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Lithium fingerprick testing feasibility trial

Submission date	Recruitment status	[X] Prospectively registered
07/05/2025	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/05/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
03/09/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Mood disorders are serious mental illnesses including episodes of very high (mania) and/or very low (depression) mood. Lithium is the most effective treatment but can have serious side effects. People taking lithium therefore need
regular blood tests to ensure it is safe. Studies show that only 50% patients receive regular blood tests as recommended. This project will test a new system of lithium testing, called point-of-care. Point-of-care testing allows lithium levels to be measured using finger-prick tests, giving results within minutes instead of weeks. We expect this to be better than the current system, where results are often not communicated to patients or their doctors. Our overall
future goal is to see whether this point-of-care testing improves lithium monitoring and therefore better physical and/or mental health. We first need to test whether it is practicable: we will measure whether participants receive testing as recommended, how many participants are recruited and staying in the study and whether the new system is acceptable. We'll also measure medication changes, quality-of-life, and use of healthcare services.

Who can participate?
We will include 80 adults with mood disorders taking lithium. Participants need to be adults taking lithium, with monitoring due every 3 months.

What does the study involve?
One included, participants will be randomly allocated to either receive point-of-care testing or lithium testing as usual, for 6 months. There are three research visits over these 6 months which can be via videocall or in person.

What are the possible benefits and risks of participating?
People may enjoy the research assessments (including mood questionnaires and questions related to lithium and health) or they may not enjoy them. If randomly assigned the fingerprick testing they may find this better than the usual testing, or they may not. If not randomly assigned to the fingerprick testing, they may be disappointed at not being able to try this.

Where is the study run from?
The study will take place around London and Newcastle in certain NHS Trusts but all research visits can be done remotely. Fingerprick tests would be done in a usual place of care.

When is the study starting and how long is it expected to run for?
January 2025 to March 2027

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

Who is the main contact?
The study team can be contacted at lipoc@kcl.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Dr Rebecca Strawbridge

ORCID ID
https://orcid.org/0000-0002-2984-1124

Contact details
PO72 Centre for Affective Disorders
London
United Kingdom
SE5 8AF
+44 2078480088
becci.strawbridge@kcl.ac.uk

Type(s)
Public, Scientific

Contact name
Dr . Study Team

Contact details
Centre for Affective Disorders
London
United Kingdom
SE5 8AF
+44 2078480088
lipoc@kcl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
354568

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 68757

Study information

Scientific Title
Lithium Point-Of-Care testing to improve adherence to monitoring guidelines and quality of maintenance therapy: a randomised feasibility trial (LiPOC)

Acronym
LiPOC

Study objectives
The primary aim is to assess the feasibility of a novel approach to monitoring lithium (POC) prior to a potential future
definitive trial. As such, our primary feasibility outcomes are as follows, for people with affective disorders taking
lithium randomised to either POC or usual care:
1. Rates of participant recruitment
2. Rates of participant attrition (drop-out from the trial)
3. Adherence to lithium monitoring guidelines
4. Acceptability of lithium monitoring approach
5. Indications of potential contamination bias (where people randomised to usual care may receive better monitoring
than they would if not part of the trial).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/06/2025, London - South East Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 207 104 8151; londonsoutheast.rec@hra.nhs.uk), ref: 25/LO/0381

Study design
Feasibility randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
People with depression or bipolar disorder taking lithium

Interventions

Participants will be randomised in a 1:1 ratio to one of the two treatment arms (TAU, or POC). Randomisation is performed by the King's College Clinical Trials Unit independent web-based system. Randomisation will be stratified according to the site (Trust) via minimisation with a random component. Only the unblinded researcher and trial statistician (blinded) will have access to the randomisation system and all randomisation details will be locked following treatment allocation. The participant and their healthcare professional will be notified of their group as soon as possible after randomisation. The total duration for both groups is 6 months without follow up after this. Both arms of the study will operate alongside usual care practices. The intervention groups are as follows:

1. POC (fingerprick test) – n=40 participants: Those participants randomised to the point of care lithium monitoring intervention (n=40) will use the Medimate lithium monitoring apparatus, a handheld tool capable of determining serum lithium concentration from a finger prick blood sample within a few minutes. This is currently the only globally available POC test for lithium, having undergone rigorous validation testing following Clinical Laboratory Standards Institute (CLSI) Evaluation Protocols for US and EU standards. Participants in the intervention arm will use this device at their usual point of care and receive results during the appointment, as opposed to the standard approach of attending separate outpatient blood monitoring appointments with delays of days to weeks for results and sometimes missing results.

2. TAU (usual monitoring) – n=40 participants: There will be no changes to usual procedures in this group, but we will record the details of lithium monitoring.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Medimate point-of-care test

Primary outcome(s)
The primary aim is to assess the feasibility of a novel approach to monitoring lithium (POC) prior to a potential future
definitive trial. As such, our primary feasibility outcomes are as follows, for people with affective disorders taking
lithium randomised to either POC or usual care:
1. Rates of participant recruitment are measured via data extraction from randomisation system.
2. Rates of participant attrition are measured by ongoing recording by research team.
3. Adherence to lithium monitoring guidelines is measured by patient interviews at months 0, 3 and 6.
4. Acceptability of monitoring is assessed via a monitoring acceptability questionnaire (non-validated) at month 0, 3 and 6.
5. Indications of potential contamination bias are measured by reviewing electronic health records at the end of the study (to ascertain monitoring rates between treatment-exposed vs non-exposed services; analysing changes in monitoring rates from first to last recruitment, examining participants' monitoring history) and within clinician acceptability surveys (as to practice changes during the trial.)

Key secondary outcome(s))

We will also explore change in the following measures over time to inform a future definitive study design:
1. Health economics is measured using the client service receipt inventory and EuroQol5d questionnaires at 0, 3 and 6 months
2. Affective symptoms are measured using the young mania rating scale, Montgomery-asberg depression rating scale and maudsley visual analogue scales at 0, 3 and 6 months
3. Physical health symptoms are measured using the lithium side effects rating scale and adverse effects recording (via patient interview) at 0, 3 and 6 months

Completion date
01/03/2027

Eligibility

Key inclusion criteria
1. Aged 18 years and above.
2. Able to give informed consent.
3. A clinical diagnosis of an affective disorders.
4. Taking lithium, with monitoring due every 3 months for the upcoming 6 months and be due for monitoring at the time
of consent i.e., due to undergo three serum level tests during the study period (i.e. at baseline, month 3 and month 6).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. A planned change in lithium treatment during the 26 week study period.
2. Clinically significant manic symptoms (Young Mania Rating Scale [YMRS] score ≥20).

Date of first enrolment
01/09/2025

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR South London and Maudsley Clinical Research Facility at King's
1st Floor Cheyne Wing
King’s College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3XT

Study participating centre
West London NHS Trust
Hammersmith Hospital
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Institute of Psychiatry, Psychology & Neuroscience and South London & Maudsley NHS Foundation Trust joint office

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Rebecca Strawbridge, becci.strawbridge@kcl.ac.uk, with the type of (anonymised) data depending on the request, available from 26 weeks after data collection has been completed, subject to participants' consent.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes