

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

<b>Submission date</b> 04/12/2025	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/12/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/04/2026	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

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# 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)

approved 20/01/2026, Ethics and Integrity Sub-Committee of the University of East London (University of East London, Stratford Campus, Water Lane, London, E15 4LZ, United Kingdom; -, researchethics@uel.ac.uk), ref: ETH2526-0129

### 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**

Current key inclusion criteria as of 13/04/2026:

1. Adults (18 - 80) in the UK
2. BMI >18.5 kg/m<sup>2</sup>
3. Participants are eligible for inclusion if they meet one of two criteria: (1) a formal diagnosis of depression, anxiety, or both (with or without comorbid ADHD), alongside a score of ≥10 on the Patient Health Questionnaire-9 (PHQ-9) and/or the Generalized Anxiety Disorder-7 (GAD-7); or (2) no formal psychiatric diagnosis other than ADHD, alongside a score of ≥10 on the PHQ-9 and /or GAD-7.

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

Previous key inclusion criteria:

1. Adults (18 - 80) in the UK
2. BMI >18.5 kg/m<sup>2</sup>
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/m<sup>2</sup>
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