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# Bipolar disorder adherence project

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

## Plain English Summary

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

### ORCID ID
http://orcid.org/0000-0002-1610-626X

### Contact details
Mednet
40 Otley Road
Leeds
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 hypothesis
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

### Condition
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

### Overall study end date
05/07/2015

## Eligibility

### Participant 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

### Participant 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

### Recruitment start date
16/03/2015

### Recruitment end date
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
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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 |