Modulation of the intestinal microbiome, and its effects on endurance exercise capacity in moderately trained individuals

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

Summary

ID

NL-OMON49125

Source
ToetsingOnline

Brief title
Intestinal microbiome modulation and endurance exercise

Condition

- Other condition

Synonym
exercise performance

Health condition

spierfunctie

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: endurance exercise, intestinal microbiome modulation, prebiotics

Outcome measures

Primary outcome

The most important parameter is the outcome of the exercise test until

exhaustion.

Secondary outcome

- the fecal microbiota

- biomarkers of metabolic health; fasting glucose, insulin and SCFA

- SCFA concentration in the droppings

- permeability of the intestines after a single exercise test

- permeability of the intestines after intervention

Study description

Background summary

Nutritional advice for athletes before, during and after exercise has been well established. In practice an athlete's diet consists mainly of simple and easily digestible carbohydrates and relatively few fibers. This is associated with a reduced diversity of the gut microbiota. The role of the composition of the gut microbiota has long been underestimated, but in recent years it is brought to the attention that the possible influence exerted by gut microbiota composition on skeletal muscle metabolism and function works through the gut-muscle axis. Previous animal studies have shown that a change in gut microbiota directly affects the composition and functioning of skeletal muscle. through the

production of SCFA. These, once included in circulation, could potentially act as endocrine mediators with a significant impact on metabolism and skeletal muscle function. Therefore, we will investigate if the intake of prebiotics can result in increased SCFA production which may lead to enhanced exercise performance.

Study objective

The primary objective of this study is to investigate the effect of a six-week period personalized food intervention with prebiotic supplementation on intense exercise performance in healthy, recreationally active adults.

Further, this study has five secondary objectives:
- First to compare the effect of six weeks daily prebiotic supplementation on intestinal microbiota.
- Second, to compare the effect of six weeks daily prebiotic supplementation on biomarkers of metabolic health.
- Third, to compare the effect of six weeks daily prebiotic supplementation on faecal SCFA concentration.
- Fourth, to determine to what extend a single bout of intense endurance exercise affects intestinal permeability.
- Fifth, to assess whether six weeks of daily prebiotic

Study design

This study has a single blinded, randomized, placebo-controlled, parallel design

Intervention

The intervention will be carried out with 5 different prebiotics supplements suitable for human consumption. Thefollowing prebiotics are selected (commercially available):
1. Dietary intake or galacto-oligosaccharides (GOS).
2. Dietary intake or resistant starch from potatoes (RPS).
3. Dietary intake or Fructo-oligosaccharides (FOS)
4. Dietary intake or arabinoxylo-oligosaccharides (AXOS)
5. Dietary intake or inulin.
The placebo product contains only maltodextrin.
The products are given to the participants during an intervention period of 6 weeks. Participants must take test products twice a day.

Study burden and risks

There are small burdens volunteers can experience during this study. After the screening visit, participants will have to visit the Metabolic Research Unit

Maastricht five times. In total, a participant will spend approximately 2 hours at the university facility. They will have to take prebiotic supplementation two times daily for a time period of six weeks; the supplements used have been proven to be safe for human use. During three visits spread over 7 weeks, a total of 54 mL blood will be sampled by venepuncture via an evacuated tube system, which may lead to minor discomfort and/or a small hematoma at the site of puncture. During two of these visits an intense exercise test will be performed. Before the start of the study, a VO2max test will be performed. The performance tests can possibly lead to muscle soreness for up to two days. Subjects will bring faecal samples which is collected at home. Moreover, questionnaires will have to be filled out at several occasions during this study. Except general information about their health status during the screening visit, subjects may not perceive direct benefits as a result of participating in this trial, since effects may be small and of temporary nature. An indirect effect of this study will be the insights which will be gathered about the effectiveness of the study product, and this may contribute to development in new food products for healthy and diseased humans.

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

1. Aged from 18- 40 years
2. 18.5 < BMI < 25 kg*m-2
3. Weight-stable for at least 90 days prior to participation (no change in bodyweight, i.e. < 3kg).
4. Recreational active (performing non-competitive physical endurance exercise at least two times per week with a minimum duration of 60 minutes per exercise bout)

Exclusion criteria

1. Smoking
2. Performing regular resistance training (3+ times per week, carrying out progressive training)
3. Subject following an overly imbalanced or restrictive diet as per nutritional advice
4. Concurrent systemic disease and/or laboratory abnormalities considered by investigators to be detrimental for the participants safety or potentially interfering with the study procedures and/or study outcome
5. Hypertension (according to WHO criteria) and/or cardiovascular disease
6. Abdominal surgery interfering with gastrointestinal function, upon judgement of the medical doctor, who will decide in-or exclusion based on the surgery applied
7. Participants who received antibiotics in the previous 90 days to the start of study
8. Use of other medication will be reviewed by a medical doctor, who will decide on in- or exclusion based on the drug(s) used
9. Use of laxatives within 14 days prior to the study
10. Using medications for gastric or intestinal complaints
11. Drug use, interfering with any of the outcome parameters of this study; to be decided by the person who is medically responsible for this study
12. Self-admitted lactose intolerance
13. Having donated blood in the 3 months prior to the study
14. Administration of probiotic or prebiotic supplements, investigational drugs or participation in any scientific intervention study, which may interfere with this study (to be decided by the principle investigator), in the 14 days prior to the study

15. History of side effects towards intake of prebiotic supplements
16. Use of proton pump inhibitors

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2021
Enrollment:	34
Type:	Actual

Ethics review

Approved WMO

Date:	27-08-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL73083.068.20