

Sweet consumption and subsequent sweet food preferences and intakes:

Protocol

Study ID number: NCT05672017

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Design

This study utilised a parallel-groups, randomised controlled trial design with three arms. Participants were randomised to either increase, decrease or make no change to their daily intake of sweet-tasting foods and beverages for 6 consecutive days. All outcomes were assessed at two time points, on day 0 (baseline) and day 7 (end), alongside measures of adherence to the assigned diet.

Participants

A priori power calculations were based on changes in pleasantness ratings of approximately 6–9 mm (SD = approx. 13–17 mm), as reported in response to sweet taste exposure over 6 d in two previous studies(12,17) . For a two-sided α of 0·05 and power of 0·8, these calculations estimated the need for forty participants per intervention group. Eligibility criteria for the study were being over the age of 18 years, non-vegan and non-smoker, regularly consuming breakfast, having no food allergies, not pregnant or breastfeeding, not dieting or trying to lose weight and being willing and able to undertake all study requirements.

Participants were recruited using personal contacts, posters and online advertisements and through internal research volunteering platforms. To conceal our specific interest in sweet foods, the trial was described as a study of 'Eating Behaviours' with candidates advised that they would be required to modify specific aspects of their diet as instructed, although details of the modification were not given at this stage. In advance of participation, all interested candidates received study information and consent documents, and all participants provided written informed consent. The trial was designed and conducted according to the guidelines laid down in the Declaration of Helsinki (1983), the Ethical Guidelines of the British Psychological Society and the Research Ethics Codes of Practice of Bournemouth University, UK, and the University of Bristol, UK. All procedures involving human participants were approved by the Research Ethics Committees of Bournemouth University (ID: 47051/48807/45568) and the University of Bristol (ID: 06121760961) prior to commencement. Risk assessments were carried out before data collection, with regular reviews undertaken throughout the trial and all risks addressed accordingly.

Intervention/control

Participants were allocated to one of three trial arms: 'increase sweet food consumption', 'decrease sweet food consumption' and 'no diet change'(control). In the 'increase sweet food consumption' arm, participants were instructed to increase their consumption of sweet foods and beverages with the instruction 'Please increase your consumption of all sweet foods and drinks'. Participants were given examples of foods and beverages, taken from the SensoryDiet database(18) , which would be suitable to consume at different meals, including fruit, some sweet vegetables (e.g. tomatoes, sweetcorn, carrots), low-calorie-sweetened foods and beverages and some sugar-sweetened foods and beverages. In the 'decrease sweet food consumption' arm, participants were instructed to decrease their consumption of sweet foods and beverages with the instruction 'Please reduce your consumption of all sweet foods and drinks' and were given examples of non-sweet foods and beverages that would be suitable to consume at different meals, as above. Importantly, the foods highlighted to participants in these two groups were given only as examples. In addition, each participant was encouraged to judge for themselves which foods would be appropriate for them to consume to adjust the taste of their diet as requested. The purpose of this procedure was to ensure that the intervention was experienced by each participant as intended (i.e. as sweet or not sweet). This avoided imposing the researchers' assumptions about the foods

that are experienced as tasting sweet v. not sweet by each individual. For those in the control arm, no dietary change was required. Participants were simply asked to 'Continue consuming all foods and drinks that you were consuming last week'. Intervention instruction guides were provided to participants in written form for them to take away and refer to as they wished. In addition, on receipt of their instructions, participants were reminded that the aim of the study (as disclosed during consent procedures) was to investigate the effects of a dietary change and were asked to make this change as substantial as possible to enhance our chances of finding effects. The researcher in contact with participants was not aware of the specific instructions given, but contact details of an additional researcher were also given should questions arise during the course of the study. Participants were asked to undertake the intervention for 6 d (days 1–6) with outcomes assessed on day 0 and day 7.

Outcomes

Our primary outcomes were pleasantness and desire to eat for sweet and non-sweet foods and sweet food intake assessed at an ad libitum cold, buffet-style, breakfast meal.

Secondary outcomes were perceived sweet taste intensity of the sweet and non-sweet foods, self-reported adherence to the allocated diet and measures of appetite.

Pleasantness and desire to eat

Pleasantness and desire to eat sweet and non-sweet foods were assessed on each test day using a taste perception test. Participants were instructed to taste and consume bite-sized portions of six different foods (see Table 1), comprised of both sweet and non-sweet items of a range of textures. For the one bite of each food, participants were asked to rate pleasantness and desire to eat on 100 mm visual analogue scales using paper and pen. The instructions for these scales were 'How PLEASANT does this food taste to you right now?' (response anchors: 'not at all pleasant', 'extremely pleasant') and 'Now, rate how strong your DESIRE TO EAT more of this food is right now?' (response anchors: 'not at all strong', 'extremely strong') (19) . The foods were tasted in a prespecified order, and participants were required to take a sip of water between each food item to limit the mixing of flavours. The bite-sized portions were consumed in full to avoid differential impacts on subsequent test meal intake measures. Food order varied between participants in a counterbalanced manner, but it remained the same on day 0 and day 7 for each individual.

Sweet food intake

Sweet food intake was assessed using an ad libitum cold buffet-style breakfast(20) . Participants were presented with a variety of sweet and non-sweet foods and invited to consume as much or as little as they desired. All foods are commonly consumed in the UK and have been used in a previous study to illustrate changes in intake over time(13) . For each participant, foods were individually weighed before and after breakfast to allow calculations of the percentage weight consumed from sweet foods and sweet foods and beverages, percentage of energy consumed from sweet foods and sweet foods and beverages, the weight of sugar consumed from foods and from foods and beverages and percentage of energy consumed from sugar from foods and from foods and beverages. Due to the lack of agreement regarding the most appropriate metric for assessing dietary sweet food intake(21) , several measures of intake were employed.

Sweet taste intensity

Sweet taste intensity was assessed on each test day in the taste perception test as above. For each of the six foods provided participants were also asked to rate sweet taste intensity on paper and pen 100 mm visual analogue scales, using the instruction 'How SWEET does this food taste to you right now?' (response anchors: 'not at all sweet', 'extremely sweet').

Adherence

Adherence to the intervention instructions was assessed at the end of the intervention period. Participants were asked how well they adhered to their allocated diet ('How well did you adhere (manage to keep) to your allocated diet?', response anchors: 'not at all', 'extremely'), how difficult they found it to adhere to their allocated diet ('How difficult did you find it to adhere (manage to keep) to your allocated diet?', response anchors: 'not at all', 'extremely') and how different their allocated diet was from their usual diet ('How different was your allocated diet from your usual diet?', response anchors: 'not at all', 'extremely'). Responses were made using paper and pen 100 mm visual analogue scales and were verified using records of sweet food consumption over the previous day and verbal reports of difficulties over the intervention week.

Appetite

Ratings of hunger, fullness and thirst were also undertaken using paper and pen 100 mm visual analogue scales at the start of each test session to allow for differences in appetite on each test day. Participant age and sex were also collected for descriptive purposes.

Procedure

The study was run from both the University of Bristol, UK (February 2018–May 2018), and from Bournemouth University (January 2023–May 2023, October 2023–March 2024). The initial study began at the University of Bristol and, following disruptions due to COVID-19, was continued later at Bournemouth University. Data collection was carried out at the Nutrition and Behaviour Unit at the University of Bristol and the Eating Behaviours Laboratory at Bournemouth University. Participants visited the testing site fasted and rested on day 0 and day 7 during pre-booked time slots. Visits were scheduled between 08.00 and 11.00, and the timeslots remained the same on both occasions. Upon arrival, participants were seated individually at a table where they were presented with the taste perception test. After completing this test, participants received their cold buffet-style breakfast. The entire procedure lasted approximately 30 min and was repeated exactly on both testing occasions, with three exceptions. At the end of day 0 following all data collection, participants were provided with their dietary intervention. On day 7, participants also completed the adherence questions before the taste perception test, and they were asked about any difficulties experienced over the intervention period. After their breakfast, they were also debriefed about the purpose of the research and thanked for participating in the study. To maintain a researcher-blinded study design, an independent researcher with no contact with participants randomised participants to one of the trial arms using a random number generator. Participants were randomised at a ratio of 1 (increase): 1 (decrease) at the University of Bristol and subsequently at a ratio of 1 (increase): 1 (decrease): 1 (no change) at Bournemouth University, to result in a final sample with a ratio of 2 (increase): 2 (decrease): 1 (no change). Group allocation was concealed using white sealed, opaque envelopes, and throughout the trial, the researcher in direct contact with participants remained unaware of each participant's group allocation. To support the blinding,

participants were asked not to disclose any information about the instructions they received to the researcher conducting the testing. Although it was impossible to blind the participants to their group allocation, they were unaware of the true aim of the trial and the instructions received by other participants. Prior to commencement, the study was registered on Clinicaltrials.gov (Initial Study ID: NCT03427658, registration on 9 February 2018, Complete Study ID: NCT05672017, registration on 5 January 2023). We adhered to our trial registrations in all aspects with the exception that sweet food intake was measured only at breakfast rather than at breakfast and lunch as proposed in the registration for the initial study. The study was run using identical interventions and measures in both locations, with the exception that in Bristol, participants discussed their dietary change with a (independent) researcher and were given the written instruction guide, while in Bournemouth, participants were only provided with the written instruction guide, which included a contact to ask questions

Consent Form

Version: 1

Ethics ID number: 47051

Date: 29/12/2022



Participant Agreement Form

Full title of project: Eating Behaviour study

Name, position and contact details of researcher:

Aleksandra Bielat, Health Psychology Masters Student, s5323305@bournemouth.ac.uk

Name, position and contact details of supervisor:

Katherine Appleton, Professor in Psychology, k.appleton@bournemouth.ac.uk

To be completed prior to data collection activity

Section A: Agreement to participate in the study

You should only agree to participate in the study if you agree with all of the statements in this table and accept that participating will involve the listed activities.

I have read and understood the Participant Information Sheet (Version 1) and have been given access to the BU Research Participant Privacy Notice which sets out how we collect and use personal information (https://www1.bournemouth.ac.uk/about/governance/access-information/data-protection-privacy).
I have had an opportunity to ask questions.
I understand that my participation is voluntary. I can stop participating in research activities at any time without giving a reason and I am free to decline to answer any particular question(s).
I understand that taking part in the research will include the following activity/activities as part of the research:
<ul style="list-style-type: none">• Attending 3 testing sessions at the Bournemouth University Eating Behaviours Laboratory.• Completing an online screening questionnaire before the start of the project.• Providing a recall of foods consumed 24 hours before each testing session.• Tasting a variety of food items and providing taste ratings – on all 3 testing sessions.• Attending a cold food buffet with the opportunity to consume breakfast – on all 3 testing sessions.

- For one week, I might be required to **change my current eating habits**.

I understand that, if I withdraw from the study, I will also be able to withdraw my data from further use in the study **except** where my data has been anonymised (as I cannot be identified) or it will be harmful to the project to have my data removed.

I understand that my data may be used in an anonymised form by the research team to support other research projects in the future, including future publications, reports or presentations.

I confirm that I am aged 18+, a non-smoker, a vegan, not pregnant and have no known allergies.

I confirm that I can attend the Eating Behaviour Laboratory at Bournemouth University on three separate occasions.

	Initial box to agree
I consent to take part in the project on the basis set out above (Section A)	

Name of participant
(BLOCK CAPITALS)

Date
(dd/mm/yyyy)

Signature

Name of researcher
(BLOCK CAPITALS)

Date
(dd/mm/yyyy)

Signature