The effect of alternating energy intake compared to regular energy intake on the fat content in the blood after a meal in abdominally obese adults

Published: 03-02-2021
Last updated: 08-04-2024

The primary objective is to compare the effect of a 4-week alternating energy intake schedule to a 4-week regular energy intake schedule on the postprandial triacylglycerol (TAG) response to a mixed meal in adults with abdominal obesity. Secondary…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lipid metabolism disorders
Study type	Interventional

Summary

ID

NL-OMON52304

Source
ToetsingOnline

Brief title
Alternating energy intake and blood fat content after a meal

Condition

- Lipid metabolism disorders

Synonym
'Lipid metabolism' and 'postprandial lipemia'

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Energy intake, Glucose metabolism, Lipid metabolism, Variability

Outcome measures

Primary outcome

The primary endpoint of the study is the difference in the area under the curve (AUC) for TAG after a mixed meal challenge between the end of the 4-week alternating and regular eating schedules. Secondary endpoints include fasting lipid metabolism, fasting glucose metabolism, and postprandial glycaemic responses.

Secondary outcome

Glucose metabolism:

- Fasting glucose, insulin, and C-peptide concentrations

From the CGM:

- The total area under the curve (tAUC) for 24-hour glucose, day-time glucose (07:00 am * 22:00 pm), and night-time glucose (22:01 pm * 06:59 am).

- The tAUC for glucose during 2 hours after main meal consumption (breakfast, lunch and dinner)

- The mean amplitude of glycemic excursions (MAGE) as parameter for the assessment of glycemic variability.

- Continuous overall net glycemic action (CONGA) to assess intraday glucose variability within predetermined time windows -> 1-hour interval (CONGA-1), 2-hour interval (CONGA-2), and 4-hour interval (CONGA-4).

From the mixed meal (postprandial responses):

- TAG iAUC, maximal increase TAG, time to peak TAG

- NEFA AUC, NEFA dAUC, maximal decrease NEFA, time to nadir NEFA

- Glucose AUC, glucose iAUC, maximal increase glucose, time to peak glucose

- Insulin AUC, insulin iAUC, maximal increase insulin, time to peak insulin

- C-peptide AUC, C-peptide iAUC, maximal increase C-peptide, time to peak C-peptide

Lipid metabolism:

- Fasting serum lipid and lipoprotein profile (TC, HDL-C, LDL-C, TAG)

- Fasting serum non-cholesterol sterols as markers for intestinal cholesterol absorption (campesterol, sitosterol, cholestanol) and endogenous cholesterol synthesis (lathosterol and desmosterol)

Study description

Background summary

Increasing evidence suggests that meal timing affects metabolic health. For example, intermittent fasting (IF) may have positive effects on plasma glucose levels, insulin sensitivity, plasma lipids, and blood pressure. However, IF protocols often result in significant weight loss. Therefore, it is not clear to what extent these beneficial metabolic effects are due to IF or to weight loss. Although the effect of IF independent of weight loss has been studied, daily energy intake in those studies did not differ between the days. Therefore, we here propose to examine the effect of alternating energy intake * i.e. standardized day-to-day fluctuations in energy intake * on metabolic health independent of weight loss.

Study objective

The primary objective is to compare the effect of a 4-week alternating energy

intake schedule to a 4-week regular energy intake schedule on the postprandial triacylglycerol (TAG) response to a mixed meal in adults with abdominal obesity. Secondary objectives include fasting lipid metabolism, fasting glucose metabolism, and postprandial glycaemic responses.

Study design

A randomized, single-blind, cross-over study will be carried out. The total study duration will be at least 12 weeks, including an intervention and comparison period of 4 weeks each, separated by a washout period of at least 4 weeks.

Intervention

Participants will be randomly allocated to start with a 4-week alternating energy intake schedule or a 4-week regular energy intake schedule. Participants in the alternating energy intake schedule will be asked to alternate between caloric overconsumption (i.e. 130% of their total energy needs) and caloric underconsumption (i.e. 70% of their total energy needs) for 6 days/week followed by one ad libitum day/week. Participants in the regular energy intake schedule will be asked to consume their habitual energy intake to maintain a stable bodyweight (i.e. 100% of total energy needs) for 6 days/week followed by one ad libitum day/week.

Study burden and risks

Before the start of the study, subjects will be screened to determine eligibility during a 30 min visit. During this visit, bodyweight, height, hip and waist circumference, and blood pressure will be measured, and a fasting blood sample (5.5 mL) will be drawn by means of venapunction. Thereafter, participants will be asked to fill in a medical, general, and physical activity questionnaire.

During the study, participants will come to the University for an assessment of outcome measures on day 1, day 14, day 21, and the last three days of the 4-week eating schedule. On all visits, except for day 21, a fasting blood sample will be drawn (with a total of 70 mL spread over the 6 visits), and bodyweight, height, hip and waist circumference, and blood pressure will be measured. On day 21, anthropometrics will be performed and a continuous glucose monitor (CGM) will be attached to the upper-arm of the participant to measure interstitial glucose concentrations for 9 or 10 days. The CGM will be removed at the end of the 4-week eating schedule (day 30 or 31).

At the end of both eating schedules (i.e. on day 30 or 31) participants will come to the university for a mixed meal test. For this test, an intravenous cannula will be inserted in the antecubital vein, and blood samples will be

collected 0, 15, 30, 45, 60, 90, 120, 180, and 240 minutes (81 mL) after meal consumption.

All participants will register food intake twice a week in a diary, and report any signs of illness, medication used, and deviations from the protocol. On rare occasions, blood sampling may cause bruises or hematoma. Total time investment for the participants will be approximately 17 hours and 45 minutes.

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

* Apparently healthy men and women as judged by study physician
* Abdominally obese males (waist circumference * 102 cm) and females (waist

circumference * 88 cm)
* Aged between 18 * 75 years
* Stable bodyweight (weight gain or loss * 3 kg in the past three months)
* Willingness to give up being a blood donor (or having donated blood) from 8 weeks before the start of the study, during the study and for 4 weeks after completion of the study
* Women should be pre- or postmenopausal
* No difficult venipuncture as evidenced during the screening visit
* Sedentary (light exercise < 1 h per week) or moderately active (moderate exercise 1-2 h per week)
* Having a general practitioner
* Agreeing that the participant and general practitioner will be informed about medically relevant personal test results by a physician
* Willing to comply to study protocol during study
* Informed consent signed

Exclusion criteria

* Fasting plasma glucose * 7 mmol/l
* Fasting serum triacylglycerol * 4.5 mmol/l
* Fasting serum total cholesterol * 8 mmol/l
* Blood pressure * 160/100 mm Hg
* Current smoker, or smoking cessation < 12 months
* Drug abuse
* Alcohol abuse (* 21 alcohol consumptions per week)
* Use of medication known to affect blood pressure, serum lipid metabolism, or glucose metabolism
* Having a medical condition or history which might impact study measurements, to be judged by the study physician (e.g. myocardial infarction, angina, thrombosis, stroke, cancer, familiar hypercholesterolemia, liver or bowel disease or diabetes)
* Active cardiovascular disease like congestive heart failure or cardiovascular event, such as an acute myocardial infarction or cerebrovascular accident
* Use of an investigational product within another biomedical intervention trial within the previous 1-month
* Women who are perimenopausal, have an irregular menstrual cycle, or are pregnant
* Use of over-the-counter and prescribed medication, which may interfere with study measurements (to be judged by the principal investigator), e.g. weight loss medication
* Reported dietary habits: medically prescribed diets or slimming diets
* Reported participation in night shift work 2 weeks prior to screening and/or during the study. Night work is defined as working between midnight and 6.00 AM

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2021
Enrollment:	23
Type:	Actual

Ethics review

Approved WMO Date:	03-02-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-11-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-05-2022
Application type:	Amendment
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
Other	Het onderzoek is in Clinicaltrials.gov geregistreerd onder NCT04894526.
CCMO	NL74940.068.20