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Effects of probiotic supplementation on gut health, food tolerance and athletic performance of non-elite endurance athletes

Submission date	**Recruitment status**	[_] Prospectively registered
13/12/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/12/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/02/2026	Digestive System	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Prolonged and strenuous exercise as the one seen in endurance sports (such as running, cycling, triathlon) may cause increased intestinal permeability (so-called 'leaky gut syndrome'), inflammation, and over time lead to the development of food intolerance or even food allergy. These adverse reactions to food have a negative effect on nutritional status, sleep, mood and quality of life of those affected, and in the case of food allergy, can be life-threatening.
The study consists of two stages. The aim of stage 1 is to determine how many endurance-trained athletes have probable food allergy, celiac disease, food intolerance, and leaky gut syndrome. This will be determined based on a survey asking about adverse reactions to food and health, and analysis of the presence of specific antibodies against food proteins, e.g. against protein present in cow's milk (food allergy) and markers of the leaky gut syndrome.
The aim of stage 2 will be to assess the effects of a 2-month supplementation with the probiotic (friendly bacteria) Lactobacillus rhamnosus GG on the markers of leaky gut syndrome, or who have elevated levels of specific antibodies (are sensitised to a food(s)) or reported adverse reactions to food.

Who can participate?
Individuals aged between 18-60 years old who have been training an endurance sport discipline like running, cycling, triathlon or swimming for at least 2 years and are training for at least 4 hours/week.

What does the study involve?
Those interested in taking part will be provided the information about the study and once they given informed consent, they will be asked to arrive at the laboratory at 3-4 times to:
1. Answer a questionnaire on adverse reactions to food and health, have their body composition, lung function and bone density measured (visit 1)
2. Have their venous blood withdrawn for analysis of different markers, undergo skin prick testing, perform a graded exercise test on a treadmill or cycle ergometer (cyclists) to measure the level of aerobic fitness (visit 2)
3. Following a 8-week supplementation with either a probiotic or placebo have blood withdrawn

for analysis of different markers and perform a graded exercise test on a treadmill or cycle ergometer (visit 3).

What are the possible benefits and risks of participating?
Athletes who are found with the leaky gut syndrome, will be advised on potential causes and will be advised on how to modify their lifestyle, including the consumption of sports supplements and diet in order to improve health, quality of life and physical performance. Athletes found with probable food allergies will be redirected to allergy clinics to confirm the allergy and implement an appropriate therapy, including education on how to improve avoidance of the allergen, what to do in case of an allergic reaction (also anaphylaxis).
The study results may provide the basis for developing guidelines on the production and use of sport supplements, which often contain substances, like sweeteners and dyes that irritate the intestinal wall, and also potential allergens.
The potential risks may be associated with the following:
1. Skin prick testing: it is a minimally invasive and safe method of assessing if someone is sensitised to something (has an elevated level of specific antibodies). During skin prick testing an itchy wheal may develop.
2. Blood withdrawal: it is generally a safe procedure, but it can cause discomfort and bruising. Also, blood withdrawal may increase the risk of: local infection, hematoma, and phlebitis. Therefore, only trained and experienced personnel will be involved in blood collection.
3. Personal data: there will be a small risk associated with the processing of personal data and their unauthorized disclosure. Participants' data will be processed in accordance with the Regulation (EU) 2016/679 of the European Parliament and the Council from 27th April 2016. Only authorised individuals will have access to confidential data. The data will be stored at the Jerzy Kukuczka University of Physical Education. Data will be stored securely.

Where is the study run from?
The study is run at the Centre of Healthy Living (Centrum Zdrowego Życia) at the Jerzy Kukuczka Academy of Physical Education in Katowice, Poland.

When is the study starting and how long is it expected to run from?
June 2023 to October 2024

Who is funding the study?
Ministry of Science and Higher Education of the Republic of Poland

Who is the main contact?
Dr Barbara Hall, b.hall@awf.katowice.pl

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Barbara Hall

ORCID ID
https://orcid.org/0000-0003-1487-780X

Contact details

Mikołowska 72a
Katowice
Poland
40-065
+48 (0)692502946
b.hall@awf.katowice.pl

Additional identifiers

Study information

Scientific Title
Effects of Lactobacillus rhamnosus GG supplementation on the intestinal barrier, food tolerance and athletic performance of non-elite endurance athletes
(Original title: Zastosowanie suplementacji probiotykiem Lactobacillus rhamnosus GG u osób trenujących dyscypliny wytrzymałościowe w celu poprawy funkcji bariery jelitowej, tolerancji pokarmów i wspomagania procesu treningowego).

Acronym
ProbioAthlete

Study objectives
Endurance athletes have increased gut permeability ('leaky gut syndrome'), which causes food intolerance or sensitisation to food (probable food allergy), probiotics supplementation reduces the marker of the leaky gut syndrome.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/10/2023, The Jerzy Kukuczka Academy of Physical Education in Katowice Bioethics Committee (Mikołowska 72a, Katowice, 40-065, Poland; +48 (0)322075352; komisjabioetyczna@awf.katowice.pl), ref: 2-X/2023

Study design
Single-center interventional single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life, Screening, Treatment

Health condition(s) or problem(s) studied
Treatment of increased gut permeability (so called leaky gut syndrome) and food intolerance in non-elite endurance athletes

Interventions
Randomisation will be performed in Excel using the following function: =rand(): assign random numbers to each observation. Athletes with leaky gut syndrome and/or probable food allergy

/intolerance diagnosed based on blood serum analysis in stage 1 of the study will be randomly divided into the following four groups:
Group 1: subjects in this group will take a probiotic supplement for 8 weeks, 2 capsules a day with a meal, and will follow an anti-inflammatory diet designed for patients with Crohn's disease.
Group 2: subjects in this group will take a probiotic supplement for 8 weeks, 2 capsules a day with a meal, and will not change their eating habits.
Group 3: subjects in this group will take a placebo for 8 weeks, 2 capsules a day, and will follow the anti-inflammatory diet.
Group 4: subjects in this group will take a placebo for 8 weeks, 2 capsules a day with a meal, and will not change their eating habits.

ProbioBalance by Aliness® Rhamnosus GG Balance probiotic ingredients in the daily dose of 2 capsules: 10 x 10^9 Lactobacillus rhamnosus GG, 200 mg prebiotic, - 40 mg Plantago Lanceolata extract.

Intervention Type
Supplement

Primary outcome(s)
1. Leaky gut syndrome is measured using the serum level of intestinal fatty acid binding protein (I-FABP), interleukin 6 (IL-6) and tumour necrosis factor-alpha (TNF-alpha), and a screening interview at baseline
2. Probiotics supplementation effect is measured by potential changes in the serum level of intestinal fatty acid binding protein (I-FABP), interleukin 6 (IL-6) and tumor necrosis factor-alpha (TNF-alpha), and a screening interview at 8 weeks

Key secondary outcome(s))
1. Probable food allergy is measured by assessing the levels of serum-specific immunoglobulins (IgE >=0.35 kU/ml), skin prick test (wheal size >=3 mm/3 mm and a validated questionnaire PAFA /EuroPrevall before supplementation at baseline
2. Food intolerance is measured by assessing the levels of serum-specific immunoglobulins (IgE <0,35 kU/mL), skin prick test (wheal size < 3mm/3mm and a validated questionnaire PAFA /EuroPrevall at baseline
3. Level of aerobic fitness determined by maximum oxygen uptake achieved during a graded exercise test on a treadmill or a cycle-ergometer at baseline and 8 weeks

Completion date
31/10/2024

Eligibility

Key inclusion criteria
1. Endurance athletes who have been training an endurance event, such as running, cycling, triathlon or swimming for at least 2 years and for a minimum of 4 hours a week
2. A good state of health confirmed by a medical doctor or an ECG and blood test

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
57

Key exclusion criteria
1. Exclusion criteria:
1.1. Health contraindications to performing an exercise test confirmed by a medical doctor or blood test and ECG results
1.2. No informed consent to participate in the study
2. Specific exclusion criteria:
2.1. Skin prick test:
2.1.1. Severe eczema
2.1.2. Pregnancy
2.2. Prior to performing an exercise test:
2.2.1. Feeling unwell
2.2.2. Shortness of breath, nausea, dizziness or pain during exercise testing

Date of first enrolment
09/10/2023

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
Poland

Study participating centre
Centre of Healthy Living (Centrum Zdrowego Życia) of the Jerzy Kukuczka Academy of Physical Education
Mikołowska 72 a
Katowice
Poland
40-065

Sponsor information

Organisation
The Jerzy Kukuczka Academy of Physical Education

Funder(s)

Funder type
Government

Funder Name
Ministerstwo Edukacji i Nauki

Alternative Name(s)
Ministerstwo Nauki i Szkolnictwa Wyższego, Ministry of Science and Higher Education, Ministry of Science and Higher Education, Republic of Poland, MNiSW

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Poland

Results and Publications

Individual participant data (IPD) sharing plan

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