Group model building to address dietary health inequalities in English **L**ocal **A**uthorities: A ran**d**omised controlled tr**i**al with pr**o**cess eva**l**uat**i**on

GLADIOLI

The GLADIOLI study

REC reference:

ISRCTN:

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Trial Registration	ISRCTNXXX
Date of Registration	XXXXX
REC Reference	XXXXX
Funding Source	UK Research and Innovation, funding stream: Health inequalities in the food system (OPP667)
Study Sponsor	University of Cambridge Carolyn Read Research Governance Officer University of Cambridge, School of Clinical Medicine Box 111, Cambridge Biomedical Campus Cambridge, CB2 0SP
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Scientific Title	Group model building to address dietary inequalities in English Local Authorities: a randomized controlled trial with process evaluation.
Short Title	GLADIOLI
Countries of Recruitment	England
Intervention	A one-day tailored group model building workshop held with approx.15 stakeholders in each intervention LA; plus pre and post meets with a key informant from each LA.
Key Inclusion/Exclusion Criteria	All Local Authorities (LAs) in England will be eligible to participate. However, we will start recruitment by targeting the 40% most deprived LAs in England. Local authority Key Informants (LAKI) will be eligible if they (a) work at participating LA, and (b) have a core responsibility for food policies. Workshop participants will be eligible if they are attending the intervention workshop and happy to provide consent for participation.
Study Type	A single centred, unblinded, parallel-group superiority RCT

Target Sample Size	60 LAs, 30 per group
Primary Outcome	Number of policies planned or implemented within the last 12 months that explicitly aim to reduce dietary health inequalities (DHI)
Key Secondary Outcomes	• Distribution of polices across a scale of potential to achieve system change (Potential of policies) • Perceptions of: ○ Personal and shared local understanding of DHI (Understanding) ○ Personal and shared commitment to address DHI locally (Commitment) ○ Strength of local collaborations to address DHI (Collaboration) ○ Confidence that additional solutions to address DHI locally will be implemented in the next 12 months (Confidence)
Intervention duration	1 workshop plus around 3 pre-meets and 1 post-meet
Follow up duration	12 months
Date of first enrolment	TBC
Planned Study duration	Three years

Protocol Signatures

I agree to ensure that the confidential information contained in this document will not be used for any other purpose beyond the evaluation or conduct of the investigation with the prior written consent of the Sponsor.

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

Chief Investigator: Professor Jean Adams

Signature: 

Date: 02 Feb 2026

Protocol Revision Chronology

Version	Date	Details
1.0	02 February 2026	Original protocol

Contents

List of Abbreviations

ADPH	Association of Directors of Public Health
CLD	Causal Loop Diagram
DHI	Dietary Health Inequalities
EIC	Electronic Informed Consent
eTMF	Electronic Trial Master File
GCP	Good Clinical Practice
GMB	Group model building
ISRCTN	International Standard Randomised Controlled Trials Number
KI	Key Informant
LA	Local Authority
LAs	Local Authorities
LAKI	Local Authority Key Informant
Institute of Metabolic Sciences	
CI	Chief Investigator
PIS	Participant Information Sheet
PE	Process Evaluation
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAG	Study Advisory Group
SC	Study Coordinator
SFTP	Secure File Transfer Protocol
UH	University of Hertfordshire
UKRI	UK Research and Innovation

Trial flow chart/other figures

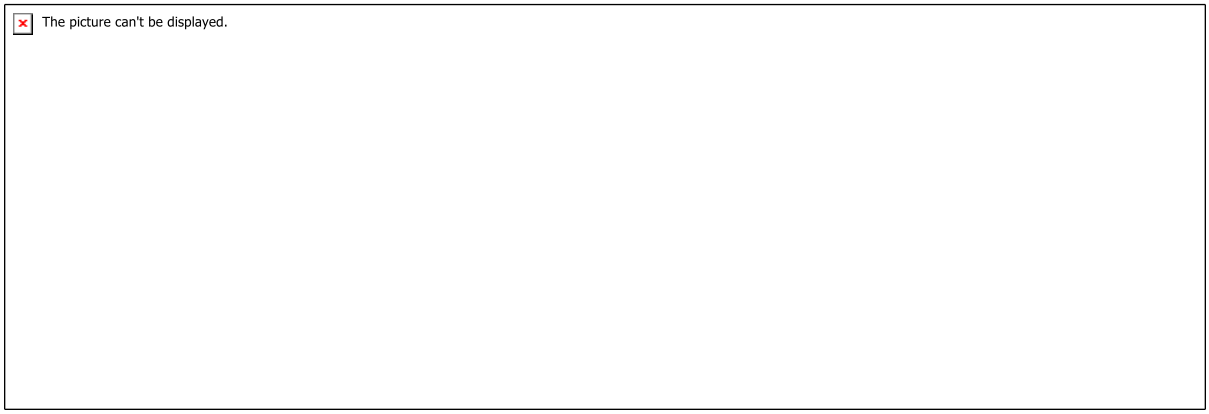

Figure 1. Theory of change

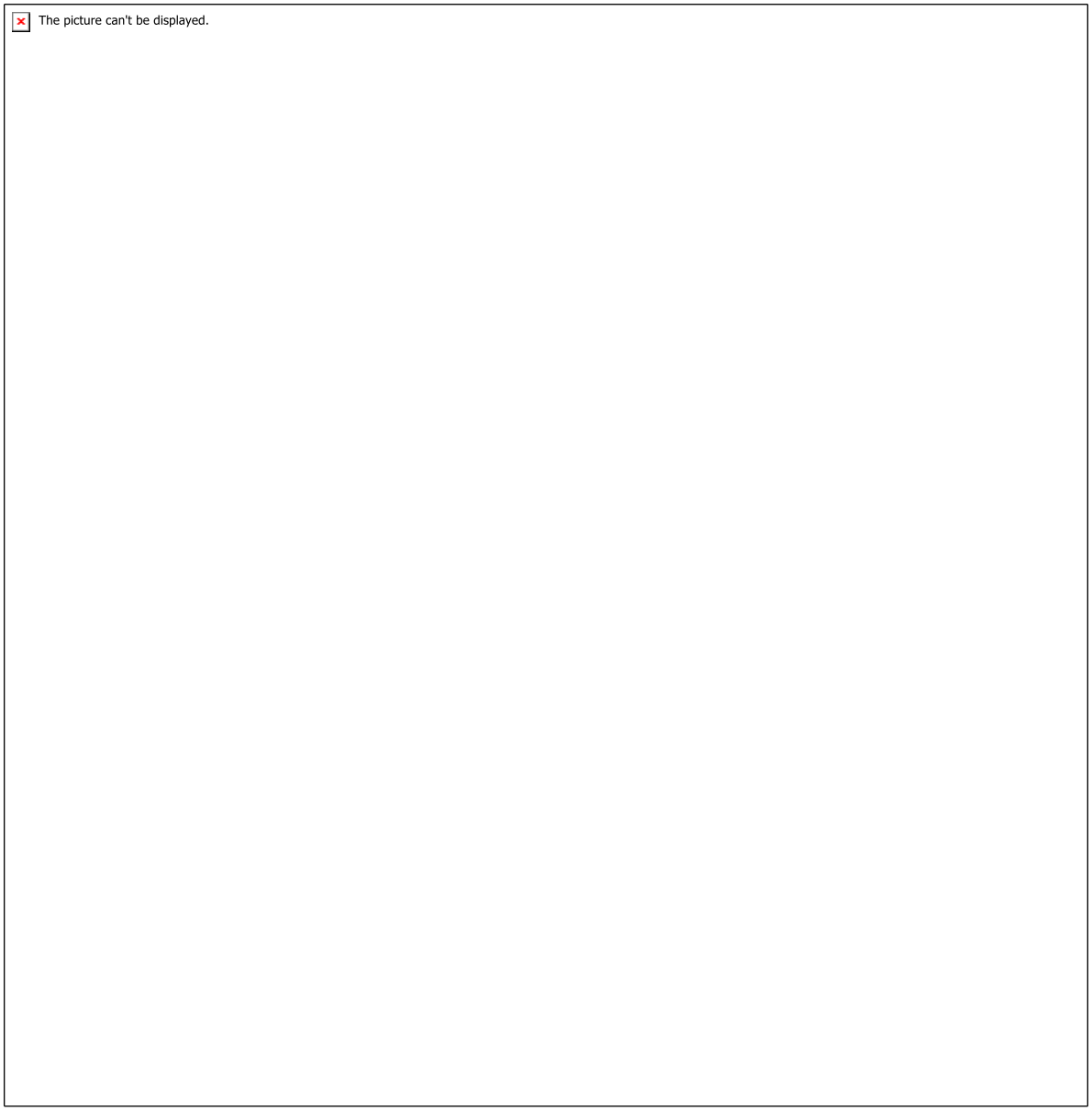

Figure 2. CONSORT diagram

1 Introduction

1.1 Background and rationale

People living in less affluent circumstances in the UK consume less healthy diets (1) and experience higher levels of diet-related disease. Almost 15% of UK households have recently experienced food insecurity. (2) Dietary health inequalities (DHI) are strongly shaped by the cost (3) and availability (4) of healthier foods and by wider, interacting local, national and international food system processes. (5)

Whilst there are many potential levers to address DHI at national level e.g. food taxes and subsidies, national-level policymaking can be slow. There is little evidence that current approaches are working. (1) Local authorities (LAs) have access to different levers and can act more flexibly than national government, e.g. by working with the community food sector, to provide place-based solutions. In England, local authorities (LAs) play a central role in shaping local environments for health and have access to a range of policy levers that enable flexible, place-based action, often in partnership with community organisations, charities, food system actors and academic institutions.

Systems thinking is "a way of thinking about and analysing things by recognising complexity, patterns and interrelationships rather than focusing on [linear] cause and effect".(6) One method to support systems thinking is group model building (GMB). (7) GMB uses facilitated, scripted procedures to help stakeholder groups create visual representations of a problem through a systems thinking lens and use this to generate potential solutions. (7) Case-study evidence suggests that GMB can improve shared understanding, cross-sector collaboration and solution generation, but evidence of its impact on implementation is limited. (7, 8) There is a near absence of randomised controlled trial (RCT) evidence evaluating the impacts of GMB. (9) Although GMB has been used to address health and dietary inequalities in settings such as Jersey (10), no RCT has evaluated its effectiveness in supporting English LAs to implement policies aimed at reducing DHI. This study aims to address this evidence gap by adapting and refining an existing GMB intervention and evaluating its impact through an RCT in English local authorities, alongside a process evaluation and documentation of intervention costs.

1.2 The Intervention

The intervention was co-developed by MW, KP and AS with Jersey's public health team, then refined and delivered in Guernsey. The Association of Directors of Public Health confirm DHI are a high priority, and the intervention would be attractive.

The intervention will be flexible to local context, is described using the Template for Intervention Description and Replication, (11) is supported by a Theory of Change (**Figure 1**), will be delivered by the research team and comprise:

- 1 or more online 2-hour pre-meet with the key informant (defined below; and relevant team members) ~3 months pre-workshop to review roles, agree upon a focus, and identify workshop participants. Workshop participants (n~15) will be local decision makers in any sector with the power to enact workshop insights (12) and representatives of local community food organisations to bring the voice of those with experience of DHI. Conducting GMB in one day is ambitious but necessary to maintain engagement. Focusing on one locally-agreed population or outcome (e.g.

children, vegetable intake) makes one-day manageable and the intervention flexible to local context. Follow-up meetings will be conducted as required.
- intelligence website circulated to workshop participants summarising local data on DHI to provide context. To be developed by Food Foundation from routinely available data (https://fingertips.phe.org.uk/) and their regular food security surveys. Including e.g. local prevalence of children in poverty not eligible for free school meals, type 2 diabetes and food insecurity.
- one-day in-person GMB workshop, developing a CLD and using this to identify potential solutions. Guided by manuals and scripts. Facilitated by 2-3 researchers.
- Around three online 1-2 hour post-meets with key informants (and team) 1week, 1 month and 3 months post-workshop to refine the CLD, identify further solutions, and support solution prioritisation. Informed by our comprehensive database of Food System Transformation Solutions enabling sharing of best practice.(13)

1.3 Research Questions

1) What is the impact of the intervention on the primary and secondary outcomes listed below?

2) How do local stakeholders understand DHI and their potential solutions, how does this evolve during the course of the intervention?

3) What are the costs of the intervention?

1.4 Primary & Secondary outcomes

1.4.1 Primary outcomes

Number of policies planned or implemented within the last 12 months that explicitly aim to reduce DHI

1.4.2 Secondary outcomes

- Distribution of policies across a scale of potential to achieve system change (Potential of policies)
- Perceptions of:
  - Personal and shared local understanding of DHI (Understanding)
  - Personal and shared commitment to address DHI locally (Commitment)
  - Strength of local collaborations to address DHI (Collaboration)
  - Confidence that additional solutions to address DHI locally will be implemented in the next 12 months (Confidence)

2 Methods

This protocol presents the quantitative data collection methodology led by the University of Cambridge, followed by the qualitative process evaluation methodology led by the University of Hertfordshire (Section 2.8)

2.1 Trial Design

A single-centre, unblinded, parallel-group, superiority randomised controlled trial with 1:1 allocation, alongside a mixed-methods process evaluation.

LAs that are randomised to the control arm of the trial will be provided with intervention materials at the end of the study.

2.2 Study Setting

English Local Authorities.

2.3 Eligibility criteria

We will recruit LAs, one key informant per LA and ~15 workshop participants per intervention LA.

All LAs in England will be eligible, although we will begin with inviting LAs based in the most deprived 40% of England. If we are unable to meet the recruitment target with these invites, we will then extend recruitment to 50%, 60% and so on until we meet the recruitment target of 60 LAs. LAs with existing food strategies (or similar) or who are members of e.g., Health Determinants Research Collaborations will be included as these may represent those with greatest motivation to progress, as well as those who have already made good progress. Randomisation will help ensure these characteristics are evenly distributed. We will exclude non-English localities to provide a reasonably consistent policy context.

Individuals will be eligible to be key informants if they (a) work at a participating LA, and (b) have a core responsibility for food etc. All key informants will be eligible to take part in the study.

Workshop participants will be local decision makers in any sector with the power to enact workshop insights and representatives of local community food organisations, all workshop participants will be eligible to take part in the study.

2.4 Recruitment

We will identify the 40% most deprived LAs in England and their Directors of Public Health with help from our third-sector collaborator the Association of Directors of Public Health (ADPH). ADPH work with selected LAs across England in Health Determinants Research Collaborations (HDRC), and their website has an LA directory with current Directors of Public Health (DPH). Any LAs missing a DPH in the directory will be located through internet searches. Each LA's key informant (LAKI) (one for each LA, n=60) will be recruited as we recruit the LA.

We will work with LAs to recruit approx.15 stakeholder participants to attend a one-day intervention workshop in each intervention LA. Within boundaries of our inclusion criteria, we will encourage key informants to think broadly in terms of diversity (i.e., gender, ethnicity, sector and career stage) when selecting workshop participants.

As this intervention is targeted at professional stakeholders, we have not conducted and will not conduct any specific PPI activities. We did seek feedback from public health professionals (via the Association of Directors of Public Health) on the idea for the work as it was being developed who confirmed that DHI are a high priority and the intervention would be attractive. Further, we will include one or two representatives of local community food organisations to bring the voice of those with experience of DHI in each workshop. To ensure wide participant recruitment, we will provide LA key informants with example roles (e.g., school catering manager).

2.5 Randomised Control Trial Data collection

2.5.1 Local authority level baseline and 12-month data collection for primary outcome

Based on the logic model described in Figure 2, data will be collected from each LA on the primary outcome at baseline and 12 months to document existing policies related to dietary inequalities prior to randomisation and intervention implementation. These data provide a reference point for assessing change at the 12-month follow-up interview. A structured interview guide will be used with a checklist of questions (**Table 1**) to identify policies. All interviews will be recorded on Microsoft Teams. Interviews will be conducted by a member of the research team with the LAKI. The interview recording and generated transcription will be stored until the data capture form has been completed and will then be deleted.

Table 1. Key Informant interview guide for baseline data collection

Variable	Interview guide
Date	1. Date of data collection
LA and KI information	1. Name of LA 2. What role does the Key Informant have 3. How long as the Key informant been in their current role? 4. How long has the Key Informant been in a role relevant to dietary inequalities
Current food strategies	1. Does the LA have a current Food Strategy (Y/N) 2. Is the LA part of a local food partnership (Y/N) 3. Is the LA a member of the Health Determinants Research Collaboration (Y/N)
Current policies for DHI (known)	1. Can you tell me what policies have been put in place in the last 12 months or will be put in place in the next 12 months to address dietary inequalities (defined as any intentional actions explicitly aiming to address dietary inequalities)? Use relevant prompts with examples from the Food System Transformation Solution Bank

	2. **For each policy**: what was (or will be) the date of implementation? *3.* **For each policy:** please tell me more about that, what it involves etc Is there anything else that's relevant for this policy? (for each response on a particular policy, ask again about details and repeat until data saturation is achieved *for that policy).* 4. Are there any other policies in place to address dietary inequalities? Repeat the above questions (i.e., 2-4) for each policy until all policies known to the Key Informant are given.

2.5.2 Intervention workshop data collection

Subject to consent, we will carry out a short, Likert-style questionnaire at the start and end of the intervention workshop with all workshop participants to capture information on the majority of the secondary outcomes **(Table 2)**. The questionnaire will be hosted within a purposely designed REDCap webform and links provided to workshop participants via email at the start and end of the day providing they have consented.

Table 2. Pre- and post-workshop questionnaire

Statement (please circle your response for each statement)
1. I have a good understanding of dietary inequalities in my local area • Strongly agree • Agree • Neither agree nor disagree • Disagree • Strongly disagree
2. My organization has a good understanding of dietary inequalities in our area • Strongly agree • Agree • Neither agree nor disagree • Disagree • Strongly disagree
3. I am committed to taking action to reduce dietary inequalities in my local area • Strongly agree • Agree • Neither agree nor disagree • Disagree

• Strongly disagree
4. My organization is committed to taking action to reduce dietary inequalities in our area • Strongly agree • Agree • Neither agree nor disagree • Disagree • Strongly disagree
5. I am confident that I can contribute to reducing dietary inequalities in my area • Strongly agree • Agree • Neither agree nor disagree • Disagree • Strongly disagree
6. I am confident that my organization can contribute to reducing dietary inequalities in our area • Strongly agree • Agree • Neither agree nor disagree • Disagree • Strongly disagree
7. There will be meaningful collaboration between local partners to reduce dietary inequalities in our area over the next 12 months • Strongly agree • Agree • Neither agree nor disagree • Disagree • Strongly disagree
8. I am comfortable working with 'complex' or 'wicked' problems (these are problems that require intersectoral collaboration and not just more time and more money) • Strongly agree • Agree • Neither agree nor disagree • Disagree • Strongly disagree
Please provide your details • What is your role within your organisation?

- How long have you been in this role?
- How long have you been in a role relevant to dietary inequalities?

2.5.3 Consent

Electronic informed consent (EIC) will be collected for each LAKI ahead of baseline data collection and workshop participants at the start of each intervention workshop. All EIC will be collected in a study specific Research Electronic Data Capture (REDCap) webforms. This secure, GDPR-compliant platform will guide participants through the consent process step-by-step, ensuring they understand the study and their participation. The form will include detailed information about the study's aims, procedures, data confidentiality measures, and the voluntary nature of participation (outlined in a relevant participant information sheet). Participants will have the opportunity to discuss any questions or concerns with the research team before completing the e-consent process. All EIC responses will be stored within the IMS Epidemiology Unit's Secure Research Domain (SRD).

2.5.4 Intervention cost data collection

The mean cost of the intervention will be calculated based on time, travel and accommodation costs to the research team; time and hosting costs to LAs; and time costs to workshop participants. The study team will keep notes of their costs for each workshop held and estimate costs to LAs based on seniority of LAKIs and venues used, and costs to workshop participants based on seniority and organisation.

2.6 Intervention

As we deliver the intervention outlined above in section 1.2, we expect to make modifications to further refine it. Given the intervention is entirely researcher delivered, we don't expect participant-led deviations from protocol, nevertheless we will conduct an intention to treat analysis. To monitor changes or adaptations to the intervention and ensure the intervention is being delivered with fidelity, we will use the Framework for Reporting Adaptations and Modifications-Enhanced (FRAME). (14) This framework will allow us to track the kinds of changes being made to the intervention and the purpose of the changes. Changes made will be recorded in a spreadsheet modeled after this framework.

2.7 Participant timeline

We expect each LAKI in the intervention arm to be required to commit approximately 2 days over the course of approximately 12 months to the study for both data collection and intervention. Those in the control arm will be required to commit around 2 hours over ~12 months for data collection only. For workshop participants (stakeholders recruited by the LA), time commitment will be one day for the workshop. LAKI and workshop participants may also be invited to take part in interviews for the qualitative process evaluation as described below. We anticipate starting the recruitment process in April 2026 with data collection completed by June 2028.

2.8 Qualitative Process Evaluation Methodology

2.8.1 Process Evaluation Background

Our qualitative process evaluation (PE) involves the study of implementation, mechanisms and context and can help understand why intervention effects occurred (or did not). (15) Our secondary quantitative outcomes also include potential mechanisms. The exploratory quantitative analysis will assess differential effects based on context. In addition to these quantitative components, the PE will also include qualitative observations and interviews. This aspect of the PE will adopt a realist- and systems-informed approach, guided by the MRC framework for process evaluation of complex interventions (15, 16) and aligned with systems-oriented perspectives such as ENCOMPASS. (17)

2.8.2 Aims and Objectives of the qualitative aspect of the Process Evaluation

To understand how the GMB workshops are implemented, experienced, and interpreted by participants, and identify mechanisms through which they may (or may not) lead to changes (intended/ unintended) in local food systems addressing DHI.

Objectives:

1. **Implementation Fidelity:** Assess how GMB is delivered across LAs, the extent to which delivery aligns with the protocol, what adaptations occur and why;
2. **Context:** Examine how local, regional, and national contexts shape the framing of DHI, barriers/enablers to solution development, and patterns of engagement;
3. **Mechanisms of Change:** How participants interpret, respond, and act on the intervention, including mechanisms theorised in the 'theory of change' logic model e.g. developing shared understandings, commitment, collaboration and confidence.
4. **Evolution of Understanding:** Track how stakeholder understandings evolve during and after GMB, and compare this to the control arm;
5. **Outcome Linkage:** Assess whether and how GMB influences the type and prioritisation of solutions proposed, and the extent to which these are implemented locally. This is to complement the RCT's quantitative outcome data and to support with interpretation rather than assess effectiveness.

2.8.3 Methods

Overview and sample

The qualitative PE will use a qualitative mixed-methods, embedded design. Data collection will occur in approximately 20 purposively sampled local authorities (~10 intervention, ~10 control), representing diverse geographies, organisational structures, and socio-demographic profiles. Within each LA, we will work with the key informants to identify people to interview (intervention and control) based on their role, knowledge, and involvement in DHI-relevant activities and suitable workshops/meetings to observe (control LAs only).

In each of the ~10 intervention PE sites activities will include:

- Intervention workshop **observations**
- post workshop **semi-structured interviews** with the key informant and one other workshop attendee
- 6-12 month post workshop follow-up semi-structured interviews with the same two participants (i.e key informant and one other meeting attendee)

In each of the ~10 control PE sites , we will identify and recruit interview participants in collaboration with the LAKI and work with them to select and negotiate access to relevant team meetings or planning events they are involved in that could serve as a comparable control to the intervention workshops. This will include gatherings like holiday hunger working group meetings, food programme meetings, and food poverty action plan workshops. We will then observe these meetings / events and interview around two attendees (LAKI plus one other) using the same data collection tools and approaches as we are using for the intervention workshops, so that that they can be compared. This will help us distinguish between features, outcomes and perceived effects that are either (i) inherent to some collaborative team-based approaches to addressing dietary health inequalities or (ii) particular to the intervention workshop.

Workshop observations

Intervention LAs (≈10) and Control LAs (≈10):

- Structured observations of intervention workshops using a semi-structured pro forma.
- Unstructured fieldnotes documenting emerging reflections, unexpected observations, and contextual insights.

Observations will explore issues such as how DHI are characterised and framed, how lived experienced and other local contextual factors are taken into account, the types and reach of proposed solutions, consideration given to different types of evidence, how different individuals and sectors contribute, and conflict and consensus. Alongside unstructured fieldnotes, we will use a semi-structured observation pro-forma, drawing on principles of organisational ethnography.

Post observation semi-structured interviews
Interviews with two participants (LAKI plus one other) from each of the 10 control LAs and the 10 intervention LAs (a total of ≈ 40 participants)

- Interviews to be conducted with individuals (who will have attended the intervention workshop or comparable control event) within one week of the observation.
- Follow-up paired interviews with these same individuals 6 to 12 months after the initial interview.

Semi-structured interviews will explore participants' understandings of DHI, and potential solutions, and how these evolve. Two individuals will be interviewed from each LA either as a pair or separately, depending on their preference, either online or in person. Follow-up interviews will explore any changes in perception, understanding, working practices, collaborations, and approaches around dietary health inequalities. Interviews will be audio-recorded (with consent), transcribed and pseudonymised according to job title.

3 Statistical Considerations

3.1 Sample Size for quantitative analyses

We will recruit 60 LAs: 30 each in the intervention and control arms. We will recruit one key informant per LA (n=60). We aim to recruit all workshop participants (n=~450). Given novelty, we do not have robust data to inform sample size calculations. Instead, we used best practice guidance on pilot studies suggesting ~25-35 per arm to

detect small effect sizes with 90% power. (18) A sample size of 60 has 72% power to detect a difference of two policies if the standard deviation is 3, and 97% if it is 2.

We will use baseline data to re-estimate the sample size required to detect a difference of two policies with 90% power. (19) If this is ≤60, we will consider the study adequately powered. If it is >60, we will consider it underpowered and disseminate as a pilot study. Our data will be made available for others (or us) to add to in the future.

3.2 Randomisation & Enrolment

Trial LAs will be unblinded (open label) and randomised using a computer-generated randomization list with a 1:1 ratio. Specifically, our study statistician will generate the randomisation list using Stata statistical software. Stata makes use of a computer system clock as the seed point, which produces a pseudo-random list generally regarded as acceptable for RCTs.

3.3 Analysis Plan

The main analysis will use linear regression to compare the mean number of policies between intervention and control groups, adjusted for baseline. It will include all LAs in the group they were randomized to (i.e., intention-to-treat). We will similarly assess changes in potential of policies to achieve system change, and Understanding, Commitment, Collaboration and Confidence in an RCT framework in LA key informants at baseline and 12 months; and in a pre-post framework in all workshop participants at the start and end of workshops. Exploratory interaction and sub-group analyses will assess if the intervention is differentially effective in LAs based on differentiating characteristics between LAs (for example those in HDRC partnerships or those with food strategies) to gain insight to DHI-focused policy implementation and understand better any potential limitations to generalizability.

Qualitative data will be managed and thematically analysed (Thorne S 2000) using NVivo, following an iterative, interpretive coding process:

- Open coding (informed by Theory of Change (**Figure 1**)): initial identification of key ideas, actions, participant responses, mechanisms, and contextual influences emerging from the data.
- Axial coding: Organisation and refinement of codes into broader analytic categories e.g. implementation fidelity, mechanisms of change, contextual influences, and the evolution of understandings and practices over time.
- Integrative analysis (selective coding): development of an integrated explanatory account, informed by realist principles, which explores how mechanisms operate under different contextual conditions and how this varies between GMB and control settings.

Analytic credibility will be supported through triangulation across observations, interviews, and documentary sources, and through comparative analysis of GMB and control settings with attention to contextual variation and emergent processes. Where appropriate, qualitative findings will be used to aid interpretation of quantitative outcome measures.
In order to provide context for the data collection and analysis we will scope relevant documents including:

- workshop agendas, scripts, attendance lists, CLDs and other workshop outputs

- LA food strategy documents, policy submissions
- Food Foundation DHI data

4 Data Management

4.1 Data storage

Data will be handled and stored in line with IMS Epidemiology data management policies for all quantitative data collected.

For interviews recorded on Microsoft Teams, the data will initially be captured as a video/audio mp.4 file. This recording will automatically save into OneDrive on the University's Microsoft's 365 platform which the study researcher has access to using their RAVEN credentials. The Microsoft Teams functionality for transcription will also be used during the interview. Following the interview, a transcript will be available in Teams and will be downloaded into OneDrive as a Word document. Following the interview, the video/audio mp.4 file will be converted to an audio only mp.3 file, using the software VLC. The audio only mp.3 file and transcript Word document, will then be saved into the IMS Epidemiology Unit's Secure Research Drive (SRD), a separate server which requires two factor security authentications to access. Once safely transferred to the SRD, all files will be deleted from Microsoft Teams and OneDrive.

All recordings and transcripts will be saved on the SRD using the study name, LA name and the date/time of the interview. Transcriptions will be anonymised. Audio recordings will be destroyed once transcriptions have been checked. Anonymous transcripts will be kept separately from identifying information, which will be retained for administration purposes until coding has been completed and then destroyed.

Due to the nature of the research topics, the research team is confident that the content of the interview data will fall within Level 2 or lower under the 'University data security classifications and guidelines', which is a requirement for data storage on the public cloud service when using Microsoft Teams.

4.2 Data protection and patient confidentiality

We will store personal and identifiable data carefully using a secure computer drive within the IMS Epidemiology Unit. Information collected during the research will be kept strictly confidential and in accordance with current laws (including the General Data Protection Regulations - GDPR).

Research data will be separated from identifiable data and stored separately. Contact information (such as name, email address, telephone number) for the LAKI will be retained by the research team to maintain contact until the end of the study when dissemination is complete. These will be stored on a secure computer network with access only given to members of the GLADIOLI research team involved in this study.

The University of Cambridge will act as the sponsor for this study. IMS Epidemiology will act as the Data Controller. In line with routine procedure, the data from this study may be made

available to our Sponsor for monitoring purpose if requested. Identifiable data from this study will be kept for a maximum of 10 years after study completion and then destroyed. Non-identifiable research data may be retained for longer for research purposes.

Only authorised members of the research team (or authorised persons acting on behalf of the Sponsor) will be allowed access to the non-anonymised/personal and identifiable data for participants. Participants will be informed that verbatim quotes may be used in outputs of this research. If necessary, quotes will be modified to ensure the anonymity of the individual participants as well as the departments/organisations which they represent.

Data collected for the process evaluation include: names, roles and contact details of participants, audio recordings of interviews, transcripts of interviews, fieldnotes from workshop / meeting observations, workshop / meeting observation proformas (ie, structured observation sheets). Contact details will be stored separately from interview audio files/transcripts and observation fieldnotes / proformas. All identifying data will be anonymised and names will be replaced with an ID and pseudonym. All data will be stored securely on the University of Hertfordshire OneDrive; only the research team will have access to the project folder and any documents containing contact details will be password protected. Audio-recordings of interviews will be stored securely on the OneDrive and deleted from the device they were recorded on once uploaded. Audio-recordings will be sent to a University of Hertfordshire (UH) approved and trusted transcription service for transcription purposes. After data from paper copy proformas and fieldnotes will be scanned or typed up in word and uploaded to the OneDrive. Paper copies will then be destroyed.

Participants will be informed that their personal details will be kept securely by the research team and that these details will not be transferred to any other party. UH are fully compliant with GDPR requirements for transparent, fair and legal data protection. The research team will adhere to these obligations.

5 Monitoring & Archiving

5.1 Risk Assessment & Monitoring Plan

A risk assessment & monitoring plan will be written and approved by the Chief Investigator before any data collection starts. The risk assessment will help define all study monitoring activities and frequencies.

In accordance with the conditions and principles of Good Clinical Practice (GCP), an electronic Trial Master File (eTMF) will be established at the beginning of the study and held by the Study Coordinator at the IMS Epidemiology Unit. All essential documents which together demonstrate the compliance of the study and study personnel with the conditions and principles of GCP and any applicable regulatory requirements will be stored in the TMF. On a regular basis the eTMF will be reviewed as per the Unit's auditing process to confirm adherence to GCP guidelines and any applicable regulations. Monitoring reports are sent to the study CI who ensures any findings are appropriately addressed and reported on to the Sponsor when appropriate. Those persons from the regulatory bodies and representatives of the Unit and the Sponsor may require access to participant level data to verify that the conduct of the study is in line with the applicable regulations.

Those responsible for undertaking the collection of data from study participants will be subject to appropriate training, review and assessment by the relevant Unit specialist before being deemed competent.

The CI and SC will ensure that a risk assessment is performed to verify the level of monitoring required for the study. The extent and nature of monitoring should be proportionate to the risk to the participants; for GLADIOLI the risks with study participation are low.

6 Ethical Considerations

This study will involve recruitment of human participants. The study will be subject to ethical approval from the University of Cambridge's Humanities and Social Science ethics committee. All work will comply with law and adhere to good research governance standards. Participants will be provided with information on what participation involves and asked to provide informed consent before data collection begins. We do not expect our research to lead to participant harm. Researchers will be courteous and polite throughout and if participants appear uncomfortable, data collection will move to other topics, or be stopped. Participants will be informed of their right to terminate the interview, observation or to withdraw from the study. Participants will be made aware that it will be possible to withdraw their data from the study up until the point where it is combined with other study data and analysis has commenced. After this point, it will not be possible to withdraw their data, but their quotes will not be used in any outputs of the study.

6.1 Qualitative Process Evaluation

Informed consent will be obtained for all interviews. Interviews will be conducted in private spaces and, in addition to participant information sheets, researchers will reiterate the aims of the study, explain the anonymity procedures and right to withdraw, and give the opportunity to ask questions before the interviews begins.

For the intervention observations, permission to observe meetings will be sought from each attendee by the researchers delivering the intervention (as they will be instrumental in deciding who is invited to attend.

For the control group observations, permission to observe meetings / events will be sought from the key informants verbally, via email correspondence, and confirmed in the informed consent form (via check box). In line with organisational ethnography principles (Plankey-Videla, 2012), meeting attendees will be notified ahead of the meeting (via email or agenda) that researchers will be present. At the meeting / event observation the researcher(s) will be introduced by the key informant and we will explain the purpose and scope of the observation, noting that:

1. The meeting will not be audio- or video-recorded.
2. Researchers will take written notes only and will not take part in the meetings, other than to introduce ourselves or ask questions

If some of the attendees do not want to be observed then we will leave the meeting altogether and negotiate access to an alternative meeting / event at a later date. This is a different approach to that taken with the intervention group because, as far as is practically possible, we want to avoid influencing what is discussed in the meetings by contacting and negotiating with every potential attendee individually. The meeting and observation should

be as naturalistic as possible. So, we will ask contacts to notify the group of our request to observe beforehand and we will introduce and explain ourselves on the day. Of course, there is some risk that one or some observations will need to be abandoned if attendees do not want to be observed. However, as these will be large, multi-stakeholder meetings that are minuted and concerned with public health policy (are thereby semi-public), and we are public health researchers, we do not anticipate significant challenges in this area.

7 Governance

7.1 Advisory Group

A Study Advisory Group (SAG) will be convened to provide independent advice and oversight for the duration of the study. The SAG will include academic experts and stakeholder representatives with relevant experience. The group will meet at key points to advise on study design, conduct, analysis, and dissemination, and to ensure the research remains methodologically rigorous and relevant.

7.2 Statement of Indemnity

The University of Cambridge will provide indemnity in the case of negligent and non-negligent harm for research conducted through its Units when it is Sponsor and for employees or others acting on behalf of the University.

7.3 Protocol/GCP compliance

Protocol compliance will be ensured through regular monitoring and documentation. The research team will adhere to the approved protocol and promptly address any deviations.

Protocol Deviations:

- Accidental protocol deviations will be documented using the appropriate forms and reported immediately to the Chief Investigator and the sponsor.
- Recurring deviations will be reviewed, and corrective actions will be implemented to prevent future occurrences. If frequent deviations occur, they may be classified as a serious breach and escalated for investigation.

Compliance Monitoring:

- Regular team meetings will include a review of protocol adherence. Any concerns will be addressed collaboratively with the Chief Investigator and sponsor.

8. Dissemination

The Food Foundation has extensive experience in engaging diverse stakeholders in food conversations and will lead on dissemination. They will develop written and video summaries of findings and disseminate via direct mailing, social media, target conversations, conferences and a project dissemination workshop. Intervention materials will be freely available via our website.

We will disseminate to other researchers via peer-reviewed publications and presentations at academic conferences.

We anticipate that our findings will also be of interest to those working within various government departments, public health policy, public health research and food system stakeholders. We will develop a summary of findings that we will share with all LAKI participants.

We will work with the Knowledge Exchange team in IMS Epidemiology to maximise the quality and reach of our dissemination and impact.

Possible outcomes may include:

- Recommendations/learnings about engaging food industry partners in the process of co-designing and evaluating interventions to make the food system healthier and more sustainable
- Development of public health theory and evidence

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