**SWEET BREAKFASTS STUDY**

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**Protocol**

This is a randomised controlled parallel-groups trial, in which participants will be randomized to consume either a sweet breakfast or a non-sweet breakfast for 6 days and then a further 13 days. Ratings and intakes of other sweet and non-sweet foods will be assessed at breakfast and at lunch on day 0 (baseline), day 7, and day 21.

The study will be run in the Eating Behaviours Laboratory at Bournemouth University, UK. Participants will come to the laboratory on six occasions: for breakfast and lunch on Day 0 (baseline), Day 7 and Day 21. On each day, participants will be asked to arrive fasted, having consumed no alcohol or undertaken any heavy exercise the day before. On each occasion, participants will first undertake the taste test and second eat from an ad-libitum test meal. The same procedure will be followed at breakfast and lunch. Breakfast will be consumed between 8:00am and 9:30am on each day, and lunch will be consumed four hours later. Participants will be required to adhere to the same times for breakfast and lunch on each test day. At the end of the test day on Day 0 and Day 7, participants will also receive a designated box of cereal with or without sweetener identified by ID number. At the start of the test day on Day 7 and Day 21, participants will be queried regarding compliance. Returned cereal boxes will also be checked for consumption. At the end of the test day on Day 21, participants will also be queried over the taste of the breakfasts they had consumed and debriefed.

Taste tests will be used to assess our primary outcome of pleasantness for sweet tasting foods and drinks at breakfast. Ad-libitum test meals will be used to assess our primary outcome of sweet food intakes at breakfast. Assessments will be made at lunch as well as breakfast for further secondary outcomes.

**Taste tests:** Participants will be required to consume a pre-specified small sample of each of three sweet foods and three non-sweet foods. These foods will be chosen as foods that consistently differ in taste, are familiar to all participants, represent a variety of textures, and are also served in the ad-libitum test meal. Real foods as opposed to sugared water solutions or similar will be used to enhance the validity of the ratings. Participants will be asked to consume each food in full in a pre-specified order, focus purely on the taste of the food in their mouths and then rate it immediately after consumption. Participants will then be asked to rinse their mouths with water and move to the next pre-specified food. Participants will rate the samples using 100 mm visual analogue scales (VAS) of: Pleasantness: *'How PLEASANT does this food taste to you right now?,* anchors *'not at all pleasant', 'extremely pleasant'*; Desire to Eat: *'Now, rate how strong your DESIRE TO EAT more of this food is right now?',* anchors *'not at all strong', 'extremely strong'*, and Sweetness: *'How SWEET does this food taste to you right now?',* anchors *'not at all sweet', 'extremely sweet'.* Data for each measure will be combined across all three sweet foods and all three non-sweet foods for analysis.

**Ad-libitum test meals:** The meal will be composed of foods that represent a standard UK cold buffet meal that could be acceptable for breakfast or lunch, and where an acceptable meal that is entirely sweet, entirely non-sweet or a mixture of sweet and non-sweet foods could be composed. All foods will be familiar to participants and are commonly consumed in the UK. Participants will be free to consume as little or as much as they wish, and intake will be assessed by measuring weight consumed. Weight of food consumed will then be converted into energy consumed and sugars consumed using manufacturers' information. Outcomes for the study include percent weight consumed from sweet foods, percent energy consumed from sweet foods, and percent energy consumed from sugars.

Outcomes will be assessed at breakfast and lunch, on days 0, 7 and 21. Taste tests will be consistently undertaken immediately in advance of the buffet meal, thus measures of pleasantness, desire to eat and sweetness will not be affected by measurements of intake, and because the taste tests involve consumption of regulated specific small amounts of foods, intake outcomes are unlikely to be affected by the rating measures.

**Additional measures:** Gender, age and BMI will be recorded to allow description of the sample. Hunger, fullness and thirst will also be measured prior to each meal to ensure against confounding. These measures will be made using 100mm VAS of: Hunger: '*How HUNGRY do you feel right now?',* anchors *'not at all hungry', 'extremely hungry'*; Fullness: *'How FULL does your stomach feel right now?,* anchors *'not at all full', 'extremely hungry'*; and Thirst: *'How THIRSTY do you feel right now?',* anchors *'not at all thirsty', 'extremely thirsty'*.

**Analysis Plan**

Data will be compiled in Excel and analysed in IBM SPSS. All data will be analysed on an Intention-to-Treat basis, with missing data completed using last observation carried forward. Modelling techniques will not be used to estimate missing data, due to the number of outcomes to be considered. Significance is set at p=0.05.

In advance of our main analyses, data will be investigated for differences between groups in demographic and baseline measures. This will be undertaken to investigate whether analyses investigating differences between intervention and control groups should consider these variables as confounders. If differences between groups are found, the variables will be included in subsequent analyses. These analyses will be undertaken using independent t-tests.

To address our primary research questions, rating data will be analysed using 2x3x2 ANOVA for differences between exposure conditions (sweet vs non-sweet) over time (Day 0, 7, 21), for the sweet and the non-sweet foods ((sweet vs non-sweet). Intake data will be analysed using 2x2x3 ANOVA for differences between genders (male vs female) and exposure conditions (sweet vs non-sweet) over time (Day 0, 7, 21). Main effects of gender will demonstrate known effects in food intake measures adding confidence to other findings. If interactions are also observed, these analyses will remain. If no interactions with gender are found, intake data will be re-analysed using 2x3 ANOVA for differences between exposure conditions (sweet vs non-sweet) over time (Day 0, 7, 21). This will be allow greater power. To allow the separation of our primary and secondary outcomes, analyses will be undertaken first for measures taken at breakfast, and secondly for measures taken at lunch.

Associations between rating and intake outcomes will also be investigated using correlations across the whole data set. For these correlations, all data will be treated equally, regardless of day and breakfast / lunch test context, resulting in the inclusion of as many data points as possible.