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Personalized diets for treatment of fatty liver and central obesity

Submission date 20/06/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/06/2024	**Overall study status** Completed	
Last Edited 25/06/2024	**Condition category** Digestive System	

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
http://orcid.org/0000-0003-3107-0813

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

Type(s)
Scientific

Contact name
Mr Jukka Hintikka

ORCID ID
http://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

EudraCT/CTIS number

Nil known

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/m²
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