# Personalized diets for treatment of fatty liver and central obesity

Submission date 20/06/2024	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>		
		<pre>Protocol</pre>		
Registration date 26/06/2024	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 25/06/2024	<b>Condition category</b> Digestive System	[] 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

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#### Type(s)

Scientific

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# Additional identifiers

# EudraCT/CTIS number

#### **IRAS** number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

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

# Secondary study design

Non randomised study

# Study setting(s)

Home

# Study type(s)

Other, Quality of life

## Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

# 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 measure

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

#### Secondary outcome measures

- 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)

#### Overall study start date

01/01/2019

#### Completion date

01/06/2020

# **Eligibility**

# Key inclusion criteria

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

# Participant type(s)

Healthy volunteer

## Age group

Adult

#### Lower age limit

18 Years

## Upper age limit

75 Years

#### Sex

Both

#### Target number of participants

50

#### Total final enrolment

#### 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 Jyvaskyla, Faculty of Sport and Health Sciences

Rautpohjankatu 8 Jyvaskyla Finland 40700

# Sponsor information

#### Organisation

Academy of Finland

#### Sponsor details

Hakaniemenranta 6 PL 131 Jyväskylä Finland 00531 +358 29 533 5000 kirjaamo@aka.fi

#### Sponsor type

Research council

#### Website

https://www.aka.fi/

#### **ROR**

https://ror.org/05k73zm37

# Funder(s)

#### Funder type

Research council

#### **Funder Name**

Research Council of Finland

#### Alternative Name(s)

Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

#### **Funding Body Type**

Government organisation

# **Funding Body Subtype**

Universities (academic only)

#### Location

**Finland** 

#### **Funder Name**

Juho Vainio Foundation

#### Alternative Name(s)

Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

#### **Funding Body Type**

Government organisation

#### Funding Body Subtype

Universities (academic only)

#### 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**

#### Publication and dissemination plan

First publication on cross-sectional data: 2023 (status: published doi.org/10.1128/mbio.02663-22) Longitudinal study results 2024 (in preparation)

# Intention to publish date

01/08/2024

#### 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