Protocol for acute and repeated dose impact of sweeteners and sweetness enhancers on appetite-related behaviour, physiology, and health: a multi-centre, double-blind, cross-over, randomised, controlled trial in people with overweight/obesity. The SWEET project.

Supplemental Material 6: Trial Registration Data Set

Trial registration data	
Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT04633681
Date of registration in primary registry	November 2021
Secondary identifying numbers	N/A
Source(s) of monetary or material support	European Union Horizon 2020 Program
Primary sponsor	European Union Horizon 2020 Program
Secondary sponsor(s)	N/A
Contact for public queries	Professor Graham Finlayson (G.S.Finlayson@leeds.ac.uk)
Contact for scientific queries	Professor Graham Finlayson (G.S.Finlayson@leeds.ac.uk)
Public title	Impact of Sweeteners on Behaviour, Physiology & Health (SWEET-WP2-P2)
Scientific title	Acute and Repeated Impact of Sweeteners and Sweetness Enhancers on Food Behaviour, Physiology & Health (SWEET Work Package 2 Phase 2)
Countries of recruitment	Denmark, France, Spain, United Kingdom
Health condition(s) or problem(s) studied	Eating Behaviour
Intervention(s)	Consumption of food product with sweetener and sweetness enhancer
	Consumption of sucrose-sweetened control food product
Key inclusion and exclusion criteria	Ages eligible for study: ≥ 18 ≤60 years ; Sexes eligible for study :both; Accepts healthy volunteers: yes
	Inclusion criteria: BMI 25-35kgm2; Use of contraceptive methods or not planning to become pregnant for the duration of the study (women only); Regular consumption of sugar-containing foods and willing to consume sugar and artificially-sweetened food products; Liking of the intervention foods defined by a response of 'Yes' for the product during the pre-screening interview and a score of 40% or above on the Liking Visual Analogue Scale for the sucrose-sweetened control product; Able to participate on the Clinical Investigation Days during normal working hours; Healthy as determined from the self-reported medical history or when a clinical condition exists, when this is considered to be irrelevant (i.e. not influencing study outcomes) for the study by the study medical doctor; Consuming breakfast regularly (at least 5 days per week); Able to understand and be willing to sign the informed consent form, and to follow all the study procedures and requirements; Capacity to store at-home intervention quantity of intervention product
	Exclusion criteria: Blood donation < 3 month prior to study or for full duration of the study; Food allergy, intolerance, restriction or avoidance of any of the study foods (e.g. veganism) or history of anaphylactic reaction to any food; Likelihood for disordered eating defined as a score ≥20 on the Eating Attitudes Test; Currently dieting to lose weight; Having lost or gained >4.5 kg in the last 3 months; Smoking or having quit <3 months prior to study; Habitually consuming >14 units/week of alcohol in women or >21 units/week in men in the last 3 months; Performing >10 h of intense physical activity per week in the last 3 months; Night or late shift work (ending later than 11 pm on a permanent basis). Rotational shift work allowed if can attend on days that do not follow a late/night shift; Self-reported use of drugs of abuse within the previous 12 months; Pregnancy, lactation (women only); Persons who do not have access to either (mobile) phone or internet (this is necessary when being contacted by the study personnel during the study); Insufficient communication in the national language; Proven or suspected inability, physically or mentally, to comply with the procedures required by the study protocol as evaluated by the daily study manager, site-PI, PI or clinical responsible. This includes volunteers for which insufficient collaboration may be foreseen; Subject's general condition contraindicates continuing in the study as evaluated by the daily study manager, site-PI, PI or responsible clinician; Simultaneous participation in other relevant clinical intervention studies; Previous university or college training related to eating behaviour research; Self-reported eating disorders; Diagnosed anaemia; Diagnosed diabetes mellitus; Abnormal G.I. function or structure such as malformation, angiodysplasia, active peptic ulcer; Active inflammatory bowel disease, coeliac disease, chronic pancreatitis or other disorder potentially causing malabsorption; History of G.I. surgery with permanent effect (i.e. surgical treatment of obesity); Medical history of Cardiovascular Disease (e.g. current angina; myocardial infarction or stroke within the past 6 months; heart failure; symptomatic peripheral vascular disease); Significant liver disease, e.g. cirrhosis (fatty liver disease allowed); Malignancy which is currently active or in remission for less than five years after last treatment (local basal and squamous cell skin cancer allowed); Thyroid diseases, except those on Levothyroxine treatment of hypothyroidism if the person has been on a stable dose for at least 3months; Psychiatric illness (e.g. major depression, bipolar disorders); Use currently or within the previous 3 months of prescription or over the counter medication that has the potential of affecting appetite, satiety or body weight incl. food supplements. Except: low dose antidepressants if they, in the judgement of the daily study manager, site-PI, PI or clinical responsible, do not affect weight or following the study protocol. Levothyroxine for

	treatment of hypothyroidism is allowed if the person has been on a stable dose for at least 3 months. Cholesterol lowering medication, if the dose has changed during the last3 months (i.e., the medication is allowed if the participant has been on a stable dose for at least 3 months)
Study type	Interventional
	Allocation: Randomised. Double-blind, within-subjects, cross-over trial
	Primary purpose: Evaluation
	Phase: N/A
Date of first enrolment	April 2021
Target sample size	213
Recruitment status	Recruiting
Primary outcome(s)	Incremental area under the curve (iAUC) for composite appetite sensations in response to each product.
Key secondary outcomes	Leeds Food Preference Questionnaire (LFPQ) Explicit Liking, Implicit Wanting, Relative preference, Explicit wanting; Control of Eating Questionnaire (CoEQ): Craving Control, Craving for Sweet, Craving for Savoury, Positive Mood; Blood Glucose Incremental Area Under the Curve; Blood Insulin Incremental Area Under the Curve; Cephalic and intestinal satiety biomarkers: Glucagon-like peptide-1 (GLP-1)Incremental area under the curve for blood GLP-1 concentrations in response to each product (120 min post intake);Ghrelin Incremental area under the curve for blood Ghrelin concentrations in response to each product (120 min post intake).