Developing Realist Economic Evaluation Methods (REEM) and Guidance to Evaluate the Impact, Costs, and Consequences of Complex Interventions

PROTOCOL

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Short Title

Realist Economic Evaluation Methods (REEM)

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Summary of research (abstract)

It is increasingly recognised that the 'big problems' in health and social care require well-designed complex solutions and robust evaluation, which itself is often complex. Realist evaluations were designed to take account of that complexity, offering an explanation of 'what works, for who, in which circumstances and why?'. Concurrently, policymakers and research funders require economic appraisals to accompany evaluations of complex interventions, to inform difficult decisions in the context of resource scarcity. However, economic evaluation methods often ignore context and do not capture variations in resource use or outcomes across groups, or recognise the implications this may have for the relationship between resource use and outcomes. Additionally, realist evaluations do not tend to explicitly capture the economic consequences of interventions. This research will develop realist economic

evaluation methods (REEM) and guidance to better understand and evaluate the costs and consequences of complex interventions. It will bring together realist and economic evaluation to enable evaluators to establish what works, for whom, in which circumstances, whist integrating better understanding of costs and consequences (including opportunity cost). This research addresses the following questions in three phases:

- Phase 1 (Months 0-12): What are the theoretical, methodological and practical similarities and differences between realist and economic evaluations? This phase will use literature scoping, online discussion boards (including short activities), and facilitated virtual meetings to develop provisional REEM guidance for piloting.
- Phase 2 (Months 13-30 months): What lessons can we learn from using REEM in practice to improve it? This phase will pilot REEM and investigate its feasibility in research across three evaluations.
- Phase 3 (Months 31–36): How can we use empirical and expert knowledge to produce consensus REEM guidance? This phase will use an online Delphi method followed by a Consensus Development Conference to agree the core elements of REEM and produce finalised guidance.

The outputs from this research will be REEM guidance, a checklist, and summary notes for use by PPIE members. These outputs will allow REEM to be utilised by academics and scrutinised by research funders. Additional outputs include: peer reviewed academic journal articles, conference presentations, webinars for research funders, policy makers and commissioners. Short term impact will be facilitated through: stakeholder involvement from the outset of the research, development of international academic networks, and established international academic reach. Long term impact will include the use of REEM to: make better-informed commissioning and policy decisions; reduce research waste, and better target interventions to those that need them.

Background and rationale

Health and social care require well-designed complex interventions and robust evaluation, which itself is often complex [1-4]. Interventions are considered to be complex for several reasons including but not limited to: the number of components of the intervention, the expertise or skills required to deliver or receive the intervention, the scale of the intervention (numbers of groups or settings), and the flexibility of intervention [1]. Complex interventions thus have many implications for evaluation, not least, embracing and accounting for complexity. Realist evaluation was designed to evaluate complex social interventions [5-7]. Realist approaches that evaluate how and why interventions are effective for different groups and in different settings have increasingly been used by applied researchers and research funders [e.g., [8, 9]]. The National Institute for Health Research (NIHR) Health and Social Care Delivery Research (HSDR) Programme alone currently has 15 active or contracted projects using realist approaches. Concurrently, policymakers and research funders require economic appraisals to accompany evaluations of complex interventions to inform difficult decisions in the context of resource scarcity. However, realist evaluations do not tend to explicitly capture the economic consequences of interventions [7]. Additionally, economic evaluation methods often ignore context and do not capture variations in resource use or outcomes across groups, or recognise the implications this may have for the relationship between resource use and outcomes[10-12]. For example, not only is there likely to be variability in outcomes between groups and communities receiving the intervention, but the resources required to achieve those outcomes will vary. It is further argued that the results of economic evaluations in health and social care are often poorly generalisable (transferable) and should take better account of the role of context, population variations, and the conceptual challenges of evaluating complex interventions [13-17]. Yet the actual methods of economic evaluation have made very few advances in these directions. This is despite the potential for more useful, context-sensitive approximations of the ‘cost’ of complex interventions. This represents a

methodological gap in the evaluation of complex interventions and a key limitation to providing applicable evidence for policy and service delivery [1, 2, 16, 17].

The update of Medical Research Council (MRC) guidance outlining a new framework for developing and evaluating complex interventions states that: "*complex intervention research goes beyond asking whether an intervention works in the sense of achieving its intended outcome—to asking a broader range of questions (e.g. identifying what other impact it has, assessing its value relative to the resources required to deliver it, theorising how it works, taking account of how it interacts with the context in which it is implemented, how it contributes to system change, and how the evidence can be used to support real world decision making)*" [[1], pg.1]. The new framework outlines 6 core phases of evaluation to be considered to answer the following questions: 1) how does the intervention interact with its context? 2) what is the underpinning programme theory? 3) how can diverse stakeholder perspectives be included in the research? 4) what are the main uncertainties? 5) how can the intervention be refined? 6) do the effects of the intervention justify its cost? Drawing heavily on realist and economic evaluation methods, the updated MRC framework represents a significant step in bringing together these disciplines. Yet how to do this and overcome the barriers presented by differences in underpinning epistemology, ontology, and academic disciplinary roots (which prevent simply combining such methods) is unclear.

Currently, there is very little literature, theoretical or applied, that integrates realist and economic evaluation [13]. Recent examples are limited to guidance for synthesising realist and economic evidence in health and criminal justice (EEMIE) [18], the theoretical development of economic informed programme theories [19], and most recently, the development of economically optimised programme theories [20]. More commonly, where realist and economic evaluations are undertaken together, they are done so in parallel or sequentially, with each using narrow discipline-specific guidance (e.g. RAMESES II Quality Standards for Realist Evaluation [21], ISPOR Good Research Practices for Cost-Effectiveness Analysis [22]), resulting in incomplete knowledge for policy and decision makers and limiting opportunities to share valuable learning between the evaluations.

Despite their different (implicit or explicit) ontological and epistemological bases, there is considerable potential for realist and economic evaluations not only to learn from each other but to be merged. Our research will advance understanding of how these approaches can be integrated and provide added value to evaluators, decision-makers and funders by developing a form of evaluation that both enables economic evaluation to become more context-sensitive and explanatory, and realist evaluations to better capture the role of resources and the opportunity costs.

We will achieve this through the development of REEM, including methodological guidance to better evaluate and understand the costs and consequences of complex interventions. It will integrate the core elements of realist and economic approaches to enable evaluators to establish what works, for whom, in which circumstances, whist integrating better understanding of costs and consequences (including opportunity cost). It is important to acknowledge here that there is no one single way to undertake a realist evaluation and no single economic evaluation approach, and therefore, we do not anticipate agreeing a singular highly protocolised approach to REEM. Instead, REEM can be considered as augmenting theory of change and action (realist evaluation) on one hand and the theory of value creation (economic evaluation) on the other [23].

Ultimately, REEM will provide a useful way to evaluate complex interventions and ultimately provide policy makers and commissioners with the integrated information needed to make better decisions which are applicable in the 'real world'. This will enable better informed commissioning about complex health, social and civil society initiatives and will also provide

added value for funders who recognise the importance of producing research findings that are context-sensitive and cumulative.

Research Questions, Aims, and Objectives

Research Question 1: What are the theoretical, methodological and practical similarities and differences between realist and economic evaluations?
Aim 1: To understand and develop REEM, principles, and applications.

- **Objective 1**. To scope and map the evidence about current approaches and advances in realist and economic analysis in complex evaluations.
- **Objective 2.** To agree on a set of common definitions and principles for REEM and how they might be applied in practice.
- **Objective 3.** To use the outputs from Objectives 1 and 2 to develop provisional REEM guidance for piloting and an accompanying framework to evaluate the feasibility and value of using REEM in practice.

Research Question 2: What lessons can we learn from using REEM in practice to improve it?
Aim 2: To apply and evaluate the feasibility and value of using REEM in practice.

- **Objective 4.** To pilot the application of methods guidance developed in Aim 1, Objective 3 and evaluate the feasibility of applying REEM in practice (in terms of strengths, weaknesses, application, outcomes and value, to inform further refinement).

Research Question 3: How can we use empirical and expert knowledge to produce consensus REEM guidance?
Aim 3: To refine REEM principles and develop guidance for wider application and further development.

- **Objective 5.** To synthesise the findings from Aims 1 and 2 and agree the core elements of REEM guidance; integrate into existing guidance, quality and reporting standards for evaluation of complex interventions; and highlight further opportunities for development.

Overall Research plan (including data collection, data analysis and sampling)

SET-UP PHASE [3 Months -3 to 0]: We will establish an International Interdisciplinary Advisory Group (IIAG) to provide disciplinary and applied expertise to oversee the research. The group will also challenge the research team, ensuring rigour and that the methodological developments are consistent with realist and economic principles held by other scholars beyond the project team, as well as with the policy and funding context. Membership of the IIAG will include a mix of internationally renowned academic experts in either health economic or realist evaluation, policy-makers, and research funders. As we progress the research, we will seek to expand membership of the IIAG to ensure representation in terms of method and geographical location, including adding partners from the pilot evaluation sites in Phase 2. In addition, we have PPIE embedded throughout all the phases, further details of which are outlined in the PPIE strategy.

PHASE 1: TO UNDERSTAND AND DEVELOP REEM, PRINCIPLES, AND APPLICATIONS [Months 0 to 12]. Addresses Research Question 1, Aim 1 (Objectives 1 to 3).

Objective 1: To scope and map the evidence about current approaches and advances in realist research and economic analysis when evaluating complex interventions.

Data Collection. We will undertake a scoping review to: identify the available evidence, gaps in knowledge, clarify key definitions, and examine *what* the theoretical and methodological barriers and facilitators to integrating these methods are. This will include finding examples of *how* programme theory has been applied in economic evaluations and *how* costs/resource

use and cost-effectiveness have been captured in realist evaluations [24]. The searches will gather guidance documents and studies to address four sub-questions:

a) What are the recent developments in methods/guidance recommended for economic evaluation of complex interventions in health and social care?
b) How are realist concepts i.e., programme or intervention theory or context-dependency (a description of the causal association between programme components, resources and outcomes) captured theoretically or applied in the conduct of economic evaluations, including any examples that have demonstrated this?
c) What are the recent developments/guidance recommended for realist evaluations of complex health and social care interventions?
d) How are economic concepts i.e., resource use/impacts, outcome valuation and opportunity costs of interventions, captured theoretically or applied in the conduct of realist evaluations including any examples which have demonstrated this?

We are aware that a modest amount of relevant methods guidance exists for realist evaluations and for economic evaluation of complex interventions (Questions (a) and (c)). Conventional literature searches for documents mentioning 'methods' would retrieve a large amount of mostly irrelevant results. We will therefore use search methods recommended for conducting reviews of methods papers [25, 26] to gather methods documents efficiently for Questions (a) and (c). First, we will gather key guidance, methods papers and chapters from our IIAG and project team members. We will identify further relevant sources using forward and backwards citation search techniques using Science and Social Science Citation Indexes (Web of Science) and Google Scholar. Finally, a focussed literature search of databases (Assia, Medline, EconLit, Web of Science databases) and a Google search will supplement our collection of methods guidance. Searches for Question (b) will aim to identify published and unpublished studies that have attempted to use realist concepts or programme theory within economic evaluation. The databases and sources will be the same as those outlined above. The initial search strategy will include the search terms 'programme theory', 'causal mechanisms' and 'intervention theory', combined with a purposive search for economic evaluations. Searches for Question (d) will identify published and unpublished realist evaluations that capture costs or resource use. Searches will run in the sources listed above, using the search term 'realist evaluation' and words, synonyms and index terms for 'costs' or 'resource use'. This approach ensures we will draw on research, experience, and knowledge across multiple disciplines and countries (published and grey literature sources, ongoing projects, and training materials). Searches will be peer-reviewed by an independent information specialist. For all searches, an iterative approach will be used; features and key words from initially included studies will be used to re-seed searches for relevant studies.

Draft searches developed as part of this proposal are available in the additional files. They indicate a manageable workload for the scoping review, generating the following approximate number of abstracts: A (300), B (1000), C (200), and D (300). Additional references will be found through contact with the IIAG and citation searching. Given the overlap in search terms used for each question we anticipate finding considerable duplicate records. EndNote software will be used to manage and remove duplicates. Studies will be coded for which question(s) they relate to, noting that some studies/reports will be relevant to more than one review. The reviews will be led by RAn and JW who bring expertise in reviewing and literature searching in economic and realist evaluations, plus methodology reviews. The review protocol will be registered with the Open Science Framework and the reporting will follow PRISMA ScR guidelines [27].

Summary and synthesis. There will be no formal or standardised quality assessment; instead, each source will be judged in terms of their clarity of reporting (especially methods/recommendations) and its contribution to the emerging synthesis. This will involve tabulating the main characteristics of included papers/sources, grouping them, identifying outliers/discrepant points/evidence, and discussing them initially within the research team.

We will use the findings from the scoping review to produce four briefing papers, addressing questions (a) to (d) posed above. These briefing papers will be presented for debate in the online discussion board and meetings described below (Objective 2).

Objective 2: To agree on a set of common definitions and principles for REEM and how they might be applied in practice.

Data collection. The briefing papers produced in Objective 1 will be presented to the wider research team and the IIAG and form the basis for discussion and debate on the following topics:

a) How epistemological and ontological commonalities and differences between realist and economic evaluation undermine or support and shape the theoretical development of REEM;
b) How realist and economic approaches/methods are applied in evaluations (particularly of complex interventions and systems) and how they can be combined pragmatically in the development of REEM. This will include critiquing previous/ongoing attempts.
c) The language (semantics and terminology) to be used in the description and definition of REEM.

Discussion and debate will be facilitated through:

a) An online moderated discussion board hosted via Microsoft Teams. The functionality of Microsoft Teams matches the demands of the research (i.e., sharing of files, images and links) and all members of the research team and IIAG are familiar and have prior experience of using it. PPIE members will be given training where necessary.
b) Short activities (e.g., white board think aloud exercises, JamBoard, research critiques, etc.) will be posted on the online discussion board. An in-depth review and critique of any particularly significant papers identified through the scoping review will be conducted.
c) Three facilitated recorded virtual meetings (max 2 hours each) to allow further/wider discussion and elaboration on the discussion board topics and facilitated short activities.

Data analysis. Thematic synthesis [28] will be used to further understand and analyse all qualitative data sources (online moderated discussion board, facilitated short activities, facilitated recorded virtual meetings). This approach is usually used to synthesise published primary research studies, however it will help us to understand findings across several data sources in this research phase, as outlined here. Furthermore, thematic synthesis was developed out of a need to conduct reviews of qualitative research that addressed questions relating to need, appropriateness and acceptability, as well as those relating to effectiveness [29]. Thematic synthesis has three stages: the coding of text 'line-by-line'; the development of 'descriptive themes'; and the generation of 'analytical themes'. The analytical themes represent a stage of interpretation whereby the reviewers (AB, SD and SRA) 'go beyond' the primary studies and generate new interpretive constructs, explanations or hypotheses. This approach will allow us to synthesise learning across all data sources to draw together common operational definitions of and principles for applying REEM.

Sampling. A purposive sample consisting of all members of the research team, the IIAG and PPIE members will be invited to participate at all stages of data collection and to reflect on the analysis.

Objective 3: To develop provisional REEM guidance for piloting and an accompanying framework to evaluate the feasibility and value of using REEM in practice.

Data collection. The results of the thematic synthesis will be presented in a 2-day workshop at the end of Year 1/start of Year 2. Participants at the workshop will be asked to reflect on these findings to:

a) finalise the common operational definitions and principles of what REEM are.

b) guide the design of provisional REEM guidance for piloting and agree strategies to evaluate the feasibility of using REEM in practice (in Phase 2).

Data Analysis. The intention at this phase is to collate all the views of all participants, rather than to try to reach consensus. We anticipate that there will be disagreements between participants but contend that consensus at this point is not necessarily useful; if we can identify where there is agreement and disagreement, identify causes and the nature of disagreements, we can propose responses to these (e.g., more than one definition, principle or strategy; piloting multiple strategies of REEM within pilot evaluations, etc.).

Sampling. A purposive sample consisting of all members of the research team, the IIAG and PPIE members will be invited to participate in the workshop. To reduce unnecessary travel and costs, the workshop will be held alongside international conferences that participants anticipate attending. Virtual attendance will also be offered as an alternative.

Phase 1 output. The results from each of the objectives will be written into discussion papers and peer-reviewed publications (co-authored by all participants) where appropriate. Furthermore, from these results, we will produce provisional guidance on how realist and economic evaluation methods can be integrated; common operational definitions and principles; and how these can be applied in practice. These will be tested in Phase 2.

PHASE 2: TO APPLY AND EVALUATE REEM, AND UNDERLYING PRINCIPLES IN PRACTICE [18 Months 13 to 30]. Addresses Research Question 2, Aim 2 (Objective 4).

Objective 4. To pilot the application of methods guidance developed Phase 1 and evaluate the feasibility of applying REEM in practice (in terms of strengths, weaknesses, application, outcomes and value, to inform further refinement).

In this Phase we will conduct three parallel pilot evaluations (detailed below) to test the feasibility and value of applying the provisional guidance of REEM (developed in Phase 1), to inform its refinement. These pilots have been selected on the basis that they reflect a range of health and social care interventions and varied geographical locations. Hence the resulting evaluations will test REEM across this range of interventions and sites. The evaluations will be running in the proposed research time frame and there are ongoing relationships with the evaluation partners. The pilot evaluations are:

- **An NHS prehabilitation programme (Waiting Well) for patients undergoing surgery (Led by Northumbria University in partnership with South Tees NHS Trust, Teesside. SD, AB, AF).** Waiting Well is a service delivered by South Tees Hospitals and Public Health South Tees which is designed to support patients in improving their fitness, health and wellbeing before a planned surgical operation or treatment.
- **An e-health maternity screening programme (C-it Du-it) in a low-income country context (in partnership with the Kenya Medical Research Institute (KEMRI), Nairobi. MK, SR, GWe).** C-it Du-it aims to improve access to antenatal sonography for low-income women in Nairobi and is an important part of the national strategy more widely in Kenya to reduce maternal and neonatal mortality.
- **A community enterprise café aimed at reducing social isolation and loneliness among Housing Association service users. (Led by the Yunus Centre at GCU in partnership with ImpactArts, Edinburgh. RB, CD, GWo).**
  This pilot evaluation will focus on Craft Café workshops. The Cafés are a safe, welcoming spaces for people to socialise and express their creativity, bridging the gap between care and housing support, to reduce social isolation and loneliness, and increase wellbeing.

Letters from the pilot evaluation site partners detailing their support are attached. Pilot evaluation partners will provide support to the research including: staff time to attend meetings related to the evaluations and research interviews, facilitating access to internal data,

brokering initial contact and access to services and individuals between the research team and the interventions being evaluated, and hosting or providing access to facilities for the Research Assistant (RA) where required. A RA will be recruited to each pilot site for the duration of each pilot evaluation. In addition, the Senior Research Assistant (SRA) based at Northumbria University will take a leading role in working closely with the other RAs as a point of contact throughout the evaluations, ensuring complementarity and optimising opportunities for learning across pilot sites and synthesising learning at the end. We will attempt to recruit a range of skills across the RAs and will provide additional methodological training (costed).

Data collection and analysis. REEM will be applied in each of the pilot evaluation sites using the provisional guidance developed in Phase 1, thus we cannot specify REEM in detail now. However, data collection in REEM will be driven by the realist programme theories generated in each pilot evaluation. Initial programme theories (IPTs) will drive subsequent data collection and analysis, as is usual practice in a realist evaluation [5]. Therefore, whilst it is not possible at this stage to state what data we will need to collect and thus how we will analyse it, we will draw on established methods of data collection and analysis commonly utilised in realist and economic evaluations (specified below). Primary and secondary data collection methods will be used generate qualitative and quantitative data to identify and test the causal mechanisms, contexts, and outcomes (CMOs) and the societal costs and consequences (positive and negative, intended and unintended) associated with the intervention in question. These methods are outlined in the following iterative and cyclical steps which incorporate the six core elements of the new MRC framework for developing and evaluating complex interventions [1]:

- **Step 1. Identify and define the scope/boundaries of the evaluation and stakeholders.**
  Data collection methods and data sources: literature scoping, documentary review and analysis, realist theory gleaning interviews, and participant observation.
- **Step 2. Develop initial programme theories identifying economic costs and consequences.**
  Data collection methods and data sources: stakeholder workshops.
- **Step 3. Test initial programme theories, measuring and valuing economic costs and consequences.**
  Data collection methods and data sources: realist refining interviews, routine health and social care data, outcome measurement and valuation, economic modelling.
- **Step 4. Refine REEM programme theories**
  Data collection methods and data sources: realist theory consolidation interviews, sensitivity analysis.

The specific methods of data collection and analysis adopted within the steps above will be decided in light of Phase 1 findings but our preliminary approaches are outlined below.

a) Realist interviews: (n=20 in each pilot evaluation). Realist theory gleaning, refining and consolidation interviews [30] with stakeholders (programme architects and/or implementers and those receiving the programme) will be used to provide a nuanced understanding of the generative mechanisms and associated contexts leading to outcomes (positive, negative, intended, and unintended). They will also allow elicitation of information about resource use and available cost data. We will adopt a realist purposive sampling strategy, which is determined through the programme theories to be investigated [13] for identifying programme theories. We will adhere to RAMESES II quality and reporting standards [21].

b) Stakeholder workshops: Two workshops will be held with the identified stakeholders. Workshop 1 will allow informal consultation with stakeholders (programme architects and implementers [30, 31]) to develop initial programme theories (IPTs). Initial explorations of the economic costs and consequences will be considered alongside the development of IPTs and will be further nuanced in Workshop 2. Though it is not possible at this stage to state what the costs and consequences will be (as they will be bound up in the development of the IPTs), in Workshop 2 we will seek to identify: direct and indirect costs

and consequences, relevant data sources, gaps in data, and suitable approaches to valuation of consequences and outcomes, etc.

c) **Realist Analysis:** Realist interviews [30] and stakeholder workshops will be transcribed verbatim and imported into NVivo. All qualitative data will be analysed in Nvivo using a realist CMO lens [32]. Analysis will move iteratively between analysis of particular examples, refinement of programme theory, and further iterative searching for data to test [33]. Throughout the data collection period, the pilot evaluation teams will partake in a deeply reflexive, iterative data analysis approach, to spark insight and develop meaning [34]. It consists of multiple rounds, revisiting the data as new additional questions emerge and connections are established, thus deepening the understanding and meaning of the findings
d) **Administrative data:** Pilot site administrative data sets will be used to extract both cost and outcome data. Participant records from the pilot evaluations will be accessed through the pilot evaluation sites and pseudonymised data will be transferred to the research team in Microsoft Excel. Data will be analysed using SPSS or Stata, as appropriate.
e) **Routine health and social care data:** Routine health and social care data sources (such as Hospital Episode Statistics, Secondary Uses Service, NHS reference costs, and unit costs of health and social care (PSSRU)) will be used to analyse cost and outcome data, where available and necessary. Data will be extracted from routine data sources using standardised codes. Version control will be applied to the datasets.
f) **Participant surveys or proforma:** will be used to supplement cost and outcome data collection. This may include: validated measures of health, quality of life, wellbeing, or capabilities (where relevant), standardised participant costing proforma, and in(direct) outcome valuation methods such as stated preference measures (e.g. discrete choice experiments, willingness to pay).
g) **Economic modelling:** Economic models may be used in this phase to depict the complexity of the intervention, using insights drawn from the realist analysis to define and compare the model pathways and parameters and capture the associated costs and consequences. The choice of model will vary between the evaluation sites and will depend on the final evaluation question and data generated earlier stages of the evaluation. Examples of cohort or individual-based models more suited to complex interventions include system dynamic models, agent-based models, and social network models [35].

The pilot evaluation partners will work closely with the research team and have costed for their time to do so. The project partners will act as the gatekeepers to recruit participants for the evaluation. They will distribute the participant information and gain consent. The contact details of the RA at each of the pilot evaluation sites will be shared and participants will opt in.

The pilot evaluation partners will receive a full final evaluation report and be offered co-authorship on subsequent outputs. Participants will be asked if and how they would like to be informed of the evaluation findings (full report, lay summary), provided via email or hardcopy.

Phase 2 output: Lessons on the application of REEM from the pilot evaluation sites will be brought together in a discussion paper and used to update the provisional REEM guidance in line with these lessons. This will be circulated to the IIAG and used as a basis to develop methodological guidance in Phase 3. In addition, the pilot evaluation reports will be shared with project partners and published in peer reviewed journals.

PHASE 3: TO REFINE REEM AND PRINCIPLES, AND DEVELOP GUIDANCE FOR WIDER APPLICATION AND FURTHER DEVELOPMENT [6 Months 30 to 36]. Addresses research question 3, Aim 3, Objective 5.

Objective 5: To synthesise the findings from Aims 1 and 2 and agree the core elements of REEM guidance; integrate into existing guidance, quality and reporting standards

for evaluation of complex interventions; and highlight further opportunities for development.

Data Collection. We will use an online Delphi method followed by a Consensus Development Conference (CDC) [36] to synthesise the outputs from Phases 1 and 2 and agree the core requirements for integrating and applying REEM in practice. We reviewed several deliberative consensus development methods including the Delphi Method, the RAND/UCL appropriateness method, Nominal Group Techniques and the CDC. Due to the infancy of REEM and the two different approaches of realist and economic evaluators, we believe that it will be more conducive to have complex discussions and agree consensus in person and thus propose the addition of the CDC, where iterative feedback is generated through several rounds of group discussion, which will build on the Delphi.

We will use an online Delphi method which has previously been successfully used to develop quality and reporting standards in the RAMESES II [21]. The Delphi panel will be run online in 2 rounds (or more if required) using Survey Jisc or similar. In round 1, panel participants will be provided with briefing materials including the updated version of the provisional REEM guidance from Phase 2 and invited to rate the importance of each updated item in the REEM guidance. Participants will also be given opportunities to provide additional suggestions for revisions or new items which will form the basis of the beginning of discussions in the CDC (below). Responses will be analysed (as below) and fed into the design of questionnaire items for round 2. In round 2, participants will be asked to rank each potential item twice on a Likert scale (strongly disagree to strongly agree), to agree 1) which are relevant (i.e., should an item on this theme/topic be included at all in the guidance?), and 2) item definitions (i.e., to what extent do you agree with the specific wording for the guidance?). Those who agree that an item is relevant, but disagree with the definition/wording, will be invited to suggest changes via a free-text comments box. In this second round, participants will again be invited to suggest additional topic areas and items which will be further discussed in the CDC.

The online Delphi will be followed by a CDC. The CDC is a rapid data synthesis method used for the collation of balanced advice about a technology or approach, and for the definition of the need for further information and research [37]. The aim of the CDC will be to achieve consensus amongst members of the CDC, who come from different epistemological backgrounds. We believe that achieving consensus will benefit from in-person discussion and have costed for this to be conducted as a 2-day face-to-face meeting. To reduce unnecessary travel and costs, the CDC will be held alongside international conferences that members anticipate attending. However, it can also be delivered entirely virtually using online consensus methods if required. Following analysis, the results of the Delphi will be fed into the CDC for further discussion with the project team and IIAG. The CDC will involve reviewing the results of the Delphi and further rounds of moderated discussion for items where consensus was not reached through the Delphi. AB and SD, along with the SRA, will chair and facilitate the CDC using audio recording alongside extensive notes and live editing of the REEM guidance on a large screen for members to view, consider and input further. The CDC will use reflective practice [38] drawing on the Theory of Consensus [39] to consider REEM guidance and engage in a process of continuous learning from one another to reach consensus. Throughout the CDC, SD and AB will articulate proposals related to specific parts of REEM guidance and facilitate the 'process model of consensus building' outlined in Figure 2. Use of this model will allow participants to reflect on their experience and expertise, drawing in values and theories which inform their approach, to lead towards informed consensus (or disagreement) for REEM guidance. Using reflective practice and the process model of consensus building AB and SD will draw together arguments, synthesise and reflect these back to participants, highlighting potential consensus and disagreement. Using a cyclical reflection process will allow participants' arguments to be conveyed back to them to move towards consensus. We plan to report residual non-consensus and the nature of the dissent described. Making such dissent explicit tends to expose inherent ambiguities (which may be philosophical or practical) and acknowledges that not everything can be resolved; such findings may be more use to those who use REEM.

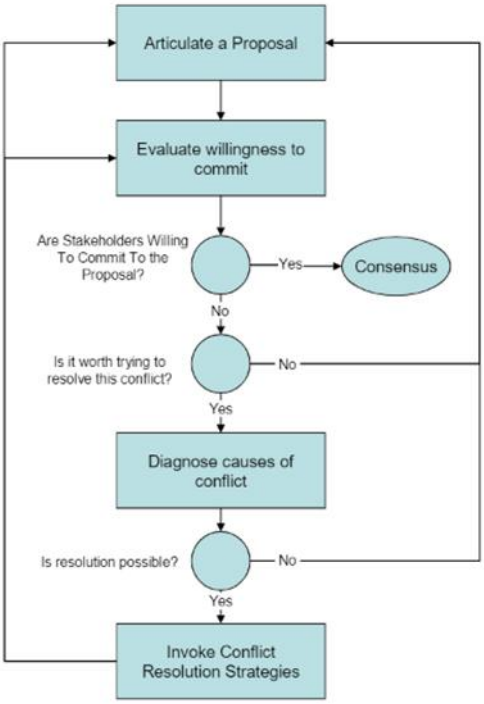

Figure 2. A process model of consensus building to be used in CDC (a rectangle indicates an activity, a circle a decision).

Data Analysis. For the online Delphi, each participant's responses will be collated and the numerical rankings entered onto an Excel spreadsheet. The response rate, average, mode, median and IQR for each participant's response to each item will be calculated. Items that score low on relevance will be omitted from subsequent rounds. We will invite further online discussion on items that score high on relevance but low on validity (indicating that a rephrased version of the item may be needed) and on those where there was wide disagreement about relevance or validity. The panel members' free text comments will also be collated and analysed thematically. Consensus will be considered reached in each Delphi round if at least 70% of the participants strongly agree/disagree [40]. The results of the vote will be written into any subsequent publications in order to show transparency in agreement

(or disagreement). Where agreement is not reached or there are suggestions for altered or new items, these will be debated further in the CDC. Where disagreement is high then this will be detailed thoroughly in subsequent reports and publications [37].

The final template will be agreed within the CDC but also distributed to participants for approval after the CDC, allowing for time for further reflection.

Sampling. The Delphi panel will include members of the research team, the IIAG and participation will be widened to include a further 20 people identified as key academics from papers identified in the scoping synthesis, (a minimum of 40 potential participants in total). The CDC participants will include a purposive sample of the research team, members of the IIAG, project partners and PPIE members who will all be invited to join.

Phase 3 output. The agreed and finalised guidance will outline the definitions, principles, and methodological quality of REEM with respect to a) planning, b) conducting, and c) reporting. We recognise that any REEM guidance should facilitate fidelity in the application of REEM, whilst also allowing diversity in methods and the continuation of its development, rather than imposing rigid methods. To ensure that REEM are subsequently used in practice, we will compile a REEM checklist similar to the updated CHEERS II Statement [41] and produce summary notes for PPIE members. We will share the findings with research funders, policymakers, and academics (see dissemination strategy). Furthermore, we will ensure that the guidance is integrated in line with further developments of the RAMESES project [21], MRC Complex Intervention Guidance [1], and CHEERS II Statement [41].

Dissemination Strategy and Outputs

We have identified our primary audience (academics, research funders, policymakers and commissioners) prior to attaining funding and invited them to input into the research via the IIAG. This means that they will be involved from the planning of the study through to dissemination, with regular communication and input (online discussion boards, regular emails, virtual meetings) throughout the research, across all three phases.

A range of targeted outputs will be produced to correspond with the identified research users:

- The primary outputs will include the REEM guidance, checklist and the summary notes for use by PPIE members. These outputs will allow REEM to be utilised by academics and scrutinised by research funders. A webinar will be hosted for research funders, policymakers and commissioners (beyond those involved in the IIAG) to promote the REEM Guidance, check list and PPIE guidance notes. Funders with whom the research team have worked with (including: MRC, ESRC, NIHR, CSO, The Health Foundation) will be invited, amongst others (such as the Association of Medical Research Charities) and those in local health and social care commissioning (networks contacted through the IIAG).
- We will ensure that the guidance is integrated in line with further developments of the RAMESES project [21], MRC Complex Intervention Guidance [1], and CHEERS II Statement [41].
- PPIE guidance notes will be co-produced with PPIE members and shared in a webinar via PPIE networks (e.g. the ARC NENC Public Advisory Network and the Fuse (Centre for Translational Research in Public Health) Public Involvement and Engagement Committee.
- In addition to the final report, the outputs from all three Phases will be published in leading peer-reviewed journals in health economics and evaluation, notably Value in Health and Social Science and Medicine.
- Abstracts will be submitted to national and international conferences in realist and health economic methods (such as International Realist Research, International Health Economic Association, and Health Economists Study Group). In addition, REEM workshops at these conferences will be scheduled within 2 years of the conclusion of the study.

- We will develop and maintain a research website and host an online seminar to disseminate the results and promote the outputs listed in this section. Social media channels including Twitter, and the active international RAMESES JISCmail and Health Economics distribution lists, will be used to promote the research and outputs.
- The research team will seek further funding to test the principles of REEM in future empirical work outside of health and social care and further build and develop our relationships and activities with key stakeholders (e.g. policymakers) to ensure REEM is used, useful and useable.

The research team has established and strong links with several international realist and economic research groups important disseminating this research including the RAMESES project and RAMESES JISCMail listserv which has over 1296 realist researchers world-wide, The Realist Research Evaluation and Learning Initiative at Charles Darwin University, Northern Realist Research Team Hub (NoRTH), Fuse (The Centre for Translational Research in Public Health), a UK Clinical Research Collaboration (UKCRC) Centre of Public Health Research Excellence, ARC NENC, Health Economists' Study Group and International Health Economics Association. In addition, IIAG members are in a position to promote and disseminate REEM through established networks, with discussion papers being developed into workshops, seminars and publications where appropriate.

Project management and timetable

SD and AB will jointly manage the project to ensure sufficient representation of realist and economic expertise. This will be achieved through 2 weekly meetings with the SRA, and 2 monthly co-applicant meetings. Regular monthly mentoring meetings will also take place with CD and Gwo throughout the research, with capacity to add ad-hoc meetings where necessary. In Phase 2, SD and AB will also meet with the pilot evaluation RAs and leads (MK and RB) once every two weeks, to ensure progress and capture feedback. A detailed timetable is outlined below:

Timetable (36 Months. Start 01 September 2022).

Month	Activities	Events
-3-0	Set-up Phase. Convene IIAG and PPIE members. Seek ethical approvals. Recruit SRA. Submit study protocol.	Research Team meeting
1-5	Phase 1. Objective 1. Conduct literature scoping and narrative synthesis analysis. Findings to be written into briefing papers.	Launch Meet (M1)
6-11	Phase 1. Objective 2. Share briefing papers, conduct short online activities (JamBoards, reviews of papers etc) and host 3 virtual meetings with research team, IIAG, and PPIE members. Synthesise learning across all data sources to draw together common operational definitions of and principles for applying REEM.	3 virtual meetings (M6,8,10)
10-12	Phase 2. Objective 4. Set-up of pilot evaluation sites with project partners. Recruit RAs. Seek ethical approvals.	
12	Phase 1. Objective 3. Host 2-day workshop with research team, IIAG, and PPIE members to finalise the common operational definitions and principles of REEM and agree strategies to evaluate the feasibility of using REEM in practice (in Phase 2). Produce provisional guidance for applying REEM.	2-day IIAG workshop
13-15	Phase 2. Objective 4. Evaluation Step 1. Identify and define scope/boundaries of the evaluation through literature scoping, documentary review and analysis, realist theory gleaning interviews, and participant observation.	Training for RAs. Virtual meetings with project partners

16-18	Phase 2. Objective 4. Evaluation Step 2. Develop programme theory and identify possible economics costs and consequences through stakeholder workshops	
19-24	Phase 2. Objective 4. Evaluation Step 3. Test programme theories and measure and value the economic costs and consequences through realist theory refining interviews, routine health and social care data, direct and indirect valuation methods, validated outcome measures, economic modelling.	
25-27	Phase 2. Objective 4. Evaluation Step 4. Refine programme theory through realist theory consolidation interviews.	
27-30	Draw together findings and share with project partners. Produce discussion paper regarding the application of REEM and update provisional guidance in line with the lessons learnt from the pilot evaluations.	
31	Phase 3. Objective 5. Circulate the updated provisional REEM guidance	
32	Phase 3. Objective 5. Refine and develop guidance 2-day CDC and Delphi	2-day CDC
33	Phase 3. Objective 5. Circulate final guidance to IIAG and research team for final reflection	
34-36	Finalise framework and guidance; produce final report for HSDR.	

Ethics

Ethical approval will be sought from Northumbria University Ethical Approval System for the full project, excluding Pilot Evaluations 2 and 3 (Phase 2). Ethical approval for the Pilots will be sought from their respective institutional ethical review panels, namely: Strathmore University Institutional Review Board and Glasgow Caledonian University School of Health and Life Sciences Ethics Panel, and the Health Research Authority Research Ethics Service for data collection involving NHS staff or patient data where applicable. All research and the pilot evaluations will be conducted in line with ethical principles of anonymity and confidentiality, and all participants will have to provide informed consent to participate.

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Waiting Well:
Protocol for a Realist Economic Evaluation

Contents

General info

Title: Waiting Well: A Realist Economic Evaluation

Pilot study as part of *Developing Realist Economic Evaluation Methods (REEM) and Guidance to Evaluate the Effectiveness, Costs, and Benefits of Complex Interventions*

Funder: NIHR Health and Social Care Delivery Research programme (Award ID: NIHR135102)

Term: November 2023 – November 2024 (pilot study only)

https://www.realist-economic.co.uk/

Participating organisations and key people

NECS

- Karen Lane, Project Manager delivering WW for Durham and Tees Valley ICB

North Tees WW

- Dr Esther Mireku, Project Manager
- Tess Moore, Service Delivery Manager

South Tees WW

- Esther Carr, Project Manager
- Professor Gerard Danjoux, Project Manager

People of interest (to be identified)

- Social Prescribing Link Workers; Health and Wellbeing Coaches; community organisation (to which service users are referred) leads; service users
- Patient and Public Involvement and Engagement (PPIE) representatives, who will work with the REEM PPIE team

Northumbria University

- Dr Andy Fletcher, Research Fellow
- Profs. Sonia Dalkin & Angela Bate, REEM Principal Investigators

Background and rationale

Complex interventions require complex evaluation. Realist evaluations aim to offer explanations of 'what works, for who, in which circumstances and why?' Policymakers and research funders also require economic evaluations to inform decisions on resource use. However, realist evaluations tend not to explicitly capture the economic consequences of interventions, while economic evaluation methods often ignore context. This research combines realist and economic evaluation (REE) approaches to establish what works, for who, in which circumstances, why, and with what related resource impacts and opportunity costs. The overarching aim is to develop a set of guidance that can be used by other evaluators to conduct realist economic evaluations of complex programmes or interventions. As part of this, the Waiting Well evaluation will develop our previous methodological work in a real-world setting by conducting a realist economic evaluation of the Waiting Well programmes in North and South Tees.

Waiting Well uses a social prescribing approach that aims to improve health and wellbeing for people on elective surgical waiting lists. This can yield multiple benefits, including addressing social inequality, improving health in an ageing population, and improving surgical outcomes, such as faster recovery and spending less time in hospital.

"An intervention is conceived to be complex either (1) because of the characteristics of the intervention itself, for example multiple components or mechanisms of change, and/or (2) because how the intervention generates outcomes is dependent on exogenous factors, including the characteristics of recipients, and/or the context or system within which it is implemented" (Skivington et al., 2021). Waiting Well is inherently complex, targeting a population with various health and social needs. A single integrated evaluation would therefore enable insights into why/how Waiting Well works (and for whom, etc.) and its economic implications. Establishing which components of Waiting Well lead to successful outcomes would help to make the programme more effective and efficient.

Waiting Well

Emerging from the 'Prepwell' prehabilitation initiative, the Waiting Well programme seeks to improve the mental and physical wellbeing of patients in the lowest IMD deciles (1-4) who are on three-month+ waiting lists for elective surgery. Based on a social prescribing model, WW makes use of services in the local communities. The North East North Cumbria (NENC) Integrated Care Board has invested £7.4m to deliver WW over three years.

North Tees and Hartlepool NHS FT

Patients are referred to a range of existing community services. There is also a digital offer, 'Surgery Hero', https://www.surgeryhero.com/.

South Tees Hospitals NHS FT

Patients are referred to specific Waiting Well services, including Benefits advice/support, housing, weight management, pain management (https://www.flippinpain.co.uk/), medicines management (opioid reduction), psychological support, healthy eating on a budget (run in conjunction with local colleges), exercise and education (preparing for surgery), social support, and Surgery Hero.

WW has been running for longer in North Tees than in South Tees, but the community services in South Tees are more integrated, due to a collaboration agreement between secondary care (South Tees NHS FT) and the Public Health team across South Tees.

For REEM

This study has two functions: 1) testing the draft REE guidance; and 2) to achieve this, we will be undertaking an evaluation of the different ways that the WW programme is delivered in North and South Tees, as pilot evaluation sites. For example, by focusing on the tailoring (or not) of services for those awaiting surgery.

Study aims and objectives

Aims

A) To determine the best ways of delivering Waiting Well.
B) To field-test the draft REE guidance.

Objectives

A) Define and describe WW programme in South and North Tees with staff who deliver it (Guidance section 3)
B) Revisit the evaluation question and refine in light of a more detailed understanding each of the interventions (Guidance section 5)
C) Generate initial realist economic programme theories (iREPTs) about how WW 'works', for who, in which circumstances and why, and with what related resource impacts and opportunity costs, in both South and North Tees (Guidance section 6)
D) If necessary, prioritise iREPTs with stakeholders to ensure the most important are 'tested' in the evaluation (Guidance, section 7)
E) Consider specifics of data collection; understand what quantitative data is already available and whether this needs to be supplemented in light of the iREPTs (Guidance, section 8)
F) Formulate data collection methods that will work together to provide a complete evaluation picture (Guidance, section 8)
G) Collect data to test the iREPTs (Guidance, section 9)
H) Test and refine iREPTs using the data collected (qualitative and quantitative) (Guidance, section 10)
I) Follow the draft REE guidance throughout the evaluation, populating the pilot evaluation tool, which has been created to detail progress through each stage of the guidance.

Evaluation question

Primary research question

The overarching evaluation question is, *what are the best way(s) of delivering Waiting Well?*

In REE terms, this may be addressed by considering: *What are the comparative **mechanisms** that are triggered by different ways of delivering the **intervention**, and what are the associated differences in **resources** and **outcomes**, in what **contexts**?*

Secondary research question

The *process* of addressing the primary question will help the research team to 'test' the REEM guidance it has been developing. Therefore, the secondary research question is: *Can this evaluation be conducted in a meaningful way by following the draft REEM guidance? What are the helps and hinderances, and how might these be used to improve the REEM guidance?*

Research design

This study will be conducted as a Realist Economic Evaluation (REE) and will follow the recently developed guidance (https://northumbriaknowledgebank.flintbox.com/technologies/3db4bb2a-3667-4328-bab3-66fc40242f36). In practice, this type of evaluation is iterative, and the research

design will reflect this, with refinements occurring as the evaluation develops. To meet the objectives outlined above, the research will be conducted in the following phases detailed below and in Table 1.

Table 1: Mapping of Evaluation Phases, Objectives and Guidance

Phase of Research Plan	Objective	Guidance section
Pre-setup	N/A	1, 2
Phase 1	A, B	3, 4, 5
Phase 2	C, D	6, 7
Phase 3	E, F	8
Phase 4	G, H	9, 10
Phase 5	I	N/A

Pre-setup

Aligns with guidance sections 1 and 2

Being part of the wider development of the REEM guidance, the purpose of this evaluation and identification of team members (from both REEM and Waiting Well) are already established. The collaboration agreement between Northumbria University and the relevant NHS trusts is in place, and ethical applications are in progress.

Public and Patient Involvement and Experience (PPIE)

The wider REEM project has an established PPIE group and will also involve local PPIE representatives from Waiting Well. Individual members will be identified as soon as possible after a favourable ethical opinion is received and Waiting Well PPIE activity is likely to involve:

Three individuals, male and female, with at least one from each study site. They will be asked to review our developed interview / focus group protocols and reflect on their experiences of Waiting Well and their understanding of the purposes of this evaluation. They will also be considered part of the evaluation team, as described in the draft guidance, part 2b. There will be two 90 minute meetings (with some preparation) in 2024, discussing the above. The PPIE will also be involved in prioritising different aspects of the research and sense checking the research team's interpretations of the data. One of these meetings will be with the core REEM PPIE group in September 2024.

Waiting Well PPIE members will be remunerated at the NIHR rate: *£75 - For involvement in a task or activity where preparation is required and which equates to approximately half a day's activity. For example, participating in a meeting to interview candidates who have applied to join a committee, participating in a focus group, or delivering training*. Further information available here: https://www.nihr.ac.uk/documents/nihr-public-contributor-payment-policy/31626#rates-of-payment

Phase 1. Mapping the Waiting Well programme (Jan-Mar 2024)

Aligns with objectives A and B (Guidance sections 3, 4 and 5)

Initial literature searching on social prescribing has begun, as well as consultation and mapping to understand the Waiting Well programmes and determine detailed information for ethics applications. Patient journeys will also be checked with PPIE group members, to ensure this reflects their experience. This mapping will support the refinement of the REE evaluative question.

Data collection: mapping data will be generated through informal consultation with WW leads and analysis of internal documents (such as patient pathways and minimum datasets), and academic and grey literature.

Data analysis: produce patient journey maps using Miro, an online collaboration tool, to be built upon and refined through informal meetings. This information will guide literature searching and reviewing, helping to generate a more detailed causal pathway/system diagram, including the ultimate outcomes of interest. Mapping will determine what the evaluation can capture with the time and resources available.

Samples: WW leads including KL, EM, TM, EC, GD. Consent not required.

Phase 2. Generate initial Realist Economic Programme Theories (iREPTs) (Mar-Apr)

Aligns with objective C and D (Guidance sections 6 and 7)

iREPTs articulate theorised comparative configurations (between the two study sites) involving context, intervention, resources, mechanisms, and outcomes. These will be developed in line with the REE guidance and the REE evaluation question, as above. Specifically, the iREPTs will describe the relationships between context, mechanisms and outcomes, and the five different types of resources that are at play within each of these. This differs from phase 1, as it explicitly draws on REE constructs and heuristics to develop the realist economic evaluation theories.

Data collection: informal in-person stakeholder consultation with WW leads. AF will meet the WW teams at each site to discuss programme maps and develop clear descriptions of the components of interest in each programme, including proximal and distal outcomes. The team will discuss theories, based on their own observations, of how outcomes are generated. These and potential alternatives will develop through ongoing discussion, literature and emerging knowledge based on the patient feedback and routinely collected data (minimal datasets) currently being returned.

Samples: WW project managers and frontline delivery staff, e.g. Social Prescribing Link Workers, Health and Wellbeing Coaches; community organisation leads if possible. At this stage, conversations with staff will be informal, as the development of iREPTs will determine the more specific data to be collected in later phases.

Data analysis: documentary analysis, literature review, quantitative analysis of WW routine data / minimal datasets (following positive opinion) and any data on resource use.

iREPTs will be configured in line with the evaluation question: *what Mechanisms are triggered by the different ways of delivering the programme (for whom and in what contexts) and what are the associated differences in the economic Resources and economic Outcomes (costs and benefits), for whom and in what Contexts?* Further discussion and development will reveal which iREPT/s, or elements thereof, are testable given the available resources (access to data, time horizons, team

capacity and estimated sample sizes). The type of data and the data collection/generation methods will be agreed collectively, including where possible with PPIE group members. Organising meetings and setting iREPT-specific milestones (accounting for slippage as iREPTs evolve) with WW team members will ensure feasibility and overall agreement of boundaries.

iREPTs are fluid and will also be informed by the ongoing literature review, emerging information about WW, and the team's evolving perceptions and understanding of the programme. Analysis will be determined to some extent by the potentially disparate evidence, which needs to be synthesised in a way that addresses the evaluation question.

PPIE and key stakeholders will be consulted to understand which iREPTs should be prioritised in the evaluation if it should be found that there are too many to evaluate comprehensively.

Phase 3. Use iREPTs to refine study design and data collection methods (Apr-May)

Aligns with objectives E & F (Guidance section 8)

Based on the iREPTs, study design will be confirmed, which will include all types of evidence necessary to enable the identification, measurement, and valuation of outcomes that are comparable across the intervention and comparator(s) to enable the assessment of opportunity cost. A broad range of methods is likely to be required to collect the relevant data and evidence needed to test the iREPTs. A range of mixed and multiple data collection methods, drawing on both primary and secondary data, will be used to increase the robustness of the iREPT 'testing' process (see below for indication of data collection).

Phase 4. Test iREPTs (May-Sep)

Aligns with objectives G and H (Guidance section 9 and 10)

Programme Theories will be tested (refuted, refined, supported) through embedded research (AF onsite at North and South Tees, one day each per week) and ongoing iterative data analysis. We are interested in the contexts and mechanisms that lead to changes in wellbeing, so interview and focus group protocols will be oriented around this. Early work will entail organising interviews and focus groups.

At this point we cannot be specific about the data requirements, as this will be determined by the iREPTs. Methods selection will be pragmatic, guided by the data required to address the programme theories. As an example, we anticipate using the following methods:

Interviews/focus groups

Data collection: The following stepwise process will be the *likely* approach to data collection, with the finer details being determined by the emerging iREPTs , as per the methodological guidance:

1. Estimate the number of patients to be approached by Waiting Well at each study site during the fieldwork period
2. Give flyer and Participant Information Sheet (see appendix) to prospective participants on first approach by WW. If they are willing to be contacted for this study, WW staff to gather contact details and pass to researcher (AF). These materials will have been examined for clarity and accessibility by the Waiting Well PPIE group.

3. Researcher to contact participant within one week of first approach by WW staff, to give more details of the study, answer any questions, and share consent form (see appendix).
4. Organise first meeting/interview (by phone, online or in person). Once written consent is given, verbal consent will be taken at each subsequent contact (ongoing consent).
5. Second interview (if possible and/or necessary) to be arranged after engagement with the programme or social prescribing activity. Patients will also be asked if they wish to participate in a focus group with other patients and Waiting Well staff.
6. Aiming to interview 25 service user participants per site over 6-7 months, based on about 70 going through WW each year.
7. Concomitant mixed focus groups (including patients, WW staff and community organisation leads) will allow for group reasoning and deliberation of emerging iREPTs.

Sample: patients; WW project managers and frontline delivery staff, e.g. Social Prescribing Link Workers, Health and Wellbeing Coaches; community organisation leads and facilitators.

Sampling of patients will be mainly opportunistic (i.e. who is present and willing to participate), but may also be purposive, driven by the iREPTs. For example, if an iREPT indicates exploration of a theory from the perspective of a particular demographic group, then a conscious effort would be made to recruit more people from that group. **Sample size** is predicated on "ability to maximise variability in context and implementation variables and also to iteratively focus attention on key contexts and mechanisms relevant to the developing theories" (Johnston & Campbell, 2018). For qualitative research, Hennink and Kaiser (2022) found saturation was reached after 9–17 interviews or 4–8 focus groups. However, realist evaluators are less interested in 'saturation' and sample sizes will instead be determined by iREPTs and opportunity.

Recruitment. Participants will be given a flyer about the research by a Social Prescriber or other member of the Waiting Well Team. They will be asked if they can take their details (name, phone number and email address) to pass on to the research team. If the person says yes, then the details will be sent to Andrew Fletcher (Research Fellow) via email. If they say no, but may still be interested or change their mind, the details are on the flyer which they can take home with them, so they can opt in later. We will also display flyers in the waiting rooms of the Waiting Well teams, for people to opt in.

Data analysis: qualitative interview/focus group data will undergo REE analysis (oriented towards uncovering causal explanations for outcomes and highlighting resources throughout the Context-Mechansim-Outcome configuration), using NVivo qualitative data analysis software (guided by Dalkin *et al*. 2020). Theory development, especially any changes that might require different data to be gathered, will be documented, generating an audit trail of how decisions were made during the evaluation. Attention will be paid to how disparate evidence can be combined to generate a 'jigsaw' explanation of how the programme is working. Ongoing consideration of iREPTs will determine if the data can adequately serve the evaluation question or if further evidence is needed.

Quantitative outcome data

Data collection: The study will also gather routine and administrative data from the programme and/or partner organisations, as well as service use tracking and bottom-up costing. The minimum datasets, already collected by the WW teams using a range of tools (EQ-5D plus some qualitative patient feedback), cover pre- & post-WW, 12-weeks, and pre-surgery. Additional measures (e.g.

Patient Activation Measure, a capability approach, the ICECAP-A questionnaire, or Personal Wellbeing ONS4) may help to create a fuller picture of participants' health and wellbeing, and further contribute to the economic analysis. These will be discussed with WW leads and added to routine data collection where necessary and possible.

Data analysis: The range of other evidence types gathered will determine the analytic approach required to collate the data with a view to refining and reporting programme theories. Quantitative wellbeing data (collected by WW teams) is likely to be analysed using the WELLBY approach (https://assets.publishing.service.gov.uk/media/60fa9169d3bf7f0448719daf/Wellbeing_guidance_for_appraisal_-_supplementary_Green_Book_guidance.pdf).

Data will be managed in Excel and version control will be applied to datasets. Analytic methods will be determined by the data collected but are likely to involve a range of statistical parametric and non-parametric tests, regression analyses and modelling. SPSS or STATA will be used as appropriate, guided by co-principal investigator, Angela Bate, a health economist. This will be subject to appropriate data sharing and governance arrangements and all such data will be pseudonymised. We will process the data accordingly and in line with the qualitative and quantitative data analysis plans above.

Phase 5. Secondary research question

Aligns with objective I

Although stated chronologically as last, this Phase will take place throughout all the previously described Phases (1-4). For each Phase and point in the guidance, the researcher/s will document what happened and how, detailing any barriers/facilitators.

Data collection: A 'pilot tool' (a form of reflective diary, structured around the draft REE guidance) is being used to record any changes to the evaluative question and the reasons why, as well as the researcher(s) experiences of following the guidance.

Data analysis: Experiences of researchers who are using the REE guidance in other pilot evaluations will be discussed in monthly meetings, where we expect to discuss and use the data from the pilot tools to synthesise learning about a) REEM as a methodology (how do you do it) and b) the REEM guidance (the document that tells people how to do it).

This data will be used to inform the secondary research question: *Can this evaluation be conducted in a meaningful way by following the draft REEM guidance? What are the helps and hinderances, and how might these be used to improve the REEM guidance?*

End of study

The final visit by the researcher to the study sites will be no later than 1 October 2024. After this point, only data analysis and report writing will take place. The report/s are expected to be complete by 1 November 2024 and will be circulated to all relevant organisations and participants who have requested these. NIHR and the Research Ethics Committee will be informed of the end of the study, and we will implement any further requests from them. All raw data will be destroyed and only anonymised data will remain.

Expected study outcomes

The study is expected to identify which elements of Waiting Well lead to successful outcomes, why and how, if those elements are cost-effective, and to determine and explain differences in outcomes between North and South Tees. This will be documented in an evaluation report focusing on what works, for whom, in which circumstances, at what cost and with what benefits.

The study will also inform the REEM project, which aims to produce guidance for use by a range of audiences, to enable realist and economic evaluation approaches to work together meaningfully, as well as relevant academic methodological outputs.

Ethics key points

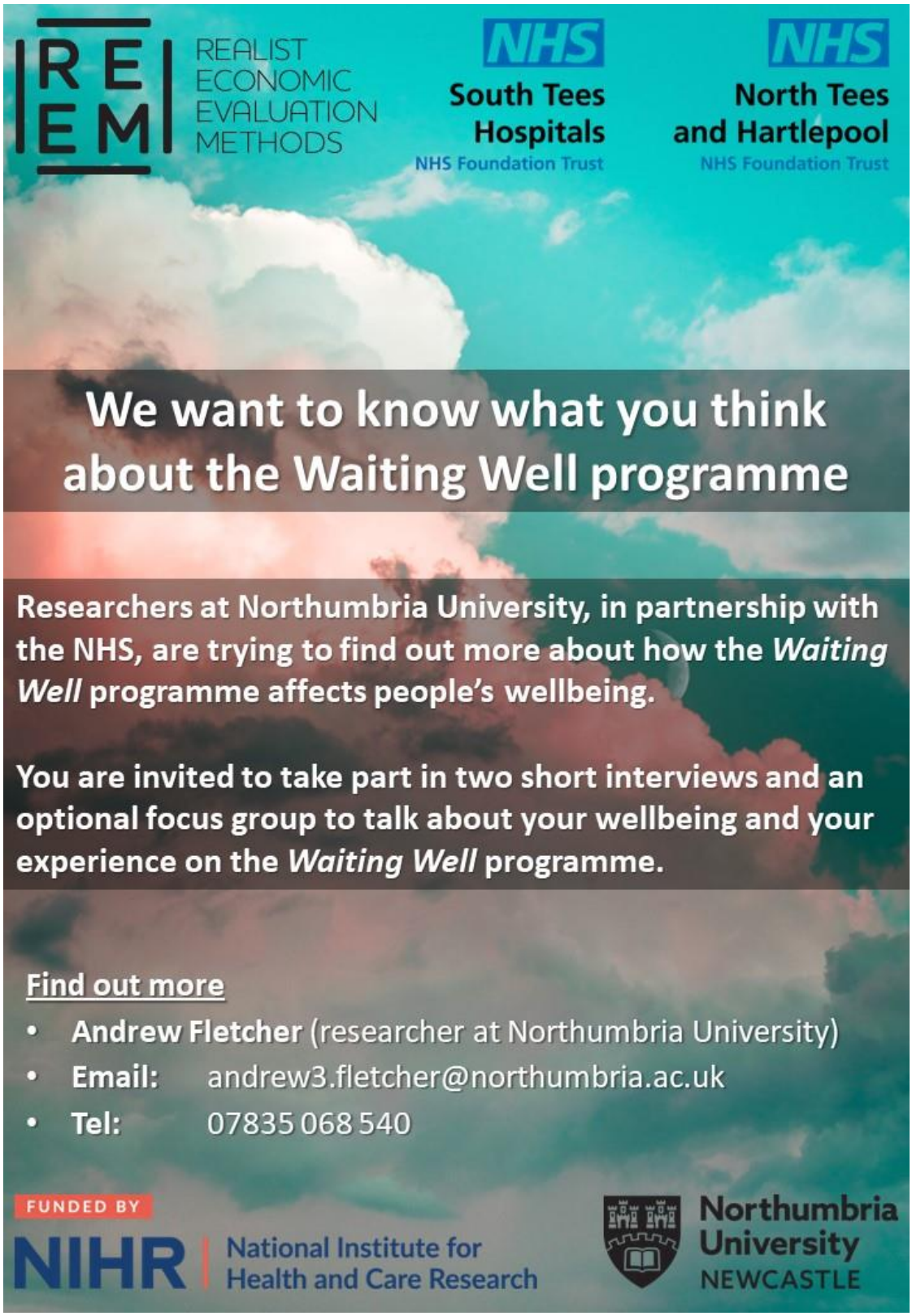
- IRAS (Integrated Research Application System) application submitted
- REC panel meeting on 8th February 2024
- REC panel opinion responded to on 11th March 2024
- Research passport application sent to South Tees Academic Centre on 9th Jan 2024
- A data sharing agreement will be developed on study setup (following REC approval)
- The researcher will adhere to Northumbria University's Research Data Management Policy, https://www.northumbria.ac.uk/research/research-data-management/.
- All project data will be stored on a password protected university or NHS laptop computer and interviews will be recorded onto an encrypted digital audio recorder. Any identifiable data will be anonymised prior to analysis and all raw data will be deleted following the end of the study (November 2025), in line with Northumbria University guidance.
- See appendix for Participant Information Sheets and consent forms.

Gantt chart

	2023		2024											
	N	D	J	F	M	A	M	J	J	A	S	O	N	
Pre-setup														
Define and describe WW programme in South and North Tees with staff who deliver it														Phase 1
Revisit the evaluation question and refine														
Generate initial realist economic programme theories (iREPTs) about how WW 'works'														Phase 2
If necessary, prioritise iREPTs with stakeholders														
Consider data collection; what quantitative data is available and should this be supplemented in light of the iREPTs?														Phase 3
Formulate data collection methods that will work together to provide a complete evaluation picture														
Collect data to test the iREPTs														Phase 4
Test and refine iREPTs using the data collected (qualitative and quantitative)														
Follow the draft REE guidance throughout, populating the pilot evaluation tool														Phase 5

Appendix. Flyer, participant information sheets, consent forms

Potential participants will be given a flyer on their first contact with Waiting Well. If they express an interest in taking part in the evaluation (at the time or subsequently), they will be given or sent an information sheet and can ask any questions. The researcher will then contact them.



WAITING WELL EVALUATION
PARTICIPANT INFORMATION SHEET (PATIENTS)

You are invited to take part in a research study about your experience on *Waiting Well*. Researchers from Northumbria University are trying to understand which elements of the service work best, to improve outcomes for patients.

Project aims

This project aims to understand your experiences of using *Waiting Well*, so we can improve it for others. This will involve asking you questions about your wellbeing, either in a one-to-one conversation or as part of a focus group. One-to-one conversations will last no longer than 60 minutes and focus groups no longer than 90 minutes.

What are the possible benefits of taking part?

You will have the opportunity to discuss and explore your experience of the *Waiting Well* service in depth, with a view to improving services for future patients. All participants will receive a £10 shopping voucher.

Are there any risks involved in taking part?

There is no risk involved in participating in this project. You do not need to discuss any aspects of your health or wellbeing if you don't want to and you may withdraw from this study at any time without giving a reason and without it affecting your participation on *Waiting Well*.

What information will be required?

If you agree to taking part in the research, we will need your name and phone number and/or email address, so we can contact you to arrange an interview.

You will be asked about your wellbeing in general, as well as any changes in your wellbeing while participating on *Waiting Well*. We are interested in any factors that have influenced how you feel, regardless of whether these are from *Waiting Well*. We are not seeking details about your specific health condition unless you feel these are relevant. We may work with the *Waiting Well* team, accessing routine health data, but this will be completely anonymous and we will not access any patient medical records.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. We will write our reports in a way that no-one can work out that you took part in the study. Anonymised data will be retained until the final paper is published.

Your rights under the terms of UK data protection law, including the UK General Data Protection Regulation (GDPR) and the Data Protection Act 2018

The researcher (Andrew Fletcher), the evaluation team and Northumbria University are committed to upholding your rights to confidentiality in accordance with UK GDPR and the Data Protection Act 2018. You can ask the researcher for any information the project has relating to you, or for this to be destroyed. Please note, once data is anonymised (within two weeks of any interview or focus group), it will be impossible to identify individuals and therefore to remove their specific data from the study.

How will information from this study be published?

All information derived from this research will be anonymised. No individuals will be identifiable in any published research. You may request a copy of any publications and you might recognise your own words or circumstances

described, but these details will not be linked to your name or any other information that could be used to identify you.

How is information relating to this study stored?

Interviews and focus groups will be recorded using an encrypted digital audio recorder or via Zoom/Teams on a password protected university computer. Encrypted data cannot be read by anyone other than the researchers. All data will be stored on Northumbria University's OneDrive system, which is password protected.

Where can you find out more about how your information is used?

- If you have any questions about this research, please contact the **lead researcher**, Dr Andrew Fletcher, andrew3.fletcher@northumbria.ac.uk
- The **Chief Investigators** of this study are Professor Sonia Dalkin, s.dalkin@northumbria.ac.uk and Professor Angela Bate, angela.bate@northumbria.ac.uk
- Should you wish to complain about the conduct of this research, please contact the **Faculty Research Ethics Director**, Professor Nick Neave, at: nick.neave@northumbria.ac.uk

WAITING WELL EVALUATION

INFORMED CONSENT FORM (PATIENTS)

You are invited to take part in a research study about your experience on *Waiting Well*. Researchers from Northumbria University are trying to understand which elements of the programme work best, to improve outcomes for patients. This will involve asking you questions about your wellbeing, either one-to-one or as part of a focus group.

More details can be found in the **Participant Information Sheet** (attached). It is important that you have sufficient information to decide whether you wish to take part in this research. To confirm your understanding, please tick the boxes overleaf and sign the bottom of this form.

Where can you find out more about how your information is used?

- If you have any questions about this research, please contact the **lead researcher**, Dr Andrew Fletcher, andrew3.fletcher@northumbria.ac.uk
- The **Chief Investigators** of this study are Professor Sonia Dalkin, s.dalkin@northumbria.ac.uk and Professor Angela Bate, angela.bate@northumbria.ac.uk
- Should you wish to complain about the conduct of this research, please contact the **Faculty Research Ethics Director**, Professor Nick Neave, at: nick.neave@northumbria.ac.uk

One copy of this signed consent form will be for you as the participant to keep. The other will be stored in a locked office at Northumbria University.

I have read and understand the purpose of the study, as outlined in the Participant Information Sheet, dated 26/02/2024.	
I have been given the chance to ask questions about the study and these have been answered to my satisfaction.	
I am willing to be interviewed.	
I am willing to participate in a focus group with other Waiting Well participants and with service delivery staff.	
I am willing for my comments to be recorded. Only the lead researcher will have access to this recording, and all recordings will be destroyed at the end of the study.	
I understand that I can withdraw from the research study at any time and that this will not affect my participation on Waiting Well.	
I understand that the Waiting Well team may share anonymised health and wellbeing data with the researchers	
I am aware that my name and any other identifying details will be kept confidential and will not appear in any printed documents.	
I am happy for any comments I make during the research to be used anonymously in a report at the end of the research.	
I agree to the University of Northumbria at Newcastle recording and processing this information about me. I understand that such information will be handled under the terms of UK data protection law, including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.	

NAME	SIGNATURE	DATE
Person taking consent:		
NAME	SIGNATURE	DATE

WAITING WELL EVALUATION
PARTICIPANT INFORMATION SHEET (STAFF)

Researchers from Northumbria University are trying to understand which elements of the Waiting Well programme work best, to improve outcomes for patients. **As part of the Waiting Well delivery team, you are invited to take part in this study**. This will involve asking you questions about how the programme works, either one-to-one or as part of a focus group.

Project aims

This project aims to understand how the *Waiting Well* programme works, for who, in which circumstances, why, and with what related resource impacts and opportunity costs. The overarching aim is to find out how to make the programme more effective and efficient.

What information will be required from me and are there any risks to do with taking part?

You will be asked to talk about the *Waiting Well* programme in general, including your own ideas about how it might work to improve the health and wellbeing of patients, and any feedback you may have received. We are not seeking details about specific patients. There will be no risk involved in participating in this project. If you agree to taking part in the research, we will need your name and email address, so we can contact you to arrange an interview.

What are my rights under the terms of UK data protection law, including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018?

- You may withdraw from this study at any time without giving a reason and without it affecting your work with *Waiting Well*.

- You can ask the researcher (Andrew Fletcher) for any information the project has relating to you, or for this to be destroyed. Please note, once data is anonymised (during transcription, within two weeks of any interview or focus group), it will be impossible to identify individual participants and therefore to extract their specific data from the study.

- Relevant contact details are at the bottom of this form.

What about confidentiality?

We (Andrew Fletcher, the evaluation team and Northumbria University) are committed to upholding your rights to confidentiality in accordance with UK GDPR and the Data Protection Act 2018.

How will information from this study be published?

All information derived from this research will be anonymised. No individuals will be identifiable in any published research. You may request a copy of any publications and you might recognise your own words or circumstances described, but these details will not be linked to your name or any other information that could be used to identify you.

How is my information stored?

Interviews and focus groups will be recorded using an encrypted digital audio recorder or via Zoom/Teams on a password protected university computer. Encrypted data cannot be read by anyone other than the researchers.

All data will be stored on the Northumbria University OneDrive system, which is password protected. Anonymised data will be retained until the final paper is published. Signed consent forms will be stored in a locked office at the University.

Contact details

- If you have any questions about this research, please contact the **lead researcher**, Dr Andrew Fletcher, andrew3.fletcher@northumbria.ac.uk
- The **Chief Investigators** of this study are Professor Sonia Dalkin, s.dalkin@northumbria.ac.uk and Professor Angela Bate, angela.bate@northumbria.ac.uk
- Should you wish to complain about the conduct of this research, please contact the **Faculty Research Ethics Director**, Professor Nick Neave, at: nick.neave@northumbria.ac.uk

WAITING WELL EVALUATION

INFORMED CONSENT FORM (STAFF)

Researchers from Northumbria University are trying to understand which elements of the Waiting Well programme work best, to improve outcomes for patients. **As part of the Waiting Well delivery team, you are invited to take part in this study**. This will involve asking you questions about how the programme works, either one-to-one or as part of a focus group.

More details can be found in the **Participant Information Sheet** (attached). It is important that you have sufficient information to decide whether you wish to take part in this research. To confirm your understanding, please tick the boxes overleaf and sign the bottom of this form.

Where can you find out more about how your information is used?

- If you have any questions about this research, please contact the **lead researcher**, Dr Andrew Fletcher, andrew3.fletcher@northumbria.ac.uk
- The **Chief Investigators** of this study are Professor Sonia Dalkin, s.dalkin@northumbria.ac.uk and Professor Angela Bate, angela.bate@northumbria.ac.uk
- Should you wish to complain about the conduct of this research, please contact the **Faculty Research Ethics Director**, Professor Nick Neave, at: nick.neave@northumbria.ac.uk

One copy of this signed consent form will be for you as the participant to keep. The other will be stored in a locked office at Northumbria University.

I have read and understand the purpose of the study, as outlined in the Participant Information Sheet, dated 26/02/2024.	
I have been given the chance to ask questions about the study and these have been answered to my satisfaction.	
I am willing to be interviewed.	
I am willing to participate in a focus group with other people involved in Waiting Well, including patients.	
I am willing for my comments to be recorded. Only the lead researcher will have access to this recording, and all recordings will be destroyed at the end of the study.	
I understand that I can withdraw from the research study at any time and that this will not affect my work with Waiting Well.	
I am aware that my name and any other identifying details will be kept confidential and will not appear in any printed documents.	
I am happy for any comments I make during the research to be used anonymously in a report at the end of the research.	
I agree to the University of Northumbria at Newcastle recording and processing this information about me. I understand that such information will be handled under the terms of UK data protection law, including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.	

NAME	SIGNATURE	DATE
Person taking consent:		
NAME	SIGNATURE	DATE

C-it DU-it REEM pilot evaluation protocol

Version 1.0

Contents

Participating organisations and key study contacts:

REEM

- Meghan Kumar, Northumbria University
- Sam Redgate, Northumbria University
- Sonia Dalkin & Angela Bate (REEM Principal Investigators), Northumbria University

Collaborating institutions

- Kenya Medical Research Institute, Centre for Global Health Research
- LVCT Health Healthy Societies
- Liverpool School of Tropical Medicine, UK
- WHO Collaborating Centre on TB and Social Medicine, Karolinksa Institute, Sweden
- Tropical and Infectious Diseases Unit, Liverpool University Hospital NHS Foundation Trust, UK
- County Departments of Health, Homa Bay
- Division of Community Health, Ministry of Health
- London School of Hygiene and Tropical Medicine
- KEMRI- Wellcome Trust Research Program
- GinD Consultants
- Division of Reproductive Health, Ministry of Health
- Division of National Malaria Program, Ministry of Health

Background

(Guidance, section 1)

C-it Du-it: Setting

Kenya is entering a period of transformation, with a move to digitise health data. This health data is rapidly changing from paper to electronic across Kenya. Multiple digital systems are being developed, but these do not link. Community health volunteers (CHVs) and facility staff need to work together using data to monitor and improve uptake of services. Antenatal care (ANC) is an example of a service where this is important as Kenya in adopting WHO's ambitious target of 8 ANC contacts (https://lvcthealth.org/c-it-du-it/).

C-it Du-it: Pilot Evaluation

A pilot evaluation of C-it Du-it is being led by LHTM. This evaluation aims to understand how and why the "C-it, DU-it" intervention works and to generate insights to support its scale-up throughout Kenya.

The evaluation consists of three parts (taken from, Study Protocol, A study of the implementation of "C-it DU-it": Community data use for integrated antenatal care, version 2):

1) *Situational analysis: before the C-It DU-It intervention is implemented.*

- We need to understand the digital data landscape in Kenya and within our study counties, specifically trying to understand the extent to which digital data are used for ANC, and what the existing barriers and facilitators are to digital data for ANC, so that we can be aware of these throughout our study of C-It DU-It's implementation. We also need to understand if and how quality improvement processes are using digital data. These insights will also be used to refine the C-It DU-It intervention. We also want to gain community perspectives about digital data. We will carry out some quantitative and qualitative data collection.
- Quantitative: mapping survey of health facilities in study counties to identify where digital health information systems are in place for ANC
- Qualitative: participatory workshops and interviews with people who use digital health data for ANC and with people who make decisions about digital health data or support its implementation, and focus group discussions with community members about perceptions of digital data and its uses

2) *Realist evaluation: while the C-It DU-IT intervention is being implemented.*
   - This part will study the implementation of C-It DU-It in-depth, trying to really get an understanding of what worked, what didn't, why, and under which conditions. This will primarily involve generating qualitative data by speaking with people who are part of the intervention's implementation (like county focal persons responsible for health information systems, electronic medical records, and community health as well as the work improvement team members responsible for collecting and using digital ANC data) and beneficiaries of the intervention (pregnant women and women who have given birth within five months) to understand what they think about the intervention and what it may be achieving. We will also observe some work improvement teams to see how they use digital data in their quality improvement activities. We will also collate a lot of process data about all C-It DU-It intervention inputs (like training and mentoring to work improve

3) *Scalability study: after C-It DU-It has been implemented.*
   - From the realist intervention, we will have a good idea about how the C-It DU-It intervention should be optimally implemented, especially in terms of what intervention inputs (for example, technical assistance for using the digital platform, training materials for work improvement teams) are needed for it to be used elsewhere, but this needs to be tested. Also, because different counties are at different stages of development of digital health systems, this may differ by context. Therefore, in this final part, we would like to gain insights from all of the key people involved in C-It DU-It, and key people from new counties in thinking about what might influence its implementation in other counties. We will then use their reflections to generate a "scale-up planning tool" of considerations that counties may need to make if they are to implement the intervention. We will then collect some qualitative data from new counties where the intervention is being rolled out to understand if that tool was useful, and also, if the intervention inputs that were shared were fit-for-purpose. At the end of a 12-month period, we will host a participatory workshop with people from the original implementation county (Homa Bay) and the three scale-up counties (Migori, Kisumu, and Kakamega) to generate a "package" of resources (including intervention materials and a refined scale-up planning tool) to give to the Ministry of Health to support nation-wide scale-up.

C-it Du-it: REEM study

This study has two functions: 1) testing the draft REE guidance; and 2) to achieve this, we will be undertaking an evaluation of C-it Du-it conducting secondary analysis on primary data collected as part of the pilot evaluation led by LSHTM as described above.

The intervention

(Guidance, section 3)

C-it Du-it targets the interface between the community and the facility influencing data digitisation at the community level. The C-it aspect of the intervention is focused on data linkage, i.e. 'seeing' the linked data. The Du-it component involves acting on the data through quality improvement.

With support from the Ministry of Health, C-it Du-it is to be implemented in Homa Bay and expanded to three additional counties (Migori, Kisumu, and Kakamega). This intervention will involve developing and introducing a digital health platform for community-level antenatal care (ANC) data – C-it component. These digital ANC data will be used by "work improvement teams", who will be supported through learning events and mentorship, in quality improvement processes to support uptake and delivery of quality ANC – Du-it component.

For the purposes of the REEM study, the Du-it component is viewed as the intervention with sites implementing C-it only, as the control/comparator. The Du-it intervention includes the following:

- Formation of quality improvement teams, involving:
    - Primary Health Centre in-charge (nurse, clinical officer)
    - Other PHC staff, if relevant
    - Community Health Promoters (2+)
    - Community members / service users (2+)
- Attendance of the quality improvement teams at three learning events, focusing on quality improvement training, including:
    - Data literacy
    - Team building
    - Problem identification
    - Data use

Study aims and objectives

Aims

1) To determine the impact of the intervention [Du-it QI training] has on outcomes for C-it Du-it.
2) To test draft REE guidance

Objectives

1) Define and describe the intervention [Du-it QI training] being delivered within C-it Du-it (Guidance section 3)
2) Revisit the evaluation question and refine in light of a more detailed understanding each of the interventions (Guidance section 5)
3) Generate initial realist economic programme theories (iREPTs) about how the intervention 'works', for who, in which circumstances and why, and with what related resource impacts and opportunity costs (Guidance section 6)
4) If necessary, prioritise iREPTs with stakeholders to ensure the most important are 'tested' in the evaluation (Guidance, section 7)
5) Consider specifics of data collection; understand what data is already available and whether this needs to be supplemented in light of the iREPTs (Guidance, section 8)
6) Receive data to test the iREPTs (Guidance, section 9)
7) Test and refine iREPTs using the secondary data received (Guidance, section 10)
8) Follow the draft REE guidance throughout the evaluation, populating the pilot evaluation tool, which has been created to detail progress through each stage of the guidance.

Evaluation question

Primary research question

The overarching *key evaluation question:* Is Quality Improvement (Du-it) worth investing in, on top of digital data eCHIS system (C-it), to drive increased antenatal care visits across the population?

In order to derive a focused REE question, this can be addressed by working through connected realist and economic questions (Guidance, section 5).

Key realist evaluation question: In what way, for whom and in which circumstances does Quality Improvement (Du-it) increase the efficacy of eCHIS (C-it) in driving action to improve poor performance in antenatal care to achieve more visits?

- Refocused on outcomes: How does the Du-it Quality improvement intervention change outcomes (in what circumstances / for whom / why) compared to standard care, plus eCHIS (C-it)?

Key economic evaluation question: What are the differences in resources and outcomes of delivering Du-it Quality Improvement training and interventions?

Key REE question: What are the comparative outcomes and resources associated with the C-it Du-it Quality Improvement intervention, compared to C-it only, and what mechanisms and contexts drive these?

Secondary research question

The process of addressing the primary question will help the research team to 'test' the REEM guidance it has been developing. Therefore, the secondary research question is: Can this evaluation be conducted

in a meaningful way by following the draft REEM guidance? What are the helps and hinderances, and how might these be used to improve the REEM guidance?

Research Design

This study will be conducted as a Realist Economic Evaluation (REE) and will follow the recently developed guidance (https://northumbriaknowledgebank.flintbox.com/technologies/3db4bb2a-3667-4328-bab3-66fc40242f36). In practice, this type of evaluation is iterative, and the research design will reflect this, with refinements occurring as the evaluation develops. To meet the objectives outlined above, the research will be conducted in the following phases detailed below and in Table 1.

Table 1: Mapping of Evaluation Phases, Objectives and Guidance

Phase of research	Objective	Guidance section
Pre-setup	n/a	1,2
Phase 1: Interactive workshops 1 & 2	1	2,3,4
Phase 2: Interactive workshop 3	1,2	3,4,5
Phase 3: Generate initial Realist Economic Programme Theories (iREPTs)	3,4	6,7
Phase 4: Use iREPTs to refine study design and data collection methods	5,6	8
Phase 5: Test iREPTs	7,8	9,10

Pre-setup

(Guidance section, 1 & 2)

Being part of the wider development of the REEM guidance, the purpose of this evaluation and identification of team members (from both REEM and C-it Du-it) are already established. Ethics applications and collaboration/data sharing agreements are in progress.

Phase 1: Interactive workshops 1 & 2

(Guidance section, 2, 3 & 4)

Two interactive workshops led by the REEM team, will be undertaken with key personnel linked to the study. A collaborated definition and overview of the intervention [QI training and change plans] will be developed to visualise and understand the complexities of the intervention, including how component

parts relate to one another. Resources will begin to be defined and steps will be taken to start to understand how these may be configured.

Data analysis

Patient journey maps to be produced using Miro, an online collaboration tool. These are to be built upon and refined through subsequent workshops and informal meetings. This information will guide literature searching and reviewing. Mapping will determine what the evaluation can capture with the time and resources available.

Phase 2: Interactive workshop 3

(Guidance section, 3,4 & 5)

Phase 2 will focus on using data from phase 1 to consolidate the intervention and comparator definition, as well as further develop definitions of resources and establish generative causal configuration. An interactive workshop led by the REEM team, will be undertaken with key personnel linked to the study.

Data analysis

Patient journey maps will be refined, helping to generate a more detailed causal pathway/system diagram, including the ultimate outcomes of interest.

Phase 3: Generate initial Realist Economic Programme Theories (iREPTs)

(Guidance section, 6 & 7)

iREPTs articulate theorised comparative configurations (between intervention vs. no intervention) involving context, intervention, resources, mechanisms, and outcomes. These will be developed in line with the REE guidance and the REE evaluation question, as above. Specifically, the iREPTs will describe the relationships between context, mechanisms and outcomes, and the five different types of resources that are at play within each of these. This differs from phase 1, as it explicitly draws on REE constructs and heuristics to develop the realist economic evaluation theories.

iREPT development for the REEM study has incorporated two approaches running concurrently.

iREPT development Approach one: Utilising existing evaluation data

The pilot study evaluation, led by LHTM includes a realist evaluation which has previously developed initial programme theories pertaining to the outcomes of the C-it Du-it approach. These theories were used by the REEM team to abstract already identified key context, mechanism and outcomes from the intervention relating specifically to the REE question, *What are the comparative outcomes and resources*

associated with the C-it Du-it Quality Improvement intervention, compared to C-it only, and what mechanisms and contexts drive these? In doing so, we were able to capitalise on existing data to begin to theorise about outcomes from the intervention (Du-it).

iREPT development Approach two: Deconstructing the intervention

The second approach taken pertaining to iREPT development includes conducting a detailed examination of the intervention (D-it) based on intervention documentation (i.e. programme websites, pilot evaluation protocol) and reviewing the detailed causal pathway/system diagram produced previously. Through this process key intervention resources are identified and categorised in line with the five resources 'types' as defined in the REEM guidance.

Phase 4: Use iREPTs to refine study design and data collection methods

(Guidance section, 8)

Based on the iREPTs, study design will be confirmed, which will include all types of evidence necessary to enable the identification, measurement, and valuation of outcomes that are comparable across the intervention and comparator(s) to enable the assessment of opportunity cost.

Data collection is being led by LSTM as part of their evaluation. Data collection will include individual interviews, focus group discussions, stakeholder meeting/workshop or observations. The REEM team will work with the LSTM team to identify relevant existing data collection plans which have the ability to also test developed iREPTs through secondary analysis.

Phase 5: Test iREPTs

(Guidance section, 9 & 10)

iREPTs will be tested (refuted, refined, supported) through secondary analysis of data from the LSTM evaluation.

Phase 6: Secondary research question

Although stated chronologically as last, this Phase will take place throughout all the previously described Phases (1-5). For each Phase and point in the guidance, the researcher/s will document what happened and how, detailing any barriers/facilitators.

Data collection

A 'pilot tool' (a form of reflective diary, structured around the draft REE guidance) is being used to record any changes to the evaluative question and the reasons why, as well as the researcher(s) experiences of following the guidance.

Data analysis

Experiences of researchers who are using the REE guidance in other pilot evaluations will be discussed in monthly meetings, where we expect to discuss and use the data from the pilot tools to synthesise learning about a) REEM as a methodology (how do you do it) and b) the REEM guidance (the document that tells people how to do it).

This data will be used to inform the secondary research question: *Can this evaluation be conducted in a meaningful way by following the draft REEM guidance? What are the helps and hinderances, and how might these be used to improve the REEM guidance.*

Ethics key points

LSTM already have ethical approval for the evaluation. The REEM team will seek ethical approval from Northumbria University for the secondary analysis of the evaluation data.

Impact Arts Craft Café Evaluation Plan

Pilot study for Developing Realist Economic Evaluation Methods (REEM)

June 2024

Authors: Professor Rachel Baker[1], Professor Cam Donaldson[1], Dr Aikaterini Papadopoulou[1]

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NIHR | National Institute for Health and Care Research

Version 1.2

This document is the second version of an evaluation plan we aim to update as a live document. Throughout the research process, we will add updates according to what transpires pre-data collection (prior literature and from initial consults with stakeholders) and as results emerge.

Background and Purpose

It is increasingly recognised that the 'big problems' in health and social care require well-designed complex solutions and robust evaluation, which itself is often complex. Realist evaluations were designed to take account of that complexity, to explain 'what works, for whom, in which circumstances and why?'. A realist approach to evaluation recognises that *context matters* when we try to understand how initiatives work, and that context and mechanisms (how things work) might be different for different groups of people. Policymakers and funders also need economic information – how resources are linked to outcomes - to inform difficult decisions in the context of resource scarcity.

This Evaluation Plan is part of the realist economic evaluation methods (REEM) project, funded by the National Institute for Health and Care Research (NIHR) to provide guidance so that we can better understand and evaluate the benefits and costs of complex interventions within a realist evaluation paradigm. It seeks to bring together realist and economic evaluation to enable evaluators to establish

what works, for whom, in which circumstances, why, and with what related resource impacts and opportunity costs.

Having now developed draft REEM Guidance, the purpose of this next phase of the REEM project is to test out that Guidance in three pilot evaluations. The latest version of the Guidance is available online (https://northumbriaknowledgebank.flintbox.com/technologies/3db4bb2a-3667-4328-bab3-66fc40242f36). The remainder of this document outlines the pilot evaluation of Impact Arts' Craft Café initiative in Govan in the city of Glasgow. Craft Café is a long-standing community-based initiative, currently located within Elderpark Housing Association and about to move to Govan Library, which promotes meaningful and enjoyable arts-based experiences with the aims of combating social isolation as well as promoting self-expression and overall well-being. The duration of this phase is 18 months, beginning November 2023.

Getting Started: pre-evaluation (November 2023 to May 2024)

During this period, we will work with partners in Impact Arts and Craft Café to develop questions and outcome measures and design the research most effectively, considering the requirements of the REEM project as well as stakeholders. We will also involve people with lived experience to advise and steer the researchers on the team, forming a Patient and Public Involvement and Engagement (PPIE) group.

Prior to commencing data collection, we will consult with stakeholders who design and deliver the programme to agree research questions and objectives, discuss the initial programme theories which were based on prior work by a Glasgow Caledonian PhD student (Appendix 1), establish relevant comparators and agree on content, methods, and timeline of data collection. This includes how best to approach and recruit study participants and potential access to secondary data (if appropriate).

Programme theories explain how we think the intervention in question might work and draw on existing knowledge and data collected in the specific project. The general framework is one of context-mechanisms-outcomes (or CMOs) in the sense of how these impact on each other in the case of the initiative being evaluated. This will include impacts on resources used to put the initiative in place as well as any cost savings (or increases) that might be incurred (e.g. in the use of other in-house or external services) arising from interacting with the initiative.

This stage will also involve establishment of key roles, for example:

- The pilot evaluation partners (including the PPIE group) will work closely with the research team in project team which will meet regularly to monitor progress, review data collection strategies and ongoing written materials.
- The project researcher will manage the evaluation, data collection, ethics approval, analysis, and writing, keeping project partners informed throughout
- The project partners (Impact Arts & Craft Café staff) will act as the gatekeepers to recruit participants for the evaluation, including distribution of participant information sheets and gaining consent to participate in the evaluation.

In material to follow below, we outline the basics of our research questions and the study design, although each of these may be subject to change as a result of stakeholder consultation and as the project evolves.

Research questions

To investigate and develop our initial programme theories, our accompanying research questions are likely to be:

1. What are the outcomes from engaging with Craft Café, when do they occur, for whom, why and to what degree relative to a non-user group and users of an alternative initiative?
2. Which aspects of the contexts of Craft Café and its comparators and subsequent mechanisms (resources and reasoning triggered by such contexts) contribute to observed outcomes?
3. Within their contexts, what resources (financial, material, human etc) are required to implement the Craft Café and its comparators (‘intervention resources,’ according to draft REEM Guidance), including those already present in Impact Arts and the wider organisations of any comparators (‘context resources’)?
4. What ‘mechanism resources’ are triggered by Craft Café and its comparators?
5. What are the impacts of such mechanisms on ‘resources for participants’ and other ‘resource-related outcomes’ (e.g. arising in other community, public and private settings, such as other services?
6. How does overall resource utilisation relate to outcomes of interest for Craft Café and its comparators?

These questions place the proposed research in this pilot within the third category of comparators in the draft REEM Guidance (see Table 2 of that Guidance). However, intra-programme comparison is also possible with regard to addressing issues related to aspects such as the nature of facilitation and the location of Craft Café (given that it is currently subject to a move).

Evaluation Design (to be implemented May-November 2024)

Design and recruitment

The overall study design is a mixed-methods realist evaluation with economic appraisal.

The Craft Café group will be compared with individuals of same age, and area of residence, undertaking different activities (e.g. visiting local library) instead of participating in the Craft Café. As the Govan Craft Café is also about to change location, other possible sources for the comparator group are those who elect not participate due to this change and also non-users within the housing association in which Craft Café is hosted.

The main criteria for inclusion are adults (over the age of 60); participating in activities in Craft Café workshops in Govan Glasgow; participating in other activities in Govan Library or in Elderpark Housing Association building; or former users who no longer attend Craft Cafe due to its re-location.

As this is a pilot study, the anticipated sample size for the present study is approximately 20 (of currently actively registered members 30-40) participants for interviews (5-10 participants in Craft Café; 5-10 individuals who have a connection with members of the Craft Café, or are visiting the Govan Library, but do not participate in the arts activities or are former users of Craft Café) and, for the survey, 30-40 participants across participant and comparator groups.

Convenience sampling will be used whereby individuals who actively participate in the programme before the Craft Café move to the new location and agree to take part in the research will be sent a request to participate in the study. The same process will be followed for the comparator group, where a member from the organisation will help us identify members who no longer participate to the programme or individuals who attend the public Library in Govan regularly and is potentially interested to join. A range of different voices and perspectives will be sought by identifying people with different

characteristics. The first contact with the participants will be through the organisation's members and volunteers. This will be organised by a paid member of the study team located within Impact Arts.

Eligible people will be given study information and invited to take part and provide consent. Consent forms are included (Appendix 2). The researcher will then visit the location to collect the consent form and answer any questions that might be necessary before collecting any data. There will be no reminder to participate, but there will be a choice to participate later (in the context of the given time) if necessary.

Data collection

Given the exploratory nature of the research, data will be gathered from multiple sources and generated using primary and secondary data sources. Data will include both qualitative and quantitative data from existing records that the organisation holds and from previous academic research undertaken by a Yunus Centre PhD student who worked with the Craft Café initiative. During this PhD work, the researcher developed four programme theories by eliciting data from semi-structured interviews, a survey and regularly attending the organisation's workshops (observational/diary data). These pre-existing programme theories have been adapted for the REEM Project – see Appendix 1. In addition, we will collect further data via existing organisational records, interviews, and surveys.

Drafts of these instruments are attached in Appendix 3, but, for the most part, each addresses the CMO configuration, and the realist economic evaluation as follows:

- via the survey, the outcomes emanating from programme theories – social isolation, connectedness and social networks, physical and mental health, overall well-being/happiness, resources for participants and resource-related outcomes, .as well as any associated socio-economic factors (such as pension, social benefits, employability, location of residence, nationality, and gender).
- via the interviews, the focus will mainly be on mechanisms and thus mechanism resources.

Furthermore, for the economic evaluation, data will be collected from the organisation in reference to the costs reported in their annual reports. Any other type of costs that might be of interest will be discussed with the organisation and, if consent is given, will be included accordingly. If not, then we will attempt to cost the resource use using reference costs where applicable. This will

enable estimation of ‘intervention resources’ and ‘context resources’.

Duration of participant involvement will vary; one-off interviews are estimated to last approximately one hour, while survey participants will be engaged at different time points (baseline- and 3 months later) throughout the period of data collection.

Data management

Data will be anonymised and transferred to the research team in Microsoft Excel. Data will be analysed using SPSSS and/or STATA, as appropriate. Any qualitative data will be analysed using NVivo.

Hard copies will be stored in secure servers (GCU computers) with passwords that are regularly backed up. 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 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/.

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.

After the completion of the study data will be kept for future publications, and according to the GDPR legislation will be stored securely on the GCU servers. Data will be disposed of in line with the GCU research data retention schedule.

Study outputs (December 2024 to April 2025)

As well as contributing to development of the REEM Guidance, a report will be provided to Impact Arts focussing on findings of the pilot evaluation. Academic articles will focus on the development of

methods. These outputs will allow REEM to be utilised by academics and scrutinised by research funders. Additional outputs will arise from the stakeholder involvement to make better-informed commissioning and policy decisions and to also communicate and share evaluation results with partners, community and funders that demonstrate the success and value of the programme and the organisation.

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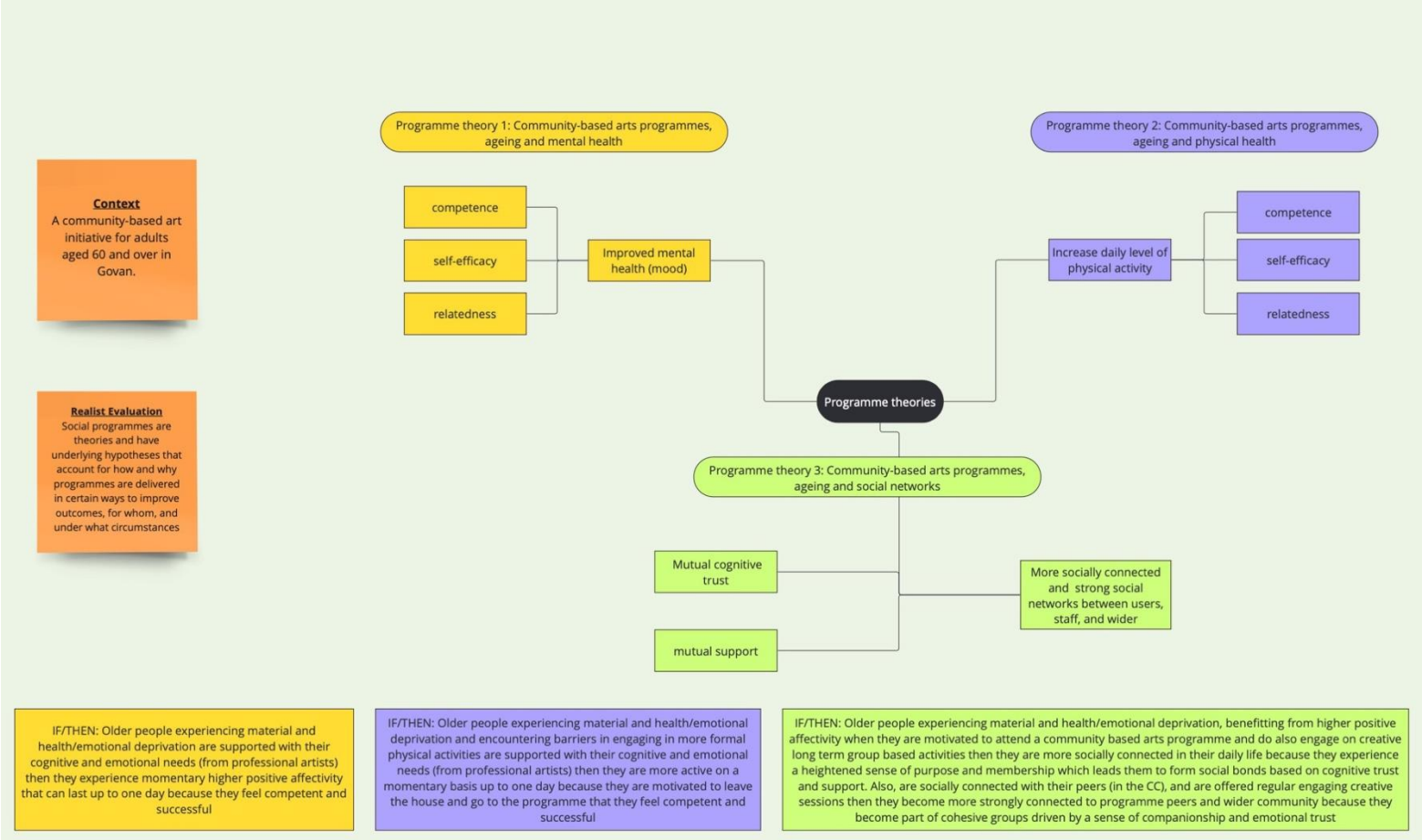
Appendix 1 Initial Results-programme theories



Appendix 2 Consent form

Developing Realist Economic Evaluation Methods (REEM)

Consent form

		Please initial box
1	I confirm I have read and understood the information sheet of this research, had the opportunity to ask questions, and had these questions answered satisfactorily.	
2	I understand my participation is voluntary and I am free to withdraw at any time without giving a reason and without my legal rights being affected.	
3	I understand my participation in any interviews will be audio-recorded and transcription may be undertaken by a 3rd party before analysis by the study team.	
4	I understand results and individual quotes may be published; however, it will not be possible to identify me in future publications.	
5	I understand information collected about me will be used to support other ethically approved research in the future and may be shared anonymously with other researchers.	
6	I confirm I am an adult and 18 years or older.	
7	I agree to take part in the above study.	

Name of participant (print)		Signature		Date DD/MM/YYYY
Person taking consent (print)		Signature		Date DD/MM/YYYY

Appendix 3 Data instruments

a) Interviews

Conversational Interview Guideline

Check

- Participant Information Sheet, time to ask questions, consent form completed.
- Permission to record the interview.

General

1. Name:
2. Age:
3. Can you tell me a bit about yourself?
   a) How long have you been involved with Craft Café?
4. Can you tell me how you got involved with the Craft Café?
   a) And why did you get involved in it?
   b) Was there something that prompted it?
   c) If someone suggested it, why do you think they did?
5. In your opinion, what kind of impacts does the Craft Café have on the people that take part?
6. How do you think Craft Café achieves these impacts?

7. How different would the life of Govan citizens have been without the Craft Café? Can you provide some examples?

Individual Wellbeing and Engagement

1. How do you usually feel after the CC activities?
2. What would you choose to do if you had not taken part in the CC activities?
3. Do you think there has been any change in your wellbeing as a result of being involved with the CC? Can you provide some examples of such changes and how they come about? Are these changes temporary or longer lasting? What was it like for you before engaging with CC?
4. Did any of these changes result in you engaging more or less with other services (like social services or visits to the GP (General Practitioner))?
5. Did you get to know new people? Did you make any friends through CC? What was this situation like for you before engaging with CC?
6. What have you learned from taking part in CC (new skills)?
7. Are there any challenges in being involved with CC?
8. Has participating in CC led you to do other things? Can you give some examples?
9. Do you have any final thoughts or comments to share that you did not have the chance to tell me yet?

b) Survey

GCU Glasgow Caledonian University

REEM Craft Café Pilot Survey

Thank you for taking part in this study. We will be asking you a range of questions regarding your health and well-being in relation to your involvement with the Craft Café, a programme offered by Impact Arts.

If you have not been involved yet with the programme, Craft Café offers arts-related activities in the community of Govan in Glasgow for senior citizens over 60 years old. Through the Craft Café participants have the opportunity to learn new skills, make new friends and enjoy the arts activities led by qualified artists and wellbeing support workers. Membership is free, as well as all art materials and equipment that you will need to get involved.

Your answers are confidential.

Section 1 Overall Quality of Life

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑

I have slight problems in walking about ❑

I have moderate problems in walking about ❑

I have severe problems in walking about ❑

SELF-CARE

I have no problems washing or dressing myself ❑

I have slight problems washing or dressing myself ❑

I have moderate problems washing or dressing myself ❑

I have severe problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

USUAL ACTIVITIES (e.g. work, study, housework, family, or leisure activities)

I have no problems doing my usual activities ❑

I have slight problems doing my usual activities ❑

I have moderate problems doing my usual activities ❑

I have severe problems doing my usual activities ❑

I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑

I have slight pain or discomfort ❑

I have moderate pain or discomfort ❑

I have severe pain or discomfort ❑

I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

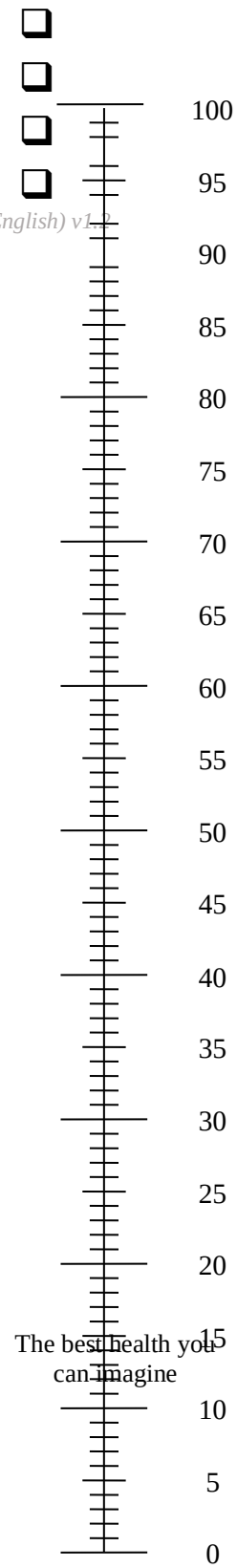
I am not anxious or depressed ❑

I am slightly anxious or depressed

I am moderately anxious or depressed

I am severely anxious or depressed

I am extremely anxious or depressed



We would like now to know how good or bad your health is TODAY.

This scale is numbered from 0 to 100.

100 means the best health you can imagine.

0 means the worst health you can imagine.

Please mark an X on the scale to indicate how your health is TODAY.

Now, write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐

The worst health you can imagine

Section 2: Mental Wellbeing

Short Warwick Edinburgh Mental Wellbeing Scale (S) WEMWBS

Below are some statements about feelings and thoughts.

Please select the answer that best describes your experience of each over the last 2 weeks.

	None of the Time / Rarely		Some of the Time / Often		All of the Time
I've been feeling optimistic about the future	**1**	**2**	**3**	**4**	**5**
I've been feeling useful	1	2	3	4	5
I've been feeling relaxed	1	2	3	4	5
I've been dealing with problems well	1	2	3	4	5
I've been thinking clearly	1	2	3	4	5
I've been feeling close to other people	1	2	3	4	5
I've been able to make up my own mind about things	1	2	3	4	5

Stewart-Brown, S., Tennant, A., Tennant, R., Platt, S., Parkinson, J., & Weich, S. (2009). Short Warwick–Edinburgh Mental Well-being Scale (SWEMWBS)

Section 3 Social Provision Scale

Instructions: In answering the following questions, think about your current relationships with friends, family members, co-workers, community members, and so on. Please indicate to what extent each statement describes your current relationships with other people. Use the following scale to indicate your opinion. So, for example, if you feel a statement is very true of your current relationships, you would tell me "strongly agree". If you feel a statement clearly does not describe your relationships, you would respond "strongly disagree". Do you have any questions?

STRONGLY DISAGREE DISAGREE AGREE STRONGLY AGREE

1 2 3 4

Rating

1. There are people I can depend on to help me if I really need it. _____
2. I feel that I do not have close personal relationships with other people. _____
3. There is no one I can turn to for guidance in times of stress. _____
4. There are people who depend on me for help. _____
5. There are people who enjoy the same social activities I do. _____
6. Other people do not view me as competent. _____
7. I feel personally responsible for the well-being of another person. _____
8. I feel part of a group of people who share my attitudes and beliefs _____
9. I do not think other people respect my skills and abilities. _____
10. If something went wrong, no one would come to my assistance. _____
11. I have close relationships that provide me with a sense of emotional security and well-being. _____
12. There is someone I could talk to about important decisions in my life. _____
13. I have relationships where my competence and skill are recognized. _____
14. There is no one who shares my interests and concerns. _____
15. There is no one who really relies on me for their well-being. _____
16. There is a trustworthy person I could turn to for advice if I were

having problems. _____

17. I feel a strong emotional bond with at least one other person. _____
18. There is no one I can depend on for aid if I really need it. _____
19. There is no one I feel comfortable talking about problems with. _____
20. There are people who admire my talents and abilities. _____
21. I lack a feeling of intimacy with another person. _____
22. There is no one who likes to do the things I do. _____
23. There are people who I can count on in an emergency. _____
24. No one needs me to care for them. _____

Cutrona CE, Russell DW. The provisions of social relationships and adaptation to stress. Advances in Personal Relationships. 1987;1:37–67

Section 4 Resource Use

Please, can you tell how many times you have used any of the following clinical and non-clinical services (in the past 3 month)? Select all that apply.

	Times used over the past 3 month					
Service	0	1	2	3-5	6-10	10+
Visited the GP/Nurse at surgery						
GP/Nurse came to your home						
Spoke to the GP/Nurse on the phone or a video call						
NHS 24 phone consultation						
Hospital outpatient appointment with a doctor or consultant or a nurse or health professional (physiotherapy, podiatry, psychology support etc)						
Visited A&E department						
Stayed overnight on a hospital ward (please write in the number of nights in the past 3 months)						
Any other costs needed for participating in the programme						

Did you have any other costs that you had to pay out-of-pocket and are related to your participation in the programme? (for example: transportation, art materials)

Yes ☐ No ☐

If yes, can you tell us about the amount for the past month?

£……

Section 5 General Questions

Please tick one box for the category that best describes you in each question below.

1. What is your gender?

Male ☐

Female ☐

Prefer not to say ☐

2. What is your ethnic group?

White ☐

Mixed ☐

Asian or Asian British ☐

Black / African / Caribbean / Black British ☐

Other ☐

Please specify……

Prefer not to say ☐

3. What is your current residence?

Govan, Glasgow ☐

Other area in Glasgow ☐

Please specify……

Other ☐

Please specify……

Prefer not to say ☐

4. What's your current living arrangements?

Living with a partner, husband, or wife ☐

Living alone ☐

Living with friends or flat mates ☐

Living with adult family ☐

Living with children under 18 ☐

Other ☐

Please specify……

Prefer not to say ☐

5. What is the type of home you are currently living in?

Own home (ongoing mortgage) ☐

Own home (without mortgage) ☐

Council/Housing Association tenant ☐

Temporary accommodation (supported housing, hostel etc.) ☐

Privately rented accommodation ☐

Relatives' home ☐

Friends' home ☐

Other ☐

Please specify……

Prefer not to say ☐

6. What is your highest education level?

No formal qualifications ☐

Primary (up to age 12) ☐

Secondary (up to age 16) ☐

Further education (16-18+) ☐

University ☐

Prefer not to say ☐

7. Do you receive any of the following compensations? income from state support?

State Pension ☐

Receive any additional benefits ☐

Prefer not to say ☐

8. What is your employment status?

In full time employment (30 hours or more a week) ☐

In part time employment (less than 30 hours a week) ☐

Self-employed (full time or part time) ☐

Looking after family or home ☐

Long term sick or disabled ☐

Retired ☐

Not in paid employment and looking for work ☐

Prefer not to say ☐

9. What is your total household income before taxes for 2023?

£0-£5,199 ☐

£5,200-£10,3299 ☐

£10,400-£15,599 ☐

£15,600-£20,799 ☐

£20,800-£25,999 ☐

£26,000-£31,199 ☐

£31,200-£36,399 ☐

£36,400 and above ☐

Prefer not to say ☐

10. Do you currently have caring responsibilities for anyone?

Yes ☐

No ☐

Prefer not to say ☐

11. Over the last 12 months would you say your health has on the whole been…

Good ☐

Fairly good ☐

Not good ☐

Prefer to not say ☐

12. Do you have any long-standing illness, disability or infirmity which limits your daily activities or the work you can do? (physical or mental)

Yes ☐

No ☐

Prefer to not say ☐

Please use the space here to leave us any comments regarding the survey.

Name	Comments