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Cognition, mood and sleep in people diagnosed with borderline personality disorder

Submission date
04/02/2025

Recruitment status
Recruiting

Registration date
06/02/2025

Overall study status
Ongoing

Last Edited
26/02/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Borderline personality disorder (BPD) is a common mental health diagnosis characterised by affective instability, interpersonal difficulties and behavioural dysregulation. Assessment of symptoms and treatment outcomes are highly reliant on self-reported symptoms and objective measures are lacking. There has been increasing interest in the use of digital devices to better objectively quantify the lived experience of those diagnosed with mental disorders.
This study uses portable digital technologies to assess cognition, brain activity, mood and sleep in individuals who have been diagnosed with BPD and those with no mental health disorder.
The primary aim of the study is to explore the tolerability and utility of the Cumulus platform which integrates measurements of brain activity using at-home wearable electroencephalography (EEG), alongside simultaneous assessment of cognition on a computer-based tablet. We will use this in combination with actigraphy watches to capture levels of physical activity, sleep patterns and light exposure, and online questionnaires to capture changes in mood.
The secondary aim of the study is to assess whether these technologies can detect variability in symptoms across time within individuals, and if there are any differences in observable characteristics between individuals diagnosed with BPD and non-affected individuals.

Who can participate?
Participants who have been diagnosed with BPD and non-affected healthy volunteers, between 18-35 years old and any gender

What does the study involve?
Eligible participants will be invited to a 2-hour in-person screening and baseline visit to undergo informed consent, clinical interview, provide demographic information and complete validated self-report questionnaires of symptoms and sleep behaviours. They will be trained in how to use the devices and take them home.
For 7 weeks, participants will be asked to complete assessments at home at regular intervals. For the first week (days 1-7) participants will be asked to use the Cumulus platform on at least two occasions, to record their brain activity at rest and during cognitive tasks (approx. 30 minutes each time). They will also be asked to complete self-report mood questionnaires once a day, and wear the actigraphy watch at all times.

On days 8-17, participants will undergo a 'high-intensity phase' and use the Cumulus platform in a repeating cycle of two consecutive days of data collection,
followed by a rest (7 times in total). They will be asked to complete self-report mood questionnaires twice a day, and wear the actigraphy watch at all times.
On days 18-38, participants will undergo a 'low-intensity phase' and use the Cumulus platform once a week (3 times in total). They will be asked to complete self-report mood questionnaires twice a day, and wear the actigraphy watch at all times.
On days 39-48, participants will again be asked to repeat the 'high-intensity phase'.
On day 49, after 7-weeks, participants will be invited for a final 1 hour in-person visit to return the devices and complete a feedback interview.

What are the possible benefits and risks of participating?
There are no direct benefits of participating in the study. Previous studies in this population have shown that most people find satisfaction in being involved in research, with a sense of empowerment, as well as the shared value of the increase in knowledge into the disorders that affect them.
It is possible that taking part in this study may lead participants thinking about their brain health more than they would normally do. If they have any concerns about their brain health, participants can speak with the psychiatrist in the study, or they will be advised to contact their GP. The Cumulus EEG headset has a UKCA mark (Class I medical device) and is registered with the Medicines and Healthcare products Regulatory Agency (MHRA). The device has undergone extensive risk assessment by Cumulus Neuroscience. The EEG headsets are non-invasive, low-voltage, dermatologically safe devices.

Where is the study run from?
Warneford Hospital (UK)

Who is funding the study?
The study is organised by the University of Oxford and funded by Boehringer Ingelheim. It is a three-way academic collaboration between Oxford University, Boehringer Ingelheim and Cumulus Neuroscience Ltd.

Who is the main contact?
cumulusbpd@psych.ox.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
345175

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 345175

Study information

Scientific Title
A prospective longitudinal observational study of cognition, mood and sleep in people diagnosed with borderline personality disorder

Acronym
CUMULUS BPD

Study objectives
This study aims to explore the tolerability and utility of a portable EEG headset (Cumulus platform) in combination with actigraphy watches and online mood questionnaires over a period of 7 weeks in order to quantify mood, cognition, brain activity and circadian patterns in a group of people diagnosed with Borderline Personality Disorder and a comparison group with no diagnosed disorder.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/12/2024, Yorkshire & The Humber - Sheffield Research Ethics Committee (NHS Blood and Transplant Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; N/A; sheffield.rec@hra.nhs.uk), ref: 24/YH/0281

Study design
Single-centre prospective longitudinal observational case-control study

Primary study design
Observational

Secondary study design

Case-control study

Study setting(s)
Home, Hospital, University/medical school/dental school, Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Borderline personality disorder

Interventions
Visit 1 - Screening visit (in person, ~2-3 hours):
Participants will be invited to the NIHR Oxford Health Clinical Research Facility (CRF) at the Warneford Hospital in Oxford for their baseline screening assessment. They will provide written informed consent and be screened by trained members of the research team using the SCID for DSM5 to confirm diagnoses. They will provide basic demographic and clinical information, and complete several self-report and researcher-administered screening tools to assess language ability and symptoms of personality disorder, impulsivity and insomnia. These will include the National Adult Reading Test (NART), Standardised Assessment of Personality – Abbreviated Scale (SAPAS), Difficulties in Emotional Regulation Scale (DERS), Barratt Impulsiveness Scale (BIS), and the Sleep Condition Indicator (SCI). Participants will then be set up and shown how to use the portable EEG headset (Cumulus platform) and actigraphy device, and how to respond to online mood questionnaires. They will take all devices home, to complete remote data collection for 7 weeks.

Orientation week (remote – study days 1-7):
During the first week of the study, participants will be asked to use the Cumulus platform on at least two occasions, at home. This will involve resting state EEG with their eyes open and eyes closed, and also whilst they perform simple cognitive tasks. This takes approximately 30 minutes to complete each time. Participants will also be asked to wear the actigraphy watch and respond to twice daily self-report measures of mood via an online questionnaire.

High-intensity phase 1 (remote – study days 8-17):
Participants will be asked to complete resting state EEG and cognitive tasks on the Cumulus platform in a repeating cycle of two consecutive days of data collection, followed by a rest (seven times in total). They will be asked to wear the actigraphy watch at all times and complete self-report measures of mood twice a day.

Low-intensity phase (remote – study days 18-38):
Participants will be asked to complete cognitive tasks and resting state EEG on the Cumulus platform once a week (three times in total). They will be asked to wear the actigraphy watch at all times and complete self-report measures of mood twice a day.

High-intensity phase 2 (remote – study days 39-48):
Participants will again be asked to complete cognitive tasks and resting state EEG on the Cumulus platform in a repeating cycle of two consecutive days of data collection, followed by a

rest (seven times in total). They will be asked to wear the actigraphy watch at all times and complete self-report measures of mood twice a day.

Visit 2 – Final visit (in-person, ~1.5 hours):
The final visit will take place in person on day 49 or within 2 weeks of this date. Participants will be asked to complete one last data collection on the Cumulus platform in-clinic and brief online questionnaires about their use of the Cumulus platform. They will then cease data collection and return all of the devices. Participants will undergo a brief, semi-structured feedback interview about their experience in the study and the devices used.

Intervention Type
Other

Primary outcome measure
1. Engagement with the Cumulus platform quantitively measured by the number of EEG test sessions completed on the Cumulus platform over the 7-week study period and qualitatively assessed via themes emerging from the post-study semistructured interviews
2. Engagement with the actigraphy watch quantitively measured by the total recorded actigraphy watch wear time over the 7-week study period and qualitatively assessed via themes emerging from the post-study semi-structured interviews
3. Engagement with online mood questionnaires quantitively measured by the number of mood prompts responded to over the 7-week study period and qualitatively assessed via themes emerging from the post-study semistructured interviews

Secondary outcome measures
1. Mood instability measured using time-adjusted root mean square of successive differences (RMSSD) in self-reported mood measures across the 7-week study period
2. Cognitive Function measured using mean performance indicators, and change over time, on the Digit Symbol Substitution test (DSST) and Flanker error-related negativity (FERN) task completed multiple times per week over the 7-week study period
3. Brain activity summary measures recorded using portable EEG multiple times per week over the 7-week study period

Overall study start date
25/07/2024

Completion date
05/01/2027

Eligibility

Key inclusion criteria
1.Participants belonging to one of the following groups:
1.1. Individuals with a confirmed diagnosis of borderline personality disorder
1.2. Individuals with no psychiatric diagnosis (healthy control group only)
2. Aged 18-35 years
3. Of any gender
4. Willing and able to give informed consent
5. Sufficient grasp of the English language to permit meaningful explanation of study

procedures and cognitive testing
6. Willing and able to engage with study procedures
7. Access to WiFi at home

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Admission to a psychiatric hospital or contact with crisis services in the 2 months prior to study entry
2. Past confirmed diagnosis of psychosis, schizophrenia or bipolar disorder
3. No past diagnosis of borderline personality disorder (healthy control group only)
4. Judged to be at significant immediate risk of suicide/self-harm
5. Clinically significant drug or alcohol misuse
6. Regular use of benzodiazepine or hypnotic drugs
7. Any other medications or health conditions which may significantly impact the data collected (e.g. epilepsy, past traumatic brain injury, high dose steroids)
8. Current participation in a research study involving an investigational medicinal product
9. Employed in shift work that may require changes to sleeping/activity patterns outside of a participant's usual routine

Date of first enrolment
11/02/2025

Date of final enrolment
17/11/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Department of Psychiatry
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Study participating centre
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
Boehringer Ingelheim

Alternative Name(s)
Boehringer Ingelheim International GmbH

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Publication and dissemination plan
The results of this research may be written up for publication in peer-reviewed scientific journals, press releases, for company websites and reports, presented at scientific meetings, or in talks at academic/commercial institutions. The published reports will not identify anyone who took part in the study.

Intention to publish date
20/01/2028

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the Principal Investigator (Prof. Kate Saunders, kate.saunders@psych.ox.ac.uk). Participants provided their informed consent for sharing their anonymised data only. Any data agreed to be shared will be done so securely and with a data sharing agreement.

IPD sharing plan summary
Available on request