Community Wealth Building Evaluation Protocol v 0.1

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

FULL/LONG TITLE OF THE STUDY

Community Wealth Building Evaluation: Learning Lessons from Scotland - a mixed method evaluation of the impact of Community Wealth Building on economic and health outcomes and health inequalities.

SHORT STUDY TITLE / ACRONYM

Community Wealth Building Evaluation/CoWBELLS

PROTOCOL VERSION NUMBER AND DATE

Version 0.1 08/01/26

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	0.1	08/01/2026	Neil Craig	Detailed research plan from NIHR-approved application with additional detail required by Health Research Authority template for qualitative research studies.

Ethics approval has been granted for work packages 1 and 2 by the Glasgow Caledonian University (GCU) School of Health and Life Sciences Research Ethics Committee (SHLS-REC) on 25th September 2025 (ref HLS/NCH/24/29).

RESEARCH REFERENCE NUMBERS

IRAS Number:	n/a
SPONSORS Number:	PURE ID 94977789 Collaboration Agreement 104929374
FUNDERS Number:	PHR NIHR 169449

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: 27/01/26

....

Name (please print): Professor Sharron Dolan.....

Position: Pro Vice-Chancellor Research.....

Chief Investigator:

Date: 28/01/26

Signature:

.....

Name: (please print): Professor Neil Craig.....
Position: Professor of Public Health Economics.....

LIST of CONTENTS

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Committees	Study Steering Committee (SSC) (contact via project administrator as above)

STUDY SUMMARY

Study Title	Community Wealth Building Evaluation: Learning Lessons from Scotland (CoWBELLS) - a mixed method evaluation of the impact of community wealth building (CWB) on economic and health outcomes and health inequalities.
Internal ref. no. (or short title)	Community Wealth Building Evaluation/CoWBELLS
Study Design	Mixed-methods, theory-based evaluation including secondary analysis of economic and health data and qualitative comparative analysis
Study Participants	Work package (WP)1: workshops with national and local stakeholders involved in CWB policy and delivery. WP2: interviews with stakeholders involved in delivering CWB in local authorities; senior CWB leads in local authorities. WP3 will involve secondary analysis of routine whole-population administrative datasets, national survey data and census data. WP4 will use data from WPs 1-3 to undertake a Qualitative Comparative Analysis (QCA). A Public Involvement Panel will be involved throughout the project to inform aspects of study design, interpretation and dissemination.
Planned Size of Sample (if applicable)	WP1 – three workshops with 10-15 participants in each. WP2 – approximately 60 qualitative interviews; survey of all 32 local authorities in Scotland. WP3 – not applicable – sample sizes determined by structure of data sources used in the secondary analyses. WP4 – QCA cases will be all 32 local authorities in Scotland.
Follow up duration (if applicable)	Not applicable.
Planned Study Period	36 months
Research Question/Aim(s)	Aim: To evaluate the health and health inequalities impacts of Community Wealth Building (CWB) as an approach to developing inclusive economies.Research Questions: 1. What are likely to be the most effective pathways for CWB to improve population health and reduce health inequalities? (WP1) 2. How has CWB been implemented in Scotland and how does it vary across local authorities? What changes have there been to policies, processes and practices on the pathways defined in WP1? (WP2) 3. What are the barriers and facilitators to the implementation of CWB? (WP2) 4. What is the effect of CWB on health and intermediate economic outcomes? (WP3a(i)) 5. What has been the impact of CWB on inequalities in health across groups defined by their individual or household social position? (WP3a(ii)) 6. What is the contribution of different components of CWB to economic and health outcomes and does the impact vary with the degree of implementation? (WP3b and WP4)

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 Helen Mason/University Investment in Research	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 Professor John Connolly, Interim Pro Vice Chancellor (Research) & Vice Dean of the Glasgow School for Business and Society, 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 (annual) 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, a final study report will be published in an open access journal.

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 principal investigators and co-applicants from Glasgow Caledonian University (GCU), University of Glasgow (UoG), Lancaster University (LU), Glasgow Centre for Population Health (GCPH), 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 SSC 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
- Recruitment, training and support of research staff
- Recruiting and building relationships with research partners and participants (stakeholders 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 a timely fashion
- Involvement of Public Involvement Panel (PIP) in planning, design, implementation of research methods and interpretation of study findings
- Production of briefing papers and blogs and other social media presence during the project
- Timely publication and dissemination of study findings according to publication policy
- Support of and career development for early career researchers

Membership of the Project Management Team

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Study Steering Committee (SSC)

The role of the SSC is to provide overall supervision of the study on behalf of the study's Sponsor and Funder and to ensure that it is being conducted in accordance with the rigorous standards set out in the Department of Health's UK Policy Framework for Health and Social Care. The SSC will:

- provide advice, through an independent Chairperson, to the study's funder, sponsor and principal and Co-Investigators on all aspects of the study
- monitor the study's progress and adherence to the protocol
- ensure the rights, safety and well-being of the participants are upheld
- ensure appropriate ethical and other approvals are obtained in line with the project plan
- agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments

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 least annually although additional meetings may be organised as required. The SSC will have its own terms of reference outlining the role and responsibilities of its members. At least on member of the SSC will be drawn from the Public Involvement Panel (PIP). 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.

Public Involvement Panel (PIP)

Throughout data collection, analysis, and interpretation, there will be engagement with local organisation and businesses involved in CWB through our PIP. The Panel will ensure that the project is shaped and informed by the ongoing expertise, voice, and perspective of people and businesses from the project locations so that the findings are meaningful and relevant to people and organisations embedding CWB in local areas across Scotland. The Panel will contribute to decisions regarding recruitment approaches, data collection methods, analysis, and interpretation of data and findings. The PIP will feed into the PMT through Co-Is McLean and Ahmed from GCPH. There will be two public members on the SSC, at least one drawn from the PIP.

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.

KEY WORDS: Community Wealth Building
Inclusive economy
Health and health Inequalities
Social determinants of health
Theory-based evaluation
Mixed method evaluation

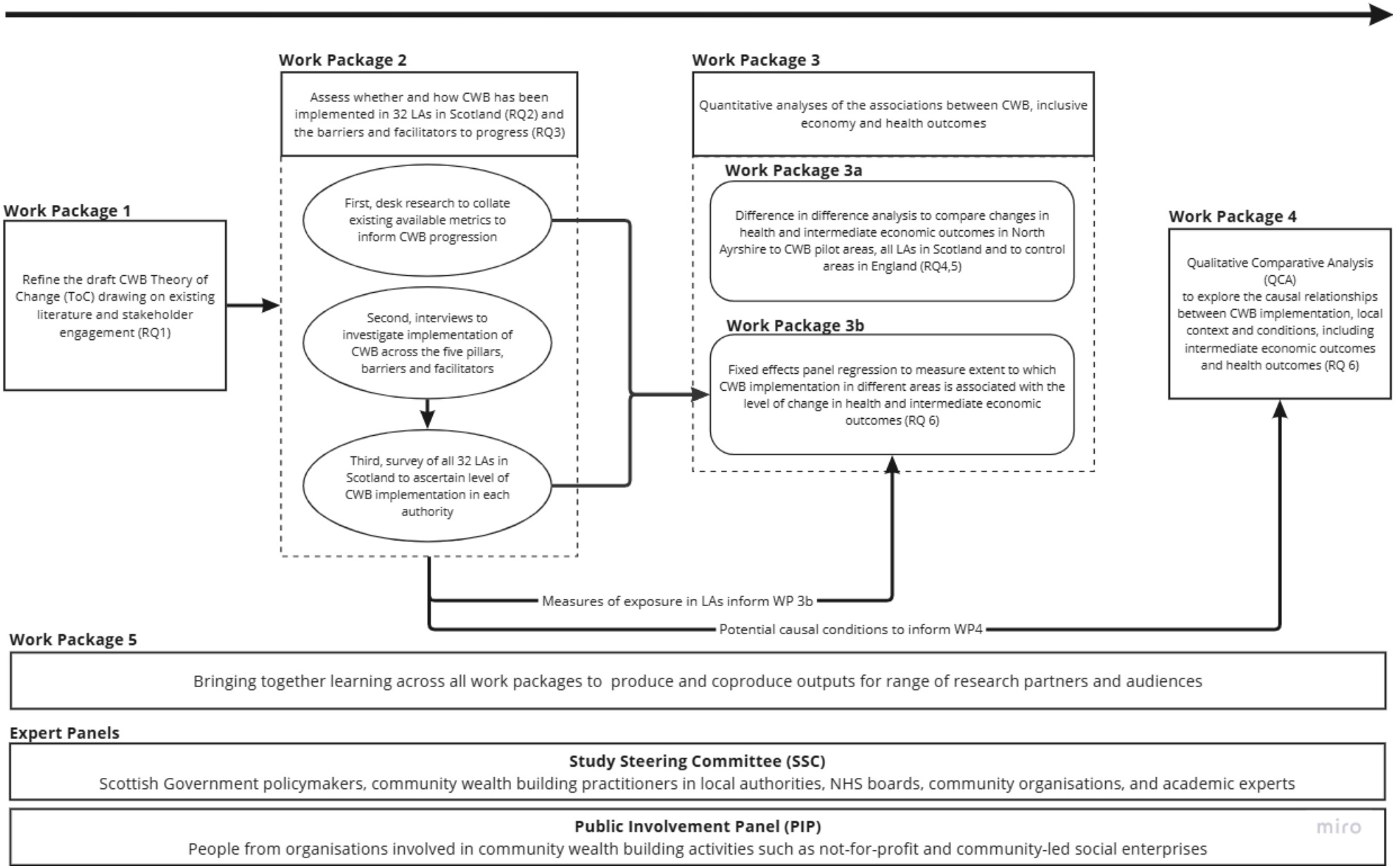
STUDY FLOW CHART

Figure 1 below presents the study flow chart.

The main stages of the study design and timescales are as follows, starting in October 2025 with a duration of three years:

WP1:	Review of theory of change for Community Wealth Building: months 1 to 6.
WP2:	Collation of indicator data: months 4 to 12
WP2:	Qualitative interviews: months 4 to 24
WP2:	Local Authority survey: months 13-24
WP3a:	Difference-in-difference analyses: months 1-24
WP3b:	Panel regression: months 1-30
WP4:	Qualitative comparative analysis: months 7-30
WP5:	Synthesis and dissemination: months 1-36.

FIGURE 1: STUDY FLOW DIAGRAM



STUDY PROTOCOL

Community Wealth Building evaluation: learning lessons from Scotland - a mixed method evaluation of the impact of community wealth building on economic and health outcomes and health inequalities.

1 BACKGROUND

Since 2012, in Scotland and the rest of the UK, life expectancy and a range of measures of general and mental health have either stopped improving, or have been worsening, especially amongst more disadvantaged groups (1,2). These trends have been driven largely by increasing inequalities in the wider determinants of health (3,4). Addressing inequalities in the social determinants of health is therefore central to reducing health inequalities.

In recent years, emphasis on local solutions to address socio-economic inequalities has increased through the promotion of place-based, community-led interventions to build inclusive economies (5,6). CWB originated in the United States (US), particularly through initiatives in Cleveland, Ohio, in the 2000s. It drew inspiration from longstanding democratic and economic development models such as the Mondragon Corporation in the Basque Country in Spain. Its adoption in the UK is largely credited to the efforts of the Centre for Local Economic Strategies (CLES), a Manchester-based charity that has played a pivotal role in promoting and implementing CWB in several locations across the UK (7). Its implementation has gained prominence since Preston, Lancashire, became the first UK local authority to adopt a CWB strategy in 2012.

The aim of CWB is to increase local communities' share of and influence over the wealth within local economies, through action across five pillars, namely: spending and procurement; workforce and fair employment; land, property and other physical assets; inclusive ownership; and finance. However, the literature reveals different conceptualisations of CWB, with implications for how CWB has been (or may be) implemented in different contexts. For example, in the US, the Democracy Collaborative coined the term 'community wealth building' in 2005 as a response to a resurgence in grassroots experimentation with forms of community and co-operative ownership, implying a more 'bottom-up' model of socioeconomic transformation (8). Elsewhere, CWB is generally understood as an approach to economic development centred on municipal stewardship of resources, with local authorities collaborating with 'anchor institutions' (defined below) to promote local economic activity, community participation and local economic ownership (6,8-10).

There is increasing interest in CWB across the UK (11-13). Public Health England includes CWB in its framework for inclusive and sustainable growth (14). The Scottish Government (SG) has adopted CWB as part of its strategy to develop a more inclusive and sustainable economy (15), which also features as one of six national public health priorities in Scotland, demonstrating an understanding of the importance of economic policy to population health outcomes (16). The 2024-2025 Scottish Government Programme for Government included a commitment to introduce a CWB Bill to promote consistent implementation of CWB across Scotland and a Stage 1 report on the Community Wealth Building (Scotland) Bill was published by the Scottish Parliament in October 2025 (17). North Ayrshire, a local authority in the southwest of Scotland, launched Scotland's first CWB strategy in May 2020. An additional five local authorities have since been designated CWB pilot areas. CWB has become integral to the SG's National Strategy for Economic Transformation (18), in support of the goal of building a wellbeing economy.

As part of the NHS Scotland Delivery Plan Guidance issued in February 2023, the SG asked all NHS Boards to develop strategic plans for increasing the impact of 'anchor institutions' on inclusive and sustainable local economic development. Anchor institutions are locally rooted organisations, such as hospitals and universities, with large economic 'footprints' as a result of being big employers, high-volume purchasers of goods and services in the locality, and owners and controllers of large areas of

land and fixed assets (19). In March 2024, all NHS Boards were asked to submit a baseline analysis of their anchor activity, based on metrics agreed in consultation with NHS Boards and other stakeholders (20,21). Public Health Scotland (PHS) have published a health impact assessment (HIA) of CWB (22) and commissioned an evaluability assessment of anchor institutions (23).

The SG, therefore, is explicitly promoting CWB on a Scotland-wide basis but with variation between areas. This provides an opportunity to explore the impact of a national policy and the potential variation in impacts and policy pathways between areas with different socioeconomic characteristics.

The approach to CWB in England is less systematised. There are local authority areas that are either pursuing CWB comprehensively (e.g. Preston City Council), or specific pillars (e.g. plural ownership in Liverpool, Newham, Islington, Newham, and Halton (24)). There is also some variance in the language of how some local authorities and city regions discuss models of economic development that have similarities to CWB, with terminology such as inclusive growth, wellbeing economy, community doughnut economics, and the foundational economy, all used in some contexts (6) However, in contrast to Scotland, there is no national level support for CWB by the UK Government, and there are also marked examples of local economic policies which take a very different approach (e.g. Freeports). England, therefore, offers a wide array of potential control areas which are unexposed to CWB, although selection of areas requires careful consideration of the potential for other interventions to be in place, or different language to be used for similar policies in different areas.

2 RATIONALE

Recent studies have begun to assess the impact of the CWB model, most noticeably in Preston. A systematic review of evidence up to October 2022 carried out as part of the evaluation in Preston found no previous empirical research that had assessed its impact on health or wellbeing outcomes (25). The evaluation found that CWB was associated with positive changes in some mental health and economic outcomes compared to synthetic controls drawn from areas where CWB had not been implemented (25). A second study estimated the effect of Preston's CWB programme on employment and examined differential effects by disability status and other equality dimensions. It found that the introduction of the programme was associated with an increase in the employment rate of 4.0% (95% CI 2.4% to 5.7%) among people living in Preston, compared with what would have been expected in the absence of the programme. The effect on employment was greater among people with disabilities, minority ethnic groups, men and people with lower levels of education (26). These studies are a valuable contribution to the evidence base, but further studies are needed. CWB takes different forms and the policy context differs between areas - CWB in Preston focused initially on coalitions of anchor institutions. In addition, the Preston study relates to a different economic context. Outcomes were measured from 2016-2019, pre-Covid-19 and before the cost-of-living crisis.

The remaining CWB evaluation literature is not focused on health. Rather, it sheds light on how CWB has been implemented and its potential impact on economic outcomes. Conclusions between studies differ, in part reflecting the different perspectives on CWB introduced above. For example, Thompson, whilst agreeing that Preston adopted an anchor institution model, argues that *community* anchor organisations, with their 'capacity and capability to channel resources more locally' have been overlooked in the Preston model (27). Lockey and Glover (28) argue that the adoption of the CWB model may have had positive economic outcomes, reflected in Preston's performance in recent years on several important metrics (i.e., deprivation, employment, wages and productivity).

PI Mazzei and Co-I Hutcheon have investigated CWB in three areas of Scotland: Comhairle nan Eilean Siar (Western Isles), North Ayrshire and Glasgow City Region (29). Three key findings are relevant to this study. First, different stakeholders had different understandings of CWB, some seeing it as a values-driven approach to economic development, some as a practical tool to deliver economic development in a distinct way, and others as a deepening and broadening of the role of community organisations in the economy.

Second, different areas had advanced to differing degrees in the implementation of the five pillars with varied results. For example, while North Ayrshire appeared to make progress in implementation across all five pillars, the Comhairle nan Eilean Siar focused on community ownership, and procurement, whilst noting challenges where community wealth building pillars were not in place to support key local inclusive economy goals such as increasing the availability of affordable housing in rural areas. In Glasgow, most activities centred around procurement and addressing derelict and vacant land. These findings echo the recent baseline report by SG which found that NHS boards are at very different stages in terms of the development of anchor institutions(20).

Third, the research highlighted the need to evaluate further the implementation of CWB and develop a framework for measuring its impact.

Other studies have focused on specific elements of CWB. For example, an evaluation by the University of Hertfordshire of CWB projects in Hertfordshire funded by the UK Community Renewal Fund, focused on accessible training and job opportunities for people who were either unemployed or economically inactive(30). Recently, US-based research assessed the impact of a small number of US healthcare organizations that have begun addressing upstream inequities by partnering with CWB initiatives (31) - such as community land trusts, resident-owned communities and worker cooperatives. To evaluate projects, the partnerships focused on process and community-level metrics (for example, housing units developed, racial equity measures) rather than individual health outcomes.

Overall, the evidence suggests that CWB has the potential to generate positive economic and health outcomes. However, evidence on the population health and health inequalities impacts of CWB remains sparse. Further research reflecting different stakeholders' understandings of CWB and the different pathways by which it might impact economic and health outcomes is important and timely. This project will take advantage of the opportunities afforded by a national policy and local variation in Scotland and availability of linked data to address the following aim and research questions.

3 THEORETICAL FRAMEWORK

CWB presents a challenge for evaluation. It comprises multiple elements delivered in varying combinations in different areas (see 'Planned intervention' section below). It aims to address a wide range of outcomes that are also influenced by many wider social and economic factors. In addition, the implementation of CWB is outside the control of researchers. It is therefore best understood as a 'natural experiment', requiring research that explicitly theorises the complex pathways by which CWB might improve population health outcomes and reduce health inequalities, and that uses a variety of methods to assess whether, how and why outcomes may have changed due to CWB (32). To meet this need, we conceptualise CWB as a complex intervention and propose a theory-based, mixed-method impact evaluation exploiting the phased implementation of CWB in Scotland to explore whether and how changes in health and inclusive economy outcomes relate to the timing, nature and extent of CWB in different areas (33).

4 RESEARCH QUESTION/AIM(S)

Aim

To evaluate the health and health inequalities impacts of CWB as an approach to developing inclusive economies.

Research Questions

1. What are likely to be the most effective pathways for CWB to improve population health and reduce health inequalities? (WP1)
2. How has CWB been implemented in Scotland and how does it vary across local authorities? What changes have there been to policies, processes and practices on the pathways defined in WP1? (WP2)
3. What are the barriers and facilitators to the implementation of CWB? (WP2)
4. What is the effect of CWB on health and intermediate economic outcomes? (WP3a(i))
5. What has been the impact of CWB on inequalities in health across groups defined by their individual or household social position? (WP3a(ii))
6. What is the contribution of different components of CWB to economic and health outcomes and does the impact vary with the degree of implementation? (WP3b and WP4)

4.1 Objectives

RO1 To develop and expand the draft Theory of Change (ToC) (see Figure 3) setting out the pathways by which CWB is expected to impact economic and health outcomes. (RQ1, WP1)

RO1a. To update existing literature review on the impact of CWB.

RO1b. To understand stakeholders' views on the pathways by which CWB will impact engagement through three workshops.

RO1c. To synthesise available evidence and views in a co-produced ToC for CWB.

RO2 To use the ToC to assess whether and how CWB is being implemented in Scotland (RQ2&3, WP2)

RO2a. To identify policies, processes and practices being put in place along the pathways using semi-structured interviews with a purposive sample of key stakeholders.

RO2b. To understand barriers and facilitators to the implementation of CWB.

RO2c. To assess the availability of and to collate indicator data on measures of implementation of CWB.

RO2d. To understand progress in implementing CWB in local authorities using a survey of all 32 local authorities in Scotland.

RO3 To analyse the effect of CWB on health and intermediate economic outcomes. (RQ4, WP3a(i)) using difference in difference analysis

RO3a. To compare changes in health and intermediate outcomes between areas with different levels of exposure to CWB.

RO3b. To compare changes in health and intermediate outcomes between areas with different levels of exposure to CWB in Scotland with control areas in England.

RO4 To analyse the impact of CWB on inequalities in health across groups defined by their individual or household social position. (RQ5, WP3a(ii))

RO5 To estimate the contribution of different components of CWB to economic and health outcomes (WP3b and WP4)

RO5a. To assess whether the impact of CWB varies with the level of implementation of different components of CWB using fixed effects panel regression models.

RO5b. To identify the combinations of conditions ('causal recipes') to explain variations in health and economic outcomes across local authorities resulting from CWB using Qualitative Comparative Analysis.

4.2 Outcome

The outcome of this study will be transferable new knowledge based on robust mixed method research. The findings will enable social enterprises and other key players in the social economy, other local private enterprises, local authorities, anchor institutions such as hospitals and universities, academics and policy makers to understand the health and economic impacts of their economic activity, the contexts and mechanisms through which these impacts are achieved, and how these impacts might be enhanced. As such the findings will help to inform national and local economic policy decisions, increasing the likelihood that those decisions take into account their potential impact on health and health inequalities.

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

5.1 Project Overview

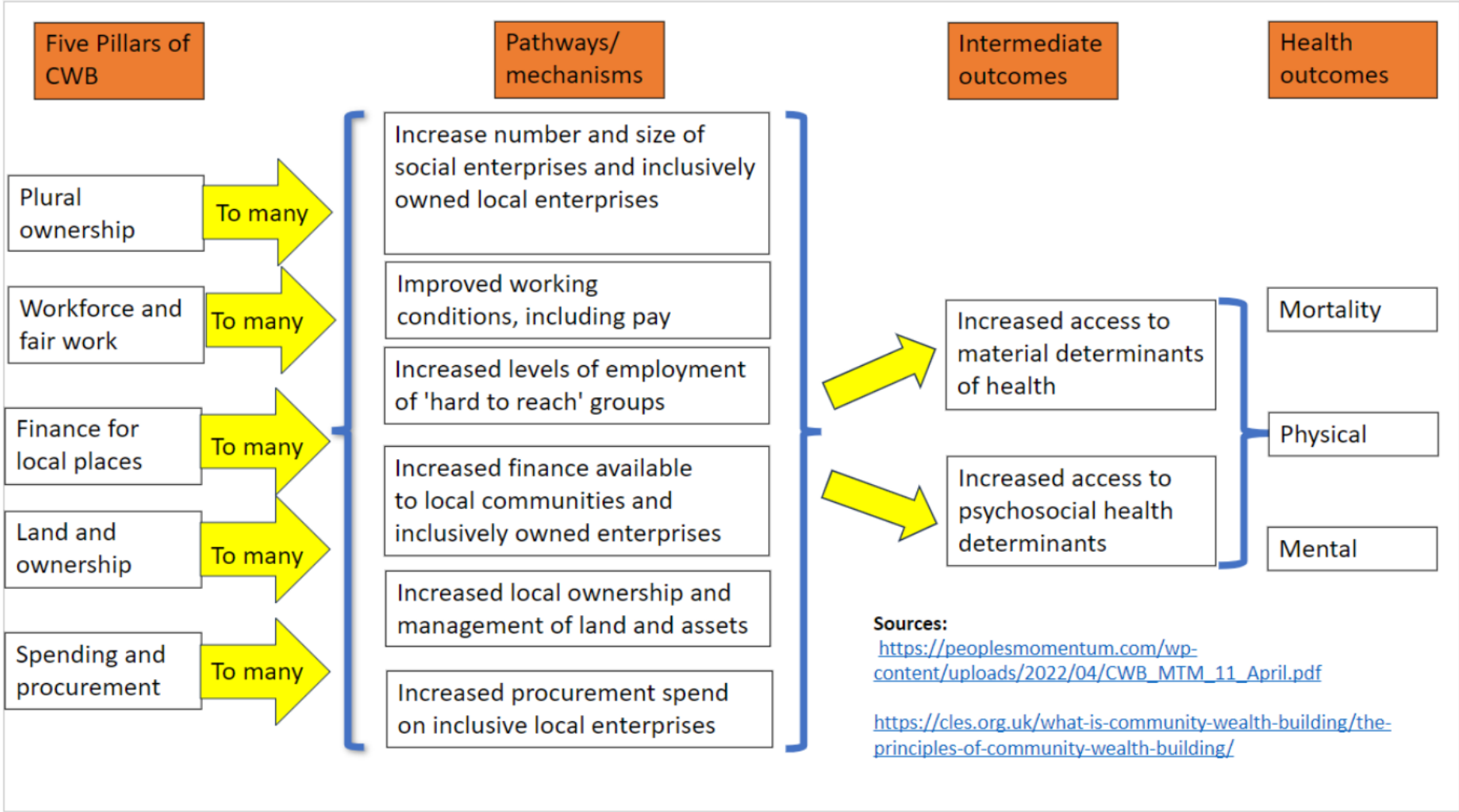
The evaluation will comprise five interlinked WPs (see Study Flow Chart, Figure 1)

- WP1 will refine the draft CWB Theory of Change (ToC) (see Figure 2) drawing on existing literature and stakeholder engagement (RQ1).

- WP2 will assess whether and how CWB has been implemented in local authorities in Scotland (RQ2) and the barriers and facilitators to progress (RQ3).
- WP3 will involve two sub-work packages. In WP3a we will compare changes in economic and health outcomes and health inequalities in areas experiencing different levels and types of progress in implementing CWB (RQ4 and RQ5). In WP3b we will assess whether the timing, extent and nature of the implementation of CWB in different areas is associated with the level of change in health and intermediate economic outcomes (RQ6).
- WP4 will identify across the 32 local authorities the combinations of factors associated with the implementation of CWB that are necessary and sufficient to bring about particular economic or health outcomes (RQ6).
- WP5 will synthesise and disseminate the results of WPs1-4.

Below we describe the planned intervention and the outcomes we will measure in the study, before describing each of the work packages in more detail.

Figure 2: Draft Theory of Change for Community Wealth Building



Note: simplified ToC illustrating two main points: CWB in Scotland is focused on the five 'pillars' and the relationships between each pillar and health outcomes are 'many to many' (i.e. each pillar addresses many pathways, each pathway is driven by many pillars, and each outcome is driven by many pathways). In developing the ToC in WP1, we will encourage stakeholders to consider whether the pillars cover all the relevant pathways.

As noted earlier, CWB comprises actions across five ‘pillars’.

The *spending and procurement pillar* comprises the procurement processes and decision-making of anchor institutions to spend more money in local economies to create dense local supply chains and networks of local small and medium-sized enterprises, employee-owned businesses, social enterprises, cooperatives and other forms of community ownership.

The *workforce and fair employment* pillar concerns the *availability* of local employment opportunities; the *quality* of employment, for example, by committing employers to pay the living wage and build progression routes for employees; and the *fairness* of local employment by, for example, promoting recruitment from lower income areas and by encouraging inclusive employment practices.

The *land, property and other physical assets* pillar aims to ensure that public bodies and anchor institutions develop governance and management structures that enable communities to take direct control of common assets and/or manage them to promote social objectives, such as inclusive and sustainable growth. This might be through bringing assets into more productive use by transferring under-used public assets to community-led organisations (CLOs) or by renting out under-used land or other assets to CLOs.

Inclusive ownership involves promoting a wider range of enterprise ownership types. These include public sector ‘in-sourcing’, municipal enterprises, worker ownership, co-operatives, community ownership and local private ownership. These models enable wealth created by users, workers and local communities to be held by them and recirculated locally, rather than generating profits to shareholders outside the area.

The *finance* pillar aims to increase investment within local economies by channelling local wealth into local investment, from sources such as local authority pension funds, or mutually-owned or regional banks with social objectives to promote local economic development.

CWB is not therefore a traditional public health intervention. It is a broad policy intervention that may have important public health impacts as a by-product of achieving other policy goals related to more inclusive and sustainable local economic development. In Scotland, these goals are being supported by duties on public bodies to produce CWB/anchor institutions strategies and by accountability frameworks that incentivise public bodies to promote CWB. The planned intervention is therefore complex, with long and intersecting causal chains leading from policy intervention at national and local level through the myriad forms of economic activity at a local level that it aims to encourage. This is reflected in the methodological approach adopted for this study.

5. 2 WP1 - Refining the CWB Theory of Change (RQ1)

WP1 will refine the draft CWB Theory of Change (ToC) (see Figure 2) drawing on existing literature and stakeholder engagement (RQ1). We will build on the work of PI Mazzei and Co-I Hutcheon, assessing how CWB is understood and implemented in Scotland. We will also draw on Public Health Scotland's Health Impact Assessment (22) and evaluability assessment of anchor institutions (23). We will use these sources to review the ToC, setting out the pathways by which CWB is expected to improve health and reduce health inequalities and identifying potential unintended outcomes.

5.2.1 Sampling

Key stakeholders including representatives from the PIP will be involved in workshops aimed at refining the draft CWB theory of change.

5.2.2 Methods for data collection

Three workshops will be carried out, one online and two face-to-face, to identify the most important pathways and key milestones along those pathways.

5.2.3 Data and statistical analysis

The workshops will be recorded and transcribed to facilitate analysis. All the material collected throughout the workshops (i.e., post-it notes, flipcharts) will be collated and synthesised by the project team. The outcome will be a refined CWB ToC and an indication of the key indicators of progress towards CWB implementation across the five pillars and within specific study areas.

5.3 WP2 – Assessment of whether and how CWB has been implemented in local authorities in Scotland (RQ2) and the barriers and facilitators to progress (RQ3)

WP2 will assess whether and how CWB has been implemented in local authorities in Scotland (RQ2) and the barriers and facilitators to progress (RQ3). Data from WP2 will inform the selection and development of measures of CWB implementation for each of the 5 pillars.

There are three main activities. First, we will identify existing metrics. Second, semi-structured qualitative interviews with key stakeholders will investigate the levels of implementation of CWB across the five pillars and gather information on what has worked well and seen progress, and what has been more challenging in implementing CWB. Third, based on the refined ToC and findings from both the desk-based review and the qualitative interviews, a survey of all local authorities in Scotland will be carried out to gather information about CWB implementation and whether conditions deemed important to the success of CWB are in place in each authority.

Survey responses, together with existing standard metrics where available, will be used to develop our measures of exposure to CWB at local authority level for use in WP3b (see below) and will inform the conditions of interest and outcomes in the QCA (see WP4 below).

5.3.1 Sampling

Interviews. We will undertake approximately 60 qualitative interviews with a maximum variation sample (MVS) of stakeholders involved in delivering CWB. MVS is a form of purposive sampling that selects participants across a range of typical and unusual experiences, behaviours, qualities, or viewpoints. The technique allows the researcher to capture a wide range of views and/or lived experiences to build understanding of the phenomenon. By identifying common aspects that occur across a broad sample, MVS can help to explain rather than simply explore a phenomenon (34).The sample will be drawn from local authorities distributed across the three CWB categories defined in the

Background section i.e. North Ayrshire, the five pilot areas involved in CWB and three 'non-CWB' local authorities. This is a relatively large qualitative sample and reflects the wide range of roles, regions, areas of expertise and levels of experience of respondents across the 5 pillars (see Table 1). In each area, the sample will include: local authority officers in departments of economic policy, regeneration, employment and skills, property and infrastructure (n=3); and representatives from key local anchor institutions (e.g. NHS Boards, Universities, Colleges, Housing Associations) and Third Sector Interfaces (n=3). The sample will also include businesses and social economy organisations (social enterprises, community organisations and cooperatives) actively involved in CWB by selling services/goods through a localised supply chain in some of the study areas, identified through snowballing (35). National stakeholders will also be interviewed, including SG representatives, NHS/PHS, Convention of Scottish local Authorities (COSLA) and membership-based organisations representing anchor organisations (e.g. Development Trust Association Scotland, Council for Voluntary Organisations, and Social Enterprise Scotland) (n=7).

Table 1. Sampling framework WP2 interviews

Pillars/areas	**Key Stakeholders**	**Study populations**
Spending/procurement	Heads of procurement; Public Sector Anchor Institutions	North Ayrshire LA CWB pilot areas: Glasgow City Region, Clackmannanshire, Fife, Western Isles, South of Scotland. Non-CWB local authorities
Workforce and fair employment	Employability/skills managers; economic development officers	
Land, property and physical assets	Property and infrastructure officers; Community Land Trusts; housing associations	
Inclusive ownership	Third Sector Interfaces, community organisations, co-ops, local development trusts	
Finance	Credit Unions and Community Development Financial Institutions; Regeneration/economic development managers; Public Sector Anchor Institutions	

Survey. The survey will be administered to each of the 32 local authorities in Scotland.

5.3.2 Methods for data collection

As indicated above, three methods of data collection will be used in WP2. First, desk-based research will be carried out to collate the existing available metrics to inform CWB progression. We will draw from existing indicators such as the LA level key performance indicators and indicators developed by the Democracy Collaborative for local councillors.1 This set of indicators includes the measurement of the extent of local ownership and participation in the economy; fairness, inclusivity and quality of job creation; levels of support for diverse forms of business ownership, including cooperatives, social enterprises, and municipally owned entities; financial flows to benefit local economies, such as through local investment strategies; and whether use of land and property benefit the community and promotes equitable development.

Second, semi-structured interviews will explore the extent and nature of CWB activities and the barriers and facilitators to implementation. The interviews will identify and explore important elements of CWB that might not be captured in existing metrics. The discussion will begin broadly and then

[1] https://peoplesmomentum.com/wp-content/uploads/2022/04/CWB_MTM_11_April.pdf

focus on specifying the conditions for effective CWB implementation across the 5 pillars. The interviews will explore interviewees' understanding of what is current as well as what is planned and the expected outcomes of CWB initiatives. Interviews will take the form of guided conversations based around a topic guide but with the flexibility to cover new information and topics introduced by interviewees. Interviews will be conducted one to one, in person or online as necessary. We will seek informed consent to record the interviews in digital audio and to transcribe them verbatim.

Third, survey questionnaires will be administered to senior leads in each local authority. These individuals may hold different positions in different authorities. Completion across all local authorities will be important to subsequent WPs. Therefore, we will work with SG stakeholders and COSLA to identify the appropriate respondent in each local authority area and ensure completion of the survey. Questions will be mainly closed and scale based, to establish which conditions are in place in each local authority that are expected to influence implementation and impact of CWB. From previous research, conditions such as leadership at senior level; collaboration and partnership working to standardise practices and co-design strategies for implementation; and resourcing the implementation of CWB through funding of specific CWB officers and dedicated investment, are considered important to the success of CWB. We will also draw from the indicators of progress in implementing CWB identified through the desk-based research. There will be space for free-text comments allowing respondents to provide additional information on unanticipated themes they see as important to CWB implementation and impacts. The questionnaire will be piloted in a small number of think aloud sessions to ensure comprehension, completeness and feasibility before roll-out.

5.3.3 Data and statistical analysis

Qualitative interviews will be audio-recorded, transcribed verbatim and uploaded to NVivo software for analysis. Data will initially be coded broadly to capture emerging themes, in particular in relation to the pillars of CWB and the research questions. Analysis will proceed thematically, combining codes into superordinate categories, and identifying patterns in responses or shared meanings across the dataset (36). Survey data will be coded and uploaded to SPSS. Descriptive statistics will summarise responses across local authorities. A set of metrics will be derived to capture progress against each of the 5 pillars of CWB and to create an overall score indicating the level of implementation of CWB. These will inform the quantitative analysis in WP3b and the QCA in WP4.

5.4 WP3 - Impact of CWB on economic and health outcomes (RQ4, 5 and 6)

WP3 will involve two types of quantitative analysis. In WP3a we will compare changes in outcomes between areas experiencing different levels and types of progress in implementing CWB (RQ4) and between different population groups (RQ5). In WP3b we will assess whether the timing, extent and nature of CWB in different areas is associated with the level of change in health and intermediate economic outcomes (RQ6). The quantitative measures from WP2 on the extent and nature of exposure to CWB in different areas will inform the analysis in WP3b.

5.4.1 Outcome measures

CWB has the potential to impact a wide range of important health and economic outcomes that are difficult to prioritise into primary or secondary. For example, it is unclear if reduced health inequalities or improved average health should be prioritised. In these circumstances, the identification of one primary outcome is not necessarily appropriate (33). We have therefore identified outcomes grouped into primary health outcomes, secondary health outcomes, and intermediate socioeconomic outcomes, as follows.

Our primary health outcomes are:

a. Mean age-standardised all-cause mortality for the total population.
b. Absolute and relative age-standardised all-cause mortality inequalities across populations ranked/categorised by area deprivation, occupational social class, educational attainment, sex and ethnicity, measured with the Slope Index of Inequality (SII) and Relative Index of Inequality (RII).
c. Mean self-assessed general health, life satisfaction, psychiatric morbidity, mental wellbeing and quality of life using data from the national health surveys (37,38).

We focus on mortality because it has almost complete ascertainment, is free of sampling and response biases, and is unambiguously a negative health outcome (unlike service use measures – see below). We acknowledge that CWB may not have been implemented sufficiently or may not have been in place long enough to lead to changes in mortality, but previous studies show mortality can change quickly following economic changes (39,40).

Mortality data will be obtained from the Office for National Statistics for English areas, and from National Records for Scotland for Scottish areas. Scottish mortality data will be linked to the census following the SHELS study approach (41), allowing inequalities to be evaluated at individual level (small-area level is subject to substantial misclassification bias) (42,43).

For some inequalities analyses (for example, by ethnicity), the size of some population groups might be small and some grouping of people with diverse characteristics may be necessary. The analysis of mortality inequalities by individual ranking measures of social position is a major strength of this project.

Survey-based measures provide evidence on health outcomes that may change more quickly than mortality in response to economic changes. However, the sample size at local level is relatively small, with risks of bias from low and differential response rates across social groups and over time (44). Although individual markers of social position are available in these datasets, inequalities analyses may be limited by the sample size for the local areas that are our unit of analysis.

Our <u>secondary health outcomes</u> are:

a. Cause- and age-specific mortality by cause and age, on the basis that larger effects may be more likely in the working-age population, where more of the direct pathways of CWB may be more likely to impact
b. Total, age- and cause-specific hospitalisation episodes by age, sex and area deprivation.
c. Prescribing data analysed by broad group and defined daily dose (by age, sex and area deprivation).

We include hospitalisation and prescribing on the basis that improved health might reduce healthcare need and therefore healthcare use relative to comparison areas. Use of these measures will also enable comparison of results with the recent studies from Preston that looked at the health impacts of CWB (25,26). However, interpretation of healthcare use is difficult because it can reflect healthcare need, supply and demand; hence the use of mortality and other health outcomes as the primary outcome measures.

<u>Intermediate socioeconomic outcomes</u>
To understand the impact of CWB on economic pathways, we will measure changes in the intervention and comparison areas in social security benefit claims (including claims due to unemployment) using data routinely available from the Department for Work and Pensions via Stat-Xplore, and changes in employment using data from the Annual Population Survey. Other measures identified through WP2 that specifically capture changes in the five ‘pillars’ of CWB will also be used if available.

5.4.2 Control/comparator group

As previously noted, all areas in Scotland are and will increasingly be exposed to CWB to some degree, given the SG's commitment to it, even if only by responding to reporting requirements, providing baseline information or being exposed to the policy conversation. In contrast, in England, there has been no national approach to CWB. This means there is likely to be an 'uncontaminated' pool of areas that have not been exposed to CWB at any level. We will use this to create comparison areas against which to compare change in economic and health outcomes in Scotland. Unexposed local authority areas in England will be identified through liaison with CLES (the organisation most closely aligned with promoting CWB approaches) and key stakeholders identified through our advisory group, noting the potential for some English areas to be implementing similar policies but using different terminology (6).

The comparator groups will therefore be local authority areas in Scotland and local authorities in England that have had no exposure to CWB. The study areas in Scotland fall into three categories in terms of their potential level of exposure to CWB: North Ayrshire, which has implemented CWB most fully; 5 pilot areas with a lower level of implementation (Clackmannanshire, Fife, Glasgow City Region, South of Scotland and Western Isles); and non-CWB areas. As all local authority areas in Scotland are likely to have been exposed to CWB to some degree, this distinction may not correspond precisely to the extent and nature of CWB implementation across the three categories, an issue we will explore further in WP2.

5.4.3 Sampling and methods for data collection

Analyses in WP3 will use routine whole-population administrative datasets, published national survey data designed to be representative at local authority level, and census-linked data to classify individuals correctly to socio-economic position. Therefore, we have not carried out sample size calculations but the data sources used will enable us to fit robust, complex regression-based models with many covariates and achieve high precision in our estimation. We focus on maximizing the statistical power and reliability of our analyses through methodologies such as Generalized Synthetic Control (GSC) and Fixed Effects Panel Regression that allow for robust comparisons across differing levels of exposure to CWB, while accounting for contextual variations and confounders.

5.4.4 Data and statistical analysis

In WP3a we will perform two difference-in-difference analyses using GSC methods. In the first analysis (WP3a(i)) addressing RQ4, we will compare changes in outcomes in local authorities in Scotland with different levels of exposure to CWB, to weighted control local authorities in England with no exposure to CWB. Initially, the N=32 Scottish local authorities will be grouped into the three levels described above (North Ayrshire, the five pilot areas and the non-CWB areas). The validity of this classification, in terms of whether these authorities represent meaningful groups in terms of the degree of CWB that has occurred, will be tested using data from WP2. If more meaningful groups are found, the sensitivity of the results of WP3a to different specifications of the comparator groups will be tested. English local authorities that are unexposed to CWB will form a 'donor pool' from which the weighted control group will be constructed. Synthetic control populations will be derived by weighting pre-intervention trends in the comparison groups to best match the intervention groups such that any divergence between more and less exposed groups after the intervention can be causally linked to CWB (45). Weights for the control units will be chosen to minimize the difference between the treated groups' outcomes and the weighted combination of the donor pool outcomes in the pre-intervention period.

In WP3a(ii) addressing RQ5, we will use the GSC method to examine whether changes in health outcomes attributable to CWB vary by social group. The analyses will exploit data-linkage, following the SHELS study approach (41), which allows inequalities to be examined at individual-level rather than area level, avoiding misclassification. This is particularly important when area-based inequality measures do not discriminate well, as is the case for several local authorities in Scotland (for example, all small areas within Comhairle nan Eilean Siar are within two of the five Scottish deprivation quintiles). English data are more limited in the inequalities analyses possible because it is less feasible to link census data with data on individual socio-economic position (SEP). English Census data have only been linked for a sample as part of the Longitudinal Study (46) which is insufficient for analyses at local authority level and thus would not support the inequalities analyses planned in this project. There is no precedent for whole-census linkage in England in the same way as in Scotland, and given the likely ethical challenges to doing so, the individually linked inequalities analyses are restricted to Scotland. WP3a(ii) will therefore compare the high and medium exposure Scottish local authorities to low exposure Scottish local authorities, using low exposure local authorities in Scotland to form a 'donor pool' from which the weighted control group will be constructed.

Because all areas in Scotland have some exposure to CWB, the analyses in WP3a(ii) may be biased towards null findings, underlining the importance of comparing Scottish to English local authorities in WP3a(i) to provide a greater contrast to the areas with the greatest degree of CWB implementation.

In WP3b, addressing RQ6, we will use fixed-effects panel regression analyses for the period 2010 to the latest available year of data to estimate the effects of the key components of CWB on health and intermediate economic outcomes. This will use the dataset created in WP2 as the exposure variables, comprising the (more granular) indicators of the CWB components that emerge from analysis of the survey in WP2. The panel regression will include unit and time fixed effects to control for time-invariant unit characteristics and common shocks. Time-varying controls available at area level will also be included. The coefficients on the indicators of the CWB components will estimate average marginal effect(s) of these components on primary and secondary health outcomes. This will allow for a decomposition of the drivers of any estimated overall effects, and examination of potential synergistic or antagonistic effects captured by interactions between component indicators. The unexposed English local authorities will act as the counterfactual group against which the effects of the components are measured.

The statistical power and computational feasibility of the fixed effects panel regression models is constrained by the number of available units/local authorities relative to the number of intervention indicators, confounders, and time periods included in the analysis. To address this we will: prioritize the inclusion of intervention indicators based on theoretical justification and empirical relevance; consider creating composite indices or grouping intervention components where conceptually and statistically appropriate; perform sensitivity analyses to evaluate the robustness of the results under varying model specifications; and use penalized regression or shrinkage methods (e.g., Least Absolute Shrinkage and Selection Operator (LASSO)) if necessary, to identify the most relevant components while maintaining model parsimony.

The different analyses in WP3 are summarised in Table 2 below.

Table 2 – Summary of analytical approaches in WP3

RQ and analysis	Method	Intervention population	Comparison population	Exposure data	Outcome data	Strengths	Limitations
RQ4 WP3a(i) Impacts of CWB compared to entirely unexposed areas	Generalised synthetic control	Scottish LAs	Unexposed English LAs (weighted to match pre-intervention trends in intervention populations)	Three-tier level of exposure to CWB across Scottish local authorities	Mean primary and secondary outcomes	Able to compare with entirely unexposed areas	Inequalities impact not possible
RQ5 WP3a(ii) Impacts of CWB on inequalities	Generalised synthetic control	Scottish LAs classified as i) high exposure and ii) medium exposure	Scottish LAs classed as having low exposure to CWB (weighted to match pre-intervention trends in intervention populations)	Three-level classification of exposure to CWB across Scottish LAs	Mean and inequalities in the primary outcomes, and mean values for the secondary outcomes	Takes advantage of individual SEP in inequalities analyses through linkage of census data.	All areas in Scotland have some exposure, biasing the impacts towards null
RQ6 WP3b Impacts of different component parts of CWB	Fixed-effects panel regression	Scottish LAs provide data to WP2 on the indicators that form the components of CWB	Scottish LAs across different levels of exposure, and English LAs classed as having no exposure to CWB	Detailed indicators of exposure to CWB across Scottish LAs from WP2, and English LAs identified as having no exposure to CWB.	Mean primary and secondary outcomes	Able to quantify marginal effects of CWB components, possible synergistic effects, and able to account for a wide range of confounders	Inequality analysis not possible; constraints related to the number of intervention indicators/ confounders relative to the number of units/LAs

Notes: Abbreviations used - Community Wealth Building (CWB) Age-Standardised Mortality Rate (ASMR) Self-Assessed Health (SAH) LA (Local authority) Socio-economic position (SEP).

5.5 WP4 - Qualitative Comparative Analysis (QCA) (RQ6)

WP4 will use Qualitative Comparative Analysis (QCA) (47,48) to identify the combinations of conditions ('causal recipes') to explain variations in health and economic outcomes across local authorities resulting from CWB (RQ6). QCA is a comparative method for identifying causal configurations that lead to specific outcomes across a small to medium number of cases. Given its potential for understanding contextualised causality in complex systems, QCA is increasingly used in evaluative research to examine the impacts of public health interventions (49,50) In this study the 'cases' of interest are the local authorities in Scotland. QCA will be used to identify combinations of CWB-related factors that are necessary and sufficient to bring about health and economics outcomes.

We plan two analyses, one to identify combinations of conditions that explain a health outcome (to be determined but starting from the list of primary and secondary outcomes listed and selecting for variation) and one that explains an economic outcome (to be determined based on variation across local authorities, for example, in Preston, CWB was found to have had a significant impact on median wages (25)). The resulting 'causal recipes' will enhance understanding of context dependency and 'equifinality', where different pathways can lead to the same outcome. The QCA will be conducted in parallel with the quantitative analyses so that where possible, the same outcome measures are used.

5.5.1 Sampling and methods of data collection

QCA cases will be all 32 local authorities in Scotland. The data on the causal conditions for inclusion in the QCA will be drawn from the ToC in WP1 and the existing metrics identified in the desk-based work, the survey and the semi-structured interviews conducted with key stakeholders in WP2.

5.5.2 Data and statistical analysis

Data on conditions (from WP1 and 2) and economic and health outcomes (WP3) will be used for the analysis. Because the conditions of interest will emerge from WP2, they cannot be specified a priori, but they will relate to level of activity against the five pillars of QCA (or a subset that show variation across the local authorities) as well as a small number of conditions that are associated with effective CWB implementation (for example, strong leadership, published CWB strategy). The conditions (or factors) chosen for the QCA will be scored i.e. transformed into values between 0 and 1 and fuzzy-set QCA (fsQCA) will then be performed on the scored dataset. Analyses will be carried out in R (48).

The QCA will help to understand whether individual conditions are necessary or sufficient for the outcome, or whether any configurations of conditions ('causal recipes') can be identified. This method will allow us to systematise our qualitative analysis and connect WPs by assessing how the conditions emerging from WP2 are related to the results of the quantitative analysis carried out in WP3, thereby comparing the 32 local authorities in terms of their implementation of CWB and their economic and health outcomes.

5.6 WP5 Synthesis and Dissemination

WP5 will comprise two strands of work. First, we will triangulate the quantitative data from WP3a and 3b with the qualitative data from WP2 and WP4 to strengthen causal inference (51,52), engaging the PIP in the process. To begin to inform debate and decision-making as early as possible, WP5 will run in parallel with WPs1-4. This will ensure that learning and findings from early stages of the work directly inform, and are shaped by the requirements of, later WPs. Additionally, complementing the quantitative analyses with qualitative data from WPs 1, 2 and 4 will help in addressing potential concerns about statistical power and sample size by providing evidence on whether the anticipated causal pathways are operating as anticipated. These measures collectively strengthen the rigour of our evaluation.

Synthesis will be informed by research team and PIP meetings dedicated to bringing together findings from each WP at appropriate points in the project, culminating in a Knowledge Exchange Workshop bringing together the findings from all the WPs. This approach of rolling knowledge exchange activities through the course of the project worked well in a previous study (53). Knowledge exchange discussions focussed less on analysis, methodological critique and managing risks and limitations (which took place within WPs), and more on synthesis in the form of bringing together findings from across WPs as they emerge, reflecting on where results complement or contradict each other, what they mean for later work packages and where the findings take us in terms of new knowledge.

Second, the findings from the project will be disseminated as part of a wider engagement strategy to a variety of audiences, including a diverse set of practitioners. Outputs emerging early in the project, for example, the ToC produced in WP1 in month 6 of the project, will be disseminated as they become available.

6 STUDY SETTING

The setting is Scotland and England. Study populations will be the populations of local authority areas in Scotland categorised into three groups: North Ayrshire, the pilot CWB areas (Clackmannanshire, Fife, Glasgow City Region, South of Scotland and Western Isles) and local authorities in the rest of Scotland. Comparator populations will be drawn from local authorities in England that have not been implementing CWB. The different study components draw samples from these settings in various ways described in the sections for each work package in Sections 5 and 7.

7 ETHICAL AND REGULATORY COMPLIANCE

7.1 Assessment and management of risk

Risk registers have been completed using GCU standard forms for gaining sponsor support for the study and ethics approval for WP 1 and 2. Risks and mitigations were also identified in the detailed research plan submitted to NIHR.

The main risks relate to availability of data on the implementation of CWB, complexity of the relationships between the pathways that CWB is following and the potential health outcomes, and timescales for gaining ethical approval for the complex data linkage involved in WP3. These will be re-visited by the PMT during study implementation and any issues where mitigation is unsuccessful escalated to the SSC and/or NIHR as appropriate.

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

Regulatory Review & Compliance

The NHS Health Research Authority decision tool and discussion with NIHR confirmed that IRAS and NHS REC approvals are not needed for sites in England or Scotland as the study does not involve NHS patients, their carers, people who lack capacity to consent for themselves, any confidential patient information about use of services or any risk to patients.

An application for ethical approval for WPs 1 and 2 has been approved by Glasgow Caledonian University (GCU) School of Health and Life Sciences Research Ethics Committee (SHLS-REC) on 25th September 2025 (ref HLS/NCH/24/29). The approval has been ratified by Lancaster University Faculty of Health and Medicine Research Ethics Committee on 27th October 2025 (ref FHM-2025-5794-ExRev-1). The GCU REC ethical approval has also been sent to Co-Investigators in the University of Glasgow and GCPH. Approval will be renewed in the event of fundamental changes to the protocol.

Analyses in WP3 are scheduled to take place in Years 2 and 3 of the study and may involve accessing raw health survey data to take account of weighting and aggregation effects arising from survey design. The details of this are still being finalised and discussed with the survey providers. Ethical approval for these elements of the study will be sought from the GCU SHLS-REC in due course. Separate ethical approval will be required from the NHS Scotland Public Benefit and Privacy Panel for Health and Social Care for the data linkage element of the study in WP3a(ii). The protocols will be updated as these approvals are obtained.

WP4 will use data derived from the other work packages for which ethical approval will already have been sought, so we do not envisage further ethical approval being required.

Amendments

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

7.3 Peer review

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

The protocol has been reviewed by the research team and submitted to NIHR as part of the start-up requirements. A summary protocol relating to WPs 1 and 2 only was reviewed by the GCU SHLS-REC as part of the process of gaining ethical approval for those work packages.

7.4 Patient & Public Involvement

Public Involvement Panel

During the project, a Public Involvement Panel (PIP) of people from local organisations involved in CWB activities such as not-for-profit organisations, place-based social enterprises and small-to-medium businesses with fair employment schemes, will inform the design, delivery and dissemination of the project. The PIP will ensure that local organisations and businesses involved in CWB are engaged throughout the project. The Panel will comprise around 18 members identified with the help of national and local community anchor institutions, such as Social Enterprise Scotland, and CWB support initiatives in each local authority area. The Panel will meet in-person approximately six times

at key points during the 3-year duration of the project, at project locations across Scotland. The Panel will ensure that the project is shaped and informed by the expertise, voice, and perspective of people and business from the project locations and that the findings are meaningful and relevant to the real-world context of embedding CWB in local areas during roll out across Scotland. The Panel will contribute to decisions regarding recruitment approaches, data collection methods, analysis, and interpretation of data and findings. Meetings will be scheduled to ensure PIP members can influence key decisions and the overall direction of the study. All PIP members will receive reimbursement for sharing their expertise and time in line with NIHR guidance (54).

Co-Is McLean and Ahmed from the GCPH will lead the establishment, engagement and work of the PIP, building on their successful recent experience on the CommonHealth Assets (53) and CommonHealth Catalyst (55) projects, in which Co-I Baker was also involved.

The approach taken will draw on the SCDC National Standards for Community Engagement *(56)*, the UK Standards for Public Involvement *(57)* as well as the learning from the PI panels on the CommonHealth Assets and CommonHealth Catalyst projects. Our approach will also be informed by the What Works Scotland Public Engagement handbook *(58)* which highlights important considerations for engagement activities, including the creation of a safe environment for views to be shared without fear of judgement and utilising co-facilitation and co-delivery methods to ensure all participants are equally empowered to contribute.

7.5 Protocol compliance

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 safeguards put in place to avoid further 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.

7.6 Data protection and patient confidentiality

For the project as a whole, data will include meeting agenda/minutes, and project management information such as protocols, presentations and event information. For WPs 1 and 2. data will include contact information, consent forms, audio recordings, interview and workshop transcripts, questionnaire responses, and survey data.

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.

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

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/

Separate and additional data protection procedures will need to be set up and approved for WP3. These approvals will be sought in the first year of the project and the protocol will be updated accordingly once they have been obtained.

7.7 Indemnity

GCU, as sponsor, holds full Professional Indemnity Insurance to meet the potential legal liability of the sponsor for harm to participants arising from the management; design; and/or harm to participants of the research. Due to the nature of the project 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 requires partners to provide full indemnity in relation to their obligations to the research project. This indemnity must cover any and all liabilities, losses, costs, charges, and expenses incurred (whether directly or indirectly) by GCU as a result of any claims, demands, actions, or proceedings brought by the Authority. This indemnity must be equivalent to the level of indemnity that GCU provides.

7.8 Access to the final study dataset

Members of the research team will have access to the datasets derived from WP1 and 2. For WP3, a range of different datasets will be used, and linkages created, which have restrictions on access due to the potential identifiability and inadvertent disclosure of individuals. As a consequence, these analyses will need to take place within a secure environment where only named and approved researchers will have access.

There are no issues of blinding data in this study. Data storage, access and security are detailed in 7.6.

DISSEMINATION POLICY

8.1 Dissemination policy

8.1.1 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.

8.1.2 Outputs and publications

On completion of the study, we will produce a final study report, which will be peer reviewed and published in an open access journal.

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 the project, acknowledging the NIHR's financial support and carrying the following disclaimer as set out in the NIHR's research outputs and publications guidance: "The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care."

A plain English summary of findings will be made available on the project website and through social media and in hard copy. We will commission an animated film summarising the findings and implications of the research and a policy briefing for use by policy makers in Scotland, England and the devolved administrations of the UK.

8.2 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.

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