

Bipolar disorder adherence project

Submission date 27/01/2015	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 10/02/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 02/09/2020	Condition category Mental and Behavioural Disorders	☐ Individual participant data ☐ 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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Mednet
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Additional identifiers

Integrated Research Application System (IRAS)
177031

Protocol serial number
319169

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

Primary study design
Interventional

Study design

Open-label single-centre pilot study

Study type(s)

Prevention

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(s)

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).

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

Northern Ireland

Study participating centre

White Abbey Hospital

Oakview House

Doagh Road

Newtownabbey

County Antrim

United Kingdom

BT37 9RH

Sponsor information

Organisation

Funder(s)

Funder type

Government

Funder Name

Small Business Research Initiative (UK)

Results and Publications

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