

FULL/LONG TITLE OF THE STUDY

Exploring Specialist schools' food and identifying evidenced-based interventions to support healthier food choices: a mixed methods study (CHOICE)

SHORT STUDY TITLE / ACRONYM

The CHOICE Study

PROTOCOL VERSION NUMBER AND DATE

Version 1.1 03.09.24

RESEARCH REFERENCE NUMBERS

FUNDERS Number:

NIHR163058

This protocol has regard for the HRA guidance and order of content

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

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

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

For and on behalf of the Study Sponsor:

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Susanne Lewis

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Date:

...03/09/24...

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Position: ... Deputy Head of Research, Faculty of Medical Sciences

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Chief Investigator:

Signature: .

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Date: 03/09/24...

Name: (please print):

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Chief Investigator:

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Date: 03/09/24

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.Dr Suzanne Spence

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KEY STUDY CONTACTS

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| Joint-sponsor(s)/co-sponsor(s) | N/A |
| Funder(s) | <p>This study is supported by funding from the National Institute for Health and Care Research Public Health Research Programme. NIHR 163058</p> |
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STUDY SUMMARY

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| Study Title | Exploring Specialist schools food and identifying evidenced-based interventions to support healthier food choices: a mixed methods study (CHOICE) |
| Internal ref. no. (or short title) | NU-018231 |
| Study Design | Qualitative, mixed methods |
| Study Participants | Young people aged 14-19 attending Specialist schools in North-East England; parent-carers of children and young people attending Specialist schools; Education and Health professionals working within Specialist schools; Specialist school catering staff; Specialist school governors; LA/independent catering providers |
| Planned Size of Sample (if applicable) | N/A |
| Follow up duration (if applicable) | N/A |
| Planned Study Period | 1 st September 2024 -28 th February 2025 |
| Background | Children and Young People (CYP) attending Specialist schools have the highest levels of need in Education, and often have at least one health condition. The food and drink (henceforth food) that CYP consume in school is important for their health. There is limited research on whether Specialist school food meets the wide-ranging needs of pupils. It is vital to identify opportunities for improving Specialist school food to help reduce increased risk of poor health, overweight, and obesity in CYP with learning disability, and of underweight in those with eating and drinking difficulties. |
| Research Question(s) | What are key stakeholder perspectives of Specialist school food, and what evidenced-based interventions exist to support healthier food choices in Specialist schools? |
| Aims | 1. To explore stakeholders' perspectives on school food. 2. To identify what evidenced-based interventions exist to support healthier food choices for CYP attending Specialist schools. |

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| Methods | <p>A mixed methods approach in two work packages (WP) will be employed.</p> <p>WP 1: a case study approach. Four North East of England Specialist schools will be purposefully sampled (including primary and secondary schools). Selected schools will provide diversity in population, location, school catering models, and educational provision type.</p> <p><i>WP1 Objectives and methods (addressing Aim 1):</i></p> <ol style="list-style-type: none"> 1. To describe current school food in Specialist schools. Study design: document review and schools menu analysis; method: freely accessible data from websites. 2. To explore key stakeholders' perspectives on Specialist school food (including parents/carers; health and educational professionals, and school catering staff). Study design: qualitative. Method: focus groups and interviews including topics such as use of school food standards, food provision/policy for pupils with eating and drinking difficulties, challenges, and facilitators in supporting healthy food choices. 3. To understand factors that influence choices related to school food consumption made by young people attending Specialist schools. Study design: qualitative. Method: focus groups, including topics such as foods on offer, perceptions of healthy foods, and factors influencing food choices. <p>WP 2: a scoping review, following the Joanna Briggs Institute framework and reported according to PRISMA-ScR.</p> <p><i>WP2 Objectives and methods (addressing Aim 2):</i></p> <ol style="list-style-type: none"> 1. To identify the existing evidence-base on interventions to support healthier food choices amongst CYP attending Specialist school (a narrative scoping review) 2. To consider how the identified interventions were developed (using MRC taxonomy) 3. To identify the intended action/effects of the interventions and what would replication of each as designed entail? (using TIDieR/ TIDierR-PHP/AACCTT) 4. To identify any intervention evaluation and describe any health outcomes (description of evaluation and primary/secondary outcomes) |
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| Anticipated impact and dissemination | <p>Impact: Findings will generate evidence for future intervention development and piloting. If effective, novel school-food interventions will improve CYP's health and well-being.</p> <p>Dissemination:</p> <p>For pupils and schools, an infographic and short, animated video.</p> <p>For academics, a final report, peer reviewed publications, and conference presentation(s). A logic model will be developed.</p> <p>Two stakeholder dissemination events are planned at local (face-to-face) and national (online) level.</p> |
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FUNDING AND SUPPORT IN KIND

| FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study) | FINANCIAL AND NON FINANCIAL SUPPORT GIVEN |
|--|--|
| University of Newcastle Upon Tyne | Research Sponsorship |
| National Institute of Health and Care Research | Provision of related research costs |
| School Food Plan Alliance | Study Advisory Group membership; in-kind support |
| Newcastle Health Innovation Partners | Local, national, and international network building; in-kind support |
| Newcastle Health Determinants Research Collaboration | Collaborator; in-kind support |

ROLE OF STUDY SPONSOR AND FUNDER

Newcastle University, as the Sponsor, will assume overall responsibility for initiation and management of the study, and will control final decisions regarding all aspects of the study.

The National Institute for Health and Care Research, as the funder, will contribute financial support and facilitate dissemination of the results.

The sponsor (NU) and funder (NIHR) have no role in the study design, management, data collection, analysis, or interpretation of study findings.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

Study Management: Spence (SS) and Andrew (MA) will have joint overall project management and delivery responsibility. The core study team (SS, MA, Woodside (JW), Pennington (LP), McSweeney (LM), Pearson (FP), Craven (MC), and the RAs will meet monthly online to ensure milestone progression, ethical/governance compliance, discuss challenges and consider outputs. SS, MA and the RAs will meet weekly to discuss and monitor progress. All meetings will be minuted with specified actions points, timelines, and persons responsible identified. JW and LP will provide senior support to ECRs SS and MA.

Project Advisory Group: A Project Advisory Group will be convened. This will comprise six external advisors (Scott Lloyd: Advanced Public Health Practitioner – topic advisor and NIHR Health Determinants Research Collaboration South Tees; Professor Jeremy Parr: Professor of Paediatric Neurodisability, Newcastle University; Professor Ashley Adamson: Professor of Public Health Nutrition and Registered Dietitian, Director of the NIHR School for Public Health Research & NIHR Senior Investigator, Newcastle University; Dr James Galpin: Developmental Psychologist, PhD, Founding Member of Special Networks (<https://www.specialnetworks.co.uk>) and Lecturer University College London and Goldsmith's University; Dr Kelly Rose: Public Health Advanced Practitioner Healthy weight, Policy and Place, Durham Council; Sean Turner: Policy Officer (Child Poverty), National Education Union; Brad Pearce, Co-Chair School Food Plan Alliance). The project advisory group which will meet online on three occasions during the study to guide and support project decision-making as required: (i) at the start of the project to provide feedback on the research plan, (ii) mid-way to discuss preliminary findings (iii) at the end to provide guidance and support on the planned dissemination activities, and to support the development of a subsequent funding applications.

Public Involvement

A study Public Involvement Panel (PIP) will be convened. The PIP will comprise two parents of children or young people who attend a Specialist school, plus a Specialist school governor with responsibility for school food. The PIP will meet three times during the study: (i) the start of the project to gain feedback on study materials, including topic guides for focus groups and interviews (ii) mid-way for feedback on dissemination planning of preliminary findings, and (iii) month 5 to obtain feedback on dissemination materials (e.g., language used). All public involvement activities will be facilitated by a Patient and Public Involvement (PPI) co-ordinator. Public involvement activities will be evaluated, in conjunction with members of the PIP, to understand what has worked well and what could have been improved, and the impact of the activities on the study. All PIP members will receive training as required to enable them to be involved in the PPI activities.

PROTOCOL CONTRIBUTORS

Joint project leads MA and SS, with the wider support of the Co-investigators conceived and designed the study and drafted the original study protocol. PPI work has also contributed to the development of the protocol. The study protocol has undergone expert peer review as part of the funding process.

The National Institute for Health and Care Research, as the funder, will contribute financial support and facilitate dissemination of the results.

The sponsor (NU) and funder (NIHR) have no role in the study design, management, data collection, analysis, or interpretation of study findings.

KEY WORDS:

Child*, Learning Disabilities*; Overweight*; Obesity*; School Food; CHOICE

*MeSH terms

STUDY FLOW CHART

Figure 1: CHOICE study visual overview

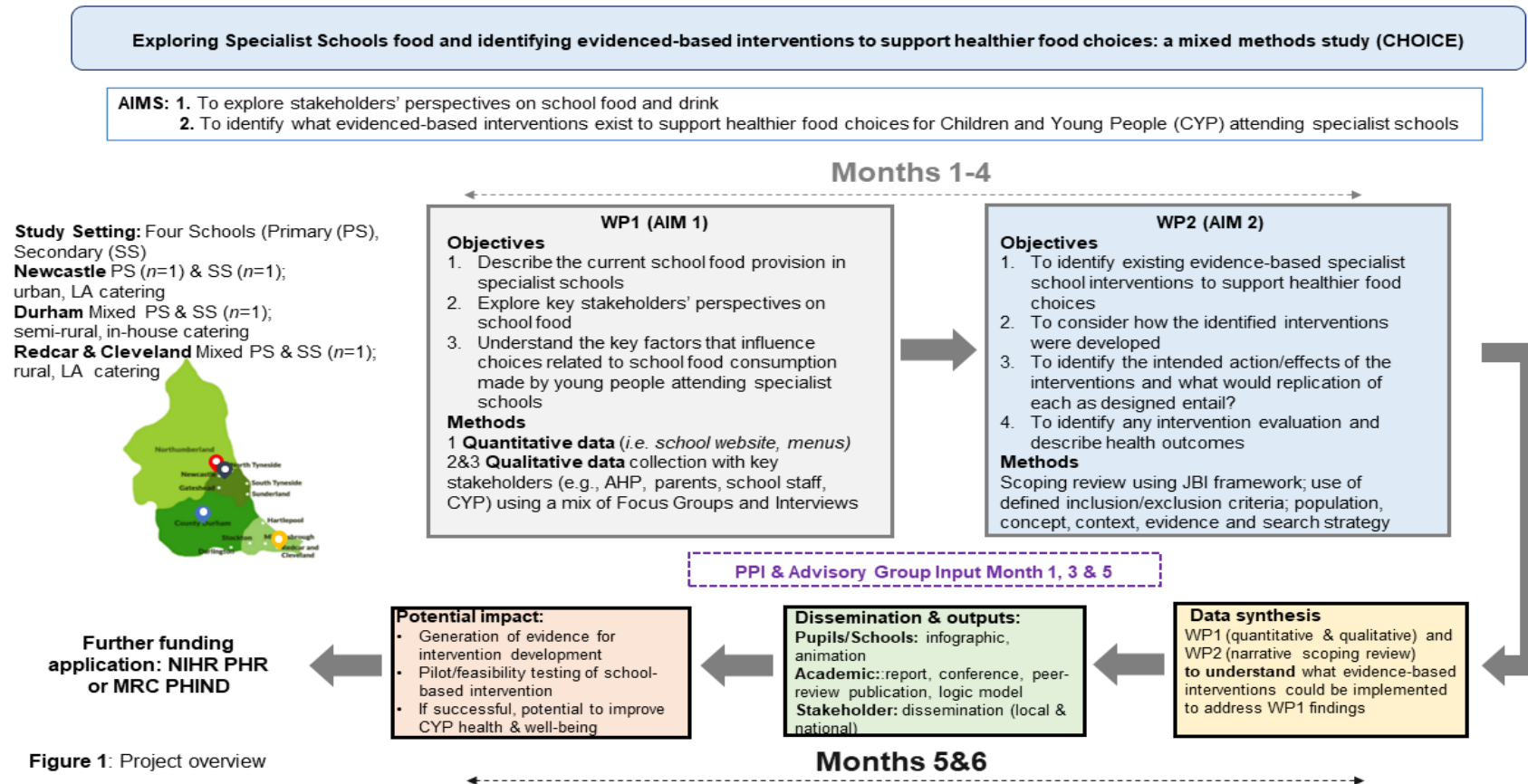


Figure 1: Project overview

STUDY PROTOCOL

Exploring Specialist schools' food and identifying evidenced-based interventions to support healthier food choices: a mixed methods study (CHOICE)

Short Title: The CHOICE Study

1 BACKGROUND

Children and young people (CYP) attending Specialist schools or Alternative Provisions tend to have the highest levels of need in Education. Over 191,000 CYP attend Specialist schools and Alternative Provisions in England¹. The educational requirements of CYP with special education need (SEN) are defined by their primary category of need. For CYP in Specialist schools and Alternative Provision settings in England, common areas of need are Social Emotional and Mental Health (SEMH) (37.2%); Autism (25.5%), any severity of learning difficulty (including learning disability (LD)) (11.0%); and Speech, Language and Communication Needs (SLCN) (11.0%)². This study will explore school food in Specialist schools only, and does not extend to Alternative Provisions. Individuals with learning disability have higher mortality, and morbidity, and are at higher risk of overweight and obesity compared to the general population³. In contrast, some CYP attending Specialist schools struggle with underweight and undernutrition because of eating and drinking difficulties. School food must take account of diverse neurodevelopmental and nutritional requirements to meet the needs of all pupils. CYP with disabilities, including learning disability, are more likely to live in poverty than children without disability⁴. Nearly 45% of Specialist school pupils are eligible for Free School Meals (FSM) compared with the average 22.5% eligibility for all school pupils⁵. Research indicates 23% of children not receiving FSM are also food insecure⁶, suggesting potential to improve nutritional status and health outcomes is not limited only to those eligible for FSM.

2 RATIONALE

Despite potential positive health impacts of school food interventions in mainstream schools^{7,8}, there is limited research looking at either current Specialist school food provision, or at interventions to support healthier food choices amongst Specialist school pupils⁹. There is a need to assess whether current food provision and food policies within Specialist schools maximise healthy-eating opportunities for pupils or whether there are potential areas requiring change through intervention.

3 RESEARCH QUESTION/AIM(S)

Key research question: What are key stakeholder perspectives of Specialist school food, and what evidenced-based interventions exist to support healthier food choices in Specialist schools?

Aims:

1. To explore stakeholders' perspectives on school food and drink (henceforth food)
2. To identify what evidenced-based interventions exist to support healthier food choices for CYP attending Specialist schools.

3.1 Objectives

WP 1. Addressing Aim 1: to explore stakeholders' perspectives on school food

- Objective 1: To describe the current school food provision in Specialist schools
- Objective 2: To explore key stakeholders' perspectives on school food in Specialist schools
- Objective 3: To understand the key factors that influence choices related to school food consumption made by young people attending Specialist schools

WP 2. Addressing Aim 2: To identify what evidenced-based interventions exist to support healthier food choices for CYP attending Specialist schools

- Objective 1: To identify the existing evidence-base on interventions to support healthier food choices amongst CYP attending Specialist schools.
- Objective 2: To consider how the identified interventions were developed.
- Objective 3: To identify the intended action/effects of the interventions and what replication of each as designed would entail.
- Objective 4: To identify any intervention evaluation and describe any health outcomes assessed

4 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

We will conduct a mixed methods study in two work packages (WP), each addressing several objectives as listed above.

WP 1. Addressing Aim 1: to explore stakeholders' perspectives on school food.

Four case study schools in North East England will be purposefully sampled (all have confirmed participation). Selected schools include one primary and one secondary school in Newcastle; one mixed primary and secondary school in County Durham; and one mixed primary and secondary school in Redcar & Cleveland. These schools have been selected to achieve diversity in population (e.g., Newcastle schools serve CYP from diverse ethnic groups), location (inner-city, semi-urban, and rural), school catering models (Local Authority (LA) and in-house), and type of educational provision.

Objective 1: To describe the current school food provision in Specialist schools

Design: Document review and menu analysis

Methods: We will use freely accessible schools' websites data on lunchtime menu options to explore if food provided is compliant with school food standards. We will report the type of school food provision (LA catering or in-house) and any school-level policies documented, for example, Healthy School Policy etc. We will collate freely accessible quantitative data from schools' websites and the Department of Education website on school level characteristics¹⁰ such as total numbers of pupils, FSM eligibility and the categories of need for CYP attending the school.

Outputs: These descriptive data will form part of the narrative school case study description and will be combined with findings from Objectives 2 and 3 (see outputs for Objectives 2 & 3).

Objective 2: To explore key stakeholders' perspectives on school food in Specialist schools

Design: Qualitative research

Participants: (i) Special Educational Needs Coordinators (SENCO), (ii) teachers, (iii) learning support assistants, (iv) school catering staff, (v) allied health professionals (AHP) involved in supporting CYP with school food (e.g., speech and language therapists with expertise in eating and drinking, dietitians, school nurses), (vi) headteachers, and/or school governors (vii) local authority/independent catering

providers, (viii) parent/carers of primary and secondary school-aged children attending Specialist schools.

Methods: Ethics: Written opt-in consent, including permission to record and store data from online focus groups and audio recorded face-to-face interviews.

Data collection: Online Focus Groups and Interviews. Zoom or MS Teams software will be used for Focus Groups for Allied Health Professionals (AHP) (n=1; participants n=4-6), and school staff (n=4; participants n=4-6/focus group). Zoom will be used for parent/carer focus groups (n=6; participants n=6/focus group) to minimise participant travel or childcare issues. Parent/carer re-imbursement for internet access is allocated. Head teachers or School Governors (n=4), and LA/independent catering provider (n=3) will be interviewed online. Participants will be given a password secured link to join. Topic guide development will be informed by the literature and our previous research experience in mainstream and Specialist schools (e.g. FEEDS)¹¹ and will be co-developed with our parent co-applicant and Patient Public Involvement (PPI). Newcastle Health Determinants Research Collaboration (HDRC), and third sector (Children North-East) involvement in development will ensure capture of aspects relevant to school food health inequality. Topic guide contents will be adjusted for relevance to each stakeholder group. Anonymised demographic data will be collected from parent/carers to include CYP's main diagnoses, presence and type of eating and drinking difficulty, ethnicity, and postcode.

Data analysis: Qualitative data will be transcribed verbatim and thematic analysis undertaken (Framework approach);¹² reporting of findings will be as per COREQ (CONsolidated criteria for REporting Qualitative research) Checklist.¹³ Divergent cases will be identified and discussed by the research team to enrich the understanding of the phenomenon and minimise researcher bias'.

Outputs: Peer-reviewed publication; generating evidence for intervention development and pilot/feasibility work underpinning a future funding application; development of a logic model; school focused infographic.

Objective 3: To understand the key factors that influence choices related to school food consumption made by young people attending Specialist schools

Design: Qualitative research Participants: Young people aged 14-19 years attending a participating Specialist secondary school

Methods: Ethics: Written young person opt-in consent (aged 16 years and over with capacity), or written parent/carer opt-in consent and young person assent (under aged 16 years), including permission to record and store data as per NU policies. Written assent will be offered for young people under 16 years of age, and for those over 16 years of age who lack capacity to provide informed consent. Research staff will have an enhanced DBS.

Recruitment: Young people aged 14-19 years from each participating secondary school (max.4-6 young people per focus group). School contacts will identify interested participants. A parent/carer and young person study information letter and young person consent or assent (as appropriate), and if required a parent/carer consent form will be distributed by the school contact.

Data collection: Focus groups will be conducted face to face. Young people will have the option to attend with a familiar communication partner or learning support assistant. Focus groups will take

place in school and be led by an experienced researcher with expertise in qualitative work. Topic guide development is as per Objective 2.

Data analysis: As per Objective 2

Outputs: Peer-reviewed publication; generating evidence needed for intervention development and pilot/feasibility work required for a future funding proposal; development of logic model; school infographic; short, animation to 'hear' the pupil voice.

WP 2. Addressing Aim 2: To identify what evidenced-based interventions exist to support healthier food choices for CYP attending Specialist schools

Objective 1: To identify the existing evidence-base on interventions to support healthier food choices amongst CYP attending Specialist schools. Objective 2: To consider how the identified interventions were developed. Objective 3: To identify the intended action/effects of the interventions and what replication of each as designed would entail. Objective 4: To identify any intervention evaluation and describe any health outcomes assessed

Design: Scoping review following the Joanna Briggs Institute (JBI) framework;^{14,15} findings reported in adherence to PRISMA-ScR.¹⁶ Review question framed using the 'Population, Concept, and Context' framework.^{14,15} Review Question: What food interventions exist to support healthier food choices amongst CYP attending Specialist schools, how have they been developed, and have they been evaluated? Methods: Search strategy development: The search strategy will be developed in full by an Information Specialist to include, as a minimum, search strings relevant to each of the following components in the review question: Population (CYP), Concept (food interventions), and Context (Specialist schools) using three types of searching: 1. Bibliographic databases (e.g. of MEDLINE, CINAHL, Scopus) thesaurus/indexing terms and key word terms; 2. Grey literature searches (e.g. for government and think tank reports and tacit practitioner knowledge) of websites, google advance, and research and public health practice networks; 3. Allied search methods (e.g. checking reference lists and citations of included records or contacting experts). Before implementation the search strategy will be peer reviewed using PRESS and reported following PRISMA-S.¹⁴⁻¹⁶

Record management and screening: Endnote will be used for record management and deduplication. To report records a PRISMA flowchart will be used. Reviewers will screen titles and abstracts, and then full texts in blinded duplicate against pre-specified eligibility criteria with any discrepancies resolved.

Eligibility criteria: highlighted with relevance to the Population (CYP), Concept (food interventions), and Context (Specialist schools) components in the review question as well as other salient criteria. Population: Records detailing design or evaluation of interventions that target CYP aged 5 years and above; Concept: Records detailing design or evaluation of interventions to support/improve school food irrespective of the planned duration of the Action (e.g., the discrete observable change in behaviour from policy setting to changing placement of products within cafeterias); Intended impact (e.g., change in school food choice or energy or nutritional intake); or, Actor (e.g., the individual or group who perform from teachers to policymaker). We will exclude records detailing design or evaluation of interventions to improve individual child-level eating; Context: We will include interventions designed for or evaluated for use within Specialist schools including high, mid and low-income countries. Publication date: We will include records published from 2000 to date; Publication language: We will include records irrespective of publication language. Data extraction and charting: The data will be extracted by two independent reviewers using a data extraction tool developed and

piloted by reviewers to ensure appropriateness and usability of the form as well as consistency of extraction.¹⁷ The extraction form will incorporate: record and study meta-data (e.g., authors, year of publication, country of origin, study aim, population demographics); interventions development method (Objective 2 using MRC taxonomy¹⁸); detailed description of the intervention and intended implementation plan (e.g., intended action, actor, context, (Objective 3 using TIDieR/TIDierRPHP/AACCTT¹⁹); and evidence of any type of evaluation (Objective 4 description of evaluation and if relevant primary/secondary outcomes). Any disagreements in extraction will be resolved through discussion. If required, authors will be contacted to request missing or additional data. Data synthesis: We will follow recommendations for synthesis within scoping reviews outlined by Pollock et al. (2023),¹⁷ extracted data will undergo descriptive analysis and be reported as frequencies in JBI exemplar tables and, or, visualisations with narrative synthesis describing how the data answer the review questions. If gaps are identified, we will draw attention to potential directions for future research. Outputs: Peer-reviewed publication of the scoping review identifying the existing evidence-base of Specialist school food interventions to promote pupil health; a complete PRISMA-ScR checklist¹⁶ documenting page numbers where each recommended action has been addressed as a supplementary file; evidence generation for intervention development plan including pilot/feasibility to underpin a future funding application; dissemination event with national stakeholders

Outputs: school infographic (WP1); short animation to 'hear' the pupil voice (WP1); Peer-review publications (WP1 &2); a logic model (WP1&2); evidence needed for intervention development and pilot/feasibility work (NIHR PHR or MRC PHIND application (WP1&2)); formation of a multi-disciplinary network for future NIHR PHR or MRC PHIND application; NIHR final report (WP1&2).

Dissemination: Conference presentation for academics (WP1&2); a local (face-to-face) and national (online) stakeholder event to share findings, including for example, the National Association for Special Educational Needs, Local Authority Caterers Association – the School Food People, British Academy of Childhood Disability, British Dietetic Association, and third sector organisations working in School Food and Health Inequalities.

5 STUDY SETTING

Four Specialist primary and secondary schools in the North-East of England will be purposefully sampled (all have confirmed participation). Selected schools include one primary and one secondary school in Newcastle; one mixed primary and secondary school in County Durham; and one mixed primary and secondary school in Redcar & Cleveland.

These schools have been selected to achieve diversity in population (e.g., Newcastle schools serve CYP from diverse ethnic groups), location (inner-city, semi-urban, and rural), school catering models (Local Authority (LA) and in-house), and type of educational provision.

6 SAMPLE AND RECRUITMENT

6.1 Eligibility Criteria

Participants will be:

- Young people aged 14-19 years who attend a participating Specialist school and who receive school food
- A member of the teaching staff at a participating Specialist school, who is involved in supporting pupils at mealtimes and/or with school food choices
- Canteen staff from participating Specialist schools

- Allied Health Professionals working in a participating Specialist school and involved in supporting pupils' eating and drinking or nutrition
- Head Teachers from participating Specialist schools
- School governors with responsibility for school food in participating Specialist schools
- Local authority/independent catering provider employees

6.1.1 Inclusion criteria

Young people:

- Individual aged 14-19 years attending a participating Specialist school
- Individual receiving school food
- Individual has capacity to provide informed consent, OR has parental informed consent from an individual with parental responsibility AND young person assent to participate
- Individual deemed able to participate in a focus group by a professional working in a participating Specialist school

Parent/carers:

- Individual with a child attending a participating Specialist school
- Individual with a child who receives school food
- Individual with capacity to provide informed consent to participate

Professionals (Education, Health and Catering providers)

- Individual working in or with a participating Specialist school
- Individual involved in the provision or delivery of school food
- Individual with capacity to provide informed consent to participate

6.1.2 Exclusion criteria

Young people considered unable to participate due to additional behavioural needs.

6.2 Sampling

This is a mixed-methods study including a qualitative study in WP1 to meet Objectives 2 and 3 (section 5).

For this WP, four schools have been purposefully sampled to represent several geographical locations across the North East (Newcastle, Durham and Redcar & Cleveland). In addition, they have been selected to achieve diversity in population (e.g., Newcastle schools serve CYP from diverse ethnic groups), location (inner-city, semi-urban, and rural), school catering models (LA and in-house), and type of educational provision (primary and secondary).

Using the key contact within schools we will purposefully recruit a sample of stakeholders as noted in section 6. (e.g. young people, AHPs).

6.3 Sample identification and recruitment

Sample identification: Focus group participants will be identified by an agreed contact at each participating Specialist school, who will check eligibility according to the inclusion and exclusion criteria listed in this protocol.

Parent/carer and Young Person Information Sheets and consent and Young Person assent forms will be sent to eligible individuals by the Specialist school contact.

Education and Health professionals working within participating schools will also be invited to participate via participating schools' contacts. School governors with responsibility for school food will be invited to participate by the school contact or Head Teacher at each participating school.

Local authority catering providers will be invited to participate via CHOICE local authority partners, who will share the study information leaflet with catering providers.

Invited professionals will be selected by background to ensure broad professional group representation. Parent/carer and young person selection will aim to achieve representation across each area of primary need to include CYP with and without eating and drinking difficulties.

6.3.2 Consent

This study involves several stakeholders. Opt-in consent will be used for all stakeholders. Participating parent carers and young people aged 16 years or over with capacity will provide written opt-in consent (including, permission to record and store data from online focus groups and audio recorded face-to-face interviews) prior to participation in the focus group. Parental written informed consent for young person participation will be requested for young people under the age of 16 years. Young people under the age of 16 years will be asked to provide written assent to participate. Young person capacity to provide consent will be determined by the parent/carer. Participants will be given the opportunity to consider the information, and to ask questions of the research team to decide whether they will participate. Information sheets and consent forms will be distributed through the school contact. School-pupil post will be used to collect forms. The school contact will return completed participant consent forms to the research team.

Parent/carer participants and parent/carers of participating young people will also be asked to complete a brief optional questionnaire for the collection of contextual demographic information, and information relating to their child's primary diagnosis, and presence and nature of eating and drinking difficulties. These data will be anonymised and handled and stored in accordance with data protection and patient confidentiality requirements section 7.7. This questionnaire will be sent to parent/carers with the study information sheet and consent form, and returned via school-pupil post in a provided sealed envelope.

Professionals will provide electronic consent (opt-in consent, including, permission to record and store data from online focus groups and audio recorded face-to-face interviews) prior to participation in the focus group or interviews. Participants will be given the opportunity to consider the information, and to ask questions of the research team to decide whether they will participate. LA catering staff will receive a study information sheet and consent form distributed via the LA collaborator (using same methods as above).

All documentation to be used in the study (e.g. information sheets and consent forms) will be reviewed and approved by Newcastle university Ethics Committee.

7 ETHICAL AND REGULATORY CONSIDERATIONS

Newcastle University will be the study sponsor. Ethical approval will be sought for all aspects of the work from Newcastle University Ethics Committee

7.1 Assessment and management of risk

There are no major identifiable potential risks to participants in the proposed study. There is a small possibility that the topics discussed may be a sensitive issue for some participants. All staff working in schools will have an enhanced Disclosure and Barring Service (DBS); research staff will not be in a room alone with pupils. There will be two researchers present whilst conducting focus groups. If pupils have any concerns and decide not to participate in the study they will be free to withdraw at any point. Any inappropriate pupil behaviour, or if, a child becomes distressed the researcher will inform a member of staff at the school who can engage the child with the relevant welfare systems in place within the school. If a researcher becomes aware of a safeguarding issue in relation to a pupil, they will immediately inform the relevant member of staff within the participating school so that the school safeguarding procedures can be followed.

Researchers contact details are provided on the study information sheet for parents/carers or pupils to contact the researcher if they have any concerns during or after the study.

All research staff will have an enhanced DBS prior to commencing work in schools. All University risk management procedures will be followed for research staff working on the project. A risk assessment will be completed for any lone working: a buddy system will be in place for school visits as the research will be conducted during normal working school hours. At schools, research staff will have a nominated contact to report to on arrival; staff will wear a photographic University ID badge and will have their mobile phones switched on with them.

Research staff using their own car will adhere to the University car insurance policy and relevant documents will be completed. All school visits will be recorded in the office diary and a colleague will know the dates/times the researcher is visiting schools. There are no perceived risks for the online Focus Groups and Interviews with adult stakeholders.

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

Newcastle University will be the study sponsor. Ethical approval will be sought for all aspects of the work from Newcastle University Ethics Committee.

7.3. Regulatory Review & Compliance

7.3.1 Amendments

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

7.4 Peer review

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

7.5 Patient & Public Involvement

We have a named parent co-applicant (MC). MC is a member of the research team, and will provide essential service user knowledge and expertise, and have joint ownership in decision making. A PPI group has been established including two parents of CYP with lived experience of Specialist school provision and one school governor with responsibility for Specialist school food. This will ensure the service user voice is embedded throughout. PPI consultation is planned on three occasions: (i) the start of the project to gain feedback on study materials, including topic guides for focus groups and interviews (ii) mid-way for feedback on dissemination planning of preliminary findings, and (iii) month 5 to obtain feedback on dissemination materials (e.g., language used).

The project has a dedicated, experienced public involvement lead (LM). This will make sure that public members have a point of contact, feel supported and valued, and that public involvement is embedded throughout the project. Public involvement will be aligned to the UK Standards for Public Involvement (<https://sites.google.com/nihr.ac.uk/pi-standards/home>). The research team, including the parent co-applicant (MC), will explore with the PPI group and advisory panel how to jointly outline shared roles, responsibilities, and expectations. The co-applicant (MC) and public members will be signposted to information on the NIHR website providing them with resources and links for personal development and any training they feel would support their involvement. We will ensure inclusive language and flexible communication methods throughout to achieve good access and engagement. The project PPI will be captured, evaluated and the impact reported using the GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research (GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research | The BMJ). This will help the monitoring of involvement activities and ensure any required changes are acted on. All public members' involvement will be formally recognised. They will be offered a range of options to thank them for their time and contributions e.g., choice of shopping vouchers, a charity donation of their choice or training options for personal development.

7.6 Protocol compliance

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

7.7 Data protection and patient confidentiality

All study researchers will comply with the requirements of the Data Protection Act 2018 and General Data Protection Regulation (GDPR). All research staff involved in data collection will have enhanced DBS checks. Data protection measures will adhere to the relevant policies and procedures of

Newcastle University. All study data collected on paper will be held securely, in a locked room or locked cabinet that is accessible only to the research team and relevant regulatory authorities. All study data in electronic form will be pseudo anonymised using ID numbers and held securely in password protected files on Newcastle University computers. Audio files will be transcribed either internally by members of the research team or by a specialist external company subject to a Confidentiality Agreement to not disclose any information to third parties. Files will be transferred via a secure server with user identifiers and passwords. Transcripts will be marked with unique and anonymised identifiers. All data will be held securely in the custody of the CI for 10 years after publication of the main study results, in accordance with Newcastle University's Research Data Management Policy.

7.8 Indemnity

Newcastle University has in place a Public Liability Policy which provides cover to the University for harm which comes about through the University's, or its staff's, negligence in relation to the design, management or conduct of the study.

This is a non-commercial study and therefore there are no arrangements for non-negligent compensation.

7.9 Access to the final study dataset

After publication of the main findings of the study, the CI will consider external requests to gain access to anonymised data. The dataset will be preserved and available for this purpose for 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 Newcastle University 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.

8 DISSEMINATION POLICY

8.1 Dissemination policy

Outputs: school infographic (WP1); short animation to 'hear' the pupil voice (WP1); Peer-review publications (WP1 &2); a logic model (WP1&2); evidence needed for intervention development and pilot/feasibility work as part of future funding application (WP1&2)); formation of a multi-disciplinary network for future funding application; NIHR final report (WP1&2). The full study report will be published in the NIHR Journals Library (<https://www.journalslibrary.nihr.ac.uk/#/>).

Dissemination: Conference presentation for academics (WP1&2); a local (face-to-face) and national (online) stakeholder event to share findings, including for example, the National Association for Special Educational Needs, Local Authority Caterers Association – the School Food People, British Academy of Childhood Disability, British Dietetic Association, and third sector organisations working in School Food and Health Inequalities.

Impacts

Impacts will be conceptual, leading to an improved understanding of school food in Specialist schools, and generation of evidence to underpin intervention development in a future proposal. If effective, novel school-food interventions will improve CYP's health and well-being.

8.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship will follow the guidelines outlined by NIHR Order of Authors Agreement. For example, an author will be an individual who has been involved in the conception, design, data collection, analysis, interpretation of findings, or revising the final report or future publications arising.

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10. APPENDICIES

10.1 Appendix 1- Required documentation

The following is a list of documents that will submitted for ethical approval prior to study commencing:

- Study Information Sheets: Parents, AHP, Young People, Education & Catering Staff and LA Catering Providers
- Consent Forms: For all stakeholders listed above
- Assent Form: For young people below the age of 16 years, or young people over the age of 16 years who lack capacity to provide informed consent
- Debrief Sheets; For all stakeholders listed above
- Topic Guides: Parents, YP, Education & Catering Staff
- Interview Guides: Headteachers & LA Catering Providers

10.2 Appendix 2 – Schedule of Procedures

| Milestones | Completion prior to 1st Sept | 1 | 2 | 3 | 4 | 5 | 6 |
|--|---------------------------------|--------|---------|---------|---------|---------|---------|
| Project Month | | 1 | 2 | 3 | 4 | 5 | 6 |
| Calendar Month | Aug-24 | Sep-24 | Oct-24 | Nov-24 | Dec-24 | Jan-25 | Feb-25 |
| Milestone 1: Study set up (contracts, PMP, Protocol, scientific abstract etc) | x | | | | | | |
| Milestone 2: Ethics submitted | x | | | | | | |
| Milestone 3: Ethics approved | x | | | | | | |
| Milestone 4: Recruitment of schools | | x x | | | | | |
| Milestone 5: Recruitment of stakeholders | | x x x | x | | | | |
| Milestone 6: Data collection: OB 1 (document review) | | | x x | | | | |
| Milestone 7: Data collection: OB 2 (eg parents, school staff) | | | x x x | x x x x | x x x x | | |
| Milestone 8: Data collection: OB 3 (young people) | | | x x x | x x x x | x x x x | | |
| Milestone 9: Data Analysis (descriptives document review (OB1) & qualitative from Focus Groups and Interviews (OB2&3)) | | | | | | x x x x | |
| Milestone 10: Scoping review protocol development | | x x | | | | | |
| Milestone 11: Literature searching to identify papers | | | x x x x | | | | |
| Milestone 12: Data extraction & narrative synthesis of findings | | | | x x x x | x x x x | | |
| Milestone 13: Draft publication for peer review | | | | | | x x x x | x x x x |
| Milestone 14: Report write-up | | | | | | x x | x x x x |
| Milestone 15: Dissemination | | | | | | | x x x x |

13.3 Appendix 3 – Amendment History

| Amendment No. | Protocol version no. | Date issued | Author(s) of changes | Details of changes made |
|---------------|----------------------|-------------|----------------------|-------------------------|
| n/a | | | | |