BMJ Open

Cocreators' experiences and effectiveness of cocreated interventions in improving health behaviours of adults with non-communicable diseases: a systematic review protocol

Ebuka Miracle Anieto ,[1,2,3] Ukachukwu Abaraogu,[1,2,4] Philippa Margaret Dall,[1] Ijeoma Blessing Anieto,[2,5] Chukwudi Martin Ogbueche,[1,6] Chris Seenan[1]

To cite: Anieto EM, Abaraogu U, Dall PM, *et al*. Cocreators' experiences and effectiveness of cocreated interventions in improving health behaviours of adults with non-communicable diseases: a systematic review protocol. *BMJ Open* 2023;**13**:e073153. doi:10.1136/bmjopen-2023-073153

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2023-073153).

Received 24 February 2023
Accepted 02 October 2023

For numbered affiliations see end of article.

Correspondence to
Ebuka Miracle Anieto;
ebuka.anieto@gcu.ac.uk

ABSTRACT

Introduction Improved health behaviours and help-seeking behaviour reduce morbidity and mortality from non-communicable diseases (NCDs). Compliance with the recommendations of lifestyle changes for the management of NCDs has been challenging, as patients find it difficult to change and sustain lifestyle behaviours for a long period of time. Studies have reported that cocreated interventions are promising in addressing negative health behaviours and improving health outcomes in people with NCDs; however, no conclusive evidence exists. Therefore, this review aims to evaluate cocreators' experiences and the effectiveness of cocreated interventions in improving the health behaviours of individuals with NCDs.

Methods and analysis This review will follow the recommendations described in the Preferred Reporting Items for Systematic Reviews and Meta-analyses guideline and the Enhancing Transparency in Reporting the Synthesis of Qualitative Research statement for the synthesis of qualitative data. The following databases: Co-creation Database (https://zenodo.org/record/6773028#.Y9h2sezP1pg), MEDLINE (via OVID), Cumulative Index to Nursing and Allied Health Literature (via EBSCO Host), EMBASE (via OVID), PsycINFO (via OVID), Scopus, Web of Science, Cochrane Library and grey literature will be searched. The identified studies will be independently screened by two reviewers to determine their eligibility. The review will target to include studies that investigated the experiences of cocreators and/or the effectiveness of cocreated interventions on the health behaviour and/or health outcomes of adults with NCDs. Two independent reviewers will also appraise the quality of the included studies, as well as data extraction. A narrative synthesis will be used to summarise the findings. Thematic synthesis and meta-analysis will be conducted for the qualitative and quantitative data, respectively. The qualitative and quantitative findings will be integrated using the parallel result convergent synthesis.

Ethics and dissemination Ethics approval is not applicable because the review will only use data from the published studies. The findings will be disseminated through publication in peer-reviewed journals and conference presentations.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ In addition to searching conventional databases, the recently developed co-creation database will be searched to ensure that all relevant studies are identified.
⇒ The study will assess the quality of intervention co-creation studies using the Adapted Checklist for Reporting Intervention Co-creation tool.
⇒ The review will integrate the quantitative and qualitative findings to have a more robust analysis of data.
⇒ There is a possibility of not finding enough studies to conduct subgroup meta-analysis for all the population groups.
⇒ There may be substantial heterogeneity due to varying population groups and intervention types.

PROSPERO registration number CRD42023391746.

INTRODUCTION

Globally, about 41 million people die each year as a result of non-communicable diseases (NCDs), and about 15 million of the deaths are recorded among individuals within the age range of 30–69 years.[1] Most of these recorded deaths are among people with cardiovascular diseases, cancers, respiratory diseases and diabetes.[1] Adopting lifestyle changes such as optimal physical activity, proper diet, reducing tobacco and alcohol intake may reduce the morbidity and mortality linked to NCDs.[2] However, adherence to therapeutic lifestyle changes has been a complex challenge for patients with NCDs, as they find it difficult to change their lifestyle behaviours or to sustain any lifestyle behaviour change.[3] In developed countries, only about half of the individuals with chronic conditions (eg, NCDs) adhere to recommended interventions.[4]

This consequently lead to poorer health outcomes and increased cost of healthcare.[4] Some of the barriers to lifestyle intervention adherence include personal factors, socioeconomic factors, nature of the disease, accessibility and the nature of the intervention.[5] Therefore, interventions should be tailored to addressing the specific barriers experienced by the patients, which varies per patient population group. The usual top–down, conventional pattern of intervention development and recommendations appear not to be effective in facilitating long-term improvement in the health behaviours of people with NCDs.[6] The design, content and mode of delivery of the conventional interventions may not be best suited to meet the patients' needs, hence, the poor adherence.[6]

It is becoming increasingly popular in implementation research and healthcare design to deploy participatory designs (eg, co-creation) with patient and public involvement in intervention development.[7] The participatory design paradigm gave birth to the concept of co-creation,[8] which is the process of involving local stakeholders (eg, end users, care providers, policy-makers) in the development of interventions.[9] Greenhalgh *et al*[10] found that co-creation has a significant positive influence on health outcomes, suggesting that it could be useful in addressing complex health behaviours.[11] This approach to intervention design represents a shift away from the traditional 'top–down' health model towards a more inclusive one that allows patients/end users to take control of service content and fully engage in the planning and execution of their health management.[12] Co-creation is promising in improving health behaviours such as physical activity (PA) performance.[13] Co-creation is also said to be beneficial in improving intervention adherence and facilitating healthcare service quality improvements.[14 15] Involving a wide range of stakeholders in intervention development has the potential of methodically addressing real-world problems,[16] developing tailor-made interventions targeted at addressing the specific needs of end users,[17] achieving sustainable outputs and effect,[18] and promoting the sustainability and scalability of interventions.[18]

The idea of democratising the health research process appears to be the solution to some of the barriers of evidence implementation.[17] Consequently, the idea has received considerable acceptance among health researchers, end users of interventions (patients and clinicians) and policy-makers. Although, there is a need to ensure that the co-creation process is rigorous and that it truly holds the projected benefits. Furthermore, it is important to put into perspective the potential risks of non-rigorous co-creation processes, which may include exposure of sensitive data, and lack of trust from the public and other relevant stakeholders.[19] It is assumed that the experiences of cocreators in the process of intervention development could influence (either positively or negatively) their willingness to be involved in future co-creations, as well as influence the intervention outcome.[20] Therefore, it is necessary to evaluate the overall experience of cocreators in the process, the overall effectiveness of cocreated interventions in improving the targeted health outcomes and the methodological rigour of the co-creation process for each study. To the best of our knowledge, no existing systematic review has explored the overall experience of cocreators involved in the development of interventions targeted at improving health behaviours of individuals with NCDs. Furthermore, some studies have used co-creation in developing interventions targeted at improving health behaviours in people with NCDs and found positive outcome in terms of improving physical activity, health outcomes and compliance with intervention[14 21]; however, studies on the overall effectiveness of this approach are still scarce, which necessitated this systematic review. Moreover, the link between how the use of co-creation design led to the recorded intervention effects and the specific features of the co-creation process that lead to intervention effectiveness remains unclear. Also, questions around the transferability of co-creation process and co-creation output (eg, interventions) to new contexts remain unclear, which also establishes the need for a synthesis of studies. Three models (distributed, generalisable and cascade) of scaling cocreated interventions have been recommended.[22] Hence, it will be useful to explore the model used by existing intervention co-creation studies while evaluating the effectiveness of the cocreated interventions. This project, therefore, seeks to evaluate the overall experiences of cocreators and the effectiveness of cocreated interventions in improving the health behaviours of individuals with NCDs.

METHODS AND ANALYSIS

Research aim and objectives

The aim of the study is to evaluate the experiences of all stakeholders involved in the process of intervention co-creation targeted at improving health behaviours and/or health outcomes, and the effectiveness of cocreated interventions in improving the health behaviours and/or health outcomes of people with NCDs.

The specific objectives of the study are to:

1. Evaluate the experiences of cocreators involved in the process of intervention development targeted at improving the health behaviours (physical activity, alcohol and tobacco intake, diet, help-seeking and screening behaviour) and/or health outcomes (eg, quality of life, biomedical markers, overall health status and disease severity) of people with NCDs.
2. Determine the effectiveness of cocreated interventions in improving the health behaviours (physical activity, alcohol and tobacco intake, diet, help-seeking and screening behaviour) and/or health outcomes (eg, quality of life, biomedical markers, overall health status and disease severity) of people with NCDs.
3. Determine the methodological quality of the studies that cocreated interventions targeted at improving the health behaviours and/or health outcomes of people with NCDs.

4. Describe stakeholders involved, outcomes used, interventions designed and the study designs used for the co-creation process.

Design

This systematic review will follow the recommendations described in the updated Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) 2020 guideline[23] and the Enhancing Transparency in Reporting the Synthesis of Qualitative Research statement for the synthesis of qualitative data.[24] The review protocol has been registered with the International Prospective Register of Systematic Reviews (PROSPERO ID: CRD42023391746).

Qualitative review processes

Eligibility criteria

Study design

Qualitative studies and/or studies describing the process of intervention co-creation will be considered for inclusion. The qualitative or process-description studies will include studies that explored the experiences of cocreators involved in the development of interventions targeted at improving the health behaviour and/or health outcomes of individuals with NCDs. Only studies published in the English language will be included. Studies such as cohort studies, case reports, reviews, study protocols and conference abstract will be excluded.

For the purpose of this review, co-creation is defined as 'the generation of new knowledge that is derived from the application of rigorous research methods that are embedded into the delivery of a programme or policy (by researchers and a range of actors including service providers, service users, community organisations and policy-makers) through four collaborative processes: (1) generating an idea (co-ideation); (2) designing the programme or policy and the research methods (codesign); (3) implementing the programme or policy according to the agreed research methods (co-implementation) and (4) the collection, analysis and interpretation of data (coevaluation)'.[25] For this review, a study will only be included if the stakeholders were involved throughout the stages of the intervention development.

Participants

Studies that involved adult (18 years and above) stakeholders who may be individuals with NCDs, caregivers of people with NCDs, healthcare providers of people with NCDs and policy-makers at the national, state or regional level. NCDs are defined as chronic diseases caused by a cumulative impact of some factors from the gene, body physiology, environment and human behaviours.[1] Cancer, chronic pulmonary illness, cardiovascular diseases and diabetes are the four most common NCDs,[1] which will be the main focus of this review. They share the same behavioural risk factors, which include physical inactivity, poor diet, excessive alcohol intake and tobacco intake.[6] However, this review will consider other NCDs in addition to the four most common, since the use of co-creation is still emerging in health research. The review may be restricted to the four most common NCDs if there are enough number of studies on them that met the review's eligibility criteria. The list of NCDs to be considered in this review is provided in the online supplemental appendix 1.

Setting

All settings, including hospitals, community, health centres, home-based, online, hybrid, will be considered. Contextual factors, such as low resource settings, will also be considered.

Outcomes

Studies that explored the experiences (assessed through interviews or questionnaires) of cocreators involved in the development of interventions targeted at improving health behaviours and/or health outcomes of individuals with NCDs will be considered for inclusion. For the purpose of this review, cocreators' experiences will be defined as cocreators' narratives of their participation (eg, how they valued the process and how they felt about the co-creation process) and the outcome (ie, intervention content and their perception of the extent the conclusions drawn from the process reflected their own views).[26]

Quantitative review processes

Eligibility criteria

Study design

To evaluate the effectiveness of cocreated interventions, the review will include robust type 1 hybrid implementation study designs such as randomised control trials (RCTs) and non-RCTs (eg, controlled before and after clinical trials). Randomised control cross over trials and/or mixed method RCTs/non-RCTs will also be considered. The studies must have been targeted at evaluating the effect of cocreated interventions on the health behaviours and/or other health outcomes of individuals with NCDs. Only papers published in the English language will be included. Studies such as cohort studies, case reports, reviews, study protocols and conference abstract will be excluded.

Participants

Studies that involved adults (18 years and above) with NCDs.

Interventions

Studies that explored cocreated interventions targeted at secondary or tertiary prevention of NCDs. For example, cocreated interventions aimed at improving physical activity, improving quality of life, improving biomedical markers (eg, lipid profile, blood pressure, blood glucose, body mass index, inflammatory markers), improving diet, smoking cessation, reducing alcohol intake, improving help-seeking behaviour, improving screening behaviour, improving intervention uptake and adherence, reducing

complications, and reducing mortality in individuals with NCDs will be considered for inclusion.

Setting

All settings, including hospitals, community, health centres, home-based, online, hybrid, low resource settings will be considered.

Outcomes

Studies that included outcomes that measure secondary and/or tertiary prevention of NCDs will be considered. Examples of such outcomes include: health behaviours—PA (eg, self-reported, activity monitor, physical activity questionnaires), tobacco intake, alcohol intake, sedentary lifestyle, diet, screening behaviour, help-seeking behaviour—and health outcomes—QoL, biomedical markers (eg, lipid profile, blood pressure, blood glucose, body mass index, inflammatory markers), overall health status, disease severity, morbidity and mortality rates.

The review will assess the short-term (<6 months) and long-term (≥6 months) effects of cocreated interventions on the above outcomes.

Outcomes prioritisation

The experiences of cocreators involved in the development of interventions targeted at improving health behaviours and/or other health outcomes of individuals with NCDs will be assessed as the primary outcome. The secondary outcomes will be those targeting effectiveness of the intervention, including: health behaviours—PA (eg, self-reported, activity monitor, physical activity questionnaires), tobacco intake, alcohol intake, sedentary lifestyle, diet, screening behaviours, help-seeking behaviours—and health outcomes—QoL, biomedical markers (eg, lipid profile, blood pressure, blood glucose, body mass index, inflammatory markers), overall health status, disease severity, morbidity and mortality rates.

Information sources and search strategy

The search strategy will be three phased. The first phase will entail searching relevant electronic databases to identify potentially eligible studies. The search method will be developed and piloted using the guidance available in the Cochrane handbook for searching qualitative and quantitative studies,[27] as well as the guidance from the Centre for Reviews and Dissemination.[28] The reviewer (EMA) will conduct the database searches in consultation with a librarian. For searching qualitative studies, the comprehensive exhaustive approaches that are used for quantitative searches will be used as provided in the Cochrane handbook.[27] Separate searches will be conducted for qualitative and quantitative. Search terms and filters specific to qualitative and quantitative studies will be used in the search strategy. The search strategy will be developed using controlled vocabularies (eg, MeSH terms) and free text terms related to the review topic. Using Boolean operators ('OR', 'AND' and 'NOT'), the search strings will be combined. The databases to be searched will include MEDLINE (via OVID), Cumulative Index to Nursing and Allied Health Literature (CINAHL) (via EBSCO Host), EMBASE (via OVID), PsycINFO (via OVID), Scopus, Web of Science, Cochrane Library and the grey literature (clinical trial registers and a directory of open-access repository websites, such as http://www.clinicaltrial.gov and http://www.opendor.org). The databases will be searched from inception to the date of the search. A draft of the search strategy for MEDLINE (via OVID) is presented in the online supplemental appendix 2.

The second phase will entail searching the recently developed Co-creation Database (https://zenodo.org/record/6773028#.Y9h2sezP1pg),[29] which is a curated open-access database housing the length and breadth of literature around co-creation from various fields and disciplines. The database currently contains 13 501 co-creation studies published from January 1970 to December 2021, which were identified from searching and screening studies from multiple databases using both human and artificial intelligence.[30] The sources of data for the development of the Co-creation Database included PubMed, CINAHL and the 17 databases contained in ProQuest platform. The search terms/keywords used for the search included: 'co-creat* (TARGETS: co-creation, co-create, co-creating, co-creators, Mode 2 co-creation, agile co-creation, value co-creation); co-conception; co-production; public and patient involvement; public participation; participatory (TARGETS: participatory action research, Participatory practice, Participatory health research, Participatory model, Participatory systems approach, Participatory design, and participatory research programs); experience based design; co-design; user involvement; collaborative design; and citizen science'.[30]

The third phase of the search strategy will entail using a snowballing technique (hand-searching the references of included studies) to identify relevant studies that may be omitted in the first two search phases.

Study selection

The studies will be selected by two independent reviewers based on the review's inclusion criteria. All search citations will be gathered, and duplicate citations will be deleted using Covidence. The software Covidence will also be used to screen the identified studies in two phases. First, two reviewers will independently screen all titles and abstracts of identified studies. Second, full-text versions of studies that passed the first step of screening will be independently screened. A third reviewer will be consulted if there are any inclusion disagreements at any level of study selection. When a conclusion cannot be reached based on the information available in a study, the corresponding author of the study will be contacted for a maximum of three email attempts to provide additional information. The study will be excluded if any of the contacted authors do not respond to the emails, and the reason for exclusion will be explained clearly. The study process will be tracked and presented using the PRISMA flow chart.[23]

Data collection procedure

Data extraction and data items

The data extraction will be conducted by two independent reviewers following the guidance from the Cochrane Consumers and Communication Review Group Data Extraction.[31] An extraction template will be developed using Microsoft Excel. Considering the first objective interested in evaluating the cocreators' experiences, the guidance for qualitative data extraction will be followed.[27] The following data items will be extracted: author details, country of study, study aim/objective, study design, recruitment/sampling process, number of cocreators involved, type of stakeholders involved, theoretical framework underpinning the co-creation, time frame for the co-creation process (number of sessions, duration of each session, duration of the entire co-creation process), structure of the co-creation process (eg, if all the stakeholders were together or there were meetings according to each type of stakeholder), information on how power dynamics were managed, study setting, context (eg, low-resource area), tools/materials used to facilitate the process, data collection methods, data analysis process, description of interventions designed and study findings on cocreators' experiences. Considering that data extraction requires an iterative process, the review team will meet regularly to discuss the extracted data and attain collective understanding.[27] The link to the data extraction Excel sheet for the first objective is provided in the online supplemental appendix 3.

For the second objective interested in the effectiveness of cocreated interventions, the guidance for quantitative data extraction will be followed.[27] The following data items will be extracted: author details, country of study, study aim, participants' characteristics (which include disease condition age range, gender composition, disease duration and chronicity, comorbidities), study inclusion and exclusion criteria, study sample size (both intervention and control groups), study design, intervention co-creation process (eg, stakeholders involved, duration of the process, structure of the process), intervention description (components/parameters, context/mode of delivery, intervention and follow-up duration, follow-up), comparison group intervention, study setting, intervention duration, time of outcome assessment, outcome(s) assessed, the outcome(s) measurement methods, baseline outcome values (treatment group), post intervention outcome values (treatment group), short-term (<6 months) outcome values (treatment group), long-term (6+ months) outcome values (treatment group), baseline outcome values (comparison group), postintervention outcome values (comparison group), short-term (<6 months) outcome values (comparison group), long-term (6+ months) outcome values (comparison group), process outcome data (eg, adherence, cost-effectiveness, patient satisfaction) and conclusions. The link to the data extraction Excel sheet for the second objective is provided in the online supplemental appendix 4. Furthermore, to enable a robust description of the interventions and to facilitate replicability, the Template for Intervention Description and Replication (TIDieR) Framework[32] will be used to extract information on the content, context and intensity of the interventions reported in the studies. The TIDieR Framework helps with quality reporting of all the necessary components of interventions, which makes it easily available for use by clinicians, patients and policy-makers.[32]

Quality assessment

For the fourth objective interested in assessing the methodological rigour of the intervention co-creation studies, the reporting quality of the intervention co-creation studies will be assessed. There are existing tools to guide the process of intervention co-creation; checklist for reporting intervention co-creation[22] and to assess whether reporting has been adequate.[33] However, neither of these tools provided a scoring system for evaluating the quality of intervention co-creation studies. Furthermore, some crucial intervention development evaluation items were not adequately described in the existing tools. Therefore, we developed a tool, adapting the existing tools, to include three items on evaluating equal participation during co-creation (eg, setting of ground rules, dividing cocreators into subgroups, reassuring cocreators of their right of equal status in group), evaluating if the cocreated intervention was adequately described (eg, intervention content, mode of delivery, dosage) and evaluating the experiences of cocreators involved in the process (eg, satisfaction on organisation, length of delivery, date(s) of delivery, setting, delivery of activities, facilitators, content of the intervention, mode of delivery, extent to which intervention reflects cocreators' input). Furthermore, we developed a scoring system for grading the quality of intervention co-creation studies. The adapted tool named 'The Adapted Checklist for Reporting Intervention Co-creation' (A-CRIC tool) contains three domains; domain 1 assesses the planning of the intervention co-creation project, domain 2 assesses the conducting of the intervention co-creation project, while domain 3 assesses the evaluation of the co-creation project. Each domain has specific items, numbering to a total of 22 items (see table 1). For this review, each of the studies will be rated as either low reporting quality, moderate reporting quality or high reporting quality depending on their scores out of the 22 items. A study with a score of ≤7 will be regarded as having low reporting quality, score of 7–14 will be regarded as moderate reporting quality, while score of 15 and above will be regarded as high reporting quality. This is to create a distinction between the methodological rigour of the studies, which may inform how stakeholders may use the evidence contained in the individual studies. However, none of the studies will be excluded based on their reporting quality score for this review. The A-CRIC tool focuses on assessing the quality of the co-creation process but not the study outcomes. Any disagreement in the screening results will be resolved through discussion,

Table 1 The Adapted Checklist for Reporting Intervention Co-creation tool

Domain	Checklist item	Score (no=0, yes=1)
(1) Planning	(1) Was the study aim adequately framed? (eg, description of the problem, objective, design, end users, cocreators, evaluation).	
	(2) Was the sampling procedure described? (sampling technique, inclusion criteria, recruitment setting).	
	(3) Was the study setting described?	
	(4) Were the cocreators described? (number, sociodemographic characteristics).	
	(5) Were the study facilitators described?	
(2) Conducting	(6) Were efforts made to facilitate ownership described? (eg, study group branding, identifying the rights and responsibilities of the group).	
	(7) Were strategies to ensure equal participation described? (eg, setting of ground rules, dividing cocreators into subgroups, reassuring cocreators of their right of equal status in group).	
	(8) Was the overall aim of the co-creation presented to the cocreators?	
	(9) Was the goal of each co-creation session/workshop/meeting presented?	
	(10) Were upskilling sessions conducted and described?	
	(11) Were the previous evidence underpinning the intervention development process presented to the group and described?	
	(12) Were the prototype intervention and the prototyping process described?	
	(13) Were the frequency and duration of meetings/sessions/workshops described?	
	(14) Were the interactive techniques and materials used described?	
	(15) Were fieldwork techniques or methods used described? (eg, testing the prototype intervention with end users not involved in the co-creation)	
	(16) Was the iterative process of co-creation described?	
(3) Evaluation: process	(17) Were cocreators' experiences evaluated and described? (eg, satisfaction on organisation, length of delivery, date(s) of delivery, setting, delivery of activities, facilitators, content of the intervention, mode of delivery, extent to which intervention reflects cocreators' input)	
	(18) Was the method of evaluation described? (eg, questionnaires, interviews, attendance rates)	
	(19) Was the method of result dissemination described?	
(4) Evaluation: outcome	(20) Was the cocreated intervention described? (eg, intervention content, mode of delivery, dosage).	
	(21) Was the method of evaluating the validity of the outcome and the process described? (eg, face validation, member checking of developed prototype).	
	(22) Were plans for the testing of the effectiveness/scalability of the cocreated intervention described?	

reflection and consensus. A third reviewer will be invited if a consensus could not be reached.

The A-CRIC tool was developed by the research team comprising of experts with experience in co-creation and health intervention development. The items added to the tool and the scoring system were discussed and agreed on by the research team; however, a structured consensus panel method (eg, the e-Delphi process) was not used, which is a limitation. Furthermore, the face validity of the tool was assessed and confirmed by the research team. For the face validity assessment, the clarity, comprehensibility and appropriateness of the items in relation to the intervention co-creation quality assessment purpose were evaluated and confirmed by the research team.

Risk-of-bias (ROB) assessment

For the first objective, it is expected that the study types may be mostly qualitative studies, and some process studies that describe the process of co-creation. Hence, the Quality Assessment Tool for studies with Diverse Designs, which was updated to the Quality Assessment with Diverse Studies critical appraisal tool will be used to appraise the studies.[34] The tool has 16 items for quality assessment and is rated on a scale from 0 to 3 representing 'not at all, very slightly, moderately and complete'. The '0' represents the lowest quality, while '3' represents the highest quality.

Given that the secondary outcomes of this review are health behaviours and health outcomes, an outcome-specific quality assessment tool will also be used to appraise the quality of the studies that investigated the effectiveness of cocreated interventions on the health behaviours and health outcomes of individuals with NCDs. For studies that are RCTs, the Cochrane Collaboration risk of bias tool V.2 (ROB V.2)[35] will be used to assess the potential risk of bias (ROB) in the studies. The

tool is divided into five domains: (1) ROB from randomisation, (2) deviations from the intended interventions, (3) missing outcome data, (4) ROB in outcome measurement and (5) ROB in outcome measurement. For all the studies included, each domain will be rated as 'high risk', 'low risk' or 'some concerns'. Depending on the ROB in the five domains, an overall ROB judgement will be made as either 'low risk' or 'high risk'. If there is insufficient information to determine the possible ROB in any study, the corresponding authors will be approached three times through mail, and if no answer or enough clarification is received, the potential ROB will be labelled as 'unclear'.

The variant of ROB V.2 known as Risk of Bias in Non-randomised Studies—of Interventions tool (ROBINS-I tool)[36] will be used to assess the quality of non-RCTs. The ROBINS-I tool has seven domains, and the judgements in each domain culminate to an overall ROB judgement. The overall ROB judgement could be low risk, moderate risk, serious risk, critical risk or no information.[36] For both ROB V.2 and ROBINS-I, the potential ROB will be judged by two independent reviewers. Disagreements will be discussed in order to reach a consensus, and/or the third reviewer will be consulted.

Data analysis/synthesis

A narrative synthesis will be conducted to summarise the results from all the included studies. A narrative summary of the data addressing the review objectives will be conducted. Findings from qualitative studies will be synthesised using thematic synthesis method developed by Thomas and Harden.[37] The method has three stages: (1) free line-by-line coding of the results from the included studies, (2) organising these 'free codes' into categories to develop 'descriptive' themes and (3) developing 'analytical' themes from interpreting and abstracting the descriptive themes into 'higher order' descriptions. We acknowledge that thematic synthesis method has some cons such complexity of the synthesis process and limited interpretive power.[38] However, the review team has expertise to conduct a robust thematic synthesis to minimise the limitations associated with this approach.

For findings from quantitative studies, a narrative summary of the results on the effects of cocreated intervention on PA and other health outcomes will be conducted. Given that there may be substantial heterogeneity in terms of co-creation process, characteristics of cocreators, intervention content and types of NCDs, which may limit the results from meta-analysis. The Cochran's X^2 test will be used to measure heterogeneity in included studies, which will be quantified using I^2 statistic.[39] In addition to the I^2 statistic, heterogeneity will be assessed through visual assessment of the forest plot. The I^2 statistic tests the percentage of variability in effect estimates that could be a result of heterogeneity other than sampling error.[27] For this review, substantial heterogeneity will be determined when the I^2 statistic is >50%. In the case of substantial heterogeneity, a sensitivity analysis will be conducted to determine the factors that led to the variability in the estimates. In any case, the pooling of data in a meta-analysis will still be conducted. However, homogenous data will be pooled together for meta-analysis using a fixed effects model and heterogenous data will be pooled together using a random effects model.[27] This approach compares standardised mean differences in the intervention and control groups for the included studies (95% CIs). A subgroup analysis will be conducted to pool studies with similar characteristics together. RevMan V.5 software will be used for the meta-analysis.

Meta-biases/publication bias

The funnel plot for asymmetry will be used to examine meta-bias, followed by the Egger regression test.[39]

Integration of findings

Given the review objectives, both qualitative and quantitative data will emerge from the included studies. This review will follow a parallel result convergent synthesis approach[40] to integrate the quantitative and qualitative data. This approach is recommended for reviews involving two or more research questions.[41] The qualitative and quantitative findings will be presented separately in the result section and integrated in the discussion section.[41] The qualitative and quantitative data will be juxtaposed in the discussion section and organised into a line of argument to develop an overall configured analysis.[27] This will facilitate the provision of a robust description of intervention effectiveness, context (eg, who it was for, and under what factors) and the mechanisms through which the cocreated interventions impact the targeted outcomes. Furthermore, the integration may help expose the link between cocreators' or participant's experiences and the intervention effects. Findings will be presented narratively where configuration is not possible.

Reporting of the review

The systematic review will be reported using the PRISMA statement as a guideline.[23] All items that are relevant to the review will be reported. A PRISMA checklist will be published with the final report. The PRISMA Protocols checklist[42] was followed for drafting the study protocol (online supplemental appendix 5).

Confidence in cumulative evidence

Two independent reviewers will be involved in assessing confidence in cumulative evidence. For quantitative studies, the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system will be used to assess the quality of cumulative evidence from the systematic review.[43] The quality of evidence will be assessed across five domains, including bias risk, consistency, directness, precision and publication bias. The cumulative evidence from the review will be categorised as 'high quality', 'moderate quality', 'poor quality' or 'very low quality' evidence.[43]

The confidence in qualitative review findings will be assessed using the GRADE-CERQual approach.[44] The

GRADE-CERQual will assess evidence from qualitative review findings based on four components: methodological limitations,[45] coherence,[46] adequacy of data[47] and relevance.[48] The cumulative evidence from the review will be categorised as 'high quality', 'moderate quality', 'poor quality' or 'very low quality' evidence (Lewin *et al*, 2018).

Patient and public involvement

Given that this will be a review of already published data, patients and public stakeholders may not be involved at the early stage of the review. However, patients and public stakeholders may be consulted for input during the results interpretation, writing and dissemination stages of the review. For example, infographics and summaries of the study results may be presented to stakeholders such as individuals with NCDs, caregivers of individuals with NCDs or healthcare providers of individuals with NCDs in a workshop or via email to get their input on the results and to understand if the findings are applicable to their context. Furthermore, a dissemination event involving the relevant stakeholders may be organised.

POTENTIAL AMENDMENTS

To avoid publication bias, there will be no deviations from the review protocol based on the findings from the included studies. However, when an amendment is very necessary and justifiable, such amendment(s) will be reported and implemented. Any amendment made will be reported in the review's publication manuscript.

DISCUSSION

Co-creation is a promising design concept that may be useful in improving the social, clinical and resource effectiveness of health interventions, as well as addressing issues related to poor uptake and adherence to interventions. However, it is necessary to evaluate the experiences of stakeholders involved in co-creation process and evaluate the effectiveness of the design in improving targeted health outcomes.

An existing review investigated the merits of involving patients as coresearchers in health research and concluded that academic skills, methodological quality and knowledge are often neglected in the bid to enhance collaborative approaches.[49] The review argued that the traditional methods of patient involvement as opposed to involving patients as coresearchers may hold more scientific benefits.[49] However, the review included only qualitative studies that merely described the process and merits of involving patients as coresearchers, and not empirical studies that evaluated the effectiveness of cocreated interventions, which limited the external validity of the review's findings. The review also did not focus on the experiences of the stakeholders involved in the collaborative processes; hence, it could not be determined if stakeholders involved in the primary studies were satisfied with the process and the extent to which their voices were heard. Hence, our review will evaluate evidence from RCTs and non-RCTs on the effectiveness of cocreated interventions and the experiences of the stakeholders involved in the intervention development processes.

Another review investigated the effectiveness of co-creation in international health research and reported that co-creation showed small-to-moderate effect in improving various health outcomes including physical health, health-promoting behaviour, accessibility of health services and self-efficacy.[50] However, the review was not focused on any specific population group and included studies involving healthy populations alongside studies involving individuals with disease conditions, and there was no subgroup analysis to explore the possible impact of the group variations on the study outcomes. This limited the generalisability of the study findings. Furthermore, some of the studies included in the review merely used participatory designs and only involved stakeholders in one of the four collaborative processes of co-creation. Hence, some of the methods used in the studies included in the review do not meet the definition of 'co-creation' as a research design. Finally, the review could not determine the long-term effect of cocreated interventions as most of the included studies measured outcomes at baseline and immediately post intervention, which limited the possibility of having conclusive evidence of effect. Therefore, our review will aim to determine both the short-term and long-term effectiveness of cocreated interventions on the target outcomes in individuals with NCDs.

Our systematic review will integrate both qualitative and quantitative data to determine the effectiveness of cocreated interventions in improving the targeted outcomes in individuals with NCDs. The integrative approach will help for more rigour, facilitate a more thorough and complete analysis, enhance the external validity of the results and provide better insights on the mechanisms through which the cocreated interventions have effects.[51] The findings from this review may inform future research and policies on the use of co-creation in the development of effective, bespoke interventions. Furthermore, our systematic review will be the first to use a scoring tool (A-CRIC Tool) to appraise the reporting quality of studies on intervention co-creation, which will set the pace for similar reviews and trigger quality assurance for future intervention co-creation studies.

Considering that contextual factors (eg, low resource settings) could influence study outcomes, and sometimes moderate the effect of an intervention,[52] this review will evaluate how contextual factors may have influenced the results of the included studies. Furthermore, the integration of qualitative data with quantitative data in this review may also provide insight on the impact of contextual factors.

The potential limitation of the review could be the paucity of rigorous clinical trials evaluating the effectiveness of cocreated interventions in improving targeted outcomes in individuals with NCDs. Hence, there may not be enough studies to conduct disease-specific subgroup meta-analysis for all the population groups considered in this review. Furthermore, there may be substantial

heterogeneity due to varying population groups and intervention types.

Author affiliations
[1]Department of Physiotherapy and Paramedicine, School of Health and Life Sciences, Glasgow Caledonian University, Glasgow, UK
[2]Department of Medical Rehabilitation, University of Nigeria—Enugu Campus, Enugu, Nigeria
[3]School of Allied Health Sciences, University of Suffolk, Ipswich, UK
[4]School of Health and Life Sciences, University of the West of Scotland, Lanarkshire, UK
[5]Department of Gerontology, Faculty of Social Sciences, University of Southampton, Southampton, UK
[6]Department of Medical Rehabilitation, Nnamdi Azikiwe University, Awka, Anambra, Nigeria

Twitter Ebuka Miracle Anieto @ebuka_anieto and Chris Seenan @chrisseenan

Contributors EMA conceived the study, designed the systematic review protocol, developed the search strategy and drafted the manuscript. UA, PMD, IBA and CS contributed substantially to the development of the protocol. All the authors provided critical review of the manuscript and approved the final version of the manuscript for publication. EMA is the guarantor of the review.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD
Ebuka Miracle Anieto http://orcid.org/0000-0002-8160-9701

REFERENCES

1 World Health Organization. Non communicable diseases. 2022. Available: https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases [Accessed 18 Jul 2023].
2 Unwin N, Alberti KGMM. Chronic non-communicable diseases. *Ann Trop Med Parasitol* 2006;100:455–64.
3 Serour M, Alqhenaei H, Al-Saqabi S, *et al*. Cultural factors and patients' adherence to lifestyle measures. *Br J Gen Pract* 2007;57:291–5.
4 Fernandez-Lazaro CI, García-González JM, Adams DP, *et al*. Adherence to treatment and related factors among patients with chronic conditions in primary care: a cross-sectional study. *BMC Fam Pract* 2019;20:132.
5 World Health Organization. *Adherence to long-term therapies: evidence for action*. World Health Organization, 2003. Available: https://apps.who.int/iris/handle/10665/42682 [accessed 18 Jul 2023].
6 Lunde P, Nilsson BB, Bergland A, *et al*. The effectiveness of smartphone apps for lifestyle improvement in noncommunicable diseases. *J Med Internet Res* 2018;20:e162.
7 Bate P, Robert G. Experience-based design: from Redesigning the system around the patient to Co-designing services with the patient. *Quality and Safety in Health Care* 2006;15:307–10.
8 Sanders E-N, Stappers PJ. Co-creation and the new landscapes of design. *CoDesign* 2008;4:5–18.
9 Janamian T, Crossland L, Wells L. On the road to value Co-creation in health care: the role of consumers in defining the destination, planning the journey and sharing the drive. *Med J Aust* 2016;204(7 Suppl):S12–4.
10 Greenhalgh T, Jackson C, Shaw S, *et al*. Achieving research impact through Co-creation in community-based health services. *Milbank Q* 2016;94:392–429.
11 Giné-Garriga M, Sandlund M, Dall PM, *et al*. A Co-created intervention with care home residents and university students following a service-learning methodology to reduce sedentary behaviour: the GET READY project protocol. *J Frailty Sarcopenia Falls* 2018;3:132–7.
12 Palmer VJ, Chondros P, Piper D, *et al*. The CORE study protocol: a stepped wedge cluster randomised controlled trial to test a Co-design technique to optimise psychosocial recovery outcomes for people affected by mental illness in the community mental health setting. *BMJ Open* 2015;5:e006688.
13 Popp J, Grüne E, Carl J, *et al*. Co-creating physical activity interventions: a mixed methods evaluation approach. *Health Res Policy Sys* 2021;19.
14 Timmerman JG, Tönis TM, Dekker-van Weering MGH, *et al*. Co-creation of an ICT-supported cancer rehabilitation application for resected lung cancer survivors: design and evaluation. *BMC Health Serv Res* 2016;16:155.
15 Polese F, Tartaglione AM, Cavacece Y. Patient empowerment for Healthcare service quality improvements: a value Co-creation view. 2016.
16 McConnell T, Best P, Davidson G, *et al*. Coproduction for feasibility and pilot randomised controlled trials: learning outcomes for community partners, service users and the research team. *Res Involv Engagem* 2018;4:32.
17 Leask CF, Sandlund M, Skelton DA, *et al*. Co-creating a tailored public health intervention to reduce older adults' sedentary behaviour. *Health Education Journal* 2017;76:595–608.
18 Beckett K, Farr M, Kothari A, *et al*. Embracing complexity and uncertainty to create impact: exploring the processes and transformative potential of Co-produced research through development of a social impact model. *Health Res Policy Sys* 2018;16.
19 Williams O, Sarre S, Papoulias SC, *et al*. Lost in the shadows: reflections on the dark side of Co-production. *Health Res Policy Syst* 2020;18:43.
20 Dong B, Evans KR, Zou S. The effects of customer participation in Co-created service recovery. *J of the Acad Mark Sci* 2008;36:123–37.
21 Paul L, Wyke S, Brewster S, *et al*. Increasing physical activity in stroke survivors using STARFISH, an interactive mobile phone application: a pilot study. *Top Stroke Rehabil* 2016;23:170–7.
22 Leask CF, Sandlund M, Skelton DA, *et al*. Framework, principles and recommendations for utilising participatory methodologies in the Co-creation and evaluation of public health interventions. *Res Involv Engagem* 2019;5:2.
23 Page MJ, McKenzie JE, Bossuyt PM, *et al*. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71.
24 Tong A, Flemming K, McInnes E, *et al*. Enhancing transparency in reporting the synthesis of qualitative research: ENTREQ. *BMC Med Res Methodol* 2012;12:181.
25 Pearce T, Maple M, Shakeshaft A, *et al*. What is the Co-creation of new knowledge? A content analysis and proposed definition for health interventions. *Int J Environ Res Public Health* 2020;17:2229.
26 Bowen S, McSeveny K, Lockley E, *et al*. How was it for you? experiences of participatory design in the UK health service. *CoDesign* 2013;9:230–46.
27 Cochrane Handbook for Systematic Reviews of Interventions, . 2022Available: https://training.cochrane.org/handbook/current [Accessed 18 Jul 2023].
28 Centre for Reviews and Dissemination. Our guidance - centre for reviews and dissemination. University of York, 2009. Available: https://www.york.ac.uk/crd/guidance/
29 Loisel Q, Agnello D. Chastin S. Co-creation database. 2022. Available: https://doi.org/10.5281/zenodo.7849501
30 Agnello DM, Loisel QEA, An Q, *et al*. Establishing a health CASCADE–Curated open-access database to consolidate

knowledge about Co-creation: novel artificial intelligence–assisted methodology based on systematic reviews. *J Med Internet Res* 2023.
31 Cochrane Consumers and Communication Review Group. Consumers and communication group resources for authors. 2016. Available: https://cccrg.cochrane.org/author-resources [Accessed 18 Jul 2023].
32 Hoffmann TC, Glasziou PP, Boutron I, *et al*. Better reporting of interventions: template for intervention description and replication (Tidier) checklist and guide. *Gesundheitswesen* 2016;78:e174.
33 McCaffrey L, McCann B, Giné-Garriga M, *et al*. Adult Co-creators' emotional and psychological experiences of the Co-creation process: A health CASCADE Scoping review protocol. 2022.
34 Harrison R, Jones B, Gardner P, *et al*. Quality assessment with diverse studies (Quads): an appraisal tool for methodological and reporting quality in systematic reviews of mixed- or multi-method studies. *BMC Health Serv Res* 2021;21:144.
35 Sterne JAC, Savović J, Page MJ, *et al*. Rob 2: a revised tool for assessing risk of bias in randomised trials. *BMJ* 2019;366:l4898.
36 Sterne JA, Hernán MA, Reeves BC, *et al*. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ* 2016;355:i4919.
37 Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic reviews. *BMC Med Res Methodol* 2008;8:45.
38 Flemming K, Booth A, Garside R, *et al*. Qualitative evidence synthesis for complex interventions and guideline development: clarification of the purpose, designs and relevant methods. *BMJ Glob Health* 2019;4(Suppl 1):e000882.
39 Egger M, Smith GD, Schneider M, *et al*. Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997;315:629–34.
40 Noyes J, Booth A, Moore G, *et al*. Synthesising quantitative and qualitative evidence to inform guidelines on complex interventions: clarifying the purposes, designs and outlining some methods. *BMJ Glob Health* 2019;4(Suppl 1):e000893.
41 Hong QN, Pluye P, Bujold M, *et al*. Convergent and sequential synthesis designs: implications for conducting and reporting systematic reviews of qualitative and quantitative evidence. *Syst Rev* 2017;6:61.
42 Moher D, Shamseer L, Clarke M, *et al*. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4:1.
43 Guyatt GH, Oxman AD, Kunz R, *et al*. GRADE guidelines: 2. framing the question and deciding on important outcomes. *Journal of Clinical Epidemiology* 2011;64:395–400.
44 Lewin S, Booth A, Glenton C, *et al*. Applying GRADE-Cerqual to qualitative evidence synthesis findings: introduction to the series. *Implement Sci* 2018;13(Suppl 1):2.
45 Munthe-Kaas H, Bohren MA, Glenton C, *et al*. Applying GRADE-Cerqual to qualitative evidence synthesis findings—paper 3: how to assess methodological limitations. *Implement Sci* 2018;13(Suppl 1):9.
46 Colvin CJ, Garside R, Wainwright M, *et al*. Applying GRADE-Cerqual to qualitative evidence synthesis findings—paper 4: how to assess coherence. *Implement Sci* 2018;13(Suppl 1):13.
47 Glenton C, Carlsen B, Lewin S, *et al*. Applying GRADE-Cerqual to qualitative evidence synthesis findings—paper 5: how to assess adequacy of data. *Implementation Sci* 2018;13:14.
48 Noyes J, Booth A, Lewin S, *et al*. Applying GRADE-Cerqual to qualitative evidence synthesis findings–paper 6: how to assess relevance of the data. *Implement Sci* 2018;13(Suppl 1):4.
49 Malterud K, Elvbakken KT. Patients participating as Co-researchers in health research: a systematic review of outcomes and experiences. *Scand J Public Health* 2020;48:617–28.
50 Halvorsrud K, Kucharska J, Adlington K, *et al*. Identifying evidence of effectiveness in the Co-creation of research: a systematic review and meta-analysis of the international healthcare literature. *J Public Health (Bangkok)* 2021;43:197–208.
51 Richards DA, Bazeley P, Borglin G, *et al*. Integrating quantitative and qualitative data and findings when undertaking randomised controlled trials. *BMJ Open* 2019;9:e032081.
52 Van der Elst M, Schoenmakers B, Dierckx E, *et al*. A search for relevant contextual factors in intervention studies: a stepwise approach with online information. *BMJ Open* 2022;12:e057048.