

Growing Well Study: The role of portion size, plant-based and commercial foods on young child growth

The Growing Well Study



This protocol has been drafted in accordance with HRA guidance

RESEARCH REFERENCE NUMBERS

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SIGNATURE PAGE

The undersigned confirm that they have read, understood, and approved the content of this study protocol. They agree that the study will be conducted in compliance with this protocol, relevant regulations, and institutional policies.

I agree to ensure that the confidential information contained in this document will not be used for any purpose other than the evaluation or conduct of the study 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 appropriate dissemination tools without unnecessary delay, providing an honest, accurate, and transparent account of the study. Any deviations from the protocol or significant issues arising during the study will be appropriately documented and explained.

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ROLE OF THE SPONSOR AND FUNDER

The sponsor is the University of Leeds and is responsible for the initiation, management and financing (or arrangement of the financing) of the Study.

NIHR is the funder of this study and was minimally involved in study design via review panel input at the review stage.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES

This study will be led by the Joint Chief Investigators, who hold overall responsibility for the scientific integrity, design, coordination, and delivery of the study. The Chief Investigators will ensure that the study is conducted in line with the approved protocol, ethical approvals, and relevant institutional and regulatory requirements.

Key personnel, chief investigators and co-investigators will meet regularly to oversee operational aspects of the study including review progress, monitor data collection and quality, manage any protocol deviations, and address logistical or methodological issues as they arise.

A Study Steering Committee with co-investigators and participation from the Patient and Public Involvement and Engagement (PPI) group will meet every 6 months and provide oversight, offer strategic input, and ensure that the study remains on track and maintains high standards of scientific rigor and ethical conduct.

ROLES AND RESPONSIBILITIES OF STUDY PARTNERS

Sub-contracts (or the Organisation Information Documents in the case of NHS partners) will detail roles and responsibilities for partners. Brief details are provided below.

National Centre for Social Research (NatCen)

- Program and host the online baseline/follow-up surveys (screening questions, electronic consent, and substantive content)
- Host the clinic appointment booking system for measurement visits
- Conduct fieldwork measurement clinics at baseline and follow-up with up to 20% in-home visits or reimbursement for taxi travel. Visits will be held in community locations in each city, operating on a 2-weekly rotating basis to allow participation across each geographical area Securely share recruitment and survey data with University of Leeds on a regular basis
- Work with the University of Leeds to plan and agree community clinic locations/schedules, in particular to permit alignment with dental therapist availability during follow-up data collection.

Queen Mary University of London

- Will contribute to the project through academic and research collaboration, including support for data processing activities. The institution may also facilitate the engagement of London-based dental examiners, where required.

NHS sites

- Participating NHS Organisations will review BaBi/Generation study participant lists and invite participants to take part in the Growing Well Study by sending letters/e-mails/text messages or making phone calls. Several rounds of contact may be needed, with eligibility/screening criteria being applied as directed from the University of Leeds Team, e.g. the need for more participants from deprived postcodes or ethnic minorities.

- Information from the University of Leeds relating to recruitment targets will inform NHS teams which participants to target with invitations or which participants may need to be offered additional support to participate.
- Support offered by NHS teams will include:
 - screening for potential participants using existing BaBi/Generation study data or in-person contact with potential participants
 - contacting potential participants via e-mail, text message, postal invitation pack (supplied by the University of Leeds) or phone call
 - answering questions and describing the study or directing potential participants to the University of Leeds Research team for any other queries
 - directing potential participants towards the online screening questions and consents
 - assisting participants in completing the online screening, consents, questionnaires and food records
- No study procedures will be conducted on site, and no sponsor staff will attend the NHS premises aside from to deliver introductory training to participating members of teams.
- No additional equipment, clinical support, or monitoring arrangements are required.
- Recruitment activity may be supported by local Research Delivery Network teams and NHS organisations will be required to coordinate or share data appropriately to enable this. For example, the BaBi/Generation study team could provide the Research Delivery Network (RDN) with a list of contact details (names and phone numbers) to contact and invite study participation (subject to data sharing agreement if appropriate).

Research Delivery Network (RDN)/ North Central London Research Network (NoCLoR)

- Assist in study recruitment from BaBi/Generation study by coordinating with local NHS teams to share workload as necessary (i.e. help with phone calls to potential participants, explaining the study outline and directing/supporting potential participants to the electronic consents and questionnaires).
- Assist in community outreach, distributing study information via existing local networks
- Assist in study data collection for participants requiring additional help e.g. take a verbal diet record and enter the data on to the myfood24 platform.
- Assist in study retention by contacting participants to thank them for participation and invite them to complete the next steps of the study.

Non-NHS sites involved in recruitment

- Early Years Services (including children's centres and nurseries) will play an active role in recruitment. We will work with local authorities and councils as appropriate in each area to ensure that we follow appropriate organisational approval processes.

PROTOCOL CONTRIBUTORS AND RESEARCH EXPERTISE

All co-investigators reviewed the protocol and provided critical feedback to ensure its accuracy and completeness.

Prof Janet Cade (JC) is a professor of nutritional epidemiology at the University of Leeds and leads the WHO Collaborating Centre in Nutritional Epidemiology. She is also Chair of the Advisory Committee for the British Nutrition Foundation. As an experienced principal investigator, JC co-led the writing of the study protocol, revised the document, secured funding, and will oversee the project.

Dr Diane Threapleton (DT) PhD is an academic researcher specialising in nutritional epidemiology, evidence-based policy, and early life nutrition. JC and DT are experienced in study management and working to project deadlines. DT co-led the writing of the study protocol, revised the document, secured funding and will oversee the project.

Dr Darren Greenwood (DG) is a biostatistician and member of the Scientific Advisory Committee on Nutrition. He will lead Work Stream 6 Analysis; supporting recruitment and data collection.

Prof Marion Hetherington (MHe) will support measures of child eating traits, parenting styles and feeding practices. Using techniques to engage participants from different backgrounds ensuring vulnerable groups are appropriately represented. She is a member of the Subgroup on Maternal and Child Nutrition of the Scientific Advisory Committee on Nutrition.

Prof Peter Day (PD) is a consultant in paediatric dentistry, with experience of calibration and leading dental teams undertaking standardised oral examinations in home and community settings. He will be responsible for training and oversight of dental teams undertaking fieldwork and will co-lead Work Stream 5.

Dr Mark Hopkins (MH) expertise is in Nutritional Physiology conducting human appetite and energy balance research. He will train the fieldworkers to undertake anthropometric measurements; co-leading WS5.

Mr Nigel Simpson (NS) is NIHR Clinical Research Network National Specialty Lead for Reproductive Health. As Principal Investigator for BaBi Leeds he will facilitate engagement with the cohort and recruitment.

Dr Elizabeth Doxford-Hook (EDH) our PPIE representative, she will facilitate participant engagement. She has contributed to writing this proposal considering key practical issues for mothers and children.

Dr Huda Yusuf (HY) Clinical Reader and Consultant in Dental Public Health. She will facilitate dental data collection in East London, ensuring quality control of dental examiners and providing expertise in engagement and PPI. Co-lead Work Stream 5.

Dr Staminata Iliodromiti (SI) is Professor of Obstetrics and Gynaecology, Queen Mary University. She will support recruitment in BaBi East London.

Dr Rebecca Spencer (RS) leads the Peas in a Pod PPI Group for BaBi Leeds, she will provide on-going protocol and study document development from a PPIE perspective.

PPIE: Volunteers identified through: i) contact with the ‘Peas in a Pod’ group, ii) Dr Threapleton’s network of parents, iii) Leeds Children’s Centres and iv) Voice have helped to develop this proposal, shaping plans for recruitment, data collection, and engagement. Volunteers played a key role in shaping the study design through several contributions. They attended an informal seminar where they learned about the study, asked questions, and provided suggestions. Suggestions from volunteers during the proposal phase focussed on ways to engage and recruit participants and how best to maintain a sense of community co-ownership of the study and findings. During the preparation phase, they reviewed participant-facing materials, provided feedback on recruitment strategies, and supported the pilot phase. Their insights were instrumental in refining both the study design and participant materials to enhance clarity, relevance, and accessibility.

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LIST OF ABBREVIATIONS

BaBi: Born and Bred in Network birth cohorts
BBSRC: Biotechnology and Biological Sciences Research Council
d₃mft: dentinal cavitation
DAG: Directed Acyclic Graphs
DHSC: Department of Health and Social Care
DMFT: Decayed, Missing, and Filled Teeth
DNSIYC: Diet and Nutrition Survey of Infants and Young Children
EDI: Equality, Diversity and Inclusion
HRA: Health Research Authority
IDACI: Income Deprivation Affecting Children Index
IRAS: Integrated Research Application System
NDNS: National Diet and Nutrition Survey
NIHR: National Institute for Health and Care Research
NPPM: Nutrient & Promotion Profile Model
PBDs: Plant-based diets
PIS: Participant Information Sheet
POST: Parliamentary Office of Science and Technology
PPI: Patient and Public Involvement
REC: Research Ethics Committee
SACN: Scientific Advisory Committee on Nutrition
WS: Workstreams

1. SUMMARY

Research question

We will answer questions posed by the recent Scientific Advisory Committee on Nutrition (SACN) report:

- What are age-appropriate food and drink portion sizes in relation to growth and dental health?
- What are the short-term effects (12 months) on growth and dental health of commercial foods for children; vegetarian/vegan/dairy-free dietary patterns?
- What is the impact on growth and dental health of macro- and micro-nutrient intakes; fruit juices/free sugars; formula milks for 12m+; sweeteners?

Background

In the UK, little contemporary data exists on diet in young children but worrying trends in preschool overweight and dental health are reported. Current young child diets do not meet dietary recommendations and evidence-driven age-appropriate portion size recommendations are missing. Further research into the impact of plant-based diets, the use of commercial foods, and toddler milks is also recommended by SACN.

Aims and Objectives

To provide new evidence on diet in children aged 6 months – 5 years, linked to optimum growth and dental health. Quantifying age-appropriate portion sizes for different foods and drinks.

- Collect data on child dietary intake, portion sizes.
- Collect data on parent and child attributes, including child anthropometrics and dental health.
- Evaluate food and nutrient intake in relation to i) growth over 12 months, ii) child and parent characteristics, including ethnic diversity, deprivation and iii) dental health.
- Make recommendations for nutrition and age-appropriate portions.

Methods

We will recruit 1,890 parents of young children (6 months - 4 years) through through a combination of community outreach and hospital-based recruitment. This will include participants from the Born and Bred in (BaBi) Network birth cohorts in Leeds, Doncaster, and East London, as well as from the Generation Study. Recruitment will include approximately equal distribution in each year bracket, 20% non-white, 20% from deprived locations, and 15% vegetarian/vegan/non-dairy diet. Protocols are in place to

ensure recruitment targets are met. Protocols, consent forms, and questionnaires have been co-designed with our Parent Advisory Group.

Baseline data will be collected using i) online survey, ii) fieldworker-measured height/length, weight, abdominal circumference, iii) 3 x 24h measures of diet spanning several months, and may possibly include iv) saliva collection in a subsample (if funding is obtained). Follow-up data collected after 12 months will repeat baseline measures and additionally include a dental assessment.

Cross-sectional and longitudinal analysis will explore how growth and dental health are influenced by nutrient intakes, diet pattern, and food portion sizes. Age/gender appropriate portion sizes for key food groups will be characterised with linear mixed-effects modelling for specific foods/food groups in relation to the child's position on the growth chart centiles.

Anticipated Impact and Dissemination

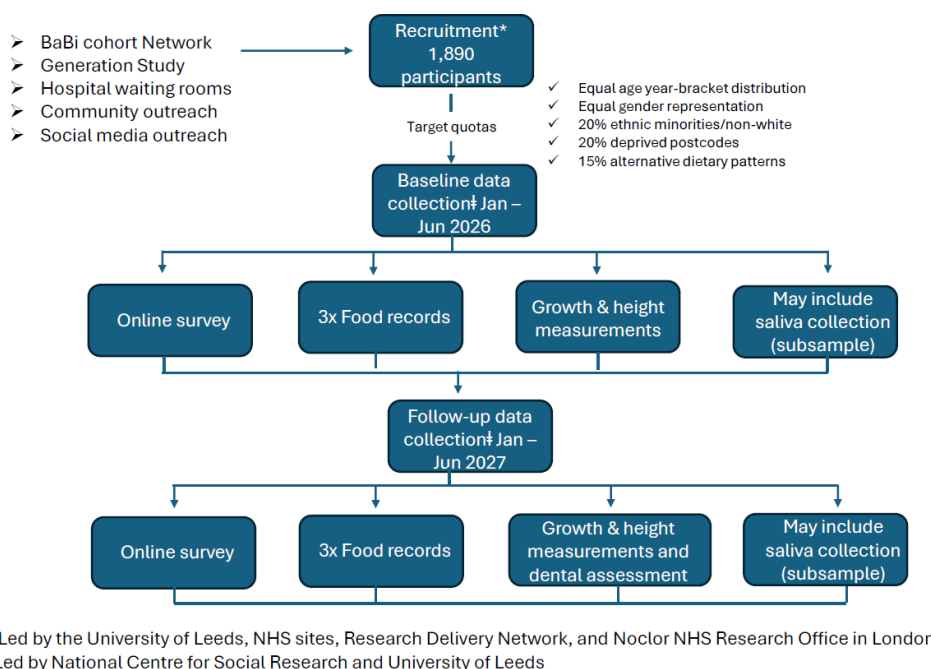
Knowledge of associations between food and nutrient intakes and growth/dental health and of suboptimal intakes in vegan/vegetarian/dairy-free or vulnerable groups will enable evidence-based guidelines on age-appropriate portion sizes and optimal diet composition.

Guideline promotion to key stakeholders and visual feedback to participants will support intake of age-appropriate portions and healthier diets. Ultimately resulting in healthier children, with better dental health. Guidelines will also highlight social inequalities, indicating specific actions to redress imbalances

2. KEY WORDS

Early Years; Children; Nutrition; Portion Size; Commercial Foods; Plant-Based Diet; Growth; Dental Health

3. STUDY FLOW CHART



4. BACKGROUND AND RATIONALE

What is the problem?

Nutrition in early years is important in ensuring positive health outcomes during childhood and later life reducing risk of non-communicable diseases. Health inequalities linked to children's health and oral health have clear social gradients associated with deprivation and ethnicity. Optimising early years nutrition may be an important step in tackling health inequalities across the life course, but there is currently limited evidence for what constitutes 'optimal' nutrition.

The UK Scientific Advisory Committee on Nutrition (SACN) recommended research on health effects of plant-based diets and commercial foods/drinks(1); concluding that the current diet of young children does not meet current dietary recommendations. Furthermore, we lack consistency in evidence-driven portion recommendations(2).

We aim to provide a comprehensive overview of nutritional intakes of children aged 6 months to 5 years (participants aged 4 at baseline will be 5 at follow-up) to inform national recommendations relating to portion size and nutrient intakes, supporting optimal growth and dental health whilst helping to minimise the impact of social inequalities.

Why is the research important?

In the UK, there is little contemporary data on diet in children aged 1 – 5 years, the most recent Infant Feeding Survey was in 2010(3) and the Diet and Nutrition Survey of Infants and Young Children (DNSIYC) in 2011(4). This project will complement the new Infant Feeding Survey. That survey has limited information on feeding children aged up to 10 months old only. **Our study will provide detailed information on diet and health outcomes for children aged between 6 months - 5 years, understanding the impact of inequalities.**

There are concerns around adequacy of iron, vitamin A intakes and vitamin D status of children 1-5 years (NDNS data). Children from lower socioeconomic backgrounds and certain ethnic groups, such as Pakistani(5), may be more at risk of micronutrient deficiency(6). The NDNS does not include a large enough sample of ethnic or disadvantaged groups(7), resulting in poor understanding of dietary behaviour.

The shift towards adopting plant-based diets raises additional concerns for calcium, iodine and vitamin B12(1) intakes. Sparse evidence on plant-based diets in children contributes to inconsistent statements on their safety in relation to growth. A systematic review of vegetarian diets in children found that growth and body weight were generally within the lower reference range(8). The more restrictive the diet and the younger the child, the greater the risk of nutritional deficiency(9). *Dental health* is a further important outcome owing to the high prevalence of tooth decay linked to dietary behaviours, such as amount, and frequency of free sugars consumed and timing of consumption(10).

Review of evidence:

The SACN report on young child feeding leads to this research call(1).

How much and *what* parents should be feeding young children is unclear. Systematic reviews in pre-school settings showed that larger portion sizes were associated with higher food and energy intakes(11–13). However, *these reviews could not identify appropriate portion sizes* required for normal growth and development. The British Nutrition Foundation(14) developed the 5532 portion size guide for 1-4 year olds. However, the source of these portion sizes is not evidenced. Parents of young children found existing food portion size guidance resources to be ineffective(15). Trial evidence indicates that large portion sizes of high energy dense food given to young children are predicted by portion sizes adults give to themselves(16,17). Parents report confusion about recommendations for portion sizes; requiring information to be accessible, child-centred, and simple(16).

Parents may *not have access to appropriate foods*. Commercially available foods may not meet nutritional requirements. We led development of the WHO Nutrient &

Promotion Profile Model (NPPM)(18) which details nutrient and promotional requirements across product categories for children. Sweet purées and snack foods dominate the market. In our validation study, around half of all baby meal purées in the UK did not reach the minimum energy requirement. Nutrient composition of many commercially produced foods and drinks for infants and young children is at odds with recommendations(19). Growth in the infant food market is largely driven by snack foods(19) with a high sugar content(20). The SACN review concluded that specific commercial foods and drinks, such as follow-on milks, are not needed for children aged 1-5 years(1).

Diets of younger children in the UK are *not in line with current national guidelines* where children aged 1.5 to 4 years *exceeded* recommendations for dietary energy, protein, saturated fat, and free sugars(6). The COVID-19 pandemic and economic crisis has **highlighted widening health inequalities** with increasing food insecurity. However, *most data relates to children above 5 years*(21).

The evidence available to evaluate the nutritional appropriateness of vegetarian diets for children is inadequate and dated. The latest NDNS found 10% were not eating meat. We lack data on the proportion of preschool children following plant-based diets. A 2021 survey of ~1000 5–16-year-olds found 8% were fully plant-based and 13% vegetarian, indicating our target of 15% should be feasible and representative(22).

Preventing tooth decay and reducing oral health inequalities are highlighted as a priority by the James Lind Alliance and WHO's Oral Health Action Plan (2023-2030)(23). Approximately a quarter of five-year-olds in England have tooth decay(10), increasing to >40% in deprived areas. There are marked social inequalities in the prevalence of tooth decay(24,25). Frequent exposure of teeth to free sugars, through consuming sugary snacks and drinks causes tooth decay(10). Systematic reviews identify that dietary behaviours beyond frequency and amount of free sugars are involved, including timing of intake(26,27). NIHR funded studies have predominantly focused on increasing fluoride application to teeth rather than considering diet.

Relevant ongoing research:

The new Infant Feeding Survey (DHSC/Ipsos) aims to understand how mothers in England feed their babies *in the first year after birth*. 20,000 mothers who gave birth in 2023 are being contacted. It will *not collect detailed information* on food and nutrient consumption of infants or assess health/growth outcomes. We (JC, DT) are leading implementation of the WHO NPPM, supporting UK and international assessment of commercial baby foods to improve product formulation. An evaluation >600 UK products, identified key concerns including frequent exposure to high levels of sugar

from an early age(28). Further work will document factors governing parental/caregiver motivation in choosing commercial foods, with a focus on deprived families.

Our team (MHe) has had BBSRC funding for food portion downsizing. Mothers were confused about recommendations for snack size. Caregivers selected the portion size they would usually serve themselves(16). This NIHR project will provide clearer guidance on age-appropriate portion sizes.

The team is working on the BaBi study (NS, SI, PD, RS) have an in-depth knowledge of the developing cohorts.

What will this study add?

- *Contemporary data* on diet in children aged 6 months - 5 years, with consideration of health inequalities. Using, for the first time, a large, branded database with an online dietary assessment tool to allow detailed exploration of nutrient intakes and food patterns.
- Identify *portion sizes by age for key food groups* linking to optimal growth and dental outcomes.
- High quality dietary data from *different ethnic backgrounds and lower income families*. Children receiving *vegetarian/vegan diets, and non-dairy consumers*, will be evaluated in relation to growth and dental health.

5. RESEARCH AIMS

Overarching Aim:

To provide new evidence on diet in children aged 6 months - 5y, linked to optimum growth and dental health. Quantifying *age-appropriate portion sizes* for different foods and drinks.

Objectives:

O1: Recruit a sample of UK children aged 6 months - 4 years with a boosted sample from deprived postcodes; ethnic groups; including vegetarians, vegans and non-dairy consumers.

O2: Collect data on child dietary intake, portion sizes, use of commercial foods/drinks including formula milks.

O3: Collect data on parent and child attributes, including different ethnicities and deprived postcodes typically marginalised from research; child anthropometrics; dental health; and may possibly include saliva collection.

O4: Evaluate food and nutrient intake in relation to i) growth over 12 months, ii) child and parent characteristics, including ethnic diversity, iii) dental health, and iv) possibly epigenetics.

O5: Make recommendations for nutrition and age-appropriate portions in relation to anthropometry and dental health.

Outcomes

The primary outcomes of this study will reflect the overarching aim and objectives, including measures of child's growth and dental health, as outlined in the Methods section.

6. STUDY DESIGN

STUDY POPULATION

The GWS will be a single-centre prospective observational study. At baseline, 1,890 children aged 6 months – 4 years and their parents or guardians will be recruited from Leeds, Doncaster, East London, and surrounding areas. Data will be collected at two time points: baseline and a 12-month follow-up, with an anticipated retention of approximately 1,350 participants. It will collect data on sociodemographic characteristics, dietary intake, growth, dental health, and potentially saliva collection. All families will be eligible to take part if their child does not have serious illnesses (e.g. children with feeding difficulties or a long-term condition that affects growth or development) and where the study team has capacity to support non-English languages.

Inclusion criteria:

Children aged 6 months to 4 years who reside in or near one of the three study locations and planned fieldwork sites: Leeds, Doncaster, or East London.

For East London, eligibility includes individuals living in or near Tower Hamlets or an adjacent borough.

Exclusion criteria:

1. Plan to move outside of the study area within the next 12 months

2. Children not living with the consenting parent/guardian for any part of the week or not living with the consenting parent/guardian at the time of data collection (e.g. in care, hospital, or living wholly with another family member).
3. Children with significant oral feeding difficulties (e.g. tube-feeding or developmental delays)
4. Children that have been diagnosed with a long-term condition that affects their growth or development (e.g. hormonal or genetic conditions)
5. Children from age subgroups where quotas have been filled will be excluded to maintain balanced representation across all ages, as well as those in a diet, ethnic group or non-deprived area where the target number has already been met

Ethical approval will be obtained via the Integrated Research Application System (IRAS), and the study will be reviewed by a Research Ethics Committee (REC) recognised by the Health Research Authority (HRA). Informed consent will be electronically obtained from the parent or legal guardian of each participating child prior to data collection through an online system programmed in Unicom Intelligence (**Appendix A**). A detailed Participant Information Sheet (PIS) (**Appendix B**), Consent Form, and Privacy Notice will be provided through the same system, outlining the study's purpose, procedures, data protection measures, and the voluntary nature of participation.

STUDY SETTING

The Growing Well Study will be conducted across three UK locations: Leeds, Doncaster, and East London. These sites were selected to ensure a diverse participant population in terms of ethnicity, socioeconomic status, and dietary practices, aligning with the study's aim to explore the impact of portion size, plant-based and commercial foods on young child growth and dental health.

Participants will be recruited through NHS Trusts, Community outreach, and social media advertising, as outlined below. Recruitment will be supported by the Research Delivery Network (RDN) and NoCLoR (NHS Research Office in London) in East London. All recruitment materials will direct participants to an online system hosted by NatCen, where eligibility screening, consent, and baseline questionnaires are completed.

Measurement visits will take place in convenient community locations such as Children's Centres to maximize convenience for participating families and encourage attendance. To further support accessibility and improve study uptake, some measurements may also be carried out within participating nurseries and schools. The study procedures in these settings will be identical to those at community venues, with

the exception that children may be measured without their parent/carer present, provided that a member of nursery or school staff is in attendance. This approach will only be used where parents/carers have provided explicit additional consent. Families will be invited through their child's nursery or school, and this additional consent option may be incorporated into the online consent process for participants using consent option A or provided as an additional consent form using consent option B (**Appendix C**). In cases where parents or guardians do not book or attend an appointment, they will be followed up to see if they are willing to have either a home visit or reimbursement for taxi travel.

RECRUITMENT

Participant identification

Participants will be recruited from Leeds, Doncaster, East London, and surrounding areas through three main routes:

1. **Community outreach**, via local media advertising, community organisations and Children's Centres invitations;
2. **NHS Trusts** (specifically Doncaster and Bassetlaw Teaching Hospitals, Barts Health NHS Trust, and Leeds Teaching Hospitals), leveraging BaBi cohorts/Generation study contact lists and on-site promotional materials (e.g. posters, flyers);
3. Potentially, **social media advertising** through Facebook.

Regarding BaBi and Generation Study participants, all NHS trust sites will serve as active research sites, being directly involved in participant recruitment (Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust in Doncaster, Barts Health NHS Trust in East London, and Leeds Teaching Hospitals NHS Trust in Leeds). As BaBi and Generation Study participants have previously provided consent to be contacted for research, invitation emails or texts will be sent directly from the NHS sites by NHS staff. In Leeds and Doncaster, recruitment will be additionally facilitated by the RDN, and NoCLoR will cover the East London site. This will ensure identifiable information for those who have not yet consented to take part in the Growing Well Study is kept within NHS teams. Additionally, recruitment will be enhanced by displaying posters or banners in waiting rooms or other convenient locations. BaBi and Generation Study presents a unique opportunity to access families who have already expressed interest in participating in research and provides access to different social and ethnic backgrounds due to their universal approach. Equality, Diversity and Inclusion (EDI) principles will be adhered to for recruitment and retention using our Patient and Public Involvement (PPI) group to help design inclusive recruitment strategies.

Recruitment will include approximately equal distribution of participants in each year bracket and equal gender distribution, of which we will target a representation of 20% from non-white populations, 20% from deprived locations, and 15% with alternative dietary patterns such as vegetarians, vegans, and children following non-dairy diets.

Since BaBi and Generation Study participants may not fully cover the GWS target ages, we will supplement recruitment through community outreach. This will include local media advertising (e.g. newspapers, newsletters, libraries) and engaging with local service provider and their networks (e.g. distribution of invitations to service users via e-mail, SMS, Whatsapp, post, flyers, and posters). We will collaborate with Early Years Services (Children's centres), daycare settings, libraries, food banks, the Healthy Child Programme, and local community groups to ensure broader representation (e.g. food banks, family support services, play groups). The RDN will facilitate agreements with Children's Centres.

The study will also include a dedicated website designed to support participant engagement and transparency. Its purpose is to facilitate future recruitment, provide accessible information about the study aims and procedures, host frequently asked questions, introduce the research team, and share newsletters summarising findings and research activities. The website will also feature academic publications, links to relevant social media channels, and contact details for further enquiries.

All posters, flyers, banners, invitations, and messages will include a link, a QR code, or both, directing individuals to an online system hosted by NatCen and programmed in Unicom Intelligence, which includes eligibility screening, consent questions, and baseline questionnaire. They will also be asked to provide details (phone and email) for the University of Leeds research staff to contact 1) in case a potential participant requires support regarding internet or language barriers, according to availability, 2) to receive links and reminders on the food records, and 3) to receive the shopping vouchers. Participants with language or internet barriers may receive support from any of the recruitment partner staff, including those from the University of Leeds, BaBi, RDN/NoCLoR teams, or local children's centres. If needed, to further support recruitment, participants will be asked to share the study invitation/Participant Information Sheet link and invite friends and contacts. If additional recruitment is required, we will use targeted Facebook marketing through the Growing Well Study's account. The ubiquitous use of social media presents a novel opportunity for efficiently strengthening recruitment in targeted locations. This approach allows for focussed advertising by location and basic demographic (i.e. young, female) and socio-economic characteristics(29). We successfully used this approach in a myfood24 diet survey in Yorkshire, recruiting 673 participants in just three weeks(30); Facebook marketing was also used to recruit pregnant women(31).

As part of our community outreach strategy, Early Years Services (including children's centres and nurseries) will play an active role in recruitment. These services will assist by distributing study information via email, flyers, social media, Whatsapp, and family contact apps, and will also support the recruitment process by helping to identify eligible families, facilitating initial consent procedures, and providing on-site support where appropriate. They will also serve as recruitment locations for in-person engagement. The University of Leeds and the RDN will further support recruitment through community advertising, including local newspapers, newsletters, playgroups, posters/flyers, community groups, food banks, family support services, and libraries.

We will work with local authorities and councils as appropriate in each area to ensure that we follow appropriate organisational approval processes for the involvement of the Children's Centres in recruitment and measurement activities.

Inclusivity

Our approach includes groups often under-represented by surveys. We aim for 20% non-white and 20% from deprived postcodes, reflecting national distribution using the Income Deprivation Affecting Children Index (IDACI). Pakistani and Bangladeshi households are most likely to have low incomes. In East London, Tower Hamlets 44%, Barking and Dagenham 26% and in Leeds 10% of the population identify as Asian. This probability approach is particularly important where diet and growth of the most vulnerable may be different to the rest of the population.

Recruitment targets by child age, gender, deprivation level, ethnicity, and dietary pattern will be set, and reviewed at regular intervals throughout recruitment. Where variation occurs, sample boosting will be undertaken through community outreach or by social media. This robust recruitment approach using existing cohorts and studies with boosting of under-represented groups will facilitate provision of high-quality data from a sufficiently large sample of children from deprived/ethnic groups and those following vegan, vegetarian and dairy exclusion diets.

Key study materials (Participant Information Sheet and consent forms will be translated into key community languages (Bengali, Urdu, Arabic, Punjabi, and Tigrinya), guided by input from our PPI group and local community contacts. Since it is not possible to translate the questionnaire and the Myfood24 platform based to availability we will assist participants who do not speak or fully understand English by offering telephone support to help them complete their questionnaire and food records accurately.

Telephone fieldwork, when needed, ensures that our study can reach all sections of society – including the 10% of the public who are not online – the six-to-nine-month data

collection period allows for multiple attempts to reach participants by post, email, text and phone, giving everyone the opportunity to take part – not just the ‘readily available’. Up to three reminders will be sent for each activity at recruitment and follow-up. Participant eligibility screening questionnaire is shown in **Appendix D**. Invitation letters and other participant communication materials are shown in **Appendix E**

Sampling and screening:

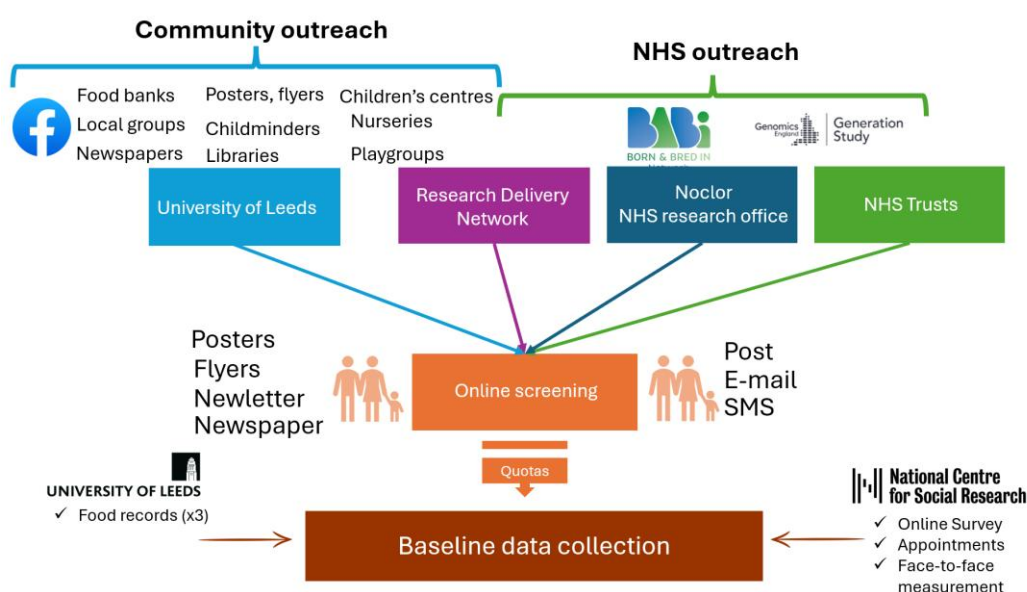
Once potential participants access the online system (either independently or with assistance in case of language or internet barriers), they will answer a few questions to determine eligibility. This will be managed entirely through the system (hosted by NatCen and programmed on Unicom Intelligence) with preestablished filters. If they are eligible, they’ll be given more information about the study and asked to give their consent for their child to take part. On completion of the appropriate consents, they will be routed to the baseline questionnaire, and to a booking link for scheduling their appointment (all within the same system, however, booking system will be external).

Ineligible participants will not proceed further. Their data will not be retained; all responses provided during the screening will be permanently deleted to ensure privacy and compliance with data protection standards.

The University of Leeds will regularly monitor the characteristics of recruited participants to ensure that recruitment quotas are met (data to be provided from NatCen on a regular basis).

An overview of participant recruitment and sampling is shown in **Figure 1**:

Figure 1. Workflow of participant recruitment and sampling



7. DATA COLLECTION AND MANAGEMENT

BASELINE AND FOLLOW-UP DATA COLLECTION

Data collection is summarized in the schedule provided in **Appendix F**. Baseline data will be collected over a six-to-eight-month period using a combination of: 1) An online survey, 2) Face-to-face (in clinic/in home) anthropometric (growth) measurements, and 3) Three 24-hour dietary recalls, spaced across several months.

Baseline questionnaire will be hosted by NatCen in the online system (**Appendix G**). Upon completion (15-20 min), parents or guardians will be automatically directed to a booking system to schedule their child's growth measurement appointment. They will be asked to bring their child's Personal Child Health Record (Red Book) to the appointment to support data collection for growth measures, birthweight and weeks of gestation. They will also receive instructions by email/post from the University of Leeds for filling their food records and receive a 'Welcome to the Growing Well Study' letter sent by post. This letter will include three food record sheets to document what their child eats out of home, as well as a sticker and a pencil. Parents or guardians will deliver the food record sheets to the day care settings, where staff will complete them by recording what the child eats on the day of the record.

The online survey will be hosted in the online system by NatCen on a secure platform programmed in Unicom Intelligence, where a unique alpha-numeric ID will be generated. During the face-to-face appointment (~15 minutes), fieldworkers will measure the child's weight, length or height, and waist circumference, as specified in the outcomes section below. Fieldworkers will also collect information of birthweight, gestational age, and two-three weight and height or length measurements from the Red Book, as shown in **Appendix H.1**. To reduce the workload for fieldworkers and make visits more efficient, the RDN/NoCLoR team will use both **Appendix H.2** to assist with collecting data from the Red Books (with the addition of weight at age 5 days of birth), as well as information on the child's eating behaviours and allergies. Additionally, should participant numbers be high, or if participants prefer, the RDN/NoCLoR team will provide printed copies of the child's eating behaviours questionnaires (**Appendix H.3**)

In-person growth measurements will be held in community locations, nurseries, schools or preschools, rotating on a two-weekly basis. These will be accessible community spaces or children's centres, with consideration given to local population density to maximise convenience for participants. Participants will be able to select their most suitable option. Where measurements take place in schools or nursery settings, children may be measured on site without their parent present, under appropriate supervision from the usual staff and in line with consent provided. Each clinic will be staffed by a pair of NatCen fieldworkers who will be responsible for running the site and data collection.

Clinics will be open for 4-5 days a week and operating for approximately three hours per session. Scheduling will include a range of weekday and weekend options, as well as varied time slots, to accommodate diverse family routines and availability.

The follow-up phase (12 months after baseline) will mirror the baseline schedule, with a shorter questionnaire version and the addition of a dental assessment during follow-up measurement visit. At follow up, data may be extracted from the Red Book if this was not captured at the baseline visit.

To support ongoing engagement with the study, we will implement a mid-way point of contact via a brief survey hosted in The University of Leeds Online Survey service. This touchpoint will serve both as a check-in and an opportunity to capture additional data on dietary information.

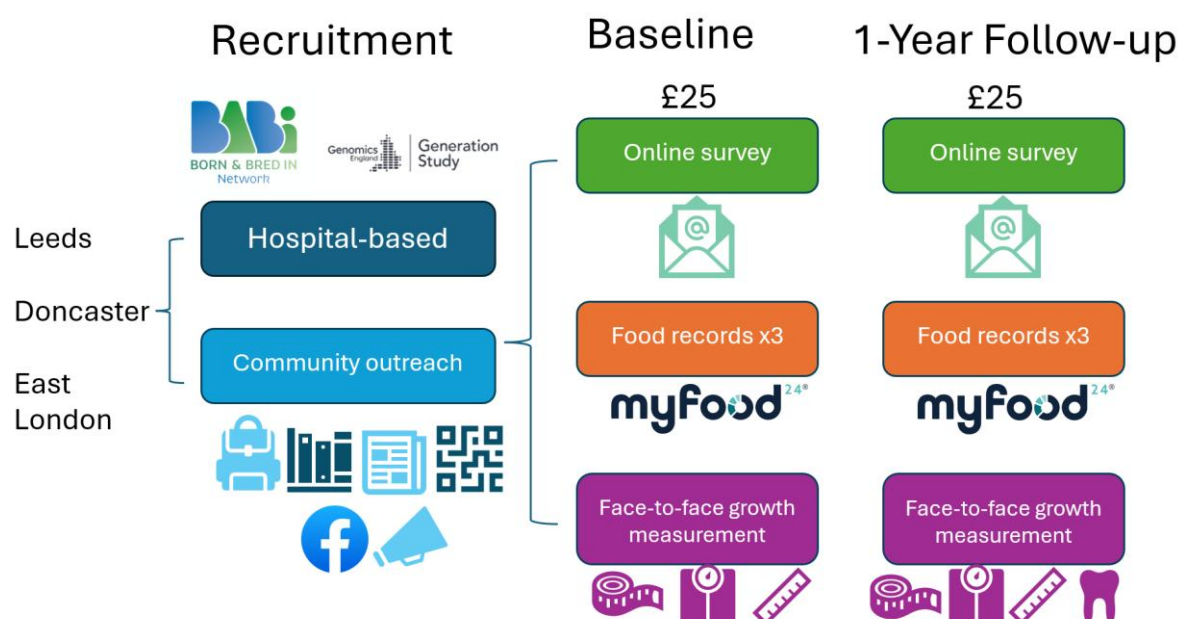
To encourage participant engagement throughout the study, prize draws may be introduced at various points. These may be used in response to factors such as lower-than-expected completion rates, scheduling challenges, or other operational considerations. Any prize draw will be clearly communicated to participants and designed to encourage timely and complete participation while maintaining voluntary involvement. Examples of prize draw communications can be found in **Appendix E**. To support inclusion and accessibility, either in-home visits or reimbursements for taxi travel will be offered for up to 20% of the total sample for those who face barriers attending clinic appointments. Data collection (survey/food records) for those without internet access or language barriers will be facilitated by research teams.

We anticipate ~71% retention rate, from 1,890 to 1,350 participants. This is realistic based on our previous work in Bradford where we achieved 84% retention over multiple visits.

If funding is secured, saliva samples may be collected at baseline and follow-up for microbiome and epigenetic analysis. This addition would be subject to approval via an ethics amendment. To minimise participant burden, the research team will only collect data essential to answering the research questions. The study is designed to be as concise and sensitive as possible. As a token of appreciation, participants will receive up to £50 of shopping vouchers per child for full participation at both stages (baseline and follow-up), with partial participation compensated on a pro-rata basis. An overview of the data collection process is shown in **Figure 2**:

For each stage of the study, up to 3 reminders will be sent. Example texts are provided in the **Appendix E**.

Figure 2. Data collection process of the Growing Well Study



PAYMENTS

Participants will receive payments as a token of appreciation in the form of shopping vouchers for their time and to help maintain engagement throughout the study. The total amount a participant can receive will depend on the extent of their participation, with a maximum of £50 available upon full completion of all study components. Partial participation will be compensated on a pro-rata basis.

Baseline and follow-up:

- £10 for completing the questionnaire, booking an appointment, and completing the first food record.
- £15 for attending the appointment and completing the additional two food records.

Members of the PPIE group will be compensated in line with NIHR guidance. Tasks requiring up to half hour of involvement will be compensated at £25, with additional time paid proportionally. These payments will also be issued via shopping vouchers.

This payment structure is designed to recognize participants' and contributors' time and input while supporting retention and meaningful involvement throughout the study.

Participants attending measurement appointments at leisure centres may be offered a complimentary one-week leisure centre pass, if such passes are made available by the centres

EXPOSURE: DIETARY INFORMATION

Dietary intake will be assessed at baseline and again at 12-month follow-up using the validated Myfood24 dietary assessment tool(32), developed with funding from the Medical Research Council(33). Myfood24 includes a comprehensive database of over 120,000 UK-specific generic and branded food items, including commercial baby and toddler foods (e.g., Ella's Kitchen, Kiddylicious), follow-on milks, and food outlet options.

Over the whole population, the sample and within-person data collection reflects a 8-month period, with 5,670 days of intake estimated at baseline. Both weekdays and weekends will be represented, with at least one recall capturing weekend intake. Parents will be asked to maintain their usual feeding practices on recall days to ensure accurate representation of typical dietary patterns.

To support accurate and user-friendly data collection, we will develop a short instructional YouTube video, co-designed with input from our PPI group, to guide parents or guardians through the process of completing Myfood24 for their children, including how to report out-of-home food consumption. Support personnel will be available to assist people who do not speak or fully understand English, as well as those with internet barriers or with any questions or technical issues. Student researchers (e.g., undergraduate or postgraduate students) will provide remote support to participants who experience difficulties completing the food diaries. This support will be delivered by telephone and will include filling in the food diary on behalf of the parent/guardian. All student researchers will receive structured training from senior research staff in study procedures, data protection, and communication with families. Phone support will be conducted in accordance with the study's confidentiality and data-handling protocols. Additionally, for participants who request it, we will provide paper versions of the food diaries by post or copies by email. Participants will have the option to return the completed diaries by post, email, or during their next scheduled contact with the research team (**Appendix I**).

After submitting a food record, participants will receive a thank-you email containing a link to a brief online questionnaire hosted in Online Surveys with additional questions about the day of food consumption (**Appendix J**).

To capture intake of infrequently consumed foods, a brief food frequency questionnaire will be included in the online survey. For children who attend nurseries, childminders, or other childcare settings where food is provided, an 'out-of-home' dietary questionnaire will be distributed by post (with the Welcome to the study letter and 1 year after) (**Appendix K**). Parents will be asked to share this with childcare providers to collect relevant dietary information in paper. Childcare providers will then be instructed to deliver the paper record to the parents/guardians who will later enter this data on the food record online.

The University of Leeds will oversee the coordination of dietary data collection, including contacting participants by email to fill in their records, provide reminders, and offer support as needed. These activities will be further supported by the RDN and NoCLoR teams.

Based on the collected data, we will determine dietary patterns and quality (e.g. vegetarian, vegan, non-dairy diets, intake of processed foods, etc.) and estimate the following:

1. **Usual nutrient intake** of main macro and micronutrients: dietary energy, proteins, fats (monounsaturated, polyunsaturated, and saturated), carbohydrates, free sugars, fibre, iron, and vitamin A, among others.
2. **Usual key food groups intake** (e.g. starchy foods, fruit, vegetables, dairy, animal proteins, plant proteins, mixed meals, drinks, low or no calorie sweeteners, and snacks)
3. **Age- and gender-appropriate portion sizes** for key food groups.

OUTCOMES

This study has two outcomes, assessed at both baseline and follow-up: 1) Child Growth
2) Child's Dental Health

1. Child Growth

Child growth will be assessed using standardised anthropometric measurements and interpreted using the UK-WHO growth charts for ages 0–4 and 2–18 years (34,35). The primary growth outcome will be weight-for-height/length. Secondary growth outcomes will include length/height-for-age, weight-for-age, waist circumference, waist circumference-for-height, and Body Mass Index (BMI)-for-age, each expressed as

percentiles or Z-scores, except for waist circumference and waist circumference-for-height, which will be reported as continuous variables.

In children aged less than 2 years, nude body weight (Class III medically approved electronic baby scale), recumbent length (infantometer) and umbilical waist circumference (anthropometric tape) will be measured. In those aged 2-5 years, we will measure body weight (Class III medically approved electronic scales), umbilical waist circumference (anthropometric tape), and standing height (paediatric stadiometer). Regarding waist circumference, if the child is under 1 year of age, the measurement will be taken in a supine position. If the child is 1 year or older, the measurement will be taken standing with assistance if necessary.

All measurements will be taken in duplicate, with the mean value used for analysis. More information on the measurement protocols can be found in **Appendix L**.

2. Child's Dental Health

Dental health will be assessed at follow-up only, due to the time required for caries to develop into dentinal lesions (typically 2–3 years)(36). The primary dental outcome will be prevalence of dental caries. The assessment will follow the National Dental Epidemiology Programme methodology, including a visual-only examination by trained and calibrated dental examiners, using the dentinal cavitation (d_3mft) as diagnostic threshold. Each erupted tooth will be assessed individually, and caries data will be summarised at the child level using the decayed, missing, and filled teeth ($dmft$) index.

The visual dental examination will be conducted using a mirror and either gauze or a toothbrush to gently clear any food debris or plaque from the teeth surfaces, if present. This ensures unobstructed visibility of the teeth. The examiner will ask the child to open their mouth and then inspect the teeth using the mirror and a light source. This non-invasive procedure is designed to be quick and comfortable for the child. The assessment will involve counting the presence of teeth, identifying if plaque is present, recording any blemishes in the enamel, and presence of decay. It is possible that the dental examiner will also collect a small sample of plaque or saliva, but this would be subject to future amendments if funding is secured.

Presence of plaque, sepsis and enamel defects associated with dentinal cavitation will be secondary outcomes and recorded as per the National Dental Epidemiology Programme methodology.

The dental examination will take approximately 5 minutes per child, with an additional 5 minutes for data verification.

COVARIATES

To account for potential confounding in our analyses, we will collect detailed information on a range of covariates related to the child and household environment. These include sociodemographic characteristics of the household (e.g., governmental benefits, parental education and occupation), parental anthropometrics (height and weight), cooking practices, and the child's exposure to second-hand smoke. Additional variables include the child's history of allergies, birth characteristics, general health status, screen time, physical activity levels, sleep duration, dental hygiene habits, parenting styles, and eating behaviours. These covariates were selected based on their potential to influence the exposures and outcomes of interest and will be used to adjust statistical models according to Directed Acyclic Graphs.

8. STATISTICAL CONSIDERATIONS

SAMPLE SIZE CALCULATION

1,890 children at baseline with 1,350 follow-up, allows estimated intakes and portion sizes to good precision. Based on data from DNSIYC and NDNS, this supports estimates of daily intake of fruit and vegetables (excluding potatoes) to $\pm 5\text{g}$ with a sample size of $n=250\text{--}300$. Across 5 distinct year groups this would be $\sim 1,500$, and permit stratification by standard demographic characteristics. This level of precision would feed through to contributing portion sizes.

STATISTICAL ANALYSIS PLAN

The study will have two analysis points. The first will be cross-sectional associations using baseline data collection. The second after 12-month follow-up, exploring changes over time in diet, portion sizes, and anthropometry. Detailed information on diet will allow us to assess impact of the following on growth over a 1 year period and dental health:

- Free sugars from fruit juice/smoothies/purees; yoghurts; sugary drinks and follow-on milks
- Commercially manufactured foods and drinks marketed for young children
- Low/no calorie sweeteners
- Saturated, mono and polyunsaturated fats
- Dietary fibre
- Animal vs. vegetable protein
- Vegetarian, vegan and non-dairy dietary patterns
- Suboptimal micronutrient intakes (including iron, vitamin A and vitamin D).

In addition, eating habits such as grazing-style, picky eaters and when food is consumed, e.g. last hour before bedtime and routine drinks overnight, will be evaluated.

Task 1. Evaluate diet cross-sectionally at baseline in relation to anthropometric outcomes.

The focus will be on:

1. Nutrient intake: energy, protein, fats – saturated, monounsaturated, polyunsaturated, carbohydrate, free sugars, fibre, iron and vitamin A.
2. Diet quality: processed food intake, low or no calorie sweeteners, vegetarian, vegan, non-dairy diets.
3. Measured food portion sizes for key food groups: starchy foods, fruit, vegetables; dairy foods; protein foods; protein- or starch- based mixed meals; drinks (including fruit juice and milk), and snacks.

Baseline diet will be linked to anthropometry – height, weight, waist circumference.

Portion sizes appropriate for age/gender for key food groups listed above will be characterised using linear mixed effects modelling using the dietary survey data for specific foods/food groups in relation to the child's position on the growth chart centiles.

As every child is growing at a different rate, we will provide a range of optimal portion sizes matching 3rd to 97th percentiles on the growth charts. In characterising portion sizes, a holistic data-led approach will be taken so that portions will not simply be based around the 'average' intake but consider optimal growth, observed nutrient intakes and existing food recommendations for good physical and dental health. For instance, if we observe excessive total and free sugar intake (>5 or 10% of energy intake) or excessive protein intake (>15% of total energy) we will recommend realistic portions based on typically consumed foods, at reduced volumes rather than based on mean consumption or consumption among those in the upper-range for growth. Similarly, if we observe generally low vegetable intakes, recommendations may be based on those with intakes at the upper end of the scale; taking into consideration micronutrient intakes. Furthermore, as recommended in a recent qualitative study, parents will be involved in portion size recommendations which will reflect between and within child intake variability(15).

Task 2. Evaluate diet in relation to follow-up measures of anthropometry and dental health.

The focus will be on:

1. Nutrient intakes (as above) at baseline and changes
2. Diet quality (as above) at baseline and changes
3. Food portion sizes (as above) at baseline and changes

Baseline and change between follow-up diet measures will be linked to anthropometry – height, weight, and waist circumference. Portion sizes appropriate for age/gender will be modelled using linear mixed-effects modelling of growth trajectories based on results from the dietary survey data for vegetables/fruits/fruit or juice/milk in relation to the child's change in position on the growth chart centiles as described above. Baseline and changes in diet will be linked to dental health at follow-up. Associations will be explored with dental health categorised as both dichotomised (e.g. caries, no caries) with logistic regression and count data (dmft) with Poisson regression.

A mixed effects modelling framework will be used allowing for potential non-independence in the data, such as children from the same nursery or family. Covariate adjustment will be guided by directed acyclic graphs.

Task 3. Stratification by age, gender, ethnicity and low income.

We will be able to undertake stratified analysis exploring food/nutrient intakes with growth trajectories and dental health by age (6 months - 5 years), gender (girl/boy); ethnicity (Asian/Black/White/Other, Mixed); and deprivation level (low/high).

Task 4. Contribution of commercial foods to energy and nutrient intakes (e.g. total sugar) and comparison to UK reference standards, the WHO Nutrient and Promotion Profile Model for commercial babyfoods (37) and child foods(38).

Our expertise(37), with detailed information on commercial foods sold for children will allow us to study the impact of these products on anthropometry and dental health. Exploration of child eating traits, fussiness (including avoidant restrictive food intake disorder) and parenting styles will support understanding of why children are given follow-on milks and high sugar commercial baby foods. Linking foods consumed to satiety responses and child hunger measures.

All statistical analyses will be conducted using Stata version 19 (StataCorp LLC, College Station, TX, USA) and R software.

9. ETHICAL AND REGULATORY CONSIDERATIONS

The protocol complies with all relevant legal, ethical, and governance requirements, including those related to informed consent, data protection, and participant safety. Approval to conduct the study will be sought through the appropriate NHS Research

Ethics Committee and Health Research Authority (HRA) processes, ensuring full regulatory compliance.

ASSESSMENT AND MANAGEMENT OF RISK

This study is observational in nature and poses minimal risk to participants. In summary, the main risks associated with this study are potential breaches of confidentiality, participant burden, the possibility that children may feel distressed by measurement procedures, the possibility of incidental findings and the possibility of feeling distressed by some personal or sensitive questions.

Potential risks and burdens will be carefully managed in the following approaches:

1. Use of identifiable data:

The study involves the use of identifiable information for the purposes of participant recruitment and follow-up. To minimise any risk, we will ensure full compliance with the Data Protection Act 2018 and the University of Leeds Data Protection Policies. At the University of Leeds, all personal, identifiable, and sensitive data will be securely stored in LASER. After pseudonymisation with a numeric code, we will store data using an access-controlled and project-specific SharePoint, with additional safeguards in place to prevent copying and sharing of data. At NatCen, information will be stored in a secure network drive folder, access-controlled, project-specific, accessible only to restricted individuals. At the NHS Trusts, identifiable data will be stored using secure NHS-approved data storage facilities that comply with national data protection standards and information governance protocols. Identifiable data will be shared either by BISCOR or GlobusFTP. Data shared for analysis and reporting will be fully de-identified. Participants will be informed of their rights, including the ability to withdraw from the study at any time without consequence or to modify their consent preferences.

2. Reluctance of children to be measured or assessed:

Some children may feel uncomfortable being measured by fieldworkers or assessed by dental examiner (dentist or dental therapist). To address this, all NatCen fieldworkers involved in the study are trained in working with children and are experienced in conducting non-invasive measurements in a respectful and sensitive manner. If a child expresses reluctance to participate in measurements or assessments, they will not be pressured. Dental examiners will also be trained and will have experience of undertaking dental assessments with young children.

3. Participant burden from questionnaires or interviews:

The study includes a range of questions, some of which may be personal or sensitive. To reduce participant burden, only information essential to the research questions will be collected. Questionnaires and interviews will be designed to be concise and administered with sensitivity. As a token of appreciation, participants will receive £50 of shopping vouchers per child for full participation, with partial participation compensated on a pro-rata basis. To avoid excess repeated contacts for non-responders we will set a contact schedule to monitor and limit the number/frequency of contacts. Wishes of anyone wanting to have no further contact will be respected.

4. Incidental findings:

There is a possibility that fieldworkers may encounter concerning observations during clinic and home visits, such as signs of over/undernutrition, poor dental health, neglect, or food insecurity. To address this, fieldworkers will be equipped with a resource sheet to help signpost families to appropriate community or health services.

While this study is not specifically intended to identify safeguarding issues, there remains a small chance that such concerns may arise during clinic/home visits or interactions—for example, signs of coercive control, neglect, or other serious welfare issues. In these instances, the fieldworkers will follow NatCen's comprehensive Safeguarding Procedures which include the Designated Safety Lead determining what action is necessary to protect the child or adult at risk.

There is also a possibility that dental examiners may identify cases of dental decay during the assessment. In such instances, children will be referred to appropriate dental health services for follow-up care.

5. Distress through sharing personal or sensitive information:

Sharing information about family circumstances (e.g. resources within the home, benefits received, pregnancy/childbirth (e.g. gestation length), or infant feeding practices (e.g. whether the child was fed breastmilk or not) may bring distress or upsetting memories. Participants will have the option not to answer any upsetting or personal questions and the closing statement of the questionnaire and participant information sheet will signpost participants to relevant help organisations.

As for benefits, participants in this study may experience both direct and indirect benefits:

- Direct benefits include the opportunity to receive additional growth measurement visits and a dental assessment. These may provide parents with useful information about their child's growth and oral health.

- Indirect benefits include contributing to research that aims to improve nutritional guidance and health outcomes for young children. Specifically, the study will inform the development of parent-friendly recommendations for portion sizes for children aged 6 months–5 years, with a focus on inclusivity and better representation of minority groups in dietary research.

As mentioned above, as a token of appreciation for their time and contribution, participants will receive up to £50 of shopping vouchers per child for full participation. Partial participation will be compensated on a pro-rata basis.

ETHICAL APPROVAL

Before the start of the study, approval will be sought from a recognised UK Research Ethics Committee (REC) via IRAS. This submission will include the full study protocol, informed consent forms, participant information sheets, and all other relevant documentation and communication materials.

No study activities will commence until a favourable opinion has been granted by the REC. Any substantial amendments to the protocol or study documents that require REC review will not be implemented until approval has been received.

The Chief Investigators will also notify the REC within 90 days of the end of the study. The end of the study will be defined as the completion of any follow-up monitoring and data collection activities as described in the protocol. Within one year of study completion, a final report will be submitted to the REC, including a summary of the study results and any related publications or abstracts.

REGULATORY REVIEW AND COMPLIANCE

Before the start of the study, the Chief Investigators will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on approval from participating organisations are in place and will comply with relevant guidance. These will include the submission of local information packs for the different NHS trusts. For any non-NHS sites involved in the study, we will follow the organisations requirements in terms of seeking the appropriate managerial approval for their involvement in the research.

The study will be conducted in accordance with the approved protocol and relevant ethical approvals. Any protocol amendments will need to be reviewed and approved by the sponsor, who will decide whether an amendment is substantial or not. If the sponsor wishes to make a substantial amendment to the REC application or the supporting

documents, a valid notice of amendment will be submitted to the REC for consideration. The REC will then provide a response regarding the amendment within 35 days of receipt of the notice. Amendments will also be notified to the national coordinating function of the UK country. Any amendments will be submitted through IRAS and communicated to all relevant parties. All protocol versions and amendments will be tracked using a version control table included at the **Appendix M**. Each entry will include the version number, date of release, summary of changes, and rationale for the amendment. The most recent version will be clearly marked and used as the reference for all study procedures.

Protocol compliance

Protocol compliance will be actively monitored throughout the study. All accidental deviations from the protocol will be documented using report forms that meet Sponsor requirements and promptly reported to the Chief Investigators and the Sponsor. Any protocol deviations or serious breaches will be reported to the Sponsor within one working day of being identified by the research team to governance-ethics@leeds.ac.uk. Serious breaches will also be reported to the Research Ethics Committee (REC) in accordance with their specified timelines. Recurring deviations will be reviewed to identify underlying causes and addressed without delay. Repeated or serious non-compliances may be classified as breaches and escalated in line with Sponsor and regulatory requirements. Regular team meetings and ongoing training will support adherence to the approved protocol, and any amendments will be clearly communicated to all study personnel.

INFORMED CONSENT PROCESS

Informed consent will be obtained from the parent or legal guardian of each participating child prior to any data collection through the online questionnaire hosted by NatCen and stored electronically.

Parents or guardians accessing the online survey will be presented with a link to view the Participant Information Sheet (**Appendix B**) and the Privacy Notice after eligibility screening (**Appendix D**), should they wish to review them. After this, the system will guide them to the Consent questions (**Appendix A**), where they can provide informed consent for their child's participation. These materials will clearly explain the purpose of the study, what it involves, how data will be used, and the rights of their child as participant. They will be available in English and translated into key community languages, as identified through consultation with our PPIE group and local community contacts. For parents or guardians who require assistance due to language or literacy barriers, telephone support will be provided to ensure they fully understand the study and can give informed consent voluntarily. Contact details for the University of Leeds

research team (e-mail and phone number) will be displayed within the online system, posters, flyers, and other communication materials, so participants can easily reach out for support. Once a request is received, we will direct it to the appropriate team (either with staff from the University of Leeds, BaBi, RDN/NoCLoR, or local Children's Centre staff), depending on the participant's location and needs. A member of the selected research team will then guide the parent or guardian by phone through the consent form and questionnaire using the same secure online system.

Parents or guardians will be informed that they may withdraw their child from the study at any time, without needing to provide a reason. Upon withdrawal, they will be asked to choose one of the following options:

- Partial withdrawal: No further contact will be made, and no additional data will be collected from their child's health records. However, data already collected will be retained and used.
- Full withdrawal: No further contact will be made, and all data collected about their child will be deleted.

Participants will also be able to change their preferences regarding future contact at any time.

All consent records will be securely stored in accordance with data protection regulations and will only be accessible to authorised personnel.

The BaBi network forms local birth e-cohort studies to link routine data with the aim of improving the health and wellbeing of families through research. The GWS is stand-alone, however, the potential to link all BaBi and Generation Study participants within GWS would enable future record linkage and tracking of health outcomes, making this data even more valuable for health impact. Although BaBi and Generation Study participant data may be accessed in the future, this would not be the case for the rest of the GWS participants.

For this reason, the GWS consent form will include two optional consent items. The first seeks permission to access routine information about the child, such as health or school records, for use in this and future ethically approved linked studies, similar to the approach used in BaBi cohorts. The second seeks permission to access the parent's historical medical records, where applicable (if they are a biological parent). Future linked studies enabled by these optional items may explore associations between early diet, allergies, growth, and child development, as well as associations between parental characteristics and child outcomes. Additionally, we may will also include an optional

consent for parents/carers invited to the study through their nursery or school, to consent for their child to be measured at the school or nursery in the presence of a member of nursery/school staff. This will be provided either by the current online process (consent option A) or as an additional form using consent option B (**Appendix C**).

Since this study addresses a significant gap in UK data by providing rich, contemporary insights into early childhood nutrition, with a sample of nearly 2,000 children—including key underserved sub-groups—this will be the most comprehensive and current dataset of its kind in the UK. These optional consent items ensure that the time and effort contributed by participants continues to inform and advance research, helping to answer emerging questions of public health relevance. Any future access to medical records—enabled by optional consent—would be either part of future linked studies, subject to separate ethical approval, or would have to be addressed through a formal amendment to the IRAS application and reviewed accordingly.

Funding is currently being sought to support saliva collection for microbiome and epigenetic analysis. Written consent would be needed for this so we may include this in a future amendment. Note that as funding is not yet secured for this, we have not included this within the current IRAS. Should this proceed, a substantial amendment would be submitted for ethical approval.

RESPECT FOR PARTICIPANT DIGNITY

All data collection methods have been designed to uphold the dignity and privacy of participants, respecting their non-verbal cues to ensure the child is comfortable particularly with growth and dental measurements. Information will be gathered in a respectful and non-intrusive manner. Participation is entirely voluntary, and participants may withdraw at any time without consequence. Sensitive topics are approached with care, and feedback from the PPI has informed adjustments to ensure cultural sensitivity and appropriateness. Confidentiality is strictly maintained throughout the study.

CONFIDENTIALITY AND DATA PROTECTION

This study will comply with all applicable data protection legislation, including the UK General Data Protection Regulation and the Data Protection Act 2018. The University of Leeds is the data controller for this study and is responsible for ensuring that all data is handled in accordance with legal and ethical standards.

All personal data collected during the study will be managed in line with the principles of data minimisation, purpose limitation, and confidentiality. Participants will be assigned a unique study ID in the online survey hosted by NatCen.

At the University of Leeds, information will initially be stored in LASER, a cloud-based Trusted Research Environment that provides a secure environment for researchers to store, handle, process and analyse sensitive data. Identifiable and sensitive data will be transferred first to a Tier 4 space. After information is pseudonymised using the unique study ID, data will be extracted and kept separately in a Tier 3 space for processing. Administrative data (names and contact information) for operational purposes such as participant follow-up and compensation will be kept in an access-controlled and project-specific SharePoint folder, accessible only to authorized research staff. Additional safeguards will be applied to prevent copying and sharing of data within the SharePoint environment.

During data collection, some administrative data (participant's name, contact information) will be transferred to support ongoing monitoring of recruitment and to enable feedback to the NHS team regarding participants already recruited from their contact lists, and those with support needs (**Figure 3**). Administrative data will be shared for specific, ethically approved purposes. Data sharing will be limited to the minimum necessary for each activity.

The research team is fully trained and compliant with the University of Leeds Data Protection Code of Practice and the Research Participant Privacy Notice. All participant data will be pseudonymised for analysis, and it will not be possible to link it back to identifiable personal information.

The RDN and NoCLoR will store all research data within secure NHS-approved data storage facilities that comply with national data protection standards and information governance protocols.

NatCen has well-established procedures in place to obtain, process, analyse, store, archive and eventually dispose of data securely while ensuring that participants' confidentiality is maintained. It is also fully accredited to ISO 27001 (information security (IS)) and is subject to annual external audits of our procedures to maintain this accreditation. It is also accredited to ISO 20252, which covers quality specifically in the social research industry. Every project that involves the collection, storage or processing of personal data in NatCen has its own data security plan, which details all the data security procedures to be applied on that project. Additional security provisions are in place for the processing and storage of personal data which are handled by named

individuals within the Secure Research Drive. All data collected by NatCen through the online questionnaire and the in-person visits (clinic/home) for the Growing Well Study will be stored in a secure access-controlled, project-specific network drive folder. NatCen will share identifiable information with the University of Leeds for the purposes of monitoring recruitment and follow-up activities, as well as for final data delivery at both baseline and follow-up stages (**Figure 3**). Additionally, NatCen will share limited contact information (participant's name, serial number, and either phone number, email address, or both) with a third-party UK GDPR compliant software platform (YouCanBookMe) to manage the bookings for clinic visit appointments.

Any data sharing between partners (University of Leeds, NatCen, NHS team, or RDN teams) will follow strict data-sharing agreements and will that only the minimum necessary data are transferred.

Regarding Myfood24, the platform is UK GDPR compliant. The University of Leeds will upload to the Myfood24 site lists with the parent's or guardian's e-mail, codes and names to send email invitations to complete the food records online. Once the data is submitted, only the University of Leeds research team will have access, and it will be downloaded directly to LASER Tier 3.

The University of Leeds Online Surveys service that will host the post-food record and mid-way questionnaires, is operated by Jisc, is also ISO27001 certified and hosted on AWS in the Republic of Ireland. It uses SSL encryption for all data transfers, enforces least-privilege access controls, and conducts regular vulnerability scans and penetration testing. Jisc staff follow strict secure working practices and receive data security training. Backups are encrypted and retained for a limited period, and the system is protected against DDoS attacks using AWS Shield and CloudFront.

Data retention and destruction will follow the schedule below:

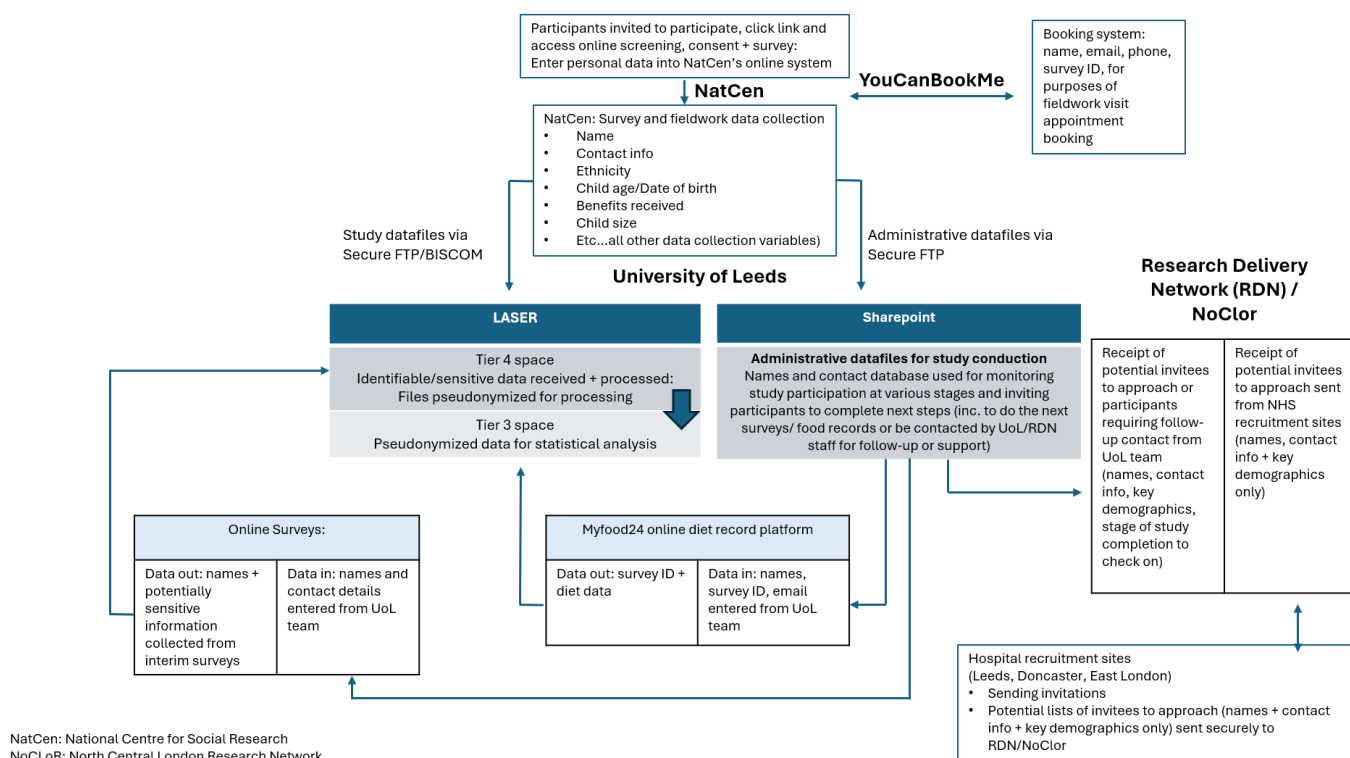
- Participant contact details and participant-generated data will be retained for 10 years after study completion (until March 2038) and then securely destroyed at the University of Leeds. For NatCen, RDN, and NoCLoR, data will be destroyed after 6 months of the end of the study.
- Datasets and consent forms will be stored in an identifiable manner for same duration and then electronically destroyed.
- Any paper records (if used) will be scanned and then shredded to ensure anonymity and reduce the risk of disclosure.

No identifiable data will be published. Any reporting or dissemination of findings will use anonymised, aggregated data to ensure participant confidentiality.

For further details, please refer to:

- **Appendix M: Data Management Plan**
- **Appendix N: Data Protection Impact Assessment (DPIA)**

Figure 3. Data flow between organisations



ACCESS TO THE FINAL DATASET

Access to the final study dataset will be limited to the Chief Investigators, designated members of the research team, and the study Sponsor. All individuals with access will be named in the data management plan and will have appropriate training in data confidentiality and security. Site investigators or collaborators may request access to the full de-identified dataset by submitting a formal request outlining their intended use, which will be reviewed by the Chief Investigators and Sponsor. Any secondary use of the dataset will require prior ethical, as reflected in the participant information materials.

DISSEMINATION POLICY

The data arising from this study will be owned by the Chief Investigators and the Sponsor. Upon completion, the data will be analysed and tabulated, and a Final Study Report will be prepared. This report will be made available and may be published in peer-reviewed journals and presented at relevant conferences. Participating investigators may request access to publish study data, subject to review and approval by the Chief Investigators and Sponsor. Any publications will acknowledge the NIHR as the funding body, and the NIHR will be informed of all planned dissemination activities in line with their requirements. Participants will be informed of the study outcomes through a summary newsletter, visual story, or presentations. The study protocol, anonymised participant-level dataset, and statistical code may be made publicly available following publication.

AUTHORSHIP ELIGIBILITY GUIDELINES

Authorship on the final study report and any resulting publications will be determined in accordance with the criteria established by the International Committee of Medical Journal Editors (ICMJE).

10. PEER REVIEW

This study underwent rigorous peer review as part of the NIHR funding application process. The proposal was assessed by an independent review panel with relevant subject matter expertise, who provided detailed feedback on the study design, methodology, and feasibility.

11. MONITORING AND OVERSIGHT

This is an observational study involving the collection of questionnaire data, anthropometric measurements, and dietary records from participants. Oversight will be proportionate to the study's low-risk nature, while ensuring adherence to ethical standards and data protection regulations.

The University of Leeds is the study sponsor and data controller, responsible for the overall conduct of the study, including data governance, participant safety, and compliance with the approved protocol. The study will be managed by the University of Leeds in collaboration with NatCen, who will act as a data processor on behalf of the University. Online and in-person fieldwork activities, including collection of consents, online survey data and body measurement data will be led by NatCen. NatCen are programming an online survey linked to a third-party booking system software for scheduling clinic appointments. NatCen fieldworkers will be staffing clinics and

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conducting subsequent home visits. Dental examiners conducting oral health assessments will be employed by the University of Leeds. There is also a collaboration agreement in place with Queen Mary University to cover the roles of Academic and Research staff within this project and any data sharing arrangements. In the case where London-based dental examiners need to be employed through Queen Mary University, we will ensure contracting and data sharing agreements are appropriately in place.

Standard operating procedures will be followed for all data collection activities. Fieldworkers will be trained and supervised to ensure consistency and protocol compliance.

A PPI group will provide ongoing input into study materials, recruitment strategies, and participant experience. Their contributions will be documented and reviewed regularly.

Insurance and indemnity

The University of Leeds has insurance cover in force, which meets claims arising from death or injury, which are brought against the University and where those claims arise from the Universities own negligence in its role and activities relating to the study (and which is subject to the terms, conditions and exceptions of the relevant policy). Clinical negligence indemnification will rest with the participating NHS Trust under standard NHS arrangements. NatCen will also have indemnity in place covering their activities in fieldwork and data collection.

Safety reporting procedures

If a safety issue arises during measurement visits, such as a child sustaining an injury (e.g., rolling or falling from a table), NatCen will be required to notify the study team immediately. Any incident or adverse event related to the study procedures will be reported to the sponsor to governance-ethics@leeds.ac.uk within 1 working day of research team awareness.

12. PUBLIC AND PATIENT INVOLVEMENT

We have two PPI co-applicants, Rebecca Spencer (RS) and Elizabeth Doxford-Hook (EDH). They have been involved throughout the study development process, attending team meetings and providing feedback which has enhanced the proposal. RS is a Obstetrician working at Leeds General Infirmary and she leads the 'Peas in a pod' PPI group, allied with Babi Leeds and represents views of potential study participants. EDH is a PhD candidate at University of Leeds and an Obstetrics and Gynaecology specialist registrar. She leads the post-partum pelvic floor PPI group which she founded. She is also

a parent to a child in the age group who is a picky eater and brings her personal experience of this to the group.

The Co-PI Dr Threapleton also has 2 children in the study age bracket and as such provides an important point of reference as to what is practical for families with young children. Dr Threapleton has also reached out to her network of parents with young children who follow plant-based diets in Leeds (identified for a separate study) and to her peers (parents with children aged 1-5 years) to provide input to this proposal.

Volunteers identified through contact with the 'Peas in a Pod' group and Dr Threapleton's network of parents have helped to develop this proposal, shaping plans for recruitment, data collection, and engagement. Volunteers contributed to study design, including through attending an informal seminar where they learned about the study, asked questions, and provided suggestions. Suggestions from volunteers focussed on ways to engage and recruit participants and how best to maintain a sense of community co-ownership of the study and findings.

The study design was updated to reflect feedback. We have increased the participant incentive to £50. We have also made provision for data collection at convenient community locations such as Children's centres and nurseries and have planned a series of participant and community engagement activities. These include a Facebook study participant community group, newsletters, and workshops/open-days at key locations where families can play and learn more about the study objectives and findings.

A Participant Advisory Group was established, comprising eleven mothers recruited from local nurseries in Leeds and via VOICE. The group has already provided valuable input on improving the Participant Information Sheet, consent form, the relevance of requesting participants to bring their Red Book, engagement with ethnic minority communities, and the sensitivity of the baseline questionnaire. Additionally, two of them volunteered during the pilot study and provided valuable feedback that led to modifications in the baseline questionnaire and logistical arrangements.

Additional collaboration with this group will include co-designed participant-facing materials and outputs, and insights on building and maintaining relationships with target audiences. Specific tasks will include among others:

- Co-designing mid-way and follow-up questionnaires
- Involvement in community outreach activities
- Designing a YouTube video for participants using Myfood24 (completed)
- Feedback on the YouTube video for recruitment (completed)

- Workshop to translate findings into user-friendly materials for wider dissemination.

Representatives from the Parent Advisory Group and our two PPI Co-Is will also be part of the project Steering Committee, meeting every 6 months of the project.

In line with NIHR guidance, our payment policy will recognise PPI contributions and ensure no one is out of pocket or excluded from participation. Childcare and travel costs/milage/parking will be covered (up-front where necessary) for in-person meetings and dissemination activities. Payment will be made for tasks such as reviewing documents, providing feedback, or attending meetings. Support will be provided to those in receipt of welfare benefits to ensure payments do not affect benefits.

Feedback will be sought to evaluate PPI activities during the project to help us improve and address any issues of concern.

The project team and parent advisory group will undertake training to unlock their potential and enhance their experience, getting the most out of study PPI activities. The freely available online 4-week course 'Public Involvement training' from Imperial College London will be offered and is suitable for researchers and the public.

13. DISSEMINATION AND OUTPUTS

Policy / academic dissemination:

- Reports to the funder (NIHR) summarising methods and findings
- Guidelines for age-appropriate food portion sizes will be prepared for relevant stakeholders/policy makers
- Policy briefing documents detailing general population and population subgroup behaviours/risks in relation to health outcomes will be prepared for stakeholders/policy makers
- Publications (study protocol and study results) in scientific journals (open access where possible)
- Presentations at relevant academic/health conferences in the UK or internationally

Participant / community dissemination:

- Community outreach events and study participant family events will be held to disseminate study methods and findings in an accessible way.

- Participant newsletters: A 3-monthly newsletter will be circulated among study participants, keeping them informed of progress, findings and relevant community outreach events in their area.
- Study Website: Progress and findings will be published on the Growing Well Study website.
- Visual storytelling/infographics will communicate key findings to participants (parents/children) and parents of young children (co-designed with PPI).
- We will launch a social media campaign to promote the study and share findings (e.g. Growing Well Study Facebook group and Instagram) and prepare tailored content for strategic partnership organisations and consumer stakeholder groups of relevance (e.g. child, dental health, nutrition).

Who will benefit:

- Parents/carers of young children will have greater confidence in how they feed their children.
- Children will form healthier eating habits.
- Policy makers will take evidence generated in this study into practical policies guiding healthier eating in preschool children, informing national guidelines, linking food and nutrient intakes with improving child oral health and allowing dentists to provide clearer guidance.

Longer-term impacts: Diet recommendations based on current nutrient intakes and growth in preschool children will have long-term impacts for health policy (national and for marginalised groups), ultimately supporting improved nutrition and minimising inequalities in health. Through linkage to the BaBi network and through seeking consent for potential future data linkage, we can explore longer-term (over years) associations between pre-school nutrition and growth with dental/health outcomes over time.

Dissemination of outputs and impact

Informing and engaging key audiences:

- Policy makers: through our ongoing stakeholder and political engagement activities around diet in young children. Findings will be disseminated via our established networks (academics, charities, non-government organisations, professional organisations including Royal College of Paediatrics and Child Health, Institute of Health Visiting, Professional Association of Childcare and Early Years, National Children's Bureau, BDA) and directly with government departments (Office for Health Inequalities and Disparity (OHID)), local authorities and politicians using our existing lines of communication. We will also

disseminate findings through our WHO Collaborating Centre in Nutritional Epidemiology, facilitating impact for international audiences.

- NHS, social care organisations: guidelines for optimal nutrition for growth, good dental health and appropriate age-based portion sizes will be shared with a range of public health organisations (eg. NHS, OHID, Food Standards Agency, non-governmental organisations).
- Food industry: commercial foods contribute significantly to early years diets. Changes in product composition will be encouraged through our recommendations. We will share these with industry facing organisation such as the British Nutrition Foundation and Institute of Grocery Distribution.
- Participants will be informed of the study results in accessible and engaging formats once data collection and analysis are complete. This project will generate a range of outputs aimed at different audiences, including policymakers, professionals, and study participants. We will ensure participants are kept informed through the following channels:
 - Community outreach events and study participant family events will be held to disseminate study methods and findings in an accessible way.
 - Participant newsletters: A 3-monthly newsletter will be circulated among study participants, keeping them informed of progress, findings and relevant community outreach events in their area.
 - Study Website: Progress and findings will be published on the Growing Well Study website.
 - Visual storytelling/infographics will communicate key findings to participants (parents/children) and parents of young children (co-designed with PPI).
 - We will launch a social media campaign to promote the study and share findings (e.g. Growing Well Study Facebook group and Instagram) and prepare tailored content for strategic partnership organisations and consumer stakeholder groups of relevance (e.g. child, dental health, nutrition)

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15. APPENDICES

These appendices are provided as separate documents and should be read in conjunction with this protocol.

APPENDIX A. CONSENT FORM

APPENDIX B. PARTICIPANT INFORMATION SHEET

APPENDIX C. ADDITIONAL CONSENT FOR MEASUREMENTS IN NURSERY/SCHOOL

APPENDIX D. ELIGIBILITY SCREENING QUESTIONNAIRE

APPENDIX E. PARTICIPANT-FACING COMMUNICATION MATERIALS

APPENDIX F. SCHEDULE OF PROCEDURES

APPENDIX G. BASELINE QUESTIONNAIRE

APPENDIX H.1 CLINIC VISIT QUESTIONNAIRE

APPENDIX H.2 CLINIC VISIT SUPPORT QUESTIONNAIRE

APPENDIX H.3 CHILD EATING BEHAVIOUR QUESTIONNAIRE, PAPER COPY

APPENDIX I. PAPER-VERSION FOOD DIARY

APPENDIX J. POST-FOOD RECORD QUESTIONNAIRE

APPENDIX K. OUT-OF-HOME FOOD RECORD SHEET

APPENDIX L. MEASUREMENT PROTOCOLS

APPENDIX M. PROTOCOL AMENDMENT HISTORY

APPENDIX N. DATA MANAGEMENT PLAN

APPENDIX O. DATA PROTECTION IMPACT ASSESSMENT (DPIA)