The effect of probiotics on gastrointestinal symptoms during endurance exercise and exercise performance in relation to the composition of the gut microbiota/metabolites.

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Primary Objective: Can the chance at and/or intensity of gastrointestinal symptoms during exercise be influenced by probiotics supplementation in recreationally trained endurance athletes who experience these symptoms and can performance be enhanced...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48006

Source
ToetsingOnline

Brief title
With help of my little friends?

Condition

- Other condition

Synonym
gastrointestinal symptoms - gastrointestinal distress

Health condition

veranderingen in samenstelling darmmicrobioom/metabolieten en voorkomen maagdarmklachten bij gezonde personen

Research involving
Human

Sponsors and support

Primary sponsor: Hogeschool Leiden
Source(s) of monetary or material Support: SIA-RAAK

Intervention

Keyword: endurance exercise, gastrointestinal symptoms, metabolomics, microbiota

Outcome measures

Primary outcome

The main study objective is to study whether fourteen weeks of supplementation with a probiotics supplement can influence the occurrence and severity of gastrointestinal symptoms during and directly after endurance exercise and the running performance in recreationally trained endurance athletes. Performance is: distance in km (on a 30 minute running time trial, preceded by two times 30 minutes submaximal running) and maximum speed in km/h and VO2max (on a maximal incremental running exercise test).

Secondary outcome

Secundary study parameters are the possible differences in changes in composition of the microbiota and possible differences in changes in the metabolites in the stool sample before and after the supplementation period in the experimental and control group. Changes in the microbiota can be changes in the occurrence of different bacterial strains and the percentual contribution to the total amount of all the strains together. Changes in metabolites can be

changes in the occurrence of different metabolites and their percentual change.

Other study parameters that will be taken into account are:

1) Body temperature, calculated by core temperature and skin temperature, and hydration status during the performance tests;

2) Training modality, training volume, training intensity and a subjective measure of training intensity perception (RPE) during the supplementation period;

3) The occurrence of gastrointestinal symptoms during the supplementation period;

4) Outcome scores of the weekly completed POMS questionnaire during the supplementation period;

5) Habitual food pattern before and after the supplementation period;

6) Height and body mass.

Study description

Background summary

Endurance exercise, such as running a marathon, is becoming increasingly popular. In addition to the many positive health effects of endurance exercise, it can also be accompanied by gastrointestinal symptoms. For example, around 30-90% of runners suffer from gastrointestinal symptoms during or in the hours after intensive/endurance running. The occurrence of gastrointestinal symptoms is probably due to the redistribution of blood volume, resulting in less blood supply to the digestive tract and a less functioning intestinal barrier. Because the intestinal barrier functions less, endotoxins can enter the bloodstream and cause inflammatory reactions. Running in the heat causes extra redistribution of the blood volume, because extra blood is needed for cooling

of the body. It is known that the gut microbiota affect food digestion, but also the functioning of the cells that line the intestinal wall and the connections between these cells. It is possible that runners with gastrointestinal symptoms face a different composition of the gut microbiota and / or metabolites during endurance exercise compared to runners without any complaints, as a result of which the gut barrier functions less well and problems may occur. Many positive effects have been attributed to the use of probiotics, including the reduction of gastrointestinal symptoms during endurance exercise, probably due to improvement in intestinal permeability. Hence, the main goal of our research project is to investigate whether the chance of and/or intensity of gastrointestinal symptoms during endurance exercise and the exercise performance can be influenced by probiotics supplementation in recreationally trained endurance athletes. This will be studied in relation to the composition of the gut microbiota and / or metabolites.

Study objective

Primary Objective:
Can the chance at and/or intensity of gastrointestinal symptoms during exercise be influenced by probiotics supplementation in recreationally trained endurance athletes who experience these symptoms and can performance be enhanced?

Secondairy Objective: Can the composition and function of the gut microbiota of recreationally trained athletes that experience gastrointestinal symptoms during exercise be positively influenced by probiotics supplementation?

Study design

A double-blind randomized placebo-controlled trial will be performed with experienced endurance runners to investigate the effect of probiotics supplementation on occurrence and intensity of gastrointestinal symptoms during exercise and on performance. The effect on the composition and function of the gut microbiota will also be studied. The duration of the supplementation period, with Ecologic® PERFORMANCE supplements, is fourteen weeks. Standardized maximal incremental exercise tests will be performed before and after the supplementation period, as well as two performance tests (before) and one performance test (after). One performance test before will be used to familiarize the participant. During the performance tests submaximal exercise will be performed for 1h after which a 30 minute time trial will be performed. The measurements before and after the supplementation period will be performed on separate days with at least 48 hours of relative rest in between. During the supplementation period training diaries, a POMS questionnaire and some questionnaires about food habits will be completed.

Intervention

Fourteen weeks of supplementation with Ecologic® PERFORMANCE probiotics supplements (or placebo). The probiotics supplement consists of a matrix with 6 bacterial strains: Bifidobacterium bifidum W23, Bifidobacterium lactis W51, Enterococcus faecium W54, Lactobacillus acidophilus W22, Lactobacillus brevis W63, Lactococcus lactis W58. They will be used within recommended dosage, 1*1010 CFU/daily dose, and not in combination with other products.

Study burden and risks

The maximal incremental exercise test (2 times) consists of a warming-up followed by incremental increase in running velocity until voluntary exhaustion. The performance tests (3 times) consists of 60 minutes of submaximal running followed by a time trial of 30 minutes in which participants need to accomplish as much distance as possible. Only participants that are healthy (low risk based on anamnesis form) and endurance trained, and thus used to the same intensity of exercise several times a week, will be included. During exercise tests in warm conditions, the injury risk is not higher compared to their normal training and races in the same conditions. In case participants might not feel well or experience unbearable discomfort, they can stop the test at all times. Participants will fill in a food frequency twice (start and end of suppletion period) questionnaire which will be sended by the Wageningen University. Participants will also fill in a questionnaire about gastrointestinal symptoms directly after and 24 hours after the performance tests. They hand in a stool sample before and after the supplementation period. Part of the stool sample will be sended by mail to MyMicroZoo. Participants will be asked to complete a food dairy prior to the tests and to maintain a training dairy during the fourteen weeks of supplementation and also fill in the POMS questionnaire weekly.

In the Human Performance Laboratory of the Faculty of Behavioural and Human Movement Sciences of the Vrije Universiteit Amsterdam, where the tests will be executed, performance tests in warm conditions are executed regularly (e.g. VCWE FGB-VU-2018-050) and health risks related to the experimental protocol are minor for the participant since they are already well-trained and the exercise intensity will be relatively well-tolerated, since they are used to similar efforts. Relative humidity will be lower compared to average Dutch relative humidity at the same temperature.

Probiotics supplements are freely available at the market, also the Ecologic® PERFORMANCE supplements are available via internet and can be bought at several farmacies. Check https://www.winbiotic.nl/consument/Verkrijgbaarheid/via-onze-partners.html., therefore it is very likely that some athletes will already know the supplements or know people that use the supplements. The same supplement has already been used in another study (Lamprecht et al, 2012) in the same dosage and no adverse effects were reported.

Participants will receive a small financial compensation, ¤50,00 + travel expenses. Benefits might the chance on a reduced risk of occurrence of gastrointestinal symptoms might be of value for potential participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

healthy male (No females because: menstrual cycle of women is an additional confounder of the possible relationship between intestinal microbiota and the development of gastrointestinal symptoms during endurance exertion. And to exclude possible gender-related effects of probiotics on exercise-induced gastrointestinal symptoms, because females show less effect on the incidence and severity of upper respiratory tract infections, this might also be the case for probiotics and the GI symptoms).

18-45 years old;
Dutch descent; Only men of Dutch descent (which is both parents from Dutch descent) are included, because ethnicity influences the gut microbiota;
maximal oxygen uptake (VO2max) * 45 mL*kg-1*min-1 (based on an incremental exercise test you are considered recreationally trained);
an average training frequency of at least three times per week;
a low risk profile based on a health-history form;
regular occurrence of exercise-induced gastrointestinal symptoms.

Exclusion criteria

smoking;
a diagnosis of gastrointestinal disorders (e.g. Crohn*s disease, celiac disease, diagnosed with irritable bowel syndrome);
use of antidepressants in the 6 months prior to the start of the study;
use of antibiotics, antivirals, antifungals, antiparasitic agents, prebiotics/probiotics supplements in the 6 months prior to the start of the study.
use of probiotic food products like probiotic yoghurt and/or probiotic (dairy) drinks in the two weeks prior to the start of the study and during the study. Examples of these products are: Actimel, Activia, Kefir, Yakult. Prebiotic supplements and probiotic supplements are also not allowed.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-11-2019

Enrollment:	44
Type:	Actual

Ethics review

Approved WMO Date:	18-10-2019
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	20-12-2019
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT03959722
CCMO	NL69974.081.19