Common Health Assets Protocol v 1.1

This protocol has regard for the HRA guidance and order of content

FULL/LONG TITLE OF THE STUDY

Common Health Assets: a mixed-methods, realist evaluation and economic appraisal of how community-led organisations (CLOs) impact on the health and wellbeing of people living in deprived areas

SHORT STUDY TITLE / ACRONYM

Common Health Assets: an evaluation of the health and wellbeing impacts of community-led organisations

PROTOCOL VERSION NUMBER AND DATE

Version 1.2 31 01 23

RESEARCH REFERENCE NUMBERS

IRAS Number:	n/a
SPONSORS Number:	RIO 19-200
FUNDERS Number:	PHR NIHR 129118

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

For and on behalf of the Study Sponsor:

Signature: .... Date: ....../....../......

Name (please print): ....

Position: ....

Chief Investigator:

Signature: .... Date: ....../....../......

Name: (please print): ....

LIST of CONTENTS

KEY STUDY CONTACTS

Insert full details of the key study contacts including the following

Chief Investigator	Rachel Baker PhD Professor of Health Economics and Director Yunus Centre for Social Business and Health Glasgow Caledonian University rachel.baker@gcu.ac.uk tel: 0141 331 8246
Project Administrator	Margaret Munro Senior Centre Administrator Yunus Centre for Social Business and Health Glasgow Caledonian University Margaret.munro@gcu.ac.uk Tel: 0141 331 3234
Sponsor	Professor Kay Currie Associate Dean of Research, School of Health and Life Sciences Glasgow Caledonian University k.currie@gcu.ac.uk tel: 0141 331 3472
Joint-sponsor(s)/co-sponsor(s)	n/a
Funder(s)	National Institute for Health Research Public Health Committee
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Committees	Study Steering Committee (SSC) (contact via project administrator as above)

STUDY SUMMARY

Study Title	Common Health Assets: a mixed-methods, realist evaluation and economic appraisal of how community-led organisations (CLOs) impact on the health and wellbeing of people living in deprived areas
Internal ref. no. (or short title)	Common Health Assets
Study Design	Mixed-methods, realist evaluation and economic appraisal
Study Participants	Approximately: 15 community-led organisations through which: 40-60 stakeholder interviewees 30-40 photovoice community participants 30-40 stakeholder workshop participants 225 questionnaire respondents 45-60 community interviewees 45-60 Q sort participants
Planned Size of Sample (if applicable)	As above
Follow up duration (if applicable)	Questionnaire respondents followed up at 1, 6 and 12 months
Planned Study Period	36 months
Research Question/Aim(s)	Research Questions 1. Do CLOs impact on health and wellbeing, by what mechanisms and in what contexts are outcomes achieved? 2. Which approaches are scalable, and which are specific, local solutions? 3. What are the key issues for sustainability of CLOs?

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**
Prof Sam Porter, Professor & Head of Department - Social Work & Social Sciences, Bournemouth University, Fern Barrow, Poole, Dorset, BH12 5BB porters@bournemouth.ac.uk	Full time, 3 year PhD scholarship. Includes stipend, fees and overheads. Topic: Setting the assets-based agenda: a critical realist exploration
Dr Karen Galway, School of Nursing and Midwifery, Faculty of Medicine and Life Sciences, Queen's University Belfast. 97 Lisburn Road, Belfast BT7IBU Email: k.galway@qub.ac.uk Telephone: +44 28 9097 2461	Full time, 3 year PhD scholarship. Includes stipend, fees and overheads. Topic: social prescribing referral routes to community led organisations.
Prof Helen Mason Yunus Centre for Social Business and Health, Glasgow Caledonian University, Cowcaddens Road, Glasgow, G4 0BA contact: helen.mason@gcu.ac.uk	Full time 3 year PhD scholarship. Includes stipend, fees and overheads. Topic: Developing realist focussed economic evaluation: theory and method

ROLE OF STUDY SPONSOR AND FUNDER

The study sponsor is Glasgow Caledonian University. The sponsor has no role in the design, conduct or reporting of the study.

As study funder NIHR are responsible for monitoring progress against key milestones, reviewing progress reports (6 monthly) and for approving the Study Steering Committee (SSC) composition.

The final report will be produced to the NIHR template and peer reviewed through NIHR processes before sign off. Once approved, NIHR will publish the final report as part of the NIHR Journal Library in Public Health Research.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Project Management Team (PMT)

The project will be coordinated by the Project Management Team (PMT). The PMT will consist of the chief investigator and co-applicants from GCU, BU, QUB, UEL, community partners, project administrator and researchers appointed to the project at the four sites.

The role of the PMT is to plan and monitor all aspects of the conduct and progress of the study, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the study itself. The PMT will report to the Study Steering Committee and seek advice from the SSC as required.

The role of the PMT is to oversee the day to day management of the project including:

- Project planning and start up tasks, agreeing timelines and deliverables
- Managing budgets and administration of the project
- Reporting to NIHR and SSC
- The recruitment, training and support of research staff
- The recruitment and relationships with research partners (CLOs) and participants (stakeholders and CLO staff, volunteers and participants)
- The monitoring of progress against project deliverables and milestones (per study objectives and project Gantt chart)
- The generation, storage, access to, and analysis of data in accordance with ethical good practice and data protection regulations
- Identification of risks and other issues affecting the project and development of strategies to mitigate these in timely fashion
- Involvement of community partners and Lived Experience Panel (LEP) in planning, design, implementation of research methods and interpretation of study findings
- Production of briefing papers and blogs, social media presence, stakeholder events and videos (digital stories) during the life of the project
- Timely publication and dissemination of study findings according to publication policy
- Support and career development for early career researchers

Membership of the Project Management Team

Name	Organisation	Role
Rachel Baker	GCU	PI
Mike Kelly	Cam	Co- PI
Margaret Munro	GCU	Project Administrator
John Cassidy	SCHW	Co-I
Sam Porter	BU	Co-I
Karen Galway	QUB	Co-I
Marcello Bertotti	UEL	Co-I
Pete Seaman	GCPH	Co-I
Researchers x 4	GCU BU QUB UEL	RA

Study Steering Committee (SSC)

The role of the SSC is to provide overall supervision of the study and ensure that it is being conducted in accordance to the rigorous standards set out in the Department of Health's Research Governance Framework. The SSC will:

- Agree the study protocol and substantial protocol amendments
- Provide advice to the investigators on all aspects of the study
- Include an independent chairperson, at least 2 other independent members
- Include a representative of the LEP
- Meet at least once per annum
- Receive quarterly updates from the Research team.

The SSC will advise the sponsor and study team with respect to decisions about continuation or termination of the study or substantial amendments to the protocol. The SSC will meet at the start of the study, and annually or as required thereafter. The SSC will have its own terms of reference outlining the role and responsibilities of its members. The SSC may invite other attendees from the study team to present or participate in discussions on particular topics. These attendees will be non-voting members.

Lived Experience Panel (LE Panel)

Throughout data collection, analysis, and interpretation, there will be engagement with community participants and stakeholders, both as members of the research team and SSC, as co-applicants and collaborators, and through our Lived Experience Panel. This Panel will inform the design, conduct and interpretation of research through participation in project management and governance and through specific activities at key points in the study development, conduct and findings as outlined in the PPI sections of this form. A key focus will be to confirm, refute and refine the programme theory as it develops. As part of these activities community participants and stakeholders will participate in the generation of research materials and will have key roles in shaping the research as it develops and how the findings are translated and communicated. The LEP will feed into the PMT through Dr Pete Seaman.

PROTOCOL CONTRIBUTORS

The funder and sponsor have not been directly involved in the study design and will not be directly involved in study delivery. The funder will approve the protocol before the project starts.

Community organisations have been involved in the development of the protocol through community Co-Is and collaborators.

KEY WORDS:

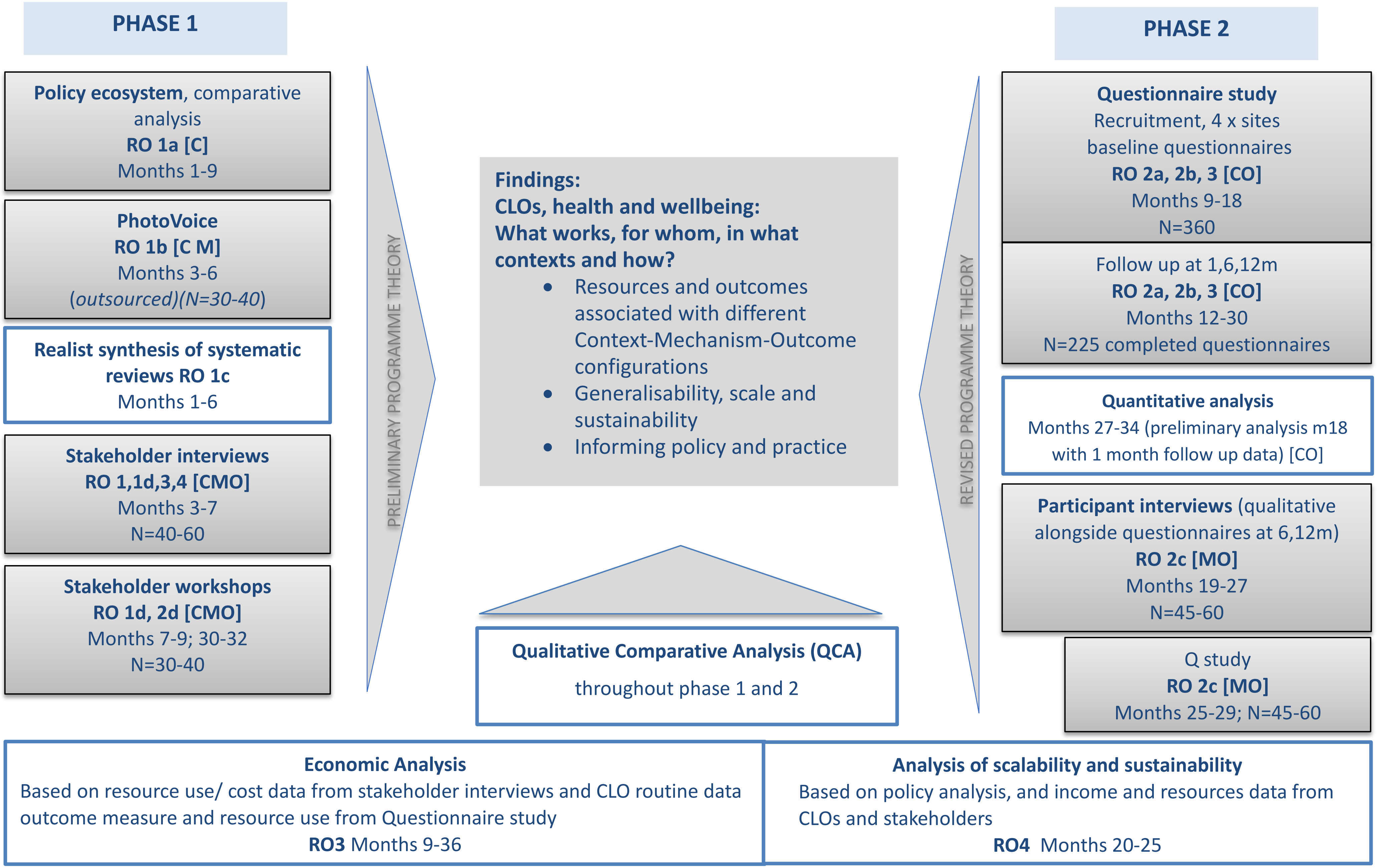
VCSE (Voluntary, Community and Social Enterprise)
Health and Wellbeing
Realist evaluation
Economic evaluation
Assets based approaches
Social determinants of health

STUDY FLOW CHART

Figure 1 below is a study diagram presenting an overview of the study.

A Gantt Chart follows in Figure 2 setting out the key tasks and milestones and their timing.

FIGURE 1 Study diagram: Common Health Assets – methodological components, objectives, timelines and sample size



PHASE 1

Policy ecosystem, comparative analysis
RO 1a [C]
Months 1-9

PhotoVoice
RO 1b [C M]
Months 3-6
(*outsourced*)(*N=30-40*)

Realist synthesis of systematic reviews RO 1c
Months 1-6

Stakeholder interviews
RO 1,1d,3,4 [CMO]
Months 3-7
N=40-60

Stakeholder workshops
RO 1d, 2d [CMO]
Months 7-9; 30-32
N=30-40

Findings:
CLOs, health and wellbeing:
What works, for whom, in what contexts and how?

- Resources and outcomes associated with different Context-Mechanism-Outcome configurations
- Generalisability, scale and sustainability
- Informing policy and practice

Qualitative Comparative Analysis (QCA)
throughout phase 1 and 2

PHASE 2

Questionnaire study
Recruitment, 4 x sites
baseline questionnaires
RO 2a, 2b, 3 [CO]
Months 9-18
N=360

Follow up at 1,6,12m
RO 2a, 2b, 3 [CO]
Months 12-30
N=225 completed questionnaires

Quantitative analysis
Months 27-34 (preliminary analysis m18 with 1 month follow up data) [CO]

Participant interviews (qualitative alongside questionnaires at 6,12m)
RO 2c [MO]
Months 19-27
N=45-60

Q study
RO 2c [MO]
Months 25-29; N=45-60

Economic Analysis
Based on resource use/ cost data from stakeholder interviews and CLO routine data outcome measure and resource use from Questionnaire study
RO3 Months 9-36

Analysis of scalability and sustainability
Based on policy analysis, and income and resources data from CLOs and stakeholders
RO4 Months 20-25

RO = Research Objectives; C=Context, M=Mechanism, O=Outcome; Grey-shaded boxes are data collection methods, contributing to different combinations of C, M and O; Unshaded boxes represent analysis to identify robust patterns in qualitative and quantitative data; Months refer to study months; Follow up months refer to data collection points, N refers to sample size

Figure 2 Gantt Chart: project timetable, research tasks, milestones and researcher workload

Research Objectives	CMO Objectives	Key tasks: n=per site/ each researcher (total x 4 sites)	Months 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
		PHASE 1																																				
		Ethics approvals *month -3 to t=0*																																				
		Research staff recruitment x 4 *months -4 to t=0*																																				
	C M O	Realist synthesis of systematic reviews	▨	▨	▨	▨	▨	▨																														
1a	CM	**Policy ecosystem**: document analysis	▨	▨	▨	▨	▨	▨	▨	▨	▨‖																											
		Establish Lived Experience Panel ~meets			▨ ~ ‖			~			~								~									~						~				
1b	CM	**PhotoVoice** n=8-10 (n=32-40)			▨	▨	▨	▨‖																														
1a 3 4	C M O	**Stakeholder interviews** n=8 (n-32)			▨	▨	▨	▨	▨																													
1c	C M O	**Stakeholder workshops** n=10 x 4 areas Derive initial programme theory/ revise, refine prog theory							▨	▨	▨‖																					▨	▨	▨‖				
		PHASE 2																																				
		Work with CLOs to set up recruitment systems in each site n=2-3 (8-12)			▨	▨	▨	▨‖																														
2a	C O	**Questionnaire study** Recruit baseline 10 per month x 4 RAs (n=360) (*monthly recruits labeled a-i*)									10a	10b	10c	10d	10e	10f	10g	10h	10i‖															90 per RA			N = 360	
2a	C O	1 month follow up (in person, phone or online, assume 20% attrition)										8a	8b	8c	8d	8e	8f	8g	8h	8i														72 per RA			N = 288	
2a	C O	6 month follow up (in person, phone or online 30% cumulative attrition)															7a	7b	7c	7d	7e	7f	7g	7h	7i									63 per RA			N = 252	
2a	C O	12 month follow up (in person, phone or online 35% total attrition)																					6a	7b	6c	7d	6e	7f	6g	7h	6i‖			58 per RA			N = 232	
	C O	**Preliminary analysis** of 1 month data to identify C O patterns and candidates for qualitative interviews														▨	▨	▨																				
2c	M O	**Qualitative interviews** with selected questionnaire participants n=15 (60)																					▨	▨	▨	▨	▨‖											
2c	M O	**Q sorts** with participants n=15 (60)																									▨	▨	▨	▨	▨‖							
3	C M O	**Quantitative and economics analysis**																								▨	▨	▨	▨	▨	▨	▨	▨‖					
4		**Analysis of sustainability/ scalability**																				▨	▨	▨	▨	▨	▨‖											
		Meetings team=O, steering group=*	O			O			O		*	O			O			O		*	O			O			O			O			O		*	O		

Key: shading indicates researcher workload; **10a** = 10 questionnaire recruits <month ‘a’ cohort>, followed up allowing for attrition at 1 month = 8a; **double line** represents key milestones

STUDY PROTOCOL

Common Health Assets: a mixed-methods, realist evaluation and economic appraisal of how community led organisations (CLOs) impact on the health and wellbeing of people living in deprived areas

1 BACKGROUND

Asset-based approaches bring people in communities together to achieve positive change using their own knowledge, skills and experience. The premise is that sustained positive health and social outcomes may occur when people and communities have opportunities and facilities to manage their own futures (1). In the words of this commissioning brief, asset-based approaches supposedly work to maximise the potential of people. Asset-based approaches are often mobilised via Community-Led Organisations (CLOs) in the VCSE (voluntary, community, and social enterprise) sector (2) where community groups work in partnership with other community organisations and networks, local government or health professionals. Such organisations have a critical role to play, not only in the delivery of health and social care but also in tackling health inequalities and underlying social determinants of health; for example reducing loneliness and isolation and increasing individual and community capacity for democratic participation (3).

When approaches are shown to work locally, issues of scale and sustainability are important for policy and practice. Indeed, effectiveness may not be connected with sustainability: our community research partners tell us that organisations might win awards for their impact but cease activity soon afterwards because of their dependence on competitive short-term funding.

Our recent systematic review (4) found that evidence in relation to community assets and health is scarce, largely presented in grey literature (5, 6) with a predominance of case studies. This is replicated by more general reviews of community development and health (7, 8) which have observed that experimental approaches and controlled trials are often impossible in a field where controlling ‘exposure’ is difficult and ‘interventions’ are complex. A systematic review of the evidence for social prescribing (which is linked to our subject, involving community organisations in improving health outcomes) found a lack of good evidence and mainly small-scale studies with short follow up periods and high risk of bias (9).

This research will generate new, theory-based knowledge on if and how **Community-Led Organisations (CLOs)** – place-based, community owned and governed organisations – improve health and wellbeing by linking the initiatives of CLOs (programme mechanisms) with the contexts in which they take place (contextual mechanisms), the experiences and responses of those involved (agency), and the outcomes that are generated to investigate what works, in what circumstances, for whom and over what duration. By distinguishing between programme mechanisms (PM), contextual mechanisms (CM), agency (A) and outcomes (O), and studying resource use and income streams, we will make recommendations about scalability and sustainability of CLOs as a means of maximising the potential of people as ‘health assets.’ Quantitative analysis and economic appraisal will examine the patterns of health outcomes across contexts and model the resource use and outcomes associated with different configurations.

2 RATIONALE

Community-led, asset-based approaches are part of a developing field of collaborative public health initiatives, but the evidence base is limited. This project will investigate the impact of community-led approaches on health and wellbeing in areas of deprivation and health inequalities, using a realist approach. This will be a powerful way to separate the rhetoric about community based approaches and how they are thought to work, from the real experiences of those involved allowing us to determine 'what works, for whom, and in what circumstances' (10).

Previous research in the voluntary, community and social enterprise (VCSE) sector provides a solid base for rigorous theory-based evaluation to explore the contexts and mechanisms through which community-led approaches lead to health and wellbeing improvements. This research is needed because policy attention on community approaches to health and wellbeing (11-14) has moved faster than the evidence base. Seldom are such interventions accompanied by rigorous, theory-based evaluation. The Common Health Assets study addresses this knowledge gap.

3 THEORETICAL FRAMEWORK

Common Health Assets brings together concepts from the empirical and theoretical literature and practice-based models. Figure 3 shows how these come together in an initial logic model with reference to Asset-based approaches (15) findings from the previous CommonHealth research programme (16-19), and practice-based models from Scottish Community Development Centre (SCDC) (20) and The Health Creation Alliance (HCA) (21). Figure 4 is an initial theory of change diagram showing possible pathways from 'intervention' to impact'.

4 RESEARCH QUESTION/AIM(S)

Research Questions

1. Do CLOs impact on health and wellbeing, by what mechanisms and in what contexts are outcomes achieved?
2. Which approaches are scalable, and which are specific, local solutions?
3. What are the key issues for sustainability of CLOs?

4.1 Objectives

RO1 To develop, with stakeholders, an initial realist programme theory, to explain 'what works, for whom in what circumstances and how' in relation to CLOs' impact on health and wellbeing and health inequalities

- RO1a. To develop a rich description of policy contexts in each country through documentary analysis and stakeholder interviews
- RO1b. To create a rich understanding of community contexts and what promotes and inhibits health in those communities from the perspective of community members, using PhotoVoice
- RO1c. To produce a realist synthesis of systematic (and other) review findings to provide tentative programme theories

RO1d. To develop an initial, co-produced programme theory in stakeholder workshops and with the lived experience panels

RO2 To test and refine the programme theory by locating existing data and generating mixed method evidence to identify context-mechanism-outcome configurations (CMOCs)

RO2a. To measure participant outcomes using

- ICECAP-A (ICEpop CAPability measure for adults) (primary outcome measure)
- Secondary outcome measures of health-related quality of life (EQ5D), mental wellbeing (WEMWBS), Satisfaction With Life Scale (SWLS), Sense of Coherence (SOC-13) and measures of social connectedness/ loneliness (UCLA/ONS)

RO2b. To identify patterns (regularities) in outcomes across contexts (e.g. differences in certain mechanisms and outcomes by geography, participant characteristics, CLO, type of activities)

RO2c. To explore qualitatively with participants and stakeholders the mechanisms that explain the patterns found in outcomes using participant interviews and Q sort methods

RO2d. To revise and refine programme theory and CMOCs through stakeholder workshops and lived experience panel

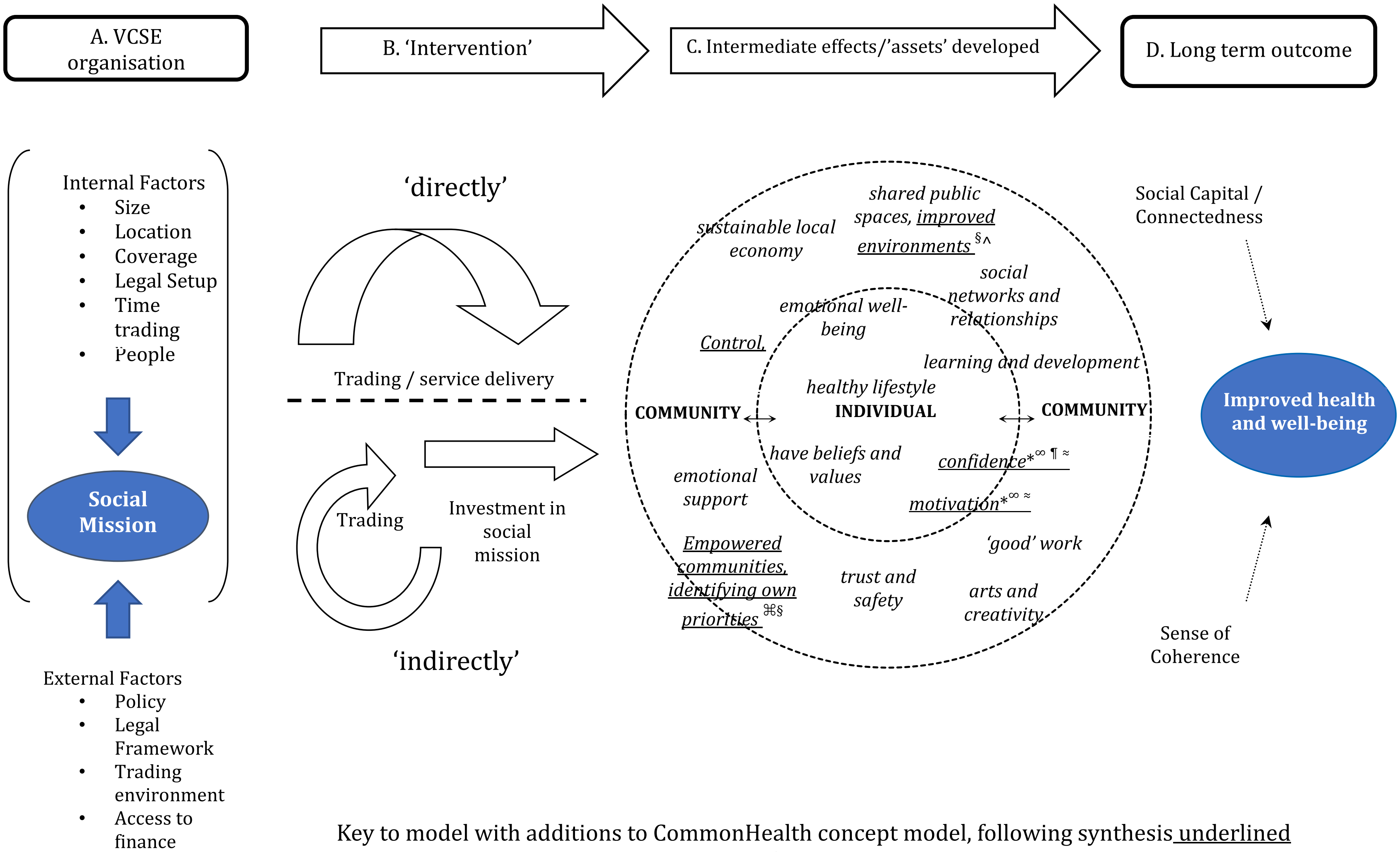
RO3 To estimate the resource use and outcomes associated with different CMOCs in an economic appraisal

RO4 To analyse CLO income streams and stakeholders' views on sustainability and scalability

4.2 Outcome

The outcome of this study will be transferable new knowledge based on robust mixed method research, that will enable CLOs, public health practitioners, academics and policy makers articulate the health and wellbeing impacts of community-led organisations, and the contexts and mechanisms through which these impacts are achieved. This will include consideration of which outcomes are scalable and sustainable and an understanding of the resources and outcomes associated with different contexts and mechanisms.

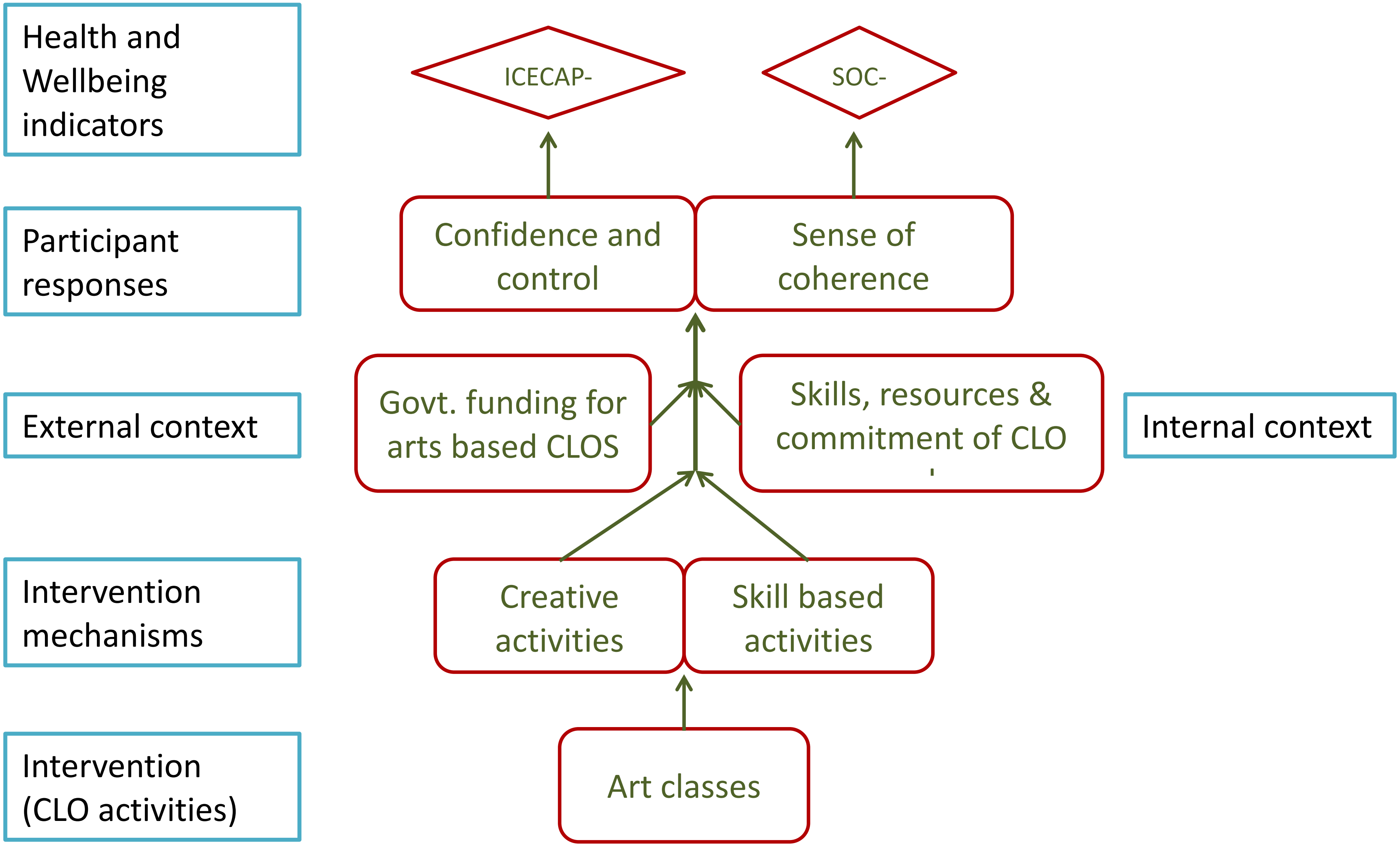
Figure 3 Logic Model – a synthesis of research and practice-based models



Key to model with additions to CommonHealth concept model, following synthesis underlined

- Calo et al (2018); ∞ Kelly et al (2019); § Macauley et al (2017); ≈ Roy et al (2017); ^Health Assets model (Morgan et al 2007, 2010) ¶ NNHSA model of health creation; ⌘ SCDC community led health model

Figure 4 Theory of Change example



5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

5.1 Project Overview

Common Health Assets is a mixed method realist evaluation and economic appraisal of costs and benefits, as depicted in the study diagram (figure 1) attached. Realist evaluation has been characterised by the question “what works, for whom, in what circumstances and how” (10). We will answer this question by identifying configurations of programme mechanisms, contextual mechanisms, agents’ responses, and outcomes (ref# 38 Porter 2015). In addition to gathering robust outcome data to evaluate the impact of CLOs on health and wellbeing, this evaluation is designed to identify the mechanisms embedded in CLOs’ activities and resources that shape this impact, and how the effects of these mechanisms’ are mediated by the context in which they are applied and by the responses of different stakeholders to them.

The study is set up in two overlapping phases summarised below, with detailed descriptions to follow.

Phase 1 (months 1-12, RO1) involves the building and refining programme theories. It begins with realist synthesis of existing systematic (and other) reviews to provide tentative programme theories. These will be tested, refined and augmented through realist interviews with practitioners, participants and other stakeholders, to generate a picture of how CLOs work in different contexts to trigger mechanisms and if and how they improve outcomes. Phase 1 includes four main components (see study diagram):

- Realist synthesis of existing reviews to provide tentative programme theories
- Comparative policy analysis to identify potential contextual mechanisms
- Stakeholder interviews and workshops to refine programme theory and gather data
- PhotoVoice, which is a creative, participatory method that will be used to capture community contexts, health assets and barriers to good health.

Phase 2 (months 9-36, RO2-4) focuses on testing programme theories. In this phase data will be generated that will permit exploration of programme mechanisms, contextual mechanisms, agency and outcomes. The programme theories will be refined to allow for transferrable conclusions about how, why and in what circumstances CLOs impact on the health and wellbeing of their participants. Data to support these research objectives will be collected through:

- a longitudinal survey of new CLO participants
- an economic appraisal and
- a Q methodology study, which investigates the perspectives of participants by ranking and sorting a series of statements.

Each of these methods including approaches to sampling, data collection and analysis are outlined in the sections below. The timing of each component is represented in the **Gantt Chart** above, which also serves to capture the **researcher workload** across the study period. Workload has been carefully plotted because this project is researcher-intensive, multi-site, and researchers’ time is key to successful delivery.

Detailed descriptions of each component of Phase 1 and 2 are provided below.

5. 2 PHASE 1

5.2.1 Realist synthesis of existing reviews to provide tentative programme theories

A literature search will identify systematic and other literature reviews relevant to community-based organisations and health and wellbeing outcomes. Its aim will be to collate what is currently known or theorised about how community-based activities promote health, in what circumstances, and for whom. It will seek to establish:

i. The mechanisms by which community-based activities are thought to promote health and wellbeing;
ii. How the contexts within which these activities take place either help or hinder their ability to promote health and wellbeing;
iii. How the stakeholders involved in these activities interpret and respond to contextually situated activities;
iv. What health and wellbeing outcomes result from the interaction of activities, contexts and people.

The results of the realist synthesis will provide an initial theoretical base for subsequent empirical enquiry. That enquiry will augment, refute or refine these initial theories.

A search strategy will begin by identifying key words and search terms from ‘pearls’ (key papers) and growing the search from there to identify additional reviews.

5.2.2 Comparative policy analysis

A comparative analysis of policies and the ‘ecosystems’ in which CLOs exist and which support, sustain or present barriers to CLOs will be based on policy documents and stakeholder interviews. This will describe contexts in terms of policies and funding at *community*, *regional* and *national* levels. While carried out as a separate exercise to the realist synthesis, this analysis will be key to addressing point 5.2.1.ii which seeks to establish how the contexts within which activities take place affect their effectiveness.

We will examine the various processes and policy instruments that presently exist (including the prevailing ‘policy rhetoric’) within which our sets of actors currently operate. These will be sourced from:

- documents on public websites (e.g. UK government, devolved governments, local authorities, NHS health boards and authorities, Public Health England/Scotland)
- discussions with various stakeholders including the CLOs and our partners Scottish Communities for Health and Wellbeing (SCHW), Scottish Community Development Centre (SCDC), Health Creation Alliance (HCA).
- documents that relate to specific areas of public health policy, or policies in other domains that impinge on public health, in the local authority areas in which the various CLOs operate. This latter set of documents is particularly important in the case where responsibilities for certain public health matters have been devolved to local authorities.
- documents which present policies and prevailing priorities for major funding bodies especially Lottery Community Fund and more local national intermediary bodies eg the Health and Social Care Alliance in Scotland
- documents recording the CLOs’ policy and process framework, including staff handbook

Our links with practitioners and policymakers will ensure that our list of policies and policy instruments is comprehensive and relevant for each site.

Qualitative Analysis

Qualitative Comparative Analysis (QCA) (see below) will be conducted to address questions such as: how, and in what ways, does the policy context matter to health outcomes? Is there a difference between policy rhetoric and reality at the local level? How do the CLOs navigate or negotiate the differences between policy rhetoric and reality for the benefit of the people they are supporting? How, and in what ways, can CLOs influence policy, particularly in relationships with the sorts of 'street level bureaucrats' (38) that we know are crucial to the success or otherwise of policies being delivered.

5.2.3 Stakeholder interviews (n=40 to 60) RO1,1c, 3,4 (months 3-7 and as required)

In-depth semi-structured interviews with stakeholders (people working in or with CLOs, such as staff, volunteers and community link workers) will explore the aims of organisations and how programmes and interventions are designed to improve health and wellbeing. Interviews will be in person if possible or by video or phone call. Stakeholders will be identified by CLOs participating in the research and the partner 'umbrella organisations' who have partnered with us in the four areas, including members of our lived experience panels. As well as CLO managers, staff and trustees they are likely to include funders and public sector and community partners, primary health care professionals, members of advocacy groups and others identified by interviewees and community stakeholders.

Researchers supervised by CIs (Co-Investigators) in each site will conduct the interviews and will explore: the contexts that promote or inhibit particular mechanisms; intended and unintended outcomes; local data on resource use, outputs and outcomes, income streams and views about sustainability. In this way the interviews serve to generate data related to several research objectives (RO 1, 3 and 4). Topic guides will be structured for realist evaluation, to investigate and develop explanations (22). Interviews will be staged, to allow theory development, and potentially involve repeat and/or group interviews. Audio recordings will be transcribed, checked and imported into qualitative analysis software (QSR NVivo) to assist with two cycles of analysis. Explanations will be generated in an iterative, 'abductive' fashion moving backward and forward among empirical data, research literature, emergent and mid-range theories. To facilitate this process, interviews will be initially coded separately in terms of statements related to contexts, mechanisms and outcomes, before a second round of 'linked coding' (23) to generate and refine CMOCs from interviewee narratives. The NIHR-funded RAMESES II training materials and publication standards for realist evaluation will be followed (24)

Sustainability and Scalability

Interviewees will be asked about best practices and key challenges involved in operating, developing and growing sustainable CLOs and what it means to be 'sustainable' in such contexts. In addition, CLO managers will be asked to provide relevant financial documents (e.g. contracts and agreements) to illustrate and support their views (note: these documents will be also used to inform our economic evaluation). Drawing on the semi-structured qualitative interviews with CLO stakeholders described in phase 1, analysis will identify key aspects associated with the sustainability and scalability of the organisations. While gathering this data (e.g. generated income vs. costs of service provision, dependence on paid staff and proportion of volunteers, availability, use and access to public resources), CLO managers, staff, trustees and other stakeholders (e.g. funders) will be asked to raise and comment on any other sustainability issues.

Previous research on scalability of CLOs (25) suggests that scalability in a community context is rarely straightforward: CLOs frequently face difficulties in maintaining their services and activities. Capacity and resource constraints often inhibit growing or seeding wider change (26). Concepts such as reinvention and adaptation are often far more appropriate to consider than standardisation, as is seeking to 'scale the impact' outside of organisational boundaries, rather than simply seeking to take a particular CLO, or model of CLO, 'to scale'. Drawing on our sample of diverse stakeholders from diverse CLOs (i.e. variation across rural/urban, organisational size and maturity, range of activities etc.) will help us to identify a variety of issues relating to scalability and sustainability. This will enable us to supplement and refine existing theories, adding significantly to the evidence base in relation to building and maintaining community assets.

Data relating to the sustainability and scalability of CLOs will be analysed together with different characteristics of CLOs as well as their impact on health and wellbeing. This analysis will also inform our realist evaluation, and so will inform and refine our programme theory, helping to explain 'what works, for whom, in what circumstances, and how'.

5.2.4 PhotoVoice (n= 30 to 40) – RO1b; 3m-6m

Participants (n=10-12) from CLOs and our lived experience panel will be brought together in four local settings to learn about photography as a means to represent their community contexts and what improves or inhibits health. PhotoVoice is a participatory method that promotes critical dialogue between communities and produces materials for exhibition and translation for practitioners and policymakers. Beginning with group discussions, outlining aims and purpose; participants will be given training in photography techniques and ethics. This process will be led by specialist PhotoVoice trainers and will complement interview and group methods that require verbal articulation with an open, visual depiction of communities and their health assets, as seen by the participants.

Participants will take photographs in response to the agreed theme and then select and discuss their images. Photographs will be printed to professional quality for exhibition in community spaces and online. This component will be outsourced to https://photovoice.org/ .

5.2.5 Stakeholder Workshops N=30-40 - RO 1d, 2d - Months 7-9; 30-32

Interviews will culminate in **stakeholder workshops** in each area to work up an initial programme theory by month 9. A second set of workshops in year 3 will focus on interpretation of findings, revision to programme theories and work on translation, dissemination and impact. The workshops will involve a number of the same interviewees and so build on interviews. They will be interactive and facilitated to develop programme theory based on what is known, and what we learn throughout the study in relation to contexts and interventions, mechanisms and outcomes. Our community partners have emphasised the value of CLO staff from a range of project organisations coming together in groups to share learning, experience and expertise.

5.2.6 Qualitative Comparative Analysis

We will employ Qualitative Comparative Analysis (QCA), a method based on Boolean algebra as a means of analysing patterns of causation in a small to moderate number of cases (27). QCA is appropriate because of the 'conceptual parallels' between QCA and Realist Evaluation (28). QCA is a method that depends on familiarity with cases (and our researchers will gain intense familiarity and knowledge of the CLOs in question). It will also enable decisive cross-case patterns to be identified, which is the usual domain of quantitative analysis. However, QCA also respects the heterogeneity of the contexts and different causally relevant conditions by comparing cases as configurations. Our QCA will be designed using contemporary best practice (29) in three distinct steps (30):

Step 1: identifying relevant cases and causal conditions;

Step 2: constructing truth tables and resolving contradictions; and

Step 3: analysing the truth table, a phase that can be undertaken using fsQCA software (31) to specify the different combinations of conditions linked to the selected outcome, based on the features of the positive cases that consistently distinguish them from the negative cases.

This method will allow us to systematise our analysis across 4 research sites working with 4 researchers and produce statements of the combination of programme mechanisms, contextual mechanisms and agents' responses that lead to improvements in health outcomes. Where there are differences in outcomes, we will seek to identify the variations in configurations of mechanisms that lead to differing results.

At the end of Phase 1 we will have produced a rich understanding of contexts in terms of policy systems, a photographic exhibition of community contexts and health assets and initial, co-produced programme theories. This will build on a realist synthesis of existing reviews, stakeholders' and LE panel views of how CLOs work to trigger mechanisms and produce outcomes.

5.3 PHASE 2

5.3.1 Access to existing local data and systems

Working with CLO staff, researchers will locate any routinely collected data in relation to

- participants (e.g. numbers of participants in different activities, socio demographics of CLO participants)
- outputs
- outcome measures (where possible)
- resource data (staffing, equipment, consumables)
- income streams (grants, income raised through trading activities, donations).

This local data will be used to inform the economic analysis and the sustainability analysis (see below).

Researchers will spend 3-5 days during the first 2-3 months of the study working with key staff and trustees in CLOs to get a sense of how each organization works. Researchers will keep reflective diaries, identify the locations and extent of available data for the economic and sustainability analyses and to establish the best ways to recruit and retain participants in each organizational context. They will work in conversation with researchers across all sites such that best practice and creative solutions can be shared. This information will be used to design recruitment processes to fit with existing CLO practices and systems.

5.3.2 Questionnaire study (RO2a ,2b, 3 9m-30m, n=225)

Data Collection: We will recruit new participants at CLOs to capture their outcomes before and after participation in CLO activities.

Data will be collected at baseline, 1, 6 and 12 months. Data at baseline will be collected by the RA at each location. To maximise response and recognise the different needs and preferences of participants, they will be offered the option of completing the questionnaires face to face with the RA, by telephone or online using REDCap © software (32). Wherever possible participants will follow the same mode of administration throughout follow up. Data collected in face to face interviews or by telephone will be entered by researchers into a secure online database developed by the statistical team at GCU.

Each participant will receive an incentive payment following the completion of questionnaires at each time point with a final (larger) completion incentive at 12 months, to encourage completion. This is an approach that we have used successfully to mitigate attrition in a study of financial diaries and health with people on low incomes. Previous work with CLOs by CI Bertotti has reported attrition of up to 50% (33), however in our financial diaries work with people with low incomes, attrition was 25% over 6 months with incentive payments designed in this way (34). Our recruitment targets allow for attrition rates of 30% at 6 months recognising that some participants will have complex lives and loss to follow-up could be high. A baseline sample of 360 will be recruited to achieve 6-month completion for 252 participants (30% attrition, see sample size section 7.2.1 and Gantt Chart in Figure 2,).

Outcome measures: Outcomes will be measured at baseline, 1, 6 and 12 months, to capture immediate and long-term changes in outcomes measured. The primary outcome measure for the questionnaire study is the ICECAP-A (ICEpop CAPability measure for adults) (35). The ICECAP-A has been selected for three important reasons: firstly the dimensions of the ICECAP-A map well onto the intermediate outcomes identified in empirical work and in practice based models (see Figure 1) and so we are measuring things that have been shown to be important to beneficiaries, practitioners and according to assets theory; secondly it is validated and is supported for use in economic evaluation by NICE (36) and thirdly preference-based population tariffs are available (37). The five ICECAP dimensions are:

- **Attachment** (an ability to have love, friendship and support)
- **Stability** (an ability to feel settled and secure)
- **Achievement** (an ability to achieve and progress in life)
- **Enjoyment** (an ability to experience enjoyment and pleasure)
- **Autonomy** (an ability to be independent)

Respondents score each dimension according to one of four levels; for example, for stability:

I am able to feel settled and secure in all areas of my life	4
I am able to feel settled and secure in many areas of my life	3
I am able to feel settled and secure in a few areas of my life	2
I am unable to feel settled and secure in any areas of my life	1

Our secondary outcome measures are EQ-5D 5L, Warwick Edinburgh Mental Wellbeing Scale (WEMWBS), Satisfaction With Life Scale (SWLS), Sense of Coherence (SOC-13) and loneliness measures as recommended by the Office for National Statistics (38). It is possible that secondary measures will be added or dropped from this list, depending on the results of our stakeholder interviews, subsequent programme theory and to minimize participant burden.

A resource use questionnaire will be designed for this study to capture relevant data on NHS, Social Care and personal resource use required for the economic evaluation. Sociodemographic questions that gather a range of personal characteristics will also be included.

Data analysis:

A detailed statistical analysis plan will be produced, and all statistical analysis programs will be developed and validated prior to database lock. Each outcome measure will be scored according to the protocol set by the developers. Summary measures of each outcome will be estimated for each participant at each time point. Statistical models will account for the realist perspective of this project by considering overall time-trend variations in the outcome measures which are also based on the individual's association with CLOs (i.e. the idiosyncratic effects that account for differences in the process of change). Descriptive statistics will be used to explore and analyse the data for associations. Random effects regressions with clustered standard errors will be employed to account for the longitudinal nature of our data and for the fact individuals are clustered in CLOs.

Multilevel modelling that explicitly acknowledges the hierarchical clustering of the data will be employed (39, 40). Multilevel models can combine fixed and random effects and account for time points nested within participants who are in turn nested within CLO organisations. These statistical models are appropriate for the study design where we are looking for changes over time in a group of individuals who are members of organisations in the presence of uncertainty and unobserved heterogeneity. The statistical models will estimate the impact of the CLOs on the outcome measures over time after controlling for individual and CLO characteristics. The analyses will be run for our primary and secondary outcomes separately.

Strategies to minimise missing data will be employed throughout the data collection process. Baseline data will include a range of personal characteristics which will be used in missing data analysis. Data on the reasons for non-response will be collected by researchers and, if necessary, we will use methods to analyse missing data that reduce the uncertainty around non-response and maximise usable data. Depending on the statistical pattern of missing data and if appropriate multiple imputation with predictive mean matching will be used to preserve sample size and statistical power and to minimise bias in all the analyses (41, 42). All statistical models will be estimated using the Stata and R statistical packages.

A preliminary statistical analysis, based on outcomes at 1 month, will inform the selection of participants for qualitative data collection to explore mechanisms and, with the Q sort data, derive the CMOCs for the economic analysis.

5.3.3 Participant qualitative interviews (n=45 to 60) – RO 2c 19m- 27m

Interviews with CLO participants will explore their experiences of participation, the outcomes they experienced and their explanations of mechanisms (what resources they recognised, what responses they had to those resources). Participants will be selected based on preliminary analysis of questionnaire data – to exemplify different emerging CMO configurations in the data. These interviews, together with the Q sort data, are crucial to identifying mechanisms. Qualitative analysis will be conducted as described under stakeholder interviews above.

5.3.4 Q methodology (n=45 to 60) – RO2c; 25m-29m

The aim of all Q studies is to identify patterns of shared perspectives. In the context of realist methods this sits well with the goal of uncovering regularities in data. We will make use of this approach to unpack the mechanisms at work in different contexts. Astbury also warns against depending too heavily on the theories of programme developers about what is taking place, which might preclude new programme mechanisms being identified (43). The Q set of statements will comprise of *candidate* *mechanisms* drawn from theory, interview and workshop data and hypotheses that emerge from preliminary analysis of context-outcome patterns in the before/after questionnaire study.

CLO participants including our lived experience panels in each of the four areas, will complete Q sorts to identify which mechanisms resonate with their own experiences and help to explain why outcomes arise in context. Mechanism statements will be presented as combinations of resources, responses and outcomes. Different mechanisms might relate to the same outcomes in different contexts and we will gather descriptive information about Q participants' contexts (socio demographic characteristics, experience of CLO activities, location and so on). Factor analysis of Q sort data based on correlations between individuals' Q sorts will reveal shared patterns of mechanisms for interpretation.

5.3.5 Economic Evaluation (RO3, 9m-36m, n=225)

The economic evaluation will take the form of a cost consequence analysis (CCA). A CCA presents the costs and outcomes in a disaggregated form (often called a 'balance sheet' approach) (44). This approach is appropriate given the multi-sectoral context in which the CLOs operate and the range of outcomes of importance, each of which may not be captured via a more-traditional cost-effectiveness analysis. Congruence between realist evaluation and the economic analysis proposed is provided through the CM+PM+A=O framework. We will seek to quantify resource implications arising from both contextual (CM) and programme mechanisms (PM) emanating from our realist evaluation, and how these relate to agents' responses and outcomes (O) covered by our use of various measures described above and the qualitative interviews. Thus, similar to building an economic evaluation alongside a more-recognised clinical assessment, via a randomised trial, we will utilise some of the data from the realist approach and enhance it for the economic evaluation. But, here, the 'interventions' to be compared will be formed by the main CMO configurations, within which CLOs will play varying parts, rather than the CLOs themselves. As with other economic evaluations, this will still require data on costs (of CLOs and other health and social care use). Missing data will be dealt with as described under 'data analysis' above.

Data on costs and outcomes

The first stage of the economic analysis will be to map out the resource inputs required to deliver the activities provided by the CLOs. This will be done in collaboration with the CLOs and will be assessed and updated throughout the project. Key categories will include any capital costs (equipment and space), which will be estimated based on purchase or rental values of properties and equipment, which, when combined with an estimated length of life, will be annualised. Labour costs for each CLO will be extracted and categorised according to types of staff and numbers of each type employed as well as wage rates for each. All other costs, generally categorised as consumption costs arising from different materials used by the CLO, will be counted in volumes of items used along with their prices. All such costs will be totalled and turned into a cost per participant in one of two ways; either by simple division of the total annual cost by annual client throughput or by calculating a cost per participant day and estimating costs for individual participants based on days of use or visits, so building some variation into the data.

Secondly, we will ask participants to self-report (via a questionnaire) at baseline on their other use of resources during the six months prior to joining the CLO and then at the 1, 6 and 12 month follow up (with adjusted recall period to cover the whole 12-month time frame). This will allow us to assess changes in resource use within the study participant group in the form of a before-and-after design. Using the checklist provided by the ISRUM (Items for a Standardised Resource Use Measure) Project

(45) we will assess impacts on hospital care, emergency services, use of primary care and other community-based health and non-health services including any resources required to participate in the CLO. Units of each item will be recorded following the ISRUM guidance and presented along with unit costs which will be derived from local sources as well as those that are publicly available (46).

By collecting detailed data on units of resource use as well as unit costs and prices, we can model different scenarios (or 'contexts' arising in the realist evaluation), following the proposal that the conception of mechanisms within realist evaluation becomes about resources as well as reasoning, and so aids generalisability (47).

Combining data on costs and outcomes

The estimates of the health outcomes from the primary and secondary outcome measures will be incorporated into the CCA along with more qualitative data from the interviews conducted in both phase 1 and 2 of the study.

Following the realist evaluation approach, the focus of the analysis will be at the CM+PM+A=O level. As stated above, the study is not designed to test the effectiveness of CLO participation against a null of no participation. Instead, we will attempt to model a null CM+PM+A=O (empirically informed from a combination of qualitative data and quantitative participant information at baseline) against other CMO configurations. Estimates of resources used will be drawn from study participants most associated with the particular contexts and mechanisms and presented alongside outcomes from the questionnaire study which also emanate from these same contexts and mechanisms. The qualitative interviews from the main realist evaluation will also be used to inform us of whether further cost estimates are required for any resource-use associated with contexts and mechanisms but not covered by the initial set of quantitative data.

Ultimately, data on costs and benefits of different CM+PM+A=O configurations will be presented in a descriptive table or 'balance sheet'. A social time preference rate of 3.5% will be used to discount costs and benefits in line with HM Treasury Green Book for any items that occur after 1 year (48).

This type of information could be used in multiple ways. A more linear approach may be to identify what CM+PM+A=O configurations have resulted in the largest health and wellbeing outcomes and the extent of funding that would be required for the CLOs which best demonstrate these CM+PM+A=O. Alternatively, data on the Contextual Mechanisms and Programme Mechanism components will allow us to extract combinations that reflect national priorities. For example, social isolation can be tackled through CLOs that aim to build social networks in specific communities and, thus, across contexts that could potentially differ from each other. The resource consequences of such alternatives could be estimated in aggregate as well as for their different CLO components. Finally, identifying differences between CM+PM+A=O would allow us to advance propositions of what works, for whom and how by identifying what resources are needed in specific contexts to trigger generative mechanisms (i.e. those mechanisms that are necessary for an outcome to be achieved and scaled up). These propositions may inform funders' and CLOs' decision making for the most effective allocations of resources in this context

6 STUDY SETTING

The study setting is 15 Community-led Organisations (CLOs) in four geographical areas: Glasgow/ Lanarkshire, Bournemouth, East London and Northern Ireland. It is thus a multi-centre study. Participants are the staff, trustees, volunteers and CLO participants (clients or users) associated with the CLOs.

Each CLO will serve a different community, operating with different systems of administration and management and delivering a diverse range of services and activities. Recruitment methods will be designed with CLO staff to suit each organisational context.

7 SAMPLE AND RECRUITMENT

Sampling for Common Health Assets relates to two levels of selection: the selection of CLOs, and then, from those organisations, selection of stakeholders and CLO participants to take part in a range of qualitative and quantitative study components. Different approaches are required for each level of selection.

For CLOs we will set out a sampling matrix to achieve maximum variation across a number of variables, as described below, allowing for new sampling variables to be identified by stakeholders. Participants will be sampled according to each study component, with broad eligibility criteria to apply across methods, and set out below.

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

- Aged over 18 years
- Stakeholder or community participant associated with participating CLOs
- For questionnaire participants only:
    - participant in an activity that involves several contacts over time (CLOs might provide one-time advice services for example but, for comparability, we will focus on a period of consistent participation).

7.1.2 Exclusion criteria for questionnaire study

- Ongoing participation in multiple CLOs.
- One time participation only
- Not within the community of the CLO.

7.2 Sampling

Selection of CLOs

15 CLOs will be recruited in two areas in England (Bournemouth and E London), and sites in Scotland (Glasgow and Lanarkshire) and Northern Ireland (Belfast and Derry), identified through our partner organisations (HCA; Scottish Communities for Health and Wellbeing; SCDC; the SPRING Social Prescribing Project in NI) and through building new partnerships.

CLOs will be based in *areas with high levels of deprivation and poor health outcomes*, and sampled to achieve variation across

- rural/ urban
- organisational size and maturity

- range of activities
- relevant variables identified by our ‘Lived Experience (LE) panel and stakeholder interviews.

Having identified an initial group of willing partner CLOs, we will work with them and with wider stakeholders and collaborators to identify the national and local contextual issues of greatest importance to each CLO and which are likely to impact on outcomes.

In this way sampling of CLOs will be staged and purposive. These contextual issues might relate to:

- size and funding of CLOs
- characteristics of their participant populations (age, needs)
- premises or other physical assets
- levels of income and employment status
- number of volunteers and professionals
- the activities they undertake or
- their relationships with local government, social and health services.

Initial work on the policy environments and developing a detailed understanding of how stakeholders view the activities and outcomes of CLOs is needed to develop the sampling frame and achieve maximum variation across relevant contextual features

Study population:

We will work with CLOs in communities with multiple disadvantages. This will be defined here as CLOs working in, and with, people in SMID deciles 1-3: that is, 10% to 30% most deprived, based on the Indices of Multiple Deprivation for each country (49-51).

7.2.1 Sample size for questionnaire study

Questionnaire Participant Sampling: The primary outcome measure for the questionnaire study is the ICECAP-A at 6 months. There is no estimate of minimal important difference available from existing datasets of ICECAP-A, so the study will be designed to detect a commonly used standardised effect size of 0.25. This represents a small to medium effect size, e.g. a change in the mean ICECAP-A score of 0.05 if the observed SD is 0.2.

A sample size of 252 will be required to provide 80% power at 5% significance (with two-sided alpha) to detect a difference of 0.25 SDs. We will recruit 360 to achieve an effective sample of 252 completed questionnaires at 6 months (see Gantt Chart), which allows for credible retention of 70%. Additionally, we anticipate 60 to 65% retention at 12 months (approximately 225 questionnaires).

Ethically we want to avoid burdening participants beyond the numbers required for statistical analysis. Initial discussion with partners (Annexe Communities, Bromley by Bow Centre) suggests that our target numbers for new participants are feasible.

7.2.2 Sampling technique

Selection of Stakeholders and Participants

Purposive qualitative sampling methods will be used to select stakeholders and CLO participants for interviews, workshops, Photovoice and Q sorts. These will involve seeking to hear different voices and perspectives by identifying people with different characteristics and roles. Practically there will be some snowball techniques used to identify stakeholders through partners. Recruitment of participants for interviews and Q sorts will be informed by their questionnaire responses, to select individuals with different experiences, contexts, and outcomes

7.3 Recruitment

7.3.1 Sample identification - Questionnaire respondents

The 4 researchers (based at GCU, BU, QUB, UEL) will each work in partnership with 2-4 CLOs to identify participants. Participants will be identified in different ways depending on CLOs' systems and preferences and according to research ethics best practice (54). The standard approach will be to work through a key contact person(s) as a gatekeeper, at the CLO who will approach the potential participant and complete a brief screening questionnaire based on the inclusion and exclusion criteria.

Posters explaining the study and inviting participants to contact the study team will be displayed at participating CLOs, we will also explore use of hyperlinks from CLO websites and social media to the research project website. This approach will be modified as needed. Recognising that CLOs are working at full capacity, researchers will take an active role and resources are built in to recognise CLOs' time for initial identification and screening questionnaires. We expect that our four researchers will spend 3-4 days each week on site with CLOs during the main recruitment months 9-18.

7.3.2 Payment of CLOs and Participants

Set up costs and identification of existing data

Researchers will shadow CLO staff during months 3-6 for 5 days.

CLOs will work with researchers to review databases and put in place systems to identify participants.

Payments will be made to CLOs to recognise this time.

Recruitment and Consent costs:

Whilst there is not standard guidance for community settings, we have included administration cost (per participant) equivalent to the recruitment and consent costs used for NHS settings.

Travel and subsistence (T&S) costs

T&S costs have been estimated for all interviews, panels and workshops

Participant costs

Participants in interviews, Q sorts and questionnaires will be paid T&S and an incentive payment for each data collection point.

7.3.2 Consent

All participants will be provided with an information sheet describing the study and the nature of their participation should they agree to take part. They will be given time to consider the information and an opportunity to ask questions before signing a consent form. These are appended (with alternatives that can be deleted depending on the part of the study they participate in).

For the questionnaire study participants who meet the inclusion criteria will be given an information sheet about the study by the gatekeeper. Potential participants who are interested in taking part in the study, and who consent to their contact details being supplied to the researcher, will be contacted to set up a meeting (either in person or virtually) to complete informed consent processes and complete the baseline measures.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

A risk register has been completed for the project using GCU standard forms. This will be re-visited with community partners to identify potential risks to participants and researchers for each study site and procedures that might be required to mitigate and/or report potential risks. Risks include safety and wellbeing of researchers and participants, in particular those with pre-existing vulnerabilities such as mental health issues. Key risks to the project completing on time are failure to recruit, loss to follow up of participants, withdrawal or closure of a community organisation, researchers leaving post for permanent positions elsewhere, and the additional risks presented by COVID-19 and related restrictions restricting recruitment or follow up. Recruitment and data collection methods will be co-designed with CLOs to uphold the dignity of participants.

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

Regulatory Review & Compliance

Common Health Assets does not involve any NHS sites, staff or patients. Using the NHS Health Research Authority decision tool confirmed that IRAS and NHS REC are not needed.

This project has been approved by the Glasgow Caledonian University School of Health and Life Sciences Ethics Committee on 15/7/21 (ref HLS/NCH/20/034) and subsequently affirmed by Ethics Committees at Bournemouth University, Queens University Belfast (MHLS 21_94) and University of East London (ETH2021-0226). Common Health Assets does not involve any NHS sites, staff or patients. IRAS and NHS REC are not required. This will be renewed in the event of fundamental changes to the protocol.

Amendments

Amendments to this protocol will require agreement of the funder, a revised protocol with a new version number, and an approved amendment to ethics applications at all sites.

8.3 Peer review

The Common Health Assets detailed project design has been peer reviewed by the Public Health Research Committee as part of the funding process.

This protocol has been reviewed by the research team and submitted to NIHR and to the University ethics committee for review as part of the start up requirements.

8.4 Patient & Public Involvement

Community involvement is designed into the research project through membership of the research team and community partners as co-investigators.

Public participation and Lived Experience Panel

Throughout data collection, analysis and interpretation there will be engagement with community participants and stakeholders, both as members of the research team and Study Steering Group, as co-applicants and collaborators, and through our Lived Experience Panel. This Panel will inform the design, conduct and interpretation of research through participation in project management and governance and through specific activities at key points in the study development, conduct and findings as outlined in the PPI sections of this form. A key focus will be to confirm, refute and refine the programme theory as it develops. As part of these activities community participants and stakeholders will participate in the generation of research materials (PhotoVoice activities and Q sorting with LE panel) and at other points they will participate in the interpretation of findings – especially through the Q study methods which produce factor solutions for interpretation and so are particularly appropriate for group activity).

Lived Experience Panel

12 panel members will be recruited to represent a diversity of perspectives and reflect the demographic characteristics of CLO populations. Our community partners and CLOs will assist in recruitment of Lived Experience Panel (LE panel) members.

The LE panel will meet at least twice a year during the project life span (six times in total) at partner locations across the UK, or online (using MT Teams/ Zoom) as necessary, to shape and influence the research plan and participate in activity relevant to key study phases (see below). Co-creation will be achieved by allowing space for the LE panel to define their areas of interests. Given the length of the project, it is not anticipated that panel membership will be static but will evolve in terms of involvement and expertise over the duration.

The panel will have a co-producing role in relation to refining research questions, co-developing and approving recruitment materials, and providing input into the scoping of ethical considerations. We will also make space for LE panels to shape the coding and analysis of data (55), identification of emerging themes and translation of findings.

Members of the LE panel will contribute as participants in PhotoVoice and Q sorting. For example in the Q study, having completed their own Q sort, they will be able to compare theirs with others' perspectives and participate in interpreting findings.

Timeline
Meeting 1: Role of LE panel, introduction to the social determinants of health, asset-based approaches, project design
Meeting 2: Research questions and methods, recruitment
Meeting 3: Introduction to Programme theory, data coding, Photovoice outputs
Meetings 4 & 5: Introduction to Q analysis and economic analysis, exploration and analysis of emerging findings
Meeting 6: Translating research findings, opportunities for dissemination.

8.5 Protocol compliance

This is a multi-site study and while different locations might have different requirements with respect to recruitment and data management systems, the same data collection instruments will be employed in each site. Compliance with protocol will be monitored by the Project Management Team (PMT) and overseen by the SSC. The PMT will meet monthly and this will be a standing item. Deviations from the protocol will be discussed by the PMT (which includes the researchers) and where necessary additional systems will be adapted to prevent accidental deviations. In the case of serious breaches of the protocol by co-investigators and researchers employed to work on the project we would consider the following i) whether to terminate the project relationship with that party ii) whether to report to the university authorities or professional bodies iii) whether to report to NIHR.

8.6 Data protection and patient confidentiality

All electronic data will be stored on a secure folder using MS Teams and Sharepoint, which is the platform recommended and supported by the information services technical team at GCU. Only members of the project research team will be given access to the MS Teams folder and this will be setup, monitored and backed up regularly by the project administrator.

Data will include contact information, consent forms, audio recordings, interview and workshop transcripts, card sort (Q sort) data, questionnaire responses, meeting agenda/minutes, and project management information such as protocols, presentations and event information. There will also be a repository folder to enable the team to capture the published and unpublished information in relation to community organisations' response to Covid-19.

Electronic data will be stored securely and backed up on secure network drives at GCU. Hard copies (e.g. signed consent forms or screening questionnaires) will be stored in a locked filing cabinet at GCU with access to the research team only.

Data will be pseudonymised and identifiable data such as names and personal details such as addresses will be stored separately. Databases and reports will use unique identification numbers and/ or pseudonyms for participants.

All data management and access will be compliant with GCU data policies, GDPR and Data Protection regulations and ethical research best practice and will be detailed in the data management plan, https://www.gcu.ac.uk/dataprotection/

8.7 Indemnity

GCU as sponsor has full Professional Indemnity Insurance in place to cover any claim made by participants as to the design or management of the research study. Full Indemnity is provided by collaborators for Data Protection against any and all liabilities, losses, costs, charges and expenses incurred (either directly or indirectly) as result of any claims, demands, actions and proceedings made or brought against the Lead Party by the Authority in respect of any loss or distress suffered by the loss or unauthorised disclosure of Personal Data or medical records by the Collaborating Parties, or any of their sub-contractors, employees, agents or personal within its control and third party Intellectual Property rights that the advice or information given by any of its employees, students, agents or appointees who work on the Project, or the content or use of any materials, works or information provided in connection with the Project, will not constitute or result in infringement of third-party rights. This carries the same level of indemnity to GCU is providing to NIHR.

A limitation in liability is capped at the value of the contract but in no way affects losses due to personal injury or death.

Due to the nature of the study there will be no arrangement for payment of compensation to participants where no legal liability arises.

There is no provision of equipment in this study.

Within the collaboration agreement GCU seeks from partners a full indemnity for Data Protection against any and all liabilities, losses, costs, charges and expenses incurred (either directly or indirectly) as result of any claims, demands, actions and proceedings made or brought against the Lead Party by the Authority in respect of any loss or distress suffered by the loss or unauthorised disclosure of Personal Data or medical records by the Collaborating Parties, or any of their sub-contractors, employees, agents or personal within its control and third party Intellectual Property rights that the advice or information given by any of its employees, students, agents or appointees who work on the Project, or the content or use of any materials, works or information provided in connection with the Project, will not constitute or result in infringement of third-party rights. This carries the same level of indemnity to GCU is providing to NIHR.

A limitation in liability is capped at the value of the contract but in no way affects losses due to personal injury or death.

8.8 Access to the final study dataset

Members of the research team will have access to the dataset. There are no issues of blinding data in this study. Data storage, access and security are detailed in 8.6.

9 DISSEMINATION POLICY

9.1 Dissemination policy

9.1.1 Ownership of data

All Background Intellectual Property used in connection with the Project shall remain the property of the Party introducing the same. Any improvements or modifications to a Party's Background Intellectual Property arising from the Project which are not severable from that Background Intellectual Property will be deemed to form part of that Party's Background Intellectual Property. Each Party grants the others a royalty-free, non-exclusive licence for the duration of the Project to use its Background Intellectual Property for the sole purpose of carrying out the Project.

The Parties acknowledge that, pursuant to condition 15 of the Main Contract, Arising Intellectual Property is to vest in the Lead so that the Lead may in turn grant a licence to the Authority. For this reason, all Arising Intellectual Property created, developed or otherwise resulting from the Project shall be owned by and vest in the Lead and, to the extent that it is legally able, each of the Parties hereby assigns, and agrees to assign on demand, its whole right, title and interest in and to the Arising Intellectual Property to the Lead.

In accordance with condition 11 of the Main Contract, each Party shall, at the request of the Authority, disclose or transfer any Research Data (as defined in the Main Contract) to the Authority or deposit both qualitative and quantitative Research Data in a nominated data archive.

9.1.2 Outputs and publications

On completion of the study, data will be analysed and a Final Study Report prepared. The final report will be peer reviewed and published in *Public Health Research* as part of the NIHR Journals Library.

Participating investigators and researchers will publish journal articles relating to components of the study according to an agreed publication policy, which will set guidelines for early communication around publications, allow all researchers to get involved in writing and avoid overlap.

NIHR will be acknowledged in all publications, citing the grant number for Common Health Assets, and including the following statement:

This study is funded by the National Institute for Health Research (NIHR) Public Health Research programme (NIHR 129118]. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

All participating CLOs will be notified of publication and of study outcomes in non-academic briefing papers and videos (digital stories) as well as through study workshops and a curated exhibition based on the Photovoice images.

A plain English summary of findings will be made available on the project website and through social media and in hard copy.

A one-page appendix will be designed specifically for each CLO to help map the key points/ evidence in the main report to some of the features and facilities offered by the participating CLOs.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship will be according to standard academic authorship criteria (e.g. *The International Committee of Medical Journal Editors* criteria) and each output will detail input from each contributing author. As a starting point the research team will aim to be inclusive and team members will be invited to contribute to each output if they can. A key consideration is the career development of earlier career researchers.

10. APPENDICES

10.1 Appendix 1- Required documentation

- Local Site Agreement
- Key contact/ project link worker
- Information sheet and consent forms adapted as required
- Posters for recruitment adapted to local CLO (eg logos, contacts) as required

10.2 Appendix 2 – Questionnaire study schedule of data collection

Activity	Baseline	1 month	6 month	12 month
Review Inclusion/Exclusion Criteria and confirm eligibility	✓			
Obtain Informed Consent	✓			
Demographics	✓			
ICECAP-A	✓	✓	✓	✓
EQ-5D 5L	✓	✓	✓	✓
Warwick Edinburgh Mental Wellbeing Scale (WEMWBS)	✓	✓	✓	✓
Satisfaction With Life Scale (SWLS)	✓	✓	✓	✓
Social Connectedness scale	✓	✓	✓	✓
Resource Use Questionnaire	✓	✓	✓	✓
Qualitative interviews Qualitative interviews with sub-sample of participants (between months 2 and 6)		✓	✓	

10.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	0.7	2 8 21	Rachel Baker	Amendments as per NIHR comments prior to protocol approval
2	1.1	17 05 22	Rachel Baker	The following amendments following coproduction activities with stakeholders 1. To remove the requirement for ‘new participants’ in the inclusion criteria 2. To replace the Sense of coherence scale in secondary outcomes with social connectedness scale

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