Protocol

Full Title	Fresh Street Food and Health Pilot study
Short Title	Fresh Street Food and Health Pilot study
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Study website	**www.freshstreet.uk**

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Protocol version control			
Version number	**Author**	**Effective date**	**Reason for change**
V1.0	**CR**	October 2020	Sent to QMERC who requested more detail
V2.0	**CR**	1st May 2021	Revisions required by NIHR Additions: internal pilot feasibility study, COVID related questions, new voucher security supplier
V3.0	**CR**	5th May 2021	Revised for QMERC
V4.0	**CR**	12th August 2021	Main study removed Revised to only include pilot study

Contents

1. Glossary

Abbreviations

CI	Chief Investigator
DEFRA	Department of Environment, Food & Rural Affairs
DHSC	Department of Health and Social Care
DQQ	Dietary quality questionnaire
DWP	Department of Work and Pensions
FV	Fruit and vegetables
ECT	Excess Treatment Costs
GDPR	General Data Protection Regulation
GP	General practitioner
IMD	Index of multiple deprivation
ISC	Independent Steering Committee
LSOA	Lower Super Output Area
PCTU	Pragmatic Clinical Trials Unit
QoL	Quality of life
QL	Qualitative data
QN	Quantitative data
RCT	Randomised controlled trial
UPRN	Unique Property Reference Number
YHS	Yorkshire Health Study

Research team

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2. Signature page

CI Agreement

The study, as detailed within this Research Protocol, will be conducted in accordance with the principles of GCP, the UK Policy Framework for Health and Social Care Research, and the Declaration of Helsinki and any other applicable regulations. I delegate responsibility for the statistical analysis and oversight to a qualified statistician (see declaration below).

CI name: **Dr Clare Relton**

Signature: 

Date: **12th August 2021**

Statistician's Agreement

The study as detailed within this research protocol will be conducted in accordance with the current UK Policy Framework for Health and Social Care Research, the World Medical Association Declaration of Helsinki (1996), Principles of ICH E6-GCP, ICH E9 - Statistical principles for Clinical Trials and ICH E10 - Choice of Control Groups.

I take responsibility for the statistical work in this protocol is accurate and take responsibility for statistical analysis and oversight in this study.

Statistician's name: **Sandra Eldridge**

Signature: 

Date: **11th August 2021**

3. Summary and synopsis

Short title/ Public title	Fresh Street Food and Health Pilot Study
Health condition(s) or problem(s) studied	Low diet quality (especially fruit and vegetable consumption), high levels of food insecurity and diet-related ill health, in areas of high deprivation.
Primary registry and trial number	ISRCTN registry. Registration number tbc
Countries of recruitment	England
Research Sites	**(1)** Doncaster Metropolitan Borough Council **(2)** Bradford Metropolitan Borough Council **(3)** London Borough of Tower Hamlets Council
Aims	To undertake a pilot study in order to inform the design and conduct of a main trial to evaluate the impact of the intervention on a range of interconnected challenges for UK public health nutrition in areas of high deprivation and low fruit and vegetable consumption.
Intervention	Fresh Street a weekly voucher scheme for fresh FV with vegetable-based recipes, brief nutritional information & healthy eating and health-related behaviour change information delivered to all households in an area; all households are eligible, regardless of size, type or income. Vouchers are redeemable with local independent FV retailers.
Inclusion criteria (clusters)	High deprivation (IMD deciles 1-4) Below average FV consumption
Methodology/ Study design	Pilot RCT with process evaluation.
Number of clusters/ Target sample size	Target - 22 clusters (est 600 households)
Primary outcome	Portions of FV eaten yesterday
Key secondary outcomes	Diet Quality, Food Insecurity, Long term health conditions
Process evaluation	To provide insight into the process of implementing the intervention, mechanisms of action of the intervention, and contextual factors which might impact the intervention.
Proposed Start and Date	1st October 2021 - 1st June 2022

4. Introduction: the problem to be addressed

4.1. Unhealthy diets and food systems

This study addresses an issue of major strategic public health importance – how to create and enable sustainable and healthy diets, eating behaviours and food systems in areas of high deprivation. Current UK dietary patterns are suboptimal for health. As a nation, we are failing to meet the recommendations for healthy eating, with areas of high socio-economic deprivation being most at risk of suboptimal diets, food deserts and food insecurity (Bates, 2016).

Many communities in the UK are experiencing food insecurity, i.e. “the inability to afford, or have access to, food to make up a healthy diet” (Department of Health 2005), and consuming diets high in processed foods and low in fresh fruit and vegetables (FV). People living on low incomes are more likely to have a higher consumption of sugar and saturated fatty acids, and lower intake of fruit and vegetables and dietary fibre than recommended (Food Standards Agency, 2007).

Although the UK population is aware of the importance of FV for health, many people lack the means to ensure that their daily diets include sufficient FV. There are multiple reasons as to why this is the case: food deserts, heavy and pervasive ‘cradle to grave’ advertising for unhealthy food products, and poverty (FV is less affordable and comparatively less value for money when the priority is filling up, palatability, convenience and avoiding waste). This leads to sub-optimal FV consumption and increased preventable morbidity and mortality, substantial associated costs to society, and one of the most obese populations in Europe.

Local food systems are complex; incorporating elements of local, national and international companies, which produce and retail groceries and ready-to-eat foods. Interventions are needed to help reorient local food systems so that they support healthy eating patterns, advance health goals and advance important economic, social and environmental goals, which impact on health in the longer term (Parsons & Hawkes 2018).

Diet-related ill health in the UK costs the National Health Service (NHS) at least £6 billion annually and is responsible for about 10% of deaths and illness (Scarborough 2011). Furthermore, the burden of disease is higher in socioeconomically disadvantaged communities. There is, therefore, an urgent need to identify effective and cost-effective interventions to minimise poor diet, by increasing the intake of healthy food and reducing the intake of sugar-sweetened beverages and foods high in salt, sugar, and saturated fats. Optimal diet means substantial increases in FV, pulses, nuts, seeds, fish, seafood, olive oil, and omega-3. The UK 5 A Day guidelines state that adults should eat at least five 80g portions of a variety of FV every day. These national guidelines are based on WHO recommendations that consuming 400g of FV a day can reduce risks of chronic diseases, including heart disease, stroke, and some cancers (Hartley et al. 2013).

4.2. Cash transfer/ Voucher schemes

There is mounting evidence that price discounts are effective in increasing healthy food purchasing (An et al, 2013) and increasing consumption of healthier foods (Brambila-Macias et al, 2011). There is evidence that opening new independent FV retail outlets (farmers markets, produce stands, mobile produce markets), increases FV consumption in the short-term (Woodruff et al, 2018), including in food deserts. There are a number of established targeted voucher (cash transfer) programmes. In the USA, two programmes target those on low incomes: (i) The Supplemental Nutritional Assistance Programme (SNAP) is used to buy a wide range of products in supermarkets (the SNAP value is doubled if vouchers are used in farmers markets), and (ii) the Women Infant and Children (WIC) programme for those on low income.

In the UK, the Department of Health & Social Care funded 'Healthy Start' programme provides vouchers worth £4.25 per week, for FV, pulses, milk and infant formula to pregnant women and carers of children under four, and £8.50 for children under 1year, in households on income support (Healthy Start). Application is via healthcare providers, and vouchers are sent monthly. There was initial observational data which indicated that 'Healthy Start' was effective in increasing FV uptake (McFadden, 2014). However, most vouchers for children under 1 year are used for infant formula rather than FV (Crawley, 2018), the targeted nature of the scheme brings about stigma (McFadden, 2014) and uptake of the scheme is declining. In 2019 just 54.2% of eligible families were using the scheme (Department of Health, 2019).

4.3. Development and feasibility of the intervention

'Fresh Street' is an innovative multi-component intervention, which combines supplier specific vouchers for fresh FV with a range of diet and health information. The vouchers are offered to **all households** in a geographical area regardless of household type, size or income. The combination of fiscal measures with regular multi-faceted communication/ marketing information has been developed to reduce food insecurity, increase daily consumption of fresh FV, and improve dietary quality, support healthy dietary habits, and increase exposure to healthy food prompts.

In 2017, CR & MB & stakeholders developed and feasibility tested the 'Fresh Street' intervention in an area of high deprivation in the north of England funded by MRC PHIND, with support from Barnsley Metropolitan Borough Council and the Alexandra Rose Charity.

The feasibility of the scheme was assessed in four streets using rapid ethnographic assessment (Manderson et al, 1992) and voucher redemption information. The 12 month scheme was popular and seen to be of benefit to local people and local traders. Most (84%, 80/95) eligible households joined the scheme and most (89%) vouchers were redeemed. Householders frequently reported that the scheme made them think more about what they were eating, and prompted them to buy and eat more FV. The local FV shop and market stalls reported new customers and that existing customers were buying more. People frequently talked (unasked) about their health and some reported that the scheme motivated them to lose weight (Relton et al, 2020).

In 2018, a second feasibility test was conducted in a block of 54 two-bedroom flats in a deprived area of Sheffield (Callow Place, Gleadless). This was situated in a food desert (i.e.

no local supply of fresh FV). Vouchers were redeemable at the four FV stalls in Sheffield Moor Market (3 miles away), or exchanged for a £5 bag of fresh vegetables and apples delivered to the flats each week. About 75% of eligible households joined the scheme and 70%+ of the vouchers issued were redeemed. Doorstep conversations revealed similar responses to the Barnsley scheme (the scheme made them think more about what they were eating, and prompted them to buy and eat more FV) and market stalls reported new customers. However, interest in the weekly delivered £5 vegetable bag was low with most preferring to choose their own FV from the market stalls.

4.4. Summary and implications for research

- Many communities in the UK are failing to meet the recommendations for healthy eating, with areas of high socio-economic deprivation being most at risk of suboptimal diets, food deserts and food insecurity.
- Although the UK population is aware of the importance of FV for health, many people lack the means to ensure that their daily diets include sufficient FV.
- Interventions are needed to help re-orientate local food systems so that they support healthy eating patterns, advance health goals and advance the economic, social and environmental goals, which impact on health in the longer term.
- There is preliminary evidence of the acceptability and deliverability of 'Fresh Street' intervention.
- Research is now needed to assess the impact of this intervention on FV consumption, diet, health and the wider environment.

5. Aim and objectives

We aim to undertake a pilot study (consisting of a pilot trial and a process evaluation) in order to inform the design and conduct of a main trial to evaluate the impact of the Fresh Street scheme on a broad range of interconnected challenges for UK public health nutrition in areas of high deprivation and low fruit and vegetable consumption.

The pilot study objectives are to:

a. Deliver the intervention in different sites
b. Assess uptake of the intervention and identify factors which may impact on intervention success
c. Create a manual describing a potential new public health intervention (Fresh Street)
d. Test, refine and optimise household survey data collection methods
e. Demonstrate that baseline primary outcome measure responses are obtainable from at least 50% of households
f. Conduct a process evaluation to assist interpretation of findings, and inform implementation of the intervention
g. Refine the methods for the main trial and process evaluation
h. Gain insight into the perspectives of key stakeholder groups (e.g. Directors of Public Health, Community, Retail)
i. Obtain additional intervention funding required for the main trial.
j. Collect outcome data from pilot sites, if required.

Research hypothesis

We hypothesise that together the different components of the intervention provide the conditions required to trigger the behaviour changes needed to increase FV consumption and improve diet quality.

6. Study design

6.1. Pilot study design

Parallel group, cluster randomised controlled pilot trial (RCT) with integrated process evaluation. Clusters (streets) are randomised to intervention or no intervention.

6.2. PICO summary for the pilot trial

Population: Areas with a high deprivation index (IMD deciles 1-4) and low fruit and vegetable consumption are eligible to participate in the pilot trial

Intervention: Provision of Fresh Street scheme

Comparison: No provision of Fresh Street scheme

Outcomes: PRIMARY: Portions of FV consumed yesterday; SECONDARY: diet quality, food insecurity, long-term health conditions, health-related quality of life, life satisfaction;; and healthcare utilisation.

6.3. Progression criteria

The following progression criteria will be assessed towards the end of the pilot study by and the NIHR and the independent project steering committee (PSC). They will consider the process data and decide whether it is feasible to proceed to a main trial. In order to evaluate the trial feasibility, the PSC will apply the following stop/ modify/ go progression criteria:

Green (continue):

- Demonstrated we can collect data on the primary outcome measure (i.e. >**50%** of both groups provide baseline data*)
- Secured intervention funding for at least **856** households for at least two years

Amber (decision required from funder on whether to continue to the main trial):

- Demonstrated we can collect data on the primary outcome measure (i.e. > **25%** of both groups provide baseline data*)
- Secured intervention funding for at least 856 households for at least one year

Red (stop as not feasible):

- N**ot** demonstrated we can collect data on the primary outcome measure (i.e. < 25% of both groups provide baseline data*)
- **Not** secured intervention funding for 856 households for at least one year

* 50% of households in study streets provide information from at least one person in that household

7. Methods

7.1. Study setting and population

The sampling frame for the pilot trial is geographical areas of high deprivation (IMD deciles 1-4) where diets are below average in FV consumption in the UK according to PHE Public Health Profile '5-a-day' indicator (https://fingertips.phe.org.uk/search/fruit).
The intervention is targeted at streets (the unit of randomisation).

7.2. Area level consent

Over-arching consent for the areas to take part in the study is obtained from each local authority (via consultation with Public Health teams, community leaders and councillors). This method for consenting areas has been successfully used in area based public health voucher based intervention trials (Relton et al, 2018).

7.3. Eligibility criteria

Clusters (streets)

- High deprivation (IMD deciles 1-4)
- Below average (<2.7) number of daily portions of FV per person consumption for area

Participants (households)

- Private residential households

7.4. Intervention

The intervention (Fresh Street scheme) is described below using the Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann et al, 2014). The pilot will enable us to deliver the intervention in different sites (objective a), assess uptake and identify factors which may impact on intervention success (objective b), create a manual describing a potential new public health intervention (Fresh Street) (objective c), (see Section 7.9 Data collection) and improve our ability to evaluate the intervention in the main trial (objectives d & f).

Table 1: Intervention description using the TIDieR checklist

Item 1. **Brief name**: Provide the name or a phrase that describes the intervention	**Fresh Street** A place-based household voucher approach to increasing fruit and vegetable consumption.
Item 2. **Why:** Describe any rationale, theory, or goal of the elements essential to the intervention	The Fresh Street combination of fiscal measures with regular multi-faceted communication/ marketing information is designed to reduce food insecurity, increase daily consumption of fresh FV, and improve dietary quality, support healthy dietary habits, increase exposure to healthy food prompts. The goal is to help re-orientate local food systems so that they support healthy eating patterns, and advance the economic, social and environmental goals which impact on health in the longer term.
Item 3. **What (materials):** Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers.	Intervention materials delivered weekly in branded envelopes to individual households. Each envelope contains a letter to households with £5 worth of Fresh Street branded paper vouchers redeemable with local independent FV retailers (not supermarkets), a healthy and seasonal vegetable based recipe and nutrition and health/diet related information. Letters may include additional content e.g. encouraging households to share unused vouchers. A branded website offers online information. Branded posters displayed at participating FV retail outlets to show they accept Fresh Street vouchers.
Item 4. **What (procedures):** Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities	Printing of secure, traceable, vouchers by A1 Security Print https://www.a1securityprint.com/, redeemable at local FV retailers Training of FV retailers (what items vouchers can be used for and how to redeem the vouchers) Writing weekly covering letters Printing letters and packing envelopes and delivering envelopes

	FV shopping and spending of vouchers by participants Redemption of vouchers by FV retailers, scanning unique QR codes using online app developed by A1 Security Print Reimbursement of voucher value
Item 5. **Who provides**: For each category of intervention provider (for example, psychologist, nursing assistant), describe their expertise, background and any specific training given	A1 Security Print have expertise in the production of secure cash transfer processes. Their clients include retail, education, government and banking. Local council staff bring their understanding of socio-economic conditions and public health issues in their local areas supplemented by the experience gained by QMUL staff in previous Fresh Street feasibility studies. FV retailers engage with households (customers) and are experts in the supply and use of FV in each local area. Community partners recruited to facilitate the weekly delivery of envelopes. This will involve local community and charity groups e.g. Good Gym (www.goodgym.org) a social enterprise which engages in community activities.
Item 6. **How:** Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention	Envelopes delivered by hand by community partners or local staff. FV picked up by participants or delivered to their door
Item 7. **Where**: Describe the type(s) of location(s) where the intervention occurs, including any necessary infrastructure or relevant features	Fresh Street is designed to be delivered in areas of high deprivation (IMD deciles 1-4) and low fruit and vegetable consumption. Fresh Street vouchers delivered by hand to households in participating streets. Fresh FV supplied by local market traders either in their own premises or through their existing delivery channels.
Item 8. **When and how much:** Describe the number of times the intervention was delivered and over what period of time	Households receive the intervention (including vouchers worth £5) every week.
Item 9. Tailoring: If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how	The recipes and healthy eating messages adapted to match the characteristics and resources in each setting (e.g. dietary habits, ethnic profiles, food geographies, and local priorities and resources) by the Fresh Street team in collaboration with local partners.
Item 10. **Modifications**:	n/a
Item 11. **How well (planned):** If intervention	We will explore the extent of any vouchers being used to purchase non FV items (i.e., 'trade' in vouchers) during

adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them	qualitative interviews with local residents and by using 'mystery shoppers' (Jumbe et al, 2019). FV vouchers will be fully auditable in order to trace any unusual or fraudulent activities.

7.5. Sample size

Sample size for the pilot trial

The target for the pilot trial is 22 clusters (~300 households in each arm). - this is 33% of our main trial size and we think this is sufficient to enable us to address the objectives of the pilot.

There is no data from randomised trials that have used the portions of FV eaten yesterday questions on which to base a sample size calculation.

The original sample size calculation for the main trial (68 clusters with an estimated 856 households in each arm) was based on an increase of 0.5 in the number of portions of fruit and vegetables per person per day assuming a standard deviation of 2.0 (estimated for Health Survey for England 2017 taking into account our target population). This constitutes a small standardised effect size of 0.25. Stakeholder views of what constitutes a relevant increase in portions of FV eaten will be obtained during the pilot stage. Combining these with baseline cohort estimates of variability of portions of FV eaten will allow to assess whether effect size 0.25 will need to be revised and the required sample size be recalculated, changing the recruitment target for the main trial.

Sample size for process evaluation interviews

Semi-structured interviews (phone or face to face) will be conducted with up to 15 intervention households and up to 6 control householders or until data-saturation is reached. A purposive sampling strategy will then be adopted to ensure a full range of views, typical of the wider population. Maximum variation samples will be attempted based on (as far as possible): households who joined the Fresh Street scheme, households who dropped out of the scheme, and those with different ages, genders and ethnicities. All vendors will be contacted and invited to take part in interviews 3-4 months after the start of the intervention delivery.

7.6. Randomisation and allocation

In each site the council chooses an area which comprises a number of streets with between 500 - 1200 households per site (1200 = maximum size for a LSOA). A proportion of eligible streets in these sites will then be randomised to either the intervention or control. The allocation ratio will be 1:1.

Stratified (by site) permuted blocked randomisation with block sizes of m=6 and 4 will be used to ensure a similar number of clusters within each arm. The randomisation will be carried out remotely by the PCTU. One researcher per site will be un-blinded and will be authorised to request randomisations. An independent statistician from the PCTU will generate randomisation lists and will return the cluster allocations to the un-blinded researcher via

email. Further details will be explained in the Data Management Plan which will be agreed and signed off between the trial study team and PCTU.

7.7. Blinding

Due to the nature of the intervention pilot trial participants cannot be blinded to treatment allocation if they are in the intervention arm and neither can the researchers working on the field and/or at Council level. However, those involved in writing the statistical analysis plan and assessing the data will remain blinded to participant's allocation until the point of analysis.

7.8. Recruitment

The participating sites (listed below and in the study collaborators section) have already been recruited and their process of recruitment is not described here. Whilst more may be added in the future, the **sites** currently involved in the Fresh Street project are as follows: **(1)** Doncaster Metropolitan Borough Council, **(2)** Bradford Metropolitan Borough Council and **(3)** London Borough of Tower Hamlets Council.

All sites will be included in the pilot once they have the relevant approvals.

N.B. **Separate** HRA approval will be sought for members of the Grounded Research Team (based at RDaSH NHS Foundation Trust) to support the evaluation and deliver the intervention during the pilot.

Strategies for data collection to support the evaluation

There are substantial long-standing barriers to recruitment and public participation in health research (lack of saliency, lack of trust, and concerns relating to lack of privacy and agency), particularly from those groups characterised as 'hard to reach'. These barriers were experienced during the evaluation of the Fresh Street feasibility study in an area of high deprivation in Barnsley (Relton, 2020). Householders were invited to complete a health questionnaire (Yorkshire Health Study). Although there was high uptake of the intervention, >90% of householders declined to complete the health questionnaire. This was in part due to concerns that information might be shared with the Department of Work and Pensions (DWP).

In order to ensure that we obtain sufficient valid information to enable a robust evaluation of the intervention in this study we are adopting a range of strategies to build trust and increase saliency and thereby maximise survey response rates:

- Door knocking with face to face request/help to complete survey by local people with letterbox delivery of survey (with pen and SAE) for non-responders
- Minimising requests for more personal/ sensitive information
- Attractive easy to complete survey format
- Framing the surveys by highlighting the locality (e.g. Doncaster), the topic (Food, Health) or issue (COVID, climate change),
- Minimising survey length
- Offer of local supermarket voucher (or donation to local food bank)
- Primary research questions at survey start, personal questions at the end

- Hand written address on the envelope

The pilot and process evaluation will enable us to assess the feasibility and utility of these strategies using survey responses and web traffic data and identify the most effective combination of approaches.

7.9. Data collection

During the pilot we will collect a wide range of quantitative and qualitative data to enable us to assess uptake of the intervention, and identify factors which may impact on intervention success (objective b).

The pilot will enable us to test, refine and optimise our household survey data collection methods (objective d) for the main trial and process evaluation (objective g). We aim to demonstrate that we can obtain baseline primary outcome measure responses from at least 50% of households (objective e).

The **primary outcome measure** for the pilot trial is portions of FV eaten yesterday. This information is asked using two questions from the Active Lives Survey questions (Sport England Active Lives Survey April 2020). This survey asks about healthy lifestyles and leisure, recreational, and cultural activities. It is conducted annually on behalf of government agencies including Sport England, Arts Council England and Public Health England by Ipsos MORI, an independent social research organisation. The survey is sent out to a randomly selected sample of households across England and completed online or on paper. The overall sample size is around 175,000 people for each survey with a minimum annual sample size for each English local authority of 500.

The two questions are:

> *"How many portions of fruit did you eat yesterday? Please include all fruit, including fresh, frozen, dried or tinned fruit, stewed fruit or fruit juices and smoothies. Fruit juice only counts as one portion no matter how much you drink."*
>
> *"How many portions of vegetables did you eat yesterday? Please include fresh, frozen, raw or tinned vegetables, but do not include any potatoes you ate. Beans and pulses only count as one portion no matter how much of them you eat."*

Extra information on what counts as a portion is provided alongside these two question (see Appendix 1 Full FV Tower Hamlets survey).

The **secondary outcome measures** include: Diet Quality (Roberts et al, 2018), food insecurity (Cafiero et al, 2018), long-term health conditions (Green et al, 2014), health-related quality of life (Rabin and Charro, 2001), and life satisfaction (Green et al, 2014). Secondary outcomes which are most likely to be impacted are listed in order.

The majority of the primary and secondary outcome measure data will be self-reported data from adults living in households in the streets.

The range of data that we plan to collect during the pilot is described in **Table 2. Data collections tools and sources.**

Surveys

Primary and secondary outcome data for the trial will be collected by contacting all households in the intervention and control clusters and asking one adult from each household to complete a survey. Collection of baseline data in the pilot will be completed before the introduction of the intervention.

If the decision is made not to progress to the main trial and/or the intervention ceases to be delivered then we will supplement baseline survey data with outcome survey data from households in all of the pilot clusters (objective j). We will use a repeated cross sectional trial design (i.e. the survey respondent from each household may not be the same at each data collection time point and respondents may also be from a different household if a new household moves into the house). This will enable us to obtain a representative picture for each of the streets.

The pilot will help us find ways to maximise survey responses (see section 7.8). We will find the best ways to frame questions (especially the primary outcome questions) by iteratively refining the script already developed. We will assess which questions need to be excluded from the survey either because householders perceive questions as irrelevant or sensitive e.g. ethnicity, vaccine status, or because the survey is too long.

Paper and/or online surveys

In the pilot we will begin with the paper survey. The research team will door knock every house in each of the streets and ask respondents to complete survey. If no one answers then the survey will be put through the letterbox with pen and stamp addressed envelope. After the first 200 households have had a chance to respond using the paper survey, if the response is insufficient (<50% provide baseline data) we will then introduce online surveys in addition to paper surveys. Using a cut-off of 200 responses will enable us to compare response rates and participant characteristics from paper and paper plus on-line surveys at the end of the pilot. After 200 responses the maximum margin of error around our assessment of response rate will be 7%.

If we collect data using both paper and on-line methods, then we need to decide whether one method gives a better representative sample than the other or whether to use both methods (and if so in what order/ time sequence).

We aim to ensure that we obtain valid unbiased data (RoB 2 for cluster randomized trials) (**see section 7.10**). Surveys will only be valid if both the name of the street and the house number is provided. This will be the case for both paper and on-line surveys. If we receive two or more valid responses (paper or paper and online) from the same household, then we will consider the paper survey response as the primary response. If two or more valid online surveys are received then we will consider the first valid online response as primary if there is no paper response.

Questions in the paper and the online surveys will be exactly the same. Paper surveys will be branded for each site e.g. Tower Hamlets Food and Health Survey (see Appendix 1).

However, the online surveys come in three different formats and have the following names*: "What do you eat?", "Do you have enough to eat?"* and "*Virus Health and Wellbeing checKer (V-HAWK)".* (see Table 2)
These online surveys will be integrated into QMUL 'Healthy People, Healthy Places' online platform (https://qmul.citizenlab.co/en/).

Table 2: Survey outcome data collection tools and sources

Data item	Measure/ Source	Online survey name
Primary outcome data		
Portions of FV eaten yesterday	Active Lives Survey (two questions)	*What do you eat?*
Secondary outcome data		
Diet Quality Score (in the past month)	Diet Quality Questionnaire (DQQ)	*What do you eat?*
Food insecurity (in the previous 12 months)	Food Insecurity Experience Scale (FIES)	*Do you have enough to eat?*
Long term conditions (fatigue, pain, insomnia, anxiety, depression, diabetes, breathing problems, high blood pressure, heart disease, osteoarthritis, stroke, cancer, long COVID, other)	Questions from the Yorkshire Health Study (YHS) Health Questionnaire	*Virus-Health And Wellbeing checKer (V-HAWK)*
Virus symptoms, COVID diagnosis		*V-HAWK*
Life satisfaction	YHS Health Questionnaire	*V-HAWK*
Health Related Quality of Life	EQ-5D	*V-HAWK*
Healthcare utilisation (last 3 months)	YHS Health Questionnaire	*V-HAWK*
Free text comments (diet and health)		*What do you eat V-HAWK*
Respondent and household information		
Respondent Ethnicity, Age group, Gender, COVID vaccine status, Consent to contact.		
Household Composition		
Street name and house number		

For qualitative interviews conducted with householders, brief topic guides will be developed and piloted, and interviews either recorded by the field researcher using written notes or digitally recorded and transcribed depending on the preferences of the interviewee.

7.10. Sources of data relating to the intervention

Types and sources of data relating to the intervention are listed in Table 3. This includes data on the delivery of the intervention (voucher data), FV supply data from vendors and also opportunistic conversations with householders and FV retailers.

Voucher distribution and redemption data will enable us to identify which households have redeemed vouchers, where and when. This will also enable us to cease supply of vouchers to households not using the vouchers. Households will be informed that if they do not use the vouchers within 4 - 6 weeks of receipt then we will stop delivering the weekly envelopes (which contain the vouchers). The rationale for this is two-fold (i) to prompt householders to use the vouchers regularly (rather than stockpile and/or trade/sell on) and (ii) unused vouchers create waste and increase the cost of the intervention. However, retailers will be told to accept all vouchers regardless of use by date so that it is easy for the retailers to rapidly accept the vouchers.

Some FV stalls and FV shops may sell non FV items. We will explore the extent of any vouchers being used to purchase non FV items (i.e., 'trade' in vouchers) during qualitative interviews with local residents and by using 'mystery shoppers' (Jumbe et al, 2019) (see section 7.15). FV retailers are made aware of the possibility of a visit by mystery shoppers on sign up. Mystery shoppers will also periodically collect data on prices of key FV products at local participating and non-participating FV retailers, to study any possible effects of the intervention on FV prices over the lifespan of the pilot and the impact of changing prices on the use of vouchers. Information on the types of FV items purchased will be collected during opportunistic conversations with householders and FV retailers e.g. during delivery of envelopes or checking with FV retailers on how the scheme is working.

Table 3: Data on the intervention

Intervention delivery data	
Type of data	**Source**
Vouchers distributed (date, household)	Log data
Vouchers redeemed (date, location)	Voucher Reimbursement system
Resources required to distribute and redeem vouchers	Study records
Items purchased (including any 'trade' in vouchers	Mystery shoppers, Opportunistic conversations with vendors, householders
FV price data	Mystery shoppers

Trained local community researchers will conduct doorstep conversations and one to one interviews, either in person or remotely, with a maximum variety, purposive, sample of householders. An experienced qualitative researcher will conduct informal interviews with local opinion leaders and stakeholders including commissioners, LA employees, local PH

staff, and FV retailers. Qualitative data, such as that inputted in the free text sections of the surveys and the data gathered through interviews and doorstep conversations, will be analyzed using content and thematic analyses. This form of analysis will enable us to identify prominent topics and key themes across the data sets collected.

7.11. Methods to reduce potential bias in outcome measurement.

Randomisation guards against much of the bias between groups in outcome measurement. However, in trials such as Fresh Street where participants providing data and/or outcome assessors are not blinded to the intervention, bias in those responding and their responses can occur. When high response rates are achieved the effect of bias in those responding is minimised. When response rates are lower there is more potential for this bias. In the pilot we are not collecting outcome data unless the pilot indicates that the main trial is not feasible; thus if the main trial goes ahead we will have no direct information on these biases prior to starting the main trial. We can, however, explore what participants say about what might affect their likelihood of responding and likelihood of responding in certain ways within the qualitative part of the pilot study.

We will take care that intervention messaging around FV consumption does not bias survey responses from the intervention group. We also plan to match intervention and control streets and collect outcome data in matched streets at the same time to ensure no differences in the mode or time of when surveys are delivered/ collected to intervention and control.

Bias in responders will occur if there are differences between responders in the intervention and control group in relation to (1) factors that are known or thought to affect the primary outcome - self-reported fruit and vegetable consumption (2) factors that might affect the uptake of the intervention.

Factors known or thought to affect fruit and vegetable consumption are mainly related to socio economic status (SEC). Data on proxy markers for SEC will be collected in the pilot study (ethnicity, health related quality of life, long term conditions and multi-morbidity). Factors that might affect the uptake of the intervention will be assessed in the pilot (e.g. Household composition). Table 4 below describes the data collected to help the pilot evaluation and includes the rationale for collecting each type of data.

Table 4: Survey evaluation data

Rationale for data sought	Type of data included
Primary outcome measure	Portions of FV eaten yesterday (two Active Lives Survey questions)
Secondary outcome measures	Diet Quality Questionnaire (DQQ), Food insecurity, Long Term Health conditions, Virus symptoms, COVID diagnosis, life satisfaction, EQ-5D
To ensure unique response from each included household and to enable outcome analyses to adjust correctly for clustering	House number, Street name
To enable subgroup analyses (especially comparison with DH funded Healthy Start Scheme)	Household composition (numbers in household, under 5 yrs, 5-18 yrs, 65yrs+)

To understand characteristics of survey responders and help assess whether intervention and control group responders are similar/balanced	Ethnicity, EQ-5D, Long Term Health conditions, multi-morbidity, Household type; age and gender
Other types of data collected	
General information	Free text "any comments about your diet" question
Process data (paper)	Date survey distributed/ returned Whether accept voucher or not Doorstep conversation data
Process data (online)	Date survey distributed/ returned IP address

7.12. Stakeholder engagement

In order to gain insight into the perspectives of key stakeholder groups (e.g. Directors of Public Health, Community, Retail) we hold a 'Fresh Street' symposium. We will invite key stakeholders in public health nutrition, food insecurity and health inequalities from both government and third sector organisations. This will include representatives from the Healthy Start programme, national healthy eating awareness programmes (EatWell, Start4Life, Change4Life), the DWP Family Resources Annual Survey and also national dietary surveillance programmes. Symposium attendees will share what is known about place-based food subsidy approaches to public health nutrition and we will share our plans for assessing the impact of the Fresh Street intervention. This symposium will enable us to refine our plans, and in the longer term, help ensure that our study provides the evidence required by stakeholders on the impact of the intervention on the broad range of interconnected challenges for UK public health nutrition

7.13. Data management

The Fresh Street pilot study will collect data from a variety of sources (see Section 7.9 Data collection).

The PCTU Data Management team will provide advice and support to ensure data is collected, stored and managed safely and robustly for the pilot, including drafting the Data Management Plan, and assisting with data transfer and data storage.

Survey data will be collected initially in paper format, and if necessary, identical questions will be collected online using the SmartSurvey platform via our CitizenLab public engagement platform 'Healthy People, Healthy Places'. The SmartSurvey online platform is DSPT compliant with all data stored in the UK in an ISO27001 compliant data centre.

Responses to paper surveys will be retrospectively added to the online dataset via SmartSurvey.

Paper surveys will be drafted by the Fresh Street research team (CR, DU, GB) and reviewed and signed off by the statistical and data management teams. The development of online surveys on SmartSurvey will be completed by the Fresh Street research team following PCTU Data Management SOPs and processes. Any changes to the survey questions will be agreed by those who will be analysing the quantitative data (statisticians) and qualitative data (Fresh Street team).

Data storage

The PCTU Data Management team will advise on appropriate data storage strategies including integrated data validation checks and audit trails.

All electronic data for the Fresh Street pilot will be stored on the QMUL BCC Safe Haven environment (https://safehaven.bcc.qmul.ac.uk/). SmartSurvey data will be downloaded and stored in the secure QMUL BCC Safe Haven environment. PCTU based research team members will have assigned access rights to access and analysis the data.

The Data Management team will advise on the transfer, storage, back-up and archiving of data on the QMUL BCC Safe Have environment.

All paper records (completed paper surveys, consent forms and recruitment logs) will be held in designated locked cabinets. Only named, designated staff who have data protection training will be given access to the paper records held at QMUL and at the local research sites.

All mobile devices and media used to collect and transfer data will be encrypted.

Data access

The QMUL Fresh Street research team will have access to all pilot data. The data analysis team will remain blind to allocation.

Access to SmartSurvey data will be controlled using designated users with permitted access rights.

Local site teams (Doncaster, Bradford and Tower Hamlets) will have access to any data collected by their community researchers i.e. **household voucher data** and the **paper survey** and **qualitative data**.

Maintaining data security

The PCTU will advise on current regulatory framework regarding data protection and data management procedures in compliance with GDPR, the Data Protection Act and trial management regulations. This advice will apply to all data in the pilot trial.

We will store the data for five years in line with the QMUL Records Retention Schedule.

Data will be made available for re-use by other bona fide researchers.

7.14. Data analysis

Analysis of voucher distribution and redemption data will enable us to assess uptake of the intervention (objective b) including weekly spending patterns of each household - how many vouchers were spent, and when and where.

We will assess what proportion of households contacted provide valid baseline primary outcome measure responses (objective e).

Any analysis of outcome data will be by intention-to-treat. All clusters and households for whom an outcome is available will be analysed according to the group to which they were randomised. Households which cannot be linked to a street participating in the study will be excluded.
The primary outcome analysis will compare the mean difference between intervention and control in portions of FV eaten the day before. A mixed regression model will be used where an individual household outcome at follow-up is adjusted for baseline cluster (street) mean score and site, and within cluster correlation is allowed for.

There is likely to be some contamination relating to sharing of vouchers, sharing of information, supplier effects and household churn i.e. households moving into or out of the intervention/ control streets. Potential sources of contamination will be monitored throughout during qualitative interviews and analyses adjusted where possible.

7.15. Health economic evaluation

In the main trial, we will use prospectively collected study data to assess the cost of implementing and managing Fresh Street from the local public services' perspective, and the impact on FV consumption and diet quality, and using external data on the association between diet and mortality, the intervention's long-term impact on survival and quality of life. A further scenario analysis will include the likely impact of Fresh Street on household's private costs for FV. We will follow a bottom-up approach to estimate the resources used in the intervention, which include the vouchers' monetary value; resources for printing and delivery; promotional activities; vouchers' reimbursement to FV retailers; and general scheme management costs.

During the pilot trial we will consolidate our approach to assessing intervention's cost and assess the feasibility (i.e. response rates) of collecting self-reported healthcare utilisation data from participating households and FV prices' data (with focus on key high-demand FV products) from participating FV retailers.

7.16. Process Evaluation

Alongside the pilot trial, we will conduct a process evaluation to assist our interpretation of findings, and inform any future implementation of the Fresh Street intervention (objective f). This will help us refine our methods for the process evaluation that will run alongside the future main trial (objective g).
The process evaluation is informed by the Medical Research Council (MRC) guidance on evaluating complex interventions (Moore et al., 2015; MRC, 2008).
The process evaluation will aim to understand how the intervention was experienced by those delivering it (FV vendors, public health teams, local stakeholders) and receiving it (householders). The evaluation will provide insight into a) the process of implementing the intervention, b) the mechanisms of action of the intervention, and c) contextual factors which impact on intervention success. If the trial is positive, this will inform the implementation of the intervention and our theory of change/ logic model. If the trial is negative, this will assist our interpretation of findings. The process evaluation will combine quantitative data

(information on voucher use, household surveys) and qualitative data (interviews with vendors and information from 'mystery' shopper interviews with households and local stakeholders and community narratives).

Theoretical framework

The 2008 MRC framework emphasises the need for a strong theoretical foundation to inform evaluation. The study will be informed by Normalisation Process Theory (NPT) – a middle-range socio-behavioural theory (May & Finch, 2009) which has been most commonly used to assist understanding of interventions as part of feasibility studies and process evaluation (May et al., 2018). NPT offers a framework with 4 constructs and 16 sub-constructs to assess the behaviour change and work that individuals and groups do to implement new practices into their daily routine (e.g. eating more FV) (Finch et al., 2013). We will also incorporate Sekhon's framework (2017) in order to further our understanding the acceptability of the intervention.

The theoretical components of the process evaluation are reported in Table 5.

Table 5: Process Evaluation elements

Normalisation Process Theory			
Construct	***Households***	***FV vendors***	***Stakeholders***
Coherence The work of making sense individually and collectively about what the voucher scheme is and why it is important	Understanding the value of eating FV and how the voucher scheme works	Understanding how the voucher scheme works	Understanding how to adapt the food environment
Cognitive Participation The work of building a community of practice around the voucher scheme	Engaging as a household/street /community in using vouchers	Engaging as a vendor and part of a supply chain in the increased provision of FV	Engaging with other stakeholders in the local area around the issue of FV uptake
Collective Action The work of operationalising the voucher scheme	Use of the vouchers	Acceptance of the vouchers	Active support for the delivery of the voucher scheme in the wider local context
Reflexive Monitoring The work of understanding how the voucher scheme affects the local FV environment.	How the voucher scheme changed FV consumption	How local FV supply chain was changed	How voucher scheme is understood to impact on local food system

We will be gathering intelligence throughout the pilot trial in order to understand the factors that may impact on the success or otherwise of the Fresh Street intervention. We have list some such factors that may impact on the success of the intervention below:

- **Individual/ household level factors**:
- Individual motivational level factors that contribute to purchasing and consuming FV
- Preference for shopping in supermarkets
- Use of other voucher schemes such as 'Healthy Start' and Rose vouchers.
- Lack of cooking skills, cooking resources (e.g. access to gas/electricity, cooker)
- Stigma associated with using the vouchers within retail outlets

- **Societal/ community level factors**:
- Availability of preferred and/or culturally appropriate FV within the retail outlets taking part
- National or local media campaigns (e.g. Marcus Rashford and free school meals).
- National and/or local lockdowns relating to COVID-19 which impact access to local shops
- Prices of food and costs of living in relation to the voucher value
- Promotions on fruit and vegetables in supermarkets
- Change in prices in participating and not-participating FV retailers

- **Project/ research specific factors**:
- Availability of funding to cover the costs of the vouchers within study areas
- Challenges in terms of weekly distribution and reimbursement of vouchers
- Willingness of households to use the Fresh Street vouchers and/or complete survey materials needed to gather information on the schemes impact
- Number of local fruit and vegetable retailers willing to engage in the project

8. Ethics and Research Governance

The study will be sponsored by QMUL and will be managed by this institution in collaboration with the University of Sheffield and the University of Cambridge.

8.1. Ethical issues

We seek Queen Mary University of London Research Ethics Committee approval for the pilot study (we will submit a second application for the main trial).
Approval for additional NHS components for the pilot (i.e. the use of NHS staff to deliver the intervention and support the evaluation) will be sought from the NHS via the Health Research Authority (HRA).

The study will be carried out according to the principles of the Helsinki Agreement and in line with Good Clinical Practice.

This is a low-risk intervention. However, we will be alert to any possible unintended consequences of the intervention, and if we come across a safeguarding issue we will alert the relevant authorities.
A number of ethical issues regarding the **design of the intervention** have already been addressed in the earlier MRC funded Fresh Street development and feasibility study (Relton et al, 2020). For example, the vouchers are **only** exchangeable with local (non-supermarket) suppliers of fresh fruit and veg, thus reducing the risk that vouchers are exchanged for cigarettes/ alcohol, and the vouchers are available to **all** households regardless of income or size of household – thus **avoiding stigma** that is often associated with voucher schemes.

With regards to the **evaluation** there are substantial long standing barriers to public participation in health research (lack of saliency, lack of trust, and concerns relating to lack of privacy and agency) particularly from those groups characterised as 'hard to reach' – many of whom live in areas of high deprivation. This is an ethical challenge for those designing and conducting research. To address this challenge we have sought to minimise the amount of personal information requested and enabled paper and online surveys to be completed with just the name of the street, house number and area provided (See Section 7.9 for details as to what information we seek to collect from individuals.)

Participants may withdraw at any time, up to the point of data analysis when data will be aggregated. Participants will be able to withdraw without giving any reason. Data collected up to the point of withdrawal will be retained for analysis. For interviews, to compensate householders in the intervention and control areas who complete paper surveys and/or agree to take part in qualitative interviews (5-15 minutes in duration) we will offer each householder one £5 local shop voucher.

If online surveys are used and there is insufficient response then we will offer incentives in the form of a Prize drawer entry for £20 voucher for each completed valid online survey.

8.2. Data protection

Survey and interview respondents will be allocated unique study ID numbers. We will manage data and its protection according to principles of good research practice, Data Protection Act (DPA) 2018, GDPR, the Research Governance Framework for Health and Social Care (UK) and in line with PCTU Clinical Trials Unit protocols.

8.3 Record retention and archiving

The UK Policy Framework for Health and Social Care Research requires that research records are kept for 5 years after the study has completed. For studies sponsored by Queen Mary the approved repository for long-term storage of local records is the Trust Corporate Records Centre. All research documentation must be archived in physical form; electronic archiving is not accepted. This section should explain the arrangements for archiving study documentation after the study has ended, and the final destruction of the records.

9. Public involvement

To ensure outputs achieved meet the needs of user and beneficiaries, we will engage stakeholders through a wide range of activities with both direct and indirect beneficiaries.

Direct beneficiaries include: households in the intervention areas, local independent fresh FV retailers, Public health partners and local authority directorates in Bradford, Doncaster and Tower Hamlets.

Indirect beneficiaries include: Public Health England, Department of Health, Department of Communities, DEFRA, DWP, House of Lords Select Committee on Food, Poverty, Health and the Environment, House of Lords Regenerating Seaside Towns committee. House of Commons Committees: Environment, Food and Rural Affairs, Health and Social Care, Housing & Communities and Local Government. National and regional charities and food partnerships concerned with food access, food supply, and food security (Food Foundation, Sustainable Food Cities, NCVO, Church Action for Poverty, and Feeding Britain). In order to engage with both local and national stakeholders we have an outward facing website for the study, and will have social media (twitter) dissemination.

Local members of the public in Doncaster and Tower Hamlets continue to be actively involved including refining the methods used to collect information from households (paper and online surveys). Local members of the public will also help with the interpretation of the data and disseminating the findings.

Key Stakeholder meetings
We will hold meetings with local public health stakeholders at the start of the study in order to ensure our actions and methods are aligned and targeted. We will provide regular feedback reports on study progress and a concluding meeting to provide results and discuss strategies for moving forward. This engagement will enable greater understanding of FV uptake; greater understanding of local food insecurity in their areas, better tools for addressing food related health inequalities and food insecurity, and enable local decision makers to make interventions that are cost effective and evidenced based and that are located in local objectives. The study will provide understanding of place based voucher schemes and their potential links for strategic infrastructure development and planning guidance.

10. Safety considerations and reporting

This is a low-risk study.

Urgent Safety Measures

The CI may take urgent safety measures to ensure the safety and protection of the study subjects from any immediate hazard to their health and safety including COVID. The measures should be taken immediately. In this instance, the approval of the REC prior to implementing these safety measures is not required. However, it is the responsibility of the CI to inform the sponsor and Main Research Ethics Committee (via telephone) of this event immediately.
The CI has an obligation to inform both the Main REC in writing within 3 days, in the form of a substantial amendment. The sponsor (Joint Research Management Office [JRMO]) must be sent a copy of the correspondence with regards to this matter.

Annual Safety Reporting
The CI will send an Annual Progress Report to the QMUL REC using the NRES template and to the sponsor.

Overview of the Safety Reporting responsibilities
The CI has the overall oversight responsibility. The CI has a duty to ensure that safety monitoring and reporting is conducted in accordance with the sponsor's requirements.

11. Monitoring and auditing

The Sponsor or delegate retains the right to audit any study, study site or central facility. In addition, any part of the study may be audited by the funders where applicable.

The study will be audited by the PCTU Quality Assurance (QA) team in line with the Unit's internal Standard Operating Procedures.

In addition, the CI will provide six-monthly study reports to the IPSC, who act to monitor the study on behalf of the funder and sponsor.

12. Study committees

12.1. Independent Project Steering Committee (IPSC)

The IPSC will double up as a Trial Steering Committee. This committee will meet six monthly. Its role is to monitor and advise on study conduct and progress on behalf of the Sponsor and the Funder. Meetings may be virtual at the discretion of the Chair. The IPSC composition is designed to provide expertise in all relevant facets of the study design and conduct. IPSC meetings will include at two members of the PPI group. Current IPSC members include:

Russell Viner - Professor in Adolescent Health, UCL
Andrew Forsey - Director 'Feeding Britain'
Nicola Corrigan - Healthy weight and physical activity lead PHE

Barbara Bray - Independent nutritionist
Karla Hemming (Chair) - Professor of Biostatistics, University of Birmingham
Megan Blake - Senior Lecturer in Human Geography, University of Sheffield
Martin Caraher - Professor Emeritus, City University
Clare Relton - Senior Lecturer in Clinical and Public Health Trials, QMUL
Andrea Barker-Philips - Lay member

Additional members of the research team/ observers will be invited to attend meetings as needed depending on the agenda, e.g. Sandra Eldridge - Professor of Medical Statistics and Director of the Pragmatic Clinical Trials Unit, QMUL.

12.2. Patient and Public Involvement (PPI)

There will be extensive public engagement during the project. The PPI Group will help ensure that the perspectives and welfare of the public remain at the centre of the study throughout. The PPI group will provide comment and advice on study materials, support recruitment and retention in the study, and advise on dissemination of progress and findings.

12.3. Study Management Group (SMG)

The SMG is led by the study CI and comprises the study applicants, the Project Manager, and relevant members of the PCTU. Its role is to oversee the study delivery and progress, ensuring it is conducted in an ethical and competent manner, that it keeps to time, and delivers its planned outcomes. The PM reports to the PPI group to ensure the latter are appraised on study progress. PPI group members will be invited to join SMG meetings as required. The SMG will meet initially monthly and then at least every two months.

As there are no major safety issues and no foreseeable reason to stop the pilot trial for inefficacy, no Data Management Executive Committee (DMEC) is required.

13. Finance and funding

The **research costs** for the study are fully funded by the NIHR (Public Health Research) programme (NIHR129937).

Intervention costs: These costs are currently estimated to be £402,584.
We currently (11.4.21) have commitments to cover £202,283 (50%) of these estimated costs from three local councils:

- Bradford - £15,000 (pilot) + £120,000 (main trial)
- Doncaster - £26,000 (pilot)
- Tower Hamlets - £15,283 (pilot)

This means that **all the intervention costs for the pilot** have been received

Additional sources of intervention costs
During the pilot we will seek to obtain additional intervention funding required for the main trial (objective i). Both Doncaster and Tower Hamlets councils have said that additional funding will be forthcoming if the pilots are viewed as 'successful'. However, no definitions of 'success' have been given and no amounts have been agreed.

We will also apply for Excess Treatment Costs (ETCs) from the Department of Health and Social Care (DHSC) subvention fund via PHE and also seek additional funds from corporate social responsibility funding sources.

14. Insurance and indemnity

The study sponsor is QMUL. The insurance that Queen Mary has in place provides cover for the design and management of the study as well as "No Fault Compensation" for participants, which provides an indemnity to participants for negligent and non-negligent harm.

15. Dissemination of findings

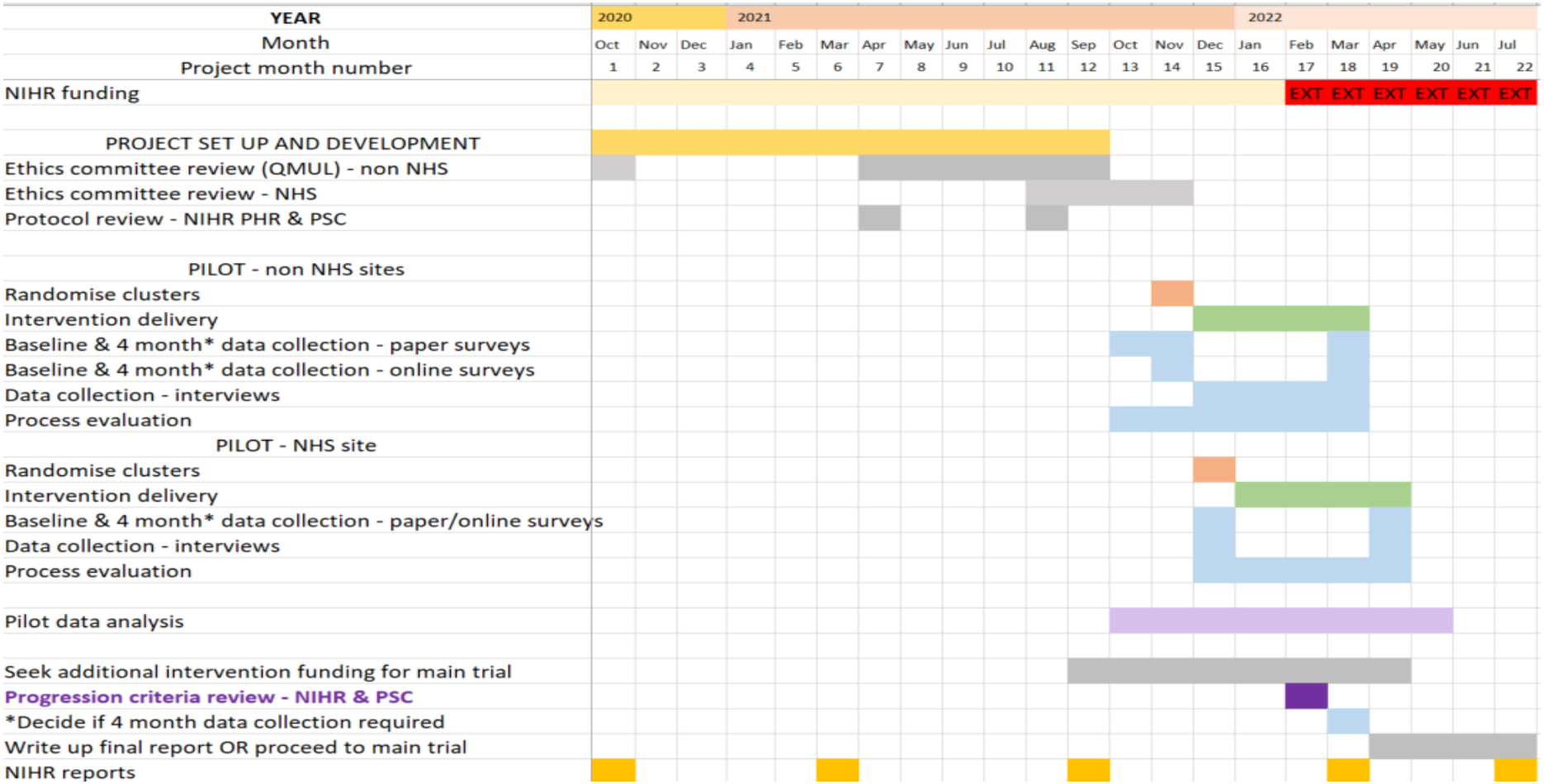
Our strategy is maximise public and professional awareness of the study and its relevance to public health nutrition policy. We have identified key stakeholder groups and linked these to our multi-channel approaches to influencing them. Dissemination is a standing item on the SMG agenda, ensuring interim study findings are rapidly and effectively communicated. Our PPI group will co-write or review all study outputs for dissemination via traditional and social media throughout the study.

The main outputs from the study will be a manual describing a potential new public health intervention (Fresh Street) and pilot trial data on the acceptability and effectiveness of this intervention that will be used to shape or influence local and national government policy relating to food systems, food insecurity, dietary quality and health inequalities.

This research has the potential to impact local communities (target streets) and those associated with services to these communities. The research will enable charities, third sector organisations, local authority public health and social exclusion teams as well as national government to acquire greater understanding of the ways to address poverty-associated issues of diet related public health. The research will have an impact in healthcare disciplines, public health nutrition, healthy eating programmes, health related behaviour change, healthy food systems and sustainable food economies. Beyond these, the research speaks to current debates in food poverty related research being studied by sociologists, anthropologists, economists, political scientists, psychologists, urban planners and geographers, and climate and environmental change. We anticipate media interest at a

local and national level due to the innovative nature of the intervention. We will also produce a policy briefing to be disseminated through local authority public health network.

16. Study Timetable



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This protocol is based on JRMO Protocol template for Research Studies