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Bipolar disorder adherence project

Submission date	Recruitment status	[X] Prospectively registered
27/01/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/02/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/09/2020	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
People with bipolar disorder will have periods of depression, during which they will feel very low and lethargic, and mania, during which they will feel very high and overactive. Biodose Connect™ is a medicines adherence service that can be used to provide medications for patients with bipolar disorder and co-medications for other medical conditions. The aim in this study is to offer patients with bipolar disorder, who have or have had issues with medication adherence, medication adherence support with web-based psychoeducation module on relapse prevention and Biodose Connect™.

Who can participate?
Adults with bipolar disorder

What does the study involve?
The community pharmacist will dispense the patient's medication into the Biodose Connect™ system and the tray will be delivered to the patient's chosen location. The community psychiatric nurse (CPN) will assign the psychoeducation module to the patient. A link will be sent by email to the patient with details of how to access the module. The patient will complete the online interactive module and take their medication as instructed. The Biodose Connect™ system will trigger a short message service text reminder to the patient if they have not taken their medication in the timeframe. It will also alert the CPN that the patient has not taken his or her medication. At the study endpoint, the patient and patient's CPN will be required to complete an assessment to evaluate the programme.

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration.

Where is the study run from?
White Abbey Hospital (UK)

When is the study starting and how long is it expected to run for?
From January 2015 to July 2015

Who is funding the study?
Small Business Research Initiative (UK)

Who is the main contact?
Miss Ayse Ibrahim

Contact information

Type(s)
Public

Contact name
Miss Ayse Ibrahim

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Contact details
Mednet
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United Kingdom
LS6 2AL

Additional identifiers

EudraCT/CTIS number

IRAS number
177031

ClinicalTrials.gov number

Secondary identifying numbers
319169, IRAS 177031

Study information

Scientific Title
Supporting medicines adherence in bipolar disorder through the use of psychoeducation and Biodose Connect™

Study objectives
To demonstrate the value of an adherence support programme through satisfaction and clinical utility scores from patients and health-care professionals

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/04/2015, Yorkshire & The Humber - Leeds West Research Ethics Committee, REC ref: 15/YH/0118

Study design
Open-label single-centre pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Bipolar disorder, currently in remission

Interventions
1. Support will be provided as a medication internet-based psychoeducation module on relapse prevention and Biodose Connect™, which is an advanced medication and adherence management system using state-of-the-art technologies.
2. The patient will complete an education module on relapse prevention, designed to increase their knowledge of their disorder and enable them to create their own individual profile to recognise early signs and triggers of a relapse.
3. The patient's medication will be given in the Biodose Connect™ system and the patient will receive reminder texts if medication is not taken in the allocated timeframe.

Intervention Type
Mixed

Primary outcome measure
Patient and health-care professional satisfaction scores will be captured with a satisfaction survey including rating scales and net promoter score at the end of the study (3 months after the start of study).

Secondary outcome measures
Changes in adherence scores from study baseline to end of the study (3 months after the start of study) will be measured with an adherence assessment tool, which includes the Medication Adherence Rating Scale score and the Clinical Global Impression score.

Overall study start date
05/01/2015

Completion date
05/07/2015

Eligibility

Key inclusion criteria
1. International Statistical Classification of Diseases and Related Health Problems diagnosis: F31.7 bipolar disorder, currently in remission
2. Taking medication for bipolar disorder
3. Will be treated by Northern Health and Social Care Trust (UK)
4. Medication Adherence Rating Scale score of 6 or less
5. Clinical Global Impression score of 3 or less (mildly ill)
6. Home access to the internet via a laptop or desktop computer
7. Informed consent and registration forms
8. Co-medications and liquid medications can be administered via Biodose Connect™
9. Age 18–64 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10 to 12

Key exclusion criteria
1. Significant cognitive impairment
2. Taking medication that is identified by the Medicines and Healthcare Products Regulatory Agency (UK) as not suitable for blister/biodose packaging
3. Poor communication and/or reading skills

Date of first enrolment
16/03/2015

Date of final enrolment
06/06/2015

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre

White Abbey Hospital
Oakview House
Doagh Road
Newtownabbey
County Antrim
United Kingdom
BT37 9RH

Sponsor information

Organisation
Mednet Consult Ltd

Sponsor details
40 Otley Road
Leeds
United Kingdom
LS6 2AL

Sponsor type
Other

Funder(s)

Funder type
Government

Funder Name
Small Business Research Initiative (UK)

Results and Publications

Publication and dissemination plan
A report will be produced for internal use. It will also be submitted to the Small Businesss Research Initiative (UK). The report will be used to assess the feasibility of the study and whether to provide further funding for phase 2.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No