

# Quetiapine effectiveness study in borderline personality disorder (QUEST)

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/05/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 21/01/2026	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

**ClinicalTrials.gov (NCT)**  
Nil known

## 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  $\geq 18$  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  $\geq 9$  at the time of randomisation
7. Ability to speak and read English

Previous key inclusion criteria:

1. Aged  $\geq 18$  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  $\geq 9$  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, arrhythmia, 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)

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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:

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5. Known hypersensitivity to quetiapine or to any of the excipients of the XL formulation.
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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)

**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