

Quetiapine effectiveness study in borderline personality disorder (QUEST)

Submission date 05/03/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/05/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/05/2025	Condition category 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1010899

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

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

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Safety, Efficacy

Participant information sheet

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

Pharmaceutical study type(s)

Pharmacoeconomic, Therapy

Phase

Phase III

Drug/device/biological/vaccine name(s)

Quetiapine fumarate

Primary outcome measure

1. Symptoms of BPD at 12 months using the total score on the ZAN BPD from baseline to 12 months

Secondary outcome measures

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

Overall study start date

03/03/2025

Completion date

31/10/2028

Eligibility

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

270

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: (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

31/05/2025

Date of final enrolment

31/07/2027

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Mersey Care NHS Foundation Trust

V7 Building

Kings Business Park

Kings Drive

Prescot

United Kingdom

L34 1PJ

Study participating centre

Cambridgeshire and Peterborough NHS Foundation Trust

Elizabeth House,

Fulbourn Hospital

Fulbourn

Cambridge

United Kingdom

CB21 5EF

Study participating centre

Birmingham and Solihull Mental Health NHS Foundation Trust

The Uffculme Centre

52 Queensbridge Road

Moseley

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Sponsor information

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Sponsor type

University/education

Website

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ROR

<https://ror.org/04xs57h96>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Peer reviewed scientific journals
Conference presentation
Publication on website
Submission to regulatory authorities
Registration on a public database.

Intention to publish date

31/10/2029

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date