Quetiapine effectiveness study in borderline personality disorder (QUEST)

Submission date	Recruitment status	[X] Prospectively registered
05/03/2025	Not yet recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
20/05/2025	Ongoing	☐ Results
Last Edited	Condition category	Individual participant data
15/10/2025	Mental and Behavioural Disorders	[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

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)

Safety, Efficacy

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

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- 6. Ability to speak and read English
- 7. Able to swallow IMP whole

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Current key 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

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- 8. History of QTc prolongation, severe neutropenia, agranulocytosis, history of cardiovascular disease (angina, stroke, myocardial infarction, arrhythmia, congestive cardiac failure)

Date of first enrolment

05/01/2026

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 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 Birmingham United Kingdom B13 8QY

Study participating centre Fulbourn Hospital

Cambridge Road Fulbourn Cambridge United Kingdom CB21 5EF

Study participating centre Vale House Mental Health Resource Centre

High St Winsford United Kingdom CW7 2AS

Study participating centre

Rowan View

Maghull Health Park Liverpool United Kingdom L31 1HW

Study participating centre Phoenix Service

The Barberry 25 Vincent Drive

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

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