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Investigating the impact of kefir on metabolic syndrome subjects in an inpatient setting

Submission date 16/06/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/06/2026	**Overall study status** Ongoing	
Last Edited 03/07/2026	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
The microorganisms in the human gut are very important for our health. Changes in these gut bacteria have been linked to diseases like diabetes and obesity. This study aims to understand how consuming kefir, a fermented milk drink, affects the bacteria and small molecules (metabolites) in the digestive tract. We specifically want to identify healthy markers in the gut after someone with metabolic syndrome drinks kefir.

Who can participate?
Men and women aged 18 to 65 years who have been diagnosed with metabolic syndrome. Participants must currently have a low intake of fruits, vegetables, and probiotic foods.

What does the study involve?
The study is a crossover trial, meaning every participant will try both the kefir and a placebo (a look-alike drink with no active kefir cultures). Participants will stay at the NIHR Imperial Clinical Research Facility for two separate 4-day visits. During these stays, we will use specialized tubes to collect samples from the stomach and small intestine after participants drink the kefir or placebo. We will also collect blood, urine, and stool samples to see how the body responds.

What are the possible benefits and risks of participating?
There may be no direct health benefit to participants, but the results will help scientists understand how fermented foods improve metabolic health. The main risks involve minor discomfort or bruising from blood samples and some temporary discomfort from the temporary intestinal tubes. Tube placement involves a very small dose of radiation (similar to 2.8 months of natural background radiation).

Where is the study run from?
The study is run from the NIHR Imperial Clinical Research Facility at Hammersmith Hospital in London, UK.

When is the study starting and how long is it expected to run for?
The study is expected to start in June 2026 and run for approximately one year.

Who is funding the study?
The study is funded by UK Research and Innovation (UKRI) through an EU Horizon grant

Who is the main contact?
Dr Isabel Garcia-Perez, i.garcia-perez@imperial.ac.uk

Contact information

Type(s)
Principal investigator, Public, Scientific

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Integrated Research Application System (IRAS)
343900

Central Portfolio Management System (CPMS)
73277

Study information

Scientific Title
To investigate the postprandial impact of kefir consumption on the digestive tract metabolites and microbiome and glycaemic and gut hormone response in metabolic syndrome participants: a double-blind, inpatient, crossed-over randomized controlled clinical trial

Acronym
KIMPACT

Study objectives
Primary aim:
To identify metabolic and microbiome markers of health post milk kefir consumption.

Secondary aim:
To assess the postprandial impact of kefir on glycemia and gut hormone response.

Tertiary aim:
To provide insight into fermented foods-microbiota-metabolite-host interactions at an individual level.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/05/2026, London - Surrey Borders Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 972 2545; surreyborders.rec@hra.nhs.uk), ref: 26/LO/0235

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Crossover

Purpose
Basic science

Study type(s)

Health condition(s) or problem(s) studied
Metabolic syndrome

Interventions
Participants will attend two 4-day inpatient stays at the NIHR Imperial Clinical Research Facility (CRF), separated by at least one week. This is a double-blind, randomized crossover trial. Eligible participants will be randomly assigned to the order of the dietary intervention using a web-based sealed envelope randomization service provided by Sealed Envelope (https://www.sealedenvelope.com).

Arm 1 (Kefir): Participants consume either 200 ml or 600 ml of milk kefir daily at breakfast.
Arm 2 (Placebo): Participants consume a matched volume of a pasteurized, acidified, and flavored milk placebo.

Methodology:
Day 1: Nasoenteric tube installation and dietary standardization.
Day 2: Ileal sample collection will start with two baseline samples taken before kefir/placebo intake and 60, 120, 180, 240, 300, 360, 420 and 480 minutes post-intake.
Day 3: Intravenous cannulation for postprandial blood samples at baseline, 10, 20, 30, 45, 60, 90, 120, 180, 240 and 300 minutes post intake of a 600 ml dose to measure hormones and metabolites. Gastric and duodenal tubes are installed later that day.
Day 4: Gastric samples will be collected on Day 4 of both study visits via the enteric tubes with the use of a syringe. Samples will be taken at 15, 30, 45, 60, 90 and 120 minutes post intake. Duodenal fluid will be collected on Day 4 of both study visits via the enteric tubes with the use of a syringe. Samples will be taken at 30, 60, 90, 120, 150, 180 and 240 minutes post intake.

Intervention Type
Other

Primary outcome(s)
1. Digestive tract metabolites and microbiome composition measured using ^{1}H NMR spectroscopy, mass spectrometry (MS) chromatography, and microbiological analysis (16S rRNA sequencing) at baseline and multiple post-consumption intervals on Day 2 (ileal) and Day 4 (gastric/duodenal)

Key secondary outcome(s)
1. Identification of urinary and stool biomarkers of kefir intake measured using metabolomic analysis (^{1}H NMR spectroscopy and mass spectrometry) of urine and stool samples at daily during the two 4-day inpatient stays

Completion date
01/07/2028

Eligibility

Key inclusion criteria
1. 18-65 years old
2. Subjects diagnosed with metabolic syndrome according to the International Diabetes Federation (IDF) criteria (file://icnas1.cc.ic.ac.uk/igarciap/downloads/IDF_Meta_def_final.pdf)

3. Low consumption (max intake 3 servings/week) of kefir or supplements/foods labelled as having probiotic effect during the prior 3 months
4. Consumption of fruits and vegetables ≤3 servings per day
5. Willing to take one daily portion of kefir or placebo and to follow the procedures as well as a 2-3 h metabolic exploration day every month of follow-up
6. Written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
10

Key exclusion criteria
1. Existence of lactose intolerance
2. Existence of type 1 diabetes
3. Existence of abnormal thyroid hormone levels
4. Existence of chronic gastrointestinal system disease
5. Existence of cancer
6. Existence of severe liver disease
7. Existence of kidney insufficiency
8. Existence of immunodeficiency
9. Presence of a pacemaker or other implanted electromedical device
10. Taking medication to regulate blood glucose (except metformin) or lipid levels for less than 3 months
11. Taking antibiotics prior to one month of the study
12. Taking supplement which may affect the metabolic outcomes such as prebiotic or omega-3
13. Dieting for weight loss or for another disease
14. Adherence to a vegetarian or vegan diet
15. Pregnant, parturient, or breastfeeding woman; for women of childbearing age: positive urine pregnancy test
16. Alcohol consumption exceeding 30 g of alcohol/day (1 alcoholic beverage dose = 10 g of alcohol) or proven abuse or dependence on another drug. Consumption of more than 3 alcoholic beverages per day is considered abusive. An alcoholic beverage corresponds, for example, to 30 ml of spirits, 120 ml of wine or 330 ml of beer
17. Contemporary participation in other studies
18. Blood donors in the last 2 months
19. Pathology detectable on clinical examination and medical questioning that may interfere with the study's evaluation criteria

20. Adult subject to a legal protection measure (guardianship, curatorship)
21. Person deprived of liberty by judicial or administrative decision

Date of first enrolment
01/08/2026

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR Imperial Clinical Research Facility
Hammersmith Hospital
Du Cane Rd
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Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available