HRA Protocol Compliance Declaration:
This protocol has regard for the HRA guidance

Full Title of Study
Evaluation of a Community of Practice seeking to facilitate regional action on Gambling-Related Harms

Acronym
n/a

PROTOCOL VERSION NUMBER AND DATE
Version 1.00

RESEARCH REFERENCE NUMBERS

IRAS Number: N/A

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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, the Sponsor's SOPs, 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 publically 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:
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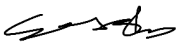

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STUDY SUMMARY

Study Title	Evaluation of a Community of Practice seeking to facilitate regional action on Gambling-Related Harms
Study Design	Mixed methods evaluation
Study Participants	Senior stakeholders and project administrators, representatives of community organisations, people with Lived Experience of GRH and representatives of target groups and communities
Planned Study Period	September 2021-June2023
Research Question/Aim(s)	Primary research question: How, for whom and in what context does a Community of Practice facilitate regional action on Gambling-Related Harms? Objectives: 1. To assess the potential of a community-led CoP to facilitate regional action on GRH and reduce gambling-related health inequalities 2. To assess the benefits and limitations of the CoP from diverse stakeholder perspectives (both internal and external to the CoP) 3. To assess the potential of Lived Experience to be actively involved in regional GRH reduction efforts and interventions

	4. To consider how context affects CoP activities and the potential for outcomes, including relevant features of the Greater Manchester setting

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHR	This study forms part of a grant of £2.5million

ROLE OF STUDY SPONSOR AND FUNDER

PHIRST London is one of 6 UK Public Health Intervention Responsive Studies Centres funded by NIHR. It is hosted by London South Bank University.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/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 Greater Manchester Combined Authority, the Office for Health Improvement and Disparities and Gambling with Lives.

Patient and Public Involvement panel.
This panel will be made up of the two PPIE representatives who sit within the project stakeholder group and three additional members recruited from the Lived Experience network in Manchester. This group will provide insight and advice into the design and delivery of all stages of the evaluation project.

KEY WORDS:

Gambling-Related Harms (GRH), community of practice, lived experience, health promotion and prevention, public health advocacy

STUDY PROTOCOL

1. BACKGROUND

This protocol has been developed in collaboration with local stakeholders from Greater Manchester Combined Authority (GMCA) through a series of workshops designed to assess the evaluability of the intervention and generate an agreed set of evaluation questions and design. Our approach to assessing evaluability is informed by the five questions identified by Ogilvie et al. (2011) and the stages within the Evaluability Assessment framework developed by What Works Scotland (Craig & Campbell, 2015): a structured engagement with stakeholders to clarify evaluation goals; agreement of an intervention logic model or theory of change; a review of existing research literature and data sources; and making design recommendations. These stages were incorporated within an introductory meeting with the Greater Manchester team followed by three structured online workshops facilitated by LSBU. Each workshop lasted between two and three hours and was attended by: the PHIRST London research team, key stakeholders from the local intervention and PPIE representation. During these facilitated workshops we worked towards a shared understanding of:

- the aims and processes of the intervention;
- the logic model and theory of change underpinning the intervention (see Figure 1);
- the existing evidence and gaps in knowledge;
- an evaluation question that is feasible and useful to both the local intervention and the wider public health community;
- an appropriate evaluation design plan.

Communication continued with the GMCA team after the formal workshop process to allow joint decision-making around specific aspects of protocol design.

The case for a public health approach to Gambling-Related Harms (GRH)

The case for a comprehensive public health strategy for addressing Gambling-Related Harms (GRH) has been steadily building (PHE, 2021). Anyone who gambles is vulnerable to GRH, including those who gamble at low and moderate levels (Browne and Rockloff, 2018). Gambling can result in a range of negative outcomes, including financial harm, relationship breakdown, psychological distress, decrements to health, cultural harm, reduced performance and criminal activity (Langham et al., 2016). These negative outcomes are experienced by people who engage in gambling and those around them, including family, friends and the wider community (Langham et al., 2016). A recent Public Health England report estimates the total social cost to be £1.27 bn, a figure believed to be conservative due to gaps in the data (PHE, 2021). The distribution of GRH in the population is also shaped by a range of socioeconomic, cultural and ethnicity factors, implicating gambling in health inequalities (Raybould et al., 2021).

The role of councils in addressing Gambling-Related Harms (GRH)

While effective action on GRH will require interventions across local, regional and national levels, national policy has been slow to respond (Wardle et al., 2019). The Government's review of the 2005 Gambling Act, initially pledged in 2019, has been delayed twice, and is now set for spring 2022. In the absence of a national policy strategy, interest has shifted to the role of councils in preventing GRH. Councils and community organisations may be uniquely positioned to modify localised risk and protective factors (Johnstone and Regan, 2020). The role of cultural, ethnicity and socioeconomic factors in shaping the distribution of GRH (Raybould et al., 2021) also aligns with council agendas vis-à-vis health inequalities. Councils such as Manchester, Leeds and Westminster have led the way in collecting data on local GRH and are beginning to develop interventions and pathways for people affected (Elbers et al., 2020); new NHS treatment centres have also been opened in Manchester, Sunderland and London (Gambling Commission, 2020), with plans in place for 14 centres across England (NHS, 2019). However, public and professional understanding of gambling and associated risks and harms remains low (Milia et al., forthcoming) and the gambling issue can be crowded out of local policy and service agendas (Elbers et al, 2020). There is a need to develop, implement and evaluate strategies for facilitating effective action on GRH at local and regional levels.

The intervention of interest

GMCA has set up a Community of Practice (CoP) to facilitate regional action on GRH. CoPs bring individuals and organisations together to solve complex problems through learning and knowledge mobilisation (Lave and Wenger, 1991). They are increasingly used in health services and public health settings, although typically the focus is on improving professional practice and service performance (Barbour et al., 2018). Here, CoP methodology is used in an innovative way to facilitate learning and action on GRH across Greater Manchester. The GMCA have created a community-led CoP that brings together people with Lived Experience of GRH and diverse community organisations, some of which are established providers in the field of GRH reduction and some are community projects offering this as a new arm of their work. This community-led approach aligns with decentralised and emergent CoP approaches, as distinct from more technocratic and instrumental applications of the method (Whiteford and Byrne, 2015). The community organisations have received funding to deliver a range of interventions for diverse target groups, including people of South Asian heritage, women and armed forces veterans. Aims for these interventions include tackling health inequalities, reducing stigma and educating children and young people about GRH. It is anticipated that CoP 'all share, all learn" (Lalani et al., 2018) sessions will optimise intervention delivery efforts, improving the potential for positive outcomes for target groups, while the project as a whole will raise awareness of GRH and risks across Greater Manchester.

As well as being community-led, a unique feature of the CoP is its involvement of people with Lived Experience of GRH in all levels of decision-making, from the set-up of the CoP and funding decisions, through to the CoP sessions and intervention delivery. A community of 10 people with experience of GRH are attached to the CoP. This reflects an increase in gambling research involving Lived Experience, including research for understanding the challenges that people face to inform intervention development (Preez et al., 2021) and

more active involvement in peer-to-peer and community outreach interventions (Niemczewska and Graham, 2020; Ortiz et al., 2021). Lived Experience is viewed as a potential counter to dominant "responsible gambler" framings that have been criticised for individualising responsibility for GRH and reinforcing stigma among those affected (Livingstone, 2019; Miller and Thomas, 2017). The literature does, however, emphasise the importance of valuing and supporting people in the role (Ortiz et al, 2021; Tracy and Wallace, 2016) and of involving under-represented groups (McCarthy et al., 2018), which can be challenging due to gaps in the availability of people with Lived Experience (Tracy and Wallace, 2016). These challenges aside, the CoP evaluated here represents an innovative attempt to nurture a large Lived Experience community across Greater Manchester and thus, utilise the potential of the approach at scale.

2. RATIONALE

The GMCA project presents a unique opportunity to study a major regional effort to facilitate action on GRH and thereby derive policy and service recommendations for other councils. This is of vital importance given rising awareness of the costs of GRH (PHE, 2021) discussed above, as well as the unique capability of councils, identified in the GRH literature, to modify local risk and protective factors (Johnstone and Regan, 2020). The evaluation has been specifically designed to extrapolate learning from the CoP in a way that will maximise the potential for feasible and robust recommendations for elsewhere.

While CoPs are increasingly showing their potential to facilitate learning and improvements to service performance in a range of health settings (Barbour et al., 2018), they are not typically oriented toward producing interventions for widespread adoption and scale-up. Their complex and multifaceted nature can make it difficult to differentiate the activities that drive outcomes from broader CoP processes and mechanisms (Ranmuthugala et al., 2011). This can blunt the potential for policy and service recommendations because precisely what is to be transferred to other settings can be unclear. Process evaluation can help in this regard, because it can derive intricate knowledge of how and why projects work that can enhance the scalability potential of participatory research (Mills et al., 2019a; Mills et al., 2022). A process evaluation of a CoP for developing a practice guideline, for example, described and evaluated the underlying process that the participants went through, finding it to have potentially widespread applicability (Kwak et al., 2017). At the same time, however, it is equally important to consider the impacts and outcomes of CoPs, for otherwise effectiveness cannot be assessed at all (Ranmuthugala et al., 2011).

The evaluation design therefore combines qualitative, process evaluation with summative outcome evaluation to provide a comprehensive account of the CoP's effectiveness. Close attention to CoP activities should provide a basis for robust and feasible recommendations for other councils. It may be, for example, that councils in other areas do not need to replicate the CoP in its entirety but to implement certain key activities that the evaluation identifies as being instrumental to outcomes.

3. THEORETICAL FRAMEWORK

Theory of Change (Toc) methodology will be utilised to develop a theoretical account of how the CoP is facilitating regional action on GRH: ToC aims to develop understanding, or mid-level theory, of how complex interventions work, typically through a logic model and accompanying narrative about the causal processes through which outcomes are produced (Breuer et al., 2016). ToC can enable evaluators to derive robust recommendations in the absence of experimental conditions and evidence (Breuer et al, 2016). An initial logic model, developed as part of the evaluation co-design process, identifies possible short-, medium- and long-term outcomes of the project and two broad mechanisms that are expected to achieve them: Community-led, Lived Experience and CoP methodology (see Figure 1).

Figure 1: An initial logic model of the GMCA project

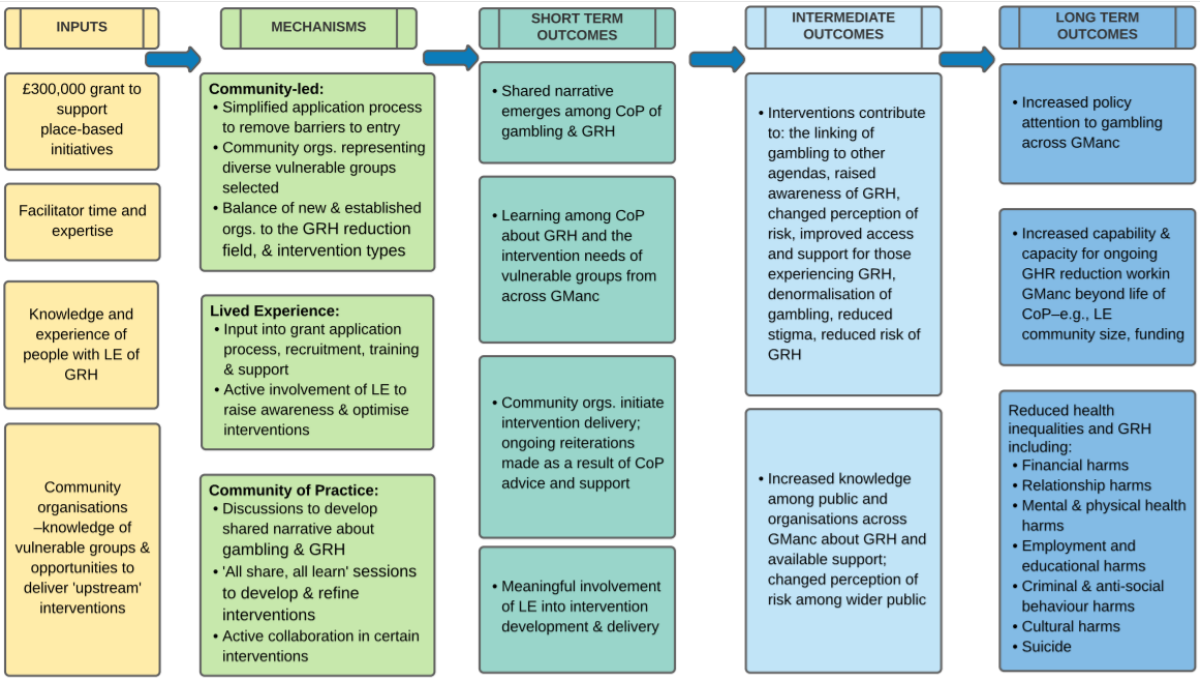

Figure 1 will be developed over the course of the evaluation through a combination of qualitative process evaluation and summative outcome evaluation. Relevant literature on community-led public health, Lived Experience and CoP methodology will provide sensitising concepts and theory to frame the analysis via abductive reasoning (Lipscomb, 2012). The aim will be to draw on existing theory about the mechanisms while paying close attention to the activities and outcomes of the project to ensure that the ToC is empirically grounded.

In testing and refining the logic model, the potentially contrasting views and experiences of the diverse stakeholders involved will be explored. This will be important as it will open up the possibility for a nuanced account of the CoP and Lived Experience mechanisms to emerge, which may be more or less helpful for particular stakeholders. The evaluation will also explore how context shapes stakeholder perspectives and the operation of the CoP as a whole. A dynamic and levelled concept of context will be adopted to facilitate insight into how CoP activities may be adapted for delivery in different contextual conditions (Greenhalgh and Manzano, 2021). As well as paying attention to the opportunities and challenges presented at the level of the Greater Manchester region, the evaluation will

consider how CoP activities and outcomes are affected by both the internal context of the CoP (including, for example, the people and relationships that constitute it) and the contexts of the individual interventions delivered by the community organisations. This context-sensitive approach will inform the development of a Real-World Logic Model (RWLM) which aim to provide a comprehensive, in context account of complex interventions. RWLM are complementary to ToC methodology and are designed to help researchers extrapolate, out of formative, participatory research projects, coherent interventions for widespread scale-up (Mills et al, 2019b; Mills et al, 2022).

4. RESEARCH QUESTION/AIM(S)

4.1 Aim:

- To develop a Theory of Change for a Community of Practice of community organisations and Lived Experience personnel seeking to facilitate regional action on GRH

4.2 Question:

- How, for whom and in what context does a Community of Practice facilitate regional action on Gambling-Related Harms?

4.3 Objectives

1. To assess the potential of a community-led CoP to facilitate regional action on GRH and reduce gambling-related health inequalities
2. To assess the benefits and limitations of the CoP from diverse stakeholder perspectives (both internal and external to the CoP)
3. To assess the potential of Lived Experience to be actively involved in regional GRH reduction efforts and interventions
4. To consider how context affects CoP activities and the potential for outcomes, including relevant features of the Greater Manchester setting

4.4 Outcomes

- An empirically informed and validated Theory of Change – including a logic model and accompanying narrative – of a CoP seeking to facilitate regional action on GRH
- Evidence-informed policy and service recommendations for councils aiming to raise awareness of and reduce GRH and gambling-related health inequalities
- Best practice recommendations regarding the use of Lived Experience at a regional level

5. STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

5.1 Overview of work packages

The research question and aims will be addressed via 3 work packages. While the work packages overlap to a certain extent and will all inform the ToC, difference in emphasis and methods warrant their separation. Table 1 summarises each of the work packages and maps them to the 4 research objectives: where WP1 will provide an overview of the project, WP2 will provide a detailed exploration of the Lived Experience mechanism and WP3 will assess outcomes.

Table 1: Overview of work packages

	WP summary	**Data collection method and sample**	**Total number of interviews**	**Research objectives**
WP1	A qualitative process evaluation will investigate the mechanisms of action, context and stakeholder views of perceived benefits of the CoP, including the potential for long-term outcomes	Observations of CoP sessions, document analysis, interviews with project administrators and senior, external stakeholders at mid- and end-points (2x n-5 to 8), interviews with lived experience personnel (n-8 to 10), interviews with representatives of community organisations at end-point (n-6 to 10)	Between 24 to 36 interviews	1, 2, 3, 4
WP2	Case study research will explore how Lived Experience insights are being applied (or not) in 2/3 interventions, barriers, enablers and outcomes, while a set of best practices for involving Lived Experience at regional level will be developed via focus groups	Focus groups, document analysis, interviews with representatives of community organisations (n-2 to 4 for each intervention), observations, interviews with target groups (n-2 to 4 for each case), brief follow-up interviews to explore long-term project outcomes and sustainability (n-8 to 24)	Between 16 to 48 depending on the number of cases selected	2, 3

WP3	Summative outcome evaluation will assess short- to medium-term outcomes and stakeholder perceptions of long-term outcomes	Analysis of final reports submitted by each project to GMCA and surveys	n/a	1, 2

WP1: process evaluation of the CoP

WP1 will investigate stakeholder perceptions of the utility and functioning of the CoP and Lived Experience mechanisms. It will explore, in detail, what stakeholders have found more or less helpful in achieving their objectives, barriers and enablers to implementation and stakeholder views on the potential for outcomes.

Researchers will record field notes throughout the duration of WP1 and it is anticipated that their observations of CoP sessions will provide crucial contextual information that will inform interview questions. Project administrators and senior, external stakeholders with insight into the local policy and service context will be interviewed at mid- and end-points (2x n-5 to 8) while small catch-up conversations with project administrators will provide snap shots of the process. These interviews will obtain official assessments of the CoP's functioning and insight into the Greater Manchester setting while also providing, via the external stakeholders, a qualitative sense of the CoP's wider visibility and impact. Interviews with the Lived Experience personnel attached to the CoP (n-8 to 10) will also be conducted: these interviews will explore their personal motivations for engaging with the CoP, the nature of the experience of GRH that they have and how that is being utilised, how they have found participating in the CoP and/or intervention delivery, what has helped or hindered them in the role and whether they think the various organisations have listened to and acted on Lived Experience insights. It is anticipated that these interviews will derive important insight pertaining to the scale-up of the Lived Experience role which will frame the further exploration of this mechanism in WP2.

Representatives of the community organisations (n-6 to 10) will be interviewed at the end-point of the CoP, including a mix of established and new providers to GRH reduction work, intervention types and vulnerable groups. The diversity of the sample will allow for variation in stakeholder perceptions to be explored: for example, CoP 'all share, all learn" sessions may have been more helpful to certain providers or intervention types than others while a lack of representativeness in the Lived Experience community may have constrained the potential of the approach to inform intervention design and delivery for certain vulnerable groups, so curtailing the potential for reductions in gambling-related health inequalities. This will be central to developing the ToC for the project and ensuring the robustness of the emergent recommendations for other councils. Finally, a further function of WP1 will be to

identify key external stakeholders who may have a unique perspective on the wider visibility and long-term impact of the project, for survey in WP3. These stakeholders may or may not have been involved in the WP1 interviews.

WP2: Focus groups and case study research of the inclusion of Lived Experience in GRH reduction efforts

WP2 will explore the Lived Experience mechanism in more detail via focus groups and case study research of the practical application of Lived Experience insights in intervention delivery. The PPI steering group will be involved in defining criteria for the selection of the cases. Between 2 and 3 cases will be selected and it is anticipated that they will have had varying levels of success in applying Lived Experience insights in practice, and represent a mix of intervention types and diverse vulnerable groups.

Rapid ethnographic research (Vindrola and Vindrola-Padros, 2018) will be carried out at case study sites, with precise data collection strategies flexing to the specifics of the cases. Relevant service documentation and performance data will be analysed to provide contextual information to frame the research. Researchers will capture observations in field note diaries while interviews with representatives of the organisations selected (n-2 to 4 for each case), observations of intervention delivery efforts (e.g., of educational events) and interviews with representatives of targeted groups and communities (n-2 to 4 for each case) are anticipated. The research will explore how Lived Experience insights are being applied in practice, challenges encountered and outcomes for target groups. Brief follow-up interviews (n-8 to 24) with case study participants will also explore long-term project outcomes and sustainability. This focus on practical service changes and outcomes will complement WP1's focus on process while the inclusion of targeted group perspectives will extend the focus beyond internal CoP stakeholders. External candidates for the WP3 survey will also be identified who have a stake in the case studies and who will provide a perspective on wider visibility and impacts.

A focus group consisting of the Lived Experience personnel attached to the CoP will be convened, at least twice, to discuss emergent findings from wp1 and the case study research. Visual imagery and media will prompt reflections on the experiences of the group (Reavey, 2011). The focus groups will co-produce a set of hypotheses, or "heuristic statements" (Plsek et al., 2007), about how the Lived Experience mechanism functions and its potential in regional GRH reduction campaigns. This will inform best practice recommendations for councils in other areas regarding, for example, how they may attract and support people with experience of GRH to be actively involved in regional change efforts. The work package will also, through the case studies, provide insights and recommendations on pathways to impact at a local level. These insights will be helpful to community organisations seeking to develop similar initiatives.

WP3: summative outcomes evaluation

WP3 will review the short-term outcomes and impacts of the projects based on an analysis of the reports provided by each community organisation to the GMCA and surveys. The review will include all projects, and the reporting format for each project will be determined

as part of a co-creation approach led by the CoP; the research team will attend a key CoP meeting, in April 2022, to participate in decisions about what indicators to include and to explore scope for integrating the short-term and intermediate outcomes listed in the logic model. The final reports will provide insights into both the extent to which the delivery of projects as-intended was achieved, as well as the immediate impacts that can be evidenced by each project. While report data will primarily be quantitative, qualitative data may also be gleaned from a broad range of sources, as some project reports may be delivered in the form of audio-visual materials (e.g., podcasts, interviews with service users). This will be analysed alongside WP1 and WP2 qualitative data (see below).

A survey of key, internal stakeholders, across all projects, may be developed and circulated to support the review of project reports. This is to be determined and its inclusion will depend on the perceived quality and comprehensiveness of the planned, final project reports which is still in development by the programme commissioners. The content of the survey itself will likely be dependent on the co-created content of reports (i.e., the survey will collect data in any areas which are not included in the final reports which are required to provide a detailed analysis of the short-term project outcomes). We will also gather information, to complement the qualitative outcome data collected through WP1 and WP2, on the sustainability of projects – the extent to which they have either been successful in embedding the activity in to business-as-usual activity, or have secured further funding to continue their activity.

In addition to the review of project reports, a further survey will be carried out of those key, external stakeholders that will have been identified, over WP1 and WP2, as likely to have a unique perspective on the extent to which projects have (where appropriate and relevant) achieved visibility and impact within their organisational and community context. This will integrate the outcomes listed in the logic model, including stakeholders' perspectives on the potential for long-term outcomes to be achieved. This will provide a vital, quantitative measure of impact beyond the perspective of immediate stakeholders involved in the project.

WP3 will strengthen the evidence-base underpinning the policy and service recommendations that emerge from this evaluation, as it will be based on an analysis of data on the outcomes and impacts of the projects rather than qualitative insights about CoP processes.

5.2 Data analysis

WP1, WP2 and WP3

Qualitative data from WP1,WP2 and WP3 will be organised and analysed using a combination of the Framework Method (Gale et al., 2013) and thematic analysis (Nowell et al., 2017). Data coding and analysis will proceed iteratively alongside data collection and multiple perspectives will be involved to ensure the validity and reliability of emergent

theory and themes (Noble and Smith, 2015). NVIVO, MS word documents and MS Excel spreadsheets will be utilised, at appropriate points, in the organisation and analysis of the data.

The Framework Method proceeds through an initial coding and categorisation phase to develop an analytical framework that is then tested and applied to the data (Gale et al, 2013). While the precise contents of the framework will be developed during the analysis to allow for emergent issues of interest to be explored, the logic model will be integrated into it to facilitate its systematic consideration via cross-case comparison. For example, how the diverse stakeholders involved (e.g., whether established or new provider to the GRH field) view the CoP and the Lived Experience mechanism will be assessed. Relevant theoretical perspectives and concepts will inform the analysis where appropriate, including literature on CoP methodology and Lived Experience. Abductive reasoning, which aims to develop prior theory through empirical research (Lipscomb, 2012), will underpin this engagement with existing literature. Thematic analysis of all qualitative data will draw out the key learning points of the evaluation in a detailed narrative account of the project's ToC.

The logic model, developed over the course of the qualitative analysis, will provide a structure to triangulate, in a descriptive format, the quantitative elements of WP3 with the qualitative analysis. The descriptive statistics derived from WP3 data will provide a measure of the extent that outcomes have been achieved and permit the testing of hypotheses, raised by the qualitative analysis, about causal pathways. It is not anticipated that more complex inferential statistical analysis would be necessary or appropriate for this data.

6. STUDY SETTING

The study will be set in the Greater Manchester region.

7. SAMPLE AND RECRUITMENT

WP1

- Project administrators will be recruited at the start of the evaluation and they will help identify and recruit the senior stakeholders via the snowballing method; between 5 and 8 participants are anticipated, including the project administrators, for interviews at mid- and end-points.
- The Lived Experience personnel attached to the CoP will be recruited via whole population sampling, following an introduction to the evaluation; between 8 and 10 Lived Experience participants are anticipated.
- The recruitment of the community organisations towards the end-point of the CoP will proceed via purposive sampling to ensure a diverse sample of organisations and intervention types.

WP2

- The Lived Experience personnel will be recruited opportunistically for the focus group research from the community of 10 attached to the CoP; between 6 and 10 Lived Experience participants are anticipated, although precise numbers for the focus groups will likely fluctuate depending on availability.
- Representatives of the community organisations (n-2 to 4 for each case) and the target groups (n-2 to 4 for each case) will be recruited via opportunistic sampling, while case study participants will be invited for a brief follow-up interview following the project's completion (n-4 to 8 for each case); as between 2 or 3 cases will be selected, total numbers will range between 16 to 48 depending on the number of cases selected.

WP3

- Stakeholders will be sampled purposefully for the internal and external surveys. Between 10 and 15 are anticipated for the internal survey and between 20 and 30 for the external survey.

8. ETHICAL AND REGULATORY CONSIDERATIONS

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

The research will receive ethical oversight from LSBU UEP as required. This oversight will include the study protocol and all participant facing documentation, and a favourable opinion will be secured before any data collection takes place. Any adverse events will be reported to the above bodies.

All research will be conducted in line with LSBU ethics panel code of conduct for research involving human participants and the British Psychological Society's ethical guidelines. These guidelines include principles of holding participants rights and dignity, anonymity, and freedom to choose to participate or not. Research will also be conducted and reviewed the way which makes it compliant with GDPR (or replacement legislation). Each strand of the research presents a number of particular ethical risks.

Informed consent will be sought from all participants who wish to be interviewed or surveyed, or be involved in the focus group. Informed consent will also be sought from participants of meetings that are observed as part of the research and where recordings of online meetings are used as data, while permissions will be gained from the community organisations involved in the ethnographic research. Participant information sheets (PIS) will be provided giving participants full information on the studies' aims, methods and risks, etc. Contact details will also be provided for participants to ask questions prior to taking part. Once participants have read this, they will give written consent to participate in the study and for use of the data. The PIS and consent forms will undergo automated readability checks and will be based on LSBU ethics panel approved templates and will be approved by LSBU UEP.

The Lived Experience personnel who participate in the PPI steering group and are directly involved in the interviews and focus groups will receive remuneration for their time in line with established the PHIRST London Patient and Public Involvement and Engagement Strategy.

8.2 Assessment and management of risk

Table 3: Risk register

Key risk	**Likelihood**	**Impact on participants**	**Impact on project**	**Mitigation**
COVID19 interferes with the availability of the research team and/or key stakeholders	Moderate	n/a	Moderate	Depth of team, clear project planning to facilitate handover, lines of alternative communication established, agreement to support the evaluation through a Memorandum of Collaborations between LSBU and GMCA
Access to key stakeholders	Low	n/a	Moderate	Ongoing collaboration with GMCA
Data not available from partners	Low	n/a	Moderate	Agreement with partners on data and ongoing stakeholder involvement, agreement in place to support the evaluation through a Memorandum of Collaborations between LSBU and GMCA
Delay to completion of a significant number of individual projects, which would impact on WP3	Low	n/a	Moderate	Ongoing progress reviews with GMCA to monitor progress. Minor delays can be accommodated by making changes to project timeline; more significant delays may trigger protocol revisions.

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. All revisions will be submitted to NIHR for approval.

8.4 Peer review

This protocol will receive a proportionate review by PHIRST London and the NIHR.

8.5 Patient & Public Involvement

Two people from the Lived Experience community attached to the CoP attended the 3x workshops for coproducing this evaluation, as well as a final meeting where the research team presented the evaluation design to GMCA local partners. They made helpful contributions throughout, which informed the evaluation design and focus, while also providing the assurance that the proposed research does not demand too much time or effort of the wider Lived Experience community. Suggestions for making the involvement of the wider community easier, such as advanced scheduling of the interviews and focus groups, were noted by the research team.

Going forward, a PPIE advisory group of five people will be formed, including the two people who were involved in the workshops and three others from the Lived Experience community attached to the CoP. This PPIE advisory group will oversee the ongoing development of the protocol, ethics applications and data collection tools. For example, they will provide feedback on topic guides for wp1 and the topic guide will be piloted with two of the five, before the interviews with the wider Lived Experience community. They will also be involved in deciding the cases for, and the focus of, the wp2 case study research. Options for direct involvement in research will be explored with the group, including the writing up of experiences for future publications. The group will also be invited to review final reports and those publications that present the findings of the focus groups with the Lived Experience community undertaken as part of wp2.

8.6 Data protection and patient confidentiality

Where data is collected on third party data collection platforms outside of LSBU (e.g. Qualtrics) data will be anonymised at the point of download, and the third party copy of the data deleted. All data will be kept in an anonymous or pseudo anonymous format and stored on LSBU secure servers. Any key files will be kept on a secure server, encrypted and passwords shared separately from files.

Quantitative data may be stored indefinitely with participant consent. Where data is offered to online repositories (see *Dissemination*, below), it will be rendered fully anonymous prior to upload. For qualitative data, in compliance with the General Data Protection Regulation, digital data will be kept for 10 years from study completion and will then be destroyed. Audio files will, however, be deleted following transcription.

When audio files are transcribed, transcripts will be pseudo-anonymised. All information which is collected during the course of the research will be kept confidential by using password protected computerised records. All written transcripts will be kept in a secured locked filing cabinet, when not in use. Any information regarding participants that is shared with others (for instance in reports, publications or shared with a supervisor) will also have pseudonyms used, which will prevent the identification of people involved in the study. All data will be secured in a locked filing cabinet for as long as required for the duration of the study and will then be destroyed 18 months after the completion of the project.

8.7 Indemnity

Indemnity will be provided by LSBU for the research activity undertaken by its staff.

9. DISSEMINATION POLICY

LSBU will own foreground IP arising from the project, including the final dataset(s) and transcripts. Details of IP ownership and usage rights will be finalised in the collaboration agreement between LSBU and GMCA.

In line with the PHIRST London Dissemination, Impact, Involvement, Communication and Engagement strategy the research team will work with the local stakeholder group to develop a knowledge mobilisation plan that identifies clear pathways to impact. This plan will identify: the knowledge areas for mobilisation, why these are original and/or significant, who the potential beneficiaries of the evaluation are and the optimum mediums that will be used for knowledge sharing.

As a minimum key research outputs will include:

1. Interim report of findings
2. A final report for the GM CAGH team and NIHR (also lodged on OSF)
3. Peer review journal articles (also lodged on OSF)
4. A briefing for local government

We will also offer a workshop event in which the study findings are presented to GMCA, and other meetings on an ad-hoc basis as required. We may also present findings to the wider Public Health professional community at conferences and through briefings.

10. Milestones.

STAGE	ACTIVITY	DATE – week commencing
Inception	Introductory meetings	Sept 2021
	Identification of project team	Sept 2021
	Identification of local stakeholder group	Sept 2021
	GRH workshop 1 - understanding the intervention	Nov 3rd 2021

	GRH workshop 2 - Understanding the theory of change	Nov 23rd 2021
	GRH workshop 3 - Agreeing a design	Dec 13th 2021
	Presentation of final design to local stakeholder group	Jan 13th 2022
	Evidence scoping	Nov-Jan 2022
	Design and protocol development	Nov-Jan 2022
	Collaboration Agreement	Feb-Mar 2022
	Ethics application	By May 2022
	Research Governance Approval	By May 2022
	Research Registration	By May 2022
	Data collection tool development	Jan-Feb 2022
	Data collection tool piloting	May 2022
	Local PPI recruitment	Jan-Feb 2022
Data Collection	WP1 – Recording taken of online CoP meetings; observations of CoP meetings once approvals are received	Jan-Dec 2022
	WP1 – qualitative interviews with project administrators and senior stakeholders	May-June 2022; Dec-Jan 2023
	WP1 qualitative interviews with Lived Experience personnel	May-Aug 2022
	WP1 qualitative interviews with community organisation representatives	Sept-Jan 2023
	WP2 – focus groups	Sept-Jan 2023
	WP2 – case study research	June-Jan 2023
	WP2 – brief follow-up interviews	Feb-March 2023
	WP3 – CoP project feedback reports	Sept-Jan 2023
	WP3 – internal and external survey	Nov-Jan 2023
Analysis	WP1 interview data transcription (external)	May-Jan 2023
	WP1 interview coding and analysis	June-Mar 2023
	WP2 case study interview data transcription	June-Nov 2022
	WP2 case study data analysis and follow-up interview analysis	June-Mar 2023
	WP3 – CoP project report analysis	Sept-Feb 2023
	WP3 – survey data analysis	Jan-Feb 2023
	Revised theoretical framework	Jan-Mar 2023
Project Management and Reporting	Local PPI meetings	Feb 2022 – May 2023
	PPI feedback and impact monitoring	Feb 2022 and ongoing
	Reporting to stakeholder group	Ongoing
	Interim findings report and programme of presentations	Aug 2022
	NIHR interim report	Aug 2022
	Finalise dissemination plan	Jan 2023
	Final report	April 2023
	Workforce outputs	Mar-June 2023
	Programme of local presentations	Mar-June 2023
	Programme of national dissemination	Mar-June 2023
	Internal dissemination	Mar-June 2023

11. REFERENCES

Barbour, L., Armstrong, R., Condron, P., Palermo, C., 2018. Communities of practice to improve public health outcomes: a systematic review. J. Knowl. Manag. 22, 326–343. https://doi.org/10.1108/JKM-03-2017-0111

Breuer, E., Lee, L., De Silva, M., Lund, C., 2016. Using theory of change to design and evaluate public health interventions: a systematic review. Implement. Sci. 11, 63. https://doi.org/10.1186/s13012-016-0422-6

Browne, M., Rockloff, M.J., 2018. Prevalence of gambling-related harm provides evidence for the prevention paradox. J. Behav. Addict. 7, 410–422. https://doi.org/10.1556/2006.7.2018.41

Elbers, M., Rowlands, J., Boo, M., Cameron, I., 2020. Building momentum for local action on problem gambling in Leeds and Yorkshire. Public Health 184, 67–70. https://doi.org/10.1016/j.puhe.2020.04.019

Gale, N.K., Heath, G., Cameron, E., Rashid, S., Redwood, S., 2013. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med. Res. Methodol. 13, 117. https://doi.org/10.1186/1471-2288-13-117

Gambling Commission, 2020. Progress Report on the National Strategy to Reduce Gambling Harms. Gambl. Comm.

Greenhalgh, J., Manzano, A., 2021. Understanding 'context' in realist evaluation and synthesis. Int. J. Soc. Res. Methodol. 0, 1–13. https://doi.org/10.1080/13645579.2021.1918484

Johnstone, P., Regan, M., 2020. Gambling harm is everybody's business: A public health approach and call to action. Public Health 184. https://doi.org/10.1016/j.puhe.2020.06.010

Kwak, L., Wåhlin, C., Stigmar, K., Jensen, I., 2017. Developing a practice guideline for the occupational health services by using a community of practice approach: a process evaluation of the development process. BMC Public Health 17, 89. https://doi.org/10.1186/s12889-016-4010-0

Lalani, M., Hall, K., Skrypak, M., Laing, C., Welch, J., Toohey, P., Seaholme, S., Weijburg, T., Eyre, L., Marshall, M., 2018. Building motivation to participate in a quality improvement collaborative in NHS hospital trusts in Southeast England: a qualitative participatory evaluation. BMJ Open 8, e020930. https://doi.org/10.1136/bmjopen-2017-020930

Langham, E., Thorne, H., Browne, M., Donaldson, P., Rose, J., Rockloff, M., 2016. Understanding gambling related harm: a proposed definition, conceptual framework, and taxonomy of harms. BMC Public Health 16, 80. https://doi.org/10.1186/s12889-016-2747-0

Lave, J., Wenger, E., 1991. Situated learning: Legitimate peripheral participation, Situated learning: Legitimate peripheral participation. Cambridge University Press, New York, NY, US. https://doi.org/10.1017/CBO9780511815355

Lipscomb, M., 2012. Abductive reasoning and qualitative research. Nurs. Philos. 13, 244–256. https://doi.org/10.1111/j.1466-769X.2011.00532.x

Livingstone, C., 2019. Identifying effective policy interventions to prevent gambling-related harm [WWW Document]. Vic. Responsible Gambl. Found. URL

https://responsiblegambling.vic.gov.au/resources/publications/identifying-effective-policy-interventions-to-prevent-gambling-related-harm-640/ (accessed 1.6.22).
McCarthy, S., Thomas, S.L., Randle, M., Bestman, A., Pitt, H., Cowlishaw, S., Daube, M., 2018. Women's gambling behaviour, product preferences, and perceptions of product harm: Differences by age and gambling risk status. Harm. Reduct. J. 15.
Milia, C., Albery, I., Moss, A., forthcoming. The Impact of Message Framing on Problem Recognition amongst Problem and At-risk Gamblers. GambleAware Final grant report.
Miller, H., Thomas, S., 2017. The "Walk of Shame": a Qualitative Study of the Influences of Negative Stereotyping of Problem Gambling on Gambling Attitudes and Behaviours. Int. J. Ment. Health Addict. 15, 1–17. https://doi.org/10.1007/s11469-017-9749-8
Mills, T., Lawton, R., Sheard, L., 2019a. Improving Patient Experience in Hospital Settings: Assessing the Role of Toolkits and Action Research Through a Process Evaluation of a Complex Intervention. Qual. Health Res. 29, 2108–2118. https://doi.org/10.1177/1049732319855960
Mills, T., Lawton, R., Sheard, L., 2019b. Advancing complexity science in healthcare research: the logic of logic models. BMC Med. Res. Methodol. 19, 55. https://doi.org/10.1186/s12874-019-0701-4
Mills, T., Shannon, R., O'Hara, J., Lawton, R., Sheard, L., 2022. Development of a 'real-world' logic model through testing the feasibility of a complex healthcare intervention: the challenge of reconciling scalability and context-sensitivity. Evaluation 13563890211068868. https://doi.org/10.1177/13563890211068869
NHS, 2019. NHS long term plan [WWW Document]. NHS Engl. URL https://www.longtermplan.nhs.uk (accessed 11.30.21).
Niemczewska, A., Graham, F., 2020. Gambling Related Harms – Intensive Mentoring from Mentors With Lived Experience. Perspect. Public Health 140.
Noble, H., Smith, J., 2015. Issues of validity and reliability in qualitative research. Evid. Based Nurs. 18, 34–35. https://doi.org/10.1136/eb-2015-102054
Nowell, L.S., Norris, J.M., White, D.E., Moules, N.J., 2017. Thematic Analysis: Striving to Meet the Trustworthiness Criteria. Int. J. Qual. Methods 16, 1609406917733847. https://doi.org/10.1177/1609406917733847
Ortiz, V., Cain, R., Formica, S.W., Bishop, R., Hernández, H., Lama, L., 2021. Our Voices Matter: Using Lived Experience to Promote Equity in Problem Gambling Prevention. Curr. Addict. Rep. 8, 255–262. https://doi.org/10.1007/s40429-021-00369-5
PHE, 2021. Gambling-related harms evidence review: summary. Public Health England.
Plsek, P., Bibby, J., Whitby, E., 2007. Practical Methods for Extracting Explicit Design Rules Grounded in the Experience of Organizational Managers. J. Appl. Behav. Sci. 43, 153–170. https://doi.org/10.1177/0021886306297013
Preez, K.P. du, Landon, J., Maunchline, L., Thurlow, R., 2021. A Critical Analysis of Interventions for Women Harmed by Others' Gambling. Crit. Gambl. Stud. 2, 1–12. https://doi.org/10.29173/cgs76
Ranmuthugala, G., Plumb, J.J., Cunningham, F.C., Georgiou, A., Westbrook, J.I., Braithwaite, J., 2011. How and why are communities of practice established in the healthcare sector? A systematic review of the literature. BMC Health Serv. Res. 11, 273. https://doi.org/10.1186/1472-6963-11-273

Raybould, J.N., Larkin, M., Tunney, R.J., 2021. Is there a health inequality in gambling related harms? A systematic review. BMC Public Health 21, 305. https://doi.org/10.1186/s12889-021-10337-3
Reavey, P. (Ed.), 2011. Visual Methods in Psychology: Using and Interpreting Images in Qualitative Research, 1st edition. ed. Routledge, Hove, East Sussex : New York.
Tracy, K., Wallace, S.P., 2016. Benefits of peer support groups in the treatment of addiction. Subst. Abuse Rehabil. 7, 143–154. https://doi.org/10.2147/SAR.S81535
Vindrola, C., Vindrola-Padros, B., 2018. Quick and dirty? A systematic review of the use of rapid ethnographies in healthcare organisation and delivery. BMJ Qual. Saf. 27, 321–330.
Wardle, H., Reith, G., Langham, E., Rogers, R.D., 2019. Gambling and public health: we need policy action to prevent harm. BMJ 365, l1807. https://doi.org/10.1136/bmj.l1807
Whiteford, M., Byrne, P., 2015. Talking about alcohol: communities of practice and patient pathways. J. Res. Nurs. 20, 12–25. https://doi.org/10.1177/1744987114548744