

Personalized diets for treatment of fatty liver and central obesity

Submission date 20/06/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/06/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/06/2024	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Dietary interventions are a new and promising way to treat hepatic steatosis, which is the buildup of fat in the liver, and visceral adiposity, which is the buildup of fat around the central organs in the body.

One type of dietary treatment involves prebiotics. Prebiotics are types of fiber and resistant carbohydrates that affect the gut microbiome. The gut microbiome consists of trillions of bacteria, yeast, and other microbes living in the intestine.

Our research focuses on the potential of xylo-oligosaccharides (XOS), a type of fiber, to treat these conditions. We also study how this prebiotic affects the gut microbiome and identify who might benefit the most from these interventions.

Who can participate?

Our study recruited overweight or obese adults aged 18 - 75 years

What does the study involve?

Participants ingest a dose of XOS daily for four months, preceded by 1 month without XOS. We measured their body composition and liver fat content in three time points and also collected blood and fecal samples to study the gut microbiome.

What are the possible benefits and risks of participating?

Participants receive potential health benefits from the dietary intervention and receive comprehensive information about their health and wellbeing. A possible adverse effect of XOS is gastrointestinal distress. Participants are inquired about adverse effects weekly and can opt out at any time.

Where is the study run from?

Research Council of Finland

When is the study starting and how long is it expected to run for?

January 2019 to June 2020

Who is funding the study?
Research Council of Finland
Juho Vainio Foundation (Finland)
Sydäntutkimussäätiö (The Finnish Foundation for Cardiovascular Research)

Who is the main contact?
satu.p.pekkala@jyu.fi
jukka.e.hintikka@jyu.fi

Contact information

Type(s)

Public, Principal investigator

Contact name

Dr Satu Pekkala

ORCID ID

<https://orcid.org/0000-0003-3107-0813>

Contact details

Faculty of Sport and Health Sciences
Po. Box 35 (LL225)
Jyväskylä
Finland
40014
+358 453582898
satu.p.pekkala@jyu.fi

Type(s)

Scientific

Contact name

Mr Jukka Hintikka

ORCID ID

<https://orcid.org/0000-0002-0481-1957>

Contact details

Faculty of Sport and Health Sciences
Po. Box 35 (LL205)
Jyväskylä
Finland
40014
+358 408055162
jukka.e.hintikka@jyu.fi

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

jyu-resd.172576021

Study information

Scientific Title

Personalized diet intervention to treat fatty liver and visceral adiposity

Acronym

MAKSA

Study objectives

XOS intervention manipulates the gut microbiome and benefits hepatic health in overweight responsive individuals

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 27/11/2019, Ethics Committee of the Hospital District of Southwest Finland (P.O. Box 52, Turku, 20251, Finland; +358 504383708; eettinen.toimikunta@varha.fi), ref: ETMK 72/2019

Study design

Single group controlled experimental study

Primary study design

Interventional

Study type(s)

Other, Quality of life

Health condition(s) or problem(s) studied

Overweight, non-alcoholic fatty liver disease

Interventions

Prebiotic nutritional supplementation: xylo-oligosaccharides 2.8 g daily in powder form. Each participant went through a 1-month control period, followed by 4 months of dietary intervention.

Intervention Type

Supplement

Primary outcome(s)

Change in liver fat, assessed with MRI at baseline (0), pre-intervention (4 wks), and post-intervention (16 wks)

Key secondary outcome(s)

1. Responses in gut microbial composition or diversity, measured with 16S rRNA sequencing at baseline (0), pre-intervention (4 wks), and post-intervention (16 wks)
2. Determinants of response to the prebiotic, measured with microbiome, metabolome, GWAS at baseline (0), pre-intervention (4 wks), and post-intervention (16 wks)

Completion date

01/06/2020

Eligibility

Key inclusion criteria

1. Age 18<75years
2. Being overweight (body mass index [BMI] >25 kg/m²)
3. High waist circumference (>102cm for males, >88cm for females)

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

75 years

Sex

All

Total final enrolment

49

Key exclusion criteria

1. Antibiotic treatment 1 month prior to the study
2. Excessive alcohol consumption (>20 g/day for females, 30 g/day for males)
3. Inflammatory bowel disease
4. Celiac disease
5. Major eating disorders
6. Hypothyroidism

Date of first enrolment

01/01/2020

Date of final enrolment

01/02/2020

Locations

Countries of recruitment

Finland

Study participating centre

University of Jyväskylä, Faculty of Sport and Health Sciences

Rautpohjankatu 8

Jyväskylä

Finland

40700

Sponsor information

Organisation

Academy of Finland

ROR

<https://ror.org/05k73zm37>

Funder(s)

Funder type

Research council

Funder Name

Research Council of Finland

Alternative Name(s)

Academy of Finland, Suomen Akatemia, Finlands Akademi, AKA

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

Location

Finland

Funder Name

Juho Vainio Foundation

Alternative Name(s)

Academy of Finland, Suomen Akatemia, Finlands Akademi, AKA

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

Location

Finland

Funder Name

Sydäntutkimussäätiö

Alternative Name(s)

Finnish Foundation for Cardiovascular Research

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Finland

Results and Publications

Individual participant data (IPD) sharing plan

Restricted use due to personal information protection. You can still contact author to ask for a copy of the material.

Metadata for the project is shared at <https://doi.org/10.17011/jyx/dataset/85068>

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article		30/01/2023	20/06/2024	Yes	No
Other unpublished results			20/06/2024	No	No