Sweet tooth: Nature or Nurture? Role of long-term dietary sweetness exposure on sweetness preferences

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To assess the effect of a 6-month regular, low and high dietary sweetness exposure on sweetness preferences, food intake, glucose homeostasis and body weight in healthy adults.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49646

Source
ToetsingOnline

Brief title
i-Sense study

Condition

- Other condition

Synonym
taste perception and liking

Health condition

smaakperceptie en voorkeur

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Arla Foods amba en Cargill R&D Centre Europe BVBA,Firmenich SA,International Sweeteners Association en American Beverage Association,Kenniscentrum Suiker & Voeding,SinoSweet en Unilever,TKI Agri & Food; Bournemouth University Higher Education Corporation Company;American Beverage Association;Arla Foods amba;Cargill R&D Centre Europe BVBA;Firmenich SA;International Sweeteners Association;SinoSweet Co.;Ltd;Stichting Kenniscentrum Suiker & Voeding and Unilever Research and Development Vlaardingen B.V.

Intervention

Keyword: intensity, liking, preferences, Sweetness

Outcome measures

Primary outcome

The difference in the change in most preferred sweetness concentration from

month 0 to month 6, measured with a preference test, between groups.

Secondary outcome

- Change in preferred sweetness intensity in a series of familiar and

unfamiliar foods from month 0 to month 1, 3, 6, 7 and 10;

- Difference in mean liking scores between familiar and unfamiliar foods at

baseline and at 1, 3, 6, 7 and 10 months;

- Change in sensory intensity scores at baseline and at 1,3, 6, 7 and 10

months;

- Change in energy intake (in kcal), measured during a test meal at baseline

and at 1, 3, 6, 7 and 10 months;

- Proportion of eaten sweet foods vs. foods from other taste modalities,

measured during a test meal at baseline and at 1, 3, 6, 7 and 10 months;

- Sweet-liker status score measured at baseline and at 1, 3, 6, 7 and 10

months;

- Food craving questionnaire scores, measured at baseline and at 1, 3, 6, 7 and 10 months;

- Taste preference questionnaire scores, measured at baseline and at 1, 3, 6, 7 and 10 months;

- Mean intake of foods based on taste modalities, measured with the Taste food frequency questionnaire at baseline and at 1,3, 6, 7 and 10 months;

- Body weight, measured with a weighing scale at baseline and at 1, 2, 3, 4, 5, 6, 7 and 10 months;

- Waist-to-hip ratio, measured using a stretch*resistant tape at baseline and at 1, 3, 6, 7 and 10 months;

- Body fat mass and lean body mass (fat free mass), measured with a DEXA at baseline and at 6, and 10 months;

- Variation in interstitial glucose (e.g. mean 24h glucose, area under the curve (AUC)) during several days, measured with glucose monitoring sensor at baseline and at 6 and 10 months (only measured in a subgroup, of 60 subjects, 20 per intervention arm);

- Change in biomarkers related to CVD & diabetes (e.g. fasting glucose. HbA1c, insulin, cholesterol, LDL cholesterol, HDL cholesterol, triglycerides), measured in blood at baseline and at 1, 3, 6, 7 and 10 months;

- Adverse events;

- Compliance.

Study description

Background summary

In recent years, social pressure has been exerted towards lowering sugar and sweetness levels in foods, with the aim of decreasing the sweetness preference of the general population. However, the resilience/flexibility of sweetness preferences and the impact on energy intake is a fundamental knowledge gap. Recent, relatively long-term studies did not find a relationship between sweetness exposure and sweetness preferences. Evidence supporting sweetness preference alterations via variations in dietary sweetness exposure is limited. Most studies investigating this focused only on specific sweet elements in the diet, (e.g. beverages; mono- and disaccharides; high-energy dense snacks) instead of sweetness in the diet as a whole. Furthermore, there is no clear evidence about the relation between dietary sweetness exposure and weight gain. Therefore, longer term, sufficiently-powered studies with a *whole diet* approach are needed to address the question whether sweet preferences can be altered (suppressed or stimulated) by variations in sweetness exposure. It is important to answer this question so that dietary recommendations can be tailored accordingly.

Study objective

To assess the effect of a 6-month regular, low and high dietary sweetness exposure on sweetness preferences, food intake, glucose homeostasis and body weight in healthy adults.

Study design

Randomized Controlled Trial with three intervention groups.Participants (n=180) will be matched on age, gender, BMI, dietary sweetness exposure in their habitual diet and sweet liker status and randomly allocated to one of the three intervention arms: (1) regular dietary sweetness exposure (control) (n=60); (2) low dietary sweetness exposure (n=60); and (3) high dietary sweetness exposure (n=60). The intervention is semi-controlled, meaning that 50 percent of the foods will be provided to participants. Foods are offered ad libitum, on a weekly basis and macronutrient composition of the offered foods is similar in energy and macronutrient composition, that is fat, protein, carbohydrates and fibers.

Intervention

Three intervention groups:
1. Regular dietary sweetness exposure (RSE) - The RSE group consumes a diet with 25 - 30 % energy from sweet tasting foods, for 6 months.

2. Low dietary sweetness exposure (LSE) - The LSE group consumes a diet with 10 - 15 % energy from sweet tasting foods, for 6 months.
3. High dietary sweetness exposure - The HSE group consumes a diet with 40 - 45 % energy from sweet tasting foods, for 6 months.

Study burden and risks

The risk associated with participation is negligible and the burden can be considered as high. Subject will be required to follow allocated diet regime for 6 months.

All foods provided to participants are commercially-available and safe for consumption. In this study sweetness exposure will be manipulated. The three groups will differ in sweet taste, which is not per se depending on their mono- and disaccharide content. The HSE is more sweet and thus will contain more free sugars and artificial sweeteners compare to the RSE and LSE diet. However, so far it has not been proven that this do not affects energy intake, diet quality or other health concerns (Rogers et al., 2016; Wittekind et al., 2018). Experienced research dieticians in this study will also ensure that all three diets contain all necessary (micro)nutrients.

Blood samples are taken by an experienced research nurse. Incidentally, a hematoma, feelings of dizziness, nausea or fainting due to fasting can occur, but the risks of these events are minimal. If during the study, concentration of, for example glucose, are outside the normal range and clinically relevant, subjects will be notified by the medical supervisor and advised to consult a general practitioner.

The subject*s burden regarding time is as follows; 60-minutes for information meeting, 60-minutes for screening, six times approx. 6 hours for a full-testing session, six times 24-hour urine collection, six times 24-hour recall (approximately 270 minutes) and approximately 125 minutes for consultation meetings with a dietician (1 time 45 minutes, 8 times 10 minutes), in the total period of 11 months.

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

- Good general health (self reported);
- Age 18 - 65 years;
- Body mass index 18.5 - 30 kg/m^2;
- Normal taste ability (assessed with taste strips test);
- Able to provide informed consent;
- Able to attend Wageningen University, as required for testing.

Exclusion criteria

- Diagnosed with diabetes currently or in the past;
- Has been notified to have insulin resistance currently or in the past;
- Diagnosed with endocrine diseases or other metabolic diseases that influence metabolism;
- Diagnosed with eating disorders;
- Diagnosed with taste or smell disorders;
- Pregnant or lactating during the study intervention;
- Gain or loss of more than 3 kg in the last 3 months prior to study entry;
- Suffering from lack of appetite (self-reported);
- Use of medication that may influence study results; such as medication that may affect blood sugar (medication use will be judged by medical investigator and self-reported);

- Having a food allergy or/and food intolerance for foods used in the preference testing (e.g. lactose intolerance, celiac disease, egg allergy)
- Participants who use soft- and hard drug;
- Participants who drink more than 14 glasses of alcohol per week;
- Student or personnel of Nutrition and Health at Wageningen University;
- Participating in another study/studies or planning to participate in another study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2020
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	28-07-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-10-2020
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
ClinicalTrials.gov	NCT04497974
CCMO	NL72134.081.19