Scoping review protocol of the use of codesign methods in stroke intervention development

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ABSTRACT

Introduction Codesign is an emerging research method to enhance intervention development by actively engaging non-researchers (eg, people who have had a stroke, caregivers and clinicians) in research. The involvement of non-researchers in research is becoming increasingly popular within health studies as it may produce more relevant and effective findings. The stroke population commonly exhibits challenges such as aphasia and cognitive changes that may limit their participation in codesign. However, the use of codesign within the stroke literature has not been comprehensively reviewed. This scoping review will determine: (1) what is the extent, range and nature of stroke research that has used codesign methods? (2) What codesign methods have been used to develop stroke interventions? (3) What considerations for codesigning interventions with people who have stroke are not captured in the findings?

Methods and analysis This is a protocol for a scoping review to identify the literature relating to stroke, and codesign will be conducted on OVID Medline, OVID Embase, OVID PsychNFO, EBSCO CINAHL, the Cochrane Library, Scopus, PEDro-Physiotherapy Evidence Database and Global Index Medicus. Studies of any design and publication date will be included. Title and abstract and full-text review will be conducted independently by two reviewers. Data will be extracted, collated and then summarised descriptively using quantitative (eg, numerical descriptions) and qualitative (eg, textual descriptions) methods. Numerical summaries will map the extent (eg, number of studies), range (eg, types of studies) and nature (eg, types of interventions developed) of the literature on this topic. A thematic analysis will provide insights into the codesign methods (eg, activities, non-researchers), including heterogeneity across and within studies.

Ethics and dissemination This review protocol does not require ethics approval as data has not been collected/analysed. The findings will highlight opportunities and recommendations to inform future codesign research in stroke and other populations who exhibit similar challenges/disabilities, and they will be disseminated via publications, presentations and stakeholder meetings.

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STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Our search strategy will be peer reviewed using the Peer Review of Electronic Search Strategies to enhance quality and comprehensiveness.
⇒ While we have broadly defined codesign in this review, we may miss studies within our search as the terminology describing codesign methods is inconsistent across health studies.
⇒ We plan to search multiple databases and include empirical and non-empirical evidence to enhance the comprehensiveness.

INTRODUCTION

Research generally tends to be conducted on patients rather than with or by patients1 as the shift to patient-centred approaches in health research has not occurred at the same pace as the healthcare system.1 Health interventions can fail to demonstrate efficacy if they are poorly designed.2 Poorly designed interventions can result from misalignment between researchers’ aims and the needs of users.3 For example, Redfern et al4 found that complex stroke interventions lacked efficacy, partly because they rarely considered the user’s (eg, patients and caregivers) views and needs within the intervention design and delivery.4

Involving non-researchers, such as people who have had a stroke, caregivers or family members, and clinicians, is becoming more common in shaping the research agenda, design, conduct and dissemination.5–9 Including non-researchers in research has been a recommended strategy within the literature,10–14 encouraged by peer-reviewed journals (eg, BMJ Open15 and BMC16) and research funding agencies (eg, the Canadian Institutes for Health Research17 and the National Institutes of Health18) to promote more relevant, higher-quality and patient-centred health research interventions.3

Codesign is a participatory research approach widely used to integrate multiple
stakeholders in health research. It is defined as the engagement of non-research groups, such as patients and healthcare providers, in research-related activities. The benefits of codesign include bridging the gap between researchers’ aim and the users’ needs, generating successful outputs, and reducing research waste. Evaluation of the impact of codesign has indicated that codesign approaches can lead to more design ideas than non-codesigned approaches, and the designs are more original than those designed by only professionals.

Codesign research methods are found to differ across populations (eg, older adults and adults with intellectual disabilities) and studies in terms of the types of codesign activities, the timing of codesign activities and strategies for participant engagement in codesign. Codesign activities can include consultations with non-research participants to capture their views on research proposals, designs, outcomes and materials (eg, verbal interviews and focus groups after reviewing research materials).

Participatory research approaches, including codesign, have been recommended in stroke research to assess intervention acceptability and feasibility and improve intervention relevancy and effectiveness on health outcomes. The stroke population commonly exhibits stroke-related impairments that can impact their communication (eg, aphasia), cognition (eg, interpersonal skills) and physical functioning (eg, hemiparesis), which may limit their participation in the codesign. Codesign methods may be customised to successfully engage people who have had a stroke in codesign activities. For instance, Kulnik et al used aphasia-friendly communication to engage people who have had a stroke that had communication difficulties in codesign. In another study, Zacharia et al conducted a codesign activity with multiple codesign participant groups, including individuals who have had a stroke, two caregivers and six dieticians. They engaged participants in a codesign activity using journey maps and personas that exemplified common stroke-related impairments that could impact adherence to a diet programme. These studies highlight the need to consider (1) stroke-related factors in codesign and (2) the inclusion of non-research participants beyond individuals who have had a stroke (eg, stroke clinicians and caregivers). Unfortunately, there is limited guidance on the use of codesign methods within the stroke literature. The lack of guidance on opportunities and recommendations for codesign in stroke research may trigger negative aspects of codesign, including the tension between researchers and participants during decision-making, tokenistic or unmeaningful participant involvement, or limit researchers from undertaking codesign in future stroke studies.

A recent scoping review protocol published by Hall et al seeks to examine patient and public involvement in stroke research. Since codesign is one method for achieving patient and public involvement, Hall et al may include and describe studies that use codesign methods, among other methods. However, their review is limited to the empirical literature (excluding opinion articles, editorials, conference abstracts and guideline documents) and the literature published during or after the year 2014 (excluding studies prior to 2014). Since non-empirical evidence can focus on methodology, excluding this evidence may exclude valuable insights into this topic. Additionally, excluding the literature published before 2014 reduces comprehensiveness, given that codesign methods existed before 2014. Thus, the current scoping review protocol outlines a plan to build on and complement the existing literature by (1) determining the extent, range and nature of stroke research that has used codesign methods, (2) identifying the codesign methods used to develop stroke interventions and (3) consulting with key stakeholders to determine what considerations for codesign interventions with people who have stroke are not captured in the current review findings. In doing so, the proposed review’s findings will highlight opportunities for future stroke studies to apply codesign methods.

Methods and analysis
This current paper presents a protocol for a scoping review. A scoping review methodology is appropriate because of the broad nature of codesign. A scoping review methodology aligns with this review’s intent to provide an overview of the extent, range and nature of studies using codesign methods to develop stroke interventions. This scoping review’s design and conduct will be guided by the Arksey & O’Malley and clarified Levac et al scoring review stages. In addition, the Joanna Briggs Institute (JBI) scoping review methodology, for conducting high-quality reviews will guide this review. As recommended by the JBI Scoping Review Methodology Group, the review conduct will follow the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines to enhance reporting quality (online supplemental file 1). We will begin this review in November 2022 and anticipate completion within a year (ie, Fall 2023).

Patient and public involvement
Patients or the public were not involved in the design of this scoping review protocol.

Stage 1: identifying the research question (RQ)
The overarching aim of this review is to learn from the use of codesign within the current stroke literature to inform future research considerations. This proposed review will address the following RQs:

- RQ1: What is the extent, range and nature of stroke research that has used codesign methods?
- RQ2: What codesign methods have been used to develop stroke interventions? The following are subquestions:
  - RQ2a: What are the characteristics of the non-research participants involved in codesign within stroke interventions?
Stage 2: identifying relevant studies
Peer-reviewed literature will be identified using a search strategy created and run by an Information Specialist and Health Science librarian (JM) and informed by the review team. To minimise search errors and enhance the comprehensiveness of the search, the search strategy will be peer reviewed. Subject headings and text words related to the following concepts will be included in the search: ‘codesign’ and ‘stroke’. Due to the lack of standard terminology for codesign within health studies, the search terms will be informed by the terminology used within a related review. To ensure we comprehensively capture relevant literature relating to codesign, we have defined codesign broadly as the engagement of one or more non-research groups in research-related activities that inform the study design of a stroke intervention. Given that codesign extends beyond those impacted by the problem being codesigned (eg, people who have had a stroke), we will also include studies that have used codesign with individuals with the power to address the problem being codesigned (eg, leaders, funders, clinicians, etc.). For comprehensiveness, no date or design limitations will be imposed. However, the search will be restricted to studies available in the English language due to resource constraints and exclude animal only studies.

The search strategy will be created, finalised in OVID Medline and then translated to OVID Embase, PEDro, Physiotherapy Evidence Database, OVID PsycINFO, EBSCO CINAHL, the Cochrane Library, Scopus and Global Index Medicus. A preliminary draft of the OVID Medline search strategy (conducted on 12 January 2022) is located in (online supplemental file 2). The search will be reported following the PRISMA extension for searching checklist. Grey literature will also be identified by hand searching relevant grey literature databases and catalogues and search engines, including ClinicalTrials.gov, stroke conferences, thesis repositories, as well as stroke research guidelines. To identify studies that were not captured within the search, we will hand-search reference lists of included articles and consult with experts in the field.

Stage 3: study selection
The search results will be added to a reference software called Endnote, where duplicates will be removed. The deduplicated studies will be imported to Covidence (a platform used to screen studies). Prior to the screening of the titles and abstracts, the inclusion criteria will be tested on a random sample of articles to confirm the minimum inter-rater agreement among screeners (ie, kappa statistic>0.61) and the inclusion criteria is clear. The team members will discuss any conflicts during the testing. If necessary, they will modify the inclusion criteria to improve clarity. The titles and abstracts of studies will be independently screened (ie, categorised into ‘yes’, ‘no’ or ‘maybe’) by two team members based on the inclusion criteria outlined in table 1. Studies not available in English or full text will be excluded. Moreover, studies that report drug-only interventions will be excluded.

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**Table 1 Inclusion and exclusion criteria**

| Criteria            | Inclusion informed by Slattery et al. | Exclusion                                      |
|---------------------|--------------------------------------|------------------------------------------------|
| **Participants**    | ≥1 Individuals impacted by the problem being codesigned for (eg, people who have had a stroke, stroke caregivers, family members) | Populations other than stroke                  |
|                     | Individuals with the power to address the problem being codesigned for (eg, leaders, decision-makers, clinicians, funders or the public) | Pharmacological interventions                  |
| **Intervention**    | Defined as a non-pharmacological ‘intervention not directly involving a medication; attempting to optimise a complex patient’s healthcare needs or to better manage their chronic illness’. The intervention must be designed for people who have had a stroke or stroke caregivers. Interventions may be non-drug complex behavioural or rehabilitation interventions | Pharmacological interventions                  |
| **Concepts**        | Codesign: engagement of one or more non-research groups in research-related activities that inform the study design. Engagement may entail ‘Consult, Collaborate, Input, Engage, Involve, Design, Produce, Codesign, Co-produce, Partner, Participate, Voice, Dialog, Opinion, Develop’ | Pharmacological interventions                  |
| **Types of sources**| Empirical and non-empirical literature and relevant grey literature (eg, conference abstracts, theses and dissertations) | Pharmacological interventions                  |
| **Design/date**     | Any study design, any date            | Literature not available in English            |
| **Language**        | English only                         |                                                 |
Two reviewers will independently review full texts of the studies that received a ‘yes’ or ‘maybe’ vote during the title and abstract screening. During the title and abstract screening or full-text review, any conflicts will be resolved through team discussions during meetings.

**Stage 4: charting the data**
The research team will create a data extraction form to extract data related to the RQs (see table 2 for sample domains to be extracted).37 43 Two team members will test the data extraction form on more than three articles, and if needed, it will be revised to ensure sufficient details are captured.36

**Stage 5: collating, summarising and reporting**
Data will be reported following the PRISMA-ScR checklist.38 To describe the extent, range and nature of stroke research that has used codesign methods (RQ1), textual descriptions and numerical tables will be used to provide descriptive summaries of data related to the extent (eg, number of studies), range (eg, types of studies) and nature of studies (eg, source, study location, types of interventions, non-research and research participants and outcome measures used to assess non-research participants’ impact) included within the review.

RQ2 seeks to provide details of the codesign methods used to develop stroke interventions, including heterogeneity across and within interventions. To address RQ2, a qualitative thematic analysis44 will analyse heterogeneity across studies relating to codesign methods (eg, activities, non-researchers) and non-research participants. The thematic analysis will involve the following stages: line-by-line coding, the development of descriptive themes and the development of analytic themes. In the first stage of the analysis, the entire study (ie, abstract, introduction, methods, results and discussion sections) will be added to NVivo (a qualitative analysis software) to ensure a comprehensive analysis of study data. The lead author will conduct line-by-line coding of any text pertaining to the codesign methodology.44 Relevant sections of text will be coded into relevant sections of the Guidance for Reporting Involvement of Patients and the Public (GRIPP2) reporting checklist to describe insights about the non-research participants and codesign process.43 46

This checklist emerged to improve reporting transparency, quality of consistency of patient and public involvement in research.46 For example, based on the GRIPP2 long form, we will code data relating to the ‘definition of non-research participants’ from the background section, the ‘level or nature of non-research participants’ involvement’ will be coded from the methods section and the ‘positive and negative impacts of non-research participants’ involvement’ will be coded from the quantitative and qualitative results (eg, themes, quotes) section.46 Two researchers will code all studies and compare the coded data to ensure accuracy. In the second stage of the qualitative analysis, similarities and differences between the coded data across studies will be examined.44 In the last qualitative analysis stage, analytic themes will be constructed based on inferences from the data across studies. Analytic themes will be coconstructed with input from multiple research team members. They will relate to methodological guidance (eg, opportunities and recommendations) for codesign in future stroke studies.44 The study findings will be shared via peer-reviewed publications, presentations and stakeholder meetings, and we will collaborate with relevant stroke stakeholders, including people who have had a stroke, to inform additional dissemination activities.

**Stage 6: consultation**
To address RQ3, we will consult key stakeholders (eg, individuals who have had a stroke, stroke caregivers, stroke researchers) to build on the research findings, enhance methodological rigour and the quality, relevance and impact of this research and help us determine what considerations for codesigning interventions with people who have stroke are not captured in the findings.36 43 Key stakeholders will add an additional informational source and help interpret findings.43 Specifically, individuals who have had a stroke and stroke caregivers will be asked to rank (based on perceived importance) the findings related to how researchers have engaged these groups.

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**Table 2 Extraction domains and examples**

| Domains to be extracted | Examples |
|-------------------------|----------|
| Source (RQ1)            | Country, date and year of publication |
| Study description (RQ1) | Purpose, design and aim of the study, characteristics of intervention being codesigned |
| Outcomes (RQ1)          | Type of outcome measures used to assess non-research participants’ involvement, experiences/impact, positive and negative impacts of non-research participants’ involvement |
| Non-research participants (RQ2a) | Who was involved (eg, sample size, participant type (eg, individual who has had a stroke, caregiver), demographics, characteristics, stroke details, physical, psychological, sensory and cognitive status) |
| Codesign methods (RQ2b) | What was their mode of involvement (eg, one-time, continuous), How were they involved (eg, type and format of codesign activities and activity adaptations) |
| Study conduct (RQ2c)    | Methodological strengths, limitations and recommendations relating to the codesign methods |

RQ, research question.
in stroke interventions. Moreover, they will be asked to reflect on the unique stroke-related considerations for codesigning interventions with people who have stroke, potential barriers to participating in stroke research codesign and recommendations for researchers to meaningfully include individuals who have had a stroke and stroke caregivers in codesign. Additionally, stroke researchers will be asked to rank the barriers and facilitators to stroke intervention codesign and discuss additional barriers and facilitators to codesign stroke interventions not reflected in the review findings and research recommendations to meaningfully include individuals who have had a stroke and stroke caregivers in codesign.

The proposed review will identify how codesign has been used in the stroke literature and inform opportunities and recommendations for using codesign methods in future stroke interventions. This review has the potential to offer insights that can minimise challenges encountered in codesign (eg, declined participation due to low level of functional capacity). By supporting the involvement of non-researchers in stroke studies, this review has the potential to guide the development of future stroke interventions that are more meaningful, appropriate and relevant to people who have had a stroke.

As with all reviews, this review will not be without limitations. First, we may miss potential studies as the terminology describing codesign methods is inconsistent across health studies. We have broadly defined codesign to mitigate this, and our search terms are informed by terms commonly used to describe codesign in health studies. Second, we have decided to limit the inclusion criteria to studies available in English due to resource constraints. However, we acknowledge that we may exclude relevant studies available in languages other than English and introduce bias. Third, stakeholders (eg, individuals who have had a stroke and caregivers) were not involved in the design of this review protocol.

Notable strengths of this review include the grey literature, which reduces publication bias and enhances comprehensiveness. In addition, we will search reference lists of included articles to minimise the number of articles that may not have been identified in the search and maximise comprehensiveness. Prior to title and abstract and full-text review, we will ascertain substantial inter-rater reliability using kappa calculations, enhancing this review’s methodological soundness (eg, transparency, replicability and clarity of inclusion criteria). Finally, the search strategy will be peer reviewed using the Peer Review of Electronic Search Strategies, enhancing quality and comprehensiveness.

ETHICS AND DISSEMINATION

This is a review protocol and does not require ethics approval as no data has been collected or analysed. The findings of this review will be disseminated to key stakeholders through publications and presentations and integrated into the team’s future research. Codesign methods can be used to integrate the perspectives of non-researchers in the research agenda, design, conduct and dissemination. However, the use of codesign methods in the stroke literature has yet to be comprehensively synthesised. The findings of this review will inform codesign methods that can be used with the stroke population and address common consequences, including aphasia and cognitive challenges. The proposed topic is critical to study to maximise the participation of the stroke population, who may have heterogeneous levels of function and require accommodations to participate in research activities, such as codesign, meaningfully. This scoping review protocol indicates a plan to comprehensively review the extent, range and nature of literature related to codesign methods within the stroke literature. Findings from the proposed review can inform the development of recommendations and opportunities for future stroke interventions to design and conduct person-centred research effectively.

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