NIHR | Public Health Intervention Responsive Studies Teams

Project summary

Study title	Southampton **Co**vid **P**articipatory **A**ction Research and **C**hampions initiative Evaluat**i**on (CoPACT)
Planned study period	1st April 2022 to 30th April 2023
Study design	Realist Evaluation
Research aim/s	To assess what works for whom and in what contexts in the setup, implementation, delivery and experience of participatory action research and covid-19 and vaccination champions initiatives targeted at 'high risk' populations in Southampton
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Co-Investigators	Dr Suzanne Bartington, University of Birmingham Dr Gavin Breslin, Ulster University Dr Neil Howlett, University of Hertfordshire (Project lead) Dr Katie Newby, University of Hertfordshire Mrs Amander Wellings, University of Hertfordshire Dr David Wellsted, University of Hertfordshire Dr Adam P Wagner, University of East Anglia
Funder	National Institute for Health and Care Research (NIHR) Award ID: NIHR131537 Project ID: NIHR135393
Protocol version number and date	V2.0 August 2022

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1 Title and additional identifiers

1.1 Full title of the study
Southampton Covid Participatory Action Research and Champions Initiative Evaluation (CoPACT)

1.2 Short title of the study
Southampton CoPACT

1.3 Registry
[add reference and date once registered]

1.4 Funding
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1.6 Plain English Summary

Overview of the project being evaluated

Southampton City Council have been trying a number of ways to help spread accurate health information during the COVID-19 pandemic and to communicate better with residents about what they need from public health services. In September 2020, a COVID-19 Champions programme was set up, which involved members of the public volunteering to help share accurate information about how to keep themselves and their families and communities safe during the pandemic. More recently, a Vaccine Champion programme has been running which aims to increase knowledge and uptake of the covid vaccine among groups where rates have been lowest. Vaccine champions can be an individual or an organisation such as primary schools. The champions are volunteers, and the idea is to get a broad range of people to have conversations with and spread key information to their families, friends, social groups, and wider communities.

Alongside the champion programmes, a community participatory action research programme has been running. This programme involved a smaller group of paid individuals becoming peer researchers. These researchers are members of the local community and were trained to conduct interviews with other community members about what is important to them (relevant to health and wellbeing and experiences of covid) and any concerns they have, so that public health services can respond in ways that are most likely to help them. There are around 15 researchers who have conducted 5-6 interviews each on average. The interview responses were looked at to find common things that are important to people. All three programmes aim to improve links with the local community and provide better communication between the local authority and groups/individuals, so that there is better support for health and wellbeing going forward.

Why this study is needed and what we are aiming to do

It is important to evaluate public health programmes to see how well they worked, who they worked for, what settings they worked best in, and how much they cost. The Southampton Covid Participatory Action Research and Champions Initiative Evaluation (CoPACT) findings will provide lessons for future champion or community participation programmes. This will help with continued support for COVID-19, but also for wider health and wellbeing programmes that might involve community members. This project is using a 'realist evaluation', which involves speaking to a range of people involved in organising and running these programmes to get their ideas of how the programmes worked and the benefits that people in the community might have had as a result. The people interviewed will include the programme managers, the champions and researchers, the charity who trained the researchers, and community members who spoke to the champions or researchers. We will also look at a range of materials from the researcher training, information leaflets used by the champions, and social media posts used to spread accurate health advice. By speaking to a range of people and looking at a range of materials, the evaluation aims to get a full picture of the ways in which the programmes work, the good (or not) things that happened as a result, and how the community and organisations involved played a role.

Research questions

The study aims to answer the following research questions:

- Who were the Champions and peer researchers and how much do they represent target communities?
- What are the factors that help recruit and keep the Champions and peer researchers?

- What are the factors that help the Champions and peer researchers engage with their communities and what benefits come out of this?
- How do the programmes compare and how can the learning help with future programmes?
- How much does each programme cost to run?

Evaluation timescales
Start of evaluation work: April 2022
Draft final report completed: April 2023
Key dissemination activities completed: April 2023

The value of the findings

The evaluation will provide value to a range of people and organisations. For the public health team and charitable organisations involved it will provide detailed findings about how these programmes worked, who benefitted most, and the best way to run them going forward. For the people being interviewed it will provide a way to have their voice heard based on their experience of running or receiving parts of the programmes. For public health leaders who might fund future programmes it will tell them how much each approach costs and how they might best organise the services going forward. From a research perspective, using the 'realist evaluation' approach is quite a new way of evaluating these programmes. The findings will be of interest to researchers and evaluators of public health services because it can be difficult to explore the benefits and challenges of these programmes, as they are complicated with many people involved and many moving parts.

Research design

1) Phase 1: This phase aims to identify how the Champions and peer researcher programmes work (or not) to produce outcomes (participation/lack of participation from individuals in the community).
2) Phase 2: These ideas are then tested through interviews with key people and by reviewing documents from each programme. This phase will also involve asking members of the public to submit photos that represent their experiences or any benefits from the programmes.
3) Phase 3: Findings are then combined together to see if any changes need to be made to the initial ideas about how the programmes work. Patterns from the interviews and documents are identified and will be used to produce a broader explanation that can apply to other programmes.

Stakeholders will be involved throughout the design and delivery of this project, adding their insight to help the researchers answer questions that are important to them. They will also help with understanding the results of this evaluation and with sharing them.

1.7 Scientific abstract

Part of Southampton City Council's response to the COVID-19 pandemic was the roll-out of three related programmes that aimed to establish better communication channels with community members that were at risk of being most disadvantaged by the pandemic. The first two were COVID-19 and Vaccine Champion models whereby a large number of volunteers were provided with accurate up to date local information about infection rates, how to protect themselves and reduce transmission, how to access support and vaccinations to share and discuss with their families, friends, social groups, and wider communities. The third programme was a community participatory action research approach that trained local residents to interview other members of their community to gain insights about their health priorities, challenges they have accessing services, and how services and support could be

optimised for them. The interview data was then analysed for overarching themes across interviews. This proposed research aims to evaluate these programmes using a realist evaluation approach. This methodology looks at what works, how, in which conditions and for whom, and builds programme theories centred around context, mechanism and outcome (CMO) configurations. This method is better suited than traditional approaches to the evaluation of complex interventions embedded in complex systems where controlling variables to determine effects is not possible. A realist evaluation happens in three phases: development of the initial programme theories, testing of initial programme theories using empirical data, and synthesis of programme theory. Realist interviews with stakeholders from across the three programmes, programme documentation, and photos submitted from the public will form the core 'data' in these stages. Project dissemination will use traditional and creative methods to mobilise the knowledge from the evaluation and will provide insights about how to replicate desired effects of such programmes in future to the public and professional programme stakeholders and wider public health teams, third sector organisations, and researchers.

2 Background information

2.1 Overview of the interventions to be evaluated and contextual information

In early 2020, the first cases of a new coronavirus that had emerged in Wuhan Province, China were detected in the UK. By March 2020, community transmission of the new virus, which causes coronavirus disease 2019 or COVID-19, had become so widespread that unprecedented measures to control the spread and reduce pressure on the National Health Service were implemented. A series of lockdowns and restrictions on contact with others began on 23rd March 2020 and lasted until the summer of 2021. Throughout this period local authority based Public Health departments in England have been responsible for a co-ordinated COVID-19 response within their areas, and a range of initiatives and actions were implemented as part of Contain Outbreak Management plans (Southampton City Council & Public Health and EPRR, 2020) across local authority regions, informed by knowledge about local population groups and their needs.

In Southampton, three initiatives that take a community centred approach to improving health and wellbeing have been adopted as part of efforts to tackle COVID-19; i) a COVID-19 Champions initiative; ii) a Vaccine Champions initiative; and iii) a community-based participatory action research programme. The COVID-19 Champions initiative began in September 2020 and involved recruiting volunteers to act as conduits into their communities for accurate and up-to-date local information about the pandemic, current data on infection rates, and how people could protect themselves and those around them and get help and support. It was also intended to be a way in which the local authority (LA) could get feedback from communities on the specific challenges they were facing, so that the LA could form a better response to local need. Anyone who wanted to volunteer was able to and the LA adopted a passive approach without targeting specific groups or communities for their involvement.

Vaccination to protect people from COVID-19 began in the UK in December 2020 (Gov.uk, 2022), with an intensive two-dose programme roll-out that lasted into the summer of 2021. A booster dose roll-out followed in late 2021 into early 2022. Although the UK has achieved very high levels of vaccination, some parts of the population are less likely than others to have the vaccine. People from Black and Minority Ethnic groups are less likely to have been vaccinated than the White British population (Dolby et al., 2022). People from more deprived socio-economic groups are less likely to be vaccinated compared with those in less deprived groups (Dolby et al., 2022). This variation in vaccine uptake is contributing to health inequalities. The Vaccine Champion programme began in February 2022 (and overlapped the COVID-19 Champion programme). The purpose of this initiative is to increase COVID-19

vaccination rates, particularly amongst communities and population groups where vaccination uptake has been lower. Existing COVID-19 Champions were invited to be involved so that existing networks could be utilised, but there has also been a focus on reaching people and organisations linked to communities with large numbers of unvaccinated people. The recruitment approach was more proactive, with very deliberate efforts to recruit members of target communities into the role. In addition, a two-tier champion approach was implemented where some Champions have been paid for their time in order to reach and engage a second tier of voluntary vaccine champions across communities. Similar to the original COVID-19 Champions, the initiative was also intended to be a way for the LA to understand community needs and priorities so that they could continue to shape their response accordingly. Funding for the Vaccine Champions work runs to July 2022.

The Community-based Participatory Action Research (CPAR) programme began in February 2022 and is funded until June 2022. It has involved commissioning of a national not-for-profit community research and social innovation organisation (the Young Foundation) to recruit and train community-based peer researchers from communities that have lower rates of vaccination and/or are disproportionately affected by COVID-19 for other reasons (e.g., Black and Ethnic minority groups, undocumented migrants, people living in deprived neighbourhoods in Southampton). Other voluntary sector organisations have been involved to help reach and engage the peer researchers. Those recruited are typically working around 2-3 days per week and are being paid a living wage for the work that they do. They have received training in gathering data from people in their communities and how to analyse the data they gather. The peer researchers are being mentored through the work. The purpose is to understand the priorities and concerns that matter to the target communities so that public health responses can be tailored effectively. All three initiatives are also intended to improve networks and communication channels between target groups and communities and the LA, to build trust and rapport and establish a foundation on which sustained support for health and wellbeing improvement for the future can be built.

2.2 Review of existing evidence

2.2.1 Champion programmes

A variety of champion programmes have been applied in the UK and internationally, both during acute emergencies and for prevention on a broader timescale (PHE, 2021). Champion programmes generally fall within two approaches that both rely on volunteers. The first is the Popular Opinion Leader approach, which utilises well-connected leaders that are already established in the community and play a role in health promotion. The second is the Community Mobilizer approach, which utilises a wide range of volunteers, typically to support prevention and outreach and allow reciprocal information sharing between communities and stakeholder organisations (PHE, 2021). Both models can be effective, particularly at reaching and communicating with target communities, while evidence on behavioural and health outcomes is harder to achieve. Increased reach is achieved through greater social connections in disadvantaged communities and better linking of communities and services (PHE, 2021).

The latest evidence suggests that successful implementation of champion models is aided by building a supportive infrastructure, embedding skills training alongside increasing knowledge, and taking a long-term approach to community engagement (PHE, 2021). Within the context of COVID-19, champion approaches are more likely to succeed when government trust is low, and the champions are given autonomy and are seen as trusted sources (SAGE, 2020). Champions can effectively reach target groups, support communications about health risks, support health facilities and workers, and are well placed to understand and deliver solutions that are appropriate to target groups or communities (SAGE, 2020). Key challenges that champion approaches face are a reliance on volunteers, due to stress

and burnout, a lack of resources, and the challenge of genuinely reaching and including seldom heard and underserved groups in the process (SAGE, 2020).

2.2.2 Community Participatory Action Research (CPAR) programmes

A different approach to achieve better understanding and connections to communities is Community Participatory Action Research (CPAR), sometimes referred to as community-based participatory research (CBPR) or participatory action research (PAR). Ortiz et al. (2020) highlight a conceptual model of CBPR involving four domains: research context (e.g., social and structural, capacity and readiness); partnership processes (e.g., relationships, partnership structures); intervention and research design as a result of shared decision making (e.g., community-involved research, culturally-centred interventions); intermediate and long-term outcomes (e.g., shared power relations in research, community transformation). It has also been recommended that PAR programmes are considered in three phases, involving design (including involvement of stakeholder groups), implementation (including stakeholders to focus on appropriate health impact and outcomes), and evaluation (including participant and stakeholder perspectives and plans for sustainability; Lindquist-Grantz & Abraczinskas, 2020).

A review of community participatory approaches in health systems concluded that studies consistently highlighted improvements in the availability, accessibility and acceptability of services, with less focus on service quality and limited evidence for improvements in health behaviours or outcomes (George, Mehra, Scott, & Sriram, 2015). In line with findings for champion models, individual motivations, trust at the community level, and supportive institutional processes promoted community participation, while challenges highlighted included a lack of training, interest and information, and a lack of resources for sustainability (George et al., 2015). In terms of the research process itself, challenges can include a lack of time and financial resource to enable sustainable community engagement, and differing expectations, roles, and processes involved in partner organisations (Breen & Connor, 2014). Despite these challenges there were factors that promoted community-based research partnerships, including recognition of stakeholder expertise, reimbursement of costs, and providing variety in communication channels and methods (Breen & Connor, 2014). When looking at the effects and processes involved in CPAR approaches, it is also important to explore benefits/outcomes at multiple levels, such as volunteers/paid researchers and community organisations. Volunteer researchers reported that their involvement in CPAR programmes was valuable training for community engagement and for experience in their health field of interest (e.g., future nursing and medicine-related careers; Marriott et al., 2015). Community partners reported that having volunteers from within their communities helped understanding and acceptance of current and future research-based approaches (Marriott et al., 2015).

2.3 The problem being addressed and why this research is needed now

Existing health inequalities have been further exacerbated by the COVID-19 pandemic and efforts to address these inequalities need to be sustained over the long-term and in partnership with those who are affected. As outlined above, existing evidence about community-focussed initiatives such as Champions programmes and CPAR suggest that they can be effective for helping to improve reach and engagement with communities and could contribute to building more effective and acceptable services and initiatives for improving health and wellbeing amongst those most in need. Such initiatives, however, are complex and are introduced within dynamic contexts making evaluation of their effects difficult. To date, whilst there have been a number of evaluations of wider community/health champions and CPAR projects, published evaluations of their application in the COVID-19 context have been limited. One exception is an evaluation published by Newham Borough Council (2022) (Newham.gov.uk, 2022) in London, who were an early adopter of a Champions approach during COVID-19. Their report identifies useful insights into why people got involved, how they communicated

messaging onwards into the community, unexpected benefits, as well as identifying what could be improved. More research is needed to better understand how and why and in what circumstances participatory approaches such as these bring about desired effects and can be harnessed for improving health and wellbeing and reducing health inequalities.

2.4 Realist Evaluation

Realist evaluations focus on 'what works, how, in which conditions and for whom' using context-mechanism-outcome configurations (CMO) rather than focusing on outcome effectiveness (Dalkin, Greenhalgh, Jones, Cunningham, & Lhussier, 2015). It is an approach that is suitable for evaluating complex public health interventions, where assigning causation and the isolating of specific effects by controlling variables is not possible. Mechanisms combine the 'reasoning' or reaction to 'resources' inherent in the intervention, and it can be challenging at first to separate mechanisms from the intervention itself (Dalkin et al., 2015). There are three broad phases involved in a realist evaluation (Pawson & Tilley, 1997). These include: 1) identifying the initial programme theory in terms of CMOs via document review and discussions with stakeholders, 2) testing the initial programme theory via data collection involving interviews with key programme managers, deliverers, and participants, and 3) analysis of the CMOs and building a more refined programme theory based on the findings. The data collection phase involves a different method than traditional interviews conducted for approaches such as process evaluation, which are normally open-ended and exploratory. In realist interviews, initial programme theories about how the intervention/programme works are explained to the interviewee, for them to comment on to help refine the theories (Manzano, 2016). The content of the interview focuses on the researchers' theories, and interviewees confirm, falsify, and/or refine this theory. This relationship between interviewer and interviewee is referred to as a 'teacher-learner cycle' (Manzano, 2016), unlike the more passive and naïve recipient stance of an interviewer in other qualitative methods.

Realist evaluations have been conducted of CBPR approaches in the context of health research and practice. Jagosh et al. (2012) reviewed studies on the benefits of participatory research and highlighted a middle-range theory (a synthesis across cases, the final phase highlighted in the previous paragraph) that focused on partnership synergy as the key catalyst for effective links between the process and outcomes of these approaches (Jagosh et al., 2012). Using this lens, findings indicated that participatory research can produce culturally appropriate research, increase capacity and competence in stakeholders, improve outputs and outcomes, and promote sustainability of project goals (Jagosh et al., 2012). In follow-up work, Jagosh et al. (2015) showed that sustainability in CBPR partnerships helped achieve collaborative efforts toward health improvement, spin-off projects, and system transformations at a population level.

2.5 The current project

This project will use a realist approach to evaluate co-occurring Champion and CPAR programmes in Southampton. Both types of programme aim to increase engagement with, understanding of, and empowerment in underserved community groups, and are complex multi-faceted public health approaches, which are not suitable for traditional outcome effectiveness evaluations such as randomised controlled trials or quasi-experimental methods. By using realist evaluation, this project aims to provide unique insights that explain how such models can be implemented and what needs to be in place to optimise their delivery in the future, informing both public health and academic research stakeholders.

3 Study Information

3.1 Aim

The aims of the realist evaluation are: 1) to evaluate the Champion and Community Participatory Action Research programmes in terms of how and why they work, for whom and in what contexts; and 2) to provide clear indicators of the combination of factors that future programmes should aim to re-create to optimise the likelihood of success.

3.2 Research questions

1. Who were the Champions and peer researchers and how representative of target communities were they?
2. What are the factors (contexts and mechanisms) that led to the success or failure in engaging and recruiting the Champions and peer researchers from target communities?
3. What are the conditions under which members of target communities are enabled to take on the role of a peer researcher or Champion?
4. What are the conditions under which Champions or peer researchers are fully enabled to communicate effectively with their communities (or not)?
5. What are the conditions under which wider community members engage and respond to communication from peer researchers or Champions?
6. What are the conditions under which new insights or understandings were achieved by the local authority and its partners?
7. What were the conditions under which the local authority and the community changed their views of one another?
8. How can our explanations (programme theories set out as context-mechanism-outcome configurations) of the Champion and peer researcher programmes inform future ways of working?
9. How do the programme theories of the peer researchers and Champions compare to one another? / Are there demi-regularities (i.e., factors in common between the approaches) or are the programmes distinct?
10. How do the (health economic) resources, and associated costs, differ between the programmes? Are there any suitable metrics that can be used to compare the programmes?

4 Study design and methods

4.1.1 Realist evaluation approach

Realist research methods were originally articulated by Pawson and Tilley (Pawson & Tilley, 1997), who argued that an intervention can only achieve successful outcomes if applied to the right context with appropriate social and cultural conditions. The importance of 'context' in the design, evaluation and implementation of complex interventions is now widely recognised (Craig et al., n.d.). Realist methods address the inadequacy of the traditional randomised controlled trial (RCT) to address context-specific drivers behind the outcomes that they measure, and their relationship to the underlying intervention process. By addressing the question of 'what works, for whom, and in what circumstances', realist methods help to tailor interventions for implementation in different settings, populations and contexts (Nurjono et al., 2018).

The realist approach is a type of theory-driven evaluation that will help in understanding such complexity, by analysing how different elements of the Champion and CPAR programmes are intertwined, the mechanisms by which they work and identifying how context influences the production of outcomes. The realist approach will emphasise the contingent nature of the outcomes of

the Champion and CPAR programmes and address the questions about how these programmes work, in which settings, for whom, in what circumstances and why. Understanding these processes is key for informing practice of what contributes or hinders the success of these programmes. This explanation of how an intervention works is called a 'programme theory' which forms the basis of the realist evaluation. The 'programme theory' explains the workings of an intervention by identifying the relationships between key context (C), mechanism (M), and outcomes (O) variables, in a series of CMO configurations (Pawson & Tilley, 1997).

In the context of this research, the realist evaluation is underpinned by a premise that Champions and CPAR programmes; combine activities, roles and resources (i.e. Vaccine Champions), to solve a social problem (such as the lack of uptake of COVID-19 vaccinations). However, they rely on human volition as well as other factors, to make them work. Realist evaluation recognises the importance of context in understanding the way in which programmes work in real-life situations (Pawson et al., 2005) and that voluntary and participatory programmes implemented in different contexts will work through different mechanisms and subsequently produce different patterns of outcomes. Findings from this study should be of interest to researchers, policymakers and those working across public health and local government to improve health and wellbeing and reduce inequalities.

4.1.2 Cost Analysis

Alongside the realist evaluation, the resources and costs associated with the delivery of each programme will be examined. For the champion programmes we expect to source information from the programme managers about their budget (for example how this is allocated to general areas of delivery) and what is delivered utilising them (e.g., numbers of staff employed, activities delivered etc). We will determine if there are any components of these programmes for which a more detailed 'bottom-up' costing approach would be informative (considering the resources[1], such as staff time, required to deliver the component and attributing cost to these). We expect the 'bottom-up' approach to be most appropriate for the more structured activities of the CPAR programme (e.g., in depth training and interviews). Additionally, we will consider whether there are any metrics that may be informative when comparing the programmes (e.g., number of champions or interviews conducted) alongside the budget considerations, exploring whether a cost-consequences analysis would be helpful.

4.2 Study design overview

There are three broad phases involved in a realist evaluation (Pawson & Tilley, 1997). The first phase seeks to identify and formalise an initial programme theory. Data is gathered informally from individuals involved in the development of the intervention, its key stakeholders, and from academic and other literature. This data will be used to build hypotheses about the causal relationships between different contexts (C1, C2, C3 …), mechanisms (M1, M2, M3 …) and outcomes (O1, O2, O3 …). These hypotheses are known as CMO configurations where mechanism refers to both the resources or opportunities provided by the intervention and the stakeholders' reasoning in response to those resources or opportunities (Dalkin et al., 2015). This theory is then 'tested' in the second phase through a mixed-methods approach which involves reviewing intervention documents and conducting realist interviews with stakeholders to determine how the programme unfolds in real life contexts. In the third phase, the programme theory is refined through analysis and interpretation of the data to provide middle-range theory (i.e. ideas how about how these types of programme work that may be

[1] Here, we use 'resource' in the health economic context to describe any quantity or activity or material required to deliver a component of a programme – for example the time of service staff and items such as papers/pens etc used by staff. Thus, this different to realist terminology use of such terminology as in the previous section.

relevant for other similar programmes in other areas/contexts) statements about how, why and for whom the Champion and CPAR programmes work (or not) and in what contexts.

- Phase 1: Development of the initial programme theory
- Phase 2: Testing of initial programme theory using empirical data
- Phase 3: Synthesis of programme theory

Phase 1: Development of the initial programme theory
This phase involves the formulation of the initial programme theory using CMO configurations to explain what works, i.e. what contexts triggered what mechanisms leading to what outcomes. This stage will be completed through complementary approaches including: 1) review of documents related to the Champion and CPAR programmes that describe the rationales, components of the interventions and the programme protocols to identify the underlying assumptions about how the programmes are expected to work to achieve their intended outcomes, and 2) Informal discussions with key stakeholders e.g. the public health team and programme managers, to identify factors influencing the programme and underlying assumptions about how the Champion and CPAR programmes are expected to work and in what contexts, to achieve their intended outcomes. These initial programme theories are likely to be composed of multiple proposed CMO configurations and will be set out using the format illustrated in table 1 below. Table 1 also includes an example potential CMO configuration.

Table 1: Conceptual framework for the study

Context	**Mechanism resource**	**Mechanism reaction**	**Outcome**
C1 – Charity X has strong links into the Black African community in Southampton and has only recently started engaging with recently arrived refugee communities	Mres1 – Charity X uses existing networks with communities to promote champion/peer researcher opportunities	Mreact1 - Greater proportion of Black African community members than refugee community members recognise the benefit of involvement	O1 – proportionally more people from established Black African communities recruited than from newly arrived refugee communities

Phase 2: Testing and refining of initial programme theory
This phase involves testing and refining the initial programme theories. A mixed-methods, multiple case study design will be used in this research to guide the development, testing and refining of the programme theory through the analysis of the relationships between the contexts, mechanisms and outcomes. Both quantitative and qualitative data collection will be utilised. Realist interviews will be conducted with key stakeholders including staff involved in setting up and delivering the programmes, COVID-19 champions, Vaccine champions, CPARs and individuals who received support from or communicated with the champions and peer researchers. Realist interviews are theory-driven and will initially contain exploratory questions to try to ascertain how the programme works for whom and in what circumstances. However, as the evaluator becomes more knowledgeable about the programme, the interview questions will evolve and become less standardised and more tailored to refine specific context-mechanism-outcome (CMO) configurations (Greenhalgh et al., 2017). Documentary analysis will also be conducted of documents relevant to the CPAR programmes.

Sampling for realist interviews is theory-based, therefore, respondents are selected for the perspective and insight they may have about how and why the programme may (or may not) work (Manzano, 2016). It is important to obtain the perspective of different stakeholder groups such as the 'subjects' and 'practitioners', as a variety of perspectives are needed to investigate informal patterns and

unintended outcomes (Manzano, 2016). Practitioners (e.g. public health team, voluntary community organisation staff) are seen as having specific ideas on what is within the programme that works (mechanisms) as they are more likely to have a broad experience of successes and failures, and some awareness of people and places for whom and in which the programme works. Frontline practitioners (COVID-19 Champions, Vaccine Champions, CPAR researchers etc.) are good sources of information about the programme barriers and unintended consequences (Manzano, 2016). Different practitioners will have different experiences, and therefore have experiences relevant to different aspects of programme theory. On the other hand, subjects of the programme (i.e. target population of the Champion programmes) are more likely to be sensitised about outcomes and are likely to be experts on how some of the programme mechanisms may have influenced some of their outcomes (Pawson & Tilley, 1997).

Data collection

Realist interviews

A template for a realist interview schedule has been developed by members of the Realist And Meta-narrative Evidence Syntheses II Project (RAMESES) (Westhorp & Manzano, 2017). The RAMESES project are currently the leading methodological group of realist synthesis and evaluations (Gilmore et al., 2019) funded by the National Institute of Health and Care Research's Health Services and Delivery Research and are aimed at producing quality and publication standards as well as training materials for realist research approaches. The realist schedule will be tailored to each stakeholder group (e.g., programme managers, champions, and members of the pubic). Realist interviews are theory-driven, meaning that theory is used explicitly and systematically throughout the interview process. Whilst realist interviews are qualitative in nature, their purpose is different to other types of interviews, for example, constructivist interviews where the aim is to elicit and understand the respondent's world view and experiences (Manzano, 2016). Realist interviews investigate propositions about how, where, when and why programmes are and are not successful, by capturing the participants' stories about the programme (Manzano, 2016). These experiences illuminate the varying process (mechanisms and contexts) and manifold outcomes of the programme. To do this, the interviewer relates with interviewees in a distinctive process called the 'learner-teacher' cycle (Pawson & Tilley, 1997). The interviews will explore stakeholders' accounts of the purpose and key aspects of the Champion and CPAR programmes, their implementation, how the programmes were expected to work, barriers and its anticipated impact on practice. Interviews will be conducted either face-to-face and recorded via a Dictaphone or virtually and recorded via Microsoft Teams or Zoom. Transcriptions of interviews will exclude identifiable information of participants during the process of transcription.

Photo submissions

Alongside eliciting information on important outcomes from a range of stakeholders, members of the public who have engaged with a champion or community researcher, will be invited to submit a photo representing their experience and/or any benefit they might have gained from involvement. We will ask for a commentary alongside the photo explaining the context and how/why it depicts their experience. These photos will be submitted using a secure link and informed consent will be sought for any photos showing faces and/or other personal information (e.g., homes/locations).

Document analysis

Analysis of relevant programme documents will be carried out as a means of triangulation which Denzin and Lincoln (Denzin & Lincoln, 2000) defined as the combination of methodologies in the study of the same phenomenon. The process of document analysis will involve reviewing programme documents such as evaluations, reports, audits, service descriptions, and any routinely collected service activity data. These documents will be accessed via the organisations and will be 'summary level' data, therefore will not be identifiable to any individual.

Costing Analysis
Data will be collected from service documents/records (e.g., budget allocations) and meetings with programme managers from each service/programme. It is planned that for each service there may be up to two meetings with managers: the first will provide general context, budget and general service information; if needed, the second will allow confirmation around information and assumptions, opportunity to sense check findings and collection of any final information. Additionally, there will be some focused questions included within the realist interviews, particularly for understanding the (health economic) resources and impact of the programmes on staff and service users.

Size of sample
The sample size of participants will be determined by the need to capture variation in process, context and outcomes of implementation at organisational, and practice levels (Cheyne et al., 2013), and to ensure that theoretical saturation is reached (i.e. no new explanation for outcomes emerge). Qualitative enquiry usually advocates for a small number of interviews and common practice situates the acceptable number of interviews between 20 and 30 (Mason, 2010). However, this is not necessarily applicable to realist evaluation studies because programme theories are not confirmed or abandoned through saturation obtained in a double-figure number of qualitative interviews (Pawson, 2013). Saturation is met where consistent patterns are emerging in the data analysis process from the interviews and service documents (e.g. the programme theory under investigation meets no new challenges) (Procter et al., 2010). Moreover, due to the iteration of the realist evaluation, it is possible that additional stakeholders and/or different characteristics of the stakeholder groups (i.e. Covid Champions or Vaccine champions) might be identified that will be relevant to the aims of this study. Therefore, there will be flexibility in the sample size with respect to the number of each stakeholder group interviewed to ensure that a spread of characteristics is captured, and that saturation is reached. Additionally, members from the RAMESES II Project highlighted the difficulty in establishing a definite number of interviews with reasons being that evaluators become more knowledgeable of programme successes and barriers after conversing with staff and stakeholders (Greenhalgh et al., 2017). This would lead to a more definite interview sample being identified as the project evolves (Greenhalgh et al., 2017).

Recruitment
Southampton Voluntary Services were commissioned to coordinate the CPAR programme and, have charitable partners who work directly with and in the communities of interest. The Young Foundation were commissioned to recruit and train peer researchers for the CPAR work. Therefore, contact will be made with Southampton Voluntary Services and the Young Foundation to obtain contact details of key charitable partners. Information about this study will be provided for dissemination into local communities. Attempts will be made to recruit staff and individuals from the local authority, as well as Champions and community researchers via standard channels of communication with these individuals. It is anticipated that the champions will assist in the recruitment of individuals and organisations who they have communicated with as part of their programme activities e.g. via Whatsapp and Facebook. Innovative methods will be developed to reach people locally who might not have had direct contact with the CPAR or champion programmes. This could include contacting the local radio station to broadcast the research on their channel or by advertising the study through newspaper advertising and other local media.

Attempts will be made to reach individuals who dropped out of the CPAR/Champion programmes via contact with Southampton Voluntary Services and the Young Foundation and the charities that they are working with, as well as the Vaccine/Covid Champions and staff managing and supporting the programmes.

Data analysis

In adherence to the realist methodology (Manzano, 2016), the data analysis process will utilise a retroductive approach, supported by both inductive and deductive analytical processes to multiple data sources (e.g. interview transcripts and programme documents), while also incorporating the researchers' own understanding to uncover generative causation. The process will require the researchers to move back and forth between the initial programme theories and the data, to identify elements of contexts and mechanisms that explain the outcomes (Bergeron & Gaboury, 2019), and to refine the initial programme theories according to the CMO configurations and newly identified patterns. Data analysis will commence during the data collection phase of the research, thereby following an iterative approach whereby the developing programme theories are deliberated, discussed with the research team and refined through subsequent interviews. Initial themes that are identified from the interviews and specific areas warranting additional investigation will be explored in further interviews.

It is anticipated that the qualitative interviews with participants will be the main sources for CMO configuration coding and therefore the primary source of testing and refining the programme theories as they are likely to be the only data source that contain extractable CMO configuration in their entirety. Interview transcripts will be used as the starting point and then the researcher will move on to programme documents and photo submissions to triangulate and inform the testing and revision of the theories by identifying information that will support/refute/refine the CMO configurations.

The analysis and synthesis of data will follow guidance by Gilmore et al. (Gilmore et al., 2019) which allows for a transparent and rigorous analysis process to be conducted. A realist logic of analysis which employs COM configurations (Wong et al., 2016) will be used to build and refine the programme theories. NVivo, a type of computer-assisted qualitative data analysis software will be used for coding the interview transcripts. This software supports *''code-based inquiry, searching and theorising combined with ability to annotate and edit documents''* (Richards, 1999) (p.142). RAMESES II guidelines (Wong et al., 2016) highlight that every realist evaluation presents itself differently, therefore there is no standardised use of NVivo and this requires flexibility and should be tailored to the specific programme and focus of the research (Dalkin et al., 2020).

Coding of the transcripts will involve extracting information on contexts, mechanisms and outcomes from sections of the text that provide supporting evidence. The champion and CPAR programme documents will be reviewed to identify information that would help to support/refute/refine the CMO configurations. Using NVivo, the researcher will index and link relevant explanatory accounts to identify inter-relationships and overlaps before further development. The step-by-step process (see below) will be followed across all cases:

1) Data from interview transcripts and programme documents will be entered into NVivo as an individual 'source'
2) Separate folders will be created in NVivo to differentiate the stakeholder groups e.g. Interview transcripts of: COVID-19 Champions, Vaccine Champions etc.
3) A 'node' is created for each initial programme theory (identified in phase 1).
4) A 'child node' is created to represent any revision of the initial programme theory as a result of the data from the literature or interview. Hence, any coding to the revised theory will occur under the new child node.
5) Each source is reviewed and if CMO components can be extracted from the data, a memo is created and linked to the relevant node (and any new child node) in order to record the decision-making process and rationale for refinement of the theory.

6) In circumstances where the interview text produces more than one CMO configuration, this will be written individually and labelled as 'CMO 1', 'CMO 2' etc.

Health economic data analysis
Required analysis will depend on the data collected. Primarily, we expect the analysis to be descriptive, likely utilising tables to compare across programmes. Where suitable quantitative data can be collected, it will be summarised (if needed) using descriptive statistics. Where (health economic) resources (e.g., staff time) need to be costed, we will draw on costs from the appropriate programme and standard sources (e.g., Jones & Burns, 2021) as needed, using the latest cost year for which data is available. We expect the primary costing perspective to be that of the individual services.

Phase 3: Programme theory specification
This phase involves interpreting and synthesising the findings from the data analysis in phase 2. The aim of this phase is to collate all refined programme theories and review these in order to identify demi-regularities; as well as to translate the demi-regularities and programme theories in order to identify middle-range theories. These middle-range theories will help to articulate theoretically robust and empirically tested model of complex relations between the contexts, mechanisms and outcomes of the CPAR and Champion programmes.

The process to synthesising the findings will be conducted manually, instead of continuing the synthesis within NVivo (Gilmore et al., 2019). A search for demi-regularities (outcome patterns/patterns of regularity) will be conducted across the case study findings following the steps below:

1) All refined programme theories and CMO configurations from all cases are combined and inputted onto a blank Microsoft Word document.
2) Commonalities within the combined programme theories and CMO configurations are searched for and recorded.
3) Demi-regularities within the grouped programme theories and CMO configurations are identified.
4) When demi-regularities are identified, all CMO configurations are reviewed to identify any additional explanatory information.

Once complete, the resulting demi-regularities identified are used to identify relevant abstract theories that reported on related causal chains or moderating factors which Marchal, et al. (Marchal et al., 2010) described as a 'plausibility check'. This also helped to expand the explanatory mechanisms.

4.3 Co-production and PPI

4.3.1 Co-production
Co-production is a central tenet of the PHIRST initiative and all PHIRST Connect evaluations. This evaluation will be co-produced by the PHIRST Connect team with local partners and stakeholders, all working together to plan, design, deliver, and disseminate the evaluation. We will routinely communicate and consult with these partner organisations and stakeholders, and in addition present proposals and updates to our Independent Core Advisory Board (composed of relevant stakeholders in the field of public health and evaluations, which includes academics, third sector, governmental and public expertise) and our CoPACT specific Advisory Group (similarly composed of key stakeholders but with membership more closely reflecting the subject and area of the evaluation). The feedback they provide will shape key decisions within the research process including design, ethics and dissemination. Further details on our PHIRST advisory and consultative groups can be found in section 6.2 below.

4.3.2 Patient and public involvement and engagement (PPIE)

The University of Hertfordshire is committed to involving the public in all stages of its research and has an existing Public Involvement in Research group (PIRg) comprised of members of the public, service users and carers. PPIE (patient and public involvement and engagement) is key to the PHIRST Connect and will be integral at all stages. All PPI activities will be co-ordinated by the PPI co-investigator (Amander Wellings), the academic PPI co-investigator Professor Julia Jones and members of the PHIRST team.

The PHIRST Connect Public Involvement in Research Group (PIRg) provide public, service user and carer perspectives to all the public health evaluation projects conducted by the team. The eleven members of the PIRg meet monthly to discuss key aspects of PHIRST Connect evaluation work (for example, research questions, methodology, literature review, research tools, and dissemination), and in between meetings, work closely with the PHIRST to co-produce our evaluations.

For this evaluation, PPIE will be embedded through both the PHIRST Connect PIRg's input and wider lay and public contributors recruited to a project specific 'Public Voice' group. Three members of our PIRg have been supporting project development since the evaluability phase of our work, attending project meetings and commenting on ideas and proposals. We are currently in the process of recruiting local people and people interested in these types of programmes through the 'People in Research' website (https://www.peopleinresearch.org/) to continue to support the development, delivery, analysis and knowledge mobilisation on the project. Timings of planned meetings with the Public Voice group are included in the project Gantt in section 10 below.

4.4 Dissemination

Recommendations will be generated by the research team, through consultation with the project steering group, CoPACT Advisory Group, the PIRg, and CoPACT Public Voice group. Recommendations will be further developed with key stakeholders, including those who have accessed the programmes. This will help to ensure that the recommendations for future optimisation of CPAR and champion programmes generated by the evaluation are appropriate and feasible, fit within wider transformation plans, and that a range of stakeholders are involved in their co-production.

In terms of dissemination, the research team will consider the value of findings to the wider public health system and its stakeholders and how outputs can be effectively communicated and mobilised to other regions and sectors. Dissemination will likely occur through several key routes, including the following options:

- Recorded presentation and accompanying set of PowerPoint slides or alternative format as agreed with the local authority and their partners
- Bitesize briefing that focuses on key findings and messages and recommendations
- PHIRST website, jointly managed by the six PHIRST teams
- Creative outputs such as video and interactive content, including a video lay summary
- Social media channels
- Traditional academic routes of conference presentations and peer-reviewed, open access journal articles
- Dissemination through professional networks of which our project-specific Advisory Group are members

All outputs will be informed by consultation with the PIRg, Co-PACT Public Voice group, and the project Advisory group.

5 Research governance and project management

5.1 PHIRST Connect governance and project management

Appendix B presents an organogram of the PHIRST Connect showing the team structure and roles.

Project Leads

The project is being led by the PHIRST co-investigator, Dr Neil Howlett, under the direction and supervision of the PHIRST Chief Investigator, Professor Katherine Brown.

Management Group

The PHIRST Connect Management Group meets on a weekly basis to provide oversight and guidance to the PHIRST Connect. The Management Group comprises the Chief Investigators and the eight PHIRST Co-applicants listed in section 1.5.

5.2 PHIRST advisory groups

PHIRST Connect Independent Advisory Board

An Independent Advisory Board (PHIRST Connect Independent Advisory Board) has been convened to provide independent, external and policy-orientated advice to the PHIRST Connect. The Board provides specific advice and support in relation to the strategic direction of the PHIRST Connect and its allocated projects. It comments on the ongoing work plan and progress in line with study protocols, acts as a sounding board for new ideas and developments and advises on opportunities for wider dissemination and for translating research into policy and practice. It is an advisory only body and does not make decisions, or report to any other group or committee.

The Board will meet up to three times per year and is comprised of experts in the fields of public health and evaluation from academic, third sector, governmental and public sector backgrounds. It is comprised of the following members:

Name	Job title	Organisation
Mrs Helen King (Chair)	Former Deputy Director and Director of Public Health / currently Independent Public Health Consultant	Solihull Public Health Department
Dr Nicola Armstrong	Programme Manager, HSC & R&D Division	Northern Ireland Public Health Agency
Professor Katherine Brown	Professor of Behaviour Change in Health	University of Hertfordshire (non-independent)
Mr Geoff Brown	CEO	Healthwatch Hertfordshire
Dr Tim Chadborn	Head of Behavioural Insights and Evaluation Lead	Office for Health Improvement & Disparities
Dr Suzanne Connolly	Senior Health Improvement Manager	Public Health Scotland
Professor Steve Cummins	Co-Director of the Population Health Innovation Lab	The London School of Hygiene and Tropical Medicine

Dr Sarah Hotham	Senior Research Fellow & NIHR RDS SE Research Adviser	University of Kent
Professor Margaret Maxwell	Director of MHANP Research Unit	University of Stirling
Mrs Marion Cowe	PPI Expert by Experience on PHIRST Connect Public Involvement In Research Group (PIRg)	Independent Member
Professor Toby Prevost	Director, Nightingale-Saunders Clinical Trials & Epidemiology Unit at King's CTU	Kings College London
Mrs Genevieve Riley	Programme Manager	West of England Academic Health Science Network
Professor Sarah Stewart-Brown	Professor of Public Health	University of Warwick
Dr Ruth Tennant	Director of Public Health	Solihull Metropolitan Borough Council
Mrs Amander Wellings	PPI Expert by Experience; Chair of PHIRST Connect PIRg	University of Hertfordshire (non-independent)

PHIRST Connect Co-PACT Evaluation Advisory Group

A project-specific Advisory Group has been convened to offer specific advice and support in relation to the Co-PACT evaluation. The Advisory Group will meet up to six times per year for the duration of the Co-PACT evaluation.

Name	Job title	Organisation
Ms Anne Bowers	Strategic Community Engagement Lead (Group Chair)	Newham Council
Ms Pawan Kaur Lall	BAME Population and Workforce manager	Solent NHS Trust
Dr Wendy Lawrence	Associate Professor of Health Psychology	University of Southampton
Dr Jo Mackenzie	Evaluation lead	Hertfordshire County Council
Mr Jason Murphy	Stronger Communities Manager	Southampton City Council
Mr Paul Ogden	Senior Adviser	Local Government Association
Professor Julie Parkes	Professor in Public Health	NIHR Wessex ARC
Dr Robin Poole	Consultant in Public Health	Southampton City Council
Dr Melanie Handley	Senior Research Fellow with expertise in Realist Evaluation	University of Hertfordshire

6 Ethical considerations and approvals

Whilst an ethical framework guides the work of the PHIRST, ethical considerations for this project particularly relate to the interviews being conducted in Phase 2 and the following sections therefore largely relate to these elements of the study.

This project approaches ethics as an ongoing reflexive exercise relevant to all aspects of data collection, analysis and publication. While the below provides a description of the ethical issues identified, it is possible that unexpected ethical issues will arise in the course of the research. The research team will monitor and document ethical concerns arising during the research which will be captured in the study's issue log. When necessary, these will be discussed with partner organisations (in accordance with provisions of confidentiality). PPI input will be sought in any discussion about ethical matters at all stages of research, both routinely, as and when different forms and data collection instruments are developed, as well as when particular issues arise.

6.1 Informed Consent and withdrawal

All participants will be aged 18 years or older. All potential participants will be provided with detailed Participant Information, which will convey comprehensive information about the project to allow them to provide informed consent. They will be requested to record this consent in an electronic format within REDCap prior to the interview date. Participants will be informed about their right to withdraw from the study at any time. For the photo capture there will an additional section that asks participants to opt in to consent for their photos to be used in a range of dissemination formats such as presentations, teaching materials, or a study website.

Participant information will be written in a style of language that is accessible to participants. To ensure this, we will seek input/review from our PIRg. A dedicated telephone number and email address (phirst@herts.ac.uk) has been set up for participants to contact the research team with queries.

6.2 Data protection

All data will be stored and processed in line with GDPR and our Data Protection Impact Assessment (DPIA). Data will be stored on our project-specific drive (on UH server) and only accessible to those within the research team who require this. The secure drive will be used to store, details of those interested in participating in interviews, audio recordings and transcripts of interviews. Also see section 8 below (data protection and management).

6.3 Confidentiality

This project will maintain full participant confidentiality (although see limits to confidentiality in next section). Participants' contributions to the research will not be shared with service providers or their organisations and will be anonymized in publications.

6.4 Risks, safeguarding and referrals

It is not expected that the nature of the project will give rise to safeguarding concerns beyond those of any other project. A PHIRST safeguarding protocol has been developed which will be used to guide decision-making/actions as and when necessary. A copy of the safeguarding protocol is available on request from the Chief Investigators. The team is also familiar with the new University of Hertfordshire, School of Life and Medical Sciences safeguarding policy, which will be adhered to.

6.5 Potential benefits for study participants

This project focuses on evaluating champion programmes and community action participatory

research and will provide recommendations for how these approaches should be delivered in the future. It is possible that organisations modify their service delivery based on the findings of this project. Thus, this is a rare opportunity for participants to see the effects of their participation in action. Participants will be informed that a report and video summary will be produced and disseminated that will contain recommendations.

6.6 Approvals

Ethical approval for this project has been granted by the University of Hertfordshire Health, Science, Engineering & Technology ECDA (protocol number: LMS/SF/UH/05067).

7 Data protection and management

The PHIRST is an NIHR funded initiative, and the University of Hertfordshire is leading a consortium involving Ulster University, the University of Birmingham and the University of East Anglia. Staff at the University of Hertfordshire will take full responsibility for organising data collection and the safe management and storage of data.

This study has been assessed using the University of Hertfordshire Data Protection Impact Assessment (DPIA) checklist. The checklist was sent to the Data Protection Officer, and it has been agreed that this study does not require a full DPIA. Any changes to the methodology will require a reassessment of the project against the checklist and a re-notification of the Data Protection Officer. A copy of the current DPIA checklist assessment is available on request from the Chief Investigators.

8 Project timescales/GANTT chart

Activity	Apr 22	May 22	June 22	July 22	Aug 22	Sept 22	Oct 22	Nov 22	Dec 22	Jan 23	Feb 23	Mar 23	Apr 23
DPIA and DSA production if required													
Protocol production													
Ethics application													
Project meetings													
Advisory group meetings													
Public Voice consultation													
Phase 1: Data source gathering and Initial programme theories development													
Phase 2: Recruitment of stakeholders													
Phase 2: Semi-structured interviews and document analysis													
Phase 3: Synthesis and interpretation													
Reporting													
Dissemination													

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Appendix A: **PHIRST Connect team organogram**