.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
An online randomised controlled trial to assess the feasibility, acceptability and potential effectiveness of "Living With Bipolar": a web-based self-management intervention for bipolar disorder

Acronym
LWB

Study objectives
The aims of this study are to assess the feasibility, acceptability and potential effectiveness of the 'Living with Bipolar' intervention, a new recovery informed web-based self-management intervention for Bipolar Disorder.

The specific objectives are to:
1. Assess whether it is feasible to deliver a web-based intervention for individuals with a

diagnosis of Bipolar Disorder
2. Assess whether the LWB intervention is acceptable to individuals with a diagnosis of Bipolar Disorder
3. Assess whether the LWB intervention is effective on psychological outcome
4. Pilot methods for a larger scale (Phase III) randomised controlled trial (e.g. recruitment, randomisation, follow-up, suitability of measures)

Ethics approval required
Old ethics approval format

Ethics approval(s)
School of Health & Medicine Ethics Committee at Lancaster University, 06/07/2011, ref: SHMREC1000005

Study design
Phase II randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
http://www.livingwithbipolar.co.uk/rct.php

Health condition(s) or problem(s) studied
Bipolar Affective Disorder

Interventions
Group 1 : Waiting list control group - participants receive normal treatment and are given access to the intervention at the end of the trial

Group 2 : The 'Living with Bipolar' intervention aims to support individuals with a diagnosis of Bipolar Disorder to:

1. Learn more about themselves, their condition and how it is affecting their lives
2. Increase their self-esteem and self-efficacy to self-manage their condition and pursue personally meaningful recovery goals
3. Learn self-management techniques to effectively manage their condition and
4. Learn practical and interpersonal skills to live a fulfilling life alongside their condition

After an extensive development phase involving a systematic review of the literature and a period service user consultancy, 10 comprehensive modules were developed. The core content of the modules is presented as an audio-visual slide show presentation with voice narration.

Worksheets to enhance learning and make the content personal can be downloaded and printed out. Participants can also interact directly with the material by completing online quizzes, monitoring their mood and recording goals for the future. The modules are delivered distance-based with minimal external support. To maintain participation there are two means of external support: Motivational emails prompts and an online peer support forum for you to talk to other people using the intervention about the content.

The 'Living with Bipolar' modules:
1. Recovery & Me - The process of recovery, fostering the development of self-esteem and self-efficacy
2. Bipolar & Me - The characteristics and course of Bipolar Disorder
3. Self-Management & Me - Introduction to the philosophy of self-management
4. Medication & Me - Medication, the myths, facts and managing a regime
5. Getting to know you - Exploring the individual experience of mood swings including life charting
6. Staying well with Bipolar - Self-management techniques to maintain wellness including lifestyle and early warning signs
7. Depressive Relapse & Me - Self-management techniques to manage depressive relapse
8. Hypo/Manic Relapse & Me - Self-management techniques to manage hypo/manic relapse
9. Talking about my diagnosis - Talking to family, friends, employers and services
10. Crisis & Me - Developing a crisis plan and using advance directives

Intervention Type
Other

Phase
Phase II

Primary outcome measure
1. The primary aims of this trial are to assess the feasibility and acceptability of the LWB intervention
1.1. Feasibility will be assessed quantitatively by analysing recruitment rates and retention rates and qualitatively through the research team's experience, considering the practicalities and barriers of delivery
1.2. Acceptability will be assessed quantitatively by analysing website usage statistics including patterns and frequency of use and a specifically designed user satisfaction scale, and qualitatively in a series of in-depth qualitative interviews
2. The secondary aim is to assess the potential effectiveness of the intervention on psychological outcome
2.1. The Quality of Life in Bipolar Disorder scale (Brief version) (QOL.BD-Brief)
2.2. The World health Organisation Quality of Life assessment tool, brief version (WHOQOL-BREF)

Measured at 3 months (half way through trial) and 6 months (trial end)

Secondary outcome measures
1. Internal State Scale (Bauer et al., 1991)
2. Social Adaption Self-evaluation Scale (SASS) (Bosc et al., 1997)
3. Bipolar Recovery Questionnaire (Jones, In Preparation)
4. The Brief Illness perception questionnaire (BIPQ) adapted for Bipolar Disorder (Broadbent et al., 2006)

5. The Self Efficacy for Managing Chronic Disease Scale, Brief Version (Lorig et al., 2001)
6. The Hayward Stigma and Self Esteem Questionnaire (Hayward et al., 2002)
7. Hypomanic Interpretations Questionnaire (HIQ-10) (Jones et al., 2006)
8. Interpretations of Depression Questionnaire (IDQ-10) (Jones & Day, 2008)
9. Coping Inventory for Prodromes of Mania (Wong & Lam, 1999)
10. Response Styles to Depression Questionnaire (Nolen-Hoeksema & Morrow, 1991)
11. Stephenson Medication Adherence Interview (Stephenson et al., 1993) adapted for use as a self-report instrument

Measured at 3 months (half way through trial) and 6 months (trial end)

Overall study start date
01/09/2011

Completion date
29/02/2012

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Living in the United Kingdom
3. Have a diagnosis of Bipolar Disorder (type I or type II) by a mental health professional and meet criteria on the Mood Disorders Questionnaire (MDQ)
4. Must be able to understand written English and have access to the internet a printer and an email account

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. They are aged under 18 years
2. They are living outside the United Kingdom
3. They don't have a health professional diagnosis of Bipolar Disorder and don't meet criteria on the Mood Disorders Questionnaire (MDQ)
4. They can't understand written English and don't have access to the internet, a printer or an email account

Date of first enrolment
01/09/2011

Date of final enrolment
29/02/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lancaster University
Lancaster
United Kingdom
LA1 4YT

Sponsor information

Organisation
Lancaster University (UK)

Sponsor details
c/o Director of Research & Enterprise Services
Research and Enterprise Services
University House
Lancaster
England
United Kingdom
LA1 4YW

Sponsor type
University/education

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

ROR
https://ror.org/04f2nsd36

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Mersey Care NHS Trust (UK)

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?
Results article	results	01/12/2014		Yes	No