Project reference no: NIHR129771

Family Food Experience Study – London

(Formerly Kids Will Eat Better study)

Study Protocol Version 6 (Dec 2021)

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The Family Food Experience study – London (FFES-L): how can local authorities improve the efficiency and effectiveness of interventions to address inequality in childhood obesity?

Background and Scientific Rationale

England faces a severe problem of inequality in child obesity: the prevalence of childhood overweight/obesity in the most deprived neighbourhoods (as defined by the Index of Multiple Deprivation, IMD [1]) is over double the least deprived [2]. Analysis suggests that improving diets as well as physical activity, will be vital to addressing these inequalities [3]. Poverty and deprivation are associated with unhealthy diets among young people [4,5]. Eating habits and food preferences are shaped in infancy and early childhood, and track into later adolescence and adulthood [6-9]. Poor quality diets in turn have a major impact on children's growth and development, including their weight, which typically 'tracks' through the life course [6]. Overweight/obesity have major negative implications for children's short- and long-term health.

Inequality in overweight/obesity and diet exists despite at least 15 years of government action to improve child diets nationally and locally [10]. National policies include restrictions on broadcast advertising of foods high in fats, sugars and salt; the School Fruit and Vegetable Scheme; Healthy Start; school food standards; and Change4Life. Since 2016, national government has had a Childhood Obesity Plan (Chapters 1 and 2) aiming to significantly reduce England's rate of child obesity and "the health inequalities that persist" [11]. Chapter 2 called for action by local authorities. Actions by local authorities to date include certification schemes for food outlets; sugary drink campaigns; planning restrictions on takeaways, and "whole system" approaches [12-15]. Actions by NGOs include programmes for disadvantaged groups, like *A Better Start* [16], fruit/vegetable vouchers [19] and food bank schemes. Food companies now also have healthy eating campaigns, sugar reduction initiatives and fruit/vegetable promotions [18,19].

Despite these interventions, inequality in overweight/obesity is growing [20]. This growth in inequality reflects continued increases in the most deprived areas, combined with declines in the least deprived [21]. Thus emerges a key question: why has the combination of existing policies and interventions (i.e. 'actions') that have been implemented at multiple levels by multiple actors not been more effective in tackling inequality, and how could they become more effective?

There is a range of plausible, multifaceted, reasons why existing actions appear not to have effectively tackled inequality. The first set of reasons relates to the **context of implementation**: despite the combination of interventions that have been rolled out over recent years, there are a wide range of implementation challenges [12]. PPI during the development of this proposal showed that funding, capacity and political commitment to deliver at scale can be lacking. The second set of reasons relates to the **contexts of deprivation - the realities of people's lives.** The published evidence - and the PPI for developing this proposal - indicates that three particular aspects of context may undermine the effectiveness of existing actions:

- *Local food systems* in deprived communities do not tend to make healthy diets available, affordable or appealing [22]. For example, there are more hot food takeaways in these neighbourhoods, resulting in local children tending to eat more of these less healthy options; or higher concentrations of convenience stores making unhealthier food options a more convenient choice for lower-income households experiencing increasingly busy and complex lives [23,24]. The same applies in specific food sub-systems like schools, where a healthy meal is reported to be unaffordable with the free meal allowance and where fresh water may not be freely available [25]. Within food retailers, foods high in salt, fats and sugar are often prominently placed or marketed [26] and children are surrounded by advertising on billboards [24].
- *Socioeconomic conditions* like financial insecurity, unstable employment patterns and long working hours create competing pressures, making harder for families to prioritise healthy diets [25,27,28]. Poor quality housing and food preparation spaces exacerbate challenges in preparing food [24]. Financial stress also lowers the psychological resources needed to navigate these challenging circumstances and unhealthy environments [29]. These pressures are present in millions of families in the UK; an estimated 14.3 million people live in poverty,

including 4.6 million children [30] and an estimated 2.5 million children live in households unable to afford the full variety of foods needed for a healthy diet [25].

- *Learned cultural norms* among parents shape home food environments, including their own eating habits and child feeding practices. Early home environments have a major influence on emotional overeating (eating in response to negative emotion), food responsiveness (compulsion to eat in response to the sight, smell or taste of energy dense foods regardless of hunger level), and preference for energy dense foods/drinks [31,32]. Emotional overeating emerges in early childhood and appears to be significantly shaped by parents offering food to soothe their child ('emotional feeding') [33] and to reward/control behaviour ('instrumental feeding') [34], while food responsiveness is linked to excessive restriction of energy dense foods [35]. In the other direction, there is a wealth of evidence that repeated exposure to vegetables in a positive, supportive environment with non-controlling feeding practices enables healthy preferences [36]. There are indications feeding norms matter for inequalities; a recent study found that children from more deprived backgrounds had greater increases in 'food responsiveness' and 'emotional eating' from toddlerhood to early childhood [37]. It also makes sense that families fearful of food waste are less likely to feed their children vegetables given children need to be repeatedly exposed to these foods up to 15-20 days in a row before acceptance. However, there is a gap in substantial evidence in this area.

Each of these contexts could plausibly undermine the impact of existing actions designed to improve food environments. For example, a child offered healthy food at nursery may be less willing to eat it if never exposed at home; advertising restrictions may be rendered less effective by the convenience of local chicken shops; restricting in-store promotions maybe undercut by family food culture. These contexts may also combine to undermine impact. Evidence that different aspects of context interact is indicated by research that socioeconomic position (SEP) interacts with psychosocial factors [29], women's psychological resources influence how they interact with store food environments [38] and adults with less education are more susceptible to exposure to fast food outlets [39-40].

There have been a range of recent systematic reviews on the effect of childhood diet and obesity interventions [41-45]. There is very limited evidence of impact on inequality, and results show mixed effectiveness [42]. Two reviews indicate "upstream" community-based and structural strategies are more likely to be effective in lower SEP participants than information-based [41,43] but another was unable to identify the same pattern [42]. A review of family/school nutrition programs found dietary impacts limited, suggesting complementary interventions are needed [44]. The most recent Cochrane review from 2019 concluded that "there is no evidence that interventions that only focus on diet are effective" among children in reducing obesity [45]. However, these reviews are drawing their conclusions largely from an evidence base of studies on single interventions in isolation. The reviews reveal a major gap in the types of studies that have been done: no studies assess how combinations of contextual factors affect how families of lower SEP engage with, or respond to, interventions. Moreover, even though studies often conclude that multi-component interventions are needed to effect change, there is no evidence on how multiple existing interventions combine in children's real lives. There is thus a core evidence gap in understanding if and how the ability of policies/interventions to have impact may be undermined (or supported) by the different aspects of context of lower SEP children lives, nor if/how combinations of actions are actually touching their lives. With their focus on isolating effects, traditional intervention studies are not able to fill this gap.

The Family Food Experience study-London will thus take a novel approach to help fill this evidence gap by exploring how children experience existing policies and interventions in their real-life contexts and what can be learned about how adapt obesity plans to address inequality. The focus will be on food environment interventions but all interventions that aim to reach children will be included. The **aim** is to produce guidance to local authorities on how they can adapt and augment their existing obesity plans so that they work more effectively and efficiently to reduce inequalities, building on guidance already available to local authorities [12,14,46,47] and on addressing obesity inequalities generally [48,49]. The ultimate **objective** is to reduce inequalities in obesity (a goal of the government's Childhood Obesity Plan [11]) and reduce costs to the NHS by improving the diets of children aged 4-11. The rationale for focusing on local authorities is:

- Local authorities have scarce financial resources, so evidence on how to make existing actions work better could help make more efficient use of these resources. Indeed, if they do not act, existing actions may end up perpetuating and further *increasing* inequalities.
- Policies and interventions are implemented at multiple levels by multiple stakeholders, but it is at the local level where they are most amenable to adaptation to local contexts.
- Many local authorities are now actively committed to preventing obesity, including through the 'Trailblazer' initiative, PHE's "whole systems approach to obesity programme," the Local Authority Declaration on Healthy Weight, Sustainable Food Cities and Bite Back 2030.
- A recent review found an appetite for strengthening evidence use in local government [50].

By proposing ways to increase the efficiency of *existing* interventions, the results of this study will allow these local authorities to allocate resources to obesity interventions in a more rational way. Interventions at local authority level impact on health services costs, offering potentially significant savings to the NHS, at almost zero cost to the NHS. It is estimated that in 2014/15 the NHS spent approximately £6.1 billion on obesity-related ill-health, while the costs to the wider economy can be as high as £27 billion per annum [51]. For reasons explained below ('Study Setting') the specific local authorities involved in this research will be in Greater London.

Research Questions

The overarching research question is: how do the contexts into which existing policies and interventions on diet are delivered influence their ability to have impact among children living in deprivation and how could these policies/interventions be improved to address inequality? The purpose is not to measure whether interventions are effective or not, but provide practical insights into how they could work better. The focus will be on environment interventions (albeit not only) and five aspects of context: local food systems; socioeconomic conditions; cultural norms in families at home; presence of complementary interventions; implementation barriers. Following selection of research participants, eight neighbourhoods, and a Caregiver Advisory Panel (CGAP) for PPI (see online form), the main question will be answered through nine specific research questions (SRQs):

- SRQ1. What is the existing combination of policies and interventions in the selected neighbourhoods and how would they be expected to work for children aged 4-11?
- SRQ2. From the perspectives of local stakeholders, what influences engagement with, and responses to, these policies and interventions by children/caregivers?
- SRQ3. What are the cultural norms around food among children/caregivers in these neighbourhoods, and how do they differ with local deprivation and family SEP?
- SRQ4. What are the routes do children in these neighbourhoods follow in their daily lives and what interventions reach them along these routes ('touchpoints')?
- SRQ5. What characterises food environments on these routes?
- SRQ6. How do contexts of deprivation influence how and why children/caregivers engage with, and respond to (or fail to respond to) existing policies and interventions?
- SRQ7. What are the local barriers to implementing interventions?
- SRQ8. How do existing interventions need to be adapted or augmented to make them more effective and efficient in addressing inequality in each neighbourhood, and what are the generalisable insights for other local authorities and relevant stakeholders?
- SRQ9. How much would the adapted and additional interventions cost to local authorities?

Since the study is not an intervention we do not include the recommended sections on this detailed research plan which are specific to more traditional intervention studies (e.g. control group) and group several elements under "methods for data collection and analysis."

Research Plan / Methods

Design and conceptual framework

This study embraces the complexity of the influences on what people eat. Rather than trying to isolate the effect of different contexts and interventions designed to facilitate healthy eating, it seeks to provide insights into how they combine and come up against the reality of people's lives. We have

therefore adopted a conceptual framework that intrinsically allows for such complexity: a "complex systems approach." Complex systems thinking posits that outcomes are more than the sum of separate parts, and emerge from interactions [52]. Systems contain linked factors and actors which interact in a changing, unpredictable, non-linear fashion over time. Elements of the system may adapt and change themselves over time. The intention behind using a systems approach is that it enhances the way we perceive the various components of a problem, the 'system' as a whole at multiple levels and the interactions between them [53]. By framing how people experience existing dietary interventions as the outcome of interdependent factors within a connected whole [54], the research explicitly recognises that peoples' responses to dietary interventions are affected by the entirety of the system in which they live [55]. It likewise recognises there are no definitive "solutions" which evaluation can prove definitively work or not, but actions for which impact can be *improved* to take account of context [56].

Complex systems thinking is the theory behind several specific research methods, including 'group model building' (GMB) [57] and system mapping techniques like that applied in the seminal 2007 UK Government Foresight report on obesity [58]. A systems approach provides what is essentially a framing tool, a useful artefact encapsulating what is considered expedient for the research in hand. The value of calling the problem in hand a 'system' is to highlight that it is not possible to consider any element without contextualising it in a dynamic whole [59].

In adopting complex systems thinking, the study takes a "whole systems approach" to obesity [14,47]. As defined by Public Health England (PHE), this involves "local stakeholders, including communities, to come together, share an understanding of the reality of the challenge, consider how the local system is operating and where there are the greatest opportunities for change" [47]. Our study design has deliberately aligned with the steps PHE recommend to create a whole systems approach [47]. For example, it will create a shared understanding of how unhealthy diets are being addressed in a specific locality and bring local stakeholders together to prioritise areas of action [47]. It will also contribute to building evidence of how to operationalise a whole systems approach, which a recent review concluded is "still in its infancy" [60].

Our approach is also aligned with more holistic understandings of drivers of eating behaviours. Notably, social practice theory [61-63] posits that specific behaviours - or 'practices' - emerge from the multiple contexts in which people live. Applied to diets, it implies that decisions about what to eat are not the result of a fixed group of influences (such as income, price and preference, as theorised in economics) but are embedded in the multitude of these contexts, which have the potential to come together collectively to influence how different populations respond to interventions designed to change those practices [61-63].

Our methodology directly emerges from the project's complex systems framework, aiming to show how existing actions could be *improved*, rather than attempting to prove if actions work in isolation. We do so by putting children and those who care for them (parents, siblings, grandparents etc) at the centre of the research design, assessing if and how the combination of existing interventions actually touch their lives, and how they may be undermined (or supported) by their lived experiences. We have selected diverse quantitative and qualitative methods from different disciplines to capture the multiple contexts and complexities shaping children and caregiver engagement with these existing interventions and their conscious and unconscious responses to them: focused ethnography, systems-based participatory co-creation, quantitative surveys and quantitative food environment measures. Given the risk created by embracing complexity, and the challenges of recruitment to such studies, we have carefully staged the methods to enable increasing focus towards a set of priorities. Each of the methods have already been used and validated by members of the research team; the study will be novel in bringing them together.

<u>Setting/context</u>

The study will be conducted in Greater London for four main reasons.

a. London has the most extreme problem of obesity inequality in the country. Prevalence of overweight/obesity among 10/11-year olds is 38%, with a range 17.4%-51.9% [64]. 10-11 yr-old children living in the top 10% of deprivation are twice as likely to experience overweight/obesity

than those in the bottom 10% (47.6% to 24.9%). However, London is also the only region in England not showing a statistically significant increase in inequality for 4-5 year olds and overweight/obesity in this age group is trending slightly downwards [64].

b. A wide range of obesity plans, policies and interventions are in place in London, meaning all children (4-11) are likely being reached and there is a base of actions to adapt and augment.
c. There is significant heterogeneity between neighbourhoods in obesity levels, degree of deprivation, local food systems, and number/type of existing interventions. Our design will take account of this local variation by purposefully selecting an equal number of families from deprived and affluent households from London neighbourhoods for the quantitative survey, and selecting participants from eight neighbourhoods (wards) with different characteristics for qualitative work.
d. The lead applicant has close relationships with decision-makers and programme implementers in London as a result of her role as Vice Chair, London's Child Obesity Taskforce [65]. The presence of existing relationships means that the critical and time-consuming task of forming relationships to both conduct the study and influence intended end-users are already in place, as is an intimate knowledge of the nature of the problem in London. These relationships have enabled us to bring the key groups involved in designing and delivering policies and interventions to improve diets in London as a group of study collaborators: Association of Directors of Public Health (ADPH) London, Public Health. England (PHE) London, Greater London Authority (GLA), Guy's & St Thomas' Charity (GSTC), and Sustain (see uploaded letters of support). They have already informed the study, as described in the PPI online form.

Planned intervention

There is no planned intervention. However, the study will identify how existing interventions could be adapted and augmented for more equitable impact. As described below (in 'Methods for Data Collection and Analysis') we will start by listing these interventions (SRQ1). The interventions included will depend on which are reaching children aged 4-11 in their daily lives (SRQ4). We will ensure key interventions in London of interest to our study collaborators are included by selecting neighbourhoods where they are present. The type of interventions we might expect to include are:

- National policies. These include initiatives in the Childhood Obesity Plan [11], such as taking out 20% of sugar in products most consumed by children and the sugar levy, as well as earlier policies, such as Change4Life.
- Local authority programmes. The majority of the 33 local authorities ('Boroughs') in London have plans for reducing childhood obesity, including consideration of inequalities, with an array of activities such as corporate sponsorship policies, cooking programmes, water-only schools, water fountains, efforts to promote Healthy Start uptake, and early years training.
- Greater London Authority measures. These include statutory approaches (e.g. food advertising restrictions on Transport for London land); award schemes (e.g. Healthier Catering Commitment scheme to incentivise fast food outlets to improve their offer and Healthy Early Years London which awards early years settings for measures that promote healthier eating); and funding (e.g. to local authorities to develop Good Food Retail plans).
- NGOS and foundations. For example, Sustain: the Alliance for Better Food and Farming partners with local authorities on 'Sugar Smart' to reduce children's sugar intake (e.g. Fizz Free February); the Peas Please initiative incentivises vegetable intake in London schools; and Guy's and St Thomas' Charity is funding a wide array of initiatives in two Boroughs.
- Early years settings. Some are taking independent action, such as the Chefs Academy of the London Early Years Foundation which delivers training for nursery chefs.
- Partnerships with the private sector. For example, Collaboration for Healthier Lives is delivering nudge interventions in small London supermarkets and the Greater London Authority (GLA) has partnered with Thames Water to install drinking fountains ('Refill London').
- Community groups. For example, establishing not-for-profit retailers in community centres and enhancing the offer from food banks.

Study population

The primary study population will be children aged 4-11 years and their caregivers living in London neighbourhoods with a large range of IDACI scores (Income Deprivation Affecting Children Index;

proportion of all children aged <15 years living in income deprived families in a lower layer super output area [LSOA]). Primary school aged children (aged 4-11) will be the focus given the significant increases in overweight/obesity during these years, and the fact that parents still have a strong influence at that age alongside external influences. It will include boys, girls and a range of ethnicities. In-depth qualitative work will be conducted with populations selected from 8 neighbourhoods in 4 of London's 33 local authorities/Boroughs. Neighbourhoods are defined as a 'ward,' electoral district subdivisions of local authorities represented by one or more councillors.

The second study population will be 'local stakeholders' involved in the development and delivery of interventions within the four local authorities, including relevant local authority staff, local councillors, early years staff, voluntary sector programmes in place in specific wards, local business initiatives. They are participants of key parts of the study and a core group of intended users of our research outputs. Study collaborators are a form of local stakeholders but referred to separately.

Sampling

For the **quantitative survey** (SRQ3), the requisite sample size was estimated from pilot data derived from a population-based birth cohort of children born in England and Wales in 2007 (Gemini – Health and Development in Twins), when the children were 4/5 years of age. This data compared children in the lowest and the highest tertile of deprivation (indexed using the National Statistics Socio-Economic Classification, NS-SEC). For children living in the lowest compared to the highest tertile, the home food environment was more 'obesogenic' (Cohen's d=0.281) and chaotic (d=0.33); parents used more instrumental feeding (d=0.116), were less likely to monitor food intake (d=0.258), model healthy eating (d=0.270), overtly/covertly restrict foods high in sugar, fat and/or salt (d=0.218-0.237), control eating (d=0.180), and structure mealtimes (d=0.248). CL's recent study examining associations between SEP and 'obesogenic' eating practices found that SEP (based on a composite score of 7 aspects of SEP) explained 0.9-4.5% of the variance in emotional eating (0.9%), food responsiveness (1%) and desire to drink (4.5%) at five years old (minimum Cohen's f2=.009). Given that the Gemini cohort is slightly more affluent, leaner and healthier than the general population, we anticipate that the differences between our most deprived versus most affluent wards will be larger than those in Gemini (minimum d=0.2), and the size of the continuous association between SEP and eating behaviour will be larger than f2=.009. To detect a Cohen's d of 0.2 or a Cohen's f2 of .009, at $p<.05$ with 80% power we require ~n=700 children (n=350 children living in most deprived households; n=350 children in least deprived). The sample will allow us to examine associations between family-level SEP and outcomes as continuous, independent and dependent variables, and to examine outcomes as continuous variables according to high/medium/low IDACI score at a ward level.

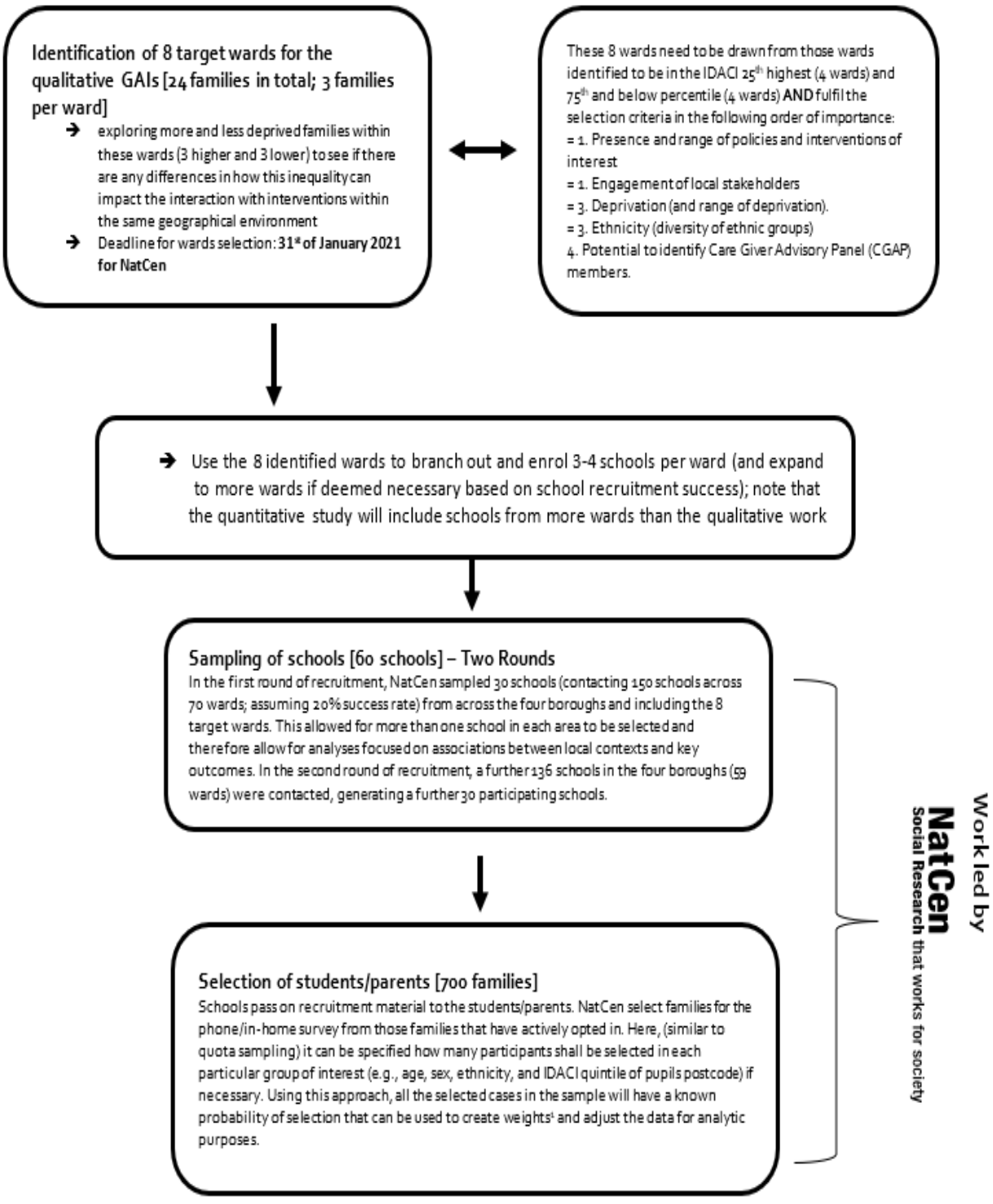
NatCen Social Research will conduct the recruitment and data collection. We have worked closely with them to develop the recruitment strategy, which will use their established methods and approaches and a team of experienced field workers. To answer SRQ3, NatCen will select families whose children attend primary schools in Greater London from 'Get Information about Schools' (formerly Edubase), a Department for Education register of schools in England. They will stratify the sample by IDACI to include schools in areas of the highest and lowest levels of deprivation, that are large enough for recruitment purposes, as well as schools in the mid-range, to allow for a large range of deprivation scores. Within each school, the sampling approach will not use quotas, with the risk that those who opt-in are not representative of the population the survey intends to represent. However, the school-based method is designed to cover a range of age, sex, deprivation levels and ethnicities across the sample. In recognition of NIHR reviewer feedback, participants from the lower IDACI neighbourhoods will be oversampled to compensate for anticipated higher rates of attrition.

Members of the Core Management Group together with partners at NatCen have developed a pragmatic sampling strategy to align both the aims of the quantitative and qualitative parts of the overall study. This was deemed necessary as recruitment of qualitative study participants is nested within the overall final quantitative study sample (approx..700 families).

The decision was made to approach the overall sampling strategy by prioritising sampling criteria to allow recruitment of a satisfactory geographically diverse sample for in-depth qualitative studies, Group Model Building, and go-along interviews with community members (n=24 families). Moreover, the final sample also needed to allow for the selection of local stakeholders involved in the development and delivery of interventions in each sampled ward.
To allow for sufficient flexibility so that all these factors could be taken into account during the ward selection process, the overarching developed sampling strategy consisted of three distinct sequential stages:
[1] Selection of study wards (minimum of 8 wards across 4 boroughs; identified to be in the IDACI 25th (4 wards) and 75th percentile (4 wards), and needed to fulfil the selection criteria as shown in Figure below). For the first round of recruitment, NatCen approached schools in 70 wards – half of which were in the top 25% IDACI least deprived and half of which were in the top 25% IDACI most deprived. The 1st round of recruitment did not achieve the required number of parent opt-ins so NatCen undertook a 2nd round of recruitment during which they approached schools in the remaining 59 neighbouring wards with a mid-range IDACI score.
[2] Selection of schools (30 schools; contacting up to 150 schools and assuming 20% success rate). NatCen undertook 2 rounds of school recruitment; 150 schools were contacted in Round 1; the remaining 136 schools in the four London Boroughs were contacted in Round 2. The City Research Team also personally recruited schools in target wards for the go-along interviews, in order to ensure that there were sufficient numbers of schools within the target neighbourhoods.
[3] Selection of students/parents (700 families). NatCen are aiming to recruit 1000 parent opt-ins to achieve 700 completed interviews.

The figure below summarises the overall sampling strategy.

Figure 1 - Proposed sampling strategy for FFES-L



Abbreviations:
IDACI = Income deprivation affecting children index; Measures in a local area the proportion of children under the age of 16 that live in low-income households; GAI = Go-along interviews

As demonstrated in the above figure NatCen will recruit around 60 primary schools by phone to participate in the study, over 2 rounds of recruitment. Participating schools will be sent the study information letter and leaflet to send to parents via e-mail, who will be able to opt in to the study. This opt-in approach will generate a named household sample of eligible and willing respondents for fieldwork. NatCen will contact 1,000 families who have opted-in to the study, of whom 700 are expected to take part (assuming a 70% response rate) for the quantitative survey, which will take place over a 9m period.

Potential participants will also be asked by NatCen if they would be willing to participate further in the **qualitative** aspects of the study (SRQ4-8). Those who agree will form a pool for qualitative sampling. The researchers will then seek to recruit participants from this pool in eight wards, which will be the subsequent focus of the study. These eight wards will be selected based on the range of IDACI, the presence of key policies/interventions (especially those of interest to study collaborators), the potential to identify participants of the Caregiver Advisory Panel (see 'PPI' online) and variation in local food systems. For the go-long interviews (SRQ4), 24 families/households (a child and a caregiver) will be purposively sub-sampled from the ~700, drawn from the most and least deprived in eight selected wards (3 households per ward - 1 higher SEP, 2 lower SEP) to participate in a minimum of two go-along interviews. Ethnicity will also be considered when recruiting for go-along interviews across all 8 wards. We will strive to ensure adequate representation from the following ethnic groups in recruiting for go-along interviews: Black African, Black other, Black Caribbean, and Bangladeshi ethnic groups. This is based on the estimate that we will have adequate representation from these ethnic groups in our quantitative sample, though this cannot be predicted with certainty. This will allow us to further explore household dynamics and cultural practices that may play a role in food practice and receptiveness to existing interventions among these ethnic groups. For the second round of GMB, an additional 11 low SEP caregivers would be recruited per ward from the most deprived to give 14.

Given the burden, participating schools will be given a £150 book voucher in appreciation of their time. To incentivise families to take part and to show appreciation of their time, quantitative respondents will receive a £30 gift card per household. Those who participate in the subsequent go-along interviews, will be compensated for their time with an additional £50 gift card for the first two interviews they participate in (equivalent of £25for each interview), and a further £25 gift card should they participate in a third. Caregivers who participate in the half-day GMB sessions (the second round of workshops) and as part of our PPI-related activities (CGAP participants) will be compensated in line with NICE PPI involvement guidelines. For in-person GMB sessions parents/caregivers will receive £75 for their participation in a half-day session, in addition to being provided a meal and being compensated for any childcare / caregiver costs that may be incurred as a result of their participation in the session. Due to Covid-19 restrictions initial CGAP meetings will be held online and, going forwards it is anticipated that three meetings a year will take place online, and one in-person. As a compensation for CGAP members time parents/caregivers will receive a £50 supermarket gift card (of their choice) for each 60–90-minute CGAP meeting they attend. To further facilitate attendance to online sessions parents/caregivers will be provided with a tablet, if required. For in person CGAP meetings participants will be compensated for any travel and childcare / caregiver costs that may be incurred as a result of their participation in the meeting.

CGAP members will also be recruited, one for each ward. These lay members of the public will be recruited through the study collaborators, who will connect us with local residents already engaged with health issues, such as "health ambassadors" and Sugar Smart local campaign leaders, who can in turn help identify suitable candidates. The process will benefit from the significant local activity in place in many neighbourhoods. We will meet potential CGAP members on a 1-1 basis or in small groups by ward initially, in an online forum. We will provide them with a clear description of the study aligned with INVOLVE guidance and discuss the research process, their role and payment terms. If COVID-related restrictions allow, one meeting in four with CGAP members will be held in person at a community venue which is part of their ward/locality (i.e., in an informal and familiar setting).

Local stakeholders (see 'study population' above) relevant to each of the eight London wards will also be identified after the collation of the list of interventions in the first step of the study. People

relevant to these interventions (e.g., staff in a day care centre, local retailer, local councillor) will be approached to discuss the interventions, GMB participation and for later interviews on barriers.

Methods for data collection and analysis

Data will be collected to answer each SRQ in the order set out on the uploaded flow diagram.

SRQ 1. Identifying the combination of existing policies and interventions in the selected neighbourhoods and assessing how they would be expected to work for children 4-11. The multiple levels and stakeholders implementing actions mean there are likely to be many with potential to reach children aged 4-11 from the selected wards (see 'Planned Intervention'). CH will lead on collecting data on these actions from the lists of policies and interventions already compiled for each local authority by London's Child Obesity Taskforce under CH's supervision, along with lists of national government action made available to CH in her Obesity Policy Research Unit (OPRU) co-investigator role. These lists will then be used as the basis of informal conversations with study collaborators and local stakeholders to identify any additional actions (e.g., local business, voluntary sector), including areas where people from those wards spend time. This will begin to create a shared understanding of how unhealthy diets are already being addressed.

Building on a method tested in the United States [66], the actions will be then coded in six ways: jurisdictional level (national, local, ward); initiating stakeholder (government, business etc); food targeted (e.g. vegetables, sugary drinks); age targeted (4-5 etc); where they have potential to reach children in their daily lives (e.g. 'nurseries for Healthy Early Years London; 'home' and 'conventional retail' for Change4Life); and whether they influence food systems, socioeconomic conditions or cultural norms. On the basis of one or more of these categorisations, logic models will be developed on how these interventions are designed to impact the diets of children aged 4-11 (e.g., caregivers buy lower-sugar drinks for children in response to a tax; children in nurseries select healthier options in response to healthier food being served).

The output will be (a) lists of actions per ward (b) categorisation of actions, adapted into clear, eye-catching posters for use in the second round of the GMB with parents/caregivers, drawing on advice of the CGAP and local stakeholders (SRQ2 and SRQ6); (c) logic models for each set of actions for possible use in the go-alongs (SRQ4).

SRQ2. Views of local stakeholders on what influences engagement with, and responses to, these policies and interventions by children/caregivers. Information will be collected using GMB workshops, a participatory method that guides participants through collaborative discussion to generate a visual representation of complex issues with many interconnected elements and how they are related causally [57,67]. These workshops will be convened online (via Zoom) due to COVID-related restrictions. Drawing on systems thinking, GMB recognises the inextricable links between different actors and factors in any given system. Applied in community settings, GMB has been used widely with members of the public [68], including adolescents [68,69], and is carefully designed to be easy to follow under the guidance of an experienced facilitator. The GMB workshops involve the generation of "causal loop diagrams (CLDs), which illustrate factors participants perceive drive the issue (i.e., degree of engagement with interventions) and, via arrows, how those factors are linked causally (example at [67]). The software we use (STICKE), which will be used by the workshop facilitators in the zoom meeting, enables participants to see their views represented as the CLD is generated live on screen. During a GMB participants are steered to express their views on structural factors, not their personal experiences. This approach helps foster openness from participants, who may share views on sensitive, personal factors they would not necessarily reveal if we were seeking their individual experiences.

The initial round of 4 GMB will be held online with local stakeholders only. The reason for starting with this group is to create a shared understanding of what actions exist at different levels and encourage engagement with potential reasons why they may not be having the expected effects. An aim is to create their buy-in to the study so they are more likely to take-up our outputs, while enabling us to better understand their mindsets and knowledge so we can tailor our outputs accordingly.

NS will lead the online GMB sessions and a co-facilitator research assistant will take notes throughout (without identifying participants). Broadly, the first round of workshops will take the following format:

a. General introduction to facilitation team, workshop process, logistics, consent.
b. Introduction **-** presenting lists of existing actions and logic models of the expected *modus operandi* of existing interventions from SRQ1 to stimulate their reflections.
c. Participants guided using tried and tested, scripted methods [71] through stages of examining the 'seed question' which will be: "what things do you think affect whether children and their caregivers do or do not respond to actions such as X?" [Where X is the lists from SRQ1].
d. Participants asked to make links between the variables that they have, themselves, come up with, to generate a CLD (created live, online by a facilitator typing the participants suggestions into STICKE software)
e. Discussions to examine where in the system may be amenable to change in the direction of the desired outcome through adapting and adding to existing actions ('action ideas').

The output will be: (a) four CLDs representing the factors perceived by local policy stakeholders to affect engagement with, and response to, diet policies and interventions in their locality; (b) gaps in their understanding where they would welcome insights from research participants; (c) 'action ideas' for how interventions could be adapted or augmented to be more effective.

It is important to note here that GMB is both a research method and a practice of bringing practitioners (stakeholders) together around a complex problem with the goal of increasing understandings of the problem and its causes and then generating agreement on joint actions. Indeed, the primary use of GMB in other contexts has been to convene stakeholders to generate a system map of the problem at hand. Research evaluating the impact of GMB as conducted by practitioners indicates it can be successful in attaining this goal. By engaging stakeholders, it also enhances pathway to impact. Thus, for the purposes of our study, GMB is being used as a stakeholder engagement tool that will be used to convene all stakeholders (local authorities and CGAP representation during the second round of GMB workshops) to generate a new knowledge and shared understandings through the system diagram. It is thus being used as both a research method – by generating new knowledge – and a practice to bring stakeholders together and enhance pathway to impact. It is important to note that: (a) GMB is a valid as a research method since it is designed as a highly rigorous process; (b) part of this rigor involves including people who experience the problem as key stakeholders, which is why we are including one member of the CGAP in the second round of workshops.

SRQ3. Measuring cultural norms around food and socioeconomic position, age, and gender. Quantitative data will be gathered during home visits or phone calls (due to Covid-19 restrictions) by NatCen from the 700 research participants on the outcome measures:

- *Primary:* Associations between family level SEP and ward-level IDACI for four measures of cultural norms: (i) home food environment (availability and accessibility of healthy and unhealthy foods/drinks); (ii) parental feeding policies and practices (including emotional and instrumental feeding, restriction, pressure, modelling and monitoring); (iii) children's 'obesogenic' eating styles (eight styles, including emotional eating and food responsiveness); (iv) children's food preferences for energy dense snacks, fruit, vegetables, dairy, protein, and starch-based foods.
- *Secondary:* Differences between low/middle/high IDACI groups for children's age- and sex-adjusted body mass index (BMI-SDS) and continuous associations between family-level SEP and children's BMI-SDS.

As exposure measures, family SEP will be characterised using an adapted version of a detailed composite measure developed and validated by CL's group for the Gemini study [71]. It includes 7 distinct factors: individual (education level, occupation, income), household (tenure, household composition) and neighbourhood [66]. It was initially planned that further questions may be added based on CGAP feedback, such as job security, debt, kitchen/cooking equipment. Due to unforeseen delays in setting up the CGAP and recruitment of members, we were not able to incorporate feedback by caregivers and parents on the content of the questionnaire (prior to pilot study commencement). There will still be opportunity for the CGAP to provide feedback post pilot study completion focusing particularly on areas highlighted by the NatCen interviewers delivering

the survey. High (top 25th percentile), low (within the lowest 25th percentile) and middle (in between the 25th and 75th percentile) IDACI scores will be used to index the deprivation level of the ward they live in.

The Quantitative survey pilot will involve recruiting 20 families form two London-based schools, one in a high and one in a low IDACI ward, matched on variables such as income and ethnicity to the wards selected in the 4 research Local Authorities (Boroughs). NatCen researchers will contact potential schools by phone to participate in the study. Participating schools will be sent the study information letter and leaflet to send to parents via e-mail, who will be able to opt in to the study and form a participant pool who will be stratified where possible in line with the study criteria mentioned above. Due to Covid-19 restrictions it is anticipated that the pilot survey will be conducted remotely (via phone call with parents). In the case of remote data collection participants will be posted all study-related information and documentation including 'show cards' to support with questionnaire responses. Participants will also receive a measuring tape and protocol to measure their child's height and will be asked to self-report their child's height and weight during the telephone interview.

In terms of milestones and progression criteria, this is how we plan to track progress in the pilot:

Milestones	**Progression criteria**
Recruitment of two **primary schools** for piloting	Successful recruitment within (/close to) the allocated recruitment budget
Recruitment of twenty **families** for piloting	Recruitment processes work as anticipated Sample design assumptions broadly as anticipated. Adjust if necessary.
Study materials are effective	Participant feedback indicates materials meet requirements. Adjustments made if necessary.
Successful training of three pilot interviewers	Interviewer completion of study training. Accreditation in height/weight protocols.
Data collection instruments are fit-for-purpose	Pilot participant and interviewer feedback. Adjustments made if required.
Interview length as planned	Pilot timings data indicate interview length as planned. Cuts made if required.
Interview burden acceptable to participants	Pilot participant and interviewer feedback. Consider cuts if necessary.

The household visit will include a mixture of a Computer Assisted Personal Interviewing (CAPI) questionnaire with one parent in the household, and physical measurements (height and weight) of all primary school aged children in the household. NatCen has an existing CAPI instrument for the collection of height & weight measurements; this protocol is used for a number of National Statistics publications. During the home visit, child height will be measured using portable stadiometers and child weight will be measured using Class III Seca scales. The home visits will last approximately 80 minutes. Family-level SEP will be measured through a detailed self-report of the exposure measures. In light of the Covid-19 pandemic and the ensuing 'The Health Protection (Coronavirus, Restrictions) (England) Regulations 2020', we have planned for an alternative covid-secure approach to allow for the data collection to proceed safely. Participating families will be given the choice whether the interviewer visits them (a) at home or, (b) calls them to complete the interview over the phone (in line with Government rules at the time of study commencement). If the latter option is chosen, then ahead of the interview date chosen by the family, NatCen will send out a measuring tape with instructions on how to measure child height. NatCen will also ask parents to take a weight measurement of the child. If the family does not own a body weight scale, then parents will be invited to take the child to their local GP surgery, Boots or any other chemist that has weighing scales. The anthropometric data will be recorded by the NatCen interviewer at the time of the interview on the phone.

The home food environment will be assessed using the most comprehensive measure to date applied successfully by CL in the Gemini project [72]; and children's food preferences [32], eating styles [73], and caregiver feeding practices [74] using easy-to-complete parent-report psychometric measures developed and validated by CL's team. Food insecurity will also be measured for parents and children [75].

The output will be the first comprehensive quantitative dataset characterising the home family food environment, feeding practices, eating styles, food preferences, food security, and weights of primary school-aged children from a range of social and economic backgrounds in London. Associations between family level SEP and high and low ward-level IDACI group for each outcome will be estimated using Complex Samples General Linear Models, adjusting for clustering of children in schools and families (B). 10 models will be run to establish if there are significant associations between either family level SEP (continuous independent variable) or high, medium or low IDACI group (3-level categorical independent variable), and each of the five primary and secondary outcome measures (modelled as continuous dependent variables), controlling for age, sex and ethnicity. The findings will provide much-needed clarity on the key aspects of food-related family culture that vary with family- and local-level deprivation. Also, given the importance of ethnic groups, we will conduct some preliminary analyses (means and proportions with confidence intervals) to see if there is a suggestion of differences across ethnic groups. Our ability to do so will depend on the numbers we get for relevant ethnic groups.

SRQ4/6. Documenting the routes children follow in their daily lives, what interventions reach them along these routes ('touchpoints') and insights into how/whether they engage/respond to them. Dr Tessa Pollard will lead the collection of data on where children/caregivers spend time by conducting an adapted form of 'go-along' interviews with a sub-sample of children and caregivers from eight wards. This will not just serve to map out where participants spend their time (e.g., home, streets, transport, children's centres, schools) but also to understand, from their personal perspective (in contrast to the GMB), how and whether they engage with, and respond to (consciously or unconsciously) policies and interventions along these routes. Previous research in London shows that people in deprived areas tend to use the same, limited, routes every day, making this method practically viable [24]. The selection of adapted go-along interviews as a method builds on the successful use of similar qualitative methods used by the City team in their research for the NIHR-funded OPRU. This experience will be drawn upon to inform the go-along interviews in this study.

Go-along interviewing is a well-established, qualitative, participatory method that involves accompanying research participants during their everyday activities, including in their neighbourhood and anywhere else they go in, order to gain an understanding of the context in which health is experienced, while it is being experienced [76-80]. Children and caregivers will lead the researchers on their journeys, with the researcher observing behaviour while talking about what participants are experiencing, aiming to elicit similar forms of information sought from long-term ethnographic engagement. It is expected that the journeys will extend beyond the wards where they live to other parts of the local authority and possibly beyond.

The go-alongs will be conducted in the following manner: Families will participate in a minimum of two go-along interviews at a time where the caregiver and child are out and about. Routes will be pre-determined with the interview and will consist of regularly taken routes (e.g., route home from school, shopping trip, local service/activity). Interviews will last approximately 2-3 hours. Starting at the participants' home or school, the researcher will accompany the participants on these activities, mapping out the route (as determined by the participant) as they go. It is anticipated that the routes participants take will cover locations where interventions are being implemented. One of these trips will end with a more standard sitting interview with caregivers within their homes to explore actual or possible interactions with interventions in the local area, and to gain a wider sense of family shopping and eating practices in order to improve our understanding of differences in the family contexts in which interventions unfold in the most and least deprived areas. This interview is likely to occur in the participants' kitchens and will also involve a 'kitchen go-along' where the kitchen environment will prompt the interview discussions.

The researcher will have two tools on them during the go-along: The first is an easy-to-read list of actions with potential to reach them from SQR1. This will enable the researcher to look out for places where policies could be expected to reach participants (e.g., streets for advertising ban; store for private sector retail interventions, children's centre for a healthy meal programme) and specifically observe behaviour at that point. The second will be a series of interview prompts (in the form of an interview guide) which the researcher will use after observing the behaviour. These prompts, based on the logic models, will aim to uncover the reason behind the participants behaviour around the interventions, and if and how it departs or aligns with what is expected based on the logic models drafted in SRQ1 (e.g., if the participant buys a full sugar drink for their child even when it's more expensive than a lower sugar version as a result of the sugar levy). These two tools will be critical in enabling us to systematically describe how participants experience the interventions and draw implications about their impact. Probing questions will also draw on the perspectives of local stakeholders from SRQ2 and where they seek further insights.

There are several advantages to this method: First of all, it takes a person-centric approach to understanding how people relate to their food environments. Research now indicates that understanding how individuals navigate their environments and characterizing the space within which people move during the course of their daily activities, rather than only where they live, may provide a more comprehensive and accurate assessment of the environment to which individuals are exposed and utilize [81-83]. Previous work in London has also demonstrated that recording daily routes provides an effective means of understanding how contexts combine [84,85]. The 'go-along' approach also allows for flexibility in designing the format of the interview to suit the participant, enabling researchers to have a more open and honest conversation with study participants, while empowering participants as they essentially act as guides, directing the researcher to those places where they spend their daily lives rather than being dictated to by the researcher.

However, there are also drawbacks that need to be managed. Disadvantages include limitations on observations made based on the time of day the go-along interviews are conducted, safety concerns, and limitations in recording equipment choice [76]. Based on prior City experience with this methodology, we plan to address these concerns by: providing options for both hand held recorders and/or clip-on microphones (which have shown to be effective for this approach in the past); taking hand-written notes during the interview to compliment recordings and facilitate transcription and analysis; accompany participants on their already planned excursions, so we will only observe and discuss what, in their environments they are exposed to during those particular times of day; walking in groups of 3 or more (researcher caregiver, child/ren) and sticking only to existing routes taken by the participant and/or caregiver on an everyday basis to ensure acceptable levels of safety.

The go-along interviews will be piloted before being used for data collection to assess, in part whether the above-mentioned strategies will be effective in managing the drawbacks, and to test out the process of observing expected behaviours and follow-up questions. Piloting will include interviews with 2 families recruited from pilot survey participants and 2 families recruited from mainstage survey participants but who were ineligible for mainstage go-along participation due to living outside wards of specific interest. The pilot presents an important opportunity to test various aspects of the go-along methodology including recruitment, questions, routes, flow and interview length. We will collect detailed feedback from interviewers. There will also be an opportunity to collect feedback from pilot participants in the form of follow-up questions, if desirable (e.g., to gauge burden).

Go-along interviews will be recorded and transcribed verbatim and input into the qualitative analysis software NVIVO along with field notes written by the researcher. Data will be analysed thematically, following an iterative process where an initial list of themes will be drawn up and then added to as increasing numbers of transcripts are analysed. Once all the transcripts have been coded, the researchers will develop a set of high-order, analytical themes [86].

The outputs here will be twofold: (a) a series of maps overlaying the physical routes of the participants with 'touchpoints' where everyday lives intersect with the interventions, built from publicly-available OS maps of London wards [87], and then converted into eye-catching maps for

use in SRQ8 and dissemination; (b) written reports on the thematic analysis of the interviews, one report/ward, and another with generalisable findings and key differences between wards, focusing on how the contexts of deprivation may be undermining the expected impacts of policies/interventions and the differences between higher and lower SEP participants.

SRQ5. Characterising food environments on 'go-along' routes. Led by MS, systematic data on food environments will then be collected along go-along routes using an adapted, people-centred version of the observational tool, Environmental Profile of a Community's Health (EPOCH) [88]. Exact routes will be purposefully selected from the 'bank' of routes identified and mapped out as part of the go-along initial visit. Four routes will be selected from each Borough (2 from a high deprivation ward and 2 from a low deprivation ward), totalling 16 routes. Final routes will include both school trips, as well as shopping trips purposefully selected to be most reflective of high traffic areas in each ward.

EPOCH is a quantitative physical environment audit tool in which researchers directly observe and systematically record physical aspects of the environment. It was developed as part of the Prospective Urban Rural Epidemiology (PURE) study from a detailed review of the literature on social and environmental determinants. It has been evaluated and found reliable in multiple countries and settings and has already been used by MS in other urban settings. EPOCH is composed of two main questionnaires but for the purposes of this study, only two relevant sections of Part 1 – 'Direct Observations of the Community Environment' will be used a gather environmental data given the aims of this study:

(i) 'Community observation walk' – an observational walk along the predefined 'go-along' routes designed to systematically observe and record food environment factors such as advertisements, food retail outlets, food banks, food at children's centre, as well as locations of existing interventions.

(ii) 'Assessment of a food retail store' – in which the presence, price, and quality of food products will be noted in stores and eating outlets, as well as promotional activity. An effective sampling approach to selecting the amount and types of food retail outlets in the wards will be identified based on feedback from study participants and knowledge of local stakeholders. This will also determine what is recorded in each retail outlet e.g., the presence/price of 'healthier' food options available in a fast-food outlet; the sale of unhealthy snacks at children's eye level.

Outputs will be (a) food environment maps along the selected routes; (b) collated touchpoint and food environment maps converted into visually engaging outputs to effectively communicate study findings, based on input from the CGAP and local stakeholders; and (c) a dataset with tallies of types of food retail outlets by study locations, and measures taken within them.

SRQ6. How context influences how and why children/caregivers engage with and respond to (or fail to respond to) existing policies and interventions. This question has already been addressed in part by the observations and probing questions on the go-alongs. We will also address it from another perspective using a second round of GMB workshops (described in SRQ2) to give research participants the opportunity to step outside their personal zone and interrogate more deeply the structural elements of why they and fellow residents may/may not engage with interventions. Invited participants will be the three caregivers from the lower SEP families recruited for the go-alongs, 11 additional participants from lower SEP families and the local member of the CGAP, making a total of 15 participants per GMB. The focus on lower SEP is to enable us to gain greater understanding from the group most disadvantaged by inequalities. Children will be invited to participate with their caregivers if they would like to contribute. The aim is to stimulate a shared understanding of the interventions that exist and what might influence engagement with them, followed by co-production of action ideas to make improvements to existing actions to feed into the later workshop (SRQ8).

The outputs will be: (a) four further CLDs showing perspectives on how and why the intended users of existing interventions do or do not engage with them; (b) a report comparing the perspectives identified in the two sets of CLDs (SRQ2 and SRQ6) and with the logic models from SRQ1.

SRQ7. Identifying local barriers to implementing interventions. An in-depth understanding of the local decision-making context is pivotal if we are to understand how limited resources can be deployed to promote cost-effective, equitable local policies. To this end, MS will lead on semi-structured interviews with local stakeholders to understand challenges to implementation of existing interventions, success factors in overcoming them, and potential barriers to the initial action ideas from the GMBs and ways to overcome them. Semi-structured interviews are valuable in that they have the structure of an interview, but still allow the flexibility for an interviewer to capture unique perspectives on a single topic of inquiry, especially when that relates to policy development and implementation [89]. An interview guide will be carefully developed according to current best practice [90] and qualitative findings thematically analysed [86]. The output will be a report with identified common themes and insights on barriers and key factors to success.

SRQ8 Prioritising adaptations and additions to local obesity plans to make them more effective and efficient in addressing inequality in each neighbourhood and identifying generalisable insights. This part of the study will bring together all the previous findings to answer the overarching research question and to identify local priorities. The first stage of answering this question will involve developing a thematic report synthesising the data (family home survey, CLDs, touchpoint/food environment maps, go-along interviews, local stakeholder interviews) to collate ideas for priority actions to adapt obesity plans for each of local authorities in which the eight wards are based. The research team will then meet with CGAP members to discuss findings and informally seek their ideas on priority actions. The next stage will be an extended workshop with the full research team, local stakeholders, study collaborators and the CGAP to consolidate findings and prioritise actions. This will be done in two stages: firstly, using the 'action ideas' segment from the GMB method, to situate findings in the system maps; secondly drawing on the established method of ranking priorities through a Nominal Group technique [91]. The whole process will also draw out generalisable insights pertinent to any local authority and other relevant London and national stakeholders and discuss the costs of different interventions.

The output will be (a) a set of locally agreed priorities for adapting and adding to existing obesity plans for each local authority (b) a report of generalisable learnings about how to take contexts of deprivation into account when designing policies and interventions as a base for final outputs for dissemination.

SRQ9. Cost of adapted and additional interventions cost to local authorities. Under the supervision of CSt, KG will perform an economic analysis to estimate the net economic impact of the proposed interventions to the local authorities. She will work with local stakeholders to estimate the cost of the actions for each borough before and after the actions proposed by the study. It is estimated that the new set of interventions will require both re-costing of current actions that are likely to be adapted and costing of new actions to be taken. It is also anticipated that some actions currently taken may be removed if shown ineffective. Ultimately, the economic analysis of the strategy for each borough will allow the assessment of affordability of the plan by the relevant local authority and will allow them to allocate resources in a more rational way.

For this analysis, we plan to use the method *Budget Impact Analysis (BIA),* which ultimately allows the budget holder, in this case the local authorities, to consider issues of affordability rather than return to investment. The analysis will:

a) determine and cost the current mix of interventions (we will work closely with local authorities to understand the interventions they currently use to tackle obesity in their area and the associated costs); and
b) estimate the costs of the new mix of interventions that the study will propose.

In particular, and following NICE's guide and template for BIA, we will consider the following points:

- Perspective: We will use the perspective of the budget holder, which in our case is the local authority.

- User population: We will need to estimate the part of the population that will be affected by each of the set of interventions as compared to the current set of measures. For example, if free school meals are considered as an intervention, we need to estimate the number of children in the area who are likely to benefit from the scheme. This information will be available at a local authority level, though for certain interventions, such as apps, we may need to rely on expert opinion regarding the uptake and account for variations in a sensitivity analysis (see below). The NICE BIA template is pre-populated with relevant national and regional populations which may be very useful in our study.
- Unit Costs: BIA only considers costs and benefits, which are monetised; non-financial benefits are not included in a BIA. For the costs of interventions, we will largely rely on local authorities to identify how much each intervention costs/is likely to cost as they are the main commissioners and will have this information.
- Sensitivity Analysis: We will conduct deterministic one-way sensitivity analysis (DSA) of the key variables that are likely to change the overall outcomes of the analysis. Variables that are likely to be consider here are mainly the uptake of intervention by a certain group and the level of adherence to the interventions.

BIA allows us to consider a time horizon of 2-5 years. Depending on how long the interventions are likely to be implemented for, we will determine the time horizon to be used. No discounting is undertaken of costs and benefits in future years in BIA.

Quantifying the effectiveness of the new actions to be taken by local authorities goes beyond the general scope of this study. Therefore, an economic evaluation study, such as cost-effectiveness or cost-utility analysis, is not possible as there will be no measurable outcomes on the effectiveness of the new strategy. The output will thus be a set of costings for each set of locally agreed priorities for adapting and adding to existing obesity plans.

Study costs

The guidance document requests cost for each stage of the research. Owing to the complexity of the overlap between various activities, we have divided costs as follows. Full economic costs are:
Stage 1: Preparatory work (months 1-3): £66,652
Stage 2A: Quantitative survey (NatCen only): £408,226
Stage 2B: Qualitative work (months 4-19): £354,194
Stage 3: Analysis synthesis of results, including 2nd GMB workshops (months 20-34): £345,433
Total = £1,174,505 full economic cost

Scalability and translation

The analysis of the study findings will include identification of generalisable findings relevant to other local authorities in London and the UK. Since the study focuses on the role of context it will be able to draw out how context influences the ability of different policies and interventions to address inequalities, which will be used to inform the final guidance by highlighting the contexts local authorities need to be aware of when designing obesity plans.

Socioeconomic position and inequalities

The ultimate intended outcome of this study is to reduce inequalities. To do so, it uses a novel combination of methods that involve people experiencing inequality in different parts of London. The sampling and recruitment will be based on deprivation level measured at the ward level (IMD), and detailed information about each family's SEP will also be collected. The study is unique in using a detailed composite measure of family SEP that collects information about the individual parents (e.g., education, occupation and income), the household (tenure, number of bedrooms and cars) as well as the immediate neighbourhood (home postcode). It also uses qualitative methods directly involving the beneficiaries of the research and to co-produce improvements to existing actions.

Dissemination, Outputs and anticipated impact

What we will produce from our research and for whom

We will produce a series of internal evidence reports from each SRQ as milestones for reporting on study progress and for use as a basis for subsequent outputs, and a final report on all the findings,

as listed in Methods section. Drawing from these we will issue three sets of final outputs for external dissemination aimed at the following different audiences:

1. **London policy stakeholders** - engaged throughout the research as study collaborators and local stakeholders.
2. **London communities** - local residents concerned about health issues, including those who have been engaged throughout the research as the CGAP and research participants
3. **UK policy stakeholders** - local authorities, national government (e.g., PHE, DHSC), NGOs, community groups and businesses across London and throughout the UK involved in developing and delivering policies and interventions for children
4. **Wider public** - the health-engaged public eager to see change
5. **Academics** - working on obesity, diet quality, health inequalities and food insecurity

Set 1. Policy guidance. *Different products for different audience as guidance reports/briefs*

- *Local priorities reports.* For audience 1, eight reports with sets of locally agreed priority actions for adapting existing obesity plans, one for each local authority in which the wards are located. The reports will include costings, explanation of how they would enable them to more cost-effectively tackle inequalities, options for overcoming implementation barriers and information about local food environments.
- *Guidance report*. For audiences 1,2,3,5, guidance report on how to design policies/interventions to take contexts of deprivation into account so that they work to reduce inequalities, along with all pertinent findings of the study, tentatively titled “How to tackle dietary inequalities among children: a practical guide” It will include a summary of findings of how the five different aspects of context may be undermining existing actions in London,
- *Guidance briefs.* For audiences 1-5, a package of four short, eye-catching “how to” guides about how to address different aspects of context, targeted to lay readers in these audiences and the CGAP and disseminated to the media to enable them to reach the wider public.

Set 2. Eye-catching visual assets. *Used in the study and to engage all audiences and media to tell stories about problems and solutions; standalone and as part of guidance, briefs, papers*

- Clear, eye-catching lists of existing policies and interventions
- Clearly-drawn CLDs representing factors perceived by participants to affect engagement with diet policies/interventions, and action ideas for how they could be adapted to be more equitable.
- Children’s common journey routes, with food environments and intervention touchpoints along those routes, noting gaps and opportunities for change

Set 3. Academic papers and conference presentations. *Targeting 3,5*

- Draw on the internal reports to publish and present the key findings of the study, including on methodology, with considerations of strengths and limitations

<u>How we will inform and engage our target audiences</u>

The intended outcome of our dissemination strategy is that our policy stakeholder audiences follow the guidance in our outputs, thereby maximising their ability to influence the diets and reduce inequalities among children (4-11). This impact will be achieved through deep, broad engagement, enabled through 5 mechanisms.

1) Involving intended users of the research in the research. This will gain buy-in to the study from our intended users so they are more likely to act on the guidance we produce. Study collaborators are vital decision-makers; other local stakeholders in London will be engaged start to finish. Intended beneficiaries, involved as research participants and the CGAP, provide further channel for dissemination and ensure our outputs appeal to our audiences.

2) Using group model building. This project has inbuilt mechanisms for meaningful, regular, responsive outputs (CLDS). Not only will the views of local stakeholders and residents be represented in the CLDs, but the CLDs will be constant touchstones for local stakeholders into the future. Though they represent views situated in a particular locality at a particular time, the CLD are an agile tool which can be revisited and adapted over time. Local stakeholders will be encouraged to use the diagrams in their area as a reference tool, modifying them over time to improve the implementation and adaptation of their interventions. The revised diagrams can provide a regular

springboard for ongoing planning. The “dissemination, outputs and impact” therefore go beyond traditional outlets and time-lagged feedback to participants; they are a constant feature of the study.

3) Face-to-face engagement to build capacity with local authority and associated networks in London and throughout the UK. Given the evidence that face-to-face interaction enhances impact, we will identify opportunities for face-to-face interactions to build capacity to use our guidance, such as London’s Child Obesity Taskforce, quarterly meetings of the local London obesity leads and Boroughs Good Group, the Trailblazer learning network, meetings of the local authorities involved in the Local Healthy Weight Commitment, Bite Back’s Metro Mayors initiative and Sustainable Food Cities, plus the PHE’s whole systems programme. This will be facilitated by the lead applicants (CH) close involvement (advisory, steering committees, etc.) and relationships with leaders of these initiatives. Study collaborators will also host interactive workshops on the implementation of the guidance. This will start from the very beginning of the study, starting by sharing information about the study and then outputs as they emerge. There will be an estimated 15 such engagements in London and 15 elsewhere in the UK throughout the course of the study.

4) Seeking the insights and engagement of our CGAP. We will seek feedback from the CGAP on how to most effectively encourage uptake of our guidance, including through their own networks, to create demand for implementation of our findings from the research participants and their local communities.

5) Dissemination of our outputs on a dedicated website, email list, social media, blogs, high-profile events and academic channels. Drawing on the visuals, this dissemination will aim to create demand for uptake among the wider ‘health-engaged’ public by creating excitement about the results. It will take as its starting point insights and stories of the ‘real people’ we have encountered in our research (aligned with ethical standards) to help explain how context influences people’s ability to engage with interventions and opportunities to improve. The publications of London’s Child Obesity taskforce have showed this approach is effective in encouraging engagement and understanding [85].

<u>Further funding or support required to have impact if this research is successful</u>

Local governments and other stakeholders involved in delivering actions would need to have sufficient funds to implement our suggested adaptations to their existing plans, as costed on the study. Potentially making these changes would make actions more cost-effective in addressing dietary inequalities among children, potentially leading to cost-savings since what children eat tracks into adulthood, affecting total disease burden. Further support would be needed for academics to evaluate the results of implementing the guidance.

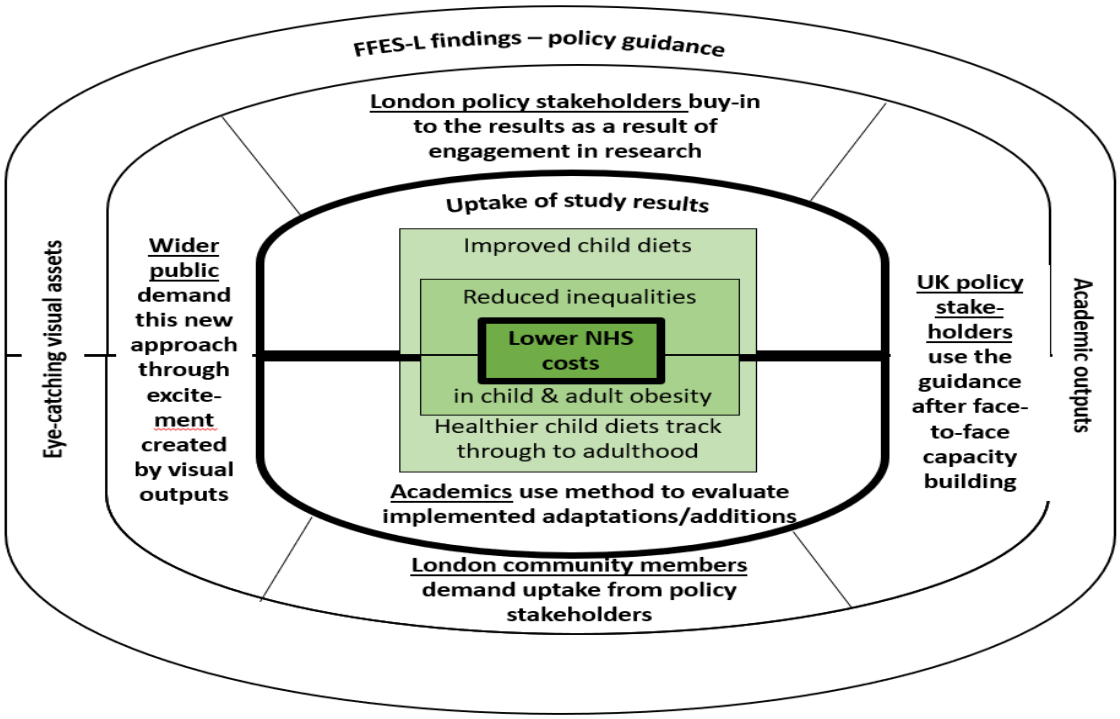
<u>Possible barriers to adoption and implementation of our findings</u>

The guidance produced by this study will not have any impact if it is not adopted and implemented. The study is designed to increase the accessibility to users of the research results by engaging with a group with whom the lead applicant CH) already has relationships owing to her role in London’s Child Obesity Taskforce. It is likewise designed to enhance acceptability of our guidance through involving the intended users of the research and beneficiaries, starting with the study collaborators, and by co-producing ideas and priorities for improvements to existing policies and interventions, and using the GMB method proved to create a positive environment for engagement. A possible barrier is if the findings are politically uncomfortable for the local stakeholders, or not aligned with their mindsets about how to tackle the problem. A far greater potential barrier is that implementation does not prove feasible due to economic, political barriers and lack of capacity – barriers already in evidence in London. For this reason, the study will include consideration of barriers of implementation when prioritising the actions, and pathways to impact include mechanisms designed to encourage wider engagement with the results to encourage a demand for change.

<u>Pathways to impact</u>

Collectively, the intention is that the outputs, audiences and engagement mechanisms combine to lead to impact over the medium-long term, as set out in the figure.

Figure: Pathways through which intended impact will be achieved



Project timetable: This will be a 2yr10m (34m) study, conducted to the timetable overleaf.

Project management and governance

As PI, Prof Hawkes will provide overall leadership and be ultimately responsible for all governance and management aspects of the study. In this, she will be supported by a half-time Project Manager and three levels of governance:

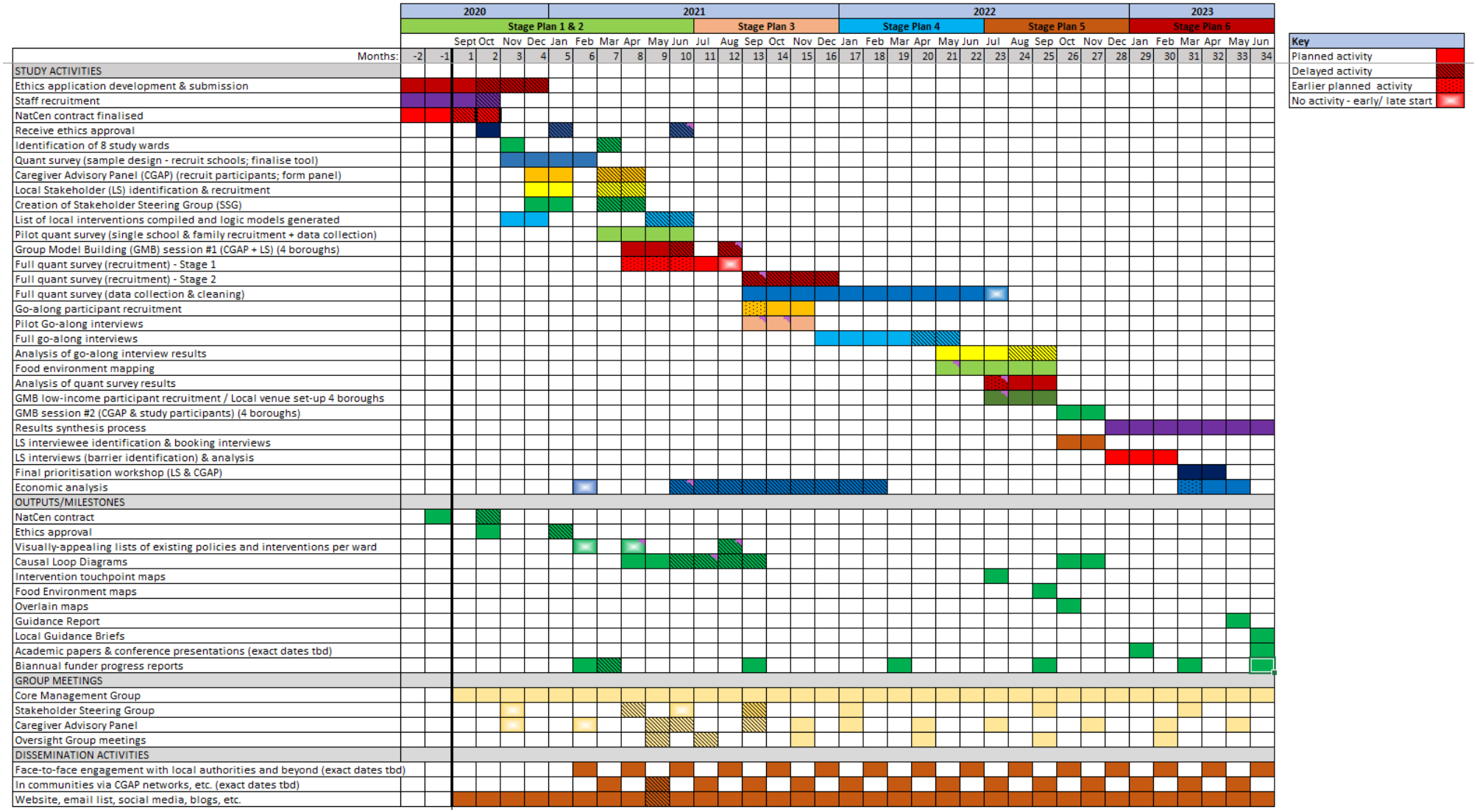
1) A **Core Management Group** (CMG) will be established of the co-applicants and Project Manager (PM) and convene monthly to monitor study progress and adherence to the project timeline, trouble shoot any challenges, address project management concerns and make decisions on next steps. In addition, research reference groups have been established to plan, implement and monitor each research area reporting into the CMG on a monthly basis.

2) A **Stakeholder Steering Group** (SSG) will be established at the start of the study to meet five times to steer study implementation throughout the duration of the funded project. It will ensure that study outputs remain relevant to the needs of Local Authorities implementing local obesity plans and provide their expertise to help steer the study throughout its implementation. It would include at least two study collaborators, two local stakeholders, stakeholders in other local authorities e.g., public health leads outside London). It will be chaired by the PI, Prof. Hawkes.

3) A **Caregiver Advisory Panel** (CGAP) will be established in order to provide the much needed and valuable community perspective that will, in turn guide the governance and management of this study. The role of the CGAP is described on the online PPI form.

4) **Study Steering Committee / Oversight Group** – This Committee is established according to the guidelines set out by NIHR Research Governance Guidelines (nihr.ac.uk). This will include academics in the following disciplines: Statistician, Qualitative methods, Health Economist, Ethics & Systems Thinking. The Group also includes two members of the public with an interest in child health.

NIHR Progress Report September 1st 2021 - Gantt Chart indicating planned and actual / re-programmed activities **Updated November 2021**



Ethics/regulatory approval

Between them, the co-applicants have a wealth of experience conducting research with families and children. These experiences have directly informed the design of this study, specifically how interactions with all participants will be handled and how resulting study findings will be shared with relevant stakeholders and disseminated more broadly.

Before any interactions with participants take place, ethical approval will be sought through the City, School of Health Sciences Research Ethics Committee. A robust procedure will be put in place given the extensive involvement of children, including measures to safeguard the confidentiality of the participants and ensure the data is secure. NatCen Social Research (who are fully accredited to ISO 27001, the international standard which covers information security) will collect and initially store all quantitative data. Their information security procedures are subject to regular external audit to ensure continued compliance and all staff are trained regularly to ensure compliance with the General Data Protection Regulations. NatCen have rigorous procedures to ensure respondent confidentiality. Every project that involves the collection, storage or processing of personal data has its own data security plan, which details all of the data security procedures to be applied on that project. Access to respondent details and any information which could identify respondents is restricted to those who need to check and process the data. NatCen have a comprehensive series of daily and weekly back-ups to protect against data loss. Once cleaned, quantitative data will be securely transferred via a secure FTP server to CL at UCL where it will be stored in Data Safe Haven for analyses. Data will be pseudonymised using a participant ID number.

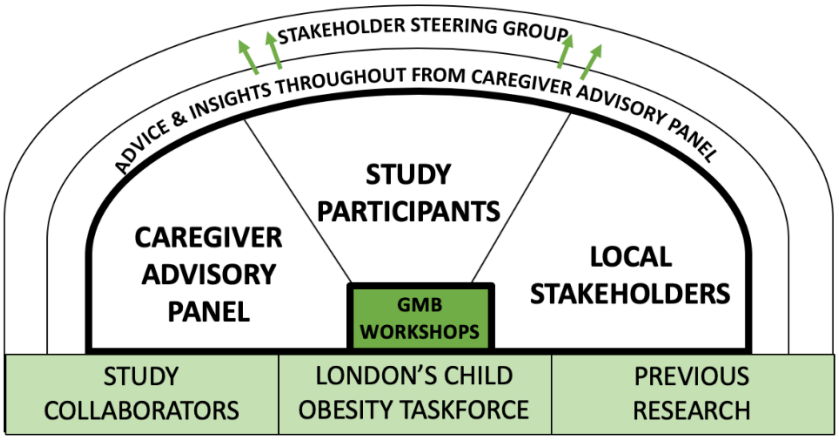
Adopted methods will also be appropriately adapted to the needs of the children in the study and will be subject to ongoing advice from the CGAP. The CGAP will also provide crucial feedback and perspective in helping to frame the findings in an appropriate and non-stigmatizing manner. Regardless of feedback, all findings that are disseminated, whether to policy makers, journalists, or in academic publications will be anonymised. For example, based on CH's previous work with the London Childhood Obesity Taskforce, when disseminating study findings, a fictitious character was created and used to illustrate specific study findings through a specific storytelling approach. Similar, appropriate approaches will be adopted in this study, to be largely informed through feedback from the CGAP and participants themselves.

To mitigate the burden of the time commitment required, participants will be paid appropriately for their time and reimbursed for any travel and/or childcare costs incurred as a result of participating (in line with National Institute for Health and Care (NICE) recommendations). CGAP participants will also be provided with meals during their regular meetings. Participating schools will also be generously compensated for their involvement in the study.

All researchers working with children will obtain an enhanced DBS certificate.

Public involvement

This is described on the online form and summarised in the figure below.



Project / research expertise

Lead Applicant

Professor Corinna Hawkes (CH) - FTE-10%. Professor Hawkes will provide intellectual oversight to the whole project. She will chair the Core Management Team and oversee the work of the Project Manager as well as other staff based at City. A major responsibility will be to manage relationships with the study collaborators, local stakeholders, and other research users, building on her role in London's Child Obesity Taskforce. She will have ultimate responsibility for outputs, dissemination and impact. She brings with her the experience as Vice Chair, London's Child Obesity Taskforce, Co-I of the NIHR-funded Obesity Policy Research Unit (OPRU) and 20 years working in the field.

Co-applicants

Dr Clare Llewellyn (CL) & Dr Andrea Smith (while CL is on maternity leave) - FTE-10%. CL (& AS) will lead the quantitative part of the research. She will design the survey and oversee the recruitment strategy in collaboration with NatCen, with whom she has closely collaborated with during the drafting of this proposal. She will oversee the data collection process, and design and oversee the data analysis, in collaboration with the statistician at City. With the Obesity Research Group at UCL's Department of Behavioural Science which she leads, she has developed and validated all of the measures that will be used in the quantitative survey. She also brings with her experience of leading the Gemini twin cohort, the largest twin study ever set up to study genetic and environmental contributions to early weight gain and the development of eating behaviour. She has a background in Health Psychology, and is a co-applicant on the NIHR-funded Obesity Policy Research Unit, for which she leads two of the 'early years' projects.

Dr Natalie Savona (NS) - FTE-20%. NS will lead the group model building (GMB) sessions, conducting workshops to produce causal loop diagrams (CLD) and analysing them. She will train the project's research assistant to co-facilitate the GMB sessions by teaching the fundamentals of systems thinking and the process of the GMB workshops. She will also play a key role in anchoring the project in a systems framework – embedding the use of the CLD amongst both researchers and stakeholders, ensuring that the principles of systems thinking are considered throughout. She brings with her direct experience of leading GMB processes in London as part of the EU-funded Co-Create project and works on systems approaches with Professor Harry Rutter.

Dr Mark Spires (MS) - FTE-20%. MS will oversee and conduct the implementation and analysis of the City-led methods of go-along interviews and food environment mapping, and supervise the Research Assistant throughout the duration of the study. He will also lead on the preparation of outputs. Dr Spires is an experienced food environment researcher, having conducted food retail outlet audits in multiple parts of the world, complementing these findings with qualitative inquiry exploring the lived experiences of these environments. His findings have informed intervention- and policy-related recommendations.

Dr Charitini Stavropoulou - FTE-2%. CS is a Senior Lecturer in Health Services Research at City, University of London with a background in health economics and policy. She has provided health economics expertise in previous NIHR awarded projects, including an RfPB grant completed in 2019. Between 2012-2014 she was a health economics advisor for NIHR's RDS South East Coast. She will supervise KG in conducting the economic analysis.

Dr Kyriaki Giorgakoudi - FTE 10%. KG is a Senior Research Fellow in Economic Evaluation at City, University of London and has been working with Dr Stavropoulou since 2016, providing health economics expertise in various projects. She has experience of leading health economics packages in NIHR grants including a recently awarded EME grant. KG will be responsible for the health economics analysis portion of the study (under CS's supervision). She will be involved in the first stage of the study that requires mapping the current actions in order to engage with the local stakeholders with a view to understand their cost. When new actions are proposed later in the study, she will calculate the new costs of the proposals and compare them to the ones currently offered to provide a net economic benefit for each local authority.

Professor Carolyn Summerbell - FTE-5%. CSu will lead the PPI strategy and implementation for the project. This will follow the recommendations of the new (arrangements for April 2020) NIHR centre for patient and public involvement, engagement and participation and research

dissemination. The plan will utilise the project team's strong engagement with existing policy, practice and public stakeholder groups in London and community members. Professor Summerbell will chair the Caregiver Advisory Panel (CGAP) and oversee their inputs into the research. She will also provide an overall advisory role to the project of the evidence base for interventions to prevent childhood obesity, particularly in relation to inequalities. She will bring value and provide connectivity between this project and a programme of work funded by the NIHR SPHR which is examining the policy context for reducing health inequalities among children/young people. CSu is one of the leads of this NIHR SPHR research, with childhood obesity one of the three key areas of in-depth research.

Dr Tessa Pollard - FTE 10%. TP will lead the ethnographic portion of the study (i.e. the go-along interviews). Dr Pollard is an anthropologist whose current work uses ethnographic methods to examine how complex interventions work, with a particular focus on understanding variation in the impact of interventions according to socioeconomic position. Her primary research focus is on physical activity and she has used 'go-along' methods in a study on walking groups, and currently to explore children's experiences of policies to promote active travel to school. She has also conducted research on food choice.

NatCen Social Research - A leading independent social research institute with a wealth of research experience in the area will be subcontracted to conduct all study recruitment tasks, and all quantitative data collection. We have worked closely with NatCen to develop the recruitment strategy, which will use their established methods and approach, and a team of field workers who have undertaken similar research previously. NatCen will also provide 56 hours of statistical support in order to ultimately provide a cleaned and weighted dataset.

Sabine Parrish - Research Fellow - FTE-100%. Based at City but working with all of the co-applicants, the RF will support and conduct many of the research, PPI and dissemination activities (excluding NatCen's responsibilities), such as creating CGAP, developing list of interventions and associated logic models, facilitating GMB workshops, conducting the go-alongs, thematic analysis, etc. S/he will be primarily supervised by MS and co-supervised by CH, NS and CL.

Adrian White - City-based Project Manager - FTE-50%. The PM will manage the whole study and provide administrative support for the lead and all co-applicants. Tasks will include timeline management, meeting arrangements, CGAP contact point, NatCen contract management, coordinating and setting up GMB and other study-related meetings, etc. The PM will also be responsible for any tasks related to communications and dissemination, such as website, social media management and development of visual assets.

Mr David Boniface - 120 hours. DB, a Senior Research Associate at the Institute of Epidemiology & Health at UCL will ensure additional statistical expertise on the study team. DB has significant experience as a statistician: he has joint authored 46 scientific publications, is a Royal Statistical Society chartered statistician, is an MRC Statistician, and was Head of the Statistical Consultancy Unit at the University of Hertfordshire (1997-2002).Under the guidance of CL, Mr Boniface will provide initial input into the creation of the quantitative data analysis plan, as well as conduct all the quantitative data analyses.

Dr Anna Isaacs - 0% FTE. AI will donate her time to the study as a non-funded research advisor, and as such will provide research advice for the go-along interviews. Dr Isaacs is an experienced health ethnographer based at the Centre for Food Policy at City, University of London who was involved in designing the method proposed for the go-along interviews in this study.

Study collaborators – The leading entities involved in improving diets in London are the Association of Directors of Public Health (ADPH) London, Public Health. England (PHE) London, Greater London Authority (GLA), Guy's & St Thomas' Charity (GSTC), and Sustain: The Alliance for Better Food and Farming. As they state in the five uploaded letters of support, they have committed to supporting the study. They have already informed the study, as described in the PPI online form, and will be involved throughout, including by helping with appointing the CGAP; supporting the development of lists of interventions; inputting into discussions and workshops on results and action ideas; and providing feedback on dissemination materials. Importantly, study collaborators will also

host interactive workshops on the implementation of the guidance we produce and are themselves key intended users of the outputs.

Success criteria and barriers to proposed work

Study success within the time period of the study will be measured in large part by the following:

- Local stakeholders and community residents have a greater understanding of the combination of interventions in place in their neighbourhoods and the impact they might be having, and the impact they *could* have, if adapted or added to, to account for contexts of deprivation.
- New knowledge about how key aspects of food-related family culture vary with family- and local-level deprivation has been produced (the output of the quantitative survey, which will be the first comprehensive quantitative dataset of its kind).
- Causal loop diagrams have short-term and potential lasting usefulness to local stakeholders in enabling them to continually reflect on the drivers and variables they need to focus on
- Local level stakeholders have been reached and engaged to increase the likelihood that they will implement more effective and efficient policies and interventions beyond the length of the study.
- "How to" guidance generalisable to local authorities and other stakeholders throughout the UK on how to tackle dietary inequalities has been widely disseminated and read.
- The research team, study collaborators and local stakeholders have a greater understanding of how to take a whole systems approach to improving children's diets and reducing obesity.
- A group of parents and other caregivers (our CGAP) is robustly engaged and animated to champion and demand the implementation of more effective and efficient interventions to improve children's diets in their neighbourhoods.
- The study is successfully completed. As a novel, innovative study, a key measure of success is that it is completed as planned.

We recognise that there are a range of key barriers and risks to proposed work. We list these risks below and show how we intend to mitigate against them.

- *The novel nature of the study means it will not work.* It is inevitable that a novel study has risks. This has been managed by bringing together tried and tested methods (in unique combination); testing methodological adaptations with pilots; developing a very detailed plan with risk management built into it; bringing together the right team to deliver; adopting a steering committee to guide it and a panel of lay people to advise it (CGAP); and appointing a half-time project manager. The team consists of experts in each method with time to invest in the study plus two senior academics, one (CSu) with in-depth experience of NIHR projects and child diet/obesity interventions to act as an all-round advisor and lead the PPI; and another (CH) bringing relationships with research users. The Stakeholder Steering Group, with well-chosen academics plus research users, will be vital in guiding the study and the CGAP in ensuring the research design and dissemination work. Risk is thus present but low.
- *The ability to assess how existing policies/interventions are experienced by research participants will prove challenging*. This study does not seek to measure the effectiveness of existing interventions. Rather, it takes a largely qualitative approach to understanding how people engage with, and respond to, these interventions. By using existing methods in new ways, there is a medium-level risk that they will be unsuccessful in achieving these results. This has been managed by a carefully constructed approach of using both in situ methods to uncover individual lived experience (go-alongs) in both higher and lower SEP families, and group reflection processes designed to help participants stand back from their own realities. The go-alongs have been adapted to enable a systematic approach to both observing behaviour relative to logic models, and then using interviewing techniques to uncover the rationale of the behaviour. Quantitative measurements have been included to provide vital data to inform the analysis as well as innovating a new dataset.
- *Delays to ethical approval.* We have estimated the time needed for ethical approval by the timing of the meetings of the ethics committee and our previous experiences. We also plan to develop our ethics application two months before the official project start date. Risk is therefore low.

- *Staffing*. As soon as approval is received, City HR will commence with job description creation and the recruitment for both the proposed Project Manager and Research Assistant. However, finding candidates with the right fit can be challenging and there may be delays. We anticipate this risk will be low because of the inclusion of co-applicants from leading universities with whom ambitious early career researchers and project managers will want to work
- *Participant recruitment.* The experience of different members of the study team show that the risk of problems with recruiting participants in London area is high. We have managed this by employing the services of NatCen as our recruitment partner. NatCen have extensive experience recruiting for health-related studies in London and are well equipped to administer and oversee this process. NatCen are also well suited, and highly experienced in quantitative data collection.
- *Sampling.* Since the sampling for the quantitative survey will not use quotas, there is a medium risk that those who opt-in are not representative of the population. This is managed by the school-based method to cover a range of age, sex, deprivation levels and ethnicities across the sample.
- *Participation from local stakeholders.* This study relies on participation of local stakeholders whom we do not yet know will buy-into the study. We have managed this medium risk by engaging from the start with London-wide study collaborators who have influence in local authorities, and by conducting the study in a locality where the lead applicant already has close connections. It also uses tried and tested methods designed to create shared understandings from early on in the study.

Version control table

Version	Author	Purpose/change	Ethics approved?
1	Mark Spires & Corinna Hawkes	Originally submitted protocol – approved by NIHR with suggested changes	No
2	Mark Spires & Corinna Hawkes	Updates based on NIHR feedback	No
3	Mark Spires & Corinna Hawkes	Updates based on NIHR feedback	No
4	Mark Spires & Corinna Hawkes	Final updates based on NIHR feedback (added funding acknowledgement and version control table) removed salary information.	No
5	Multiple	Updates made to various methods (highlighted areas)	Mostly (30.3.2021)
6	Multiple	Minor updates made	Mostly (03.12.2021)

Acknowledgement: Research funded by the National Institute for Health Research (NIHR).