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Effects of a probiotic strain, Lacticaseibacillus rhamnosus OF44, on gut bacteria in healthy adults

Submission date 18/09/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol
Registration date 11/10/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 18/09/2026	**Condition category** Digestive System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
The bacteria in our gut help us digest nutrients, keep the gut healthy, support the immune system, and send signals between the gut and the brain. However, it is not yet clear how specific types of bacteria settle and remain in the human gut, and there is little evidence from clinical studies. This study will compare OF44 with a placebo in healthy adults to find out how well OF44 settles in the gut, how it changes the gut's bacterial community, and whether prebiotics help it work better.

Who can participate?
Healthy adults aged 18–60 years with a body mass index (BMI) of 18.5–28.0 kg/m². Participants must not have used antibiotics in the past 3 months or probiotics in the past month. They must be willing to provide faecal samples and complete questionnaires.

What does the study involve?
Participants will be randomly assigned to one of three groups: OF44 alone, OF44 plus prebiotic, or placebo. They will take the product for 28 days and be followed for 14 days. Faecal samples and questionnaires will be collected on Day 0, 7, 14, 21, 28, 35, and 42.

What are the possible benefits and risks of participating?
There may be benefits for gut health, but this is not guaranteed. Possible risks include mild gastrointestinal discomfort. Safety will be monitored throughout the study.

Where is the study run from?
BGI Precision Nutrition (Shenzhen) Technology Co., Limited (China)

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

Who is funding the study?
BGI Precision Nutrition (Shenzhen) Technology Co., Limited (China)

Who is the main contact?
Dr Yajie Xiao, xiaoyajie@genomics.cn

Contact information

Type(s)
Principal investigator, Scientific, Public

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Study information

Scientific Title
Effects of a probiotic strain, Lacticaseibacillus rhamnosus OF44, on gut bacteria and metabolism in healthy adults

Acronym
OF44-Gut

Study objectives
1. To evaluate the colonisation dynamics of Lacticaseibacillus rhamnosus OF44 in the gut of healthy adults and to analyse changes in gut microbiota after intervention.
2. To verify the synergistic effect of prebiotic combined with Lacticaseibacillus rhamnosus OF44

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/09/2026, Institutional Review Board of BGI (BGI STOmics Center, No. 9 Yunhua Road, Meisha Subdistrict, Yantian District, Shenzhen, 518083, China; +86 (0)755-36307890; bgi-irb@genomics.cn), ref: BGI-IRB 26049

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Gut microbiota composition and faecal metabolite profile

Interventions
Eligible participants are allocated in a 1:1:1 ratio to one of three arms using block randomisation:
Group 1 (probiotic): Lacticaseibacillus rhamnosus OF44 at a dose of 3 × 10^{10} CFU per day, taken orally once daily for 28 consecutive days.
Group 2 (synbiotic): Lacticaseibacillus rhamnosus OF44 at a dose of 3 × 10^{10} CFU per day combined with galacto-oligosaccharide , taken orally once daily for 28 consecutive days.
Group 3 (placebo): placebo identical in appearance, taste, weight and mode of administration to the active products, taken orally once daily for 28 consecutive days.

Intervention Type
Supplement

Primary outcome(s)
1. Faecal colonisation dynamics: intestinal colonisation by Lacticaseibacillus rhamnosus OF44 measured using strain-specific quantitative PCR (qPCR) at days 0,7, 14, 21, 28 (end of intervention), 35 and 42, with the primary endpoint at day 28

Key secondary outcome(s)
1. Gut microbiota measured using metagenomic sequencing at days 0,7, 14, 21, 28 , 35 and 42

2. Gastrointestinal symptoms measured using the Gastrointestinal Symptom Rating Scale (GSRS) at days 0, 14, 28 and 42

3. Stool consistency measured using the Bristol Stool Form Scale at days 0,7, 14, 21, 28 , 35 and 42

4. Safety measured using adverse events recorded throughout the study at days 0,7, 14, 21, 28 , 35 and 42

Completion date
31/05/2027

Eligibility

Key inclusion criteria
1. Aged 18–60 years, male or female
2. In good general health, with no severe chronic disease
3. Body mass index (BMI) between 18.5 and 28.0 kg/m²
4. No antibiotic use in the past 3 months and no probiotic-containing food or dietary supplements in the past month
5. Willing to participate in the study and to provide written informed consent
6. Willing to provide faecal samples and to complete the study questionnaires as required by the protocol

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Pregnancy or lactation
2. Known hypersensitivity or allergy to any component of the investigational product
3. Severe cardiovascular, cerebrovascular, hepatic, renal, haematological or endocrine disease
4. Severe gastrointestinal disease (for example inflammatory bowel disease, irritable bowel syndrome or peptic ulcer)
5. Participation in another interventional clinical trial within the previous 3 months
6. Any other condition that, in the judgement of the investigator, makes the participant unsuitable for inclusion

Date of first enrolment
01/12/2026

Date of final enrolment
31/01/2027

Locations

Countries of recruitment
China

Study participating centre
BGI Precision Nutrition (Shenzhen) Technology Co., Limited (China)
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Sponsor information

Organisation
BGI Precision Nutrition (Shenzhen) Technology Co., Ltd. (China)

ROR
https://ror.org/00em1jy13

Funder(s)

Funder type

Funder Name
BGI Precision Nutrition (Shenzhen) Technology Co., Ltd. (China)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available