

**HRA Protocol Compliance Declaration:**

This protocol has regard for the HRA guidance

**Full Title of Study**

A realist evaluation of a public health community of practice advocacy project to restrict outdoor advertising of high fat, salt and sugar foods.

**FUNDERS Number:** NIHR133204

**Version:** 2.0

## SIGNATURE PAGE

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

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

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

**Chief Investigator:**

Signature:



Date:

13/1/2021

Name: (please print): Dr Susie Sykes

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## KEY STUDY CONTACTS

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## STUDY SUMMARY

Study Title	A community of practice advocacy project to restrict outdoor advertising of high fat, salt and sugar foods: a realist evaluation.
Study Design	Realist Evaluation
Study Participants	Policy Advocates – from Local Authorities in Yorkshire and Humber region Policy stakeholders – from 5 case study local authorities in Yorkshire and Humber region
Planned Study Period	Jan 2021 – October 2021
Research Question/Aim(s)	What works, how and in what contexts in public health advocacy to reduce outdoor advertising of high fat, salt and sugar foods in Yorkshire and Humber?

## FUNDING AND SUPPORT IN KIND

<b>FUNDER(S)</b> (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	<b>FINANCIAL AND NON FINANCIAL SUPPORT GIVEN</b>
NIHR	This study forms part of a grant of £1.5million

## **ROLE OF STUDY SPONSOR AND FUNDER**

PHIRST London is one of 4 UK Public Health Intervention Responsive Studies Centres funded by NIHR. It is hosted by London South Bank University.

## **ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS**

PHIRST London Centre Executive Committee (CEC)

The CEC sits within the sponsor organisation, LSBU. It has management and governance responsibility for PHIRST London and is made up of the Centre Co-Investigators, senior academic staff at LSBU and a lay representative from LSBU's People's Academy

PHIRST London Advisory Group.

The Advisory Group provides overall supervision for the project on behalf of the Project Sponsor and Project Funder and ensures that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. Membership has been approved by NIHR.

Project Stakeholder Group.

A local stakeholder group is in place to ensure liaison between the research team, the local project leads and PPIE representatives. The group is represented by each of the 15 Local Authorities within the Yorkshire and Humber region as well as the Yorkshire and Humber Healthy Weight and Physical Activity Community of Practice.

### **KEY WORDS:**

Advertising restrictions; reducing high fat, sugar and salt food; public health advocacy; realist evaluation.

## **STUDY PROTOCOL**

A community of practice advocacy project to restrict outdoor advertising of high fat, salt and sugar foods: a realist evaluation.

### **1 BACKGROUND**

The Yorkshire and Humber Association of Directors of Public Health Network (Yand H - ADPH) agreed to support an advocacy project from the Yorkshire and Humber Healthy Weight and Physical Activity Community of Interest. This provides a regional approach to the development of local policies to support the reduction of exposure to foods high in fat, salt and sugar (HFSS foods). This also supports the seventh commitment in the Local Authority Declaration on Healthy Weight and contributes to the regional wide work program to reduce obesity across Yorkshire and Humber to deliver on the government policy on tackling obesity (DHSC, 2020). The regional Community of Interest is made up of representatives from five Unitary Authorities, one County Council and nine District Councils. As such it represents diverse and complex local governance structures as well as varied demographics.

The impact of restricting outdoor advertising of HFSS on people's awareness of HFSS foods and beverages, household purchasing of HFSS foods and beverages is currently being evaluated through a project led by London School of Health and Tropical Medicine (LSHTM). There is little evidence in the published literature of what works in the process of implementing a policy change to restrict outdoor HFSS advertising, including how such restrictions should be designed, monitored, enforced, maintained and adapted. There is a small evidence base examining the advocacy process in the wider related field of nutrition policy. This identifies a series of actions required for the achievement of a policy goal. These actions include intelligence gathering, investing in relationships, developing a clear and unified solution, employing a policy entrepreneur, engaging policy champions, increasing public will, re-framing and amplifying the issue (Cullerton, *et al.* 2016a, Cullerton, *et al.* 2017, Cullerton, *et al.* 2018). The importance of understanding and engaging with stakeholders as part of this process as well as the central role played by policy entrepreneurs or advocates is emphasised across the literature (Chung, *et al.*, 2012; Cullerton, *et al.*, 2016b; Cullerton, *et al.*, 2016c; Cullerton, *et al.*, 2017; Osman, 2018)

### **2 RATIONALE**

A series of coproduction workshops were carried out with the project leads from the 15 local areas in order to undertake an evaluability assessment and agree a research design. Priorities that were identified by the local stakeholders during these workshops were for evaluation findings that would enable them to understand what works in the delivery of advocacy projects. Learning about the advocacy process was prioritised in order to inform the ongoing delivery of this project but also for future planned initiatives for advocacy work to be facilitated at a regional level through communities of practice. The project is at a very early stage of delivery and the longer term outcomes of changes in consumption of HFSS foods were not anticipated within the lifetime of the evaluation. A study is already being undertaken into the impact of restricted advertising of HFSS foods on public transport in London and it was felt to be important not to replicate this work. Understanding the relationship between the very different and complex contextual factors influencing each of the local areas as well as the mechanisms used to influence policy change were seen to be important to understand.

### **3. THEORETICAL FRAMEWORK**

Realist evaluation (Greenhalgh et al, 2015; Pawson and Tilley, 1997) is a theory driven model of evaluation based on the assumption that projects and programmes only work under certain conditions and are heavily influenced by the ways in which different stakeholders respond to them and the decisions and actions made along the way. It is interested in the interaction of three elements: the mechanisms of change, the context within which programs operate and the outcomes they achieve. The realist methodology achieves this through the development of a theory of change that is then tested and refined in a range of cases that offer different contextual settings or mechanisms for delivery. The theory of change informing this evaluation has been developed through a series of stakeholder workshops using logic modelling and a scoping of nutrition policy advocacy literature. It draws upon a conceptual model developed by Cullerton et al (2018) which synthesises policy process and network theories to develop a process for effective policy action. The resultant programme theory statement is “Successful advocacy for public health policy change is informed by intelligence gathering, investing in relationships, developing a clear and unified solution, employing policy advocates, engaging policy champions, increasing public will, re-framing and amplifying the issue. This results in a highlighting amongst policy stakeholders of the nature and scale of the problem, offers a feasible policy response and achieves local political support in order to open a policy window resulting in changes to local guidelines and contracts restricting advertising of HFSS foods via council owned outdoor spaces.”

The co-produced logic model for the intervention which represents the programme theory is illustrated below:

<b>BASELINE</b>	<b>Inputs</b>	<b>Activities (Policy planning and development)  MECHANISMS</b>	<b>Short term outcomes (Policy implementation)  OUTCOMES</b>	<b>Interim outcomes (Changes to the policy/issue environment)</b>	<b>Long term outcomes (pop health outcomes)</b>
1.Initial political will  2.Initial guidance for external advertising contracts  3.Initial content of external contracts for advertising  4.Initial council policies on advertising spaces  5.Initial Y and H ADPH policy development approach to HFSS advertising	Community of Practice  Policy Entrepreneur  Sustain	1.Intelligence gathering  2.Building relationships  3.Developing clear unified solution  4.Engaging policy champions  5.Reframing issue  6.Amplifying issue  7.Increase public will  8.Other	1.Increase in political will ↓ 2.Changes to guidance for external advertising contracts  3.Changes to content of external contracts for advertising  4.Changes to council policies on advertising spaces  5.Y and H ADPH adopt shared policy development approach to HFSS advertising  6.Other	Reduced HFSS advertising on public transport systems  Reduced HFSS advertising on council owned advertising space	Reduced consumption of HFSS  Reduction in obesity levels

**CONTEXT - External factors**  
 Ideological environment/ environmental pressures/governance process/democratisation of knowledge.

#### 4. RESEARCH QUESTION/AIM(S)

##### 4.1 Aim:

To investigate the factors that influence the achievement of advocacy goals to restrict outdoor advertising on council owned spaces of HFSS foods in Yorkshire and Humber.

##### 4.2 Question:

What works, how and in what contexts in public health advocacy to reduce outdoor advertising of high fat, salt and sugar foods in Yorkshire and Humber?

##### 4.3 Objectives

- To identify the stakeholders who have an interest in this project, the role they play and the power they hold to influence its outcomes
- To identify the process and procedures involved in the advocacy process
- To identify the barriers and enablers to policy change

- To explore the role of the community of practice
- To examine the skills and traits of a policy entrepreneur
- To identify the achievement of short-term project goals from a baseline position

#### **4.4 Outcomes**

- Empirically-based logic model of advocacy and theory of change for restricting advertising of HFSS foods
- Stakeholder map and analysis
- Process framework detailing effective mechanisms for advocacy within communities of practice
- Identification of traits of policy advocates.

### **5. STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS**

Using a realist methodology, the evaluation will test the programme theory of change in a range of cases that offer different contextual settings and mechanisms for delivery. Relevant contextual variations were identified through co-production workshops with local authorities.

A mixed methods of data collection will be conducted comprising of:

1. A baseline and summative survey of all areas to establish the current restrictions on advertising and establish the contextual factors.
2. Baseline and summative documentary analysis to evidence changes in local policy and identify the policy context.
3. A baseline and summative survey of stakeholders within the case study sites to establish baseline levels of political will and changes in political will.
4. Baseline, formative and summative interviews with policy advocates from case study sites. These will be carried out in month one, four and eight and will examine the mechanisms applied through the advocacy process and impact of contextual factors.
5. Summative interviews with community of practice leads to explore mechanisms, context and outcomes.
6. Focus group with policy advocates from all areas to establish characteristics and traits applied within the advocacy process
7. Summative case study stakeholder interviews with selected stakeholders close to the policy centre.

Interviews and focus groups will be transcribed and all data will be stored and managed on NVivo software. In line with realist approaches, data analysis will take a 'retroductive' approach that seeks to identify hidden causal forces behind patterns (Greenhalgh, *et al.* 2016). This involves the application of inductive and deductive logic as well as researcher insight to the multiple data sources. Principles of data analysis for realist evaluation developed by Gilmore, *et al.* (2019) will be applied to code data for context, mechanism and outcome (CMO) in order to test the initial programme theory. The analysis process includes data preparation, CMO extraction and elicitation, using CMOs to refine the programme theory and synthesising across case studies to refine the programme theory.

## 6. STUDY SETTING

The study will be set in Yorkshire and Humber. Baseline and summative data will be collected from each of the 15 local authorities with additional more in depth data being collected from 5 case study sites.

## 7. SAMPLE AND RECRUITMENT

### Case Studies

5 case study sites were selected through the mapping of contextual variants identified during co-production workshop. Contextual variants included: project maturity, degree of the rural/urban make up, complexity of demography, complexity of local political and organisational structure, degree to which they had existing partnerships to companies and corporations, and competing priorities. (n=5)

### Policy Advocates

The Local Authority leads within the Yorkshire and Humber Healthy Weight and Physical Activity Community of Interest. (n=15)

### Policy Stakeholders

1. Representatives within the case study local authorities identified by the policy advocates as having power and influence over advertising policy. (n=5x15)
2. Snowball sampling via the initial stakeholders identified. (n=5x?)

### Community of Practice Leads

Yorkshire and Humber Healthy Weight and Physical Activity Community of Interest project leads (n=2)

#### 7.1 Inclusion and Exclusion Criteria

Sample group	Inclusion Criteria	Exclusion criteria
Case study site	<ul style="list-style-type: none"><li>• A Local Authority within Yorkshire and Humber</li></ul> <p>AND reflects 1 of the following positions</p> <ul style="list-style-type: none"><li>• A low level of structural complexity (eg a Unitary Authority) AND high level of project maturity (has begun to work towards project objectives)</li></ul>	<ul style="list-style-type: none"><li>• A Local Authority outside of Yorkshire and Humber</li><li>• A Local Authority stating that they do not have capacity to contribute as a case study site.</li></ul>

	<ul style="list-style-type: none"> <li>• A mid-range structural complexity (eg Metropolitan Borough within a Combined Authority) AND high level of project maturity (has begun to work towards project objectives)</li> <li>• High level structural complexity (eg Top tier system) AND low level of project maturity (not yet begun working towards project objectives).</li> <li>• A low level of structural complexity (eg a Unitary Authority) AND low level of project maturity (not yet begun working towards project objectives).</li> </ul>	
Policy advocates	<ul style="list-style-type: none"> <li>• Member of Yorkshire and Humber Healthy Weight and Physical Activity Community of Interest.</li> </ul> <p>AND</p> <ul style="list-style-type: none"> <li>• Public Health practitioners with lead responsibility for HFSS restrictions project.</li> </ul>	<ul style="list-style-type: none"> <li>• Members of Yorkshire and Humber Healthy Weight and Physical Activity Community of Interest who do not have lead responsibility for HFSS restrictions project in their own LA</li> <li>• Members of LA Public Health teams in Yorkshire and Humber involved in the HFSS restrictions project but without lead responsibility</li> </ul>
Policy stakeholders	<ul style="list-style-type: none"> <li>• Local Authority employees or</li> </ul>	<ul style="list-style-type: none"> <li>• Stakeholders outside the case study sites</li> </ul>

	partners within the case study sites <ul style="list-style-type: none"> <li>• Identified as having a specified role in development or change of advertising policy within La OR</li> <li>• Identified as having potential influence over changes in advertising policy</li> </ul>	<ul style="list-style-type: none"> <li>• LA employees or partners with no role in development or change of advertising policy within LA</li> <li>• LA employees or partners with no potential influence over changes in advertising policy</li> </ul>
Community of practice leads	<ul style="list-style-type: none"> <li>• Those with Management responsibility for the Yorkshire and Humber Healthy Weight and Physical Activity Community of Interest.</li> </ul>	<ul style="list-style-type: none"> <li>• Members of the Yorkshire and Humber Healthy Weight and Physical Activity Community of Interest who do not have responsibility for its management.</li> </ul>

## 7.2 Consent

Gatekeeper permission to conduct the evaluation has been granted by the Yorkshire and Humber Association for Directors of Public Health. Written consent will be secured from participants prior to interviews and focus groups. An opportunity to provide consent will be attached at the beginning of the online survey.

## 8. ETHICAL AND REGULATORY CONSIDERATIONS

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

The study will conform to the principles set out in the LSBU Code of Practice for Research with Human Participants <https://www.lsbu.ac.uk/research/governance/ethics> and has been approved by the School of Health and Social Care Ethics Panel (ETH2021-0083). No patients or members of the public will be included in data collection for this research and it is not located within the NHS. It will therefore not require HRA approval. Doncaster Council required an application to their Research Governance Committee and approval has been received.

## **8.2 Assessment and management of risk**

The primary risk identified is that the project implementation does not progress due to any increased commitment for the Public Health Community of Practice to respond to the Covid-19 pandemic. The data collection strategies for the evaluation, including the use of case studies, have been developed with this in mind and has kept expectations on practitioners to a minimum. The co-produced design means there is an understanding of and commitment to the data collection strategy among the community of practice. The inclusion of an analysis of context means that the evaluation will capture the impact of the pandemic on the outcomes. An additional risk is a low response rate amongst the policy stakeholders. The policy advocate within the community of practice are well linked to the stakeholders and can encourage uptake.

## **8.3 Amendments**

Amendments to the protocol will be directed to the PHIRST London Centre Executive Committee for approval and where necessary to the LSBU HSC research ethics committee

## **8.4 Patient & Public Involvement**

LSBU hosts a People's Academy which includes patients and service users to ensure patient and public involvement and engagement in research studies. A member of the Academy has contributed to the co-production and design of this evaluation by supporting the planning of and attending each of the co-production events and providing feedback on the protocol development. Patient and public involvement and engagement will also be secured at a local level through the existing Public Forum hosted by Doncaster Council. Members of this Forum will provide feedback on the initial evaluation design. Consultation points will be built into the life of the evaluation to feedback progress and seek views.

## **8.5 Data protection and patient confidentiality**

The research project does not involve access to records of personal or sensitive information concerning identifiable individuals. All participants will be allocated a number and all documentation will be saved according to this number. All names and identifying information will be removed from transcripts. Data will be stored in a password protected project specific shared drive in the cloud to protect against hardware loss. Separate password will also be applied to each file and backups will be scheduled to sync daily. Data will not be shared outside of LSBU other than for transcription purposes using and LSBU approved supplier. In compliance with GDPR, personal data will only be retained for as long as required (the duration of the project) and will be destroyed once the dissemination of the project has been completed; research data will be retained for a five year period after completion of the project.

## 9. DISSEMINATION POLICY

Upon completion of the study a final study report will be made available via the NIHR website and the PHIRST Centre website. All participating Local Authorities will receive a copy of the final report. Publications will be submitted by the research team to relevant academic journals. Local presentations and evidence briefings will be made to the Regional Community of Practice, the Regional ADPH and other stakeholder groups. NIHR as the funder will be acknowledged within all reports and publications.

## 10. TIMEFRAME AND MILESTONES

STAGE	ACTIVITY	DATE – week commencing
Inception	Introductory meetings	Sept 2020
	Identification of project team	Sept 2020
	Identification of local stakeholder group	Sept 2020
	Sandpit workshop 1 - understanding the intervention	Oct 19 <sup>th</sup> 2020
	Sandpit workshop 2 - Understanding the theory of change	Nov 9 <sup>th</sup> 2020
	Sandpit workshop 3 - Agreeing a design	Nov 23 <sup>rd</sup> 2020
	Sandpit evaluation survey	March 2021
	Evidence scoping	Sept -Nov 2020
	Design and protocol development	Nov-Dec 2020
	Ethics application	By Jan 2021
	Research Governance Approval	By Jan 2021
	Research Registration	By Jan 2021
	Data collection tool development	Dec 2020
	data collection tool piloting	Jan-Feb 2021
	Local PPI recruitment	Feb-March 2021
Implementation	Baseline area survey	Feb-March 2021
	Baseline case study stakeholder survey -round one	Feb-March 2021
	Baseline case study stakeholder survey -snowballed	March-April 2021
	Case study policy entrepreneur interviews	March 2021; June 2021; Oct 2021
	COP lead interviews	Sept 2021
	All area policy entrepreneur focus group	Sept 2021
	Summative case study stakeholder survey	Oct 2021
	Summative case study stakeholder interviews	Oct 2021
	summative all area survey	Oct 2021
Analysis	data transcription	April 2021; Nov 2021
	Interview coding	May 2021; Nov 2020
	Baseline data analysis	May 2021
	Revised theoretical framework	June 2021
	Summative data analysis	Nov 2021
	case study and cross case analysis	Dec 2021
	Local PPI meetings	March 2021 TBC

Project Management and Reporting	PPI Feedback and impact monitoring	June and ongoing
	Reporting to stakeholder group	ongoing
	interim Findings report and programme of presentations	Sept 2021
	NIHR interim report	April 2020
	Finalise dissemination plan	Nov 2021
	Final report	Feb 2022
	Workforce outputs	TBC Feb-April 2022
	Programme of local presentations	TBC Feb-April 2022
	Programme of national dissemination	TBC Feb-April 2022
	Internal dissemination	TBC Feb-April 2022
	Academic publications	TBC Feb-April 2022

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