The impact of eating rate of ultra-processed foods on dietary behaviour

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The primary objective of this study is to determine the role of eating rate of ultra-processed food (14 day) diets in moderating ad libitum energy intake over time.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55899

Source
ToetsingOnline

Brief title
REVAMP study

Condition

- Other condition

Synonym
overweight and obesity

Health condition

overgewicht en obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: GB foods,General mills,Nestlé Research,Tate

and Lyle,TKI top sector agri-food research funds "Restructure project" ,Unilever

Intervention

Keyword: Body composition, Dietary behaviour, Eating rate, ultra-processed foods

Outcome measures

Primary outcome

The main outcome measure is the average (across two weeks) daily energy intake (kcal/day) in each diet arm

Secondary outcome

Secondary study parameters include: food (gram) ,energy (kcal) and nutrient (gram, EN%) intake in gram and kcal on the level of the food, meal day and week, pre-, and post meal appetite, body weight and body composition changes and distribution fat mass vs fat free mass, changes in postprandial hormone responses and respiratory quotient to a mixed meal tolerance test as a marker of metabolic flexibility, changes in blood pressure, continues glucose levels and long term satiety hormones (leptin, ghrelin),

Study description

Background summary

Consumption of industrially processed foods has been associated with obesity and related adverse health outcomes. Yet it is unknown what properties of industrially processed foods drive this association. Extensive research has shown that foods that can be consumed more quickly, lead to higher food intakes and this has been suggested as one of the ways in which processed foods promote excess in calorie intakes. We therefore hypothesize that food texture moderates energy intakes from processed foods.

Study objective

The primary objective of this study is to determine the role of eating rate of ultra-processed food (14 day) diets in moderating ad libitum energy intake over time.

Study design

We will conduct a randomized controlled cross-over trial with 2 treatment arms, examining the effects of a ultra-processed slow eating rate (UPFslow) diet versus a ultra-processed fast eating rate (UPFfast) diet on ad libitum energy intake. The study will have a run-in period to determine habitual dietary habits (baseline) and a washout period in between the two treatments to prevent carry-over effects. All participants will receive both treatments and are their own control (within participant design).

Intervention

The two treatments are 1) a 14-days ultra-processed slow eating rate diet, and 2) a 14-days ultra-processed fast eating rate diet. During the treatment period participants will eat all of their main meals in the research diner room on week days and will receive pre-packed meals to consume at home for the weekends. Meals will be served ad-libitum, meaning in portions that are > 200% of a regular portion size. Participants are asked to eat until they feel comfortably full. In between the treatment periods there will be a 14-day wash-out period.

Study burden and risks

The risk associated with participation is negligible and the burden can be considered as high. Participant have to attend one information session, a screening and will participate in a baseline week, two times a 2 week intervention period, and a 2 week washout period. During the intervention weeks, participants have to consume all of their main meals at the study site on week days. During the weekends of the intervention period participants will be asked to consume only the pre-packed weekend meals and bring back the remaining after the weekend. Participants will be asked to wear a glucose monitor during the two- 2 week intervention periods. During the baseline, intervention and washout weeks participants will be asked to wear an accelerometer and during the baseline and washout week they will be asked to log their dietary intake in an app. Additionally we will collect different types of bio-samples (blood, feces faecal and urine) which is burdensome for the participant to collect. Participants will receive financial compensation for their time and effort and will receive free meals for a total duration of 1 month. In demonstrating the impact of eating rate in moderating energy intakes from processed foods, the project will provide *design rules* on the application of texture to different product portfolios, and encourage the application of texture innovations to slow the rate of calorie intake. To

summarize, this project provides insight in whether or not processed foods can be part of healthy diet or whether some foods may be avoided or (re)formulated to ultimately promote health and prevent chronic diseases.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Between 21-50 years old at the day of inclusion
- Being able to read and understand English
- BMI 21-27 kg/m2
- Good general and mental health and appetite (self-report)
- Commonly (5 out of 7 week days) eating three meals a day around approximately the same times (self-report).

Exclusion criteria

- Difficulties with swallowing, chewing and/or eating in general - Suffering from an endocrine or eating disorder, gastrointestinal illness or illness of the thyroid gland, cardio-vascular diseases, bowel diseases, respiratory disease, neurological diseases, or diabetes, anaemia, cancer, or psychiatric conditions such as clinical depression, burnout or anxiety or bipolar disorder. - Having a history of low blood pressure - Having taste or smell disorders self-report - Braces (not including a dental wire) or oral piercing - Followed an energy restricted diet during the last 2 months - Currently using or in the past 3 months (calculated from the first day of the study) used prebiotics supplements, probiotic supplements and/or antibiotics - Gained or lost 5 kg of body weight over the last half year - High restrained eater (DEBQ restrained eater scale >= 2.90 for males and >= 3.40 for females [23])* - Use of medication, including but not limited to hormone therapy or medications that affect the immune system or any medication that influences study outcomes such as food intake, appetite in general or metabolic responses (self-report) - Consuming on average more than 21 (men) or 14 (women) glasses of alcohol per week - Pregnant or lactating women, or women who are planning on becoming pregnant within the study period. - Smoking (daily) - Not willing to stop using drugs during the study period (from inclusion till last test session) - Not willing to stop consuming alcohol during the intervention weeks - Exercising more than 4 hours per week (excluding biking and walking at a normal pace and distance) - Following a vegetarian or vegan diet - Allergies or intolerance to any ingredient of the test meals - Not willing to eat the test food because of eating habits or believes - Do not like > 20% of the test foods or its ingredients based on pictures and descriptions of the meal (scoring items <= dislike on a nine point likert scale)* - Majority > 50% of dietary food intake (g) is derived from ultra-processed foods (based on a food frequency questionnaire (FFQ) based on normative data collected in pre-trial.* The 50% cut-off is based on median intake of UPFs in Dutch cohort studies - Being unfamiliar with > 25% of the test meals - Signed up for participating in another research study - Being an employee or thesis student of the Division of Human Nutrition and Health at Wageningen university - Radiological investigation during past 7 days where iodine or barium containing contrast fluids have been used (DEXA contra-indication) - Nuclear medical investigation involving isotopes during past 7 days (DEXA contra-indication) Exclusion after screening: - HB value is not between 7.5-11.0 mmol/L (women), 8.5-11.0 mmol/L (men) - Fasted glucose level is below > 3.5 mmol/L or higher than 8 mmol/L - Blood pressure is below 90/60 mm hg (below 90 and/or below 60 mm hg) - Veins are not suited for blood sampling (as judged by trained research nurses) - Persons with little difference (< 20%) in the eating rate of a hard and soft carrot. - Do not like > 20% of the test foods based tasting small portions (1 bite) of each of the meals (scoring items below <= dislike on a nine point Likert scale)* * This exclusion criterion will not explicitly be communicated

to the participants to prevent desirable answers

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2023
Enrollment:	39
Type:	Anticipated

Ethics review

Approved WMO Date:	30-09-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-12-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL83462.091.23