EFFECTS OF DIETARY RECOMMENDATIONS FOR REDUCING FREE SUGAR INTAKES, ON FREE SUGAR INTAKES, DIETARY PROFILES AND ANTHROPOMETRY: A RANDOMISED CONTROLLED TRIAL

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Abbreviations: %FS: free sugars as a percentage of TEI; %TEI: percentage of TEI; BMI: Body Mass Index; BW: Body weight; CHO: carbohydrate; cm: centimetres; FAO: Food and Agriculture Organization; FCQ: Food Choice Questionnaire; FS: free sugars; gLMS: general linear magnitude scale; GSLTPAQ: Godin-Shephard Leisure-time physical activity questionnaire; kg: kilogrammes; LCS: Low-calorie sweeteners; m: metres; ml: millilitre; mm: millimetres; M: molar; N: Nutrient-based recommendations; NF: Nutrient- and Food-based recommendations; NFS: Nutrient-, Food- and Food-Substitution-based recommendations; PROP: 6-n-propylthiouracil; SD: standard deviation; SE: standard error; SF-36: 36-item short form survey; TEI: total energy intake; TFEQ: Three Factor Eating Questionnaire; UK: United Kingdom; VAS: visual analogue scales; WHO: World Health Organization

ABSTRACT

Free sugar intakes are currently higher than recommended for health, yet effective strategies for reducing consumption are yet to be elucidated. This work investigated the effects of different dietary recommendations for reducing free sugar intakes, on relevant outcomes, in UK adults consuming >5% total energy intake (TEI) from free sugars. Using a randomized controlled parallel-group design, 242 adults received nutrient-based (N=61), nutrient- and food-based (N=60), nutrient-, food- and food-substitution-based (N=63) or no (N=58) recommendations for reducing free sugars at a single timepoint, with effects assessed for the following 12 weeks. Primary outcomes were free sugar intakes as a percentage of TEI (%FS) and adherence to the recommendations at week 12. Secondary outcomes included TEI, diet composition, sugar-sweetened and low-calorie-sweetened food consumption and anthropometry. In Intention-to-Treat analyses adjusted for baseline measures, %FS reduced in intervention groups ($\%FS_{change}$=-2.5 to -3.3%) compared to control ($\%FS_{change}$=-1.2%) (smallest B=-0.573, p=0.03), with effects from week 1 until week 12, and no differences between interventions (largest B=0.352, p=0.42). No effects of intervention were found in dietary profiles, but change in %FS was associated with change in %TEI from non-sugar carbohydrate (B=0.141, p<0.01) and from protein (B=-0.171, p=0.02). Body weight was also lower at week 12 in intervention groups compared to control (B=-0.377, p<0.05), but associations with %FS were weak. Our findings demonstrate benefit from dietary recommendations for reducing free sugar intakes in UK adults. Limited advantages were found for the different dietary recommendations, but variety may offer individual choice.

Trial Registration: Clinicaltrials.gov: NCT04816955, registration date: 24.03.21.

1. INTRODUCTION

Free sugar intakes are associated with a number of poor health outcomes, including increased risk from excess energy intake resulting in increased risk from overweight, obesity, and several chronic health conditions[1]. As a result, the World Health Organization (WHO) currently recommends '*In both adults and children, the intake of free sugars should be reduced to less than 10% of total energy intake'*[1, p.4], and *'A reduction to less than 5% of total energy intake would provide additional health benefits'*[1, p.4].

Public health agencies around the world have followed suit[2-4], but while the recommendations are well-defined, appropriate strategies to achieve adherence to these consumption levels by the general public, remain unclear. Of particular note, the recommendations are provided at a nutrient level, i.e. they are based on *sugars*, while in 1998, the WHO and Food and Agriculture Organization (FAO)[5] recommended that consumer guidelines should be based on foods; the rationale being that consumers are largely unaware of the nutrients in foods; that foods, not nutrients, make up dietary choices; and that encouraging change to whole dietary patterns would benefit multiple single nutrient goals and synergies[5]. Advice based on nutrients typically focusses on the amount of a nutrient found in foods or beverages, and appropriate targets or limits for consumption. Systematic reviews and meta-analyses suggest some benefit from this type of information in the form of product labels, for consumer understanding[6] and food selection[7,8], but impacts on intakes can be limited[7-10]. Ninety countries, however, now provide food-based dietary guidelines, and 84% of these include recommendations specifically on high-sugar foods[11]. Adherence to free sugar recommendations, thus, may be aided by recommendations not only based on the nutrient, but also based on the relevant foods.

Sugars and sugar-rich foods are commonly consumed for reasons related to their sweet taste[12,13]. Substitution with whole fruit, intrinsic milk sugars and low-calorie sweeteners (LCS) may maintain this sweet taste without contributing free sugars[13]. Recommendations to replace sugars with non-sweet alternatives are also increasing[2,3]. Studies where sugar-rich foods are replaced with low-sugar alternatives demonstrate success from this substitution strategy for reducing free sugar intakes[14-18]. Meta-analyses on product reformulation demonstrate benefits for sugar intakes and body weight, although limited studies are currently available[14]. Studies using behavioural substitutions similarly suggest benefit[15-18]. Participants in the CHOICE trial showed a 44-54% reduction in percent energy consumed from free sugars following encouragement to replace ≥2 servings per day of caloric beverages with LCS-sweetened or unsweetened beverages[15,16]. Ebbeling et al.[17] report a 58-65%

reduction in free sugar intakes following the replacement of ≥1 sugar-sweetened beverages (SSBs) with LCS-sweetened or unsweetened beverages. Wise et al.[18] report a 42-48% reduction from baseline energy consumed from sugars in participants asked to dilute sugary drinks and replace high-sugar foods with items higher in complex carbohydrates, protein, and/or fats.

Reviews of interventions to reduce free sugar intakes are available[19,20]. However, no study as far as we are aware has investigated these differing nutrient-based, food-based and food-substitution-based strategies for reducing free sugar intakes within the same study. The WHO appeal for the '*need to evaluate different behavioural-change approaches to promote the reduction of free sugars intake'* in the recommendation guidelines[1, p.20], and discussions on food-based dietary guidelines suggest a need for real-world monitoring and evaluation[5]. The WHO further highlights a '*need for longer term (>8 weeks) controlled trials of the effect of increasing or decreasing free sugars intake on body weight in free-living individuals'*[1, p.20]. This study investigated the effects of three different dietary recommendations for reducing free sugar intakes on free sugar intakes, dietary profiles and anthropometry over 12 weeks. Our primary research purpose was to better understand free sugar intakes, how to reduce these, and the role that different dietary recommendations can play in this. We hypothesized that all dietary recommendations would result in changes in free sugar intakes versus control.

2. METHODS

2.1. Design

Using a randomised controlled trial design, members of the general adult population of the UK consuming >5% total energy intake (TEI) from free sugars, were randomised to receive: nutrient-based recommendations (group N); nutrient- and food-based recommendations (group NF); nutrient-, food- and food-substitution-based recommendations (group NFS) or control (control group) at a single time point, with effects assessed for the following 12 weeks. Given the public health focus of sugar reduction, our study was specifically conducted with the general population, in a public health context. Our primary outcomes were free sugar intakes as a percentage of TEI (%FS) and adherence to the recommendations at week 12. Secondary outcomes were dietary profiles (daily total energy intake, diet composition, sugar-rich and LCS-sweetened food consumption), anthropometry (body weight, body mass index (BMI), waist circumference), outcomes related to sweet taste, and barriers and facilitators to dietary change at week 12, and %FS and adherence at weeks 1, 2, 4 and 8. This report focuses on the main trial methodology and findings from our primary outcomes and secondary outcomes related to dietary profiles and anthropometry. Methods and

findings for the outcomes related to sweet taste and the barriers and facilitators to dietary change will be reported elsewhere.

Approval for the trial was gained from the Research Ethics Committee of Bournemouth University, UK (ID: 30612) on 28.04.20 with amendments approved on 29.03.21. The work was undertaken in accordance with the Declaration of Helsinki (1983), the Ethical Guidelines of the British Psychological Society, and Bournemouth University's Research Ethics Code of Practice. The trial was registered on Clinicaltrials.gov (ID: NCT04816955) on 24.03.21. A full protocol for the study was also published[21]. We adhered to our study registration and published protocol in all respects with a few minor refinements, as given below.

2.2. Participants

Volunteers were eligible for inclusion in the trial if they were: aged 18-65 years, consuming >5%TEI from free sugars, and able to provide informed consent and complete all trial measures. Exclusion criteria were: pregnancy or breastfeeding; underweight (BMI<18.5kg/m^2); pre-existing medical conditions affecting swallowing ability, taste and/or smell perception; currently, or within the previous three months, smoking or following a specific dietary programme (e.g. slimming world); pre-existing clinical conditions, including food allergies, diabetes mellitus, eating disorders, Crohn's disease, leading to the use of external nutritional advice and dietary restrictions.

Sample size equations aimed to test for a 2% change in %FS from baseline to Week 12 at a power of 80% for an alpha of 0.05. Due to a lack of literature on the use of dietary recommendations for reducing free sugar intakes at trial conception, sample size equations were based on the reported effects of a trial on the use of dietary recommendations for reducing saturated fat intakes[22]. The highest standard deviation calculated from these data (SD=2.4) was used to calculate a required group size of N=46 per trial arm[23]. This sample size was also assumed to be adequate for our second primary outcome - adherence, as this outcome involved categorizing participants based on %FS or change in %FS (see section 2.4.1). Allowing for a 20% drop-out rate and unequal recruitment across trial arms, we aimed to recruit 240 individuals.

Potential participants were recruited via: personal contacts; University contacts and outlets, including a participant pool; contacts with local groups, e.g. church groups; social media advertising; and advertising in local news outlets, public buildings, e.g. libraries, and eating establishments. The study was marketed as *'A study investigating different types of dietary advice'.* Potential participants provided electronic written informed consent, then completed eligibility, including a 3-day diet diary to assess free sugar intakes. This 3-day diet diary also served as an opportunity to train participants,

allow them to gauge the commitment required for the study and ensure they were competent in the diet diary data collection methods prior to their enrolment. Participants were not recruited until they were comfortable with the diet diary data collection methods and the commitment required.

Eligible participants were randomised to one of four trial arms at a ratio of 1:1:1:1 using blocked stratified randomisation, based on gender, BMI, and %FS at baseline (block size: 8 participants). An exception was made where participants lived with other participants to avoid contamination between intervention groups. These participants were randomized as a pair or group, based on the stratification of the person making the initial query. Randomisation was undertaken by a researcher with no direct contact with participants (KMA) using a random number generator.

2.3. Intervention / Control

There were four trial arms: three arms delivering recommendations for reducing free sugar intakes and one control arm. The three differing dietary recommendations were nutrient-based, nutrient- and food-based, and nutrient-, food- and food-substitution-based, as below. Nutrient-, food- and food-substitution-based information was investigated in an additive manner to aid consumer understanding. All recommendations used publicly available information as provided by the UK Government or related public health agencies at the time of trial conception[24-26]. In addition to the specific information provided, all groups were also asked to record their food intakes, and given instructions for this.

Group N: Nutrient-based recommendations

Nutrient-based recommendations began with the instruction: *'Your dietary recommendation is to reduce your intake of free sugars to less than 5% of your total energy intake'.* This sentence was followed by one page of nutrient-based information, including the different names for sugars and how to identify the sugar content of foods, e.g. '*high in sugar – 22.5g or more of total sugar per 100g'*. Recommendations from Public Health England[24] were amended to provide only the nutrient-based information that related to sugars.

Group NF: Nutrient- and Food-based recommendations

These recommendations began with the instruction: *'Your dietary recommendation is to reduce your intake of free sugars to less than 5% of your total energy intake. To aid with this, reduce your intake of foods high in free sugars'.* Participants were then provided with the same nutrient-based information as for Group N plus four additional pages on foods that are commonly high in free sugars, with examples of how much sugar is included, e.g. '*A bowl of sugary breakfast cereal could*

contribute 70g of sugar (up to 22 sugar cubes) to your diet over a week'. Recommendations from Public Health England[24,25] were amended to provide the nutrient- and food-based information that related to sugar and sugar-rich foods.

Group NFS: Nutrient-, Food- and Food-Substitution-based recommendations

These recommendations began with the instruction: *'Your dietary recommendation is to reduce your intake of free sugars to less than 5% of your total energy intake. To aid with this, reduce your intake of foods high in free sugars and replace these with low sugar versions'.* Participants were then provided with the same nutrient- and food-based information as Group NF, plus five additional pages on low-sugar-versions of foods that are usually sugar-rich, and on LCS. This information suggested low-sugar substitutions for high-sugar products, e.g. *'biscuits – swap for oatcakes, oat biscuits, or unsalted rice cakes'*, and provided details on LCS, where they are found, and their different uses. Recommendations from Public Health England[24,25] were amended to provide the relevant information, and information on LCS was obtained from Diabetes UK[26] to include only the information on LCS, with all references to diabetes removed.

Control group: Control

The control group were given no dietary recommendation related to free sugars, but were only asked '*to keep an accurate diet diary using the Nutritics software*'. This group undertook all trial measures in the same manner as those in the intervention groups. The group was intended to control for the act of dietary recording throughout the study; a behaviour that may increase dietary awareness and impact intakes[27,28].

Recommendations were delivered to participants at a single timepoint, as may occur in a public health context. Recommendations were provided in written format in a sealed opaque envelope, alongside an instruction *'to keep an accurate diet diary using the Nutritics software'*[29] and a user guide for the *Nutritics Libro App*[29]. This instruction was carefully worded, such that for participants in the control group, this instruction could be construed as a dietary recommendation, with the intention of aiding compliance. All groups received the same instructions regarding the diet diaries, thus all groups received a sealed envelope. On provision of their sealed envelope, all participants were also informed that a dietary recommendation could be anything from simply recording your diet to the provision of specific instructions. Envelopes were packaged to include the same number of pages regardless of intervention or control group through the addition of blank pages, to conceal

group allocations from the researcher in contact with participants. Full copies of each intervention, as provided to participants, are given in the Supplementary Materials (Figure SM1).

Participants were provided with their recommendations following baseline measures. They were not permitted to ask questions, in line with the current scenario for the UK public where dietary recommendations are often provided, e.g. via TV advertisements, without the opportunity to ask questions. An inability to ask questions also ensured that the same information was provided to all participants, maintaining intervention fidelity.

All envelopes containing intervention/control information were identical, sealed and coded by the researcher undertaking the randomisation. The researcher in direct contact with participants (LRB) remained blind to treatment allocation throughout all data collection. Participants were not blinded to condition, but were blinded to the trial aims and to other conditions. To further disguise the purpose of the trial, all participants completed questionnaires on other aspects of their diet alongside those focusing on sugars and sweet foods.

2.4. Outcomes

Primary outcomes were %FS and adherence to the recommendations at 12 weeks. Secondary outcomes were: dietary profiles (daily energy intake, diet composition, food consumption), and anthropometry (body weight, BMI, waist circumference) at week 12, and %FS and adherence at weeks 1, 2, 4 and 8. Demographic variables, sweet taste sensitivity, sweet liker status and bitter taste sensitivity were also assessed at baseline, and various attitudes (to sweet foods, towards eating behaviour, for food choice), some dietary knowledge, leisure time physical activity, quality of life and adverse events were assessed at baseline and week 12.

2.4.1. Primary Outcomes (Baseline, Week 12):

% Free Sugar Intakes (%FS): Free sugar intakes, as %TEI, were measured using diet diaries, completed using the *Nutritics software platform* (research edition, version 5, GB and IE databases) and '*Libro' App*[29]. Dietary intakes at baseline and week 12 were calculated from three days of diet diaries comprising of 2 weekdays and 1 weekend day at both time points[28]. Diet diaries, such as these are recognised as a valid and reliable method for assessing short-term dietary intake in the real world[27,30-32], and were selected here as the best method for assessing intakes and changes to intakes in a comprehensive manner over a 12 week period of free living[27,30-32]. Training with participants was undertaken prior to enrolment into the study, and all subsequently submitted food diaries were checked for likely missing data at the time of submission[27]. Portion-size rather than weighed diaries, and handheld portable digital diary entry methods[27,32,33] were used to reduce

participant burden and minimize any effects as a result of this, while maintaining data integrity and validity. Participants had access to all UK and Irish foods, supported by the *Nutritics* British (GB) and Irish (IE) databases, plus supermarket and brand specific information, ensuring correct and specific foods could be easily found, with aspects, such as bar code scans for food identification, also available[29]. Any issues with dietary recording throughout the trial were addressed the same day by the researcher (blinded to treatment allocation and supported by the *Nutritics Support Team*), and supplemented with handwritten email, text message or paper recording, where necessary.

Free sugar intakes, as a percentage of TEI were calculated using the *Nutritics database* and manufacturer's information. The *Nutritics software* is supported by an extensive food database, where food composition data are repeatedly internally validated[29]. The database contains a high number of foods with free sugars data[29], and where these data were not available from databases, data were sought from manufacturers. Where data on free sugars could not be obtained, foods were replaced with the closest available food for which free sugar data were available. The closest available food was selected using nutritional values for energy, carbohydrates and total sugars, by a registered Nutritionist with experience of the UK food supply (blinded to treatment allocation).

Adherence: Adherence was defined as a reduction in free sugar consumption of ≥2%TEI from baseline, or free sugar intake at ≤5%TEI, to result in classification of participants as 'adherent' or 'non-adherent'. Participants were also asked an adherence question: '*Are you currently following the dietary recommendations you were given?*' Reductions of free sugar intakes ≥2%TEI and an answer 'YES' resulted in a classification of 'active adherent', reductions of free sugar intakes ≥2%TEI and an answer 'NO' resulted in a classification of 'passive adherent', reductions of free sugar intakes <2%TEI and an answer 'NO' resulted in a classification of 'active non-adherent', and reductions of free sugar intakes <2%TEI and an answer 'YES' resulted in a classification of 'passive non-adherent'.

2.4.2. Secondary Outcomes (Baseline, Week 12):

Dietary Profiles: Daily total energy intake (TEI), diet composition and food consumption were assessed from diet diaries as measures of dietary choice. TEI was summed from all foods and beverages consumed. Diet composition, in terms of macronutrient and select micronutrient consumption, were also calculated to result in measures of percent TEI consumed from carbohydrate, protein, fat, and saturated fat, and amounts of dietary fibre (g) and sodium (mg) consumed. Food consumption was assessed through the identification of high-sugar, medium-sugar, and low/no-sugar foods, based on the criteria used for the UK traffic light system[34], where high-sugar foods have >22.5g sugar/100g, medium-sugar foods have 5-22.5g sugar/100g, and low/no-

sugar foods have <5g sugar/100g. LCS-sweetened foods were also classified as any sweet food or beverage described as 'diet', 'low-sugar', 'low calorie' or 'sugar-free' that was clearly sweetened with LCS. This description may not capture all foods that include LCS, but was intended to capture foods that were likely to have been selected by study participants because they were LCS- rather than sugar-sweetened. Consumption of all food types was measured as number of foods and weight (grams) of food consumed.

Anthropometry: Participant height (m), weight (kg), and waist circumference (cm) were recorded in a fasted state, by a trained researcher, using a portable stadiometer (*SECA 213 Height Measure, Germany*), digital scales (*Tanita Body Composition Analyzer BF-350, Tanita Europe, Germany*) and a flexible tape measure (*SECA, Germany*), respectively.

2.4.3. Secondary Outcomes (Weeks 1, 2, 4 and 8):

% Free Sugar Intakes and Adherence: Eighteen daily diet diaries, in addition to the three diaries at baseline and at 12 weeks, were undertaken over the 12-week period. These diaries were used to calculate %FS and adherence at weeks 1, 2, 4 and 8, as above.

2.4.4. Additional Variables (Baseline only):

Demographic information: Direct questioning assessed: gender, age, ethnicity, occupation, education level, income level, diet type (e.g. vegan), and cooking habits.

Sweet taste sensitivity and sweet liker status: Sweet taste sensitivity and sweet liker status were assessed using 10ml samples of an 1M aqueous sucrose solution. Participants first reported perceptions of sweet taste intensity using a 100mm pen and paper version of the general linear magnitude scale (gLMS)[35] following training in this method[35,36]. Liking was then assessed using 100mm visual analogue scales (VAS)[37-39], and ratings were subsequently categorised to describe participants as 'sweet likers', 'those with an inverted U-shaped sweet liking function', or 'sweet dislikers' using published methods[37]. To allow for any situation where the solutions were not appropriate, tests were also conducted using taste papers saturated in the same 1M solution.

Bitter taste sensitivity and bitter taste status: These characteristics were assessed using a taste paper impregnated with 6-n-propylthiouracil (PROP). Participants were asked to mark the intensity of the bitter taste using 100mm gLMS, a 100mm VAS and a 9-point category scale[40], and were subsequently classified as 'non-tasters', 'medium-tasters' or 'super tasters' according to published

classifications[35,36,40]. A control paper with no impregnation was also tasted and rated between the measures for sweet taste and those for bitter taste.

2.4.5. Additional Variables (Baseline, Week 12):

Attitudes towards sugars, sweeteners and sweet foods: were assessed using a recently developed questionnaire[41], describing six attitudes towards sugars, sweeteners and sweet-tasting foods, to reflect earlier qualitative work[42].

Attitudes towards eating behaviour: were assessed using the Three Factor Eating Questionnaire (TFEQ)[43], to result in scores for 'cognitive restraint', 'uncontrolled eating' and 'emotional eating'.

Motives for food choice: were assessed using the Food Choice Questionnaire (FCQ)[44]; a multi-level measure of nine motives related to food choice.

Knowledge of current UK dietary recommendations: were assessed using a single open-ended question requesting participants report all dietary recommendations of which they were aware. Answers were scored where participants were given one point for all correct dietary recommendations reported (total knowledge) and separately, one point for any reference to free sugars (sugar-related knowledge).

Leisure time physical activity levels: were measured using the Godin-Shephard Leisure-time physical activity questionnaire (GSLTPAQ)[45,46].

Quality of life: was assessed using the 36-Item Short Form Survey (SF-36)[47], and scored using standard procedures[47-49], to provide separate scores for mental and physical health.

Adverse Events: Participants were asked to report adverse events at any time, regardless of whether they considered these to be associated with the trial or not. To ensure adverse events were comprehensively reported, specific questions on difficulties undertaking the study were also requested at weeks 4, 8 and 12, and adverse events were verified at study end.

2.4.5. Assessment schedule

An overview of the assessment schedule for all variables is given in the Supplementary Materials (Table SM1). All participants undertook all measures, in the same manner, regardless of study arm.

Dietary assessments and all questionnaires, including the questions on adherence and difficulties, were completed via the *Nutritics software*, using a study-specific *Nutritics program*. This program, on specific days, requested diary completion and/or provided participants with online links to all study questionnaires, to be completed via an online questionnaire programme[50]. All dietary and questionnaire responses were checked by a researcher (blinded to treatment allocation) on submission for completeness. Food intakes that appeared low (less than 5 items recorded) were queried with the participant, confirmed or corrected. Incomplete questionnaires were completed.

Compliance with all trial measures was also enhanced using a bogus pipeline method[51-53]. Participants were asked to provide a saliva sample at baseline and at trial end, for the supposed purpose of examining salivary enzymes that may vary with dietary change, but in reality, these analyses were not planned nor undertaken. Suggestion of an objective measure to check compliance however, has previously been found to increase compliance in participants[51-53], and was considered to be a valuable addition to this trial where our primary outcomes were self-reported. Participants were informed on completion of the trial that their saliva samples had not been analysed.

2.5. Procedure

The trial was run from Bournemouth University, UK from April 2021 – December 2022. Participants completed all measures throughout the year to avoid seasonal effects, but no participants took part over the Christmas period to avoid poor compliance as a result of festive intakes.

All baseline and Week 12 assessments were conducted in two single test sessions. Sessions were conducted at the University where possible, or in the participant's home via video-conferencing. The trial was run towards the end of the COVID-19 pandemic and during some related restrictions in the UK (March 2020 – July 2021), thus 'at-home' test sessions were used if participants were unable or unwilling to come to the University. At-home test sessions may also have opened the trial to participants who would otherwise have been unable to take part, enhancing study inclusivity. Participants were tested in the same location at both baseline and trial end, where possible. All participants completed all measures and in the same manner regardless of their completion of test sessions at the University or 'at-home', under the direction of the same researcher, with a few exceptions: Participants who were tested 'at-home' did not undertake the solution-based measures of sweet taste sensitivity and sweet liker status, and completed their own anthropometric measurements after provision of the necessary equipment, while the trial researcher observed via video-conferencing.

All test sessions commenced with participants in a fasted state, at the same time of day at baseline and trial end. The day before testing participants were also asked to consume no alcohol, to consume nothing after 10pm, and to undertake no heavy exercise.

Individuals were debriefed on exit, or at their original trial end time-point if other household members were taking part. During the debrief, participants were asked for their understanding of the trial purpose to investigate the success of our methods to disguise the trial aims, and were given the true purpose of the trial. Following the debrief, participants were offered a consultation on their diet by a UK Registered Associate Nutritionist (UK Association for Nutrition), as a thank you for taking part. Participants received no other compensation.

2.6. Analyses

Complete data collection was ensured where possible throughout the trial, as above. At trial end, diet diaries were first screened to ensure that all entered foods contributed to composition totals and where data, e.g. grams of free sugars, were unavailable for certain foods, these foods were replaced in totality with the closest available food with complete data. All data were handled only at the end of data collection, by the researcher responsible for data collection while blinded, to ensure consistency across participants.

Three distinct analyses were specified in advance[21]: 1) Analyses of quantitative data from the population as a whole to investigate free sugar intakes and the effects of the three different types of dietary recommendation versus control; 2) Analyses of quantitative data to investigate the effects of the dietary recommendations in different population subgroups, and 3) Investigation of qualitative data for barriers and facilitators to success. Analyses 1 and 2 for primary and secondary outcomes as above, are reported here. Analyses 1 and 2 for sweet taste outcomes, and Analyses 3 will be reported elsewhere. Analyses were conducted on an Intention-to-Treat basis. Missing data at single time points were estimated using multiple imputation[54,55]. This provided data for 11.7% diet diaries and 8.7% questionnaires. All presented results are taken from the pooled analyses.

For analyses 1, multiple regression analyses were used[56-58]. These analyses allowed us to directly addresses our primary intended research purpose – to better understand free sugar intakes, how to reduce these, and the role that different dietary recommendations can play in these, while also allowing consideration of a number of other factors of likely influence in free sugar intakes, making maximal use of all available data[56-58]. Regression analyses were considered more appropriate than ANCOVA, considering our primary intended research purpose and the number of factors for consideration[56-58]. Alternative analyses, such as ANOVA or ANCOVA, would also allow test of the recommendations, but would not so comprehensively describe free sugar intakes in our

population and the role of the recommendations in these[56-58]. Regression models also allowed us to consider the additive nature of our recommendations in all analyses through use of the intervention/control group variable as a continuous, rather than a categorical, variable based on number of recommendations provided[56].

Regression models were conducted for all outcomes, to predict outcomes at Week 12, and change in outcome from baseline to Week 12. Primary regression models included intervention/control group, gender, age, baseline %FS, baseline body weight (as randomization variables), baseline variable of interest, TEI at Week 12 and physical activity at Week 12 (continuous scores), allowing simultaneous adjustment for all these variables. Baseline body weight was used in place of baseline BMI for all analyses considering the importance of body weight rather than body weight in relation to height, i.e. BMI, in our outcomes. Secondary models were also undertaken to include any additional variable that correlated with each outcome when assessed independently, at a significance value of $p<0.01$. Analyses of effects at weeks 1, 2, 4, and 8 were only undertaken using secondary models. Select exploratory analyses were also undertaken, only using secondary models. Effects for all continuous variables were investigated using multiple linear regression (enter method), following checks for multi-co-linearity between variables. Effects for adherence were investigated using logistic regression to predict adherence vs non-adherence, again following appropriate checks for multi-co-linearity. Use of the 'active' and 'passive' descriptors were not discriminatory – almost all participants reported themselves to be following the recommendations that they were given, but subsidiary analyses to investigate differences between those reporting this correctly or mistakenly are given in the Supplementary Materials, following all other analyses.

For analyses 2, the above analyses using secondary models were conducted in females only (no analyses were undertaken in males due to an insufficient sample size), in three sub-groups based on BMI: lean (BMI < 25.01 kg/m2), with overweight (BMI 25.00 - 30.00 kg/m2), with obesity (BMI > 30.00 kg/m2); and in three sub-groups based on sweet liker status: sweet likers, those with an inverted U-shaped sweet liking function, sweet dislikers.

All analyses were registered in advance as part of our trial registration (Clinicaltrials.gov: NCT04816955) and are provided in our protocol paper[21]. Proposed analyses on the variables described here as 'additional' were not undertaken considering the exploratory nature of these analyses and the number of analyses undertaken. Analyses were conducted in SPSS version 28.0. Significance was set at $p<0.05$.

3. RESULTS

3.1. Study Sample

In total, 1,147 individuals registered their interest for the study. Of these, 538 completed consent, and following all screening processes, 242 participants were recruited. Of these, 61 participants were randomized to group N, 60 to group NF, 63 to group NFS and 58 to the control group. A total of 200 (83%) participants completed the study and provided data for our primary outcomes at week 12. Flow through the study is detailed in the CONSORT diagram, Figure 1. Characteristics of each intervention/control group based on gender, age, body weight, BMI, and %FS at baseline are given in Table 1. Full details of the sample are given in the Supplementary Materials (Table SM2).

Figure 1 about here
Table 1 about here

Number of participants who withdrew from the study was 42: 17 participants from the control group, 9 from Group N, 7 from Group NF and 9 participants from Group NFS. Five participants experienced adverse events during the study period, 2 participants in Group NFS, and 1 participant in each other group. None of these adverse events were related to the study. When asked at study-end, 16 individuals thought the study was targeted towards or about sugar intakes, however only 1 individual thought we were investigating the effects of different types of advice specifically for reducing sugars. This individual was in Group NF.

Of the 242 participants, 179 participants took part in the study by attending the University, 63 participants took part via video-conferencing. No systematic differences were found between participants in these groups at baseline, with the exception that participants attending 'at-home' rated the sugar-sweetened paper as more sweet ($t(241)=2.53$, $p=0.01$) and more liked ($t(241)=4.12$, $p<0.01$) than University attendees, although no differences were found in perceptions of the control paper (largest $t(241)=1.62$, $p=0.11$). Participants rating liking for both the paper and solution at the University (N=179) demonstrated scores that differed by 3.3% (solution liking: mean (SD) = 50.4 (25.3) mm, paper liking: mean (SD) = 52.3 (18.4) mm), although the scores were only weakly correlated ($r=0.135$, $p=0.07$). For categorisation of sweet liker status, all liking scores for participants attending 'at-home' were adjusted down by 3.3%. Scores for sweet taste liking for both measures and in all groups are given in the Supplementary Materials (Table SM3). Following adjustment and categorization for sweet liker status, given the absence of other differences between the two groups, the study population was then treated as single sample with an N of 242.

3.2. ANALYSES ONE

3.2.1. PRIMARY OUTCOMES: % FREE SUGAR INTAKES AND ADHERENCE (Week 12, Change from Baseline – Week 12)

Data for %FS at week 12, adherence at week 12 and change in %FS over the 12 week study period, per intervention group are given in Table 2. Results from primary and secondary regression models are given in Tables 3 - 5, with correlation coefficients to identify additional variables for secondary models provided in the Supplementary Materials (Tables SM4 and SM5). Both primary outcomes were significantly predicted by the regression models. Lower %FS at week 12 was associated with being in an intervention group vs control (B=-0.573, p=0.03) and lower %FS at baseline (B=0.311, p<0.01). Greater adherence was associated with greater %FS at baseline (B=0.181, p<0.01). A greater reduction in %FS over the 12 weeks was associated with intervention vs control (B=0.610, p=0.03), greater %FS at baseline (B=0.631, p<0.1), and a greater reduction in %TEI from carbohydrate (B=0.105, p<0.01). For all three outcomes, regression analyses using secondary models in only the three intervention groups revealed no significant differences between interventions (W12 %FS intakes: B=-0.310, p=0.46; adherence: B=0.005, p=0.98; change in %FS: B=0.352, p=0.42).

Tables 2 - 5 about here

3.2.2. SECONDARY OUTCOMES: DIETARY PROFILES: TOTAL ENERGY INTAKE, DIET COMPOSITION AND FOOD CONSUMPTION (Week 12, Change from Baseline – Week 12)

Data on TEI, diet composition and high-sugar, medium-sugar, low/no-sugar and LCS-sweetened food consumption are given in Table 6.

Table 6 about here

Results from the primary and secondary regression models for TEI data at Week 12 and for data on change from baseline to Week 12 are given in the Supplementary Materials (Table SM6). In all models, TEI at Week 12 and for change from baseline to Week 12 were predicted, where baseline TEI was a significant predictor (smallest B=0.232, p<0.01) alongside various measures of diet composition. There were no associations with intervention/control (most significant B=3.689, p=0.86).

Regression models for diet composition data at Week 12 and for change from baseline to Week 12 are given in the Supplementary Materials (Tables SM7 and SM8 respectively). All models were statistically significant, with the exception of the secondary model for percent TEI consumed from

fat at week 12. In all other models, excepting the secondary model for Sodium intake at week 12, baseline consumption was a significant predictor (smallest B=0.115, p=0.04), and for all outcomes excepting those for fat and saturated fat, TEI at week 12 or change in TEI from baseline to TEI was a significant predictor (smallest B=-0.006, p=0.03). Some other measures of diet composition and some demographic variables were also significant predictors. There were no associations with intervention/control (most significant B=0.373, p=0.37).

Regression models for the food consumption data at Week 12 and for data on change from baseline to Week 12 are given in the Supplementary Materials (Tables SM9 and SM10 respectively). Models for all food consumption measures at week 12 (items and grams) were not significant. All models for change in food consumption from baseline to week 12 (items and grams) were significant, where change in food consumption was negatively associated with baseline consumption (smallest B=-0.954, p<0.01).

3.2.3. SECONDARY OUTCOMES: ANTHROPOMETRY (Week 12, Change from Baseline to Week 12)

Data on body weight, BMI and waist circumference over the 12 week period are given in Table 7.

Table 7 about here

Results from the primary and secondary regression models for data at Week 12 and for data on change from baseline to Week 12 are given in the Supplementary Materials (Tables SM11 and SM12, respectively). In secondary models, all anthropometry outcomes at Week 12 and for change from baseline to Week 12 were predicted. For all outcomes at Week 12, baseline variable was a significant predictor (smallest B=0.885, p<0.01). In addition, intervention/control group was a significant predictor for body weight at week 12 (B=-0.377, p=0.047), where body weight was lower in intervention groups compared with control. No significant differences between interventions were found (B=-0.251. p=0.40). Change in anthropometry over the 12-week period was associated with baseline characteristics, other aspects of anthropometry and some dietary measures. There were no associations with intervention/control (most significant B=0.283, p=0.13).

3.2.4. SECONDARY OUTCOMES: EFFECTS IN %FREE SUGAR INTAKES AND ADHERENCE AT WEEKS 1, 2, 4, 8 AND 12

Effects in %FS and adherence at different time points are demonstrated in Figures 2 and 3; data and results of the regression analyses are provided in the Supplementary Materials (Tables SM13 –

SM15). Effects of intervention vs control were found in %FS at all time points (Week 1: B=-0.791, p<0.01; Week 2: B=-0.921, p<0.01; Week 4: B=-0.659, p=0.02; Week 8: B=-0.668, p=0.01; Week 12: B=-0.573, p=0.03), and in adherence at weeks 1 (B=0.418, p<0.01) and 8 (B=0.314, p=0.03). Analyses of only the three intervention groups revealed no differences based on intervention, except in %FS at Week 2 (B=-0.836, p=0.04), where group NFS had a lower %FS than groups N and NF. %FS and adherence at each time point were also associated with baseline %FS (smallest B=0.138, p<0.01), and high correlations were found between %FS at all time points (smallest r=0.448, p<0.01).

Figures 2 and 3 about here

3.2.5. EXPLORATORY ANALYSES: Change in % Free Sugar Intakes (Change from Baseline – Week 12)

Considering our interest in %FS and the association in change in %FS with change in %TEI from carbohydrate, additional analyses investigated change in %FS using all baseline and change variables for diet composition. Results are shown in the Supplementary Materials (Table SM16). A greater reduction in %FS was associated with being in an intervention group vs control (B=0.605, p=0.03), greater baseline %FS (B=0.677, p<0.01), greater baseline %TEI from protein (B=0.207, p=0.04), a greater reduction in %TEI from carbohydrate (B=0.106, p<0.01) and an increase in %TEI from protein (B=-0.193, p=0.01). Considering %FS contributes to %TEI from carbohydrate, analyses were also redone using %TEI from intrinsic sugars and %TEI from non-sugar carbohydrate in place of %TEI from carbohydrate (see also Table SM16). A greater reduction in %FS was associated with intervention vs control (B=0.537, p=0.04), greater baseline %FS (B=0.693, p<0.01), greater baseline %TEI from protein (B=0.217, p=0.02), a greater reduction in %TEI from non-sugar carbohydrate (B=0.141, p<0.01) and an increase in %TEI from protein (B=-0.171, p=0.02).

Considering our interest in the use of nutrient-, food- and food-substitution based recommendations to enable change in %FS, exploratory analyses also investigated change in %FS using baseline and change in sugar and LCS-sweetened food consumption. Results are shown in the Supplementary Materials (Table SM16). A greater reduction in %FS was associated with being in an intervention group vs control (B=0.643, p=0.03) and greater baseline %FS (B=0.626, p<0.01), but not with sugar-sweetened or LCS-sweetened food consumed (largest B=-0.061, p=0.11).

3.2.6. EXPLORATORY ANALYSES: Body weight, BMI and Waist Circumference (Week 12)

Considering our interest in anthropometry and the effects of group on body weight at week 12, exploratory analyses were also conducted to investigate any changes in diet composition that were

associated with body weight, BMI and waist circumference. Regression models are provided in the Supplementary Materials (Table SM17). Limited effects were found. Body weight at week 12 was associated with age (B=0.033, p=0.05) and baseline body weight (B=0.044, p<0.01), BMI at week 12 was associated only with age (B=0.012, p=0.04), and waist circumference was associated with baseline waist circumference (B=0.081, p=0.02), baseline %TEI from fat (B=0.401, p=0.01) and change in TEI (B=0.002, p=0.04). Similar effects were found if %TEI from carbohydrate was separated as %TEI from intrinsic sugars and %TEI from non-sugar carbohydrate (Table SM17).

3.3. ANALYSES TWO

Analyses for %FS, adherence, TEI, BW, BMI and WC were undertaken using secondary models as defined above, at Week 12 and for change from baseline to Week 12, in the following population sub-groups: females only (N=214); lean individuals (BMI <= 25.00 kg/m2) (N=85); individuals with overweight (BMI 25.01 – 30.00 kg/m2) (N=85); individuals with obesity (BMI > 30.01 kg/m2) (N=72); sweet likers (N=91); those with an inverted U-shaped sweet liking function (N=90); sweet dislikers (N=61). Full description of the groups, results and commentary are given in the Supplementary Materials (including Tables SM18 – SM31). Analyses based on correctly vs mistakenly reporting adherence (active adherent (N=126) vs passive non-adherent (N=84)) are also given (Table SM32).

To highlight any differences based on intervention/control, in females only, %FS at Week 12, change in %FS and body weight at week 12 were associated with being in an intervention group vs control (smallest B=-0.422, p=0.04), but no differences between interventions were found. Mean (se) %FS at week 12 for each group was Control = 8.9 (0.8) %, N = 7.8 (0.7) %, NF = 7.6 (0.8) % and NFS = 6.9 (0.6) %. Mean (se) change in %FS for each group was Control = -1.3 (0.8) %, N = -2.7 (0.8) %, NF = -2.9 (0.8) % and NFS = -3.5 (0.7) %. Mean (se) body weight at week 12 for each group was Control = 76.2 (2.4) kg, N = 74.0 (2.1) kg, NF = 78.1 (2.4) kg and NFS = 73.0 (1.9) kg, with a mean (se) change in body weight from baseline to week 12 for each group of Control = -0.2 (0.4) kg, N = -0.6 (0.4) kg, NF = -1.5 (0.5) kg and NFS = -1.3 (0.5) kg. In participants with overweight, BMI at week 12 was associated with intervention vs control (B=-0.195, p=0.04), but no effects of intervention type were found. In individuals with obesity, body weight at week 12 was associated with intervention vs control (B=1.036, p=0.04), but no differences between interventions were found. In those with an inverted U-shaped sweet liking function, effects of intervention vs control were found in body weight and BMI at week 12 (least significant B=-0.622, p=0.02), but no effects of intervention type were found. In sweet dislikers, effects of intervention vs control were found in change in %FS (B=1.283, p0.02)

with a marginal difference between interventions (B=1.588, p=0.052). Mean (se) change in %FS for each group was Control = -1.4 (1.5) %, N = -0.7 (1.2) %, NF = -3.8 (1.7) % and NFS = -3.5 (1.4) %.

4. DISCUSSION

This randomized controlled trial investigated the effects of nutrient-, nutrient- and food-, and nutrient-, food- and food-substitution-based dietary recommendations versus control for reducing free sugar intakes, on free sugar intakes, various measures of diet, and anthropometry, in UK adults consuming >5% total energy intake from free sugars. A total of 242 participants were recruited, with a mean %FS at baseline comparable to that reported in the UK population as a whole[59], and 200 (83%) participants completed the study. In Intention-to-Treat analyses, adjusted for baseline and select additional measures, we found reduced %FS in all intervention groups compared with control, reductions in %FS at week 1 that remained until week 12, no differences between interventions, some effects in diet composition, but limited effects in measures of food consumption. We also found a lower body weight in intervention groups compared with control at week 12, no effects in BMI or waist circumference, no adverse events, and few differences in population subgroups based on body weight or sweet-liker status.

Free sugar intakes reduced in all intervention groups throughout the study to result in reductions by week 12 of 2.5% to 3.3% of TEI. Based on a standard deviation of 4.8%, as gained from the sample as a whole at baseline, our findings represent moderate effect sizes from 0.52 – 0.69 SDs. These effect sizes are consistent with and larger than the effect sizes reported in meta-analyses of reductions in sugar intake following a range of public health strategies[19], but smaller than those that have previously been reported with more intensive dietary manipulations[15-17]. Participants in the CHOICE trial report a reduction in free sugars as a percentage of TEI of 5.2 - 5.7% over a comparable time period[15,16], and Ebbeling and colleagues report reductions of 7.3 – 9.9% TEI over 12 months[17]. Participants in the more intensive studies however, also typically consumed a higher percentage of TEI from free sugars at study start (from 14.5% to 27% TEI), and greater reductions in those with higher baseline intakes is an effect we also find.

Our effects were achieved using a low-intensity single time-point intervention. Effects were found furthermore from week 1, but were seen to reduce over the 12-week period. Our participants were willing volunteers, eager to make a dietary change, thus early effects may be unsurprising. Psychological theories recognise and numerous studies demonstrate the importance of motivation for behaviour change[60-63], and a potential impact of participant motivation on our findings can not

be denied. Our participants were also monitoring their food intakes throughout the study, and while this was also the case for all participants (regardless of intervention/control allocation), various studies also demonstrate the impact of dietary recording for increasing awareness of dietary intakes, to result in dietary change[28,64-66]. These factors however, do not diminish the value of our findings. Our trial was designed to investigate effects in a public health setting; thus, while effects may be smaller than those of more intensive interventions, our findings can be considered achievable by the general public, and our interventions would likely have greater reach than can be gained from more intensive protocols.

No differences were found between interventions. These findings may suggest limited added value to the additional information provided in the food-based and food-substitution-based recommendations, compared to that provided on nutrients. Secondary analyses further reveal no differences between intervention groups in sugar-rich or LCS-sweetened food consumption, as targeted differently for the differing groups. However, while no changes at the food level were found, exploratory analyses on diet composition do reveal associations between a reduced intake of free sugars, a reduced intake of energy consumed from non-sugar carbohydrate and an increase in energy consumed from protein, with no effects found in energy consumed from fat, or in fibre or sodium intakes. These findings suggest that participants were specifically targeting sugars and high carbohydrate foods, by reducing their consumption of food items such as sugar-sweetened beverages, confectionary and desserts, or replacing these with non-sweetened or naturally-sweetened food sources, such as fruit and milk-based beverages and desserts such as yoghurts. Dietary profiles lower in free sugars and higher in protein intakes were also found in the CHOICE trial[15,16], and will be beneficial for health from both dietary changes[2,4]. Adverse effects on dietary profiles, e.g., through increases in fat or salt consumption as a result of the replacement of high-sugar foods with high-fat savoury foods, were not found.

The lack of clear effects at the food level suggests that changes in the individual foods consumed were small and varied among participants, but over the diet as a whole and when deconstructed as dietary components resulted in effects that were detected. These findings likely reflect the unconstrained nature of our interventions, where participants in all intervention groups were free to reduce their consumption of high-sugar foods and increase their consumption of non-sweetened or LCS-sweetened foods as they wished whether they were given this advice or not. Indeed, the absence of effects of intervention versus control in all measures of food consumed suggest few differences between groups. These findings suggest that participants undertook only small changes

to their diets, and may suggest benefit to retaining the inclusive nature of an intervention by offering participants multiple solutions and free choice. The only difference between interventions in our study demonstrates a greater reduction in %FS at week 2 from the nutrient, food- and food substitution-based recommendations. These findings may suggest some benefit to recommending food substitutions[15-18], but these recommendations also provided many small behavioural changes that offered choice. Other researchers suggest value from small dietary changes in relation to body weight and body weight loss[67-70], and Stroebele et al.[71] demonstrate value specifically for sugar intakes. The behavioural changes implemented in some sugar reduction studies that have yielded success can also be suggested as small (e.g. replacement of 1 sugar-sweetened beverage per day)[17], and small changes are often preferred for product reformulation to avoid impacts on acceptability[14,72,73]. Choice and autonomy have also been applauded for health behaviour change[60-63], and success following implementation of these ideas has again been documented[63]. Thus, on a preliminary basis, recommendations for dietary change that provide options and alternatives, for small changes to behaviour, may be appropriate at a population level. Many existing public health interventions take this approach[19,20,74-76], and while evaluations typically state shortcomings as a result of not knowing which elements of an intervention have caused an effect, our findings suggest that this concern may not be justified. Beyond recommendations for reducing free sugar intakes, our findings may further be relevant to guidelines for reducing or increasing other dietary components. Testing would be required, but various studies suggest poor adherence to dietary guidelines for several aspects of the diet[77-79], and a lack of understanding that would be aided by practical solutions[77]. Evidence-based strategies to increase adherence to dietary guidelines would clearly contribute positively towards health.

Effects on body weight were also found at week 12, accounting for baseline body weight and a range of additional variables, where intervention groups had lower body weights, having lost 0.7 – 1.4 kg body weight over the 12 week period compared with 0.2 kg in the control group. Effect sizes are small, but comparable with the effects of other interventions targeting sugar reduction[14,16,80]. Haslem et al.[14] report a body weight reduction of 1.04 kg in a meta-analysis of three studies on product reformulation, and we report a body weight reduction of 1.06 kg in a meta-analysis of 29 studies comparing sugar with LCS consumption[80]. While related to our interventions, however, changes in body weight were not associated with free sugar intakes, or any other dietary measure. These findings may again reflect the small and varied nature of the dietary changes undertaken on an individual basis by members of our study population. Greater changes over the 12 weeks in those with a higher body weight at baseline, both in our main analyses and our sub-group analyses, are

consistent with the literature[17,81-83], as are the positive associations between body weight at baseline and at week 12[81,82].

Limited additional consistent effects were found in subgroup analyses based on population group. Effects in females reflect those found in the whole sample. The limited effects based on BMI or sweet-liker status are most plausibly explained as a result of an inability to detect small dietary changes against a back-drop of high dietary variety in small samples. The one effect found in sweet dislikers (a greater reduction in %FS in NF and NFS groups) may suggest some changes to food intakes, but sample sizes are now very low. However, the low correlations between liking perceptions for the sweet solution and the impregnated taste paper may also cast doubt on the 'trait' status of sweet-liker status, and while the proportions of sweet likers, sweet dislikers and those demonstrating an inverted U-shaped sweet liking function in our study population are comparable to those found in other studies[38,39], our study population also consumed only around 10% intake from high-sugar foods and 4% intake from LCS-sweetened foods at baseline. Further analyses on the perceptions of sweet taste in this study and other outcomes related to sweet taste will be reported elsewhere.

Strengths of our study include adherence to our pre-registered protocol[21], achievement of our estimated sample size and drop out rate, resulting in recruitment and inclusion of a large and diverse study sample, and our use of ITT analyses on an imputed data set. Important limitations must also be considered. Firstly, our primary outcome was assessed using diet diaries, which can be subject to misreporting[28-32]. Food diaries, however, are considered an appropriate method for capturing dietary intakes in a free-living situation[29-32], demonstrate validity[29-32], and have been found to demonstrate good intra-individual reliability, as is required for investigating short-term changes over time[30]. Reported TEI does decrease over our 12 week assessment period, but weight loss also occurred over the study period, thus a reduction in reported TEI would be expected. All dietary recording was checked at the time of submission, by a researcher blinded to intervention group, difficulties with reporting, including difficulties with digital recording or the necessary software were remedied quickly, our bogus pipeline method and dietary consultations for taking part were intended to encourage accurate reporting, and our control group was designed to control for dietary recording. Furthermore, no group-based differences were found in TEI, while differences were found in our primary outcome (%FS), an assessment adjusted for reported energy intake, rather than an absolute quantity. We can make no comment on the possibility (or not) of sugar-specific misreporting. Considering the weight loss incurred across the study period and the desire by many

participants to lose weight as a reason for taking part, standard checks for misreporting[84,85] on the select days when reporting was requested, furthermore, are unlikely to be valid. In the absence of a biomarker for sugar intake, we consider our methods to be the most appropriate available for assessing free sugar intakes in the real world. Second, calculations of free sugar content were only based on the information available, or calculated from products with known content, but variety between products can exist, and some of this variation will have been lost by our methods[14]. As above, however, there will be no systematic bias between groups or over time in our data because all dietary data were cleaned only after data collection, by a researcher blinded to treatment allocation, and foods with missing data were consistently replaced with the same alternative. LCS-sweetened foods were also classified as such, based on product description rather than product ingredient list. This description was used to identify foods that study participants were likely to have selected because they were LCS- rather than sugar-sweetened, based on the details in our recommendations, but this description may not reflect all LCS-sweetened foods, and will certainly not reflect all foods that contain LCS. With over 8,000 foods consumed as part of the study, and considering our study aims, the methods used were considered most pragmatic. Again, furthermore, the method was implemented only after data collection, in all participants and over all time points equally, by a researcher blinded to treatment allocation, thus no systematic bias between groups or over time will have been introduced.

Our study sample, while large, was also not powered to detect differences smaller than 2% TEI, and free sugar intakes at baseline were only slightly above the 10% TEI recommendations of the WHO[1], thus differences between interventions may have been difficult to detect. Further study in those of higher free sugar intakes would be of interest. Our interventions were also not based solely on nutrient information, food-based information or food-substitution-based information, which would have resulted in a purer test of the different types of information, but the interventions were designed for use in a public health context. Our sample was diverse in terms of age, education and occupation, but was dominated by females, thus generalization to males or the population as a whole is not possible. Females are known to be more interested in diet and health than males[86], thus over-recruitment in this group is unsurprising, but females are also still more commonly responsible for dietary purchasing and food provision within the household[86,87] (and indeed the majority of the sample reported themselves as 'the main cook within their household'), thus effects in this group will be of value. Our study must also be considered in context. Our study was advertised as a study of dietary change, to recruit those who might be inclined to comply with our dietary change requests and so provide the best test of our hypothesis. The study thus likely

attracted participants who were thinking of and motivated to change their diet, and some of our effects will likely have resulted from this motivation[60-63]. In this respect, it is probable that effects of our recommendations in the general population may be smaller than those identified here. This initial desire to change one's diet may also explain the drop-out rate in the control group. Drop-out was noticeably higher in the control compared to the intervention groups, and some anecdotal comments from participants in this group suggested a dissatisfaction with the dietary recommendations that they were given. We can also make no comment on the length of time over which the effects of our interventions may last, particularly once dietary recording ceased, nor can we offer any suggestion of the value of our recommendations compared to alternative interventions offering dietary advice[88], or to alternative types of intervention, such as changes to the environment, e.g. via product reformulation or limiting availability, and changes to public policy, such as increased taxes and legislation requiring reformulation[19,20].

Conclusion

In this randomized controlled trial, we sought to investigate the effects of nutrient-, food- and food-substitution-based dietary recommendations for reducing free sugar intakes in UK adults consuming >5% total energy intake (TEI) from free sugars. The study was conducted in a public health context, where free-living members of a community sample were given recommendations at a single time point, with outcomes assessed over 12 weeks. Free sugar intakes (as a percentage of TEI) reduced in all intervention groups compared with control, from week 1 to remain for 12 weeks. No differences between interventions were found, nor were differences detected in sugar-rich and LCS-sweetened food consumption, but effects were associated with reductions in non-sugar carbohydrate consumption and increases in protein intake. Reductions in body weight were also found, and no adverse events were reported. Our findings demonstrate benefit from public health recommendations for free sugar intakes, and suggest no universal benefit from any one strategy or another, but instead may suggest benefit from recommendations with multiple options for individual choice.

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Table 1: Participant Characteristics (gender, age, body weight, BMI, and %FS) (N or mean ± standard deviation) for the sample as a whole and for each intervention/control group (N=242)

	Whole Sample (N=242)	Control Group (N=58)	Group N (N=61)	Group NF (N=60)	Group NFS (N=63)
Gender					
Male (N)	28	5	7	8	8
Female (N)	214	53	54	52	55
Age (years) (mean ± SD)	41.3 ± 13.1	41.7 ± 12.6	42.4 ± 14.0	38.3 ± 12.2	42.5 ± 13.4
Body weight (kg) (mean ± SD)	77.8 ± 17.6	76.7 ± 16.7	77.4 ± 18.7	81.2 ± 18.5	76.2 ± 16.3
BMI (kg/m^2) (mean ± SD)	27.7 ± 5.7	27.5 ± 5.8	27.5 ± 5.7	28.5 ± 5.9	27.4 ± 5.6
% FS (%)(mean ± SD)	10.3 ± 4.8	10.4 ± 5.1	10.1 ± 5.2	10.7 ± 4.8	10.2 ± 4.4

N: Nutrient-based recommendations; NF: Nutrient- and Food-based recommendations; NFS: Nutrient-, Food- and Food-Substitution-based recommendations.

Table 2: Percent free sugar intakes (mean ± standard error) at baseline, week 12, change in percent free sugar intakes over the 12 week study period, and adherence at week 12 (N (%), per intervention group (N=242), statistically-significant differences between the three intervention groups and control in % free sugar intakes at week 12 and change in % free sugar intakes from baseline to week 12 ($p<0.05$), different letters signify significant differences between groups, as gained from regression analyses.

		Control Group (N=58)	Group N (N=61)	Group NF (N=60)	Group NFS (N=63)
% Free Sugars	Baseline	10.4 ± 0.7	10.1 ± 0.7	10.7 ± 0.6	10.2 ± 0.6
	W12	9.2 ± 0.7[a]	7.7 ± 0.7[b]	7.4 ± 0.7[b]	7.1 ± 0.6[b]
Δ Baseline – W12		-1.2 ± 0.8[a]	-2.5 ± 0.8[b]	-3.3 ± 0.8[b]	-3.1 ± 0.7[b]
Adherence	W12	Adherent: - active: 23 (40) - passive: 2 (3) Non-adherent: - active: 3 (5) - passive: 31 (53)	Adherent: - active: 34 (56) - passive: 4 (7) Non-adherent: - active: 8 (13) - passive: 15 (25)	Adherent: - active: 36 (60) - passive: 3 (5) Non-adherent: - active: 4 (7) - passive: 17 (28)	Adherent: - active: 33 (52) - passive: 6 (10) Non-adherent: - active: 3 (5) - passive: 21 (33)

N: Nutrient-based recommendations; NF: Nutrient- and Food-based recommendations; NFS: Nutrient-, Food- and Food-Substitution-based recommendations.

Table 3: Primary and secondary regression models for %FS at week 12[1]

	W12 %FS							
	Primary Model				Secondary Model[2]			
	R^2=0.21 adj.R^2=0.18, F(7,241)=8.68, p<0.01				**R^2=0.29 adj.R^2=0.27 F(9,241)=10.76, p<0.01**			
	B	se.	p	95% CI	B	se.	p	95% CI
Group	**-.636**	**.29**	**.03**	**-1.205, -.066**	**-.573**	**.27**	**.03**	**-1.104, -.043**
Gender	-.782	.97	.42	-2.680, 1.116	-.660	.96	.49	-2.533, 1.213
Age	.015	.03	.56	-.034, .064	.018	.02	.46	-.030, .066
BL %FS	**.377**	**.07**	**<.01**	**.248, .507**	**.311**	**.07**	**<.01**	**.183, 439**
BL BW	**-.040**	**.02**	**.04**	**-.079, -.002**	-.033	.02	.08	-.071, .004
W12 TEI	.001	.00	.22	-.001, .002	.001	.00	.40	-.001, 002
W12 PA	.013	.02	.51	-.026, .053	.008	.02	.68	-.031, .047
W12 %TEI CHO					**.093**	**.03**	**<.01**	**.026, .160**
W12 %TEI Protein					**-.201**	**.07**	**<.01**	**-.338, -.064**

95% CI: 95% confidence intervals; %FS: Free sugar intakes as a percentage of TEI; BL: Baseline; BW: Body Weight; W12: Week 12; TEI: Total Energy Intake; PA: Physical Activity; %TEI CHO: Percent energy consumed from carbohydrate; %TEI Protein: Percent energy consumed from protein.

[1]Primary models investigated effects of intervention/control group (control = 0, N = 1, NF = 2, NFS = 3) and included adjustment for gender, age, baseline %FS, baseline body weight, W12 TEI and W12 physical activity; secondary models consisted of primary models plus correlating secondary outcomes. Statistically significant effects are given in bold. Correlation coefficients to identify additional variables for secondary models are given in the Supplementary Materials (Tables SM4 and SM5).

[2]Additional variables: W12 %TEI CHO; W12 %TEI Protein.

Table 4: Primary and secondary regression models for adherence data at week 12[1]

	Adherence							
	Primary Model				Secondary Model[2]			
	CS R^2=0.11, N R^2=0.14, $X^2(7)$=26.92, p<0.01				**CS R^2=0.22, N R^2=0.29, $X^2(10)$=59.33, p<0.01**			
	B	se.	p	95% CI	B	se.	P	95% CI
Group	**.274**	**.14**	**.05**	**.208, .360**	.274	.15	.07	.204, .369
Gender	.058	.48	.91	.023, .148	.029	.54	.96	.010, .083
Age	-.009	.01	.42	-.009, -.009	-.002	.02	.92	-.002, -.004
BL %FS	**.123**	**.04**	**<.01**	**.115, .132**	**.181**	**.04**	**<.01**	**.166, .197**
BL BW	.017	.01	.10	.017, .017	.012	.01	.27	.012, .012
W12 TEI	.000	.00	.49	.000, .000	.000	.00	.85	.000, .000
W12 PA	-.005	.01	.60	-.005, -.005	-.002	.01	.89	-.002, -.002
BL FCQ Natural factor					-.365	.25	.14	-.226, -.591
W12 %TEI CHO					**-.051**	**.02**	**.01**	**-.049, -.053**
W12 %TEI Protein					**.005**	**.04**	**<.01**	**.005, .005**

95% CI: 95% confidence intervals; %FS: Free sugar intakes as a percentage of TEI; BL: Baseline; BW: Body Weight; W12: Week 12; TEI: Total Energy Intake; PA: Physical Activity; %TEI CHO: Percent energy consumed from carbohydrate; %TEI Protein: Percent energy consumed from protein. FCQ: Food Choice Questionnaire.

[1]Primary models for adherence used binary models – adherent vs non-adherent, to investigate effects of intervention/control group (control = 0, N = 1, NF = 2, NFS = 3) and included adjustment for gender, age, baseline %FS, baseline body weight, W12 TEI and W12 physical activity, secondary models consisted of primary models plus correlating secondary outcomes. Statistically significant effects are given in bold. Correlation coefficients to identify additional variables for secondary models are given in the Supplementary Materials (Tables SM4 and SM5).

[2]Additional variables: BL Food Choice Questionnaire (FCQ) Natural content factor; W12 %TEI CHO; W12 %TEI Protein. W12 %FS not included due to concerns over multi-co-linearity.

Table 5: Primary and secondary regression models for change in %FS over the 12 week period[1]

	Change %FS							
	Primary Model				Secondary Model[2]			
	R^2=0.34 adj.R^2=0.32				**R^2=0.39 adj.R^2=0.36**			
	F(7,241)=17.55, p<0.01				**F(9,241)=16.34, p<0.01**			
	B	Se.	p	95% CI	B	se.	p	95% CI
Group	**.639**	**.29**	**.03**	**.067, 1.211**	**.610**	**.28**	**.03**	**.051, 1.169**
Gender	.895	.97	.36	-1.006, 2.796	.570	.99	.52	-1.364, 2.504
Age	-.018	.03	.46	-.067, .031	-.021	.03	.41	-.070, .029
BL %FS	**.616**	**.07**	**<.01**	**.488, .744**	**.631**	**.07**	**<.01**	**.490, .772**
BL BW	**.039**	**.02**	**.05**	**.000, .078**	.034	.02	.09	-.005, .073
Change TEI	.001	.00	.30	-.001, .002	.001	.00	.06	-.000, .003
Change PA	-.013	.02	.50	-.051, .025	-.014	.02	.46	-.052, .024
W12 %TEI CHO					-.070	.05	.20	-.176, .037
Change %TEI CHO					**.105**	**.04**	**<.01**	**.028, .183**

95% CI: 95% confidence intervals; %FS: Free sugar intakes as a percentage of TEI; BL: Baseline; BW: Body Weight; W12: Week 12; TEI: Total Energy Intake; PA: Physical Activity; %TEI CHO: Percent energy consumed from carbohydrate.

[1]Primary models investigated effects of intervention/control group (control = 0, N = 1, NF = 2, NFS = 3) and included adjustment for gender, age, baseline %FS, baseline body weight, change (baseline to W12) in TEI and change (baseline to week 12) physical activity, secondary models consisted of primary models plus correlating secondary outcomes. Statistically significant effects are given in bold. Correlation coefficients to identify additional variables for secondary models are given in the Supplementary Materials (Tables SM4 and SM5).

[2]Additional variables: Baseline %TEI CHO; Change %TEI CHO.

Table 6: Daily total energy intake (TEI), diet composition (%TEI from carbohydrate (CHO) (%), protein (%), fat (%), saturated fat (%), fibre (g), sodium (mg)) and high-sugar, medium-sugar, low/no-sugar and LCS-sweetened food consumption, in number of food items consumed and grams of food consumed / day (mean ± standard error) at baseline, week 12, and change from baseline to week 12, per intervention group (N=242), no statistically-significant differences between control and intervention groups.

		Control Group (N=58)	Group N (N=61)	Group NF (N=60)	Group NFS (N=63)
TEI (kcal/day)	Baseline	1782 ± 71	1727 ± 64	1774 ± 62	1684 ± 55
	W12	1516 ± 56	1512 ± 60	1466 ± 70	1495 ± 56
	Δ Baseline – W12	-266 ± 79	-215 ± 63	-308 ± 59	-188 ± 69
%TEI CHO (%)	Baseline	42.1 ± 0.9	43.1 ± 0.9	40.9 ± 1.0	42.1 ± 0.9
	W12	42.9 ± 2.2	41.4 ± 1.9	41.9 ± 1.7	41.3 ± 1.9
	Δ Baseline – W12	-0.8 ± 2.3	-1.8 ± 1.9	1.0 ± 1.9	-0.8 ± 2.0
%TEI protein (%)	Baseline	16.5 ± 0.7	17.1 ± 0.6	16.6 ± 0.5	17.0 ± 0.6
	W12	17.3 ± 0.9	18.1 ± 0.7	17.9 ± 0.8	17.8 ± 0.7
	Δ Baseline – W12	0.9 ± 1.1	1.0 ± 0.8	1.3 ± 0.8	0.8 ± 0.9
%TEI fat (%)	Baseline	29.1 ± 0.6	28.8 ± 0.6	30.6 ± 0.7	29.6 ± 0.6
	W12	30.6 ± 2.0	30.8 ± 1.5	30.3 ± 1.3	30.2 ± 1.3
	Δ Baseline – W12	1.4 ± 2.1	2.0 ± 1.6	0.3 ± 1.4	0.7 ± 1.4
%TEI saturated fat (%)	Baseline	10.1 ± 0.3	9.7 ± 0.3	11.2 ± 0.4	10.2 ± 0.4
	W12	11.1 ± 0.7	10.9 ± 0.7	10.6 ± 0.6	10.6 ± 0.6
	Δ Baseline – W12	1.0 ± 0.7	1.1 ± 0.7	-0.6 ± 0.7	0.4 ± 0.6
Fibre (g)	Baseline	19.4 ± 1.0	19.8 ± 1.2	18.3 ± 0.9	18.4 ± 1.0
	W12	16.3 ± 1.1	17.7 ± 1.3	16.6 ± 1.0	16.8 ± 1.3
	Δ Baseline – W12	-3.2 ± 1.3	-2.2 ± 0.9	-1.7 ± 0.9	-1.5 ± 1.2
Sodium (mg)	Baseline	1985 ± 103	2136 ± 114	2179 ± 125	2053 ± 90
	W12	1873 ± 98	1955 ± 96	1945 ± 108	1839 ± 84
	Δ Baseline – W12	-112 ± 124	-181 ± 115	-234 ± 154	-214 ± 110

N: Nutrient-based recommendations; NF: Nutrient- and Food-based recommendations; NFS: Nutrient-, Food- and Food-Substitution-based recommendations.

Table 6: Daily total energy intake (TEI), dietary composition (%TEI from carbohydrate (%), protein (%), fat (%), saturated fat (%), fibre (g), sodium (mg)) and high-sugar, medium-sugar, low/no-sugar and LCS-sweetened food consumption, in number of food items consumed and grams of food consumed / day (mean ± standard error) at baseline, week 12, and change from baseline to week 12, per intervention group (N=242), continued, no statistically-significant differences between control and intervention groups.

		Control Group (N=58)	Group N (N=61)	Group NF (N=60)	Group NFS (N=63)
HS foods (% food items/day)	Baseline	10.1 ± 1.2	9.3 ± 1.0	10.1 ± 1.2	10.6 ± 1.3
	W12	8.1 ± 1.6	8.1 ± 1.4	7.0 ± 1.3	8.7 ± 1.5
	Δ Baseline – W12	-2.0 ± 2.0	-1.2 ± 1.8	-3.1 ± 1.8	-1.9 ± 2.0
MS foods (% food items/day)	Baseline	20.5 ± 1.7	20.0 ± 1.4	18.0 ± 1.7	17.9 ± 1.5
	W12	18.4 ± 1.9	16.5 ± 1.8	18.8 ± 1.8	15.5 ± 1.8
	Δ Baseline – W12	-2.1 ± 2.7	-3.5 ± 2.5	0.8 ± 2.5	-2.4 ± 2.3
L/NS foods (% food items/day)	Baseline	69.4 ± 2.0	70.7 ± 1.6	71.8 ± 1.8	71.5 ± 1.9
	W12	73.5 ± 2.5	75.4 ± 2.3	74.2 ± 2.2	75.8 ± 2.4
	Δ Baseline – W12	4.0 ± 3.3	4.7 ± 3.1	2.3 ± 2.8	4.3 ± 3.0
LCS foods (% food items/day)	Baseline	4.0 ± 0.9	4.4 ± 1.1	4.8 ± 1.1	3.5 ± 0.8
	W12	2.8 ± 6.5	5.2 ± 10.9	2.2 ± 7.0	3.5 ± 8.4
	Δ Baseline – W12	-1.4 ± 1.6	1.3 ± 2.0	-2.5 ± 1.5	0.2 ± 1.3
HS foods (% grams/day)	Baseline	3.9 ± 0.6	4.6 ± 1.1	3.7 ± 0.8	4.0 ± 0.8
	W12	3.3 ± 1.3	2.7 ± 0.7	2.9 ± 0.9	3.2 ± 1.1
	Δ Baseline – W12	-0.6 ± 1.4	-2.0 ± 1.3	-0.8 ± 1.1	-0.9 ± 1.4
MS foods (% grams/day)	Baseline	17.8 ± 2.1	15.5 ± 1.8	14.5 ± 1.9	12.1 ± 1.4
	W12	16.2 ± 2.8	12.9 ± 2.1	12.6 ± 1.7	11.2 ± 2.2
	Δ Baseline – W12	-1.6 ± 3.7	-2.6 ± 2.9	-1.8 ± 2.4	-1.0 ± 2.6
L/NS foods (% grams/day)	Baseline	78.4 ± 2.2	79.9 ± 2.0	81.9 ± 2.0	83.9 ± 1.4
	W12	85.8 ± 8.3	87.3 ± 4.2	86.0 ± 3.9	89.8 ± 6.4
	Δ Baseline – W12	7.4 ± 8.6	7.4 ± 4.7	4.1 ± 4.3	5.9 ± 6.6
LCS foods (%grams/day)	Baseline	7.9 ± 1.9	6.6 ± 2.0	8.7 ± 1.9	6.6 ± 1.8
	W12	4.4 ± 3.3	8.5 ± 3.2	3.4 ± 1.9	5.5 ± 1.9
	Δ Baseline – W12	-3.6 ± 3.8	1.9 ± 3.8	-5.4 ± 2.8	-1.0 ± 2.5

N: Nutrient-based recommendations; NF: Nutrient- and Food-based recommendations; NFS: Nutrient-, Food- and Food-Substitution-based recommendations.

Table 7: Body weight (kg), BMI (kg/m^2) and waist circumference (cm) (mean ± standard error) at baseline, week 12, and change from baseline to week 12, per intervention group (N=242), statistically-significant differences in body weight between control and the three intervention groups at week 12 ($p<0.05$), different letters signify significant differences between groups, as gained from regression analyses.

		Control group (N=58)	Group N (N=61)	Group NF (N=60)	Group NFS (N=63)
Body Weight (kg)	Baseline	76.7 ± 2.2	77.4 ± 2.4	81.2 ± 2.4	76.2 ± 2.1
	W12	76.5 ± 2.2[a]	76.6 ± 2.4[b]	79.7 ± 2.2[b]	75.1 ± 1.9[b]
	Δ Baseline – W12	-0.2 ± 0.4	-0.7 ± 0.4	-1.4 ± 0.5	-1.1 ± 0.5
BMI (kg/m^2)	Baseline	27.5 ± 0.8	27.5 ± 0.7	28.5 ± 0.8	27.4 ± 0.7
	W12	27.4 ± 0.8	27.2 ± 0.7	28.1 ± 0.7	27.1 ± 0.7
	Δ Baseline – W12	-0.1 ± 0.2	-0.2 ± 0.1	-0.4 ± 0.2	-0.3 ± 0.2
Waist circu-mference (cm)	Baseline	87.4 ± 1.6	89.0 ± 1.9	90.5 ± 2.2	88.4 ± 1.6
	W12	87.0 ± 1.9	87.7 ± 2.0	87.7 ± 2.0	86.5 ± 1.6
	Δ Baseline – W12	-0.4 ± 1.1	-1.3 ± 0.7	-2.8 ± 0.8	-1.8 ± 0.8

N: Nutrient-based recommendations; NF: Nutrient- and Food-based recommendations; NFS: Nutrient-, Food- and Food-Substitution-based recommendations.

Figure Legends

Figure 1: CONSORT Diagram demonstrating flow through the study

Figure 2: Time course effects in % free sugar intakes. %FS (mean, standard error) shown at weeks 1, 2, 4, 8 and 12 in Group N (Nutrient-based recommendations) (N=61), Group NF (Nutrient- and Food-based recommendations) (N=60), Group NFS (Nutrient-, Food-, and Food-Substitution-based recommendations) (N=63) and the Control Group (N=58), statistically-significant differences between control and all intervention groups at all time points, taking account of gender, age, baseline %FS, baseline body weight, W12 total energy intake (TEI), W12 physical activity, W12 %TEI Carbohydrate and W12 %TEI Protein ($p<0.05$), statistically-significant differences between intervention groups N, NF and NFS at week 2, taking account of gender, age, baseline %FS, baseline body weight, W12 total energy intake (TEI), W12 physical activity, W12 %TEI Carbohydrate and W12 %TEI Protein ($p<0.05$).

Figure 3: Time course effects in adherence. Adherence (% of N) shown at weeks 1, 2, 4, 8 and 12 in Group N (Nutrient-based recommendations) (N=61), Group NF (Nutrient- and Food-based recommendations) (N=60), Group NFS (Nutrient-, Food-, and Food-Substitution-based recommendations) (N=63) and the Control Group (N=58), statistically-significant differences between control and all intervention groups at week 1 and 8, taking account of gender, age, baseline %FS, baseline body weight, W12 total energy intake (TEI), W12 physical activity, Baseline Food Choice Natural content scale, W12 %TEI Sugars, W12 %TEI Carbohydrate and W12 %TEI Protein ($p<0.05$).