Scientific title

An evaluation of the implementation of national school food standards in secondary schools and their impact on the school food environment and pupil intake of free sugars: a mixed methods study

Short title

Food provision, cUlture and Environment in secondary schooLs (FUEL) study

Protocol version

Version 4 18th November 2019

Protocol amendment history

Protocol version	Date	Changes
Detailed project plan	Submitted 17-04-2018	N/A
Version 1	01-02-2019	1. Age group of pupil recruitment changed from year groups 7, 9 and 11 (age 11-16 years) to year groups 7, 9 and 10 (age 11-15 years). This change has been made in response to feedback from our senior teacher Investigator, who has stated that pupils in year 11, which is their GCSE year, will not be in a position to engage with the study and so it would not be possible to recruit pupils in this year group. 2. Sampling plan changed from recruiting 40 schools and 2400 pupils to recruiting 44 schools and 1980 pupils (which gives the same study power). NB: recruitment of 44 schools and 1980 pupils was given as a contingency plan in the detailed project plan. 3. Planned consent procedures for participants under the age of 16 years has changed from parental opt-out consent to parental opt-in consent. 4. Planned dietary data collection has changed to a minimum of one 24 hour recall with participants and a maximum of two 24 hour recalls on non-consecutive days, replacing a plan to ask participants to record dietary intake over 3 days and use this data to complete 3 x 24 hour recalls.
Version 1.1	25-02-2019	5. Following discussion with the Investigator team, the Sponsor Legal Services team and exploration of relevant research evidence we feel the best ethical approach for the study would be to obtain passive (opt-out) parental consent for pupil participants and so have changed parental consent plans to an opt-out approach. We will provide full justification of this approach to the University Research Ethics Committee.
Version 1.2	02-05-2019	6. In the school sampling approach, we plan to use routinely available data from schools to develop propensity scores. We have added two further data types to include in the propensity score development: selective/non-selective admissions policy and religious affiliation/secular.
Version 1.3	21-05-2019	7. Following discussion with the Study Steering Committee (SSC) about defining the two school groups to be sampled, it has been agreed with the Committee that schools that are exempt from mandatory adherence to the school food standards (SFS) should not be excluded

		if they are voluntarily signed up to the standards. Therefore, the two school groups to be sampled are: 1) academies and free schools mandated to adhere to the SFS; and 2) academies and free schools not mandated to adhere to the SFS (regardless of voluntary sign up status). The rationale for this change is because schools that are voluntarily signed up to the SFS have not necessarily done so themselves, but they may have been signed up by their external catering contractor. Therefore, they are less likely than we originally anticipated to differ from the schools that have not voluntarily signed up to the standards in terms of their motivation and support for healthy eating. The SSC have requested that if possible, in the group of schools exempt from mandatory adherence to the SFS we compare school and pupil-level outcomes between schools voluntarily signed up to the SFS and those that are not voluntarily signed up. We have updated the protocol to reflect these changes to sampling and the suggested additional exploratory analyses. 8. We have provided additional detail in our school sampling plan regarding how we plan to deal with Multi-Academy Trusts when sampling schools. 9. We have now included a preference-based quality of life measure in our planned data collection with school pupils (the Child Health Utility-9D). This will facilitate the construction of Quality-Adjusted Life Years (QALYs) and enable a cost-utility analysis.
Version 2	13-06-2019	10. Following discussion with the SSC, it has been agreed to change the propensity score matching part of the sampling procedure. Instead of dividing the schools in the sampling frame into 5 groups based on propensity score quintiles, we will now divide the schools into 4 groups based on propensity score quartiles. The reason for this is that the original approach gave very low numbers of schools in one of the sampling groups, which made it very unlikely that we would be able to meet our target recruitment number in this group. The change to the sampling process increases the likelihood of us being able to meet the recruitment target in this group.
Version 3	09-09-2019	11. We initially intended to compare dietary outcomes across the two school groups (including the primary outcome of sugar intake) at school day lunch and during a full 24 hour period on a school day. Through our piloting and PPI engagement we have come to understand that secondary school pupils may not always identify their food intake as 'lunch' or may have their main school-time food intake at a time outside of the normal lunch period. We have therefore included an additional set of dietary outcomes, defined as the intake during a full school day (i.e. during all hours spent in school). Therefore, we will be comparing across the two school groups dietary intake during: i) school day lunch; ii) the full school day; and iii) a full 24 hour period on a school day.
Version 4	18-11-2019	12. Regarding recruitment of school pupils, we initially planned to randomly sample one class from each of years 7, 9 and 10. However, since starting recruitment of schools it has become apparent that logistical issues, such as timetabling the data collection sessions and organising staff time around these, precludes us undertaking random sampling of classes. Instead we are asking teachers to identify either

		form groups or class groupings where there is no streaming and all pupils have to attend (e.g. Personal, Social and Health Education (PHSE) classes), and select one class from each year group to suit their logistical considerations. 13. We have changed the time period for which we are requesting food sales data from schools; we will now ask for data from the same two (non-continuous) months of the academic year from all schools to increase comparability of the data across the schools.

Research reference numbers

Sponsor reference number	18-1094
ISRCTN number	ISRCTN68757496
University of Birmingham REC reference number	18-1738

Signatures

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigators agree to adhere to the signed University of Birmingham's Sponsorship CI declaration.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

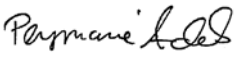
I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigators:

Miranda Pallan

Signature:  Date: 1st Feb 2019

Peymane Adab

Signature:  Date: 1st Feb 2019

Sponsor statement

Support of the University of Birmingham as Sponsor is a prerequisite for ethical approval to be granted by the University of Birmingham Research Ethics Committee. Therefore, ethical approval granted from the University of Birmingham REC will serve as confirmation of approval of the protocol by the Sponsor.

Contents

Key study contacts

Chief Investigators	**Dr Miranda Pallan** (MP); m.j.pallan@bham.ac.uk Tel: 0121 414 7990 **Professor Peymane Adab** (PA); p.adab@bham.ac.uk Tel: 0121 414 3777 Murray Learning Centre Institute of Applied Health Research University of Birmingham Edgbaston, Birmingham B15 2TT
Study Co-ordinators	**Dr Emma Lancashire** (EL); e.r.lancashire@bham.ac.uk Tel: 0121 414 3777 **Dr Marie Murphy** (MM); m.murphy.3@bham.ac.uk 0121 415 8018 Murray Learning Centre Institute of Applied Health Research University of Birmingham Edgbaston, Birmingham B15 2TT
Sponsor	**Dr Birgit Whitman** Research Support Group Room 119 Aston Webb Building University of Birmingham Edgbaston, Birmingham B15 2TT Phone: 0121 415 8011 Email: researchgovernance@contacts.bham.ac.uk
Funder	This study is supported by funding from the National Institute for Health Research Public Health Research Programme (17/92/39)
Key Protocol Contributors (Co-Investigators)	Institute of Applied Heath Research University of Birmingham Edgbaston, Birmingham B15 2TT: **Dr Emma Lancashire** (EL); e.r.lancashire@bham.ac.uk **Dr Emma Frew** (EF); e.frew@bham.ac.uk **Professor Jayne Parry** (JP); j.m.parry.1@bham.ac.uk **Ms Alice Sitch** (AS); a.j.sitch@bham.ac.uk **Dr Suzanne Bartington** (SB); s.bartington@bham.ac.uk **Dr Kiya Hurley** (KH); k.hurley@bham.ac.uk **Professor KK Cheng** (KKC); k.k.cheng@bham.ac.uk Birmingham Dental Hospital and School of Dentistry

	University of Birmingham 5 Mill Pool Way Birmingham B5 7EG: **Dr Vahid Ravaghi** (VR); v.ravaghi@bham.ac.uk Human Nutrition Research Centre Institute of Health & Society and Newcastle University Institute for Ageing Newcastle University M1.151 William Leech Building Framlington Place Medical School Newcastle upon Tyne NE2 4HH: **Professor Ashley Adamson** (AA); ashley.adamson@ncl.ac.uk Faculty of Humanities and Social Sciences University of Bath 1 West University of Bath Claverton Down, Bath, BA2 7AY: **Dr Tania Griffin** (TG); t.l.griffin@bath.ac.uk Services for Education Unit 3 Holt Court Holt Street, Birmingham, B7 4AX: **Dr Sandra Passmore** (SP); sandra.passmore@servicesforeducation.co.uk Wheelers Lane Technology College Wheelers Lane Kings Heath, Birmingham, B13 0SF: **Mr Scott Wheeldon** (SW); wheeldons@wheelerslane.bham.sch.uk
Committees	**Study Management Group** Co-chairs: Dr Miranda Pallan & Professor Peymane Adab Other members: Dr Emma Lancashire, Dr Emma Frew, Ms Alice Sitch, Professor Jayne Parry, Professor Ashley Adamson, Professor KK Cheng, Dr Suzanne Bartington, Dr Sandra Passmore, Mr Scott Wheeldon, Dr Tania Griffin, Dr Kiya Hurley, Dr Vahid Ravaghi, Dr Marie Murphy, Ms Rhona Duff. **Study Steering Group (SSG)** Professor Robert West (Chair; statistician; University of Leeds; R.M.West@leeds.ac.uk) Professor Christopher Owen (epidemiological research expert; St. George's, University College London; cowen@sgul.ac.uk)

	Dr Helen Carter (public health consultant; Public Health England, West Midlands; Helen.Carter@phe.gov.uk) Dr Alexander Turner (health economist, University of Manchester; alexander.turner@manchester.ac.uk Mrs Sheila Birdi (teacher and public representative; sheilacork@yahoo.co.uk) Ms Ann Hughes (public representative; ahughes67@btinternet.com) Dr Miranda Pallan (Chief Investigator) **Public Advisory Group** Chair: Mrs Sheila Birdi Other members: Mrs Irina Hoffman, Mrs Sarah Dickson, Mrs Andrea Gartner, Ms Sarah Bolton, Mr Joey Islam.

Study summary

Title

An evaluation of the implementation of national school food standards in secondary schools and their impact on the school food environment and pupil intake of free sugars: a mixed methods study

Short title

Food provision, cUlture and Environment in secondary schooLs (FUEL) study

Background

National School Food Standards were introduced in 2006 and are a legal requirement for most state schools. In 2013, the School Food Plan, a wider set of voluntary recommendations for schools, was developed, and subsequently updated standards were introduced in 2015. There is little information on the impact of School Food Standards on school food provision and pupil food intake in secondary schools, and the impact of the updated standards and the School Food Plan recommendations has not been explored. The way in which the School Food Standards legislation has been introduced means that all academies and free schools set up between 2010 and 2014 are not obliged to meet the standards. This gives an opportunity to examine the influence of a legal requirement to meet the standards by comparing schools which are, versus those that are not required by law to meet them. Specifically, we want to assess whether the standards influence pupils' sugar intake, as adolescents have high levels of sugar consumption, which can lead to obesity and poor dental health.

Aims

We aim to make comparisons between secondary schools required to meet the standards and those who are not required to meet the standards. We will compare: the food provided and sold in schools; the school eating environment and ethos; the healthy eating and cooking skills curriculum; the cost to schools of measures to improve healthy eating and food provision; the consumption of foods high in sugar, other elements of the diet and dental health in pupils. We will also explore the extent to which schools vary in how the School Food Standards and School Food Plan are implemented.

Design

We will recruit 44 secondary schools in the West Midlands to take part (22 who are required to adhere, and 22 that do not have to adhere to the standards). We will examine whether a requirement to adhere to the standards policy is associated with the provision, sale and consumption of healthier foods (focusing on sugar intake) in schools, and whether and how requirement to adhere relates to the implementation of the School Food Plan. This will be done through collation of data from a variety of school documents (including relevant school policies, food and catering contracts, relevant curricular teaching), researcher observations (to ascertain the school environment and culture including the food on offer and the eating spaces in schools) and questionnaires to key staff members, governors and parents to gain their views and experiences of the food standards, the school eating environment, culture and curriculum. We also aim to recruit around 1980 pupils from years 7, 9 and 10 from the 44 participating schools. In school time we will ask them to complete an online survey including a 24-hour recall tool, and questions about the food they eat and the health of their teeth. We will compare the average sugar intake, tooth decay symptoms and treatment, and intake of other food types among pupils in the two school groups. We will compare information on school food sales across the two school groups. We will use the above information to identify 4-8 schools with varying levels of provision and sale of healthy foods, in which we will collect more in-depth information through interviews with key staff members and small discussion groups with pupils. We will explore whether consumption of sugar and other foods is influenced by how well the School Food Standards and School Food Plan are implemented.

Public involvement

Secondary school pupils, parents and teachers in senior management positions have contributed to the study design. We have convened a panel of parents, governors, and teachers to consult with at key points during the project. We will also regularly consult with a secondary school council of pupils.

Dissemination

We will communicate the findings to key health and educational organisations nationally and locally. Findings will help shape future school food policy.

Funding and support

Organisation	Funding or Other Support
University of Birmingham	Research sponsorship, and financial contributions to researcher salary and support costs [e.g. IT services, telephone, printing, desk space]
National Institute for Health Research	Provision of research related costs

Roles of Study Sponsor and Funder

The University of Birmingham, as the sponsor, will assume overall responsibility for initiation and management of the study, and will control final decisions regarding all aspects of the study. The National Institute of Health Research, as the funder, will contribute financial support and facilitate dissemination of the results.

Roles and Responsibilities of Study Management Committees/Groups & Individuals

Study management

MP and PA (Chief Investigators) will have overall responsibility for the study. MP, PA, EL (Co-Investigator) and the Study Coordinator (MM) will form a core study management team, which will meet weekly or at an agreed regular interval to oversee all aspects of the study. All Co-Investigators, together with the core research team, will form a Study Management Group which will meet approximately three times per year to guide the study. Study Management Group meetings will be minuted with specified action points, timelines and persons responsible identified.

Study Steering Committee

An external Study Steering Committee, comprising the MP (Chief Investigator) and 5 external, independent members (RW (Chair and statistician), CO (epidemiologist), HC (public health consultant), AT (health economist) and SB (public representative)) will advise and oversee study processes. The Study Steering Committee will meet twice per year. Study Steering Committee meetings will be minuted with specified action points, timelines and persons responsible identified**.**

Public Involvement

A Deputy Headteacher of a secondary school (SW), is a Co-Investigator. There is also a teacher representative on the Study Steering Committee (SB) who has experience of working within academy settings. We have convened a group of parents, teachers and secondary school governors to consult with at key points throughout the study (2-3 consultation meetings per year). This group will be chaired by the teacher/public representative of the Study Steering Committee (SB). We will also consult with a secondary school council throughout the project to gain pupil perspectives on aspects of the study. In addition we have a manager from an external catering contractor who will advise on an ad hoc basis throughout the study.

Protocol contributors

The Chief Investigators (MP and PA), with the wider support of the Co-investigators conceived and designed the study and drafted the original study protocol. Teachers and school pupils were also involved in the development of the protocol, as described in section 4.5. The study protocol has undergone multiple rounds of expert peer-review as part of the funding process.

Keywords

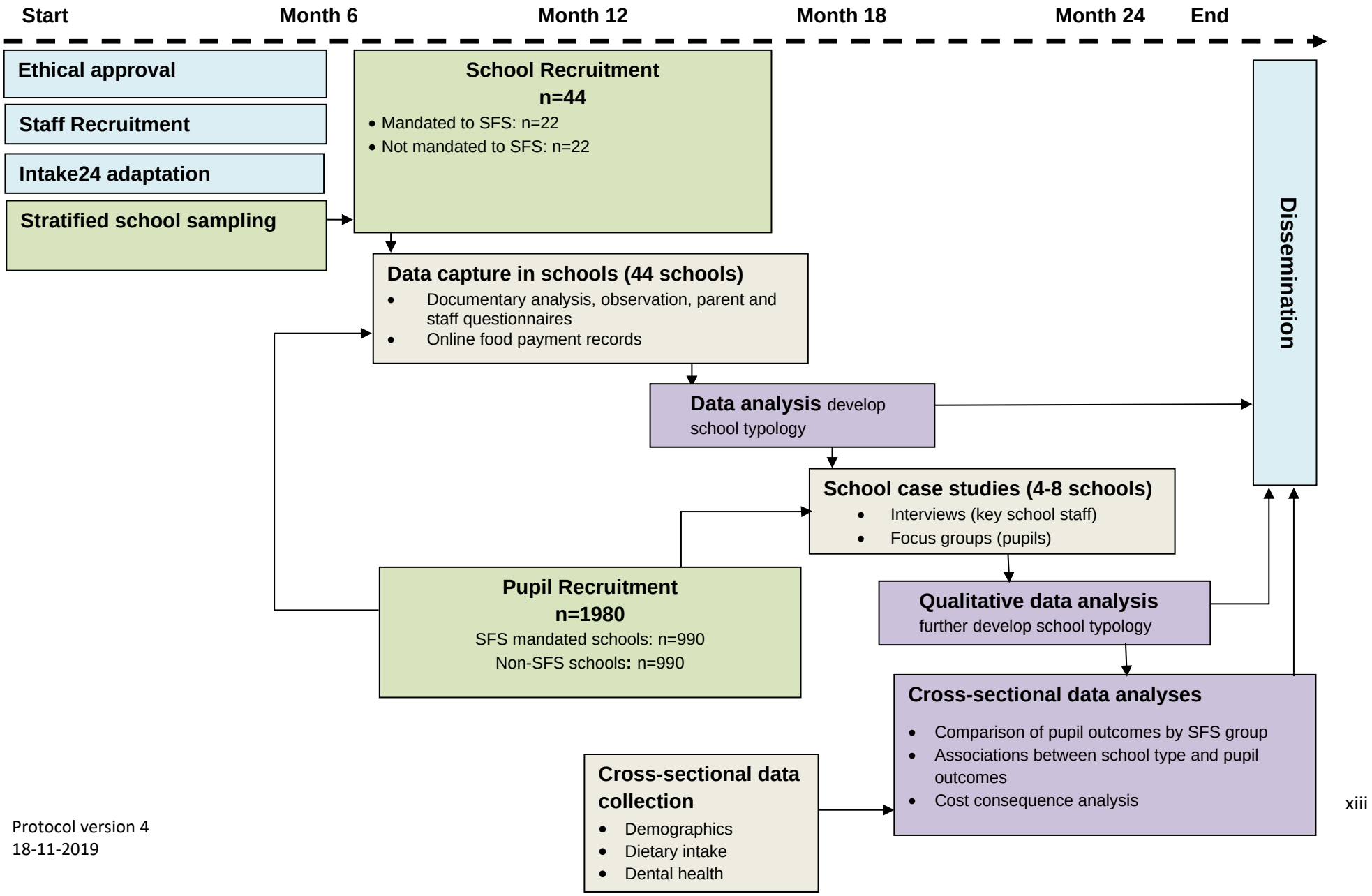
Schools*, food*, standards*, policy*, nutrition, diet*, dental health, dental caries*

[*MESH terms]

Project Plan

Year		2019										2020												2021				
Project Month		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
Calendar Month		Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
Milestone	Description																											
1	Complete staff recruitment	x	x	x																								
2	Ethical approval	x	x	x	x	x	x																					
3	Intake 24 adaptation	x	x	x	x	x	x																					
4	Develop propensity scores and sample schools		x	x	x	x	x																					
5	Recruit schools							x	x	x	x	x	x	x	x	x												
6	Documentary data capture								x	x	x	x	x	x	x	x	x											
7	Observation in schools								x	x	x	x	x	x	x	x	x											
8	Staff/governor questionnaires								x	x	x	x	x	x	x	x	x											
9	School typology development														x	x	x	x	x									
10	Case study selection																	x	x	x								
11	Staff interviews																			x	x	x	x	x	x			
12	Pupil recruitment								x	x	x	x	x	x	x	x	x	x										
13	Pupil dietary/dental data collection								x	x	x	x	x	x	x	x	x	x										
14	Parent questionnaire								x	x	x	x	x	x	x	x	x	x										
15	Data entry									x	x	x	x	x	x	x	x	x	x									
16	Pupil focus groups																			x	x	x	x	x	x			
17	Qualitative data analysis																			x	x	x	x	x	x			
18	Further school typology development																							x	x	x		
20	Pupil outcome data analysis																			x	x	x	x	x	x	x		
19	Cost consequence analysis																						x	x	x	x	x	x
21	Final Report writing																								x	x	x	x
22	Publication writing and dissemination activities																									x	x	x

Flow of participants and timing of data collection and analysis



Study protocol

An evaluation of the implementation of national school food standards in secondary schools and their impact on the school food environment and pupil intake of free sugars: a mixed methods study

Short title: Food provision, cUlture and Environment in secondary schooLs (FUEL) study

1 Background

Excess sugar consumption is a major contributor to increased energy intake, obesity, and poor dental health.[1] Adolescents aged 11-18 years in the UK consume three times the recommended amount of their total energy intake from free sugars.[2] Almost half of 15 year olds have dental caries[1] and nearly a third have excess weight[3] and are therefore at risk of later morbidity.[4] With the aim of improving the quality of childrens' diets, nutritional standards for school meals were first set in 1941. However there have been several iterations over time in terms of the type of standard (food or nutrient based) and the extent to which they were mandated. There were no school food standards from 1980 to 2001, at which point food-based standards were introduced.[5] Changes were made in response to concerns about children's diets[5] and findings that school lunches lacked key micronutrients and were too high in fat and sugar.[5, 6] New national school food standards (SFS) that were both nutrient- and food-based were introduced in England in 2006 following a national School Meals Review.[7]

Following a further Government commissioned independent review, a School Food Plan (SFP) was published in 2013 (see section 1.2),[8] with recommendations for Government (to further revise the SFS), schools and head teachers. The revised SFS were drafted by the Standards Panel and were food based, but underpinned by a nutrient framework. They were designed to be less onerous for school food providers and therefore operationally cheaper to implement. After pilot testing with schools and caterers to ensure that they met or improved on the nutrient content of meals provided under the 2006 SFS,[9] these standards came into force in January 2015.[10]

1.1 The current National School Food Standards

The SFS are highlighted as an approach to tackling childhood obesity in the national childhood obesity strategy,[11] and implementation of the SFS is a statutory requirement for all state-maintained primary and secondary schools, with the exception of academies and free schools established between January 2010 and May 2014.

In line with the food-based component of the 2006 SFS, the most recent standards split food and drink into six groups: i) starchy foods; ii) fruit and vegetables; iii) milk and dairy; iv) meat, fish, eggs, beans and other non-dairy sources of protein; v) foods high in fat, sugar and salt; and vi) healthier drinks. There are rules for portion, variety and permitted frequency of provision for each group, some applying across the whole school day and others specific to lunch or non-lunch provision.[10] Compared with the 2006 SFS, the standards specified for each food group in the current (2015) SFS are more comprehensive and incorporate aspects of the nutrient-based element of the 2006 SFS. For example, the 2015 standards include the daily provision of at least one portion of milk and dairy foods and the availability of low fat milk to ensure adequate provision of protein, calcium and zinc. In the 2006 SFS, minimum levels of these nutrients were specified but there were no food-based standards relating to milk and dairy.[9] Standardised checklists are available to assess school compliance for lunch provision (over a 3-week period) and for food provision at other times.[10]

1.2 The School Food Plan

The SFP provides non-statutory recommendations for action for all schools and addresses the overall ethos of the school in relation to food, promoting adoption of a 'whole school' approach. The plan's main aim was to increase school meal uptake, which fell to economically unviable levels (40%) in the mid-1980s (continuing into the 21st century), as higher school meal demand would enable better quality meals to be served at lower cost. The second aim was to provide practical support, advice and information for head teachers to help improve the quality and uptake of their school's food. In addition to lunchtime provision, the plan addresses the way healthy nutrition is incorporated within all aspects of school life and the wider community within which the school and children are involved.[8] A checklist of actions to be taken to implement the SFP is available for headteachers,[12] as well as a checklist to facilitate adopting a whole school approach to creating a healthy eating culture and ethos.[13]

Components of the SFP:

- **Headteacher leadership/promotion of health food culture**: comprehensive catering contracts; working with external agencies and charities to promote growing, cooking and eating of healthy food; involving the community in cooking/growing of food; serving food that is visually appealing, varied and tastes good at the right price; regulation of packed lunches
- **Curricular and Skills education**: incorporation of cooking and food into the curriculum up to the age of 14 years (key Stage 3); after school cooking lessons for parents and children; growing food at school; use of cooking and growing in innovative ways to teach subjects across the curriculum
- **Food Environment:** placing greater value on the catering team (up to date cooking skills training, improve catering staff morale by involvement in other aspects of school life); having attractive eating environments (clean, minimum queuing, efficient paying system, pleasant to eat in); easy access at all times to free, fresh drinking water
- **Social environment**: removing unhealthy food rewards; improving the branding of school food by encouraging school staff to eat in the canteen; offering food taster samples and theme days; seeking pupils' views to inform school food changes
- **Affordability**: attractive and affordable healthy food offers; reducing price of school meals for families with more than one child; subsidising cost of meals for those starting school
- **Whole school approach**: consistency of nutrition messages from classroom to canteen.

1.3 Review of existing evidence of effectiveness of School Food Standards

School food policy interventions, such as the national SFS and SFP, operate across individual, social, physical and macro-levels to influence pupils' dietary intake.[14] Research evidence suggests a positive impact of school nutrition policies and interventions on children's diets,[15, 16] concentration, behaviour and attainment.[17]

Some evaluation of the impact of the 2006 food- and nutrient-based SFS on food provision and consumption has been conducted in primary, middle[18-20] and secondary schools.[21] The primary (n=12 schools) / middle (n=5 schools) school studies compared children's dietary intake pre (2003-4) and post (2008-9) SFS implementation in two age groups (4-7 years and 11-12 years) to determine policy effect on lunchtime and total dietary intake. Over this period there were improvements seen in the dietary intake of children. Post-implementation, the total dietary intake (across the whole day) of children in the younger age group improved, with the greatest improvements seen in those having a school-provided lunch (vs. a packed lunch). In contrast, in the 11-12 year age group, whilst lunchtime dietary intake of children having school provided meals improved post-implementation, there was limited evidence for a beneficial effect of school-provided lunch on overall dietary intake. The level of implementation of the SFS was also assessed in these studies, and found to be high in primary schools but less so in the middle schools. A related study reporting cross-sectional data gathered in 6 middle

schools in 1999-2000 (pre-SFS) and again in 2009-2010 (post-SFS) showed very limited improvement in the total diets of 11-12 year old children and levels of free sugar intake remained well above recommended guidelines.[22]

Evidence of impact of the SFS on the dietary intake of secondary school pupils is even more limited. One study in 80 secondary schools compared provision of school food and lunchtime consumption by pupils in 2011 with that in 2004, and reported an improvement in the nutritional content of school-provided food, with the greatest impact on the availability of confectionery. They also reported improvements in pupils' lunchtime food consumption, but did not examine total dietary intake.[21]

1.4 Rationale for further evaluation of School Food Standards and related policy

Whilst the evaluations described above provide valuable information, they were undertaken prior to the development of the School Food Plan and the subsequent introduction of the revised food-based standards that were introduced in 2015, which to date have not undergone rigorous evaluation. In addition, the studies in primary and middle schools were both undertaken in the North East region of England, and involved only a small number of schools, so the findings may not be generalisable. Although the study in secondary schools involved a larger national sample of schools, it was restricted to lunchtime food and drink provision and consumption, and did not evaluate the impact of the standards on children's total dietary intake. Neither did the study assess the implementation of the SFS within secondary schools. No previous studies have examined dental outcomes in relation to the SFS, and all previous studies have reported pre- and post- implementation data, with no contemporaneous comparator group. The exemption of certain academies and free schools from the SFS in recent years provides the opportunity for us to compare pupil outcomes in schools which are mandated to implement the SFS with a natural control group during the same time period. We are focusing on secondary schools because adolescence is a key period for the establishment of dietary patterns,[23] and there is more choice and greater autonomy regarding the food they eat within school, which could be influenced by a healthy school food environment.[24] It is therefore important to understand the impact of the SFP and the SFS in this age group.

The current study will add to existing evidence by investigating the differences in school food provision and sales, and wider school factors (food curriculum, culture and environment) in secondary schools mandated to implement vs. those not implementing the current (2015) SFS, and by comparing school day dietary intake, both at lunch time and during a full day, and dental health in pupils in the two groups of schools. Costs related to the implementation of the SFS will also be examined. In addition, the study will provide valuable evidence on how schools are implementing and operationalising the SFS and the supporting SFP, and the contextual influences that affect this implementation. This will also inform the wider question of how schools function as a setting for health promotion policy.

1.5 Importance of the research in terms of improving the health of the public

Although the causes of childhood and adolescent obesity are complex, the school food environment and provision are recognised to play a significant role.[15, 25] Patterns of school food consumption are an important determinant of total dietary profile,[26] with up to a third of children's energy and micronutrient intake provided by lunch on school days.[27] Evidence from dietary surveys indicates that dietary intake of free sugars and sugar sweetened beverages (SSBs) among UK children and adolescents regularly exceeds recommended levels,[28, 29] providing approximately 15% (compared to the 5% maximum currently recommended) of daily energy intake in 11-18 year olds.[2] These high intake patterns are of public health concern given a recognised association between sugar consumption and obesity.[30]

Consumption of free sugars and sugar-sweetened beverages is also a major risk factor for dental caries,[31] with implications for children and families' health and wellbeing. Good oral health among 6-17 year olds has been shown to be associated with improved school performance and better psychosocial well-being,[32] and children who experience dental caries are more likely to have school absence and reduced academic performance.[33]

Childhood obesity rates and dental health outcomes in England are strongly associated with socioeconomic deprivation, with poorer outcomes among children living in disadvantaged communities.[34] In 2011/12 the UK uptake of school lunches in secondary schools was approximately 40% (42% in West Midlands), and higher among children entitled to free school meals (70%),[27] representing a high proportion of children consuming a school provided lunch on a daily basis. This research will provide new evidence on how the current SFS are implemented in secondary schools (and how school context influences this), and the impact of the SFS on pupil health-related outcomes.

2 Research aims

Secondary schools with academy or free school status are required to adhere to the national School Food Standards (SFS), with the exception of those that acquired their status between January 2010 and May 2014. These schools can voluntarily sign up to the SFS, but the majority have not done so. In this study we plan to compare academies and free schools that are in the following two categories:

i. Schools mandated to adhere to the SFS
ii. Schools which are not mandated to adhere to the SFS

The SFS are supplemented with the non-statutory School Food Plan (SFP), which all schools are encouraged to implement.

Key research aims:

1) In the two school categories we aim to:
   - Compare the provision and sale of foods, the school environment and culture relating to food, and the healthy eating/cooking curriculum
   - Compare free sugar intake, other dietary intake, and dental health of school pupils, and examine whether any observed differences in these outcomes in the two school groups vary by year group, usual lunch type (school-provided vs. home-packed), or socioeconomic status.
   - Compare the costs of food provision, food curriculum delivery, and other measures to influence the school food culture and environment.

2) We aim to explore the variation in implementation of the statutory SFS and the voluntary SFP recommendations in secondary schools. As part of this we will develop a typology of schools relating to school food: provision; environment; culture; curriculum, and the wider school context, which will reflect the degree of implementation of the SFS, SFP and other local initiatives to improve the diets of pupils.

3) We will use the developed school typology to explore associations between the school types and pupil dietary and dental outcomes.

The specific research questions to fulfil these aims are:
1. Are there differences in the provision of school food between the two school groups?
2. Are there differences in the sales of different food types between the two school groups?

3. Are there differences in the uptake of school-provided food vs. home-packed lunches between the two school groups?
4. Are there differences in the eating environment provided / the wider school culture in the two school groups?
5. How does implementation of the SFS and SFP vary across schools?
6. How does the school context influence the implementation of the SFS and SFP?
7. What are the different school types in relation to food provision, culture, environment, the curriculum, and SFS and School Food Plan implementation?
8. What is the economic impact of the SFS and SFP?
9. In pupils in the two school groups, are there differences in:
    a. free sugar intake (on school days at lunchtime, during the school day and during the whole 24 hour period)
    b. other dietary nutrient intake (on school days at lunchtime, during the school day and during the whole 24 hour period)
    c. dental caries experience?
10. Do any differences in pupil dietary and dental outcomes across the two school groups vary by:
    a. year group
    b. lunch type (school-provided vs. home packed)
    c. socioeconomic status?
11. Is there an association between school type and dietary and dental outcomes in school pupils?

3 Research plan

3.1 Design

We are planning an observational, mixed methods study. A variety of data will be collected at the level of the school and from individual school pupils. We aim to recruit 44 schools; 22 which have a statutory obligation to comply with the SFS, and 22 which are exempt from this requirement. Within each school we will recruit a minimum of 45 pupils from three year groups (total n=1980). We will compare outcomes at the school level (food provision and sales, school meal uptake, eating environment, food curriculum, school food culture, and costs related to these factors) and at the individual level (sugar and other dietary intake, dental caries experience) in the two school groups. We will also capture data to explore the implementation and embedding of the SFS, SFP and the influence of the school context on this. Further detail on the methodology is given in subsequent sections.

3.2 Setting and population

The sampling frame for the study will comprise secondary phase academies and free schools located within 14 Local Authority areas in the West Midlands (Birmingham, Coventry, Dudley, Herefordshire, Sandwell, Shropshire, Solihull, Staffordshire, Stoke-on-Trent, Telford and Wrekin, Walsall, Warwickshire, Wolverhampton, Worcestershire). The West Midlands includes urban and rural areas and has a population of around 5 million. It is an ethnically diverse region with 14% from non-White backgrounds and nearly 9% of South Asian ethnicity, and contains high areas of deprivation (e.g. Sandwell, Birmingham, Wolverhampton).[35]

We will identify all state secondary school establishments in the West Midlands which include children aged 11-16 years using Department for Education routine data. We will exclude community schools, voluntary schools, foundation schools, secure and pupil referral units and special or alternative provision schools. We will categorise the remaining schools into two groups: 1) schools mandated to adhere to SFS; or 2) schools not mandated to adhere to SFS. The sampling frame is restricted to academies and free schools, as these now comprise the majority of schools and are the only types of

state funded secondary schools that have exemption from the national SFS (if established between January 2010 and May 2014). Other secondary school types have been excluded as they are all mandated to adhere to the SFS and significantly differ from academies and free schools in terms of their governance structures, or are for specialist/alternative educational provision. Schools and pupils will be recruited to participate from within this sampling frame.

3.3 Sampling

Schools

This is an observational study, and therefore schools are not randomly allocated to the two SFS groups. To make the schools in the two groups more comparable and therefore reduce the influence of confounding, we plan to employ propensity score methods.[36] We will obtain data on several characteristics of schools in the sampling frame: Local Authority area, establishment type (academy convertor/sponsor led/free school), urban/rural location, total pupil roll size, proportion of male and female pupils, proportion of pupils from minority ethnic groups (BME), proportion of students with English as a foreign language (EAL), proportion of students eligible for free school meals (FSM), school deprivation indicator (IDACI), inclusion of a sixth form, proportion of pupils with Special Educational Needs (SEN), selective/non-selective admissions policy, religious affiliation/secular, and OFSTED inspection outcome. These school characteristics will be used to calculate propensity scores for all schools in the sampling frame, which give an estimate of the probability of a school being in a particular SFS group, conditional on these characteristics. To obtain as representative a sample of schools as possible, we will undertake a stratified sampling approach. Schools will be divided into quarters (at the quartiles) based on their propensity score. Schools belonging to each of the SFS groups within each propensity score group will then be randomly ordered. From these eight randomly ordered lists, schools will be sequentially invited to participate until five/six schools from each have been recruited. If any of the randomly ordered lists of schools have more than one school belonging to the same Multi-Academy Trust (MAT), the first of these schools on the list will be invited to take part. If this school agrees to participate in the study the remaining school(s) from the same MAT will only be invited to take part should this be necessary to reach the recruitment target. If the final study sample of participating schools includes more than one school from the same MAT, we will include MAT as a cluster-level in the analysis.

Pupils

Within each participating school, form groups or other class groupings (such as Personal Social and Health Education (PHSE) classes) will be identified, ensuring these class groupings are representative of the general year group. From these class groupings one class from each of years 7, 9, and 10 will be selected and its pupils invited to participate in the data collection for the planned cross-sectional study. We have chosen these year groups to ensure that a range of ages is included in the sample.

3.4 Sample size

The primary outcomes on which our sample size calculation is based are the differences between the two school groups in intake of free sugar by pupils during school day lunch, and during a 24 hour period. Increasing overall consumption of free sugars is associated with adverse cardiometabolic health, reductions in consumption of essential nutrients,[37] and increased levels of dental caries.[38] Free sugar intake is also positively associated with body weight. A meta-analysis of cohort data has shown that, over 1 year, a 1 unit increase in sugar-sweetened beverage consumption results in a 0.06 increase in BMI in children and adolescents.[39] These associations are linear and there are no clear thresholds of free sugar consumption in terms of adverse clinical outcomes, therefore any reduction in sugar consumption is clinically meaningful.

The UK Scientific Advisory Committee on Nutrition (SACN) recommend that free sugars comprise no more than 5% of total daily energy intake.[28] However, the average proportion of daily energy intake from free sugars in adolescents is 14%, with only 5% of those aged 11-18 years meeting the SACN recommendation.[2] Therefore, this proportion is not a suitable effect size parameter for the sample size calculation. Instead, we have used a difference in average intake in grams of free sugar, and have based the likely difference between the two study groups on previous research into the impact of the SFS. Adamson et al. undertook a pre-post evaluation on the impact of the SFS on the dietary intake of pupils in middle schools (11-12 years), and reported reductions in free sugar intake pre- and post-SFS implementation of 2g (SD 13) in pupils having home-packed lunches and 6g (SD 11) in pupils having school-provided lunches. They also reported pre- and post-SFS reductions in 24 hour free sugar intake of 10g (SD 28).[18] Basing our sample size parameters on these data: to detect a difference in mean free sugar consumption at lunch of 4g (20g vs.16g) between the two school groups, assuming a SD of 11 with 90% power at 5% significance, we require 990 evaluable participants (responding with complete data allowing the primary outcome to be calculated) and 22 clusters (schools) in each group (cluster size=45; total number of schools=44; total n=1980). This is calculated using an ICC of 0.1 (a conservative estimate of ICC for nutritional outcomes[40]) and assuming balanced cluster sizes. Using this sample size we also have 90% power to identify a difference of 10g (83g compared with 73g) in the outcome of mean 24 hour free sugar intake assuming a SD of 28, with an ICC of 0.1 and assuming balanced cluster sizes. In studies with multiple layers of clustering (here classes within schools) it is conservative to treat clusters within clusters as one larger cluster, which is the approach used here.[41]

From the three selected classes at each school the aim would be for a minimum of 15 participating pupils (50% if class size=30), giving a cluster size of 45. This means pupils from 132 classes across the 44 schools will be invited to participate (approximately 3960 students) to achieve the required sample size. This should be achievable, as a survey undertaken in UK secondary schools using a similar sampling strategy and consent process achieved a response rate of over 90%.[42]

3.5 School data capture

We aim to compare the following outcomes between the two SFS school groups: food provision (in relation to the variation, portion size and frequency of provision for each of the specified food categories in the SFS using the SFS checklists); food sales (in relation to proportion of sales from each food category and variation within categories); school meal uptake; and the school food culture and environment (based on SFP checklists). In addition, we aim to understand the process of implementation of the SFS and SFP and assess the wider influence of the school context on this, especially the facilitators and barriers to achieving and maintaining the organisational change. This will also enable an assessment of the variation in implementation of the SFS and SFP.

In the SFS-exempt group of schools, there may be schools that have voluntarily signed up to the SFS or may have been signed up to the SFS by their external catering contractor. We will try to ascertain voluntary sign up status in this group of schools and, if feasible, explore differences in the school-level outcomes described above between those that are voluntarily signed up and those that are not.

<u>Assessing the process of SFS and SFP implementation: theoretical considerations guiding data collection and case study selection</u>

Data capture will adhere to the principles for process evaluation described by the MRC Framework,[43] and be informed by critical realism theory (realist evaluation)[44] in recognition of the likely importance of individual school context in shaping the mechanisms underpinning the intervention-outcome pathway.

We have developed a logic model which sets out the processes by which the SFS and SFP are assumed to generate pupil health gain (Figure 1). The model draws on Bonnell's (NIHR PHR-funded) work which has integrated multiple theories to produce a framework to explore how the school environment affects pupils' health,[45] and on Adamson's evaluation of primary/middle school settings and pupil dietary behaviours.[18]

Briefly, the logic model suggests health gain materialises directly via a change in food consumption in schools, and indirectly by curricular and other activities designed to change pupils' (and possibly their parents'/carers') dietary knowledge, attitudes and beliefs which impact on food consumption outside school. The extent to which the SFS and SFP achieve the presumed health gains is dependent on the degree to which each is implemented within a school, with the process of adoption and implementation determined substantially by key contextual factors such as pupil socio-demographics, staff knowledge and management priorities.

Our proposed data collection strategy will enable population of the logic model for each of the schools (n=44). These data will enable assessment both of the extent to which the primary presumed change pathway is embedded in each school (i.e. food provision, pupils' consumption), and the relative importance of contextual factors which shape implementation (see Table 1 for more detail on the methods of data capture planned to enable population of the logic model components).

School-level data capture methods

The following data collection methods will be employed in all the participating schools:

- Analysis of key documents and routinely collected data (including catering contracts, school menus, school food sales data, school meal uptake data, school food and other relevant policies, information on the school curriculum relating to food and diet, relevant documents from governors and Ofsted reports).
- Direct observation of the school eating areas (dining and communal facilities), food on offer (does actual provision match the planned provision), food consumption (where and when food is accessed and consumed) and wider environment within and surrounding the school. Observation checklists will be developed, based on the SFP Headteachers' and school healthy eating culture and ethos checklists.[12, 13]
- Questionnaires to key staff and governors who are identified within the school to have roles relating to food provision, eating environment, food curriculum, or SFS/SFP implementation (including headteachers, lead catering staff, PHSE leads, teachers with responsibility for the food/cooking curriculum, relevant representatives from the governing body).
- Questionnaires to parents of pupils participating in the study: questionnaires will be sent to parents in online and paper formats, and small monetary incentives will be offered to those who complete it.

To assess school food provision, schools will be requested to provide their catering contracts and menus for the past 3 months. Explicit reference to the SFS will be sought in the contracts, and the lunchtime menus will be checked against the published national SFS checklist.[10] Schools will also be asked for information on the food that is sold outside of the school lunchtime provision, which will be checked against the relevant SFS checklist.[10] Since 2015 the national SFS no longer include nutrient-based standards (relating to the amount of nutrients, such as carbohydrate, fibre, salt, fat, added sugar, iron, zinc etc., that should be served in school lunches), but are based on foods, i.e. related only to the availability, frequency of availability, and portion size of food types, such as starchy foods, fruit and vegetables, foods high in fat, sugar and salt etc. Therefore, we are intending only to analyse the food types served to check compliance with the current SFS and not analyse the nutrient content of the foods provided. We will also directly observe the food on offer to assess any deviation from the menus in the foods provided.

To assess sales of food in schools we will request aggregated data on food sales for two designated months in the academic year. Almost all schools use online payment management systems for the sale of school food, which provides them with data that identifies the types of foods sold. We will focus on sale of foods restricted by the SFS (including sugar sweetened beverages, confectionary, fried food, snacks etc.) and compare the proportions of sales of these food categories in the two school groups. We will undertake exploratory analysis of these data to determine whether there are any patterns of sales in schools that sell proportionally more restricted foods.

To assess uptake of school lunches, schools will be asked for routine data that they collect on school meal uptake. The number of pupils purchasing school food each day will also be obtained from the online payment data, although the availability of this data may vary across different school online payment systems.

To assess: a) the school culture and environment relating to food in all the schools; b) the process of implementation of the SFS and supporting SFP actions in schools adhering to these; and c) the influence of the wider school context on implementation, we will collect the following data: we will review school food policies (including food pricing policy), behavioural policies and other relevant policies identified by the schools. We will also assess any Board of Governor's papers or meeting minutes that relate to food provision, education or the food environment in schools. We will review Ofsted reports; in schools that are mandated to adhere to SFS, Ofsted teams inspect the food on offer in the canteen, the atmosphere and culture in the dining area, and the effect this has on students' behaviour. In addition, we will directly observe the eating and wider school environment, including where food and drink is available, where pupils go to consume foods, and food purchasing outlets within the school vicinity etc. (using the developed observation checklist as described above). Informed by the SFP headteacher and school checklists.[12, 13] we will develop questions for inclusion in the staff questionnaire that assess the food culture within the school (e.g. pupils bringing in unhealthy foods, awareness of food and healthy eating, staff attitudes regarding food and healthy eating etc.). We will include questions for staff that relate to: i) the implementation and sustained embedding of the SFS and SFP (using an adaptation of the NOMAD survey instrument (underpinned by Normalization Process Theory (see case study data capture in section 3.8) and developed to assess implementation processes[46]); and ii) the wider contextual influences such as the school leadership approach, the influence of the governing body and teacher/parent or teacher/pupil relationships. The questionnaire administered to parents will include questions to assess their perceptions of the food provision, eating environment and the food curriculum provided by schools, how they think these factors influence the dietary intake of their children and their decisions on the choice of lunch (school-provided or home-packed). The logic model in Figure 1 presents the key areas of data capture and Table 1 summarises the methods for achieving this.

Figure 1: Logic model and theory of change for the influence of school food standards on children's dietary intake and dental health outcomes

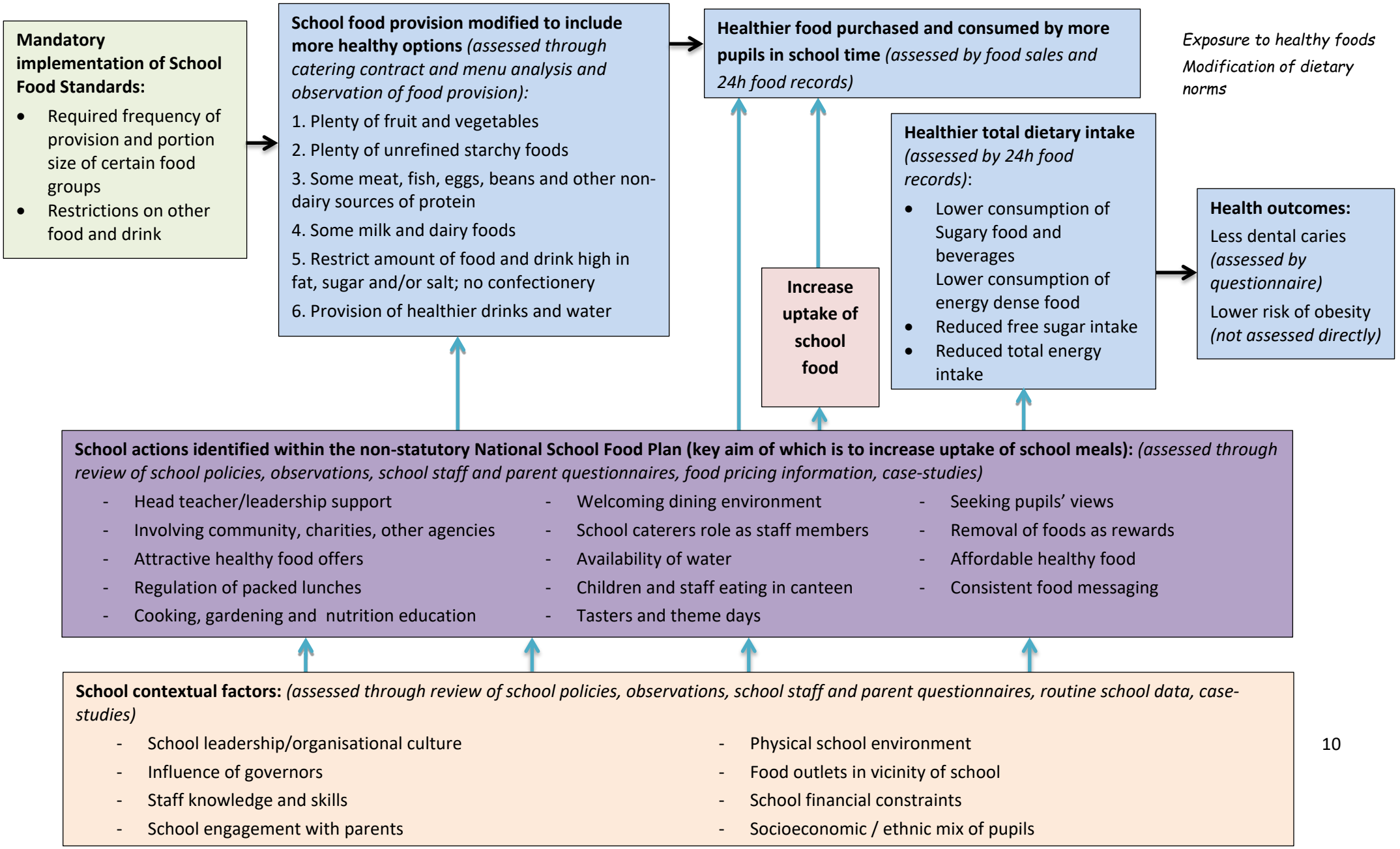


Table 1: Logic model components and planned data capture methods

Logic model component		Method of school-level data capture
Provision of school food and degree to which SFS are adhered to	School lunch provision	Assessment of menus using SFS school lunch checklist
	Other school food provision	Assessment of food offers outside of lunchtime against the SFS school food other than lunch checklist
School food purchased		Proportion of sales in restricted food categories obtained from aggregate daily school food sales data
Implementation of School Food Plan actions	Leadership support, school culture and ethos	School staff/governor questionnaires*; observation checklists*, review of catering contracts and school policies
	Dining environment and role of catering staff	School staff/governor questionnaires*; observation checklists*; review of Ofsted reports
	Social environment (staff eating in canteen, theme days, food rewards, consultations with pupils etc.)	School staff/governor questionnaires*; observation checklists*; review of school policies on food, behaviour etc.; parent questionnaires
	Affordability of school food	Review of school food policies; school staff/governor questionnaires* pricing of foods on menus
	Home-packed lunch regulation	Review of school food policies; school staff/governor questionnaires*
	Cooking, gardening, nutrition education	Review of curricular documentation; school staff questionnaires*
	Consistent messaging and whole school approach	Review of school food policies; school staff questionnaires*; parent questionnaires
School meal uptake		School data on school meal uptake
Influence of school context	Leadership, governor influence, organisational culture	School staff/governor questionnaires*; observation checklists*; school policies
	Staff knowledge and skills	School staff/governor questionnaires*
	School engagement with parents	School staff/governor questionnaires*; parent questionnaires
	Physical environment (school and surrounding environment)	Observation checklists*
	School financial constraints	School staff/governor questionnaires*
	Ethnic and socioeconomic mix of pupils	Routinely available school data

*Informed by SFP Headteachers' and school healthy eating culture and ethos checklists[12, 13]

3.6 Pupil outcomes

We aim to compare dietary intake in pupils in the two defined SFS school groups. The primary outcomes are intake of free sugars during: i) school day lunch; ii) the full school day; and iii) the full 24 hour period of the same school day. Secondary outcomes are: percentage of energy intake from free sugars, frequency of sugary food/drink consumption; total energy intake, and intake of other dietary

components (fat, confectionery, sugar sweetened beverages, fruit and vegetables, fibre) at school day lunch, the full school day and the full 24 hour period of the same school day; and dental caries experience. We will also compare these outcomes in pupils across the different school types. We are aware that pupils do not always consume their lunch during the school-identified lunchtime break, so we will identify 'lunch' intake by asking pupils when they ate their lunch.

Data collection methods

We will undertake a cross-sectional study with the participating pupils in years 7, 9 and 10. Schools we will arrange a timetabled session in the school computer cluster for each selected class. Pupils will be asked to complete an online questionnaire during the session. Researchers will be present within the sessions to provide assistance for pupils who require it. Schools will be asked to arrange a further teacher-supervised, timetabled session approximately two to four weeks later to repeat the dietary intake element of the online survey and to complete some additional questionnaire measures.

Assessment of dietary intake

Dietary intake data will be assessed using Intake24, an online self-completion 24 hour recall tool that is based on the multiple pass method. The system was originally designed for use by people aged 11-24 years and developed through four cycles of user-testing and feedback.[47] A comparison of Intake24 with interviewer-led recalls was conducted in 180 people aged 11 to 24 years. Intake24 was found to under-estimate energy intake by just 1% on average. Mean intakes of almost all macronutrients and micronutrients were within 4% of the interviewer-led recall.[48] The UK version of the system contains a database of over 2500 foods which are linked to UK Nutrient Databank composition codes.[49] A series of food photographs are used for portion size estimation. These were criterion validated in a feeding study and for convergent validity against weighed food diaries with children aged 18 months to 16 years and their parents.[50, 51]

This 24 hour multiple pass recall method has been shown to be the most accurate for assessing dietary intake in adolescents and Intake24 has been used successfully in a classroom situation to collect data from secondary school age children.[52] Intake24 will also enable estimation of frequency of consumption of sugary foods and drinks (a risk factor for dental caries[53]).

We aim to collect dietary intake data from pupils for a minimum of one complete 24 hour school day period, and a maximum of two complete, non-consecutive school days. The first 24 hour recall using Intake24 will be undertaken in the timetabled data collection session. During this session researchers will explain how to use the dietary data collection tool and be available to assist participants and answer queries. Schools will also be asked to provide a subsequent timetabled session during which participating pupils can undertake a second 24 hour dietary recall using Intake24.

Adaptation of Intake 24 for a culturally diverse population

In 11-16 year olds Intake24 has been shown to give similar estimates of energy and nutrient intakes as interviewer-led 24 hour recall tools.[48] However, development of the tool is continuing, and the developing team have recognised that, whilst Intake 24 contains a number of culturally diverse food items, it does not include some traditional foods that would be commonly consumed within the West Midlands population (particularly South Asian traditional foods). Therefore, in the first 3 months of this study, the Intake24 tool will be further adapted to include additional frequently consumed traditional food items (e.g. toor dahl, barfi). The University of Birmingham co-applicants will draw on their extensive experience of dietary data collection with children from South Asian and other BME groups to inform this adaptation process.[54, 55] The Intake24 team have experience in adapting the system for different populations, having developed versions for New Zealand, Portugal, Denmark and United Arab Emirates, as well as for the UK population with coeliac disease.

Assessment of dental caries experience

We will use validated self-report measures from the national Child Dental Health Survey[1] to assess dental symptoms in the last 3 months and treatment received in the last 24 months to indicate caries experience. To assist with interpretation of the responses, we will also ask children to recall when they last went to the dentist and whether it was for a check-up or because they were having problems.

Collection of sociodemographic and other data

During the timetabled data collection sessions, pupils will also be asked to complete questions collecting demographic data (age, gender, ethnicity) and postcode data, which will be mapped to Index of Multiple Deprivation (IMD) scores. Data will also be collected on other factors relating to dental health (frequency of tooth brushing), and school and home postcodes will be used to determine exposure to fluoridated water, as these are potential confounding factors in the association between sugar intake and dental caries. Pupils will also be asked about their usual source of school day lunch (school-provided vs. home-packed). In addition, pupils will be asked to complete a preference-based paediatric health related quality of life measure: the Child Health Utility 9D (CHU-9D; https://www.sheffield.ac.uk/scharr/sections/heds/mvh/paediatric).

3.7 Analysis of pupil outcome data

Linear multilevel models will be developed to assess differences in pupil outcomes between the two school groups, accounting for clustering (classes and schools), and adjusted for propensity scores and pupil-level confounders (year group, sex, ethnicity, IMD score, school-provided vs. home-packed lunch). The difference in the primary outcomes of mean lunchtime, school day and 24 hour sugar intake (g) between pupils in schools mandated to adhere to SFS and pupils in schools not mandated to adhere to SFS will be estimated. Differences in the secondary outcomes of %energy intake from free sugar, total energy intake, and other nutrient and food group intakes (e.g. confectionery, sugar sweetened beverages, fruit and vegetables) will be estimated for lunch, school day and 24 hr intake. Differences in dental symptoms and caries treatment will also be estimated, additionally adjusting for oral healthcare factors and exposure to fluoridated water.

We will further explore the associations between school SFS group and pupil outcomes by investigating interaction terms between SFS group and:

1. year group, to explore whether there is a differential impact of the SFS across the different year groups
2. usual lunch type (school-provided vs. home-packed), as it may be expected that the SFS would have a bigger impact on pupils having school-provided meals
3. IMD score, to explore whether there is a differential impact of the SFS across the socioeconomic spectrum.

If possible within the school sample, we will undertake further exploratory analysis within the group of schools not mandated to adhere to the SFS to examine differences in pupil outcomes between schools that have voluntarily signed up to the SFS and those that have not signed up.

In addition, we will develop further linear multilevel models to explore potential associations between the identified school types and pupil outcomes, again adjusting for clustering, potential pupil-level confounders and propensity scores, as described above.

3.8 Case study schools

Based on our previous experience of evaluating health promoting strategies in schools,[56] we anticipate there to be a high degree of variation in implementation of the SFS and SFP recommendations in schools. This variation offers the opportunity to explore more fully the barriers and facilitators facing schools when required to act as the setting for health promotion activities. We therefore propose to undertake in-depth work with a sub-sample of schools ('case studies') to generate additional learning around this.

The sampling strategy for the case study schools will be informed by the emergence of school 'types' from analysis of the logic model data. For each aspect of the SFS and the SFP we will categorise schools as "low", "medium" or "high" implementers. School types will be determined based on emerging patterns in relation to distribution of low, medium or high implementers, cross-characterised by key institutional characteristics (e.g. pupil numbers, socio-demographics, school/parent relationships). We envisage n=4-8 case studies which will include a range of school types, representative of the various characteristics and implementation types. We will also include at least n=2 schools among our case studies sampled from the n=22 schools not implementing the SFS to explore reasons for choosing not to implement the standards, and whether they are addressing pupils' dietary intake in any other ways.

Data capture in case study schools

We plan to undertake interviews with key school stakeholders and focus groups with school pupils to explore in more depth the way in which the SFS, SFP and local school policy or initiatives are introduced, embedded and sustained in the schools, and their perceived influence on the dietary intake of pupils.

In establishing the focus of the case study enquiry we have drawn on Maguire's explorations of policy enactment in English schools,[57] with data collection shaped with reference to May's Normalization Process Theory (NPT).[58] The revised SFS is a recently introduced intervention (mandated in 2015) and schools may be anticipated to be still going through the process of 'normalization'. While we are not able to collect contemporaneous data from the 'before 2015 SFS' period, we are able, through interviews with key informants, to gain some understanding of how the SFS is being embedded in schools and specifically to hear 'their story' of the adoption process. In the case study schools we do not propose to use the NOMAD instrument to collect data formally from interviewees[46]; rather we will use NPT's four constructs and their constituent components to sensitise interview prompts so that we can surface, if not volunteered unprompted by the interviewees, information to help us guide our thinking of how key informants made sense of the SFS/SFP (see example prompts; below).

Key school management, teaching and catering staff, and governors, will be identified in each of the case study schools and invited for interview. Depending on the size of the school the number of participants interviewed will vary but we would anticipate n=4-6 per school. Interviewees will be encouraged to tell their 'story' relating to their experiences of the SFS and SFP, and how the provision of food, eating environments and the food/cooking curriculum have been shaped within their schools. This narrative style is a means of enabling participants to influence the content of the interview by introducing topics and issues they feel to be most relevant. However the interviewer will be conscious of key research questions, informed by the lens of NPT, that need to be surfaced. These will include: a) What is the participant's past and present experience of the SFS and SFP and other school-determined approaches to improving school food/pupils' diets? What is their understanding of the aims of the SFS/SFP? (NPT construct: 'coherence'); b) How are the SFS and SFP 'meant to work' and achieve pupil dietary change in their school? What new working practices are now required? Does the interviewee

perceive that the SFS/SFP is working as expected to deliver this gain? ('cognitive participation'); c) How has the interviewee's role, interaction with others, and experiences changed with SFS/SFP? ('collective action'); and d) What are the facilitators and barriers to the successful implementation and maintenance of the SFS/SFP? How could these be enhanced or removed? ('reflective monitoring').

Pupils from included year groups (7, 9, 10) will be invited to participate in focus groups (FGs) to explore their views of the school food environment and contextual factors influencing this, and how they interact with this and the wider outside school environment in terms of their eating behaviour. We will also explore their views and experiences of any negative impact of SFS or SFP and regulation of foods provided. We aim to conduct 2-3 focus groups (involving 16-24 students) in each of the case study schools.

Interviews and FGs will be recorded with the consent of participants, transcribed ad verbatim and anonymised for analysis. A thematic analysis of content will be undertaken, informed by the Framework analytical approach.[59]

3.9 Health economic evaluation

To evaluate the economic impact of the SFS, and the wider SFP a cost-consequence analysis will be undertaken. This will combine and summarise information about the costs and outcomes in the form of a balance sheet. The analysis will highlight the costs to schools and families, and offer a transparent range of outcome measures for consideration. This method is relevant to this study because the costs and outcomes are wide ranging, multiple perspectives are relevant e.g. school and pupil, and it is expected that there will be variation in implementation across the schools. Furthermore, judgement for cost-effectiveness depends on the value placed on improving the outcomes by the funders of food provision in schools.

The costs of food provision will be estimated from a detailed list of resources obtained from the school staff questionnaires, observation, the catering contracts, and the school menus and pricing. Wider costs associated with implementing the SFP will be obtained from school staff, parent and pupil questionnaires and observation. From the pupil perspective, pupils and parents will be asked to estimate the average daily cost of school food consumption. Average daily cost per pupil will also be estimated from the aggregated daily food sales data and the number of pupils purchasing school food. Each resource use item will be costed using financial data supplied by the school, and obtained from published literature. Pupils will be asked to complete the Child-Health Utilities 9-Dimension (CHU-9D) instrument, a utility-based health-related quality of life questionnaire. This will enable the construction of Quality-Adjusted Life Years (QALYs) and will thus allow inferences to be made about any QALY-differences between schools mandated to the SFS versus schools not mandated, offset against cost. A cost-utility analysis will be exploratory due to the expected variation in implementation of the SFS.

3.10 Consent

For school pupils eligible to participate in the study, parents will be given written detailed information about the study, what their child's participation would involve and how their child's data will be processed. Schools will be asked to assist in the distribution of this information to parents in different formats (e.g. email, post, website etc.). Parents will not be asked for active consent, but will be given the opportunity to complete and return a form to opt their child out of taking part in the study. Prior to data collection pupils will also receive detailed study information, including what we are requesting of them and how their data will be processed. Written assent will be obtained from pupils whose parents have not opted them out of participating. Adult participants will be given detailed written information about the study, what their participation would involve and how their data will be processed. They will be asked to complete a written consent form.

4 Ethical / Regulatory considerations

The planned study adheres to the UK Policy Framework for Health and Social Care Research and involves collecting documentary, questionnaire, interview and focus group data from secondary school stakeholders, including pupils.

4.1 Assessment and management of risk

The risk to participants in this observational study is very low. There is a small possibility that the collecting of dietary data may be a sensitive issue for some participating pupils. All participants (adults and school pupils) have the right to withdraw from the study at any time. If during the collection of dietary or other data, or during focus group discussions, a school pupil participant becomes distressed, the researcher will seek agreement from the pupil to inform a member of staff at the school who can engage the student with the relevant welfare systems in place within the school. If a researcher becomes aware of a safeguarding issue in relation to a pupil, they will immediately inform the relevant member of staff within the participating school so that the school safeguarding procedures can be followed.

4.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study we will seek a favourable ethical opinion from the University of Birmingham Research Ethics Committee (reference 18-1738), which operates in line with the ESRC Research Ethics Framework.

4.3 Amendments

Amendments to the study protocol will be submitted to the Sponsor, the Funder and the Research Ethics Committee for review. Amendments will only be implemented when agreement from these parties has been gained. The amendment history will be tracked using version numbers and dates to identify the most recent protocol version.

4.4 Peer review

The funding application, including the detailed study plan, has undergone independent, expert and proportionate peer review in line with NIHR research funding guidelines. Following submission of the funding application at stage 1 we received feedback from the Funding Board. Following submission of the funding application at stage 2 we received feedback from 5 independent peer reviewers and further feedback from the Board. The study team responded to the feedback in detail, incorporating changes where required.

4.5 Public Involvement

A Deputy Headteacher of a secondary school (SW), is part of the investigator team. SW has advised on the development of the research plan in terms of engaging schools and pupils and access to school-owned food sales data, as well as providing valuable background information on school management and governance systems. We have also have a teacher representative on the Study Steering Committee (SB) who has experience of working within academy settings, and has also provided information on academy settings to inform planning of the study.

During research plan development, we consulted with a group of parents of secondary school children and a group of secondary school pupils (aged 14-15 years), who have advised on strategies to recruit

pupils and encourage them to complete the planned nutritional assessment tools, and ways to encourage parents to complete questionnaires.

We have convened a group of parents, teachers and secondary school governors to consult with at key points throughout the study (we anticipate approximately 2 consultation meetings per year). This group will be chaired by the teacher/public representative of the Study Steering Committee (SB). We will also consult with a secondary school council throughout the project to gain pupil perspectives on the various aspects of the study, and will consult when required with a manager from an external school catering contractor.

4.6 Protocol compliance

Accidental protocol deviations will documented and reported to the Chief Investigator and Sponsor. Protocol non-compliance will be reported without delay by research staff to the Chief Investigator, who will inform the Sponsor. The Chief Investigator will ensure that the issue is investigated and appropriate actions taken. The Research Ethics Committee will be notified of any serious breach of its approval conditions, security, confidentiality, or any other incident that could undermine public confidence in the research.

4.7 Participant confidentiality and data protection

All study researchers will comply with the requirements of the Data Protection Act 2018, and all research staff involved in data collection will undergo/update Good Clinical Practice training and have enhanced DBS checks. Data protection measures will adhere to the relevant policies and procedures of the University of Birmingham. All study data collected on paper will be held securely, in a locked room or locked cabinet that is accessible only to the research team and relevant regulatory authorities. All study data in electronic form will be pseudoanonymised using ID numbers and held securely on encrypted machines protected by passwords. Audio files will be transcribed by a specialist external company subject to a Confidentiality Agreement to not disclose any information to third parties. Files will be transferred via a secure server with user identifiers and passwords. Transcripts will be marked with unique and anonymised identifiers. All data will be held securely in the custody of the Chief Investigators for a minimum of 10 years after publication of the main study results, in accordance with the University of Birmingham Research Data Management Policy.

4.8 Indemnity

The University of Birmingham, as the Sponsor, has in force a Public Liability Policy which provides cover for claims for “negligent harm.” The activities of this study are included in the coverage. No provision has been made for indemnity in the event of a claim for non-negligent harm.

4.9 End of study and archiving

Following the end of the study on 31st May 2021, data will be archived at the University of Birmingham for a minimum of 10 years.

4.10 Access to the final dataset

After publication of the main findings of the study, the Chief Investigators will consider external requests to gain access to anonymised data. The dataset will be preserved and available for this purpose for a minimum of 10 years following the end of the study. Those requesting data will be asked to provide a brief research proposal including the objectives, timelines, intellectual property rights, and expected outputs, and a Data Sharing Agreement between the University of Birmingham and the requestor will be drawn up. Requestors will be required to acknowledge the research team and funders

as a minimum and consider co-authorship of any publications arising from the data. Permission for anonymised data to be shared for the purpose of future academic research will be sought from all participants via the informed consent form.

5 Dissemination

Data arising from the study will be owned by the University of Birmingham. The findings will enable further understanding of the ways in which the SFS and SFP have been implemented in secondary schools, and their impact on pupil's dietary intake and dental health. Findings will be of value at: national level (to inform government school food policy); school level (to enable effective implementation); the public (to support wider understanding of school food policy).

5.1 Anticipated outputs

The planned study will produce the following outputs:

1. An updated online dietary assessment tool (Intake24), adapted for use in a culturally diverse population. This will be of future use in nutritional epidemiological or intervention studies in culturally diverse communities.
2. Full study report published in the National Institute for Health Research Journals Library (https://www.journalslibrary.nihr.ac.uk/#/)
3. Open access publications and conference presentations on:
    a. The implementation of the school food standards and school food plan in secondary educational settings, including the variation in practice and the barriers and facilitators to implementing such policy
    b. The costs associated with implementing school food standards and related policy in secondary educational settings
    c. The impact of statutory school food standards on pupils' dietary intake and dental health
    d. The association between the level of implementation and embedding of school food standards and wider school food policy/initiatives, and pupils' dietary intake and dental health

    We will present findings at national and international conferences, and targeted journals will include both general medical journals and specialist journals
4. A short brief for policy audiences.

These outputs will be of direct relevance to the Department of Health and the Department for Education, and will inform further development of national policy relating to school food provision, education and the food environment provided by schools. The information gained from the study will also be disseminated at a local level to Local Authorities and secondary schools. All outputs will acknowledge the funders of the study.

We will disseminate findings to key national agencies (Department of Health, Department for Education, Public Health England, School Food Alliance, National Association for Headteachers etc.), and to local level organisations (Regional School Commissioners, Local Governors' Association etc.). In addition to preparing reports for different agencies, we will engage in the following dissemination activities: communicating study findings through the educational and general press; and presenting at meetings held by key networks and organisations.

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