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ABSTRACT

Introduction: Despite their proven effectiveness for stroke rehabilitation, upper limb rehabilitation robots are underutilised by rehabilitation professionals. For robotic upper limb rehabilitation in stroke to be successful, patients' experiences and those of the rehabilitation professionals must be considered. Therefore, this review aims to synthesise the available evidence on experiences of patients after a stroke with rehabilitation robots for upper limb rehabilitation and the experiences of rehabilitation professionals with rehabilitation robots for upper limb stroke rehabilitation.

Methods and Analysis: Database search will include MEDLINE(Ovid), EMBASE(Elsevier), Cochrane CENTRAL, PsycINFO, Scopus, Web of Science, and CINAHL(EBSCOhost). Grey literature, from Open Grey, PsyArXiv, bioRxiv, medRxiv, and Google Scholar, will also be searched. The inclusion criteria will be studies that include adult patients after a stroke using rehabilitation robots for upper limb rehabilitation, either supervised by rehabilitation professional or by patients themselves, at any phase in their rehabilitation. Robotic upper limb rehabilitation provided by students, healthcare assistants, technicians, non-professional caregivers, family caregivers, volunteer caregivers, or other informal caregivers will be excluded. Articles published in English will be considered regardless of date of publication. Studies will be screened and critically appraised for methodological quality by two independent reviewers. A standardised tool from JBI SUMARI for data extraction, the

meta-aggregation approach for data synthesis, and the ConQual approach for confidence evaluation will be followed.

Ethics and Dissemination: This systematic review is a secondary research project based on previously published research, which does not require ethical approval or informed consent. It is anticipated that this systematic review will highlight the experiences of patients after a stroke and perceived facilitators and barriers for rehabilitation professionals on this topic, which will be disseminated through peer-reviewed publications and national and international conferences.

Systematic review registration number: PROSPERO-CRD42022321402

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ARTICLE SUMMARY

STRENGTHS AND LIMITATIONS OF THIS STUDY

1. This will be the only qualitative systematic review that specifically focuses on the experiences of adult patients after a stroke undergoing upper limb rehabilitation with rehabilitation robots at any stage in their rehabilitation.

2. This will be the first systematic review to focus on the experiences of rehabilitation professionals providing upper limb rehabilitation for stroke patients using all types of rehabilitation robots.

3. This review will include only English-language publications due to limited financial resources, which will limit the review's comprehensiveness.

INTRODUCTION

The use of rehabilitation robots has grown over the past few decades,[1] particularly for upper limb stroke rehabilitation, and the evidence supporting their use is also increasing.[2,3] Several rehabilitation robots are available to assess and rehabilitate stroke-impaired upper limbs, including end-effectors,[4,5] (Figure 1 and Figure 2) exoskeletons,[6] (Figure 3) and exosuits.[7] (Figure 4) They are comparable and may even be superior to conventional rehabilitation in achieving various positive outcomes, such as reducing upper limb motor impairment.[2] In addition, systematic reviews of rehabilitation robots in upper limb stroke rehabilitation have demonstrated that they provide valid outcome measurements of clinically meaningful body functions and structures of the ICF domain, such as muscle viscoelasticity[8] and movement-related kinematic parameters.[9] Rehabilitation robots are therefore increasingly being incorporated into rehabilitation programs both as intervention devices and as tools for evaluating clinical outcomes.

Even though rehabilitation robots are effective in stroke rehabilitation,[1-3] few studies or reviews compare the types of robots used, which may explain the varying results.[10,11] Mehrholz et al., for example, reported that there is no difference between the types of robots and the improvements in upper limb functional performance in their meta-analysis of robot-assisted upper limb training in patients after a stroke.[10] In contrast, based on their meta-analysis, Mogio et al. determined that exoskeleton robots are significantly superior to end-effector robots in improving finger and hand motor function in patients after a stroke.[11] It should be noted that the use of exosuit robots in rehabilitation is a relatively new innovation in robotics and no comparison studies have been completed to date.[7,12,13]

Due to the variety of robots available that provide similar clinical outcomes, selecting an appropriate robotic intervention strategy for patients after a stroke by rehabilitation professionals may be complex and challenging.[10] Thus, the subjective experiences of rehabilitation professionals with robots become crucial in the selection and use of rehabilitation robots in clinical practice. Despite rehabilitation robots being clinically effective, the fact that rehabilitation professionals remain cautious when recommending them in clinical practice makes it even more important to study their experiences with and attitudes towards rehabilitation robots.[14,15] Literature also acknowledges this need, pointing out that rehabilitation professionals' attitudes are as important as the benefits derived from robots, if upper limb rehabilitation robots are to be successfully incorporated into clinical practice and emphasises the need for a systematic approach to the adoption of such robots in rehabilitation.[14,15] Therefore, it is necessary to systematically review, document, and compile rehabilitation professionals' perspectives, experiences, and views on upper limb rehabilitation robots.

Like rehabilitation professionals, the experiences of patients after a stroke, as the end-users of rehabilitation robots, are also vital. The experiences of patients with rehabilitation robots may differ from those of rehabilitation professionals, and therefore, these experiences should be analysed and reported separately. After a stroke, patients tend to prioritise their personal needs and participation in meaningful activities over that of impairment-focused rehabilitation.[16] It is therefore imperative to conduct a comprehensive review of patient experiences related to the use of rehabilitation robots, which may lead to an increase in the acceptance of such devices, and their sustainable use as well as leading to more user-centred designs. Further, a comprehensive summary of patients' likes, dislikes, and

preferences for specific upper limb rehabilitation robots is fundamental when outcomes among the types of robots are largely similar.[10]

The only systematic review to date that aimed to meta-synthesise end-user perceptions of robotics is in motor rehabilitation[17] and provides an early, generic description of the patients', caregivers', and professionals' experiences with rehabilitation robots. In the review by Laparidou et al. an overview of all types of motor rehabilitation using rehabilitation robots for various clinical conditions (shoulder instability/rotator cuff injury, spinal cord injury, stroke, brain injury, cerebral palsy, and unspecified clinical conditions) of all ages (from five to 84 years of age) is provided.[17] This review's inclusion of participants with varied clinical presentations offers valuable insight into their generalised experiences with rehabilitation robots. However, as the review focuses on a broad clinical group, it fails to provide a comprehensive focus and in-depth description of rehabilitation robots' use in adult patients with stroke. Stroke upper limb rehabilitation robots for adults require particular considerations because patients after a stroke have unique needs,[18] abilities,[19] and patterns of functional recovery[20] that are distinct from those of other patients, such as patients with spinal cord injury[21,22] or children with cerebral palsy.[23] Thus, the experiences of patients with rehabilitation robots in stroke rehabilitation must be given due consideration and fill the gap in the literature that so far has predominantly looked at multiple clinical conditions without an in-depth focus on patients with stroke, in order to assist rehabilitation professionals' decision-making about robotics in this clinical area.

A preliminary search of PROSPERO, MEDLINE, Cochrane Database of Systematic Reviews, and JBI Evidence Synthesis was conducted on 01 March 2022. This search did not identify

any current or ongoing scoping or systematic reviews that focus on patients after a stroke or their rehabilitation professionals' experience with upper limb rehabilitation robots. Reinforcing the need for a qualitative systematic review to explore and establish the full range of experiences of patients and their rehabilitation professionals with upper limb rehabilitation robots in stroke rehabilitation.

METHODS AND ANALYSIS

Objective

This review aims to collect and synthesise available evidence regarding the experiences of patients after a stroke with rehabilitation robots for upper limb rehabilitation irrespective of the ongoing involvement of rehabilitation professionals as well as the experiences of rehabilitation professionals with rehabilitation robots for upper limb stroke rehabilitation.

Review questions

1. What are the experiences of patients after a stroke when undergoing rehabilitation for stroke-related upper limb dysfunction using rehabilitation robots?
2. What are the rehabilitation professionals' experiences, perspectives, opinions, and perceived facilitators and barriers regarding the use of rehabilitation robots for upper limb rehabilitation among patients after a stroke?

Eligibility criteria

Participants

This review will consider studies that include adult patients (over the age of 18) after a stroke using rehabilitation robots for upper limb rehabilitation, either supervised by

rehabilitation professionals or by patients themselves, as part of self-administered robotic therapy at any phase of their rehabilitation.

To clarify our inclusion criteria, we have used the following definitions:

Stroke – a sudden loss of neurological function caused by haemorrhage or ischemia in the brain parenchyma caused by a vascular event, with symptoms lasting more than 24 hours, which are not explainable by other causes.

Phases of rehabilitation – time after stroke as classified by the Stroke Roundtable Consortium;[24] namely, the hyperacute phase (< 24 hours), the acute phase (2-7 days), the early subacute phase (8-90 days), late subacute phase (91-180 days) and chronic phase (>180 days).

Upper limb rehabilitation – interventions aimed at enhancing the function of the upper limb after considering the goals of patients after a stroke, which are identified following evaluations of their functional abilities and level of activity.

Rehabilitation robots – robots that have contact with a patient to provide physical interaction driven by an actuation system and controlled by the robot alone or in a robot and patient shared control to perform rehabilitation, assessment, compensation, or alleviation.[25] Rehabilitation robots may be fixed, mobile, or wearable devices used during inpatient, outpatient, home-based, or community-based rehabilitation. These rehabilitation robots may include mechanical setups such as end-effectors, exoskeletons, or exosuits.

End-effectors – robots with a single point of connection to a patient's distal segment, with joints that are neither matched to nor aligned with other joints of the patient, where the

force generated by the robot's distal interface is transmitted to other joints of the patient in accordance with the principles of close-kinematic chains.[26] (Figure 1 and Figure 2)

Exoskeletons – robots with rigid anthropomorphic structures attached to the body at multiple points through straps, cuffs, belts, or other attachments, ensuring the robotic joint axes are aligned with the anatomical joints of the wearer's body.[26] (Figure 3)

Exosuits – robots that use softer materials such as fabric instead of rigid anthropomorphic structures.[26] (Figure 4)

Upper limb robotic rehabilitation – robots assisting or resisting movement in a single joint or controlling the intersegmental coordination of the affected upper limb as well as providing and enhancing repetitive task training and task-specific training to improve range of motion, strength, motor learning, and motor control.[10,26] In addition to assessing, compensating for, or alleviating the effects of stroke-related upper limb impairment.

Studies that report patients with more than one stroke, patients under 18, or patients with other known causes of upper limb impairment besides stroke will be excluded. Studies reporting patients without upper limb motor dysfunction or having sensory impairments alone or cognitive and perceptual impairments alone will be excluded. Hospital robots, social robots, or care/assistive robots that assist patients after a stroke in their activities of daily living without being connected to their upper limb or robotic interventions other than rehabilitation robots, as previously described, will be excluded. Studies reporting upper limb rehabilitation using rehabilitation robots in body segments other than the affected upper limb will be excluded. Likewise, studies reporting upper limb robotic interventions

conducted concurrently with other robotic interventions for other body segments, presented as a whole and not sufficiently distinguished from one another, will be excluded.

This review will include rehabilitation professionals who provide stroke upper limb rehabilitation using rehabilitation robots. The rehabilitation professionals may be experts in upper limb rehabilitation, such as physiatrists, physical therapists, occupational therapists, hand therapists, or rehabilitation nurses. Other professionals such as emergency physicians, geriatricians, neurologists, neurosurgeons, or other physicians involved only in the medical or surgical management of patients with stroke who do not provide active upper limb rehabilitation will be excluded. Similarly, rehabilitation engineers, robotic engineers, biomedical engineers, orthotists, and other specialists who are typically not directly involved in physical rehabilitation or clinical care for stroke patients will also be excluded. Robotic upper limb rehabilitation provided by students, healthcare assistants, or technicians, who may not be competent to practice independently, will be excluded. Likewise, robotic upper limb rehabilitation provided by non-professional caregivers, family caregivers, volunteer caregivers, or other informal caregivers will also be excluded.

Phenomena of interest

In this review, studies that describe the experiences of patients after a stroke and/or their rehabilitation professional with upper limb rehabilitation robots will be considered. Patients' experiences during or after the use of upper limb rehabilitation robots for stroke can be positive or negative, describe complications/adverse events or any other experiences. Rehabilitation professionals' experiences may include facilitators and barriers, encounters,

perspectives, or opinions associated with preparing for or providing upper limb rehabilitation in stroke using rehabilitation robots.

Context

The context will not be restricted in this review. This review will consider studies that present patients after a stroke or rehabilitation professionals' experiences of providing upper limb rehabilitation using rehabilitation robots in any clinical setting during any phase of stroke rehabilitation. These settings may include outpatient, inpatient, community-based, or home-based intervention services or other therapeutic settings. This review is not restricted to geographical locations, funding mechanisms, healthcare facilities, or services.

Types of studies

This review will consider studies that focus on qualitative data, including, but not limited to, designs such as qualitative descriptive, phenomenology, grounded theory, ethnography, and action research. This review will also consider the qualitative results of mixed-method studies.

Methods

The proposed systematic review will be conducted in accordance with the JBI methodology for systematic reviews of qualitative evidence.[27] The review protocol is registered in PROSPERO (CRD42022321402).

Search strategy

The search strategy will aim to locate both published and unpublished studies. A three-step search strategy will be utilised in this review. First, a pilot initial limited search of MEDLINE (Ovid) and CINAHL (EBSCOhost) was undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles and the index terms used to describe the articles were used to develop a full search strategy for MEDLINE (Ovid) (see Appendix 1). The search strategy, including all identified keywords and index terms, will be adapted for each included database and/or information source. The reference lists of all included sources of evidence will be screened for additional studies.

Regardless of the publication date, articles published in English will be included to capture all relevant literature comprehensively. In view of the limited resources available to reviewers to translate literature from other languages, languages other than English will be excluded in this review. The databases will include MEDLINE(Ovid), EMBASE(Elsevier), Cochrane CENTRAL, PsycINFO, Scopus, Web of Science, and CINAHL(EBSCOhost). Grey literature will also be searched through Open Grey, PsyArXiv, bioRxiv, medRxiv, and Google Scholar.

Study selection

After the search, the citations will be collated and uploaded into EndNote X20 (Clarivate Analytics, PA, USA), and duplicates will be removed. After piloting the eligibility criteria on a sample of citations (between six and eight articles) to ensure consistency in application,[28] two independent reviewers (MC and LV) will screen all titles and abstracts to determine if they meet the review's inclusion criteria and any disagreements will be resolved by mutual

agreement in discussion with the third reviewer (VS). Potentially relevant studies will be retrieved in full, and their citation details imported into the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI) (JBI, Adelaide, Australia).[29] The full text of selected citations will be assessed in detail against the inclusion criteria by two independent reviewers (MC and LV), and any disagreements will be resolved in discussion with VS. The reasons for the exclusion of full-text papers that do not meet the inclusion criteria will be recorded and reported. The results of the search and the study inclusion process will be reported in full in the final systematic review and presented using a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram.[30]

Assessment of methodological quality

Eligible studies will be critically appraised by two independent reviewers for methodological quality using the standard JBI Critical Appraisal Checklist for Qualitative Research.[31] Any disagreements that arise between the reviewers will be resolved through discussion with the third reviewer. The results of the critical appraisal will be reported in narrative form and tables. Regardless of the results of their methodological quality, all studies will be included in the data extraction and synthesis process to ensure that all experiences are captured comprehensively, and no evidence is missed. All major quality issues of the included studies will be presented and discussed in the final review report.

Data extraction

Data will be extracted from studies included in the review by two independent reviewers using the standardised JBI data extraction tool in JBI SUMARI.[29] The data extracted will

include specific details about the population, context, culture, geographical location, study methods, and the phenomena of interest relevant to the review objectives, namely experiences of using upper limb rehabilitation robots by patients after a stroke and rehabilitation professionals' experiences of providing stroke upper limb rehabilitation using robots. The findings, and their illustrations, will be extracted verbatim and assigned a level of credibility. Any disagreements that arise between the reviewers will be resolved through discussion with the third reviewer. If necessary, missing or additional data will be requested from the authors. Even after obtaining additional information from the authors, all missing or unclear information that continues to exist will be treated in the review report as missing data.

Data synthesis

Qualitative research findings where possible, will be pooled using JBI SUMARI with the meta-aggregation approach.[32] This will involve the aggregation or synthesis of findings to generate a set of statements representing that aggregation by assembling the findings and categorising these findings based on similarity in meaning. These categories will then be subjected to a synthesis to produce a single comprehensive set of synthesised findings that can be used as a basis for evidence-based practice. Where textual pooling is not possible, the findings will be presented in a narrative form.

Assessing confidence in the findings

The final synthesised findings will be graded according to the ConQual approach for establishing confidence in the output of qualitative research synthesis and presented in a Summary of Findings.[33] The Summary of Findings includes the major elements of the

review and details how the ConQual score is developed. The title, population, phenomena of interest, and context for the specific review will be included in the summary of findings. Each synthesised finding from the review will then be presented, along with the type of research informing it, the score for dependability and credibility, and the overall ConQual score.

Patient and public involvement

Patients and members of the public were not involved in the planning of this protocol.

DISCUSSION

The main aim of this review is to describe the experiences of patients after a stroke and rehabilitation professionals' experiences with upper limb rehabilitation robots. The results from this review are expected to inform better understanding of the use of upper limb rehabilitation robots, perceptions, opinions, facilitators, and barriers to their use. This review will highlight current research and available evidence in this important and emerging topic area in upper limb rehabilitation after a stroke. The findings from this review will be published and disseminated in journals, conferences and social media, and it is anticipated that the findings from this review will be useful for patients after a stroke, rehabilitation professionals, commissioners of health and care services and developers of rehabilitation robots to inform better provision and ongoing care for patients after a stroke.

FIGURE LEGENDS:

Figure 1 illustrates an example of upper limb training using an end-effector robot, H-man. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Articares.

Figure 2 illustrates an example of upper limb training using an end-effector robot, MO.TO.RE. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Humanware S.r.l.

Figure 3 illustrates an example of upper limb training using an exoskeleton robot, ArmeoPower. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Hocoma.

Figure 4 illustrates an example of an upper limb exosuit robot described by Hoang et al. being worn by a volunteer. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Dr Thanh Nho Do.

ABBREVIATIONS:

CINAHL*:* Cumulative Index of Nursing and Allied Health Literature

PRISMA*:* Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PROSPERO: International Prospective Register of Systematic Reviews

JBI SUMARI: JBI System for the Unified Management, Assessment and Review of Information

AUTHOR CONTRIBUTIONS:

MC was responsible for the conceptualisation and design of the study with critical inputs from LV, VS, and SB. MC developed the search strategy and conducted the search with critical input from LV, VS, and SB. The protocol was drafted by MC with important intellectual input and revisions from LV, VS, and SB. All authors have read and given approval for this version and agree to be accountable for all aspects of the work. MC is the guarantor of the review.

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The authors declare that there are no competing interests or conflicting interests.

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There are currently no data associated with this protocol. However, this protocol is published in PROSPERO. Details of this citation are as follows

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33. Munn Z, Porritt K, Lockwood C, *et al*. Establishing confidence in the output of qualitative research synthesis: the ConQual approach. *BMC Med Res Methodol* 2014;14:108. pmid:http://www.ncbi.nlm.nih.gov/pubmed/25927294

Figure 1 illustrates an example of upper limb training using an end-effector robot, H-man. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Articares.

724x254mm (300 x 300 DPI)

Figure 2 illustrates an example of upper limb training using an end-effector robot, MO.TO.RE. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Humanware S.r.l.

721x265mm (300 x 300 DPI)

Figure 3 illustrates an example of upper limb training using an exoskeleton robot, ArmeoPower. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Hocoma.

718x239mm (300 x 300 DPI)

Figure 4 illustrates an example of an upper limb exosuit robot described by Hoang et al. being worn by a volunteer. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Dr Thanh Nho Do.

618x314mm (300 x 300 DPI)

Ovid MEDLINE(R) ALL <1946 to May 20, 2022>

1 exp Physiatrists/ or exp Health Personnel/ or exp Allied Health Personnel/ or exp Physicians/ or exp Primary Health Care/ or exp Nurses/ or exp Family Nurse Practitioners/ or exp Nurse Practitioners/ or exp Physical Therapists/ or exp Occupational Therapists/ or health personnel.mp. or healthcare professional*.mp. or health-care professional*.mp. or health care professional*.mp. or allied health professional*.mp. or doctor*.mp. or physician*.mp. or geriatric*.mp. or rescriber*.mp. or primary healthcare.mp. or paramedic*.mp. or family nurse.mp. or nurse.mp. or community nurse.mp. or physio*.mp. or physiotherapist.mp. or physio therapist.mp. or physical therapist.mp. or hand therapist.mp. or self treatment.mp. or (Caregiver support regime therapy or Carer).mp. or Caregivers/ or (health care professional or health care professionals or health care provider or health care providers or healthcare provider or healthcare providers or healthcare worker or healthcare workers or personnel, health or professional, health care or provider, health care or provider, healthcare).mp. (Records Retrieved – 7196481)

2 exp "Attitude of Health Personnel"/ or exp Attitude/ or exp Occupational Stress/ or exp "Delivery of Health Care"/ or exp Qualitative Research/ or experience*.mp. or feel*.mp. or encounter*.mp. or perception*.mp. or opinion*.mp. (Records Retrieved – 3027183)

3 1 and 2 (Records Retrieved – 1094496)

4 exp "Quality of Health Care"/ or exp Patient Satisfaction/ or exp Patient Compliance/ or exp Compliance/ or exp "Patient Acceptance of Health Care"/ or exp "Treatment Adherence and Compliance"/ or exp Patient Dropouts/ or exp Treatment Refusal/ or exp Patient Participation/ or exp Psychological Distress/ or exp Health Behavior/ or exp "Quality of Life"/ or exp Attitude/ or exp Qualitative Research/ or patient satisfaction.mp. or patient acceptance.mp. or patient dropout*.mp. or patient participation.mp. or treatment refus*.mp. or experience*.mp. or feel*.mp. or encounter*.mp. or perception*.mp. or opinion*.mp. (Records Retrieved – 9171170)

5 3 or 4 (Records Retrieved – 9292409)

6 exp cerebrovascular disorders/ or exp basal ganglia cerebrovascular disease/ or exp brain ischemia/ or exp carotid artery diseases/ or exp cerebral small vessel diseases/ or exp intracranial arterial diseases/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ or stroke/ or exp brain infarction/ or stroke, lacunar/ or vasospasm, intracranial/ or vertebral artery dissection/ or brain injuries/ or brain injury, chronic/ or (stroke* or poststroke or apoplex* or cerebral vasc* or brain vasc* or cerebrovasc* or cva* or SAH).mp. or ((brain or cerebr* or cerebell* or vertebrobasil* or hemispher* or intracran* or intracerebral or infratentorial or supratentorial or middle cerebral artery or MCA* or anterior circulation or posterior circulation or basilar artery or vertebral artery or space-occupying) adj5 (isch?emi* or infarct* or thrombo* or emboli* or occlus* or hypoxi*)).mp. or ((brain* or cerebr* or cerebell* or intracerebral or intracran* or parenchymal or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli* or putaminal or putamen or posterior fossa or hemispher* or subarachnoid) adj5 (h?emorrhag* or h?ematoma* or bleed*)).mp. or hemiplegia/ or exp paresis/ or (hemipleg* or hemipar* or paresis or paretic or brain injur*).mp. (Records Retrieved – 805510)

7 exp upper extremity/ or (upper limb* or upper extremit* or arm or arms or shoulder or shoulders or hand or hands or axilla* or elbow* or forearm* or finger* or wrist*).mp. (Records Retrieved – 1087124)

8 robotics/ or automation/ or orthotic devices/ or "equipment and supplies"/ or self-help devices/ or therapy, computer-assisted/ or man-machine systems/ or (robot* or orthos* or orthotic or automat* or computer aided or computer assisted or device*).mp. or (electromechanical or electro-mechanical or mechanical or mechanised or mechanized or driven).mp. or exercise movement techniques/ or exercise/ or exercise therapy/ or muscle stretching techniques/ or motion therapy, continuous passive/ or ((continuous passive or cpm) adj3 therap*).mp. or (assist* adj5 (train* or aid* or rehabilitat* or re-educat*)).mp. (Records Retrieved – 2054580)

9 5 and 6 and 7 and 8 (Records Retrieved – 4059)

S1 Table: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Systematic Reviews 2015 4:1

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	4, 50
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☒	N/A.
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	☒	☐	78, 262-263, 384-390
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	5-42
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☒	☐	371-377
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	☐	☒	N/A
Support					
Sources	5a	Indicate sources of financial or other support for the review	☐	☒	378-380
Sponsor	5b	Provide name for the review funder and/or sponsor	☐	☒	378-380
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	☐	☒	378-380
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	☒	☐	106-166

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	☒	☐	168 -172
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	179- 259
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	273-279
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	☒	☐	264-279 and Appendix 1
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	280-334
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	☒	☐	280-295
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	305-317
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	☐	☒	305-317
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including	☐	☒	N/A

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		prioritization of main and additional outcomes, with rationale			
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	☒	☐	296-304
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☐	☒	N/A
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall's tau)	☐	☒	N/A
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	☐	☒	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☒	☐	318-325
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☐	☒	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☒	☐	326-334

BMJ Open

The experiences of stroke patients and rehabilitation professionals with upper limb rehabilitation robots: a qualitative systematic review protocol

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The experiences of stroke patients and rehabilitation professionals with upper limb rehabilitation robots: a qualitative systematic review protocol

ABSTRACT

Introduction: Emerging evidence suggests that robotic devices for upper limb rehabilitation after a stroke may improve upper limb function. For robotic upper limb rehabilitation in stroke to be successful, patients' experiences and those of the rehabilitation professionals must be considered. Therefore, this review aims to synthesise the available evidence on experiences of patients after a stroke with rehabilitation robots for upper limb rehabilitation and the experiences of rehabilitation professionals with rehabilitation robots for upper limb stroke rehabilitation.

Methods and Analysis: Database search will include MEDLINE(Ovid), EMBASE(Elsevier), Cochrane CENTRAL, PsycINFO, Scopus, Web of Science, IEEE and CINAHL(EBSCOhost). Grey literature from Open Grey, PsyArXiv, bioRxiv, medRxiv, and Google Scholar, will also be searched. Qualitative studies or results from mixed-method studies that include adult patients after a stroke who use upper limb rehabilitation robots, either supervised by rehabilitation professionals or by patients themselves, at any stage of their rehabilitation and/or stroke professionals who use upper limb rehabilitation robots will be included. Robotic upper limb rehabilitation provided by students, healthcare assistants, technicians, non-professional caregivers, family caregivers, volunteer caregivers, or other informal caregivers will be excluded. Articles published in English will be considered regardless of date of publication. Studies will be screened and critically appraised for methodological quality by two independent reviewers. A standardised tool from JBI SUMARI for data

extraction, the meta-aggregation approach for data synthesis, and the ConQual approach for confidence evaluation will be followed.

Ethics and Dissemination: As this systematic review is based on previously published research, no informed consent or ethical approval is required. It is anticipated that this systematic review will highlight the experiences of patients after a stroke and perceived facilitators and barriers for rehabilitation professionals on this topic, which will be disseminated through peer-reviewed publications and national and international conferences.

Systematic review registration number: PROSPERO-CRD42022321402

Keywords: robotics; stroke; rehabilitation; experience; health personnel

Abstract word count: 297

ARTICLE SUMMARY

STRENGTHS AND LIMITATIONS OF THIS STUDY

1. This review will include literature from inter-disciplinary databases to maximise diversity of data.
2. Inclusion of grey literature in this review will provide comprehensive information of experiences in the use of upper limb rehabilitation robots that are not commercially available.
3. Use of ConQual approach will ensure confidence in the synthesised findings of this review.
4. This review will include only English-language publications due to limited financial resources, which will limit the reviews comprehensiveness.

INTRODUCTION

The use of rehabilitation robots has grown over the past few decades,[1] particularly for upper limb stroke rehabilitation, and the evidence supporting their use is also increasing.[2,3] Several rehabilitation robots are available to assess and augment rehabilitation of stroke-impaired upper limbs under direct or remote supervision, including end-effectors,[4,5] (Figure 1 and Figure 2) exoskeletons,[6] (Figure 3) and exosuits.[7] (Figure 4) The use of rehabilitation robots produces comparable results,[8] and in some cases, such as when used by individuals with upper extremity hemiplegia, who have limited chances of spontaneous recovery after stroke, they could produce better results than those achieved by other routine therapy methods.[2,3] In addition, systematic reviews of rehabilitation robots in upper limb stroke rehabilitation have demonstrated that they provide valid outcome measurements of clinically meaningful body functions and structures of the ICF domain, such as muscle viscoelasticity[9] and movement-related kinematic parameters.[10] For these reasons, rehabilitation robots are receiving increasing attention in rehabilitation programs as intervention devices and tools for evaluating clinical outcomes. Although rehabilitation robots have not been extensively examined for their adoption in routine care, the increasing number of robots being commercialised over the past decade and the increased number of robotic literature suggests a slow and steady adoption.[11]

There is some emerging evidence that rehabilitation robots may improve upper limb function after a stroke.[1-3] Studies have compared different types of robots in concluding effectiveness of upper limb function,[8,12] which may explain the varying results between studies that support or negate the effectiveness of upper limb robotic rehabilitation. Mehrholz et al., for example, reported that there is no difference between the types of

robots and the improvements in upper limb functional performance in their meta-analysis of robot-assisted upper limb training in patients after a stroke.[8] In contrast, the meta-analysis by Mogio et al. found that exoskeleton robots are significantly superior to end-effector robots in improving finger and hand motor function in patients after a stroke.[12] It should be noted that the use of Exosuits in rehabilitation is a relatively new approach in rehabilitation robotics, and no comparison studies have been completed to date.[7,13,14]

Due to the variety of robots available that provide similar clinical outcomes, selecting an appropriate robotic intervention strategy for patients after a stroke by rehabilitation professionals may be complex and challenging.[8] Thus, the subjective experiences of rehabilitation professionals with robots become crucial in the selection and use of rehabilitation robots in clinical practice. Despite rehabilitation robots being clinically effective, the fact that rehabilitation professionals remain cautious when recommending them in clinical practice makes it even more important to study their experiences with and attitudes towards rehabilitation robots.[15,16] The literature also acknowledges this need, pointing out that rehabilitation professionals' attitudes are as important as the benefits derived from robots.[15,16] If upper limb rehabilitation robots are to be successfully incorporated into clinical practice there is a need for a systematic approach to the adoption of such robots in rehabilitation.[15,16] Therefore, it is necessary to systematically review, document, and compile rehabilitation professionals' perspectives, experiences, and views on upper limb rehabilitation robots.

Renaud and Van Biljon assert that a person's adoption of technology begins when they become aware of it and ends when they accept and fully utilise it.[17] The perceptions, perspectives, satisfaction and other experiences of an end user play a significant role in

determining whether that end user will successfully adopt the technology and whether the technology will continue to be used or discontinued.[18] Thus, the experiences of patients who use rehabilitation robots after a stroke are as significant as those of rehabilitation professionals. The experiences of patients with rehabilitation robots may differ from those of rehabilitation professionals, and therefore, these experiences should be analysed and reported separately. After a stroke, patients tend to prioritise their personal needs and participation in meaningful activities over that of impairment-focused rehabilitation.[19] It is therefore imperative to conduct a comprehensive review of patient experiences related to the use of rehabilitation robots, which may lead to an increase in the acceptance and sustained use of these devices by informing improved user-centred designs. Further, a comprehensive summary of patients' likes, dislikes, and preferences for specific upper limb rehabilitation robots is fundamental when outcomes among the types of robots are largely similar.[8]

The only systematic review to date that aimed to meta-synthesise end-user perceptions of robotics is in motor rehabilitation[20] and provides an early, generic description of the patients', caregivers', and professionals' experiences with rehabilitation robots. In the review by Laparidou et al., an overview of all types of motor rehabilitation using rehabilitation robots for various clinical conditions (shoulder instability/rotator cuff injury, spinal cord injury, stroke, brain injury, cerebral palsy, and unspecified clinical conditions) of all ages (from five to 84 years of age) is provided.[20] This review's inclusion of participants with varied clinical presentations offers valuable insight into their generalised experiences with rehabilitation robots. However, as the review focuses on a broad clinical group, it fails to provide a comprehensive focus and in-depth description of rehabilitation robots' use in

adult patients with stroke. Stroke upper limb rehabilitation robots for adults require particular considerations due to their unique needs,[21] abilities,[22] and patterns of functional recovery[23] that are distinct from those of other patient populations, such as spinal cord injury[24,25] or children with cerebral palsy.[26] This work addresses the lack of an in-depth focus on patients with stroke to fill the gap in the literature that so far has predominantly looked at multiple clinical conditions.

A preliminary search of PROSPERO, MEDLINE, Cochrane Database of Systematic Reviews, and JBI Evidence Synthesis was conducted on 01 March 2022. During the search, no scoping or systematic reviews were identified that focused on the experiences of the use of upper limb rehabilitation robots by stroke patients or their rehabilitation professionals, indicating the necessity for a qualitative systematic review to further explore this.

METHODS AND ANALYSIS

Objective

This review aims to collect and synthesise available evidence regarding the experiences of patients after a stroke using robots for upper limb rehabilitation irrespective of the ongoing involvement of rehabilitation professionals and the experiences of rehabilitation professionals using robots for upper limb stroke rehabilitation.

Review questions

1. What are the experiences of patients after a stroke when undergoing rehabilitation for upper limb dysfunction using rehabilitation robots?

2. What are the rehabilitation professionals' experiences, perspectives, opinions, and perceived facilitators and barriers regarding the use of rehabilitation robots for upper limb stroke rehabilitation?

Eligibility criteria

Participants

This review will consider studies that include adult patients (over the age of 18) after a stroke using rehabilitation robots for upper limb rehabilitation, either supervised by rehabilitation professionals or by patients themselves, as part of self-administered robotic therapy at any phase of their rehabilitation.

To clarify our inclusion criteria, we have used the following definitions:

Stroke – a sudden loss of neurological function caused by haemorrhage or ischemia in the brain parenchyma caused by a vascular event, with symptoms lasting more than 24 hours, which are not explainable by other causes.

Phases of rehabilitation – time after stroke as classified by the Stroke Roundtable Consortium;[27] namely, the hyperacute phase (< 24 hours), the acute phase (2-7 days), the early subacute phase (8-90 days), late subacute phase (91-180 days) and chronic phase (>180 days).

Upper limb rehabilitation – interventions aimed at enhancing the function of the upper limb after considering the goals of patients after a stroke, which are identified following evaluations of their functional abilities and level of activity.

Rehabilitation robots – robots that have contact with a patient to provide physical interaction driven by an actuation system and controlled by the robot alone or in a robot and patient shared control to perform rehabilitation, assessment, compensation, or alleviation.[28] Rehabilitation robots may be fixed, mobile, or wearable devices used during inpatient, outpatient, home-based, or community-based rehabilitation. These rehabilitation robots may take the forms of end-effectors, exoskeletons, or exosuits.

End-effectors – robots with a single point of connection to a patient's distal segment, with joints that are neither matched to nor aligned with other joints of the patient, where the force generated by the robot's distal interface is transmitted to other joints of the patient in accordance with the principles of close-kinematic chains.[29] (Figure 1 and Figure 2)

Exoskeletons – robots with rigid anthropomorphic structures attached to the body at multiple points through straps, cuffs, belts, or other attachments, ensuring the robotic joint axes are aligned with the anatomical joints of the wearer's body.[29] (Figure 3)

Exosuits – robots that use softer materials such as fabric instead of rigid anthropomorphic structures.[29] (Figure 4)

Upper limb robotic rehabilitation – robots assisting or resisting movement in a single joint or controlling the intersegmental coordination of the affected upper limb as well as providing and enhancing repetitive task training and task-specific training to improve range of motion, strength, motor learning, and motor control.[8,29] In addition to assessing, compensating for, or alleviating the effects of stroke-related upper limb impairment.

Studies that report patients with more than one stroke, patients under 18, or patients with other known causes of upper limb impairment besides stroke will be excluded. Studies reporting patients without upper limb motor dysfunction or having sensory impairments alone or cognitive and perceptual impairments alone will be excluded. Hospital robots, social robots, or care/assistive robots that assist patients after a stroke in their activities of daily living without being connected to their upper limb or robotic interventions other than rehabilitation robots, as previously described, will be excluded. Studies reporting upper limb rehabilitation using rehabilitation robots in body segments other than the affected upper limb will be excluded. Likewise, studies reporting upper limb robotic interventions conducted concurrently with other robotic interventions for other body segments, presented as a whole and not sufficiently distinguished from one another, will be excluded.

This review will include professionals who provide stroke upper limb rehabilitation using rehabilitation robots. The rehabilitation professionals may be experts in upper limb rehabilitation, such as physiatrists, physical therapists, occupational therapists, hand therapists, or rehabilitation nurses. Other professionals such as emergency physicians, geriatricians, neurologists, neurosurgeons, or other physicians involved only in the medical or surgical management of patients with stroke who do not provide active upper limb rehabilitation will be excluded. Similarly, rehabilitation engineers, robotic engineers, biomedical engineers, orthotists, and other specialists who are typically not directly involved in physical rehabilitation or clinical care for stroke patients will also be excluded. Robotic upper limb rehabilitation provided by students, healthcare assistants, or technicians, who may not be competent to practice independently, will be excluded. Likewise, robotic upper

limb rehabilitation provided by non-professional caregivers, family caregivers, volunteer caregivers, or other informal caregivers will also be excluded.

Phenomena of interest

In this review, studies that describe the experiences of patients after a stroke and/or their rehabilitation professional with upper limb rehabilitation robots will be considered. Patients' experiences during or after the use of upper limb rehabilitation robots for stroke can be positive or negative, describe complications/adverse events or any other experiences. Rehabilitation professionals' experiences may include facilitators and barriers, encounters, perspectives, or opinions associated with preparing for or providing upper limb rehabilitation in stroke using rehabilitation robots.

Context

The context will not be restricted in this review. This review will consider studies that present patients after a stroke or rehabilitation professionals' experiences of providing upper limb rehabilitation using rehabilitation robots in any clinical setting during any phase of stroke rehabilitation. These settings may include outpatient, inpatient, community-based, or home-based intervention services or other therapeutic settings. This review is not restricted to geographical locations, funding mechanisms, healthcare facilities, or services.

Types of studies

This review will consider studies that focus on qualitative data, including, but not limited to, designs such as qualitative descriptive, phenomenology, grounded theory, ethnography, and

action research. This review will also consider the qualitative results of mixed-method studies.

Methods

The proposed systematic review will be conducted in accordance with the JBI methodology for systematic reviews of qualitative evidence.[30] The review will commence in October 2022 and end in September 2023. The review protocol is registered in PROSPERO (CRD42022321402).

Search strategy

The search strategy will aim to locate both published and unpublished studies. A three-step search strategy will be utilised in this review. First, a pilot initial limited search of MEDLINE (Ovid) and CINAHL (EBSCOhost) was undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles and the index terms (such as MeSH terms) used to describe the articles were used to develop a full search strategy for MEDLINE (Ovid) (see Appendix 1). The search strategy, including all identified keywords and index terms, will be adapted for each included database and/or information source. The reference lists of all included sources of evidence will be screened for additional studies.

Regardless of the publication date, articles published in English will be included to capture all relevant literature comprehensively. In view of the limited resources available to reviewers to translate literature from other languages, languages other than English will be excluded in this review. The databases will include MEDLINE(Ovid), EMBASE(Elsevier), Cochrane CENTRAL, PsycINFO, Scopus, Web of Science, IEEE and CINAHL(EBSCOhost). Grey

literature will also be searched through Open Grey, PsyArXiv, bioRxiv, medRxiv, and Google Scholar.

Study selection

After the search, the citations will be collated and uploaded into EndNote X20 (Clarivate Analytics, PA, USA), and duplicates will be removed. After piloting the eligibility criteria on a sample of citations (between six and eight articles) to ensure consistency in application,[31] two independent reviewers (MC and LV) will screen all titles and abstracts to determine if they meet the review's inclusion criteria and any disagreements will be resolved by mutual agreement in discussion with the third reviewer (VS/SB). Potentially relevant studies will be retrieved in full, and their citation details imported into the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI) (JBI, Adelaide, Australia).[32] The full text of selected citations will be assessed in detail against the inclusion criteria by two independent reviewers (MC and LV), and any disagreements will be resolved in discussion with VS/SB. The reasons for the exclusion of full-text papers that do not meet the inclusion criteria will be recorded and reported. The results of the search and the study inclusion process will be reported in full in the final systematic review and presented using a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram.[33]

Assessment of methodological quality

Eligible studies will be critically appraised by two independent reviewers for methodological quality using the standard JBI Critical Appraisal Checklist for Qualitative Research.[34] Any disagreements that arise between the reviewers will be resolved through discussion with

the third reviewer. The results of the critical appraisal will be reported in narrative form and tables. Regardless of the results of their methodological quality, all studies will be included in the data extraction and synthesis process to ensure that all experiences are captured comprehensively, and no evidence is missed. All major quality issues of the included studies will be presented and discussed in the final review report.

Data extraction

Data will be extracted from studies included in the review by two independent reviewers using the standardised JBI data extraction tool in JBI SUMARI.[32] The data extracted will include specific details about the population, context, culture, geographical location, study methods, and the phenomena of interest relevant to the review objectives, namely experiences of using upper limb rehabilitation robots by patients after a stroke and rehabilitation professionals' experiences of providing stroke upper limb rehabilitation using robots. The findings, and their illustrations, will be extracted verbatim and assigned a level of credibility. Any disagreements that arise between the reviewers will be resolved through discussion with the third reviewer. If necessary, missing or additional data will be requested from the authors. Even after obtaining additional information from the authors, all missing or unclear information that continues to exist will be treated in the review report as missing data.

Data synthesis

Qualitative research findings where possible, will be pooled using JBI SUMARI with the meta-aggregation approach.[35] This will involve the aggregation or synthesis of findings to generate a set of statements representing that aggregation by assembling the findings and

categorising these findings based on similarity in meaning. These categories will then be subjected to a synthesis to produce a single comprehensive set of synthesised findings that can be used as a basis for evidence-based practice. Where textual pooling is not possible, the findings will be presented in a narrative form.

Assessing confidence in the findings

The final synthesised findings will be graded according to the ConQual approach for establishing confidence in the output of qualitative research synthesis and presented in a Summary of Findings.[36] The Summary of Findings includes the major elements of the review and details how the ConQual score is developed. The title, population, phenomena of interest, and context for the specific review will be included in the summary of findings. Each synthesised finding from the review will then be presented, along with the type of research informing it, the score for dependability and credibility, and the overall ConQual score.

Reflexivity and integrity

Given that this is a review of qualitative studies, it is important to consider the reviewers' assumptions and preconceptions regarding the phenomenon of interest, as well as other potential influences that may affect the review process.

This review will be conducted in collaboration. The current review is not funded by public or private sources, and the review team have declared no conflict of interest. As a result, the review is not affected by external influences. The review team includes a robotic engineer, an occupational therapist with experience in using rehabilitation robots, an occupational

therapist, and a physiotherapist with experience in rehabilitation but not robotics. With the deliberate decision to include reviewers with varying levels of experience with rehabilitation robots and their involvement in all stages of the review process, it is anticipated that any potential influence of individual reviewers' conceptions and preconceptions regarding the phenomenon of interest will be minimised. The review team's experience will provide the necessary expertise for this review.

A conscious effort will be made to write memos during the data collection and analysis in order to examine and reflect on the reviewer's engagement.[37] This 'memoing' process will include methodological notetaking to explain the procedural aspect and observational comments to explain and explore the reviewer's feelings at different stages of the review process. Moreover, the reviewers have not published a primary qualitative study on the phenomenon of interest, despite having published primary qualitative studies on other topics. The use of the standardised JBI extraction tool for data extraction and following the standard procedures of the meta-aggregation approach for data synthesis, as well as the above-mentioned process of author reflexivity, based on Flemming and Noyes descriptions,[37] are likely to minimise the impact of the review team's preconceptions. Reflexivity and integrity will be maintained throughout the search, data collection and analysis stages.

Patient and public involvement

Patients and members of the public were not involved in the planning of this protocol.

DISCUSSION

The main aim of this review is to describe the experiences of patients after a stroke and rehabilitation professionals' experiences with upper limb rehabilitation robots. The results from this review are expected to inform better understanding of the use of upper limb rehabilitation robots, perceptions, opinions, facilitators, and barriers to their use. This review will highlight current research and available evidence in this important and emerging topic area in upper limb rehabilitation after a stroke. The findings from this review will be published and disseminated in journals, conferences and social media, and it is anticipated that the findings from this review will be useful for patients after a stroke, rehabilitation professionals, commissioners of health and care services and developers of rehabilitation robots to inform better provision and ongoing care for patients after a stroke.

FIGURE LEGENDS:

Figure 1 illustrates an example of upper limb training using an end-effector robot, H-man. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Articares.

Figure 2 illustrates an example of upper limb training using an end-effector robot, MO.TO.RE. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Humanware S.r.l.

Figure 3 illustrates an example of upper limb training using an exoskeleton robot, ArmeoPower. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Hocoma.

Figure 4 illustrates an example of an upper limb exosuit robot described by Hoang et al. being worn by a volunteer. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Dr Thanh Nho Do.

ABBREVIATIONS:

CINAHL*:* Cumulative Index of Nursing and Allied Health Literature

PRISMA*:* Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PROSPERO: International Prospective Register of Systematic Reviews

JBI SUMARI: JBI System for the Unified Management, Assessment and Review of Information

AUTHOR CONTRIBUTIONS:

MC was responsible for the conceptualisation and design of the study with critical inputs from LV, VS, and SB. MC developed the search strategy and conducted the search with critical input from LV, VS, and SB. The protocol was drafted by MC with important intellectual input and revisions from LV, VS, and SB. All authors have read and given approval for this version and agree to be accountable for all aspects of the work. MC is the guarantor of the review.

FUNDING STATEMENT:

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

CONFLICT OF INTERESTS STATEMENT:

The authors declare that there are no competing interests or conflicting interests.

DATA STATEMENT:

There are currently no data associated with this protocol. However, this protocol is published in PROSPERO. Details of this citation are as follows

Manigandan Chockalingam, Lenny Vasanthan T, Sivakumar Balasubramanian, Vimal Sriram. Stroke patients and their healthcare providers' experiences of upper limb rehabilitation robotics: a qualitative systematic review protocol. PROSPERO 2022 CRD42022321402 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022321402

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Figure 1 illustrates an example of upper limb training using an end-effector robot, H-man. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Articares.

724x254mm (300 x 300 DPI)

Figure 2 illustrates an example of upper limb training using an end-effector robot, MO.TO.RE. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Humanware S.r.l.

721x265mm (300 x 300 DPI)

Figure 3 illustrates an example of upper limb training using an exoskeleton robot, ArmeoPower. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Hocoma.

718x239mm (300 x 300 DPI)

Figure 4 illustrates an example of an upper limb exosuit robot described by Hoang et al. being worn by a volunteer. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Dr Thanh Nho Do.

618x314mm (300 x 300 DPI)

Ovid MEDLINE(R) ALL <1946 to May 20, 2022>

1 exp Physiatrists/ or exp Health Personnel/ or exp Allied Health Personnel/ or exp Physicians/ or exp Primary Health Care/ or exp Nurses/ or exp Family Nurse Practitioners/ or exp Nurse Practitioners/ or exp Physical Therapists/ or exp Occupational Therapists/ or health personnel.mp. or healthcare professional*.mp. or health-care professional*.mp. or health care professional*.mp. or allied health professional*.mp. or doctor*.mp. or physician*.mp. or geriatric*.mp. or rescriber*.mp. or primary healthcare.mp. or paramedic*.mp. or family nurse.mp. or nurse.mp. or community nurse.mp. or physio*.mp. or physiotherapist.mp. or physio therapist.mp. or physical therapist.mp. or hand therapist.mp. or self treatment.mp. or (Caregiver support regime therapy or Carer).mp. or Caregivers/ or (health care professional or health care professionals or health care provider or health care providers or healthcare provider or healthcare providers or healthcare worker or healthcare workers or personnel, health or professional, health care or provider, health care or provider, healthcare).mp. (Records Retrieved – 7196481)

2 exp "Attitude of Health Personnel"/ or exp Attitude/ or exp Occupational Stress/ or exp "Delivery of Health Care"/ or exp Qualitative Research/ or experience*.mp. or feel*.mp. or encounter*.mp. or perception*.mp. or opinion*.mp. (Records Retrieved – 3027183)

3 1 and 2 (Records Retrieved – 1094496)

4 exp "Quality of Health Care"/ or exp Patient Satisfaction/ or exp Patient Compliance/ or exp Compliance/ or exp "Patient Acceptance of Health Care"/ or exp "Treatment Adherence and Compliance"/ or exp Patient Dropouts/ or exp Treatment Refusal/ or exp Patient Participation/ or exp Psychological Distress/ or exp Health Behavior/ or exp "Quality of Life"/ or exp Attitude/ or exp Qualitative Research/ or patient satisfaction.mp. or patient acceptance.mp. or patient dropout*.mp. or patient participation.mp. or treatment refus*.mp. or experience*.mp. or feel*.mp. or encounter*.mp. or perception*.mp. or opinion*.mp. (Records Retrieved – 9171170)

5 3 or 4 (Records Retrieved – 9292409)

6 exp cerebrovascular disorders/ or exp basal ganglia cerebrovascular disease/ or exp brain ischemia/ or exp carotid artery diseases/ or exp cerebral small vessel diseases/ or exp intracranial arterial diseases/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ or stroke/ or exp brain infarction/ or stroke, lacunar/ or vasospasm, intracranial/ or vertebral artery dissection/ or brain injuries/ or brain injury, chronic/ or (stroke* or poststroke or apoplex* or cerebral vasc* or brain vasc* or cerebrovasc* or cva* or SAH).mp. or ((brain or cerebr* or cerebell* or vertebrobasil* or hemispher* or intracran* or intracerebral or infratentorial or supratentorial or middle cerebral artery or MCA* or anterior circulation or posterior circulation or basilar artery or vertebral artery or space-occupying) adj5 (isch?emi* or infarct* or thrombo* or emboli* or occlus* or hypoxi*)).mp. or ((brain* or cerebr* or cerebell* or intracerebral or intracran* or parenchymal or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli* or putaminal or putamen or posterior fossa or hemispher* or subarachnoid) adj5 (h?emorrhag* or h?ematoma* or bleed*)).mp. or hemiplegia/ or exp paresis/ or (hemipleg* or hemipar* or paresis or paretic or brain injur*).mp. (Records Retrieved – 805510)

7 exp upper extremity/ or (upper limb* or upper extremit* or arm or arms or shoulder or shoulders or hand or hands or axilla* or elbow* or forearm* or finger* or wrist*).mp. (Records Retrieved – 1087124)

8 robotics/ or automation/ or orthotic devices/ or "equipment and supplies"/ or self-help devices/ or therapy, computer-assisted/ or man-machine systems/ or (robot* or orthos* or orthotic or automat* or computer aided or computer assisted or device*).mp. or (electromechanical or electro-mechanical or mechanical or mechanised or mechanized or driven).mp. or exercise movement techniques/ or exercise/ or exercise therapy/ or muscle stretching techniques/ or motion therapy, continuous passive/ or ((continuous passive or cpm) adj3 therap*).mp. or (assist* adj5 (train* or aid* or rehabilitat* or re-educat*)).mp. (Records Retrieved – 2054580)

9 5 and 6 and 7 and 8 (Records Retrieved – 4059)

S1 Table: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Systematic Reviews 2015 4:1

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	4, 50
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☒	N/A.
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	☒	☐	79, 269-270, 414-420
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	5-42
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☒	☐	401-407
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	☐	☒	N/A
Support					
Sources	5a	Indicate sources of financial or other support for the review	☒	☐	408-410
Sponsor	5b	Provide name for the review funder and/or sponsor	☒	☐	408-410
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	☒	☐	408-410
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	☒	☐	111-172

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	☒	☐	174 -178
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	185- 265
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	280-286
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	☒	☐	271-286 and Appendix 1
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	287-367
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	☒	☐	287-302
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	312-324
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	☐	☒	312-324
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including	☐	☒	N/A

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		prioritization of main and additional outcomes, with rationale			
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	☒	☐	303-311
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☐	☒	N/A
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall's tau)	☐	☒	N/A
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	☐	☒	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☒	☐	325-332
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☐	☒	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☒	☐	333-341

S1 Table: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Systematic Reviews 2015 4:1

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	4, 50
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☒	N/A.
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	☒	☐	798, 2692-27063, 38414-39420
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	5-42
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☒	☐	37401-37407
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	☐	☒	N/A
Support					
Sources	5a	Indicate sources of financial or other support for the review	☒☐	☐☒	37408-38410
Sponsor	5b	Provide name for the review funder and/or sponsor	☒☐	☐☒	37408-38410
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	☒☐	☐☒	37408-38410
INTRODUCTION					

Commented [MC1]: Under support items- I would suggest here selecting the "Yes" answer. Even though you may not have a funder, etc., this information is included in the manuscript/protocol (lines 378-380, as you have noted).

Suggested changes have been made.

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
Rationale	6	Describe the rationale for the review in the context of what is already known	☒	☐	11106-17266
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	☒	☐	17468 - 17872
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	18579- 2659
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	28073-28679
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	☒	☐	27164-28679 and Appendix 1
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	2870-36734
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	☒	☐	2870-30295
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	31205-32417
Data items	12	List and define all variables for which data will be sought (e.g., PICO items,	☐	☒	31205-32417

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		funding sources), any pre-planned data assumptions and simplifications			
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	☐	☒	N/A
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	☒	☐	~~296-304~~303-311
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☐	☒	N/A
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall's tau)	☐	☒	N/A
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	☐	☒	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☒	☐	~~318-~~325-332
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☐	☒	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☒	☐	~~326-334~~333-341

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The experiences of stroke patients and rehabilitation professionals with upper limb rehabilitation robots: a qualitative systematic review protocol

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The experiences of stroke patients and rehabilitation professionals with upper limb rehabilitation robots: a qualitative systematic review protocol

ABSTRACT

Introduction: Emerging evidence suggests that robotic devices for upper limb rehabilitation after a stroke may improve upper limb function. For robotic upper limb rehabilitation in stroke to be successful, patients' experiences and those of the rehabilitation professionals must be considered. Therefore, this review aims to synthesise the available evidence on experiences of patients after a stroke with rehabilitation robots for upper limb rehabilitation and the experiences of rehabilitation professionals with rehabilitation robots for upper limb stroke rehabilitation.

Methods and Analysis: Database search will include MEDLINE(Ovid), EMBASE(Elsevier), Cochrane CENTRAL, PsycINFO, Scopus, Web of Science, IEEE and CINAHL(EBSCOhost). Grey literature from Open Grey, PsyArXiv, bioRxiv, medRxiv, and Google Scholar, will also be searched. Qualitative studies or results from mixed-method studies that include adult patients after a stroke who use upper limb rehabilitation robots, either supervised by rehabilitation professionals or by patients themselves, at any stage of their rehabilitation and/or stroke professionals who use upper limb rehabilitation robots will be included. Robotic upper limb rehabilitation provided by students, healthcare assistants, technicians, non-professional caregivers, family caregivers, volunteer caregivers, or other informal caregivers will be excluded. Articles published in English will be considered regardless of date of publication. Studies will be screened and critically appraised for methodological quality by two independent reviewers. A standardised tool from JBI SUMARI for data

extraction, the meta-aggregation approach for data synthesis, and the ConQual approach for confidence evaluation will be followed.

Ethics and Dissemination: As this systematic review is based on previously published research, no informed consent or ethical approval is required. It is anticipated that this systematic review will highlight the experiences of patients after a stroke and perceived facilitators and barriers for rehabilitation professionals on this topic, which will be disseminated through peer-reviewed publications and national and international conferences.

Systematic review registration number: PROSPERO-CRD42022321402

Keywords: robotics; stroke; rehabilitation; experience; health personnel

Abstract word count: 297

ARTICLE SUMMARY

STRENGTHS AND LIMITATIONS OF THIS STUDY

1. This review will include literature from inter-disciplinary databases to maximise diversity of data.
2. Inclusion of grey literature in this review will provide comprehensive information of experiences in the use of upper limb rehabilitation robots that are not commercially available.
3. Use of ConQual approach will ensure confidence in the synthesised findings of this review.
4. This review will include only English-language publications due to limited financial resources, which will limit the review's comprehensiveness.

INTRODUCTION

The use of rehabilitation robots has grown over the past few decades,[1] particularly for upper limb stroke rehabilitation, and the evidence supporting their use is also increasing.[2,3] Several rehabilitation robots are available to assess and augment rehabilitation of stroke-impaired upper limbs under direct or remote supervision, including end-effectors,[4,5] (Figure 1 and Figure 2) exoskeletons,[6] (Figure 3) and exosuits.[7] (Figure 4) The use of rehabilitation robots produces comparable results,[8] and in some cases, such as when used by individuals with upper extremity hemiplegia, who have limited chances of spontaneous recovery after stroke, they could produce better results than those achieved by other routine therapy methods.[2,3] In addition, systematic reviews of rehabilitation robots in upper limb stroke rehabilitation have demonstrated that they provide valid outcome measurements of clinically meaningful body functions and structures of the ICF domain, such as muscle viscoelasticity[9] and movement-related kinematic parameters.[10] For these reasons, rehabilitation robots are receiving increasing attention in rehabilitation programs as intervention devices and tools for evaluating clinical outcomes. Although rehabilitation robots have not been extensively examined for their adoption in routine care, the increasing number of robots being commercialised over the past decade and the increased number of robotic literature suggests a slow and steady adoption.[11]

There is some emerging evidence that rehabilitation robots may improve upper limb function after a stroke.[1-3] Studies have compared different types of robots in concluding effectiveness of upper limb function,[8,12] which may explain the varying results between studies that support or negate the effectiveness of upper limb robotic rehabilitation. Mehrholz et al., for example, reported that there is no difference between the types of

robots and the improvements in upper limb functional performance in their meta-analysis of robot-assisted upper limb training in patients after a stroke.[8] In contrast, the meta-analysis by Mogio et al. found that exoskeleton robots are significantly superior to end-effector robots in improving finger and hand motor function in patients after a stroke.[12] It should be noted that the use of Exosuits in rehabilitation is a relatively new approach in rehabilitation robotics, and no comparison studies have been completed to date.[7,13,14]

Due to the variety of robots available that provide similar clinical outcomes, selecting an appropriate robotic intervention strategy for patients after a stroke by rehabilitation professionals may be complex and challenging.[8] Thus, the subjective experiences of rehabilitation professionals with robots become crucial in the selection and use of rehabilitation robots in clinical practice. It is also pertinent to study rehabilitation professionals' experiences with and attitudes towards using rehabilitation robots in clinical practice since they remain cautious when recommending them.[15,16] The literature also acknowledges this need, pointing out that rehabilitation professionals' attitudes are as important as the benefits derived from robots.[15,16] If upper limb rehabilitation robots are to be successfully incorporated into clinical practice, there is a need for a systematic approach to the adoption of such robots in rehabilitation.[15,16] Therefore, it is necessary to systematically review, document, and compile rehabilitation professionals' perspectives, experiences, and views on upper limb rehabilitation robots.

Renaud and Van Biljon assert that a person's adoption of technology begins when they become aware of it and ends when they accept and fully utilise it.[17] The perceptions, perspectives, satisfaction and other experiences of an end user play a significant role in determining whether that end user will successfully adopt the technology and whether the

technology will continue to be used or discontinued.[18] Thus, the experiences of patients who use rehabilitation robots after a stroke are as significant as those of rehabilitation professionals. The experiences of patients with rehabilitation robots may differ from those of rehabilitation professionals, and therefore, these experiences should be analysed and reported separately. After a stroke, patients tend to prioritise their personal needs and participation in meaningful activities over that of impairment-focused rehabilitation.[19] It is, therefore, imperative to conduct a comprehensive review of patient experiences related to the use of rehabilitation robots, which may lead to an increase in the acceptance and sustained use of these devices by informing improved user-centred designs. Further, a comprehensive summary of patients' likes, dislikes, and preferences for specific upper limb rehabilitation robots is fundamental when outcomes among the types of robots are largely similar.[8]

The only systematic review to date that aimed to meta-synthesise end-user perceptions of robotics is in motor rehabilitation[20] and provides an early, generic description of the patients', caregivers', and professionals' experiences with rehabilitation robots. In the review by Laparidou et al., an overview of all types of motor rehabilitation using rehabilitation robots for various clinical conditions (shoulder instability/rotator cuff injury, spinal cord injury, stroke, brain injury, cerebral palsy, and unspecified clinical conditions) of all ages (from five to 84 years of age) is provided.[20] This review's inclusion of participants with varied clinical presentations offers valuable insight into their generalised experiences with rehabilitation robots. However, as the review focuses on a broad clinical group, it fails to provide a comprehensive focus and in-depth description of rehabilitation robots' use in adult patients with stroke. Stroke upper limb rehabilitation robots for adults require

particular considerations due to their unique needs,[21] abilities,[22] and patterns of functional recovery[23] that are distinct from those of other patient populations, such as spinal cord injury[24,25] or children with cerebral palsy.[26] This work addresses the lack of an in-depth focus on patients with stroke to fill the gap in the literature that so far has predominantly looked at multiple clinical conditions.

A preliminary search of PROSPERO, MEDLINE, Cochrane Database of Systematic Reviews, and JBI Evidence Synthesis was conducted on 01 March 2022. During the search, no scoping or systematic reviews were identified that focused on the experiences of the use of upper limb rehabilitation robots by stroke patients or their rehabilitation professionals, indicating the necessity for a qualitative systematic review to further explore this.

METHODS AND ANALYSIS

Objective

This review aims to collect and synthesise available evidence regarding the experiences of patients after a stroke using robots for upper limb rehabilitation, irrespective of the ongoing involvement of rehabilitation professionals and the experiences of rehabilitation professionals using robots for upper limb stroke rehabilitation.

Review questions

1. What are the experiences of patients after a stroke when undergoing rehabilitation for upper limb dysfunction using rehabilitation robots?

2. What are the rehabilitation professionals' experiences, perspectives, opinions, and perceived facilitators and barriers regarding the use of rehabilitation robots for upper limb stroke rehabilitation?

Eligibility criteria

Participants

This review will consider studies that include adult patients (over the age of 18) after a stroke using rehabilitation robots for upper limb rehabilitation, either supervised by rehabilitation professionals or by patients themselves, as part of self-administered robotic therapy at any phase of their rehabilitation.

To clarify our inclusion criteria, we have used the following definitions:

Stroke – a sudden loss of neurological function caused by haemorrhage or ischemia in the brain parenchyma caused by a vascular event, with symptoms lasting more than 24 hours, which are not explainable by other causes.

Phases of rehabilitation – time after stroke as classified by the Stroke Roundtable Consortium;[27] namely, the hyperacute phase (< 24 hours), the acute phase (2-7 days), the early subacute phase (8-90 days), late subacute phase (91-180 days) and chronic phase (>180 days).

Upper limb rehabilitation – interventions aimed at enhancing the function of the upper limb after considering the goals of patients after a stroke, which are identified following evaluations of their functional abilities and level of activity.

Rehabilitation robots – robots that have contact with a patient to provide physical interaction driven by an actuation system and controlled by the robot alone or in a robot and patient shared control to perform rehabilitation, assessment, compensation, or alleviation.[28] Rehabilitation robots may be fixed, mobile, or wearable devices used during inpatient, outpatient, home-based, or community-based rehabilitation. These rehabilitation robots may take the forms of end-effectors, exoskeletons, or exosuits.

End-effectors – robots with a single point of connection to a patient's distal segment, with joints that are neither matched to nor aligned with other joints of the patient, where the force generated by the robot's distal interface is transmitted to other joints of the patient in accordance with the principles of close-kinematic chains.[29] (Figure 1 and Figure 2)

Exoskeletons – robots with rigid anthropomorphic structures attached to the body at multiple points through straps, cuffs, belts, or other attachments, ensuring the robotic joint axes are aligned with the anatomical joints of the wearer's body.[29] (Figure 3)

Exosuits – robots that use softer materials such as fabric instead of rigid anthropomorphic structures.[29] (Figure 4)

Upper limb robotic rehabilitation – robots assisting or resisting movement in a single joint or controlling the intersegmental coordination of the affected upper limb as well as providing and enhancing repetitive task training and task-specific training to improve range of motion, strength, motor learning, and motor control.[8,29] In addition to assessing, compensating for, or alleviating the effects of stroke-related upper limb impairment.

Studies that report patients with more than one stroke, patients under 18, or patients with other known causes of upper limb impairment besides stroke will be excluded. Studies reporting patients without upper limb motor dysfunction or having sensory impairments alone or cognitive and perceptual impairments alone will be excluded. Hospital robots, social robots, or care/assistive robots that assist patients after a stroke in their activities of daily living without being connected to their upper limb or robotic interventions other than rehabilitation robots, as previously described, will be excluded. Studies reporting upper limb rehabilitation using rehabilitation robots in body segments other than the affected upper limb will be excluded. Likewise, studies reporting upper limb robotic interventions conducted concurrently with other robotic interventions for other body segments, presented as a whole and not sufficiently distinguished from one another, will be excluded.

This review will include professionals who provide stroke upper limb rehabilitation using rehabilitation robots. The rehabilitation professionals may be experts in upper limb rehabilitation, such as physiatrists, physical therapists, occupational therapists, hand therapists, or rehabilitation nurses. Other professionals such as emergency physicians, geriatricians, neurologists, neurosurgeons, or other physicians involved only in the medical or surgical management of patients with stroke who do not provide active upper limb rehabilitation will be excluded. Similarly, rehabilitation engineers, robotic engineers, biomedical engineers, orthotists, and other specialists who are typically not directly involved in physical rehabilitation or clinical care for stroke patients will also be excluded. Robotic upper limb rehabilitation provided by students, healthcare assistants, or technicians, who may not be competent to practice independently, will be excluded. Likewise, robotic upper

limb rehabilitation provided by non-professional caregivers, family caregivers, volunteer caregivers, or other informal caregivers will also be excluded.

Phenomena of interest

In this review, studies that describe the experiences of patients after a stroke and/or their rehabilitation professional with upper limb rehabilitation robots will be considered. Patients' experiences during or after the use of upper limb rehabilitation robots for stroke can be positive or negative, describe complications/adverse events or any other experiences. Rehabilitation professionals' experiences may include facilitators and barriers, encounters, perspectives, or opinions associated with preparing for or providing upper limb rehabilitation in stroke using rehabilitation robots.

Context

The context will not be restricted in this review. This review will consider studies that present patients after a stroke or rehabilitation professionals' experiences of providing upper limb rehabilitation using rehabilitation robots in any clinical setting during any phase of stroke rehabilitation. These settings may include outpatient, inpatient, community-based, or home-based intervention services or other therapeutic settings. This review is not restricted to geographical locations, funding mechanisms, healthcare facilities, or services.

Types of studies

This review will consider studies that focus on qualitative data, including, but not limited to, designs such as qualitative descriptive, phenomenology, grounded theory, ethnography, and

action research. This review will also consider the qualitative results of mixed-method studies.

Methods

The proposed systematic review will be conducted in accordance with the JBI methodology for systematic reviews of qualitative evidence.[30] The review will commence in October 2022 and end in September 2023. The review protocol is registered in PROSPERO (CRD42022321402).

Search strategy

The search strategy will aim to locate both published and unpublished studies. A three-step search strategy will be utilised in this review. First, a pilot initial limited search of MEDLINE (Ovid) and CINAHL (EBSCOhost) was undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles and the index terms (such as MeSH terms) used to describe the articles were used to develop a full search strategy for MEDLINE (Ovid) (see Appendix 1). The search strategy, including all identified keywords and index terms, will be adapted for each included database and/or information source. The reference lists of all included sources of evidence will be screened for additional studies.

Regardless of the publication date, articles published in English will be included to capture all relevant literature comprehensively. In view of the limited resources available to reviewers to translate literature from other languages, languages other than English will be excluded in this review. The databases will include MEDLINE(Ovid), EMBASE(Elsevier), Cochrane CENTRAL, PsycINFO, Scopus, Web of Science, IEEE and CINAHL(EBSCOhost). Grey

literature will also be searched through Open Grey, PsyArXiv, bioRxiv, medRxiv, and Google Scholar.

Study selection

After the search, the citations will be collated and uploaded into EndNote X20 (Clarivate Analytics, PA, USA), and duplicates will be removed. After piloting the eligibility criteria on a sample of citations (between six and eight articles) to ensure consistency in application,[31] two independent reviewers (MC and LV) will screen all titles and abstracts to determine if they meet the review's inclusion criteria and any disagreements will be resolved by mutual agreement in discussion with the third reviewer (VS/SB). Potentially relevant studies will be retrieved in full, and their citation details imported into the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI) (JBI, Adelaide, Australia).[32] The full text of selected citations will be assessed in detail against the inclusion criteria by two independent reviewers (MC and LV), and any disagreements will be resolved in discussion with VS/SB. The reasons for the exclusion of full-text papers that do not meet the inclusion criteria will be recorded and reported. The results of the search and the study inclusion process will be reported in full in the final systematic review and presented using a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram.[33]

Assessment of methodological quality

Eligible studies will be critically appraised by two independent reviewers for methodological quality using the standard JBI Critical Appraisal Checklist for Qualitative Research.[34] Any disagreements that arise between the reviewers will be resolved through discussion with

the third reviewer. The results of the critical appraisal will be reported in narrative form and tables. Regardless of the results of their methodological quality, all studies will be included in the data extraction and synthesis process to ensure that all experiences are captured comprehensively and no evidence is missed. All major quality issues of the included studies will be presented and discussed in the final review report.

Data extraction

Data will be extracted from studies included in the review by two independent reviewers using the standardised JBI data extraction tool in JBI SUMARI.[32] The data extracted will include specific details about the population, context, culture, geographical location, study methods, and the phenomena of interest relevant to the review objectives, namely experiences of using upper limb rehabilitation robots by patients after a stroke and rehabilitation professionals' experiences of providing stroke upper limb rehabilitation using robots. The findings, and their illustrations, will be extracted verbatim and assigned a level of credibility. Any disagreements that arise between the reviewers will be resolved through discussion with the third reviewer. If necessary, missing or additional data will be requested from the authors. Even after obtaining additional information from the authors, all missing or unclear information that continues to exist will be treated in the review report as missing data.

Data synthesis

Qualitative research findings where possible, will be pooled using JBI SUMARI with the meta-aggregation approach.[35] This will involve the aggregation or synthesis of findings to generate a set of statements representing that aggregation by assembling the findings and

categorising these findings based on similarity in meaning. These categories will then be subjected to a synthesis to produce a single comprehensive set of synthesised findings that can be used as a basis for evidence-based practice. Where textual pooling is not possible, the findings will be presented in a narrative form.

Assessing confidence in the findings

The final synthesised findings will be graded according to the ConQual approach for establishing confidence in the output of qualitative research synthesis and presented in a Summary of Findings.[36] The Summary of Findings includes the major elements of the review and details how the ConQual score is developed. The title, population, phenomena of interest, and context for the specific review will be included in the summary of findings. Each synthesised finding from the review will then be presented, along with the type of research informing it, the score for dependability and credibility, and the overall ConQual score.

Reflexivity and integrity

Given that this is a review of qualitative studies, it is important to consider the reviewers' assumptions and preconceptions regarding the phenomenon of interest, as well as other potential influences that may affect the review process.

This review will be conducted in collaboration. The current review is not funded by public or private sources, and the review team have declared no conflict of interest. As a result, the review is not affected by external influences. The review team includes a robotic engineer, an occupational therapist with experience in using rehabilitation robots, an occupational

therapist, and a physiotherapist with experience in rehabilitation but not robotics. With the deliberate decision to include reviewers with varying levels of experience with rehabilitation robots and their involvement in all stages of the review process, it is anticipated that any potential influence of individual reviewers' conceptions and preconceptions regarding the phenomenon of interest will be minimised. The review team's experience will provide the necessary expertise for this review.

A conscious effort will be made to write memos during the data collection and analysis in order to examine and reflect on the reviewer's engagement.[37] This 'memoing' process will include methodological notetaking to explain the procedural aspect and observational comments to explain and explore the reviewer's feelings at different stages of the review process. Moreover, the reviewers have not published a primary qualitative study on the phenomenon of interest, despite having published primary qualitative studies on other topics. The use of the standardised JBI extraction tool for data extraction and following the standard procedures of the meta-aggregation approach for data synthesis, as well as the above-mentioned process of author reflexivity, based on Flemming and Noyes descriptions,[37] are likely to minimise the impact of the review team's preconceptions. Reflexivity and integrity will be maintained throughout the search, data collection and analysis stages.

Patient and public involvement

Patients and members of the public were not involved in the planning of this protocol.

DISCUSSION

The main aim of this review is to describe the experiences of patients after a stroke and rehabilitation professionals' experiences with upper limb rehabilitation robots. The results from this review are expected to inform better understanding of the use of upper limb rehabilitation robots, perceptions, opinions, facilitators, and barriers to their use. This review will highlight current research and available evidence in this important and emerging topic area in upper limb rehabilitation after a stroke. The findings from this review will be published and disseminated in journals, conferences and social media, and it is anticipated that the findings from this review will be useful for patients after a stroke, rehabilitation professionals, commissioners of health and care services and developers of rehabilitation robots to inform better provision and ongoing care for patients after a stroke.

FIGURE LEGENDS:

Figure 1 illustrates an example of upper limb training using an end-effector robot, H-man. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Articares.

Figure 2 illustrates an example of upper limb training using an end-effector robot, MO.TO.RE. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Humanware S.r.l.

Figure 3 illustrates an example of upper limb training using an exoskeleton robot, ArmeoPower. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Hocoma.

Figure 4 illustrates an example of an upper limb exosuit robot described by Hoang et al. being worn by a volunteer. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Dr Thanh Nho Do.

ABBREVIATIONS:

CINAHL*:* Cumulative Index of Nursing and Allied Health Literature

PRISMA*:* Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PROSPERO: International Prospective Register of Systematic Reviews

JBI SUMARI: JBI System for the Unified Management, Assessment and Review of Information

AUTHOR CONTRIBUTIONS:

MC was responsible for the conceptualisation and design of the study with critical inputs from LV, VS, and SB. MC developed the search strategy and conducted the search with critical input from LV, VS, and SB. The protocol was drafted by MC with important intellectual input and revisions from LV, VS, and SB. All authors have read and given approval for this version and agree to be accountable for all aspects of the work. MC is the guarantor of the review.

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CONFLICT OF INTERESTS STATEMENT:

The authors declare that there are no competing interests or conflicting interests.

DATA STATEMENT:

There are currently no data associated with this protocol. However, this protocol is published in PROSPERO. Details of this citation are as follows

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Figure 1 illustrates an example of upper limb training using an end-effector robot, H-man. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Articares.

724x254mm (300 x 300 DPI)

Figure 2 illustrates an example of upper limb training using an end-effector robot, MO.TO.RE. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Humanware S.r.l.

721x265mm (300 x 300 DPI)

Figure 3 illustrates an example of upper limb training using an exoskeleton robot, ArmeoPower. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Hocoma.

718x239mm (300 x 300 DPI)

Figure 4 illustrates an example of an upper limb exosuit robot described by Hoang et al. being worn by a volunteer. *Note: The person shown in the picture is not a patient and was taken with the participant's knowledge and permission. Picture courtesy of Dr Thanh Nho Do.

618x314mm (300 x 300 DPI)

Ovid MEDLINE(R) ALL <1946 to May 20, 2022>

1 exp Physiatrists/ or exp Health Personnel/ or exp Allied Health Personnel/ or exp Physicians/ or exp Primary Health Care/ or exp Nurses/ or exp Family Nurse Practitioners/ or exp Nurse Practitioners/ or exp Physical Therapists/ or exp Occupational Therapists/ or health personnel.mp. or healthcare professional*.mp. or health-care professional*.mp. or health care professional*.mp. or allied health professional*.mp. or doctor*.mp. or physician*.mp. or geriatric*.mp. or rescriber*.mp. or primary healthcare.mp. or paramedic*.mp. or family nurse.mp. or nurse.mp. or community nurse.mp. or physio*.mp. or physiotherapist.mp. or physio therapist.mp. or physical therapist.mp. or hand therapist.mp. or self treatment.mp. or (Caregiver support regime therapy or Carer).mp. or Caregivers/ or (health care professional or health care professionals or health care provider or health care providers or healthcare provider or healthcare providers or healthcare worker or healthcare workers or personnel, health or professional, health care or provider, health care or provider, healthcare).mp. (Records Retrieved – 7196481)

2 exp "Attitude of Health Personnel"/ or exp Attitude/ or exp Occupational Stress/ or exp "Delivery of Health Care"/ or exp Qualitative Research/ or experience*.mp. or feel*.mp. or encounter*.mp. or perception*.mp. or opinion*.mp. (Records Retrieved – 3027183)

3 1 and 2 (Records Retrieved – 1094496)

4 exp "Quality of Health Care"/ or exp Patient Satisfaction/ or exp Patient Compliance/ or exp Compliance/ or exp "Patient Acceptance of Health Care"/ or exp "Treatment Adherence and Compliance"/ or exp Patient Dropouts/ or exp Treatment Refusal/ or exp Patient Participation/ or exp Psychological Distress/ or exp Health Behavior/ or exp "Quality of Life"/ or exp Attitude/ or exp Qualitative Research/ or patient satisfaction.mp. or patient acceptance.mp. or patient dropout*.mp. or patient participation.mp. or treatment refus*.mp. or experience*.mp. or feel*.mp. or encounter*.mp. or perception*.mp. or opinion*.mp. (Records Retrieved – 9171170)

5 3 or 4 (Records Retrieved – 9292409)

6 exp cerebrovascular disorders/ or exp basal ganglia cerebrovascular disease/ or exp brain ischemia/ or exp carotid artery diseases/ or exp cerebral small vessel diseases/ or exp intracranial arterial diseases/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ or stroke/ or exp brain infarction/ or stroke, lacunar/ or vasospasm, intracranial/ or vertebral artery dissection/ or brain injuries/ or brain injury, chronic/ or (stroke* or poststroke or apoplex* or cerebral vasc* or brain vasc* or cerebrovasc* or cva* or SAH).mp. or ((brain or cerebr* or cerebell* or vertebrobasil* or hemispher* or intracran* or intracerebral or infratentorial or supratentorial or middle cerebral artery or MCA* or anterior circulation or posterior circulation or basilar artery or vertebral artery or space-occupying) adj5 (isch?emi* or infarct* or thrombo* or emboli* or occlus* or hypoxi*)).mp. or ((brain* or cerebr* or cerebell* or intracerebral or intracran* or parenchymal or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli* or putaminal or putamen or posterior fossa or hemispher* or subarachnoid) adj5 (h?emorrhag* or h?ematoma* or bleed*)).mp. or hemiplegia/ or exp paresis/ or (hemipleg* or hemipar* or paresis or paretic or brain injur*).mp. (Records Retrieved – 805510)

7 exp upper extremity/ or (upper limb* or upper extremit* or arm or arms or shoulder or shoulders or hand or hands or axilla* or elbow* or forearm* or finger* or wrist*).mp. (Records Retrieved – 1087124)

8 robotics/ or automation/ or orthotic devices/ or "equipment and supplies"/ or self-help devices/ or therapy, computer-assisted/ or man-machine systems/ or (robot* or orthos* or orthotic or automat* or computer aided or computer assisted or device*).mp. or (electromechanical or electro-mechanical or mechanical or mechanised or mechanized or driven).mp. or exercise movement techniques/ or exercise/ or exercise therapy/ or muscle stretching techniques/ or motion therapy, continuous passive/ or ((continuous passive or cpm) adj3 therap*).mp. or (assist* adj5 (train* or aid* or rehabilitat* or re-educat*)).mp. (Records Retrieved – 2054580)

9 5 and 6 and 7 and 8 (Records Retrieved – 4059)

S1 Table: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Systematic Reviews 2015 4:1

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	4, 50
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☒	N/A.
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	☒	☐	79, 268-269, 413-419
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	5-42
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☒	☐	400-406
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	☐	☒	N/A
Support					
Sources	5a	Indicate sources of financial or other support for the review	☒	☐	407=409
Sponsor	5b	Provide name for the review funder and/or sponsor	☒	☐	407=409
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	☒	☐	407=409
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	☒	☐	111-171

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	☒	☐	173 -177
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	184- 264
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	279-285
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	☒	☐	270-285 and Appendix 1
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	286-366
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	☒	☐	286-301
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	311-323
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	☐	☒	311-323
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including	☐	☒	N/A

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		prioritization of main and additional outcomes, with rationale			
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	☒	☐	302-310
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☐	☒	N/A
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall's tau)	☐	☒	N/A
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	☐	☒	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☒	☐	324-331
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☐	☒	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☒	☐	332-340

S1 Table: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Systematic Reviews 2015 4:1

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	4, 50
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☒	N/A.
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	☒	☐	79, 2689-26970, 4134-41920
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	5-42
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☒	☐	4001-4067
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	☐	☒	N/A
Support					
Sources	5a	Indicate sources of financial or other support for the review	☒	☐	408-410 407=409
Sponsor	5b	Provide name for the review funder and/or sponsor	☒	☐	407=409 408-410
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	☒	☐	407=409 408-410
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	☒	☐	111-1712

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	☒	☐	1734 -1778
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	1845- 2645
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	27980-2856
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	☒	☐	2701-2856 and Appendix 1
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	2867-3667
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	☒	☐	2867-3012
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	3112-3234
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	☐	☒	3112-3234
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including	☐	☒	N/A

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		prioritization of main and additional outcomes, with rationale			
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	☒	☐	3023-3101
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☐	☒	N/A
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall's tau)	☐	☒	N/A
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	☐	☒	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☒	☐	3245-3312
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☐	☒	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☒	☐	3323-3401