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FAD - Food for ADHD and Depression

Submission date	Recruitment status	[_] Prospectively registered
18/06/2025	Recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/04/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/04/2026	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Many people with ADHD also experience low mood. While medications and talking therapies help some, others don't find them effective or prefer not to use them. The Food in ADHD and Depression (FAD) trial is testing whether changing your diet with the help of regular coaching can improve symptoms of ADHD and depression better than another proven dietary approach.

Who can participate?
Adults aged 18 and over of any sex or gender can take part if they have a formal diagnosis of ADHD and are currently experiencing symptoms of depression (a formal diagnosis of depression is not required). Participants need regular access to the internet and must be willing to change their diet, attend online coaching sessions, complete questionnaires and cognitive tests, and provide blood and stool samples. Some people cannot take part, including those who are pregnant or breastfeeding, have a BMI under 18.5, have type 1 diabetes, serious kidney or liver problems, follow certain diets like low-carb, vegetarian, or vegan, have eating disorders, psychosis, epilepsy, substance misuse issues, or take certain medications. A medical screening will confirm eligibility.

What does the study involve?
Participants are randomly assigned to one of two dietary programmes. Each person will have Group sessions: 45 minutes per week in an online group and One-to-one sessions: 60 minutes per week in weeks 1-2, 30 minutes per week in weeks 3-8, 30 minutes every two weeks in weeks 9-16. Assessments include online questionnaires and cognitive tests at the start, week 6, and week 16, daily 1-minute mood and energy ratings, weekly productivity ratings, daily finger-prick tests for blood sugar and ketones, blood samples at the start and week 16 at a Randox Health clinic, and stool samples at the same two time points. There is also an optional 30-minute exit interview. The study lasts 16 weeks for each participant.

What are the possible benefits and risks of participating?
You may receive personalised dietary advice that could help improve your ADHD, mood, energy levels, and overall health. You'll also be helping researchers explore new treatment options. Some mild side effects may occur, such as headaches, tiredness, digestive changes, minor bruising from blood tests, soreness from finger-pricks, or discomfort when answering mood questions or collecting stool samples. Support is available if needed. No serious risks are expected from either diet.

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

When is the study starting and how long is it expected to run for?
May 2025 to June 2029

Who is funding the study?
Baszucki Group and public donations.

Who is the main contact?
Prof Michael Browning – Principal Investigator
fad@psych.ox.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Michael Browning

ORCID ID
https://orcid.org/0000-0001-9108-3144

Contact details
Department of Psychiatry, Warneford Hospital, University of Oxford
Oxford
United Kingdom
OX3 7JX
+44 (0)1865 618316
michael.browning@psych.ox.ac.uk

Type(s)
Public, Scientific

Contact name
Mr Ewan Houston

ORCID ID
https://orcid.org/0009-0009-7954-8303

Contact details
Department of Psychiatry, Warneford Hospital, University of Oxford
Oxford
United Kingdom
OX3 7JX
-
fad@psych.ox.ac.uk

Additional identifiers

Study information

Scientific Title
Diet and coaching for the management of attention deficit hyperactivity disorder and related depression symptoms: a 16 week randomised controlled intervention efficacy study and wider mechanistic analysis

Acronym
FAD

Study objectives
This study explores how diet influences ADHD symptoms, mood, and mental well-being. Many people with ADHD struggle with focus, energy levels, and emotional regulation, and research suggests that nutrition might play a role in these challenges.

The study aims to understand whether dietary coaching can improve ADHD symptoms and overall mental health by comparing two different dietary approaches.

The study aims to:
1. Investigate whether dietary changes improve ADHD symptoms such as focus, impulsivity, and energy regulation.
2. Explore whether a low-carbohydrate ketogenic diet (KD) affects mood, productivity, and mental clarity in adults with ADHD.
3. Compare the ketogenic diet with a control diet (Hormesis Diet, HD) to determine if improvements are due to diet-specific effects or general lifestyle changes.
4. Assess biological markers (e.g., blood ketones, glucose, lipids) to understand how metabolism relates to ADHD symptoms.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 01/05/2025, University of Oxford MS IDREC Ethics Committee (Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, United Kingdom; +44 1865 (6)16577; ethics@medsci.ox.ac.uk), ref: 1090731

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
ADHD and related depression symptoms

Interventions

Current interventions as of 28/04/2026:
The study lasts 16 weeks.

100 adults with ADHD will be randomly assigned to one of two diet groups:
Ketogenic Diet (KD) Coaching Group (low-carb, high-fat diet).
Hormesis Diet (HD) Coaching Group (control diet, used as a comparison).

Participants will receive weekly coaching sessions (group + individual) to help them follow their assigned diet.
Participants will complete self-reported mental health and productivity assessments.
Metabolic health will be monitored through blood testing.

The intervention consists of online coaching on how to use and maintain a ketogenic diet for mental health. Compliance will be assessed by monitoring blood ketone levels. Participants in this arm will meet with their coach online using Microsoft Teams video conferencing software. They will be offered 45 minutes per week in an online group, and 60 minutes per week in weeks 1-2, 30 minutes per week in weeks 3-8, 30 minutes every two weeks in weeks 9-16 week one to one online with their coach. Sessions will provide information about using ketogenic diet for mental health, and coaching to encourage participants to set and maintain goals.

The comparator arm will receive time-matched online coaching from a dietitian on how to use and maintain the Hormesis Diet for mental health. The comparator arm will have access to an Oxford university hosted webpage detailing the Hormesis Diet. Compliance for both arms will be assessed by monitoring daily fasted capillary blood beta-hydroxybutyrate (BHB) and glucose readings using a Keto-Mojo device, in addition to self-reported adherence discussed during weekly coaching sessions.
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The aim is not to blind participants to the different names of the diet in their arm, but to foster equivalent enthusiasm in the prospect of their diet to improve their mental health.

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Intervention Type
Behavioural

Primary outcome(s)
ADHD symptoms measured using the Adult AttentionDeficit/Hyperactivity Disorder SelfReport Scale (ASRS) at baseline and end of week16

Key secondary outcome(s))
1. Metabolic wellness is measured using daily fasted capillary βhydroxybutyrate (BHB) and blood glucose (BG) readings with a Keto Mojo device, and venous mitochondrialdriven Metabolic Dysfunction Risk Testing (MitoGENE), advanced lipid panel, and comprehensive metabolic panel at baseline and end of week 16
2. Mood, energy, and clarity of thought are measured using self-reported ecological momentary assessments (EMAs) rated 0 to 10 daily throughout the study
3. Productivity, effectiveness, and procrastination are measured using self-reported ecological momentary assessments (EMAs) rated 0 to 10 weekly throughout the study
4. ADHD symptoms are measured using the Adult AttentionDeficit/Hyperactivity Disorder SelfReport Scale (ASRS) at baseline and end of week 6
5. Depression symptoms are measured using the Patient Health Questionnaire9 (PHQ9) at baseline and end of week 16
6. Early changes in depression symptoms are measured using the Patient Health Questionnaire9 (PHQ9) at baseline and end of week 6
7. Anxiety symptoms are measured using the Generalized Anxiety Disorder 7item scale (GAD7) at baseline and end of week 16
8. Early changes in anxiety symptoms are measured using the Generalized Anxiety Disorder 7item scale (GAD7) at baseline and end of week 6
9. Work and daytoday performance are measured using the Work and Social Adjustment Scale (WSAS) at baseline and end of week 16
10. Early changes in work performance are measured using the Work and Social Adjustment Scale (WSAS) at baseline and end of week 6
11. Sleep quality is measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline and end of week 16

12. Early changes in sleep quality are measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline and end of week 6
13. Baseline thyroid function is measured using blood level of Thyroid Stimulating Hormone (TSH) at baseline
14. Personality traits are measured using the Big Five Inventory (BFI) at baseline and end of week 16 and correlated with blood βhydroxybutyrate (BHB) and cognitive function tests
15. Early changes in personality traits are measured using the Big Five Inventory (BFI) at baseline and end of week 6 and correlated with blood βhydroxybutyrate (BHB) and cognitive function tests
16. Microbiome composition is measured using homecollected stool samples for microbiome analysis at baseline and end of week 16
17. Cognitive function is measured using the Cambridge Neuropsychological Test Automated Battery (CANTAB) at baseline, end of week 6, and end of week 16
18. Safety of the intervention is measured using continuous adverseevent monitoring at all times
19. Eating disorder symptoms are measured using the Eating Disorder Examination Questionnaire (EDE-Q) at baseline, end of week 6, and end of week 16
20. Adverse childhood experiences are measured using the Adverse Childhood Experiences (ACE) questionnaire at baseline (optional)
21. Exploratory blood biomarkers: Exploratory blood biomarkers are measured from plasma samples collected at clinic visits at baseline and end of week 16. Assays are performed by Prof. Andreazza's lab, University of Toronto, and include: mitochondrial metabolomics (TCA cycle intermediates, redox cofactors, energy metabolites, ketone bodies, amino acids, glutathione, free carnitine), mitochondrial stress markers (cell-free mitochondrial DNA, GDF-15, GDF-11, FGF-21), inflammatory cytokines (IL-1beta, IL-6, IL-18, IL-10, TNF-alpha), kynurenine pathway metabolites (kynurenic acid, quinolinic acid), and plasma fatty acid profile (EPA, DHA, linoleic acid). These are exploratory, hypothesis-generating analyses.
22. Exploratory genetic moderators: Nuclear-encoded mitochondrial gene variants and fatty acid desaturase loci (FADS1, FADS2, FADS3) are genotyped from DNA collected at baseline. Genotype data are used to explore whether genetic variation moderates metabolomic profiles (Item 21) or treatment response. Analyses include the association between FADS cluster variants and change in plasma fatty acid levels (linoleic acid, arachidonic acid, EPA, DHA), and genotype-by-treatment interaction for exploratory outcomes. All analyses are exploratory and hypothesis-generating.

Completion date
22/06/2029

Eligibility

Key inclusion criteria
1. Has a previous diagnosis of ADHD given by a UK psychiatrist
2. Scores 14 or more on Part A of the ASRS
3. Scores 5 or more on the PHQ-9 test, either with or without a previous depression diagnosis
4. Willing and able to give informed consent for participation in the trial
5. Male or female, aged 18 and over
6. In the Investigator’s opinion, is able and willing to comply with all trial requirements
7. Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Female participant who is pregnant, lactating or planning pregnancy during the course of the trial
2. Significant known history of renal or hepatic impairment
3. Scheduled elective surgery or other procedures requiring general anaesthesia during the trial
4. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participant at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial
5. Already on a ketogenic, low carbohydrate (under 100g per day), vegetarian, or vegan diet
6. Has been diagnosed with anorexia nervosa or bulimia
7. Low BMI (<18.5kg/m^2)
8. Has a bipolar disorder or schizophrenia diagnosis, or has experienced psychosis
9. Has type 1 diabetes
10. Acutely suicidal, and/or has engaged in self-injurious behaviour within the past two months
11. Active substance misuse or alcohol dependence, defined as scoring two or more on the CAGE questionnaire, any use of class A drugs in the past three months, or any use of cannabis in the last month
12. Has serious food allergies (experiencing food hypersensitivity that leads to anaphylaxis or other severe symptoms, which may require hospitalisation or are life-threatening) or otherwise requires a special diet that cannot be accommodated within a ketogenic diet, such as phenylketonuria
13. Treated with insulin, sulfonylureas, meglitinides, GLP-1 analogues, or SGLT2 inhibitors
14. Has gallstones, cholecystectomy, cachexia, porphyria, renal tubular acidosis, kidney stones, small bowel malabsorption, or a history of pancreatitis
15. Has no access to cooking facilities or ingredients to make appropriate recipes

Date of first enrolment
01/04/2026

Date of final enrolment
01/02/2027

Locations

Countries of recruitment
United Kingdom

Study participating centre
Department of Psychiatry, University of Oxford
Warneford Hospital
Oxford
England
OX3 7JX

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Baszucki Family Foundation and public crowdfunding

Results and Publications

Individual participant data (IPD) sharing plan
All information obtained during this study, including personal information, questionnaire/task responses, and blood and stool sample results will be kept strictly confidential and will not be shared with anyone outside the study. Electronic data for analysis will be stored on secure servers that only the principal investigator, project coordinators, and research team have access to. Data from which participants cannot be identified will be posted on the Open Science Framework, which means it will be accessible by anyone interested in analysing the data - participants will not be identifiable from this data. Identifiable data will be permanently destroyed at the end of the study.

• Repository: Open Science Framework (OSF)
• Type of data: Deidentified participant-level data
• Process for access: Publicly available - no access request required
• Timing: Available after publication of primary results
• Consent: Participants consent to deidentified data being shared publicly
• Anonymisation: All data will be fully anonymised before upload; participants will not be identifiable
• Ethical/legal restrictions: None beyond standard anonymisation
• Persistent weblink: Will be provided once the OSF project is created

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	12/01/2026	09/03/2026	No	No