ISRCTN16864220 https://doi.org/10.1186/ISRCTN16864220

Quetiapine effectiveness study in borderline personality disorder (QUEST)

Submission date
05/03/2025

Recruitment status
Recruiting

Registration date
20/05/2025

Overall study status
Ongoing

Last Edited
21/01/2026

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) describes a collection of problems including negative feelings about self, fears of being let down, an acute sense of abandonment and rapid, distressing changes in mood. People with BPD find it difficult to maintain relationships, have high levels of mental health problems like depression and drug misuse, and high rates of self-harm and suicide. There are currently no drugs licensed for the treatment of BPD and clinicians are often unsure how best to help people with BPD.

Quetiapine is the most widely prescribed antipsychotic medication for BPD in the UK despite limited evidence that it works. There is only one published trial of quetiapine for BPD treatment which found that quetiapine was more effective than a 'dummy tablet' (placebo) in improving symptoms of BPD. However, the trial was short with a small number of participants so a longer and larger trial of quetiapine is required to see if these promising results can be repeated. It would be a very important finding and provide evidence for use of quetiapine to treat BPD. If the result does not provide evidence of the benefits of quetiapine, then clinicians would review whether treatment with quetiapine should be continued.

Who can participate?
We will recruit people in contact with mental health services in the NHS in regions in England that are under-represented in mental health research.

What does the study involve?
In this trial, people with BPD will be allocated, by chance, to receive either placebo or quetiapine for 12-months alongside their usual treatment. We will also examine any changes in cost that result from prescribing this drug and whether any changes in costs are worthwhile in terms of improvements in outcomes.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
March 2025 to October 2028

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
questtrial@liverpool.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
Ms Nadia Ismail

Contact details
Liverpool Clinical Trials Centre, Block C, Waterhouse Building, 1-5 Brownlow Street
Liverpool
United Kingdom
L69 3GL
-
questtrial@liverpool.ac.uk

Type(s)
Principal investigator

Contact name
Dr Inti Qurashi

Contact details
Parkbourn
Liverpool
United Kingdom
L31 1HW
+44 151 472 4045
inti.qurashi@merseycare.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1010899

Protocol serial number
UoL00181894

Study information

Scientific Title
The clinical and cost effectiveness of quetiapine for people with borderline personality disorder: A pragmatic, double-blind, placebo-controlled, randomised trial

Acronym
QUEST

Study objectives
Primary objective:
To test whether adding quetiapine to treatment as usual, in comparison to placebo and treatment as usual, improves the mental health of people with borderline personality disorder

Secondary objectives:
1. To examine whether the addition of quetiapine improves social and occupational functioning, quality of life and reduces the incidence of suicidal behaviour in comparison to placebo and TAU
2. To compare the levels of adherence and the incidence of side-effects, including change in weight, amongst those prescribed quetiapine and those prescribed placebo.

Economic Objective:
To examine the cost, cost-effectiveness and cost-utility of adding quetiapine to TAU for adults with BPD in comparison to placebo and TAU.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/05/2025, West Midlands - Edgbaston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048137; edgbaston.rec@hra.nhs.uk), ref: 25/WM/0052

Study design
Interventional double blind randomized parallel group placebo controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Safety

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

Interventions
Participants will be randomised (ratio 1:1) via a secure, 24-hour, web-based randomisation system controlled centrally by the LCTC to receive either quetiapine or matched placebo.
Route of administration: oral
IMP: Quetiapine prolonged release tablets (overencapsulated) in 50mg and 150mg.
Dose: 150mg daily. Participants will be up titrated to this regime as follows: Week 1 – 50mg

daily, Week 2- 100mg daily, Week 3 and onwards: 150mg daily
Higher or lower doses will be permitted according to clinical response and tolerability (minimum dose of 50mg daily and maximum dose of 750mg daily)
Placebo: Overencapsulated capsules filled with lactose to match IMP, in 50mg and 150mg.
Dose: Same as IMP
Trial treatment duration is 12 months

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Quetiapine fumarate

Primary outcome(s)
1. Symptoms of BPD at 12 months using the total score on the ZAN BPD from baseline to 12 months

Key secondary outcome(s))
1. Standardised Assessment of Personality Abbreviated Scale at 12 months using SAPAS at baseline and 12 months
2. Total score on the ZAN-BPD over 12 months measured at baseline, 3, 6, 9 and 12 months
3. Total score on the 21 item Beck Depression Inventory at baseline, 3, 6 and 12 months.
4. Mood Instability using the Affective Lability Scale – Short Form at baseline, 3, 6 and 12 months
5. Incidence and severity of suicidal behaviour and self-harm using the Deliberate Self-Harm Inventory at baseline, 6 and 12 months
6. Self-Reported Version of ZAN BPD at baseline, 3, 6, 9 and 12 months
7. Social functioning measured via the Work and Social Adjustment Scale (WSAS) at baseline, 6 and 12 months
8. Health-related quality of life measured using EuroQoL-5D-5L at baseline, 6 and 12 months
9. Side effects using the Antipsychotic Non-Neurological Side Effects Scale (ANNSERS) at baseline, 3, 6, 9 and 12 months
10. Medication adherence using the Brief Adherence Rating Scale (BARS) at 3, 6, 9 and 12 months
11. Use of alcohol and other drugs via ASSIST-Lite at baseline, 6 and 12 months
12. Body Weight in Kg at baseline and 12 months
13. Serious adverse events up to 12 months
14. Use of rescue medication at 6 and 12 months
15. Sleep Disturbance using PROMIS Sleep Disturbance -Short Form at baseline, 3, 6, 9 and 12 months
16. Use of health and social services using the ADSUS at baseline, 6 and 12 months

Completion date
31/10/2028

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 03/10/2025:
1. Aged ≥18 years

2. Able to provide written and informed consent and agreement to comply with the requirements of the trial
3. In contact with secondary care mental health services
4. Contraception is to be used for the duration of the trial
5. Meet diagnostic criteria for borderline personality disorder using the Structured Clinical Interview for DSM-V Personality Disorders (SCID-5)
6. A ZAN-BPD total score of ≥9 at the time of randomisation
7. Ability to speak and read English

Previous key inclusion criteria:
1. Aged ≥18 years
2. Able to provide written and informed consent and agreement to comply with the requirements of the trial.
3. In contact with secondary care mental health services.
4. Meet diagnostic criteria for borderline personality disorder using the Structured Clinical Interview for DSM-V Personality Disorders (SCID 5).
5. A ZAN-BPD total score of ≥9 at the time of randomisation.
6. Ability to speak and read English
7. Able to swallow IMP whole

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 21/01/2026:
1. Prescribed an antipsychotic medication (oral or intramuscular) within two weeks of baseline assessments
2. Have a current clinical diagnosis of schizophrenia, bipolar I or bipolar II disorder
3. Pregnant, trying to conceive and/or breastfeeding
4. Women of childbearing potential who are unable or unwilling to use a highly effective method of contraception for the duration of the trial
5. Known hypersensitivity to quetiapine or to any of the excipients of the XL formulation
6. Concomitant administration of erythromycin, clarithromycin or nefazodone within 14 days

7. Concomitant administration of cytochrome P450 3A4 inhibitors, such as anti-fungal medicines: (itraconazole, ketoconazole, voriconazole, posaconazole); medicines used to treat cancer: idelalisib, tucatinib, ceritinib; medicines used to treat HIV: atazanavir, cobicistat, darunavir, fosamprenavir, lopinavir, ritonavir, saquinavir, tipranavir
8. History of QTc prolongation, including congenital long QT syndrome, severe neutropenia, agranulocytosis, history of cardiovascular disease (angina, stroke, myocardial infarction, arrythmia, congestive cardiac failure, heart hypertrophy)
9. Unable/refusal to undertake blood tests
10. Clinically significant findings that, in the opinion of the investigator, are contraindicated for inclusion in the study
11. Unable to swallow IMP whole
12. Individuals who are being investigated for or have a confirmed diagnosis of dementia (any kind)

Previous exclusion criteria as of 03/10/2025:
1. Prescribed an antipsychotic medication within 2 weeks of baseline assessments
2. Have a current clinical diagnosis of schizophrenia, bipolar I or bipolar II disorder
3. Pregnant, trying to conceive and/or breastfeeding
4. Women of childbearing potential who are unable or unwilling to use a highly effective method of contraception for the duration of the trial
5. Known hypersensitivity to quetiapine or to any of the excipients of the XL formulation
6. Concomitant administration of erythromycin, clarithromycin or nefazodone within 14 days
7. Concomitant administration of cytochrome P450 3A4 inhibitors, such as anti-fungal medicines: (itraconazole, ketoconazole, voriconazole, posaconazole); medicines used to treat cancer: idelalisib, tucatinib, ceritinib; medicines used to treat HIV: atazanavir, cobicistat, darunavir, fosamprenavir, lopinavir, ritonavir, saquinavir, tipranavir
8. History of QTc prolongation, severe neutropenia, agranulocytosis, history of cardiovascular disease (angina, stroke, myocardial infarction, arrhythmia, congestive cardiac failure)
9. Unable/refusal to undertake blood tests
10. Clinically significant findings that, in the opinion of the investigator, are contraindicated for inclusion in the study
11. Unable to swallow IMP whole

Previous key exclusion criteria:
1. Prescribed an antipsychotic medication within 2 weeks of baseline assessments.
2. Have a current clinical diagnosis of schizophrenia, bipolar I or bipolar II disorder.
3. Pregnant, trying to conceive and/or breastfeeding.
4. Women of childbearing potential who are unable or unwilling to use a highly effective method of contraception for the duration of the trial.
5. Known hypersensitivity to quetiapine or to any of the excipients of the XL formulation.
6. Concomitant administration of erythromycin, clarithromycin or nefazodone within 14 days.
7. Concomitant administration of cytochrome P450 3A4 inhibitors, such as anti-fungal medicines: (itraconozole, ketoconazole, voriconazole, posaconazole); medicines used to treat cancer: idelalisib, tucatinib, ceritinib; medicines used to treat HIV; atazanavir, cobicistat, darunavir, fosamprenavir, lopinavir, ritonavir, saquinavir, tipanavir.
8. History of QTc prolongation, severe neutropenia, agranulocytosis, history of cardiovascular disease (angina, stroke, myocardial infarction, arrhythmia, congestive cardiac failure)

Date of first enrolment
09/02/2026

Date of final enrolment

31/07/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Mersey Care NHS Foundation Trust
V7 Building
Kings Business Park
Kings Drive
Prescot
England
L34 1PJ

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trust
Elizabeth House,
Fulbourn Hospital
Fulbourn
Cambridge
England
CB21 5EF

Study participating centre
Birmingham and Solihull Mental Health NHS Foundation Trust
The Uffculme Centre
52 Queensbridge Road
Moseley
Birmingham
England
B13 8QY

Study participating centre
Fulbourn Hospital
Cambridge Road
Fulbourn
Cambridge
England
CB21 5EF

Study participating centre
Vale House Mental Health Resource Centre
High St
Winsford
England
CW7 2AS

Study participating centre
Rowan View
Maghull Health Park
Liverpool
England
L31 1HW

Study participating centre
Phoenix Service
The Barberry
25 Vincent Drive
Birmingham
England
B15 2FG

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date