

TITLE: The CANTEEN Study: Free School Meals, Diet Quality and Food Insecurity in Secondary School Pupils: a Mixed Methods Study

Protocol version	Date	Changes from previous version
Final v1.0	05/04/2023	Not applicable
Final v2.0	27/06/2023	Clarification on: purpose of personal data being collected, the participant withdrawal process, inclusion of pupils with special educational needs in mainstream schools, the school liaison person; renaming of 'School contract' to 'Memorandum of Understanding'; rephrasing of the process for parents to opt their child out of the study and citing of data protection legislation as per current University Research Governance guidance.
Final v3.0	26/09/2023	Process added (Key Pupil Information form) to capture pupil's educational attainment, Free School Meal eligibility, whether English is an additional language for them, and if they are registered as having any special educational needs. We are asking for this information in order to understand more about the relationship between different pupil characteristics and uptake of Free School Meals. Questions to capture fruit and vegetable knowledge and intake were added to the pupil and parent questionnaires as an indicator of nutrition knowledge. Detail added in relation to interview administering the Caterer and Business Manager questionnaires.

I. STUDY SUMMARY

Study Title	The CANTEEN Study: Free School Meals, Diet Quality and Food Insecurity in Secondary School Pupils: a Mixed Methods Study
Short title	The CANTEEN Study: Free School Meals in Secondary schools
Study Design	Mixed methods, cross-sectional, observational study design
Study Participants	Secondary school pupils from Northern Ireland (years 8 and 11) and the Midlands (England, years 7 and 10) Parents of selected pupils Secondary school staff with roles in Free School Meal administration and food provision
Planned Sample Size	Data collection: 1440 pupils from 32 schools (720 pupils from 16 schools in NI and 720 pupils from 16 schools in England) Case study: 6-8 schools will be included. From each school we will interview school stakeholders (n=4/school) and parents (n=8/school), and have focus groups with pupils (n=2-3 focus groups/school; n=8 pupils/group)
Data collection Period	Quantitative: August 2023 – June 2024 Case study: August 2024 – January 2025
Planned Study Period	January 2023 – June 2025

II. ROLES AND RESPONSIBILITIES FOR STUDY MANAGEMENT COMMITTEES/GROUPS

This project is led by QUB (Woodside, JW) and who will have overall study responsibility. There will be two recruitment sites, Northern Ireland (NI) and the Midland and each site has co-leads (Woodside and McKinley for NI; Pallan and Murphy for the Midlands).

Site Management Team (SMT)

The Site Management Team, will include site leads and research staff in each site will meet bi-weekly by teleconference (with face-to-face meetings also planned where required). These meetings will ensure consistency of processes between sites and allow discussion of progress. The site co-leads will also meet weekly with their site staff. There will also be email contact between meetings as needed. Co-Is with specific expertise (e.g. dietary assessment) will be invited to attend the Site Management Team meeting as required at particular stages of the study. Other sub-group meetings will be scheduled as required during study setup and progression through key milestones.

Study Management Group (SMG)

The four site leads will form a Study Management Group (SMG) with the other Co-Is, appointed research staff and a PPI representative, meeting x4/y, again with email contact between meetings as needed, e.g. for troubleshooting purposes. Study Management Group meetings will be minuted with specified action points, timelines and persons responsible identified.

Study Steering Committee (SSC)

An external Study Steering Committee (SSC), consisting of the PI, other independent academics with relevant research interests and school stakeholders from both regions will meet x2/y.

The SSC will provide overall supervision of the trial on behalf of the sponsor and funder and will ensure the trial is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care.

1. BACKGROUND AND SCIENTIFIC RATIONALE

1.1 The problem

Food insecurity is common in children; 19% of UK children aged <15 y live in moderate-severely food insecure households [1], and food insecurity is consistently linked with poor health outcomes [2]. Free School Meal (FSM) provision is a government-implemented means-tested strategy intended to improve food insecurity and nutrition and reduce dietary inequalities [3]. FSM eligibility has been increasing, particularly post-pandemic (15.4% 2019; 17.3% 2020; 20.8% 2021) [4], but there are concerns that food insecure children are not always eligible for FSM based on current criteria [5]. Furthermore, FSM uptake is variable, with around 20% (range 0-88%; figures based on pre-pandemic data) of eligible secondary pupils not taking FSM [6–9]. Even though this is one of the government's key strategies targeting dietary inequalities, almost no evaluation of its impact on diet, food insecurity, health

or other outcomes has been conducted. Food insecurity is likely to be exacerbated by the current cost of living crisis, making it imperative that one of the main government strategies to tackle food insecurity, means-tested FSM, is fit for purpose.

1.2 Importance of the research for improving health/wellbeing

Unhealthy dietary habits are common in UK adolescents, with high intakes of saturated fat and sugars, and low intakes of fibre and fruit and vegetables (FV), with socioeconomic differentials [10]. Unhealthy diets are associated with poorer school attendance, behaviour, educational achievement, health/well-being outcomes and increased risk of later non-communicable disease (NCD) risk [11]. In the most food insecure children, access to sufficient food is a further concern, with FSMs being a main nutrition source [12, 13].

Little research has examined the impact of the current means-tested FSM policy on food intake, diet quality and food insecurity, particularly at secondary level. Evidence of effectiveness of the current FSM policy is essential to support the status quo, but also to inform proposed changes, e.g. the National Food Strategy's recommendation to extend FSM eligibility criteria and simplify enrolment [14], a change supported by the Local Government Association [15]. Given the rise in those eligible for FSM as a result of the global pandemic and the current cost of living crisis, there is also now active discussion around extension of the policy at a regional level, for example, Plaid Cymru have recently announced an aim to extend universal FSM to secondary schools in a local elections pledge [16].

1.3 Review of existing evidence

FSMs, dietary intake, diet quality and food insecurity:

Evidence relating to FSMs and diet outcomes in the UK comes mostly from younger children (4-7 y), where limited evidence suggests that universal FSM programmes could reduce obesity and improve dietary choices [17, 18]. A global systematic review [19] of universal FSM programmes demonstrated positive effects on meal participation, diet quality and academic performance, with some limited evidence of a positive impact on food security. There is almost no evidence on the impact of the current UK means-tested FSM policy on dietary intake and food insecurity. A single cross-sectional study collecting data from n=2660 students aged 11-18 y in two schools in Yorkshire, with data collection occurring in 2012, found that those taking FSMs in secondary schools chose the dish of the day, which tends to be more nutritious, more often than non-FSM pupils [12].

Factors determining FSM uptake:

The majority of variance in FSM uptake is at school, rather than local authority, level. Therefore, understanding individual school contexts, and their influence on FSM uptake, is important to inform strategies or interventions to optimise policy [20]. Most of the research conducted to date exploring FSM uptake is qualitative in nature. Potential reasons for low FSM uptake include: school system factors (FSM registration, food pricing and payment systems), school pro-activity around FSMs, lack of clarity about eligibility, and fluctuations in family circumstances [21–23]. Stigma around FSM has also been suggested, although this is not consistent [21] and may be related to both the school system (with the cashless canteen system contributing to anonymity [21] and to the level of entitlement within the community [23]). Other influences on FSM uptake are similar to those affecting school meal uptake by all pupils, such as food preferences, eating environment, social aspects and school ethos and leadership. Higher FSM uptake is associated with higher general uptake of school lunches, thus increasing overall school meal uptake may also increase FSM uptake [20].

1.4 Capacity to generate new knowledge

The means-tested FSM policy was established in primary and secondary settings, throughout the UK, with the aim of providing FSM to disadvantaged pupils and based on a recognition of the likely benefits of providing a healthy school meal to the most disadvantaged pupils. However, the formal evidence base for this provision is limited. There is a dearth of evidence regarding effectiveness and cost-effectiveness of this approach in the secondary schools setting, alongside considerable ongoing discussion around food, school food, socioeconomic inequalities and policy approaches to improve diet quality, nutritional status and long-term outcomes. This study will allow us to explore the effectiveness and cost-effectiveness of the current FSM policy in the secondary school setting, considering dietary and food insecurity but also longer term outcomes. It will also enable us to gather data on which to model the likely impacts of policy change. Finally, given the variability in FSM uptake, we will be able to determine modifiable factors that are associated with differences in uptake. These findings can be disseminated to schools, local authorities, national governments and other school stakeholders to help support changes to the food system within secondary schools.

2. OBJECTIVES AND OUTCOME MEASURES/ ENDPOINTS

2.1 Overall aim

To evaluate the effectiveness and cost-effectiveness of the current means-tested FSM policy in UK secondary schools on diet and food insecurity outcomes, understand what factors are associated with uptake, and test the potential impact of the proposed policy change.

2.2 Research questions

The proposed study aims to answer the following research questions (RQ):

- 1) What is the effectiveness and cost-effectiveness of the FSM policy in UK secondary schools on FV intake and overall diet quality?
- 2) What is the effectiveness and cost-effectiveness of the FSM policy on food insecurity, attendance and educational attainment?
- 3) What would be the effect of FSM policy changes on FV intake, diet quality and food insecurity?
- 4) What school factors are associated with differences in FSM uptake?

2.3 Objectives

To address the four research questions, a series of seven objectives have been developed:

- 1 Undertake an observational study to investigate the means-tested FSM policy, utilising the variation in FSM uptake and collecting school-level factors and parent- and pupil-level outcomes (RQ1-3).
- 2 Conduct multi-level modelling of pupil outcomes on FSM uptake at the school-level to evaluate the association between FSM uptake levels and FV intake, overall diet quality, and food insecurity in all pupils, irrespective of FSM status (RQ1,2), also exploring aggregated attendance and educational attainment data.

- 3 Conduct multi-level modelling to compare FSM eligible pupils who take FSM and FSM eligible pupils who do not take FSM and assess the effect of FSM uptake on FV intake, diet quality, and food insecurity (RQ1,2).
- 4 Conduct economic analysis of FSM uptake, using a cost-utility approach (RQ1,2).
- 5 Model policy change impacts of extending FSM eligibility and increasing uptake on FV intake, overall diet quality and food insecurity (RQ1,2,3).
- 6 Conduct a mixed methods study to assess barriers and facilitators and characterise schools with different levels of FSM uptake (RQ4).
- 7 Conduct workshops to gain stakeholder views on study findings and guide future intervention (dissemination).

3. RESEARCH METHODS

3.1 Research design

The proposed analyses are based on data collection using an observational, cross-sectional study design, with outcomes collected at school-, parent- and pupil-level, and accompanying economic evaluation. As the FSM policy already exists in the secondary school setting, traditional approaches (for example, a cluster randomised controlled trial) are not possible. We will therefore utilise the variable levels of FSM uptake to explore, both at school and pupil level, the impact of variation in FSM uptake on dietary and food insecurity outcomes. Data will then be used to model the impact of future policy change. A case study approach, with mixed methods data collection will help to understand the variability in FSM uptake. See flow diagram (Figure 1) and draft logic model (Figure 2). Further detail on the methodology is given in the subsequent sections, structured for clarity according to objectives and with links to research questions.

FSM terminology and definitions:

In England, a child at secondary school can be eligible for FSM if their parent receives one of a range of benefits (e.g. Income Support, income-based Jobseeker's Allowance, income-related Employment and Support Allowance, support under Part VI of the Immigration and Asylum Act 1999, for full list see [24]). The system is similar in Northern Ireland, although the income threshold is higher [25] .

Routine data on FSM uptake are collected in England and Northern Ireland on census days where schools are required to report a range of data, including current pupils' current FSM eligibility and uptake. As it stands, these FSM eligibility and uptake data will only reflect the particular single day when data have been collected. For the purposes of the data collection for this research, we will consider uptake more broadly, i.e. usual school meal behaviour rather than a single day/data collection point and will utilise the combined responses of pupils and parents to capture this usual behaviour.

Theoretical considerations guiding data collection and the intervention being evaluated:

The means-tested FSM policy in secondary schools is the intervention being evaluated. FSM uptake rarely reaches 100% and use of utility-maximisation theory, or a trade-off between barriers and facilitators, to explain non-take-up has been supported in a number of studies (studies summarised in [20]). Where take up is low, there is a disutility in accessing the benefit (e.g. stigma, unpleasant dining environment, lack of preferred foods/menus, friends not eating

in that environment [20, 26]). There may be different utility maximising strategies for all the different actors involved – young people, parents, caterers, school staff and the local community.

In terms of our approach to evaluation and data capture, this will be informed by critical realist theory (realist evaluation [27]), which can be used to explain outcomes and events in natural settings, pertaining to questions about how and why events or phenomena occur [28]. We recognise the likely importance of individual school context in shaping the mechanisms underpinning the intervention-outcome pathway; thus this integrity of context will be preserved and a socio-ecological perspective as used, for example, in [23], which encompasses context in its broadest sense.

Flow diagram - Free School Meals, Diet Quality and Health in Secondary School Pupils

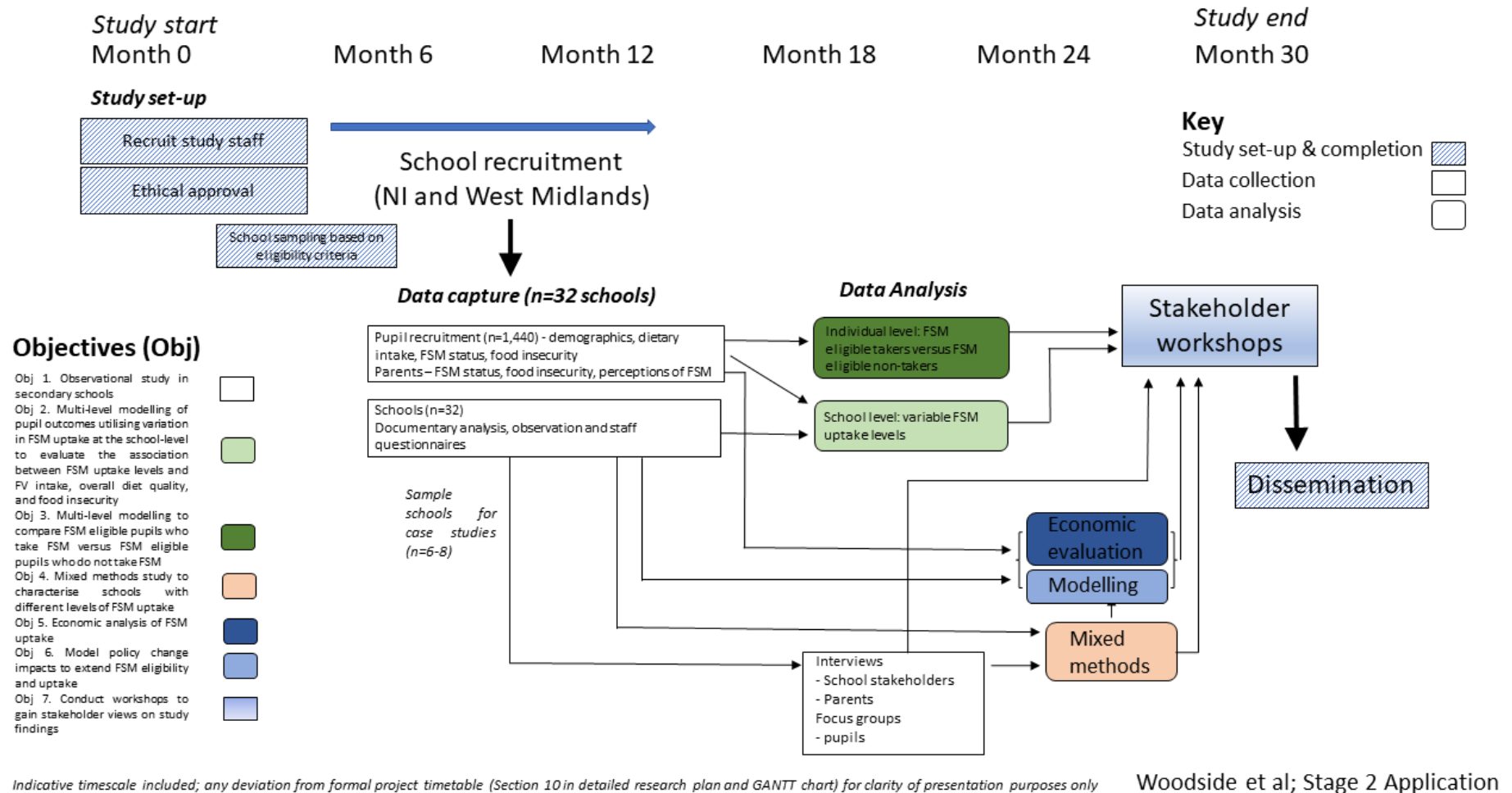


Figure 1. Flow Diagram

Preliminary logic model and theory of change describing the influence of the UK means-tested free school meal (FSM) policy on children's dietary intake, diet quality and food insecurity outcomes, as well as factors influencing FSM uptake

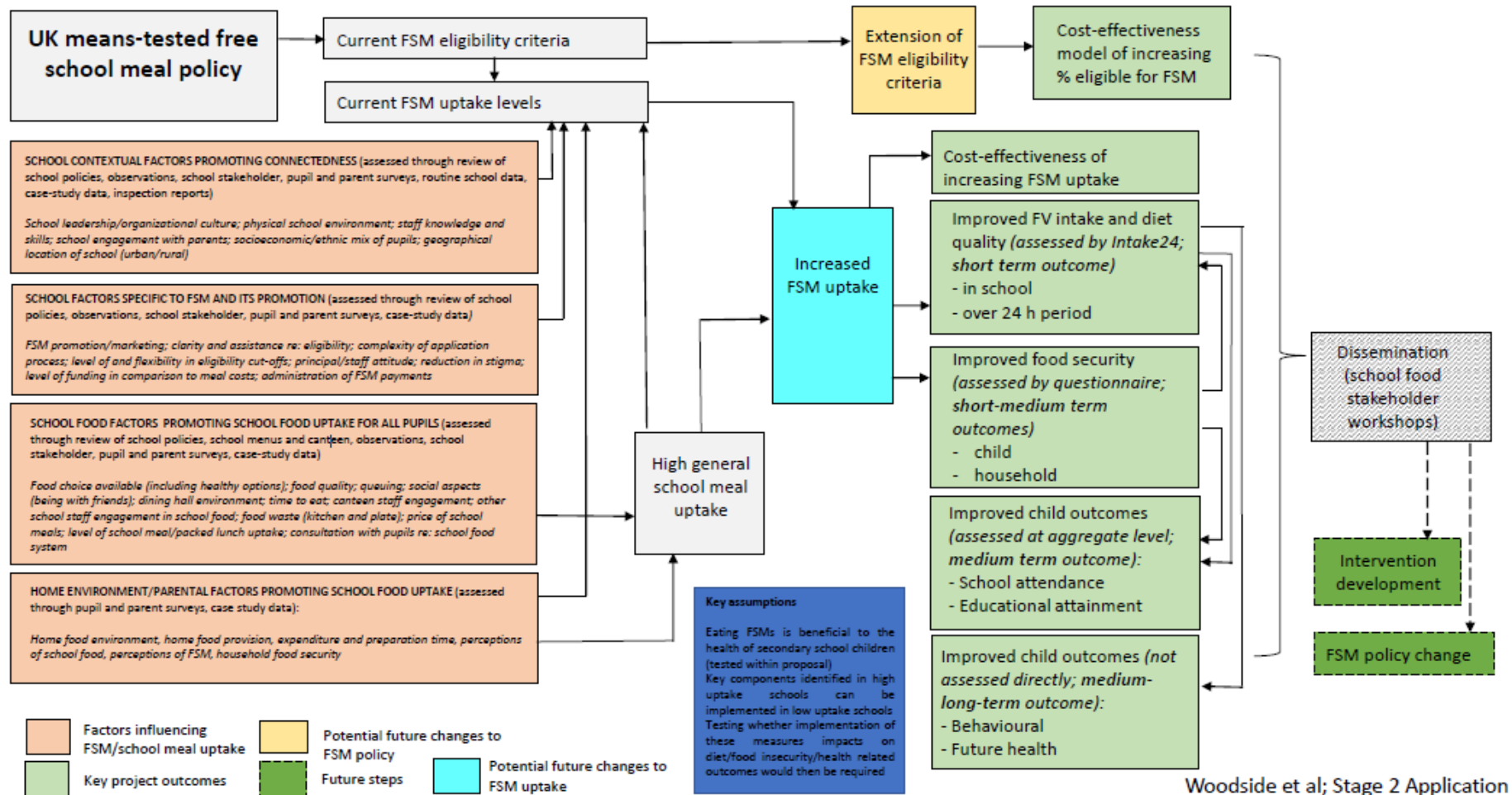


Figure 2. Logic Model

3.2 Setting, population and sampling

The sampling frame for the study will comprise secondary schools located within Northern Ireland (NI) and the Midlands in England, which differ in population density, ethnic diversity, FSM eligibility criteria and school systems; both include areas of high deprivation.

We will identify all state secondary schools including children aged 11-15 y using Department for Education (DE) routine data. Schools will be identified in which >20% of children are eligible for FSM (based on the 50th eligibility percentile across all secondary schools in NI and the Midlands; cut-point based on most recent eligibility data available). We will therefore recruit 32 secondary schools with an above average proportion of pupils eligible for FSM, but across the full range of FSM uptake. School selection will be stratified according to recruitment site and percentage FSM uptake of those eligible (in thirds), but, within these strata, schools will be randomly selected. We anticipate a range of school level FSM uptake based upon available data e.g. in the Midlands, the mean FSM uptake is 86% (SD=20%, range 3% to 100%; IQR 73% to 99%) and in NI the mean FSM uptake is 77% (SD=12%; range 42% to 100%; IQR 74% to 85%) [4, 29, 30].

3.3 Recruitment and consent

Using routine data collected by the Department of Education, all secondary schools (NI and Midlands) will be identified and schools in which >20% of children are eligible for FSM. Schools will be selected and stratified into thirds according to recruitment site and percentage FSM uptake of those eligible, but, within these strata, schools will be randomly selected. We will exclude secure and pupil referral units, special or alternative provision schools and non-English language speaking schools. Pupils with special educational needs in mainstream schools will be included.

We aim to recruit 32 schools (n=16 Midlands, n=16 NI) and within each school, one-two representative classes from each of years 7 and 10 (Midlands) and 8 and 11 (NI) will be selected (by the schools), and pupils and their parents invited to participate. Within each school (n=32), we will recruit a minimum of 45 pupils from the two year groups (total n=1440).

The research team will invite schools to take part in the study by sending an invitation letter via email to the school Principal containing the school Participation Information Sheet. Principals can make contact with the research team using contact details provided within the information. If the research team do not hear from the school, a member of the research team will then contact the Principal via telephone (one to two weeks after sending the invitation email). This call will be to discuss the study, allow the school to ask and have answered any questions they have about participation and ascertain interest in the school taking part. For schools who indicate they are interested in taking part, a time to visit the school to complete the recruitment process will be arranged (ideally within one week of the telephone conversation). Ahead of this visit, a school Memorandum of Understanding (MoU), which is a document that details exactly what is expected of the school and also what the school can expect from the research team) will be emailed to the school. At the visit to the school, schools will be asked to sign two copies of the school MoU – one for the school to keep and the other for study records. Once the school have signed the MoU, it will be requested for each school to identify a liaison person as a main point of contact with the school for the research team. This could be, for example, a school principal, vice-principal, a member of teaching or administrative staff and will differ between schools. The name, job role and contact details (work phone number and/or work email address) of the person identified by schools as the liaison person will be recorded by the research team. The School Principal/ school liaison person or nominated gatekeeper at each participating school will nominate a member of school teaching or administrative staff to complete the 'Key School Information form'. The job role of the individual completing this form will therefore differ between schools.

School staff, governors whose role is relevant to the implementation of school food policies and school caterers and business managers whose role is relevant to school food provision and school food costs should and who therefore should receive an invitation to complete a school staff questionnaire will be identified by the School Principal or nominated gatekeeper/school liaison person at each participating school. The school staff/ governor questionnaires will be self-completed. Caterers and business managers will self-complete part of the questionnaire (Section A) and the remainder of the questionnaire (Sections B and C) will be interview administered by a member of the research team. Participants will be given the option to self-complete the full questionnaire ahead of the questionnaire interview session with the researcher or to fully self-complete the questionnaire if that is their preference.

These individuals (school staff, governors, caterers and Business managers) will be sent a participant information sheet including detailed information about the study and what is expected of them. After at least a 7 day interval, they will receive a staff participant consent form and staff survey tailored to their staff group; this will be made available to them as a hard copy, and also electronically. The staff members can return the consent form and questionnaire either electronically or by hard copy in sealed envelopes provided (these will be returned to the school liaison person and collected by the researcher during the last visit to the school).

At each participating school one-two classes from each of two school years (7 and 10 Midlands; 8 and 11 NI) will be selected by the school for inclusion in the study. All pupils from participating classes will be invited to participate. Parents of the children in participating classes will be sent a parent information sheet that provides detailed information on the study and what it involves for their child. This includes an opt-out form for them to complete and return should they prefer their child not to take part. A hard copy of the parent information sheet and opt-out form will be distributed to the relevant parents through the school. Additional methods that the school usually uses to communicate with parents (such as email, post, website) will also be utilised to ensure that parents receive this information from the school. The alternative methods for parental communication at each school will be agreed following school-specific consultation. Parents will be asked to return opt-out forms in sealed envelopes to the class teacher (via the child) which will then be collected by the school liaison person. Where possible, this form will also be made available in electronic format, depending on the school's usual methods of communication with parents.

At the same time as distribution of the parent information sheet, a pupil information sheet will be distributed by the teacher to all pupils in classes selected to take part in the study by hard copy. Data collection with pupils will take place at least 7 days after distribution of the parent and pupil information sheets. At the point of data collection, pupils will see an electronic version of the pupil information sheet and will be asked for assent (electronically) to participate at this point. Additionally, at least 7 days after distribution of the parent information sheet, and after pupils have completed their data collection, parents will receive an email with a link to an online version of the consent form for parent participants and the parent survey. They will be asked to complete the consent form and survey electronically. Paper copies will also be sent home with pupils which can be returned to the school. Distribution of parental questionnaires by schools will be agreed following school-specific consultation (ideally via email or hard copy however alternative approaches will be considered e.g. interview administered via phone or face-to-face by the school or research team).

3.4 Outcome measures

Pupil outcomes (relevant to objectives 2-6)

Primary outcome and justification:

The primary outcome is FV intake (n portions) over 24 h. FV intake is a key UK government dietary intake target [31], and it has consistently been linked with better overall diet quality [32], reduced risk of future NCDs [32, 33] and reduced food insecurity [34–36]. The World Health Organization report, Global Strategy on Diet, Physical Activity and Health, lists FV as the key nutrient dense food group for improved health, together with reductions in consumption of fats, sugars and salt [37, 38].

Secondary outcomes and justification:

In addition to FV, overall diet quality will be assessed using the validated Diet Quality Index for Adolescents (DQI-A) (24 h) [39], which comprises three components (diet quality, diversity and equilibrium). The DQI-A will be calculated by researchers based on 24 hour recall data obtained from Intake24. DQI-A is a secondary outcome because the evidence for a link between this specific index or, indeed, any measure of diet quality in this age group, and either food insecurity or health has not yet been robustly or consistently established [40]. Indeed, few indices have been evaluated for validity and reliability in this age group [40]. Our selected method has been validated [41] and already applied to UK data by a Co-I [39].

Other secondary outcomes are FV intake at school, meeting the FV 5-a-day recommendation, and intake of total energy (kcal), dietary fibre, free sugars, and other key micro- and macronutrients. Nutrients will be measured as micro/mg/grams and also expressed as a percentage of energy intake for food consumed both at school and over 24 h. Food insecurity is a further secondary outcome [42, 43]. Fruit and vegetable intake and knowledge will be collected as an indicator of nutritional knowledge.

Pupil educational attainment, whether they are eligible to receive Free School Meals, whether English is an additional language for them, and if they are registered as having any special educational needs will be collected from schools. We are asking for this information in order to understand more about the relationship between different pupil characteristics and uptake of Free School Meals. This information will be collected via the Key Pupil Information form completed by the school. School attendance and educational attainment data will also be collected at school level and used as an aggregated outcome.

Sample size – primary and secondary outcomes:

A simplified power calculation was initially conducted dichotomising school-level FSM uptake into high and low. To detect a difference in FV portions/d of 0.5 between the high and low FSM uptake groups, assuming a SD of 1.9 (pooled SD from FUEL [44], NI schools [45] and the National Diet and Nutrition Survey [10] with 90% power at 5% significance, we would require data from 720 pupils from 16 clusters (schools) in each group (cluster size n=45; total schools n=32; total n=1440). This is calculated using an ICC of 0.03 (based on latest FUEL data) and assuming balanced cluster sizes [46].

However, in the primary analysis we will investigate the linear increase in outcome per 10% point increase in school-level FSM uptake and hence will have greater power than suggested by the initial simplified calculation. Therefore a separate sample size calculation was conducted based upon linear regression [47] testing the slope of the regression of mean FV intake on school FSM uptake, assuming a linear association and using an SD of the mean FV

at school level of 0.65 (also based on latest data from FUEL). The study, including 32 schools, **would have over 90% power to detect as statistically significant at the 5% level an average increase in mean FV intake of 0.27 portions per 10% increase in school FSM uptake.**

We will also have 80% power to detect meaningful differences in diet quality (3.5% (3.7% at 90% power)), free sugars (8 g (9.2 g at 90% power)) and fibre (1.1 g (1.3 g at 90% power)) intake.

The sample size calculations were conducted using the core STATA routine “power two means” and confirmed in PASS Power Analysis and Sample size package.

Effect size justification:

The sample size calculation was based on the primary outcome of pupil FV intake over 24 h. We have powered the study to detect an increase of 0.27 portions per day per 10% increase in FSM uptake. This would represent an increase in daily FV intake of <10%, given the typical intake of three portions per day currently being reported in this age group [48]. Given the lack of research specifically exploring FSM and FV and overall dietary intake in secondary schools, this figure has been based on the most relevant systematic reviews (SR) and primary research available. We believe this improvement in FV is achievable based on existing research in children and young people [12, 49–52]:

- A SR of primary school-based interventions (in populations younger than this one) to improve FV intake reported that interventions typically increase FV intake by 0.25 portions/d [49].
- A SR assessing the impact of school food environment policies (from pre-school through to secondary) on dietary habits, adiposity, and metabolic risk in children, reported that direct food provision policies increased FV intake by 0.28 servings/d; school lunch standards (mostly lunch) increased fruit intake by 0.76 servings/d) [50].
- A further SR, assessing the effectiveness of interventions on the food environment within and around schools found that interventions had a significant and meaningful effect on fruit consumption (0.19 portions/d) but not on vegetable intake (0.01 portions/d) [51].
- A SR of behavioural interventions to promote FV intake reported increases of 0.39 servings/d in children [52]
- Finally, Ensaff et al. [12], in a study exploring the eating patterns of secondary school students, found that the dish of the day, the more nutritionally valuable option, was chosen on a significantly greater ($P<0.001$) percentage of days by FSM students compared with the non-FSM students. The percentage of days a ‘meal deal’ was chosen was also significantly higher ($P<0.001$) for FSM students compared with non-FSM; this is relevant as the meal deal includes a dish of the day as well as a side portion of vegetables.

In terms of secondary outcomes, an increase of 3% in the DQI-A score is equivalent to an increase of approximately one portion of FV (8) or the equivalent of an increase of 0.5 portions of FV and a decrease in 0.5 portions of food or drink higher in fats and/or sugars [39]. This is smaller in scale to what was observed in cross-sectional research set in secondary schools using the same DQI-A tool [39]. Reporting on diet quality by lunch type in secondary school students using UK NDNS data, the reported overall difference in daily DQI-A between young people having a school meal and lunch bought in a café was 6%; the equivalent of a one portion increase in FV together with a one portion (1 glass) decrease in sugar sweetened beverage consumption [39].

Feasibility of achieving sample size:

To achieve this sample size, 45 pupils will be recruited from between two and four classes at each school. The exact number of classes selected will depend on class sizes, with the required response rate being around 75% if class size=30 and two classes are recruited. This is achievable, given that FUEL has a response rate of >90% with a similar sampling and consent approach.

Parent outcomes (relevant to objectives 2-6)

Parent outcomes that will be utilised include household food insecurity [43], FSM eligibility and children's usual food choices (school meal type). Similar measures will also be collected from pupils, with the ability to link and therefore validate responses. Linkage of parent and pupil responses will be achieved by requested name and date of birth from both pupil and parent; these will only be used for the purposes of linking the responses. Further data collection will include school FSM system perceptions, usual home food practices and expenditure (specifically to inform Objective 4). Food insecurity will be assessed with the 18-item household food security module [43]. Fruit and vegetable intake and knowledge will be collected as an indicator of nutritional knowledge. Parental data will be gathered from parents of all participating pupils through schools (n=1440).

School outcomes (relevant to objectives 2-6)

School level data capture will include routinely collected data and policies, including aggregated data on attendance and educational attainment, school meal data including uptake, as well as research observation of school eating environments and food offered (School food environment observation checklist) and staff questionnaires, which will be used to address objectives 1-6.

3.4 Outcome data collection

Outcomes will be collected at school-, pupil- and parent-level to address the objectives and research questions.

Pupil outcomes (relevant to objectives 2-6)

Pupils will be asked to complete online data collection twice during timetabled sessions, with researchers present. Each pupil survey will take about 30 minutes to complete, with a total data collection time of one hour. As part of this session, dietary intake will be assessed using Intake24, an online self-completed 24-hour recall tool validated in adolescents [53]. Dietary data will be collected for two complete, non-consecutive school days and averaged to account for daily variation. This will allow quantification of intake at the food group, food and nutrient level (over an average 24 h intake period, but also in school and out of school), and the calculation of diet quality via DQI-A [39]. Intake24 has been successfully used to collect data from secondary school pupils in this way in the recently completed FUEL study (17/92/39) and is now the dietary assessment platform used by the National Diet and Nutrition Survey [10].

Data will also be collected on demographics (age, DOB (for linkage only), gender, ethnicity) and postcode (Index of Multiple Deprivation (IMD)), usual school lunch consumption (meal type), FSM eligibility and uptake, money spent on food outside of school, quality of life (Child Health Utility 9D (CHU-9D)) [54] and physical activity (Single-item minutes based assessment, SIMBA [55]). Food insecurity will be measured using the 9 item Child Food Security Survey Module, which has been validated in adolescents [42, 56].

Pupils will be asked at this stage whether they are willing to be contacted for future focus group participation if their school is later selected as a case study school.

Parent outcomes (relevant to objectives 2-6)

The parent survey will consist of a number of validated questionnaires and will take about 20-30 minutes to complete. Household food insecurity will be assessed using the 18-item household food security module [43] with a 12 month reference period. This is identical to the 10-item adult module but with 8 additional items relating to children in the household, as it will provide adults' reporting of child food insecurity which will allow the validation of the children's responses. Both food insecurity measures were developed by the USDA (59), and are used in UK surveys, e.g. the Family Resources Survey [57, 58] and the FSA Food and You survey [57]. Data will also be collected on FSM eligibility and child's usual school food choices (meal type), school FSM system perceptions, usual home food practices and expenditure.

Questionnaires will be distributed to parents of all participating pupils through the schools (n=1440), providing a range of options for completion according to what best suits each participant, including online, on paper or by telephone. Parent and child responses will be linked and data collected for the purposes of linking the parent-child responses will be collected and stored in line with UK data protection legislation. PPI input has advised that online and/or telephone methods will be best received by schools and parents, and advised on the level of reward for completion, but a flexible approach that is adaptable to school context and parental time, literacy and media access will be utilised to maximise completion rates and ensure any barriers to completion are removed.

Parents will also be asked to indicate their willingness to be invited for case study interviews, and to provide contact details if they agree to be contacted about the case study in future.

School outcomes (relevant to objectives 2-6)

School level data capture will include:

- Analysis of key documents, policies and routinely collected data (including FSM promotion, eligibility, registration processes, school food and other relevant policies, school meal data (including uptake)), aggregated attendance and educational outcome data (GCSE), relevant inspection reports
- Direct observation of the school eating environments, and food offered. Observation checklists, developed by FUEL based on the School Food Plan (63-65), will be adapted where required
- Questionnaires to key staff with roles in FSM administration and food provision exploring i) FSM implementation, and ii) wider contextual/school food system influences (school leadership, school/parent engagement, pupil consultation mechanisms)
- Additionally, schools will be asked to provide some information on pupils that take part which will include their educational attainment, whether they are eligible to receive Free School Meals, whether English is an additional language for them, and if they are registered as having any special educational needs.

3.5 Data analysis plan (RQ1&2) - objectives 2-3

Objective 2 - statistical analysis – FSM uptake at school level and primary and secondary outcome analysis:

We will conduct a detailed analysis of the school-level characteristics, policies and practice that drive differences in FSM take-up and pupil outcomes. We will first conduct a logistic regression using DfE data on the population of schools in England to estimate the propensity score (probability of having high FSM uptake [59]) for each school, based on routinely observed school characteristics (school type, urban/rural, school deprivation measure, selective/non-selective admissions policy, religious affiliation/secular, pupil numbers, proportion of pupils (i) who are male/female, (ii) from minority ethnic groups, (iii) eligible for FSM, (iv) with English as an additional language, (v) with Special Educational Needs). We will then stratify our 32 study schools based upon the percentiles of the propensity score [60], and identify any usually-unobservable differences in pupil demographics and the school-level policies and practices observed in our school-level data capture (e.g. system for FSM auto-enrolment; presence/characteristics of dining space versus takeaway only; menu offered; method of administering cashless catering) that characterise schools into high (>median) and low (<median) take-up bands, for a given propensity score as calculated above.

This exercise will provide information on school factors that may influence uptake. Analysis will be guided by and allow population of the draft logic model, and will also inform the later case study approach to develop understanding of school types related to FSM provision and support for FSM uptake.

Focusing on our 32 study schools, we will then develop multilevel models to estimate the linear increase in pupil outcomes per 10% point increase in FSM uptake at school levels, accounting for clustering (schools) and adjusted for both the routinely observed school-level and pupil-level characteristics, plus any additional usually-unobservable school and pupil characteristics that cannot be manipulated as a matter of policy. Given these adjustments, the increase in pupil outcomes per 10% point increase in FSM uptake will reflect FSM uptake that is potentially modifiable by school-level policy. Similar analyses comparing pupil outcomes in high (>median) versus low (<median) FSM uptake schools; and a sensitivity check focusing on schools within the range of common support of the propensity score, will both be conducted.

A further analysis will use a fractional response probit (which is designed for continuous outcomes bounded between 0 and 1) to extract a predicted take-up rate (conditional on routinely observed characteristics) for each of our 32 schools. Adjusting for this predicted take-up rate rather than every characteristic separately has the benefit of minimising the potential for overfitting or limited degrees of freedom.

A final analysis, but at the school level rather than considering pupil-level outcome, will consider FSM uptake and association with aggregated attendance and educational outcomes; this will be exploratory in nature.

Objective 3 – statistical analysis - comparison of FSM eligible pupils who take FSM and FSM eligible pupils who do not take FSM in terms of primary and secondary outcomes:

We will, because of our primary analysis, collect data from pupils eligible for and taking FSM, and those who are eligible but not taking FSM. The FSM eligibility will be collected from schools, pupils and parents and uptake data will be collected from both pupils and parents. FSM eligibility and uptake will be inferred from these multiple sources to allow identification of pupils who are eligible and take school meals as well as those who are eligible and do not take schools meals. Using these inferred data, we will conduct an additional exploratory analysis using data from FSM-eligible participants, comparing diet and food insecurity outcomes between FSM takers and non-takers, and adjusting for school-level and pupil-level characteristics and clustering.

3.6 Economic analysis of FSM uptake (RQ1&2) – objective 4

We will undertake a cost-utility analysis of FSM participation, which will be exploratory due to the expected variation in costs and models of FSM implementation, and ranges in assumptions about the persistence of changes in diet and impacts on health conditions.

Marginal costs of increasing FSM uptake will be calculated from (i) revenue funding from central government, plus an estimate of any shortfall met through school funds (from interviews with school leaders) (ii) capital expenditure on and depreciation of school kitchen infrastructure (iii) other opportunity costs e.g. supervisory staff time.

Marginal benefits of FSM uptake will be calculated from (i) pupil completion of the CHU-9D, a utility-based health-related quality of life questionnaire, enabling calculation of contemporaneous changes in Quality-Adjusted Life Years (QALYs); (ii) estimates of future gains in QALYs.

The National Institute for Health and Care Excellence deems cost-effective treatments that cost up to £20,000 per QALY gained [61]. Assuming a marginal cost of providing FSM of £437 per year, or £5244 over 12 years, to be a cost-effective treatment FSM needs to promote a contemporaneous improvement of 0.022 QALYs if there are no future benefits; or 12 years of FSM to generate 0.262 QALYs in future benefits if there are no contemporaneous benefits.

Future gains in QALYs will be estimated based on changes in risks of future adverse health events that result from the observed impacts on overall diet quality, FV intake, and food insecurity; and estimated impacts on progression to post-compulsory education.

We will use recent estimates (e.g. [62]) of the effect of these dietary outcomes on immediate health states (BMI, systolic blood pressure, cholesterol), and assume tracking of these health states from adolescence into adulthood and impact on subsequent adverse health outcomes (e.g. cardiovascular disease, Type 2 diabetes) following a similar exercise to Vale et al., [63]. We will estimate the association between FSM take-up and progression by linking publicly available school-level data on these outcomes for the whole of England ('Schools, pupils and characteristics' [64] with 'Revised Key Stage 4 pupil destinations' for disadvantaged pupils [65]), and use assumptions about causal impacts of an additional year of education on chronic or activity-limiting health conditions taken from the recent economics literature (keywords "Causal Effect Education Health" in the Research Papers in Economics database [66]). For example, Janke et al. [67] who show an additional year of education in the UK causes a 3.6%pt reduction in probability of developing diabetes [68–70].

We will convert the estimated effect of FSM uptake on risk of future adverse health conditions into expected QALYs gained by using estimates from systematic reviews on the NHS Economic Evaluation Database ([71], e.g. [72]), and calculate estimates of the net present value reduction in future NHS costs according to recommended treatment packages from the British National Formulary [73] and their NHS reference and unit costs [74, 75].

3.7 Modelling changes in FSM uptake and eligibility (RQ3) – objective 5

The National Food Strategy's has recommended to increase FSM eligibility to all children of parents receiving Universal Credit [14]. The proposed data collection and economic evaluation offers the opportunity to model the impact of the recommended changes on cost and dietary outcomes, providing evidence to support future decision making.

We will assign QALY gains to both (i) newly FSM-eligible and (ii) previously eligible non-takers who switch to taking a school meal, modelling the numbers doing so based on assumptions about (i) the impact of the change in price, and (ii) the role of peer effects meaning that the existing FSM-eligible become more likely to take up their entitlement (e.g. [76]). Whether we assign QALY gains to those already paying for a school lunch, who no longer need to do so, will be informed by our observations. We would estimate additional costs from a combination of (i) DfE revenue funding, (ii) assumptions about depreciation of equipment, and (iii)

information from case studies about capacity constraints and additional investment requirement to enable higher levels of take-up.

3.8 Mixed methods study to assess barriers and facilitators and characterise schools with different levels of FSM uptake (RQ4) – objective 6

Data collection methods – objective 6:

The large variation in FSM uptake seen across schools offers the opportunity for deeper exploration of barriers and facilitators to FSM uptake and school food systems more generally. We therefore propose undertaking in-depth work with a sub-sample of schools ('case studies') to generate additional learning around this. A qualitative case study is a research methodology that helps in exploration of a phenomenon within some particular context through various data sources, and it undertakes the exploration through a variety of lenses in order to reveal multiple facets of the phenomenon [77, 78]. We will therefore use a mixed methods approach, undertaking qualitative work with n=6-8 already recruited schools representative of FSM uptake levels; data collected across all schools will be used within the case studies, but will also inform the sampling strategy to ensure representation of the wider range of schools within the case study sample. We will undertake interviews with school stakeholders (e.g. catering and finance manager; principal; n=4/school) and parents (n=8/school). Each interview will take about 30 minutes. Focus group discussions will be held with pupils (n=2-3 focus groups/school; n=8 pupils/group), using pre-designed semi-structured topic guides to explore views of the FSM system, school food environment, and broader school contextual factors (e.g. capacity constraints and additional investment requirement to enable higher levels of take-up). Focus groups will take about one hour and use vignettes to explore views on FSM of both FSM- and non-FSM-eligible pupils, as selection based on FSM status could be stigmatising for pupils. Pupils will be recruited from the classes in whom data collection occurred for the quantitative study. Parents and pupils will be asked to indicate interest in the focus groups/interviews at the time of quantitative data collection and will then be selected and invited to participate. Selection will ensure a range of characteristics we will seek to include, i.e. parents of those eligible and not eligible for FSM, those whose children eat school lunch and packed lunch and those who are eligible for FSM and whose children do not eat school lunch.

Focus groups with pupils will take place in school, but interviews will be offered, either via telephone, online or in person, as per parental preference. The pupils participating in the focus groups will be supported in advance (led by Prof Michelle McKinley and working with a specific researcher within each site) in terms of training as to how they can contribute, guiding them as to what they can expect and supporting them in preparation for the focus groups. As for all elements of the data collection, they will be free to withdraw at any time. Interviews and focus groups will be audio-recorded.

Interview guides and focus group topic guides will be developed specific for the stakeholder group attending and following the initial quantitative data collection, but will each be aiming to gather views on barriers and facilitators to FSM uptake and school food systems, including school meal provision in general. We will use an iterative process for data collection and analysis, whereby findings from early interviews and focus groups can be incorporated as topics to explore in subsequent sessions.

Data analysis methods – Objective 6:

Focus group and interviews will be transcribed, anonymised and checked by the researcher. We will explore thematic analysis techniques [79] which seek to identify and classify the content of qualitative data, to explore patterns and differences across accounts, with the aim

of providing explanatory conclusions clustered around themes. The transcripts will be coded, then collated into themes and sub-themes according to conceptual similarity of codes. Agreement on concepts and coding will be sought between members of the research team (including across recruitment sites) throughout the analysis process to ensure reliability. A proportion of the data (20%) will be coded by two different team members to check for inter-coder reliability. Thematic analysis will be supported by qualitative analysis software (NVIVO).

The sequential nature of the quantitative and qualitative data collection will allow a mixed methods approach drawing on sequential explanatory design [80–82]. In this way, the qualitative data collection can help explain, or elaborate on, the quantitative results obtained initially. The quantitative data and their subsequent analysis will provide a general understanding, with the qualitative data and their analysis refining and explaining the results by exploring participants' views in more depth [80–82]. The propensity score band analysis described in Section 3.5 will also feed into the typology development. School factors across the different levels of uptake will be explored and commonalities and differences in factors related to FSM provision and support, allowing characterisation of schools according to these different levels of uptake.

3.9 Workshops to gain stakeholder views on study findings – objective 7

Findings across all research questions will be shared via stakeholder workshops, occurring online and ensuring regional representation and a range of stakeholders, with the purpose of refining the logic model, identifying key aspects of successful FSM uptake and guiding future school policy and interventions. Materials developed for these workshops, and summaries prepared after the workshops, can be refined and used in later dissemination activity.

3.10 Rewards for participation and completion of data collection

As a thank you for time spent participating in the observational study schools will receive £500. A further £500 will also be given to schools that complete the case study data collection. Vouchers will also be given to parents (£15 voucher) and pupils (£5 voucher) who complete data collection (one voucher for completion of the questionnaire at least one of two data collection sessions and/or completion of the case study), with a further contribution made to the school for each parent questionnaire and parent interview completed (£5).

Should any schools withdraw prior to the start of data collection they will not receive any financial compensation. Should any schools withdraw part way through the data collection process they will receive compensation proportional to the stage at which they withdraw from the data collection process.

3.11 Methods for sharing study progress and findings with study participants

Other dissemination methods are described in Section 7, but individual school reports will be produced for each participating school summarising findings on their current school food systems, including the FSM provision and uptake, and sharing pupils' views of school food, which is intended to be an incentive to participate.

3.12 Assessment of unanticipated outcomes

As we are evaluating an already existing policy utilising different levels of uptake, consideration of unanticipated outcomes resulting from implementation of a new intervention is not relevant. The risk to participants in this observational study is very low. However, we will be monitoring a range of outcomes to comprehensively evaluate the effect of the policy, for example, dietary intake and quality of life and will be conducting focus groups (pupils) and

interviews (parents). We will record any safeguarding, mental health or wellbeing concerns, or other unintended consequences of study participation. For example, there is a small possibility that the collection of dietary data may be a sensitive issue for some pupils. Any such concerns will be recorded in study records. Any concerns identified by the research team will be raised with the relevant school who will deal with it in line with their established safeguarding procedures. All researchers will be trained re: the protocols and be aware of the school safeguarding point of contact. All participants (adults and school pupils) have the right to withdraw from the study at any time and without having to provide a reason. Participants will be able to skip any questions they do not wish to answer.

In terms of unanticipated outcomes of the intervention, which in this case is the means-tested FSM policy, evidence has already highlighted the potential for stigma to be placed on pupils who receive FSM [21]. In some schools, this may be more evident than others. However, our methodologies already intend to capture this information. A longer term unanticipated outcome of the research could be the removal of the current means-tested FSM provision or changes to the provision if effectiveness and cost-effectiveness are not demonstrated.

4. DATA COLLECTION AND MANAGEMENT

Only data required by the protocol will be collected.

4.1 Data collection tools and source document identification

Below is a list of all questionnaires and data collection tools

Data collection tools	Purpose
Pupils	
INTAKE 24	A 24-hour recall to capture pupil dietary intake (FV intake over 24 hours captured through an online 24-hour recall method; overall diet quality using DQI-A and INTAKE 24 data); FV intake at school; Meeting 5 a day recommendations; intake of total energy, dietary fibre, free sugars and other key micro- and macronutrients at school and over 24 hours)
Socio-demographic information	Name, school year group, age, ethnic background, sex, home postcode
Pupil online diet survey	Survey to capture FSM eligibility and uptake, usual school lunch consumption and money spent on food outside of school
Child Health Utility 9D (Paediatric Quality of Life)	To capture pupil Quality of Life
9 item Child Food Security Survey Module	To measure pupil food insecurity
SIMBA questionnaire	To measure pupil physical activity (1-item tool)

	Single-item minutes based assessment (SIMBA) Validated in the adolescent population. With a suggested modification to categorise minutes of activity in the past week as opposed to the number of days on which they achieved 30 minutes or more.
Parents	
Parent questionnaire	FSM eligibility, child's usual food choices, FSM perceptions, usual home food practices and expenditure
18-item household food security module	To capture FSM eligibility, child's usual school food choices, school FSM system perceptions, usual home food practices and expenditure
School	
Teacher Questionnaire; Senior Leadership Staff Questionnaire; School Governor Questionnaire; Catering Staff Questionnaire	Exploring FSM implementation, wider contextual/school food system influences (school leadership, school/parent engagement, pupil consultation mechanisms)
Key School Information Questionnaire	To capture information on the school food environment, food provision, food education, FSM data and collection of relevant school documents and policies
Business Manager Questionnaire	To capture information relating on costs incurred by the school for food provision, eating environments, activities and facilities that the school has to support
School food environment observation tool	To enable direct observation of school eating environment
Key Pupil Information form	To capture information on pupil's educational attainment, whether they are eligible to receive Free School Meals, whether English is an additional language for them, and if they are registered as having any special educational needs).
Case study	
Focus groups with pupils and Interview schedules with school staff and parents	To assess barriers and facilitators to FSM and characterise schools with different levels of FSM uptake
Stakeholder workshop schedule	Post-study workshops to discuss findings from the CANTEEN Study and how they can be used to help schools optimise FSM uptake and guide future interventions

To maximise completeness of data, researchers will be present during the data collection in the schools.

All data will be collected, stored and disseminated in accordance with relevant Data Protection legislation. All study investigators and researchers working on the study must be compliant with these regulations with regards to the collection, storage, processing and disclosure of participant's personal and sensitive information. Detailed descriptions of the study data processing have been documented in a Data Privacy Impact Assessment and in the Privacy Notice weblink given to participants in PIS. Data access will be limited to only individuals necessary for quality control, audit and analysis.

All study data collected on paper will be held securely, in a locked cabinets in locked offices accessible only to the research team by staff card and key access in buildings alarmed outside of normal working hours. All study data in electronic form will be stored confidentially (anonymised using ID numbers) and held securely on Queen's University Belfast network servers. Access will be password protected and restricted to researchers with designated responsibility for the conduct of the study or encrypted machines protected by passwords. Identifiable information (consent forms) will be stored separately from other data (e.g. questionnaires).

Personal data collected via Qualtrics survey software will be downloaded by the research team and stored in a password protected database on a secure University server. It will only be accessible to the research team. Personal data collected via hard copy will be stored in a locked cabinets in locked offices accessible only to the research team. Personal data as detailed will be stored in a separate database to other study data and only stored until pupil and parent data has been matched and vouchers distributed, at which point it will be removed. Participants will be informed of this in participant information sheets.

Sensitive Personal data provided about pupil's by their school (via the Key Pupil Information form) will be given to the research team via email in a password protected excel file. Alternatively, schools will provide this information to the research team face-to-face as a paper copy that will be temporarily stored in a locked filing cabinet in a locked office in a secure building at the Centre for Public Health, Queen's University Belfast or the Institute of Applied Health Research, University of Birmingham. Paper copies of this information will be entered onto excel by the research team and then the paper copy destroyed. All personal data and Sensitive Personal data will be pseudonymised post collection and stored in a separate database to other study data.

Our collaborators at Newcastle University will directly access dietary intake data as it will be collected through the online Intake24 tool, which is owned by Newcastle University. However, they will not have any access to corresponding personal identifiable data from participants (participants will use pre-generated usernames to log-in to this software).

Study documentation will be kept for 10 years after the end of the study/ publication of data in-line with requirements from the sponsor and will be held securely in the custody of the PI. At the end of this period the Principal Investigator (PI) will review the data to determine whether or not there is a need to retain any of the data beyond this time point. Data that are no longer required will be securely destroyed (shredded and disposed in confidential waste) in line with QUB policy.

Personal data (e.g. name or any data from which a participant might be identified) will not be kept for longer than is required for the purpose for which it has been acquired. At the end of the study, each site will send original source documentation (hard copy or electronic) along with consent forms and contact details for individuals who have provided consent to be contacted about future related studies to QUB for archive. Sites will be responsible for archiving general site files accumulated during the day-to-day operation of the study.

Participants who consent to take part in study interviews will provide information which will be recorded using a digital recorder. Audio files will be downloaded to password protected systems, named according to the participant's unique study ID and transferred securely via secure encrypted file transfer to a QUB approved transcription service. The transcription service provider will be required to sign a confidentiality agreement. Audio files will be transcribed verbatim and transferred back to QUB via the secure Dropoff facility. They will be stored on password protected computer systems as for all other electronic data. When transcripts are received, they will be checked for accuracy against the audio recordings and any potentially identifiable information with the transcript such as names will be removed. Audio recordings will be destroyed when it has been satisfied that the transcript is an accurate written record of the interview. Data from qualitative interviews will be anonymised by removing any information which could potentially identify the participant. Only interview transcribers who are approved by the sites and meet confidential data handling requirements will be used. Each participant will have a unique participant study ID. The interview recordings, transcriptions and NVivo database will be password protected and encrypted and stored securely as for other files. When transcripts have been prepared and checked for accuracy, the recordings will be deleted.

4.2 Data management

Following the entry of participant data into the study database, the data will be processed as per the study specific Data Management Plan (DMP). Data queries will be generated electronically for site staff to clarify data or provide missing information. The designated site staff will be required to respond to these queries. All queries will be responded to or resolved within the study database and amended in the study database.

4.3 Access to Data

Direct access to all study records and source documents will be granted to authorised representatives from the sponsor (or delegate), representatives of the REC, host institution and the regulatory authorities to permit study-related monitoring, audits and inspections in-line with participant consent.

Only members of the research team employed on the study will have access to the personal/sensitive data of participants.

At the end of the study, the study manager, study statistician and health economist will have access to the anonymised dataset to permit analysis.

The PI will manage access rights to the trial data set in collaboration with the sponsor. Any transfer of data to other institutions will be governed by a Data Access Agreement and will be in the form of an anonymised dataset (i.e. will contain participant study ID but will not contain any personal identifiers such as name or date of birth).

4.4 Archiving

Study documentation will be kept for 10 years after end of study/publication of data in-line with requirements of the sponsor. Archiving will be authorised by the sponsor following submission of the end of study report. Destruction of essential documents will require authorisation from the sponsor.

Personal data (e.g. name and address, or any data from which a participant might be identified) will not be kept for longer than is required for the purpose for which it has been acquired. Destruction of archived documents will require authorisation from the Sponsor and CI.

At the end of the study, each site will send original source documentation (hard copy or electronic) along with consent forms and contact details for individuals who have provided consent to be contacted about future related studies to QUB for archive.

Sites will be responsible for archiving general site files accumulated during the day-to-day operation of the study.

5. MONITORING, AUDIT & INSPECTION

Direct access to all study records and source documents will be granted to authorised representatives from the Sponsor (or delegate), representatives of the REC, host institution and the regulatory authorities to permit study-related monitoring, audits and inspections in-line with participant consent.

The study will be monitored and audited in accordance with the Sponsor's policy, which is consistent with the UK Policy Framework for Health and Social Care Research.

Direct access to all study records and source documents will be granted to authorised representatives from the Sponsor (or delegate), representatives of the REC, host institution and the regulatory authorities to permit study-related monitoring, audits and inspections in-line with participant consent.

Sites will assist the sponsor in monitoring the study as required, for example, hosting site visits, providing information for remote monitoring, or putting procedures in place to monitor the study internally.

The SSC will be informed of the main findings of any monitoring, audit or inspection of the study.

6. ETHICAL AND REGULATORY CONSIDERATIONS

6.1 Research Ethics Committee review

The research will be conducted in line with the principles of good practice set out in the UK Policy Framework for Health and Social Care Research. Full review and approval will be sought from the Research Ethics Committee of the Faculty of Medicine, Health and Life Sciences, Queen's University Belfast. The University will act as the sponsor for the study and has in place comprehensive standard operating procedures both for the approval and monitoring of research of this type.

Participation in the study will be voluntary and if a participant withdraws from the study, their data will not be retained and no new data will be collected from them. Participants can withdraw until the end of the study data collection period.

Effective communication as well as information sheets will ensure both parents and pupils are well informed of what the study entails. For pupils, parents can opt out of their child taking part and pupil written assent will be obtained; all other participants will give informed written consent. This model of using parental opt-out and pupil assent is being used in the recently completed FUEL school food study. Parents will be given the opportunity to withdraw their

child from the research should they wish. All data collected as part of this project will be completely anonymous and participants and schools will not be identified in any published material. The study will be conducted in-line with the Data Protection Act 1998. Data will be stored on password protected computers in locked offices in buildings that are alarmed outside of normal working hours.

6.2 Public and Patient Involvement

PPI was integral to initial research question development; school staff reported concern about children's nutrition and the effectiveness of the current FSM policy, particularly in light of COVID-19 and the changes being seen in those eligible for FSM; similar concerns were expressed in GENIUS surveys [83]. Secondary school pupils, parents and school staff and principals, including via FUEL, advised on recruitment and data collection methods and levels of monetary rewards in order to make the project appealing to schools, parents and pupils. They suggested a school report format offering specific information on the current school food system and pupil views of school food to encourage participation (such as [84]). A secondary principal (SR; PPI Co-I and on SMG) advised on engaging schools and pupils, encouraging parental completion of questionnaires and accessing school environment/management data; another Co-I's role is to manage the PPI activities; researcher time has been costed (10% FTE) to co-ordinate and support PPI activities. A separate PPI sub-group including parent, school staff and pupil group representation will meet bi-monthly during the planning stages (discussing recruitment and outcome data collection) and then x2/y; their views will be fed into the SSC and SMG by PPI representatives on both, and there will be reciprocity, with both SSC and SMG discussions being fed back to the PPI sub-group. Meeting location will be appropriate for those attending, and online/hybrid opt

ions considered as required. We will carry out PPI on an ad hoc basis if required during the course of the study, for example if recruitment materials need to be adapted during the school recruitment phase. Our PPI representatives will help shape the dissemination plan and develop the dissemination materials to ensure effective communication of findings to users and stakeholders. They will also be directly involved in dissemination activity (e.g. attending/presenting at a conference). Thus PPI will occur at all project stages and will adhere to national standards [85]. PPI group members will receive training and all input will be supported accordingly, with reimbursement in the form of Amazon vouchers. PPI input will be guided by and invoke the principles of INVOLVE and according to UK standards for public involvement [85].

6.3 Protocol compliance

All researchers will undergo training on all trial processes and SOPs including the collection of informed consent to ensure the protocol is understood and implemented consistently across sites. There will be no prospective, planned deviations or waivers to the protocol. If an accidental deviation from the protocol should occur it will be documented on the relevant forms and reported immediately to the CI and sponsor. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

6.4 Data protection and patient confidentiality

All data will be collected, stored and disseminated in accordance with relevant Data Protection legislation. All study investigators and researchers working on the study must be compliant with these regulations with regards to the collection, storage, processing and disclosure of participant's personal and sensitive information. Detailed descriptions of the study data processing have been documented in a Data Privacy Impact Assessment and in the Privacy Notice weblink given to participants in PIS. Data access will be limited to only individuals necessary for quality control, audit and analysis.

We will ensure that participant confidentiality is maintained throughout the study. When a participant consents to join the trial, they will be allocated a unique participant study ID which will be used to pseudonymise sensitive personal data collected in questionnaires and interview transcripts, with the key held by the site teams in password protected files. Electronic data will be stored on password protected computers in locked offices in buildings that are alarmed outside of normal working hours. Paper based data will be stored in locked cupboards in locked offices in buildings that have keypad entry and are alarmed outside of normal working hours. Identifiable information (e.g. name, DOB, postcode) will be stored separately from the survey data. Participants will not be identifiable from any published report from the study.

Participants who consent to take part in study interviews/focus groups will provide information which will be recorded using a digital recorder. Audio files will be downloaded to password protected systems, named according to the participant's unique study ID and transferred securely via secure encrypted file transfer to a QUB approved transcription service. The transcription service provider will be required to sign a confidentiality agreement. Audio files will be transcribed verbatim and transferred back to QUB via the secure Dropoff facility. They will be stored on password protected computer systems as for all other electronic data. When transcripts are received, they will be checked for accuracy against the audio recordings and any potentially identifiable information with the transcript such as names will be removed. Audio recordings will be destroyed when it has been satisfied that the transcript is an accurate written record of the interview.

Data from qualitative interviews will be anonymised by removing any information which could potentially identify the participant. Only interview transcribers who are approved by the sites and meet confidential data handling requirements will be used. Each participant will have a unique participant study ID. The interview recordings, transcriptions and NVivo database will be password protected and encrypted and stored securely as for other files. When transcripts have been prepared and checked for accuracy, the recordings will be deleted.

Data for consenting participants will be stored, as described above, for 10 years until the research has been completed and after final publication of study results. Documents that contain personal data will then be shredded and disposed of as confidential waste.

Data transmitted to sponsors and co-investigators will contain participant study ID but will not contain any personal identifiers such as name or date of birth.

6.5 Amendments

The PI will be responsible for the decision to amend the protocol. Substantial and non-substantial amendments will be discussed with the SMG and Sponsor.

All protocol amendments will be undertaken in accordance with the regulatory requirements. Substantial changes to the protocol will require REC prior to implementation.

The PI will be responsible for communicating substantive changes to relevant stakeholders (e.g. REC, funder, study registries, R&D, regulatory agencies).

The amendment history will be tracked in the protocol. The most recent protocol version will be provided to all study staff as well as the Site Management Team and Study Management Team.

6.6 Access to the final study dataset

At the end of the study, the study manager, study statistician and health economist will have access to the full dataset to permit analysis. Following publications addressing the study objectives, there may be scope to conduct additional analyses on the data collected. In such instances, formal requests for data will need to be made in writing to the PI, who will discuss this with the Sponsor. The study will comply with the good practice principles for sharing individual participant data from publicly funded studies and data sharing will be undertaken in accordance with the required regulatory requirements. In the event of publications arising from such analyses, those responsible will need to provide the PI with a copy of any intended manuscript for approval prior to submission.

7. DISSEMINATION, OUTPUTS AND ANTICIPATED IMPACT

7.1 What do you intend to produce from your research?

A range of outputs are anticipated: a refined logic model, National Institute for Health Research (NIHR) interim and final reports, peer-reviewed publications, conference presentations for academic audiences, policy briefings for Government, public health bodies and for those responsible for school food policy development, guidance and summary report/materials for schools (and to be shared with their stakeholders, e.g. pupils, parents) and research summaries for non-academic audiences including the media. In particular, we will focus on the potential suggested options for changes to the FSM policy and what our data suggests are the implications of those changes as well as the modifiable factors associated with FSM uptake. The study dataset will also be made openly available. Our final objective, objective 7, is to share findings via stakeholder workshops, with the purpose of refining the logic model, identifying key aspects of successful FSM uptake and guiding future school policy and interventions. Materials developed for these workshops, and summaries prepared after the workshops, can also be considered as research outputs.

7.2 How will you inform and engage patients/service users, carers, NHS, social care organisations and the wider population about your work?

In line with NIHR guidance, a dissemination plan will be developed during the first year of the project and this will be revisited annually. We will seek the input of our PPI group, the schools we recruit and school stakeholders we engage with, our Co-Is and their networks and the study steering committee. The audience will include pupils, parents, school stakeholders and policymakers. Dissemination will use a range of methods such as online, social media and print media and will make use of use of our established UKPRP GENIUS network, the NIHR School for Public Health Research and other country-specific as well as national networks and events.

7.3 How will your outputs enter our health and care system or society as a whole?

This study will provide evidence on which to base policy changes. Findings could influence policy at school (e.g. policies to encourage FSM uptake), local authority (FSM enrolment systems) and regional and national government level (FSM eligibility); dissemination strategies will take account of this (e.g. producing a toolkit for schools and conducting policy briefings at a range of levels). As an example, our collaborative work with local authorities (particularly MB) has highlighted a clear need for areas to better understand the impact of FSM in order to inform spending decisions (particularly in areas considering a local extension of eligibility). By engaging with and disseminating to local authorities, we can provide an evidence base to support their decision making. Ultimately, evaluating and refining the FSM policy could impact on the diet quality and food insecurity of low income children and their families and reduce socioeconomic inequalities, but this requires effective dissemination of our outputs.

7.4 What are the possible barriers for further research, development, adoption and implementation?

There are no IP implications of this research and barriers to further research and implementation evaluation, as described in 9.4, are limited to funding availability. In terms of research implementation and achieving policy influence, as we are evaluating current policy, it is difficult to predict further barriers as they depend on study findings and how that shapes recommended changes to policy, but key to impact of this research is successful dissemination. We believe the plan above and the network and connections of the current Co-Is will ensure that this will be effective. Implementation and policy influence will also depend on concurrent policy change that may be relevant to this research, e.g. nationally, the White Paper response to the National Food Strategy (23), the implications of the Levelling Up the UK White Paper (91) and regionally the proposal to extend universal FSM provision to secondary schools in Wales (25), and we will monitor these developments closely and be agile in our response.

7.5 What do you think the impact of your research will be and for whom?

This proposal has the potential to influence, in the short-term, schools in terms of the methods used to encourage FSM uptake and school meal uptake in general. This will, in turn, make the school meal provision more sustainable and benefit schools and caterers. In the longer term, the study will provide robust data on the effectiveness and cost-effectiveness of the current means-tested FSM policy, and the likely impact of changes to eligibility or reach of the policy. Therefore the research has the potential to provide the evidence base for the current FSM policy, directly inform policy change, and guide efficient implementation of the policy. Ultimately, if the FSM policy in secondary schools can be optimised, this research could benefit pupils' dietary intake, food insecurity and future educational and health outcomes.

7.6 How will you share with study participants the progress and findings of your research?

We will share our study findings with the schools who participate and will ask that these are shared with pupils and parents and other school stakeholders who have participated; our dissemination plans will include materials to allow this. This is in addition to the school reports produced for each school that takes part summarising findings on school systems to support optimisation of FSM provision and pupil views of school food. These reports are intended to encourage schools to participate (similar report strategies are used and have been demonstrated to be effective by the Scottish Schools Health and Wellbeing Improvement Research Network (SHINE) network [86], who we have direct connections with via the

GENIUS network, with one Co-I (SC) also a member of the SHINE team). The study finding dissemination materials for schools will be guided by PPI but options (not an exhaustive list) include: a written summary, with infographics, a YouTube video, a webinar and, potentially, could contain a range of materials forming a toolkit. We will communicate the findings to our schools and participants in advance of, or simultaneously with, any media releases associated with the study.

8. PROJECT TIMETABLEProject duration 30 months in total; project start date 1st January 2023

<i>Milestone number</i>	<i>Milestone</i>	<i>Start date</i>	<i>End Date</i>	<i>Month no.</i>
-	<i>Contracts, collaboration agreements, recruit administrative staff, commence ethical approvals</i>	<i>October 2022</i>	<i>December 2022</i>	-
<i>1</i>	<i>Study set-up, ethical approval confirmed, recruitment of other staff</i>	<i>January 2023</i>	<i>June 2023</i>	<i>0-6</i>
<i>2</i>	<i>School recruitment</i>	<i>June 2023</i>	<i>Oct 2023</i>	<i>6-10</i>
<i>3</i>	<i>Quantitative data collection</i>	<i>August 2023-</i>	<i>June 2024</i>	<i>8-18</i>
<i>4</i>	<i>Qualitative data collection</i>	<i>August 2024</i>	<i>January 2025</i>	<i>20-25</i>
<i>5</i>	<i>Data analysis</i>	<i>Jan 2024</i>	<i>April 2025</i>	<i>12-28</i>
<i>6</i>	<i>Modelling</i>	<i>January 2025</i>	<i>April 2025</i>	<i>25-28</i>
<i>7</i>	<i>Stakeholder workshops</i>	<i>March 2025</i>	<i>April 2025</i>	<i>27-28</i>
<i>8</i>	<i>Report writing</i>	<i>May 2025</i>	<i>June 2025</i>	<i>29-30</i>

Abbreviations

CEA	Cost-effectiveness analysis
CO-I	Co-Investigator
CONSORT	Consolidated standards of reporting trials
DOB	Date of Birth
DE	Department of Education
DQI-A	Diet Quality Index for Adolescents
FTE	Full-time employment
FSM	Free School Meals
FV	Fruits and Vegetables
GCP	Good Clinical Practice
GENIUS	Generating Excellent Nutrition in UK Schools
H	Hour
MRC	Medical Research Council
N	Number
NCD	Non-communicable disease
NI	Northern Ireland
NIHR	National Institute for Health Research
PI	Principal Investigator
PIS	Participant information sheet
PPI	Patient/Personal and Public Involvement
QALYs	Quality adjusted life years
QUB	Queen's University Belfast
REC	Research ethics committee
R&D	Research and Development
RQ	Research Question
SOP	Standard Operating Procedure
SR	Systematic review
SSC	Study Steering Committee
UK	United Kingdom
Y	Year

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