

# Food provision, culture and environment in secondary schools (FUEL) study

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
31/07/2019	No longer recruiting	<input checked="" type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input checked="" type="checkbox"/> Statistical analysis plan
17/10/2019	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
25/10/2024	Nutritional, Metabolic, Endocrine	

## Plain English summary of protocol

### 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 was introduced means that all academies and free schools set up between 2010 and 2014 are not legally 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 required by law to meet them with those that are not. 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 will make comparisons between secondary schools required to meet the standards and those that are not required to meet the standards. We will compare: the food provided and sold in schools; the school food environment and culture; 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.

### Who can participate?

Secondary schools in the Midlands and pupils from years 7, 9 and 10 in those schools.

### What does the study involve?

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 how well the School Food Plan is implemented. 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 assess the school environment and culture including the food on offer and the eating spaces in schools) and questionnaires to key staff members and governors to gain their views and experiences of the food standards, the school eating environment, culture and curriculum. We will ask pupils from years 7, 9 and 10, in school time, to complete an online survey including a 24-hour dietary 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 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.

**What are the possible benefits and risks of participating?**

The results will help us to assess the impact of the national School Food Standards. This information will be used to inform the Department for Education and Department of Health to enable further development of national policy relating to school food. In turn, this may help to shape the health of future secondary school pupils. Additionally, pupil participants will be given a £5 shopping voucher as a thank you for their time spent participating in our study.

Schools will be provided with a summary of the data collected from their school, which may support any internal evaluation of school food. The process of collecting the views of pupils, parents, staff and Governors will also provide an additional method for the school to ensure their voices on school food provision and education are heard. All schools who take part in the study will be given £300 to cover the costs of their involvement.

There are no anticipated risks to those taking part in this study.

**Where is the study run from?**

The University of Birmingham, UK

**When is the study starting and how long is it expected to run for?**

September 2019 to September 2022

**Who is funding the study?**

National Institute for Health Research (NIHR), UK

**Who is the main contact?**

Dr Miranda Pallan (scientific), [m.j.pallan@bham.ac.uk](mailto:m.j.pallan@bham.ac.uk)

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## Contact information

**Type(s)**

Scientific

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**Type(s)**

Public

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

17/92/39; CPMS 43416

## Study information

**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

**Acronym**

FUEL

## **Study objectives**

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. These high intake patterns are of public health concern given the association between sugar consumption and obesity. Patterns of school food consumption are an important determinant of total dietary profile, with up to a third of children's energy and micronutrient intake provided by lunch on school days. Adolescence is a key period for the establishment of dietary patterns, and in school adolescents have more choice and greater autonomy regarding the food they eat compared with younger children. Therefore a healthy school food environment may have a significant influence on the dietary intake of adolescents.

National School Food Standards (SFS) have been in place in England since 2006 and were updated in 2015. They are a legal requirement for most state schools. The Standards are a set of requirements for school food to help children develop healthy eating habits and ensure that they get the energy and nutrition they need across the whole school day. In addition to the national SFS, the School Food Plan (SFP) was launched in 2013. This provides a wider set of non-statutory recommendations for schools which aim to address the overall ethos of the school in relation to food, promoting adoption of a 'whole school' approach. There has been little evaluation of the impact of the SFS on the diets of pupils in secondary schools, and to date, there has been no evaluation of the implementation of the SFS within secondary schools, or the influence of the wider SFP recommendations on the overall ethos of the schools in relation to food.

The way in which the SFS legislation has been introduced in England means that there are a group of academies and free schools that are exempt from the legal requirement to meet the Standards. This gives an opportunity to examine the influence of the SFS legislation by comparing these exempt schools with those that are mandated to meet the Standards.

We aim to assess whether the mandatory SFS and additional SFP recommendations influence the food provided and sold in secondary schools; the school food environment and ethos; and the healthy eating and cooking skills curriculum. We also aim to assess the impact of the SFS and SFP on sugar and other dietary intake, and the dental health of secondary school pupils. In addition, we will explore the extent to which schools vary in how the SFS and SFP recommendations are implemented; the cost to schools and families of measures to improve healthy eating and food provision; and the economic impact of the SFS and SFP.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 20/08/2019, University of Birmingham Ethics Committee (Research Support Group, C Block Dome, Aston Webb Building, University of Birmingham, Edgbaston, B15 2TT, UK; +44 (0) 121 414 8825; s.l.cottam@bham.ac.uk), ref: ERN\_18-1738

## **Study design**

Observational mixed methods study

## **Primary study design**

Observational

## **Study type(s)**

## Prevention

### Health condition(s) or problem(s) studied

Dietary intake and dental health

### Interventions

Current intervention as of 17/05/2021:

This research consists of two stages. In the first stage, a variety of data on SFS and SFP implementation and school and pupil outcomes will be collected at the school and individual pupil level. We will aim to recruit an equal number of schools mandated and not mandated to comply with the SFS, with pupil recruitment occurring from one selected class (form groups or class groupings where there is no streaming and all pupils have to attend) from each of three different year groups for every school. 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. In the second stage, a smaller number of case study schools (4-8) will be identified for in-depth qualitative evaluation with school staff (interviews) and pupils (focus groups). The sampling approach for case study schools aims to ensure representation of schools serving areas with high deprivation (IDACI and FSM); and a range of levels of engagement with school food, healthy eating and food education, as indicated by presence / absence of a school food policy; strength of the school's food education offer; and use of external / in-house catering. We will ensure that there is variation in the catering provider across case study schools. We aim to 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.

Data will be collected through the following methods/tools:

- Key information survey to head teachers
- Costings survey for completion by senior management
- Survey to key staff and Governors identified by the school to have roles relating to food provision, eating environment, food curriculum, or SFS/SFP implementation (including head teachers, lead catering staff, PHSE leads, teachers with responsibility for the food/cooking curriculum, relevant representatives from the governing body)
- Pupil survey, including a Paediatric Quality of Life measure (CHU-9D) and dental health measures
- Pupil 24-hour recall dietary assessment tool
- Observation checklist for auditing the school food environment and ethos (food outlets; dining and communal facilities; food consumption behaviours; wider environment within and surrounding the school)
- School food compliance checklist for auditing school food provision (using menus, price lists and observation)
- Canteen sales data (aggregated data on food sales for two (non-continuous) months in the academic year)
- Analysis of key documents from schools e.g. policies; minutes of Governors meetings; catering contract; menus
- Collection of key data from schools e.g. school meal take-up

Data collection tools to measure compliance with the SFS are based on the national SFS checklists for school lunches and school food other than lunch.

Data collection tools to measure implementation of the SFP are based on the national School

Food Plan checklist for head teachers, guidance for Governors and the creating a culture and ethos of healthy eating document aimed at school Senior Leadership Teams.  
Normalization Process Theory has underpinned the design of staff survey questions relating to the implementation and sustained embedding of the SFS and SFP recommendations

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Previous intervention as of 31/12/2019:

This research consists of two stages. In the first stage, a variety of data on SFS and SFP implementation and school and pupil outcomes will be collected at the school and individual pupil level. We will aim to recruit an equal number of schools mandated and not mandated to comply with the SFS, with pupil recruitment occurring from one selected class (form groups or class groupings where there is no streaming and all pupils have to attend) from each of three different year groups for every school. 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. We aim to 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. In the second stage, a smaller number of case study schools (4-8) will be identified for in-depth qualitative evaluation with school staff (interviews) and pupils (focus groups). Schools will be sampled to ensure inclusion of a range of schools in terms of level of SFS/SFP implementation and institutional characteristics such as school size.

Data will be collected through the following methods/tools:

- Key information survey to head teachers
- Costings survey for completion by senior management
- Survey to key staff and Governors identified by the school to have roles relating to food provision, eating environment, food curriculum, or SFS/SFP implementation (including head teachers, lead catering staff, PHSE leads, teachers with responsibility for the food/cooking curriculum, relevant representatives from the governing body)
- Pupil survey, including a Paediatric Quality of Life measure (CHU-9D) and dental health measures
- Pupil 24 hour recall dietary assessment tool
- Parent survey to parents of pupils participating in the study
- Observation checklist for auditing the school food environment and ethos (food outlets; dining and communal facilities; food consumption behaviours; wider environment within and surrounding the school)
- School food compliance checklist for auditing school food provision (using menus, price lists and observation)
- Canteen sales data (aggregated data on food sales for two (non-continuous) months in the academic year)
- Analysis of key documents from schools e.g. policies; minutes of Governors meetings; catering contract; menus
- Collection of key data from schools e.g. school meal take-up

Data collection tools to measure compliance with the SFS are based on the national SFS checklists for school lunches and school food other than lunch.

Data collection tools to measure implementation of the SFP are based on the national School Food Plan checklist for head teachers, guidance for Governors and the creating a culture and ethos of healthy eating document aimed at school Senior Leadership Teams.

Normalization Process Theory has underpinned the design of staff survey questions relating to

## the implementation and sustained embedding of the SFS and SFP recommendations

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Previous intervention as of 09/02/2021:

This research consists of two stages. In the first stage, a variety of data on SFS and SFP implementation and school and pupil outcomes will be collected at the school and individual pupil level. We will aim to recruit an equal number of schools mandated and not mandated to comply with the SFS, with pupil recruitment occurring from one selected class (form groups or class groupings where there is no streaming and all pupils have to attend) from each of three different year groups for every school. 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. We aim to 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. In the second stage, a smaller number of case study schools (4-8) will be identified for in-depth qualitative evaluation with school staff (interviews) and pupils (focus groups). Schools will be sampled to ensure inclusion of a range of schools in terms of level of SFS/SFP implementation and institutional characteristics such as school size.

Data will be collected through the following methods/tools:

- Key information survey to head teachers
- Costings survey for completion by senior management
- Survey to key staff and Governors identified by the school to have roles relating to food provision, eating environment, food curriculum, or SFS/SFP implementation (including head teachers, lead catering staff, PHSE leads, teachers with responsibility for the food/cooking curriculum, relevant representatives from the governing body)
- Pupil survey, including a Paediatric Quality of Life measure (CHU-9D) and dental health measures
- Pupil 24-hour recall dietary assessment tool
- Observation checklist for auditing the school food environment and ethos (food outlets; dining and communal facilities; food consumption behaviours; wider environment within and surrounding the school)
- School food compliance checklist for auditing school food provision (using menus, price lists and observation)
- Canteen sales data (aggregated data on food sales for two (non-continuous) months in the academic year)
- Analysis of key documents from schools e.g. policies; minutes of Governors meetings; catering contract; menus
- Collection of key data from schools e.g. school meal take-up

Data collection tools to measure compliance with the SFS are based on the national SFS checklists for school lunches and school food other than lunch.

Data collection tools to measure implementation of the SFP are based on the national School Food Plan checklist for head teachers, guidance for Governors and the creating a culture and ethos of healthy eating document aimed at school Senior Leadership Teams.

Normalization Process Theory has underpinned the design of staff survey questions relating to the implementation and sustained embedding of the SFS and SFP recommendations

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## Previous intervention as of 31/12/2019:

This research consists of two stages. In the first stage, a variety of data on SFS and SFP implementation and school and pupil outcomes will be collected at the school and individual pupil level. We will aim to recruit an equal number of schools mandated and not mandated to comply with the SFS, with pupil recruitment occurring from one selected class (form groups or class groupings where there is no streaming and all pupils have to attend) from each of three different year groups for every school. 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. We aim to 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. In the second stage, a smaller number of case study schools (4-8) will be identified for in-depth qualitative evaluation with school staff (interviews) and pupils (focus groups). Schools will be sampled to ensure inclusion of a range of schools in terms of level of SFS/SFP implementation and institutional characteristics such as school size.

Data will be collected through the following methods/tools:

- Key information survey to head teachers
- Costings survey for completion by senior management
- Survey to key staff and Governors identified by the school to have roles relating to food provision, eating environment, food curriculum, or SFS/SFP implementation (including head teachers, lead catering staff, PHSE leads, teachers with responsibility for the food/cooking curriculum, relevant representatives from the governing body)
- Pupil survey, including a Paediatric Quality of Life measure (CHU-9D) and dental health measures
- Pupil 24 hour recall dietary assessment tool
- Parent survey to parents of pupils participating in the study
- Observation checklist for auditing the school food environment and ethos (food outlets; dining and communal facilities; food consumption behaviours; wider environment within and surrounding the school)
- School food compliance checklist for auditing school food provision (using menus, price lists and observation)
- Canteen sales data (aggregated data on food sales for two (non-continuous) months in the academic year)
- Analysis of key documents from schools e.g. policies; minutes of Governors meetings; catering contract; menus
- Collection of key data from schools e.g. school meal take-up

Data collection tools to measure compliance with the SFS are based on the national SFS checklists for school lunches and school food other than lunch.

Data collection tools to measure implementation of the SFP are based on the national School Food Plan checklist for head teachers, guidance for Governors and the creating a culture and ethos of healthy eating document aimed at school Senior Leadership Teams.

Normalization Process Theory has underpinned the design of staff survey questions relating to the implementation and sustained embedding of the SFS and SFP recommendations

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## Previous intervention:

This research consists of two stages. In the first stage, a variety of data on SFS and SFP

implementation and school and pupil outcomes will be collected at the school and individual pupil level. We will aim to recruit an equal number of schools mandated and not mandated to comply with the SFS, with pupil recruitment occurring from one randomly selected class from each of three different year groups for every school. 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. We aim to 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. In the second stage, a smaller number of case study schools (4-8) will be identified for in-depth qualitative evaluation with school staff (interviews) and pupils (focus groups). Schools will be sampled to ensure inclusion of a range of schools in terms of level of SFS/SFP implementation and institutional characteristics such as school size.

Data will be collected through the following methods/tools:

- Key information survey to head teachers
- Costings survey for completion by senior management
- Survey to key staff and Governors identified by the school to have roles relating to food provision, eating environment, food curriculum, or SFS/SFP implementation (including head teachers, lead catering staff, PHSE leads, teachers with responsibility for the food/cooking curriculum, relevant representatives from the governing body)
- Pupil survey, including a Paediatric Quality of Life measure (CHU-9D) and dental health measures
- Pupil 24 hour recall dietary assessment tool
- Parent survey to parents of pupils participating in the study
- Observation checklist for auditing the school food environment and ethos (food outlets; dining and communal facilities; food consumption behaviours; wider environment within and surrounding the school)
- School food compliance checklist for auditing school food provision (using menus, price lists and observation)
- Canteen sales data (aggregated data on food sales for each school day for the previous 3 months)
- Analysis of key documents from schools e.g. policies; minutes of Governors meetings; catering contract; menus
- Collection of key data from schools e.g. school meal take-up

Data collection tools to measure compliance with the SFS are based on the national SFS checklists for school lunches and school food other than lunch.

Data collection tools to measure implementation of the SFP are based on the national School Food Plan checklist for head teachers, guidance for Governors and the creating a culture and ethos of healthy eating document aimed at school Senior Leadership Teams.

Normalization Process Theory has underpinned the design of staff survey questions relating to the implementation and sustained embedding of the SFS and SFP recommendations.

## **Intervention Type**

Other

## **Primary outcome(s)**

Current primary outcome measures as of 25/01/2021:

Intake of free sugars (g):

1. during school day lunch
2. whilst at school
3. during the full 24-h period of the same school day

This will be measured cross-sectionally using Intake24, an online self-completion 24-h dietary recall tool that is based on the multiple pass method. A minimum of one and a maximum of two (non-consecutive) dietary recalls on school days will be undertaken for each pupil participant, with a mean value taken when two recalls are completed.

We will replicate the methods for calculation of free sugars provided by Public Health England with values derived from the UK Nutrient Databank composition codes.

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Previous primary outcome measures:

Intake of free sugars (g) during:

1. School day lunch
2. The full school day
3. A full 24 hour period on a school day

This will be measured cross-sectionally using Intake24, an online self-completion 24-hour dietary recall tool that is based on the multiple pass method. A minimum of one and a maximum of two (non-consecutive) dietary recalls on school days will be undertaken for each pupil participant, with a mean value taken when two recalls are completed.

We will replicate the methods for calculation of free sugars provided by Public Health England with values derived from the UK Nutrient Databank composition codes.

### **Key secondary outcome(s)**

Current secondary outcome measures as of 25/01/2021:

A range of other dietary measures (in addition to the primary outcome) will also be assessed through the Intake24 tool, administered as described above. Nutrient information will again be retrieved from the UK Nutrient Databank using standardised composition codes.

Dental caries experience. This will be measured cross-sectionally using an online self-completion survey with validated self-report measures taken from the national Child Dental Health Survey.

The secondary outcomes are listed below.

1. Percentage of dietary energy intake from free sugars for each pupil: during the school day lunch; whilst at school and during the full 24-h period of the same school day
2. Free sugar intake providing greater than 5% of total energy intake
3. Number of eating/drinking occasions (excluding plain water)
4. Total energy intake (kcal): during the school day lunch; whilst at school; and during the full 24-h period of the same school day
5. Total fat intake (g): during the school day lunch; whilst at school; and during the full 24-h period of the same school day
6. Number of sugar-sweetened beverages consumed: during the school day lunch; whilst at school; and during the full 24-h period of the same school day
7. Number of sugar and chocolate confectionery items consumed: during the school day lunch; whilst at school; and during the full 24-h period of the same school day
8. Number of fruit and vegetable portions consumed: during the school day lunch; whilst at school; and during the full 24-h period of the same school day
9. Consumption of 5 or more portions of fruit and vegetables per day
10. Fibre intake (g): during the school day lunch; whilst at school; and during the full 24-h period of the same school day

11. Number of foods high in fat, sugar and salt consumed: during the school day lunch; whilst at school; and during the full 2-h period of the same school day
12. Presence of dental caries
13. Number of dental caries symptoms (measured through 6 items of a question from the National Children's Dental Health Survey)
14. Any treatment for dental caries

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#### Previous secondary outcome measures:

Dental caries experience. This will be measured cross-sectionally using an online self-completion survey with validated self-report measures taken from the national Child Dental Health Survey. A range of other dietary measures (in addition to the primary outcome) will also be assessed through the Intake24 tool, administered as described above. Nutrient information will again be retrieved from the UK Nutrient Databank using standardised composition codes. The outcomes are listed below.

1. Percentage of total dietary energy intake from free sugars, and the proportion of participants with free sugar intake providing greater than 5% of total energy intake
2. Number of eating/drinking occasions (excluding plain water)
3. Total energy intake
4. Total fat intake
5. Frequency of consumption of sugar-sweetened beverages
6. Frequency of consumption of sugar and chocolate confectionery
7. Fruit and vegetable consumption and the proportion of participants consuming 5 or more portions of fruit and vegetables per day
8. Fibre intake

#### Completion date

30/09/2022

## Eligibility

#### Key inclusion criteria

Current inclusion criteria as of 17/05/2021:

##### School inclusion criteria:

1. Secondary phase academies and free schools
2. 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) and eight additional Local Authority areas in the East Midlands (Derby, Derbyshire, Leicester, Leicestershire, Northamptonshire, Nottingham City, Nottinghamshire and Rutland)

##### Pupil inclusion criteria:

1. Pupils from classes in Years 7, 9 and 10

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#### Previous inclusion criteria:

##### School inclusion criteria:

1. Secondary phase academies and free schools
2. 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)

Pupil inclusion criteria:

1. Pupils from classes in Years 7, 9 and 10

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Total final enrolment**

3049

**Key exclusion criteria**

Schools:

1. Community schools, voluntary schools, foundation schools, secure and pupil referral units and special or alternative provision schools

**Date of first enrolment**

02/09/2019

**Date of final enrolment**

30/04/2022

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**University of Birmingham**

Edgbaston

Birmingham

United Kingdom

B15 2TT

## Sponsor information

**Organisation**  
University of Birmingham

**ROR**  
<https://ror.org/03angcq70>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 17/92/39

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. 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.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		24/10/2024	25/10/2024	Yes	No
<a href="#">Protocol article</a>	protocol	16/10/2020	20/10/2020	Yes	No
<a href="#">Other files</a>	Health Economic Analysis Plan version 6	07/06/2022	28/06/2022	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Statistical Analysis Plan</a>	version 9	27/06/2022	28/06/2022	No	No

[Study website](#)

Study website

11/11/2025 11/11/2025 No

Yes