ISRCTN96463686 https://doi.org/10.1186/ISRCTN96463686

An online psychoeducational and support program implementing ketogenic metabolic therapy for mental illness

Submission date
04/12/2025

Recruitment status
Not yet recruiting

Registration date
11/12/2025

Overall study status
Ongoing

Last Edited
23/12/2025

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
This study aims to deliver an online group ketogenic metabolic therapy (KMT) program to community participants with varying levels of depression and anxiety and evaluate the clinical impact via measurable improvements in mental health outcomes over 7 time points: 0 (baseline), 4, 8, 12, 16, 20 and 24 weeks. The plan is to integrate KMT into an existing care delivery model. The current model includes psychoeducation and ongoing professional and community support, which can then be implemented into real-world clinical settings. There is a need to support individuals to learn and effectively apply the intervention, but also to sustain it long term if they experience improvements in their mental health symptoms and overall well-being. Previous studies have ranged from 6-16 weeks, with only one study extending up to 248 days, suggesting a need for a two-phase care model: (1) education and implementation, and (2) long-term lifestyle support. Prior research recommends investigating KMT in a remote care setting, focused on mental health symptoms monitoring, dietary adjustments based on ketone levels and frequent coaching over a period of at least 12 weeks. Although individual support is ideal, scalability needs a remote, cost-effective approach to reach individuals both geographically far and wide, as well as those who are unable to leave their homes due to symptom severity.

Who can participate?
Adult participants with a diagnosis of depression or anxiety, or both.

What does the study involve?
Participants will be recruited online through social media and mental health groups across the country. The IKRT Group Metabolic Mental Health (MMH) Program is a fully remote, structured KMT intervention delivered via GDPR-compliant platforms (PracticeBetter and Zoom). The program consists of 8 weeks of foundational education and 24 weeks of concurrent weekly professional and peer support. Participants will receive personalised macronutrient targets, a Moderate Atkins Diet (MAD; 1.5:1–2:1 ratio) matched to individual energy requirements, ketogenic food lists, recipes, educational resources, and access to a moderated private online community. All participants will prepare their own meals and track dietary intake using a food tracker. Blood ketone and glucose levels will be monitored daily using the Keto-Mojo device,

with readings synced to a remote dashboard for clinical oversight. Baseline metabolic labs (HbA1c, lipid profile, vitamin D and B12) and demographical data will be collected, and supplementation is advised when deficiencies are identified. Psychological outcomes are assessed at repeated time points using validated measurement tools at baseline and week 24. Weekly check-ins and Q&A sessions provide troubleshooting around diet implementation, ketone regulation, symptoms, and lifestyle barriers. This program is designed to complement ongoing psychiatric care and represents the only intervention of its kind currently available in the UK.

What are the possible benefits and risks of participating?
Possible benefits to participants include learning how to safely implement KMT and sustain it long term. Improvements in physical (e.g. weight loss) and mental health symptoms may also be experienced.

Possible risks to participants include discomfort from home blood tests and daily ketone measurements. There are potential side effects from starting the ketogenic diet, such as fatigue, hunger and low energy, also known as the 'keto-flu'. These are normal and usually short-lived and can be prevented with dietary adjustments.

Where is the study run from?
University of East London, UK.

When is the study starting and how long is it expected to run for?
March 2026 to March 2027.

Who is funding the study?
Baszucki Group, USA.

Who is the main contact?
Dr Erin L Bellamy, e.l.bellamy@uel.ac.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Erin Bellamy

ORCID ID
https://orcid.org/0000-0003-4469-7711

Contact details
Department of Psychology and Human Development
University of East London
University Way
London
United Kingdom
E16 2RD
+44 20 8223 3000
e.l.bellamy@uel.ac.uk

Additional identifiers

Study information

Scientific Title
Implementing ketogenic metabolic therapy for mental illness: a mixed-methods pilot trial of an online psychoeducational and support program

Study objectives
This study aims to deliver an online group ketogenic metabolic therapy (KMT) program to community participants with varying levels of depression and anxiety and evaluate the clinical impact via measurable improvements in mental health outcomes over 7 time points: 0 (baseline), 4, 8, 12, 16, 20 and 24 weeks.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Health services research

Study type(s)

Health condition(s) or problem(s) studied
Use of ketogenic metabolic therapy in individuals with depression and anxiety

Interventions
The IKRT Group Metabolic Mental Health (MMH) Program is a fully remote, structured ketogenic metabolic therapy (KMT) intervention delivered via GDPR-compliant platforms (PracticeBetter and Zoom). The program consists of 8 weeks of foundational education and 24 weeks of concurrent weekly professional and peer support. Participants will receive personalised macronutrient targets, a Moderate Atkins Diet (MAD; 1.5:1–2:1 ratio) matched to individual

energy requirements, ketogenic food lists, recipes, educational resources, and access to a moderated private online community. All participants will prepare their own meals and track dietary intake using a food tracker. Blood ketone and glucose levels will be monitored daily using the Keto-Mojo device, with readings synced to a remote dashboard for clinical oversight. Baseline metabolic labs (HbA1c, lipid profile, vitamin D and B12) and demographical data will be collected, and supplementation is advised when deficiencies are identified. Psychological outcomes are assessed at repeated time points using validated measures, including depression (PHQ-9), anxiety (GAD-7), depression, anxiety and stress (DASS-21), binge eating (BES), positive and negative affect (PANAS), mental well-being (WEMWBS), self-compassion (SCS), and PTSD symptoms (PCL-5) assessed at baseline and week 24. Weekly check-ins and Q&A sessions provide troubleshooting around diet implementation, ketone regulation, symptoms, and lifestyle barriers. This program is designed to complement ongoing psychiatric care and represents the only intervention of its kind currently available in the UK.

Intervention Type
Behavioural

Primary outcome(s)
1. Depression and anxiety measured using the Patient Health Questionnaire-9 (PHQ-9), General Anxiety Disorder-7 (GAD-7) and Depression Anxiety Stress Scales – Short Form (DASS-21) at baseline, 4 , 8 , 12 , 16 , 20 and 24 weeks

2. Participant compliance measured using the keto-mojo device at daily, across 18 of 24 weeks

3. Binge eating, positive and negative affect, mental well-being, self-compassion, and PTSD symptoms measured using the Binge-Eating Scale (BES), Positive and Negative Affect Schedule (PANAS) , Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS), Self-Compassion Scale (SCS) and the PTSD Checklist for DSM-5 (PCL-5) at baseline, 4 , 8 , 12 , 16 , 20 and 24 weeks

4. Attrition rate measured using data collected on the number of participants who consent to participate who remain in the study until the end of the study at 24 weeks

Key secondary outcome(s))
1. Glucose/ketone ratio measured using the keto-mojo device at daily, across 18 of 24 weeks

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. Adults (18 - 80) in the UK
2. BMI >18.5 kg/m²
3. Formal diagnoses of depression and anxiety, or with scale scores of at least moderate levels of depression and anxiety (PHQ-9 >10, GAD-7 >10)
4. May be on stable psychiatric medication (excluding clozapine >550 mg) and must have professional clinical oversight for medications (via a psychiatrist or general practitioner)
5. Non-diabetic or pre-diabetic
6. Clinically stable (no hospitalisation past 3 months)
7. Not pregnant, nursing, or planning to become pregnant within the next 6 months
8. Able to give informed consent in English

9. Must be capable of completing digital tracking (diet/symptom diaries, questionnaires), attending all sessions, and using applications on a compatible smartphone

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. BMI <18.5 kg/m²
2. Recent ECT or ketamine therapy
3. Active suicidal ideation with intent (captured at baseline and given support information)
4. Developmental delays, neurological conditions (e.g., dementia, ASD level 2+), diagnosis of chronic fatigue syndrome (CFS), coagulation disorders, serious food allergies, restrictive diets (e. g., vegetarian or vegan), or those unable to comply with study protocols
5. No recent or current ketogenic or low-carbohydrate diet (past three months), drug/alcohol dependence (last 6 months), or planned major surgery during study
6. Current or recent use (past 6 months) of GLP-1 medications
7. Use of incompatible medications (e.g., SGLT2 inhibitors, anticoagulants)
8. Refusal of dietary, monitoring, or testing requirements will also exclude participation
9. Involvement in any other research study
10. Detailed recommendations on medical contraindications will also be followed as per previous research trials. See a comprehensive list below:
10.1. Myalgic Encephalomyelitis (ME)
10.2. Chronic Fatigue Syndrome (CFS)
10.3. Taking Topamax, Zonisamide or Valproate/ Depakote
10.4. Acute or history of Pancreatitis
10.5. Liver Failure
10.6. Porphyria
10.7. Genetic disorders of fatty acid oxidation
10.8. Glycogen storage disease type 1 (Von Gierke’s disease)
10.9. Succinyl-CoA:3-ketoacid CoA transferase deficiency
10.10. Carnitine deficiency (primary)
10.11. Carnitine palmitoyltransferase deficiency (CPT I/II)
10.12. Carnitine-acylcarnitine translocase deficiency
10.13. Mitochondrial fatty acid beta oxidation disorders
10.14. Short-chain acyl dehydrogenase deficiency
10.15. Medium-chain acyl dehydrogenase deficiency

10.16. Long-chain acyl dehydrogenase deficiency
10.17. Very long-chain acyl dehydrogenase deficiency
10.18. Medium-chain 3-hydroxyacyl-coenzyme A deficiency
10.19. Long-chain 3-hydroxyacyl-coenzyme A deficiency
10.20. Pyruvate carboxylase deficiency
10.21. Epilepsy
10.22. Cardiovascular disease
10.23. Cholecystectomy
10.24. Renal failure
10.25. Nephrolithiasis
10.26. Osteopenia or osteoporosis
10.27. Hyperlipidaemia
10.28. History of cerebrovascular disease
10.29. History of anorexia
10.30. Severe gastroesophageal reflux

Date of first enrolment
01/03/2026

Date of final enrolment
01/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of East London
East Building 4
University Way
London
England
E16 2RD

Sponsor information

Organisation
University of East London

ROR
https://ror.org/057jrqr44

Funder(s)

Funder type

Funder Name
Baszucki Group

Results and Publications

Individual participant data (IPD) sharing plan

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