Statistical Analysis Plan for FUEL Student Outcomes

Introduction

Background and rationale

Excess sugar intake has been shown to be related to negative dental and nutritional health outcomes.(1) In the UK, adolescents on average consume three times the recommended amount of sugar.(2) Other studies have also found that by the age of 15-years nearly half of adolescents have at least one decayed tooth and that nearly a third have excess weight.(3)

Nutritional standards for schools seeks to improve health for students with the current School Food Standards (SFS) being implemented in 2015.(4) However, some schools are exempt while other schools were required to follow these standards.

Objectives of study

The primary objective of this study is to see if students' outcomes differ between schools that are required to follow SFS (SFS schools) and schools that are not required to follow SFS (non-SFS schools). Specifically, we are exploring differences between SFS and non-SFS schools in:

- Nutritional intake
    - Primary outcome measure is free sugars in grams. Other outcomes, focusing on other aspects of intake, will also be investigated (all outcomes are listed in outcomes section).
- Dental outcomes
    - The main dental outcome is the presence of caries but number of caries symptoms and other dental health measures will also be investigated.

In addition, we will organize schools into groups according to compliance with the SFS and other recommendations set out in the School Food Plan (SFP), regardless of whether they are required to follow them or not, and see how student outcomes differ among those groups.

Study Methods

Describe study design

This is an observational study that involves collecting both quantitative and qualitative data. Data will be collected at both the school level and at the student level. Nutritional intake data will also be collected at two time points from students. Prior to recruitment, the requirement (or not) for schools to adhere to SFS was obtained, as it was not possible to randomise schools to SFS or non-SFS. Since school characteristics could differ by whether SFS was required or not, propensity scoring was used to allow for differences in school characteristics and stratify schools into groups to target sampling.

Propensity scores used the following school characteristics:

- Local authority name (area)
- Establishment type
- Rural or urban categorization
- Number of pupils
- Percentage of male pupils

- Black/minority ethnic groups %
- English as an additional language %
- Free school meals %
- Income deprivation affecting children
- Sixth form
- Selective or non-selective admission types
- Religious or secular type

The propensity score was derived from a logistic regression model, fitted using these variables to predict whether or not SFS compliance was mandated. The schools were split into four strata using the propensity score quartile cut-offs, and within each strata schools were divided into SFS and non-SFS schools, giving eight sampling groups. We attempted to sample from across the eight sampling groups to minimize extraneous differences that may arise from SFS grouping.

Describe sample and exclusions and eligibility

The schools of interest are secondary phase academies and free schools. The study is recruiting these schools within the West and East Midlands areas of the UK. The school types excluded from the study are community schools, voluntary schools, foundation schools, alternative provision schools, and pupil referral units. The remaining schools have been classified as either mandated or not mandated to adhere to SFS. Academies and Free Schools established between January 2010 and May 2014 are exempt from the statutory SFS so date of establishment was used to determine group classification.

Students from years 7, 9, and 10 are purposively sampled within each school, based on their classes or other groupings. The sampling process differs by the needs and structure of each school, but aims to be broadly representative of the year group, so groupings based on student-selected subjects or academic streaming are not used. The class's pupils are invited to participate in the study and are offered a £5 shopping voucher as compensation for their participation.

Sample size and power analysis

A power analysis was conducted to get an estimate of the needed sample size. A previous study looking at the relationship of SFS and sugar intake in middle school pupils reported that after implementation of SFS there was a decrease of 6g (SD = 11) of sugar in those pupils consuming school lunch and a 2g (SD = 13) reduction in students with packed lunches. The power analysis for this study was based on the ability to detect a 4g difference between groups. Assuming an SD of 11 and an ICC of 0.1 (a conservative estimate) with 90% power and an alpha of .05, 990 pupils in each group with complete data would be needed from 44 schools (22 schools in each group). Within each year group cluster it was anticipated that there will be a minimum of 15 students with a total of at least 45 students for each school. An independent means with clustering using STATA was used to determine this sample size.

An additional power analysis was conducted in November 2021 as it was apparent that the study team were unlikely to achieve the original target sample size of 44 schools, due to ongoing interruptions resulting from the COVID-19 pandemic. At this point it was calculated that the average number of students participating from each school would be 68 rather than 45, so this larger cluster size was used in the updated power analysis. With all the other parameters kept the same, 17 schools in each group would give 88% power while 20 schools in each group would give 93% power. Power analyses were repeated accounting for a likely imbalance across SFS and non-SFS school groups. Keeping other parameters the same, 14 schools in the mandated and 20 schools in the non-

mandated groups would give 87% power, and 17 schools in the mandated and 23 schools in the non-mandated groups would give 92% power.

Which groups will be compared

The main comparison groups are students in schools required to follow SFS and students in schools that are not required to follow SFS. Since schools formed from January 2010 to June 2014 are exempt from the statutory SFS, date of school formation was used to assign them to the two groups.

Additionally, school-level data relating to food provision and wider school support for healthy eating will be used to group schools into categories ('types') based on their compliance with the SFS and the extent to which they have implemented recommendations set out in the national School Food Plan.

SFS assessment

We assess compliance with the SFS based on 1) observation of mealtimes across a full school day and 2) review of weekly menus. Compliance criteria are guided by School Food Standards: A Practical Guide for Schools and their Cooks and Caterers(5); and the UK Statutory Instrument for The Requirements for School Food Regulations 2014(6); with a Q&A document used to check interpretation(7). All foods and drinks recorded through observation or menu review will be extracted into an excel spreadsheet and coded based on the food/drink type. One researcher will carry out data extraction, with a second researcher performing a quality check by reviewing the lists and identifying any missing items. Two researchers will independently code foods and drinks and complete a daily SFS assessment and a weekly SFS assessment. Where discrepancies arise, the research team will meet to agree on final judgements. The daily and weekly SFS assessments will be combined into an overall SFS compliance judgement.

SFP assessment

Actions included in the SFP were identified following a comprehensive review of relevant SFP resources: 1) Checklist for headteachers; 2) Ofsted guidance: Creating a culture and ethos of healthy eating; and 3) Guidance for school governors (SFP documents available at: http://www.schoolfoodplan.com/resources/). Some actions were unique to each document whilst others were repeated or similar across documents. Those that were repeated or similar were merged to form single actions, retaining as much of the original wording as possible. A total of 69 actions were identified, then grouped into nine 'themes' by the research team, based on the headings used in the SFP resources.

We will assess implementation of actions from the School Food Plan using a variety of data sources, including observation, responses of schools, staff and pupils to surveys and the review of school documents e.g. curriculum documents, catering contract, meeting minutes.

A judgement of red, amber or green (RAG) will be made on each action point for each data source, with red indicating that the action point is not met, amber indicating partially met and green indicating fully met. If data are missing or if there are too few responses to surveys, a judgement cannot be made. A final judgement of 'high, medium or low' implementation will be made for each action point based on RAG ratings across all data sources. Assessment will be completed by one researcher, with queries around decisions raised with the team and agreed based on consensus.

Typology development

Schools will be grouped into 'types' primarily by their compliance or non-compliance with the SFS, with a particular focus on standards that relate to obesity or dental health (energy-dense, high in fat or sugar) and those related to a wide range of foods across the week / achieving variety. Grouping will be based on the degree of compliance with standards within these two dietary patterns, rated as 'low, medium or high compliance' based on proportion of standards met, with ≤33% indicating low compliance, 34-66% indicating medium compliance, and ≥67% indicating high compliance.

Following the development of SFS types, we will look for key features of the SFP that appear related to schools grouped in each type. We will explore patterns, variation and outliers in schools' implementation of the SFP actions (grouped by themes) and how these relate to the SFS types, further subdividing the school types according to SFP implementation, if appropriate.

Additionally, we will review contextual data for schools within each type, including demographic data, school eating arrangements, caterer types, and number of choices on offer. However, this contextual data will not contribute to the typology development.

We will compare nutritional outcomes across the identified school types to identify any patterns of variation (school types as explanatory variable).

Timeline for data collection

In the original timeline for the study, data collection was planned to start in October 2019 and continue until July 2020. However, due to school closures from the COVID-19 pandemic, the study was delayed from March 2020 to April 2021. Further, some schools who had agreed to participate before this pause in the study were no longer able to participate. Thus, data collection was extended through to April 2022.

Outcome variables

The main categories of outcome variables are reported dietary intake and dental health. The primary outcome is free sugar intake (measured in grams) at lunch, whilst at school, and during the whole 24 hours of the same school day. Sugar intake is taken from the Intake24 dietary data collection tool, which collects data on food intake over a 24-hour time frame. This self-reporting tool has been shown to be comparable to interviewer collected data regarding food intake.(8)

Each participating pupil completes Intake24 twice covering two non-consecutive days. The initial Intake24 form is completed under supervision of the researchers who explain the system and offer assistance as needed. The next Intake24 measure usually takes place in school under the supervision of teachers approximately 1-4 weeks later. Where this is not possible, the pupils are asked to complete the second Intake24 measure in their own time.

A secondary outcome is related to dental health. This is self-reported by questionnaire using questions from the national Child Dental Health Survey.(1) This tool looks at dental related symptoms in the past 3 months and treatment received for dental health in the past 24 months. The outcomes of interest from this tool are the presence or absence of caries, the number of dental caries symptoms and whether treatment for dental caries has been received.

There are also secondary nutritional/food intake outcomes that will be derived from the Intake24 data which include:

- Percentage of dietary energy intake from free sugars
- Total energy intake (kcal)
- Total fat intake (g)

- Fibre intake (g)
- Number of fruit and vegetable portions consumed
- Number of sugar-sweetened beverages consumed
- Number of sugar and chocolate confectionery items consumed
- Number of foods high in fat, sugar and salt consumed (defined according to the Nutrient Profiling model)(9)

The nutritional and food intake secondary outcomes listed above will be derived for school day lunch, whilst at school, and during the full 24-hour period of the same school day. Foods and drinks consumed whilst at school are defined as all items consumed between 9.00 am and 2.00 pm on a school day, and any additional items recorded outside of these times where the participant has indicated that they consumed these at school.

Additional nutritional/food intake secondary outcomes (derived from Intake24 data):

- Free sugar intake providing greater than 5% of 24-hour total energy intake
- Consumption of 5 or more portions of fruit and vegetables during 24 hours
- Number of eating/drinking occasions (excluding plain water) during 24 hours

Adjustment

Additional data about the schools and pupils has been collected. Pupil data were self-reported.

Schools:

- In house or external catering
- COVID-19 pandemic stage when data were collected

Pupils:

- Date of birth
- Gender
- Ethnicity (using 2011 Census categories)
- Postcode data
- Source of school-day lunch (school-provided; brought from home/elsewhere; or both)
- Frequency of toothbrushing

Ethnicity data will be categorised into high-level census categories (Asian/Asian British; Black/African/Caribbean/Black British; Mixed/multiple; White; Other). Postcode data will be mapped to Index of Multiple Deprivation 2019 scores and deciles (based on national IMD rankings across England), and to exposure to fluoridated water (based on water fluoridation status of the participant's home postcode). Additionally, the variables used to calculate the propensity scores, whether schools have in-house caterers or an external catering company and the COVID-19 pandemic stage when data were collected will be inputted as adjustment variables at the school level. We will look to simplify the model by reducing the school-level variables using backward elimination.

Missing data

If a pupil has only completed one 24-hour recall for dietary intake, a single record will be used for calculating their nutritional values. For students who have completed the dietary intake on two separate occasions, nutritional values will be calculated from an average of those two times for descriptive purposes and will be used as repeated measures in the modelling to explore associations

between groups and outcomes (see below). If there are no outcome variables present, the pupil will be excluded from analysis that is focused on that outcome.

For demographic variables, if more than 5% of the data are missing, we will attempt to impute data where appropriate, for example using average age each year group and school IMD as a proxy for home IMD. The primary analysis will use complete case data and a sensitivity analysis will include imputed values.

Statistical Analysis

Descriptive Statistics

Descriptive statistics will be used to summarise the primary and secondary outcomes for the study sample overall and also by SFS group.

Alpha value used, confidence intervals and effect sizes to report

The alpha level used for our analyses is 0.05. For the primary analysis the alpha value used for determining statistical significance is 0.05, as demonstrated by the sample size calculation. All secondary analyses and subgroup analyses were not formally powered, and we will have reduced power for interaction terms. For all model goodness of fit statistics (AIC, BIC, log likelihood) and the 95% confidence intervals for the coefficients in the models will also be listed.

Primary analysis

The primary research question is to assess whether free sugar intake (measured in grams) at lunch, whilst at school and during a full 24-hour period differs in pupils who attend SFS schools and pupils who attend non-SFS schools. The primary outcome is recorded at multiple time points, and each available observation will be used in our analyses. Linear multilevel models will be used. The 1st level will be lunch nutrition data within pupil with pupils being the 2nd level. Year groups the 3rd level will be within schools at the 4th level with the variables for these two levels being classified as random effects while the rest of the variables are fixed. SFS status (mandated or not mandated) will be a fixed variable at the 4th level while the rest of the variables are fixed. The model will be adjusted for the school level variables (see adjustment variables above) and pupil-level confounders (sex, ethnicity, Index of Multiple Deprivation scores), and source of school lunch (school provided/brought from outside of school/both school-provided and brought from outside). Models will also be investigated to see if levels or number of variables being analysed could be simplified.

Secondary analyses

There are also 11 other nutritional outcomes, 8 of which will be investigated at three time points: during school lunch, whilst at school, and the whole 24-hour day (see outcomes). The analysis of these outcomes will use multilevel linear models or multilevel Poisson models depending on the variable type (continuous or counts) and will be constructed in the same way as described for the primary outcomes. A secondary research question concerns how dental health in pupils differs between schools that are mandated to adhere to the SFS and schools that are not. The three main dental health outcomes are listed in the outcomes section. Data relating to these outcomes are only collected at one time point. Therefore, the models used for this research question will be multilevel logistic or Poisson models (depending on binary or count outcome data) pupils as the 1st level, year groups as the 2nd level, and schools as the 3rd level unit. In addition to adjusting for school-level variables and the pupil-level confounders listed above, exposure to fluoridated water and tooth-brushing frequency will also be added. The SFS school status (mandated/non-mandated) will be

included as a 3rd level fixed variable. Models will be analysed to see if number of levels or number of variables could be simplified.

Checking for assumptions

Since the primary model is a linear multilevel model we will need to check if the relationship between numerical variables and our outcome variables appear to be linear. Adjustments should be made if there appears to be a curvilinear relationship, potentially using fractional polynomials. Homogeneity of variance is also an assumption that should be checked so we will check if the residuals are approximately normally distributed. If there are any issues with the assumptions the models or imputation methods rely on, appropriate data transformations will be considered.

Sub-group analysis and interaction effects

To explore if the SFS requirement for schools is related to outcomes more strongly in some students than others (source of school lunch, year group, and IMD), interactions will be included in the model. If interaction terms are significant, additional models will be run separately for the relevant subgroups.

As well as looking at schools that are required to follow SFS or not, schools will also be grouped into 'types' relating to school food provision and support for healthy eating (using a developed method; summarised above). We will then run the models for the primary and secondary outcomes again with school type as a fixed variable (3rd or 4th level, depending on the outcome) in the multilevel regression models with the previous confounders listed also inputted into the model.

Sensitivity analysis

If necessary (missing data >5%) we will perform sensitivity analysis using imputed data (described earlier).

To explore the impact of implausible dietary intake reporting on the study analyses, we will conduct a sensitivity analysis for all primary and secondary outcomes in which we exclude all participants who reported a total 24-hour energy intake of below 400 or above 4000 kcal, these cut-offs used to examine implausible reporting in the National Diet and Nutrition Survey.(10)

Interim analysis

Due to recruitment issues caused by the COVID-19 pandemic, an additional power analysis was done for current estimations of power and how many additional schools we should be trying to recruit. This is mentioned in the power analysis section. No other interim analyses will be conducted.

References

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