Targeted PRECIsion NUTrition strategy to prevent chronic metabolic diseases

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lipid metabolism disorders
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57311

Source
ToetsingOnline

Brief title
The PRECINUT-study

Condition

- Lipid metabolism disorders
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
adult-onset diabetes, obesity, overweight, Type 2 diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Vakministerie

Intervention

- Food (substances)

Keyword: Glucose homeostasis, Insulin sensitivity, Metabolism, Personalized nutrition

Explanation

N.a.

Outcome measures

Primary outcome

Extensive characterization will be done before, during, and after the intervention. Primary outcome measure is whole-body insulin sensitivity (Matsuda index) assessed by means of a 7-point oral glucose tolerance test (OGTT).

Secondary outcome

Secondary outcomes include glycaemic variability, mean glucose levels, fasting lipid profiles, body composition, blood pressure, gene and protein expression of adipose tissue, microbial composition and functionality, metabolomics, physical activity, adherence to dietary recommendations, (mental) well-being, and quality of life.

Study description

Background summary

Worldwide, the prevalence of obesity, type 2 diabetes mellitus (T2DM), cardiometabolic diseases as well as an impaired mental health and depression has grown dramatically over the past decades. Currently employed general population-based guidelines for healthy nutrition have only proven effective in reducing type 2 diabetes (T2DM) incidence in individuals with prediabetes by up to 50%. Notwithstanding, a significant 30% of participants within these programs do not respond or adhere to such interventions. Recent studies indicate that precision nutrition interventions, tailored to metabolic phenotypes (metabotypes) with distinct T2DM aetiologies, yield superior outcomes in blood glucose control, and potentially enhance intervention adherence.

We hypothesize that the use of a precision nutrition intervention strategy, based on Metabotypes identified by an unsupervised clustering (machine learning) of prespecified accurate prediabetic state features/variables, will
improve blood glucose homeostasis and cardiometabolic risk status, as well as adherence to the intervention and (mental) well-being compared to population-based dietary guidelines.

The present project will contribute to
targeted and efficient precision-based dietary strategies for individuals at increased risk of T2DM.

Study objective

Our study aims to identify unique Metabotypes among individuals with overweight at risk of T2DM and assess their response to a 1-year precision dietary macronutrient modulation. The objective is to provide proof-of-concept that this approach improves glucose homeostasis, dietary adherence, and psychosocial well-being compared to population-based dietary guidelines.

Study design

Two-centre dietary intervention study with a double-blind, randomized controlled parallel design, based on participants* Metabotype and hypothesized optimal diet. Participants* Metabotype and intervention arm will be blinded to the participants and researchers. Metabotypes were identified through hierarchical clustering of Principal Components (HCPC) using baseline data from The Maastricht Study (participant demographics, body composition, glucose- and insulin metabolism), whereafter clusters were cross-validated in independent cohorts. Based on a combination of post-hoc analyses of dietary intervention trials and literature, for these metabotypes the optimal dietary macronutrient composition was determined.

Intervention

Following screening, baseline measurements, and determination of Metabotype, participants will be randomly assigned, using minimization, to either the Precision Nutrition (PN) group or the Control (CN) group. The PN group will receive a hypothesized optimal diet for their specific Metabotype, while the control group will be randomly assigned one of the diets optimized for a different Metabotype of the same sex. All participants will follow their assigned diets for 12 months, with each diet conforming to the Dutch healthy dietary guidelines (Gezondheidsraad, 2015).

Study burden and risks

Burdens that participants may experience include the time they need to invest in the study and the dietary restrictions during the 12-month intervention period. The total time investment during the both Characterization Week (CW) measurements will be around 8,75 hours, divided over 2 university visits and 13 days of intermediate assessments at home. Additionally, the participants will be asked to report to the University at months 1, 3, 6 and 9 and record dietary intake at home on three non-consecutive days before the visit. During the visit at 6 months, classification measurements (OGTT and DXA) will be performed again. In total, these intermediate visits will require time investment of approximately 13 additional total hours. The total study period, including screening and intervention will be approximately 13 months.

The following burdens or risks may be associated with participation:
• Wearing the continuous glucose monitor (CGM) and physical activity (PA) monitor may be considered a burden. However, previous experience has shown that most participants do not experience this as a burden. Current CGMs no longer require regular calibration by finger-prick and capillary blood glucose measurement, reducing any potential experienced burden on participants.
• The collection of faeces and urine may be considered a burden. However, based on previous experience, this procedure is quite feasible.
• Throughout the study, questionnaires will be completed and food intake will be record-ed periodically by means of a mobile app (Traqq) during daily life, which requires an extra time investment.
• During the test days, blood will be collected via a venous catheter. Venapunctures can occasionally cause a local hematoma or bruise. Some participants in previous studies reported pain during a venapuncture.
• Adipose tissue (AT) biopsies will be taken twice (pre-, post-intervention and at 6-months in MUMC+ only). An adipose tissue biopsy may cause local hematoma. Compressing the biopsy site for approximately 10 minutes will reduce the risk of developing hematoma. Discomfort during the procedure itself is minimized due to the use of local anaesthetics, although participants may experience pressure during the introduction of the needle. The incision will leave a small scar (~3 mm). To promote good wound heal-ing, the incision will be sealed with steristrips and a waterproof band-aid.
• No risks are known about the OGTT. This measurement is routinely applied in human metabolic research, and SOPs are available in the database of our department.
• The total radiation dose participants will be exposed to during the three DXA scans is <30 µSv. Since the average yearly radiation dose per person in the Netherlands is ap-proximately 2.9 mSv, the amount of radiation exposure during DXA scans is negligible.
• Dietary products provided during the intervention are widely used and freely available to consumers. Both the composition of the diets and individual food products will not cause discomfort for the participants and are in line with the Dutch healthy dietary guidelines (Gezondheidsraad 2015).

Aside from receiving information about their health status, participants are provided with specific foods that may be beneficial and may support adherence to the intervention diets or general guidelines. Furthermore, since the prevalence of overweight and cardio-metabolic disorders is continuing to rise, study outcomes could provide future health benefits for the general public. In addition, the diets that the participants will follow are advantageous to overall health.

Contacts

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Trial sites

Trial sites in the Netherlands

Universiteit Maastricht
Target size: 120

Wageningen Universiteit
Target size: 120

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Men and women with overweight and obesity (age 40-75 years, BMI 25-40 kg/m2), without (Pre-)diagnosis of type 1 or type 2 diabetes mellitus. Stable body weight for at least 3 months (+/-3 kg).

Exclusion criteria

- (Pre-)diagnosis of type 1 or type 2 diabetes mellitus (i.e., FPG >= 7,0 mmol/L) and HbA1c >= 6,5% (48 mmol/mol)

- Renal or hepatic malfunctioning (pre-diagnosis or determined based on ALAT and creatinine values)
- Gastrointestinal diseases or abdominal surgery (allowed i.e.: appendectomy, cholecystectomy)
- Food allergies, intolerances (including gluten/lactose intolerance) and/or eating disorders interfering with the study
- Cardiovascular diseases (e.g., heart failure) or cancer (e.g., non-invasive skin cancer allowed)
- High systolic blood pressure (untreated >160/100 mmHg, drug-regulated >140/90 mmHg)
- Diseases affecting glucose and/or lipid metabolism (e.g., pheochromocytoma, Cushing*s syndrome, acromegaly)
- Diseases with a life expectation shorter than 5 years
- Major mental disorders
- Drug treated thyroid diseases (well substituted hypothyroidism is allowed inclusion)
- Other physical/mental conditions that may interfere with study outcomes
- Medication known to interfere with study outcomes (e.g., PPAR-α or PPAR-γ agonists (fibrates), sulfonylureas, biguanides, α-glucosidase inhibitors, thiazolidinediones, repaglinide, nateglinide, insulin, and chronic use of NSAIDs)
- Use of certain anticoagulants other than acetylsalicylic acid
- Use of antidepressants (stable use >= 3 months prior to and during study allowed)
- Use of statins (stable use >= 3 months prior to and during study allowed)
- Chronic corticosteroids treatment (*7 consecutive days of treatment)
- Use of antibiotics within 3 months prior to the study
- Participation in regular sports activities (moderate-to-vigorous physical exercise >4 hours per week)
- Having a restricted dietary pattern interfering with the study diets (e.g., vegetarian, vegan, Atkins diet and/or other special diets)
- Plans to lose more than 5% body weight
- Abuse of alcohol (alcohol consumption >14 units/week) and/or drugs (cannabis included)
- Not willing to limit alcohol consumption to 7 drinks per week
- Regular smoking (including use of e-cigarettes)
- Use of strong vitamins or other dietary supplements (e.g., pre- or probiotics) expected to interfere with the study outcomes
- Metabotype classification is not possible
- Pregnant or lactating women, or women who are planning to become pregnant
- Inability to comply with the study diet
- Participation in possibly interfering studies within the last 3 months
- Inability to understand study information and/or communicate with staff
- Unwillingness to be randomized or sign informed consent
- Unwillingness to save data for 15 years

- Deemed unsuitable for participation in the trial, for any reason, as judged

by the research physician or principal investigator

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Other type of control
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-04-2025
Enrollment:	300
Duration:	13 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.
Registration:	No

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO

Date:	21-02-2025
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-03-2025
Application type:	Amendment
Review commission:	METC AZM/UM

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	NCT ID not yet assigned
CCMO	NL87817.068.24
Research portal	NL-005200