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Protocol for a scoping review of Skin Self-care of people with spinal cord injury

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Protocol for a scoping review of Skin Self-care of people with spinal cord injury

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ABSTRACT

Introduction In recent years, increasing methodological references have been used in scientific research; these are points of support in the search for evidence, formulation and elaboration of instruments, scales, guideline and protocols. However, significant variability currently exists in scoping review conduct and reporting, thus limiting the potential of the methodology to advance research and practice about skin self-care of people with spinal cord injury (SCI). Our objective was to perform a scoping review protocol within the health rehabilitation context of people with SCI, focusing on skin self-care. **Methods and analysis** The protocol was developed by using the scoping review methodological framework proposed by Arksey and O'Malley and further refined by the Joanna Briggs Institute, incorporating insights from more recent innovations in scoping review methodology. Sensitive searches of 10 electronic databases from 2007 to 2017 will be supplemented by grey literature searches. Two reviewers using a tool developed for this scoping review will screen eligible studies. **Ethics and dissemination** The scoping review will undertake a secondary analysis of previously collected data and does not require ethical approval; however, the ethical precepts of copyright will be respected. The results will facilitate a better understanding of the practical health rehabilitation context of people with spinal cord injury, the impacts of these rehabilitationsand how to build an evidence base for this work in the future.

Key-words: Spinal Cord Injury; Self-care; Skin; Rehabilitation

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is a novel review approach to cover a vast volume of literature on a broad topic, thus offering a map of research aboutthe skin self-care of people with spinal cord injury.
- The search strategy includes 10 electronic databases with peer-reviewed literature and a broad range of grey literature sources.
- Stakeholders, including experts in the area of rehabilitation, patients and caregivers, will be consulted and engaged throughout the study review process.
- The elaboration of this protocol will contribute to improvements in the planning and self-care of the injured person andwill enable the scientific community to present concrete steps capable of presenting strong evidence related to the subject it is intended to investigate.

BACKGROUND

In recent years, scientific research has used more methodological references, which can support the search for evidence and the formulation and/or elaboration of instruments, scales, guides and protocols.

In the health area, the use of these methodological references has promoted and disseminated studies and research capable of adding new tools and evidence, which have subsidized behaviours and have provided quality, safety and effectiveness in the diagnosis, prognosis, care and therapy of patients. Evaluating health care from a patient-centred approach has promoted safe and quality care.[1 2]

Scoping review methodology is particularly useful for examining a broadly covered topic to comprehensively and systematically map the literature and identify key concepts, theories, evidence, or research gaps. Unlike systematic reviews or meta-analyses, scoping reviews do not narrow the parameters of the review to research trials or require quality assessment. Nonetheless, this type of review is rigorous and methodical in its approach to examining the extent, range and nature of research activity in a particular field while encompassing both empirical and conceptual research with

broadly framed questions. [1] [2] [3]In this sense, it is understood that this reference methodology can subsidize the elaboration of an instrument/tool that is capable of assisting in the self-care of apatient with spinal cord injury.

The World Health Organization (WHO) defines spinal cord injury (SCI) as any injury to the structures of the spinal canal, medullary cone and equine tail that causes motor, sensory, autonomic or psychoactive changes. Because of the injury, the functions performed by the spinal cord are interrupted, causing serious and significant disabilities in various aspects of life of the patient.[4] Traumatic events usually cause the incidence levels of spinal cord injury (SCI), including increasing numbers of car and motorcycle accidents and urban violence. Epidemiological data have estimated an annual global incidence of 40 to 80 cases per million population.[5]In Brazil, approximately 7,000 occurrences of people with SCI per year were verified.[6]

Decreased physical mobility, sensitivity deficits, genitourinary and gastrointestinal repercussions, and circulatory changes make the spinal cord vulnerable to a series of serious complications and further limit the rehabilitation and social insertion processes.[7]Among the complications, the impairment of the skin structure, the limitation of active movement, the loss of tactile and/or thermal sensitivity and long-term permanence in the same position are highlighted.[8]

Recently, the prevalence of pressure ulcers in individuals with SCI has increased. The prevalence rates of pressure ulcers vary between 25 and 50% of veterans with SCI. Pressure ulcers not only pose a significant medical burden but are also associated with high costs of care. A value of $1.3 billion was projected to be the annual cost of treating pressure ulcers in the SCI population.[9]

The preventive skin care activities taught to people with SCI during rehabilitation include daily skin inspection, wheelchair pressure relief (WPR) every 30 minutes, establishing and adhering to turning and sitting tolerance, hygiene, nutrition, and equipment maintenance.[8] However, anindividual with this disorder usually presents a deficit of self-care and is considered dependent for basic daily activities.[6] [10] Thus, continuing effortstodevelop new technologies that support self-managed care are an important prevention strategy.

We believe that a scoping review may contribute to the development of a self-care tool for patients with SCI because the method will help us map the evidence from the available research and relevant literature to inform thedevelopment of new

technologies in health aimed at supporting the management of self-care practices,thereby improving participation in daily life for individuals.

Protocol development is an important component of the standard construction of scoping reviews because it increases the transparency of the method and allows readers to judge the validity and reliability and use the research appropriately.[2]Our objective is to perform a scoping review protocol within the health rehabilitation context of people with spinal cord injury, focusing on skin self-care.

METHODS

The scoping review is an ideal methodology for mapping key concepts within a research area, identifying main sources and types of evidence available, and identifying gaps in the existing research. Scoping reviews are different from systematic reviews, which attempt to answer a specific research question by collating all empirical evidence that fits prespecified eligibility criteria.[11]

This methodological study aims to present a protocol for a scoping review about self-care practices with the skin of people with spinal cord injury.Our protocol was developed using the scoping review methodological framework proposed by Arksey and O'Malley[11] and further refined by the Joanna Briggs Institute.[12] The approach describes 6 methodologicalstages: (1) identification of the research question, (2) identification of relevant studies (search for relevant studies), (3) selection of studies, (4) data extraction, (5) interpretation, summarization and dissemination of results, and (6) (optional) consultation with stakeholders.

Stage 1: Identifying the research questions

The first stage of this study is the development of one or more research questions. Thus, to construct the guiding research question, we used an adaptation of the PICo strategy (P: patient, I: intervention, C: comparison, O: outcomes), with “P” being the population (people with spinal cord injury), “I” the phenomenon of interest (self-care; skin), and “C”the context (rehabilitation) (Figure 1). The PICo strategy can provide potential readers with a significant amount of information about the focus, scope and applicability of a review to fit their needs.[13]

Figure 1. Guiding research question- PICostrategy (adapted from Briggs[13]).

Insert figure 1

In the sequence, using an interactive process that involved team discussions as we became more familiar with the literature, new issues were established. The research questions developed were defined according to Box 1.

Box 1. Research questions and operational definitions.

Research questions and operational definitions
1. *What evidenceis available in the literature that can support the self-care of people with spinal cord injury?*
✓ Support networks, health education, andhealth technologies
2. *What barriers and facilitators to implementing strategies of self-care are available to people with spinal cord injury?*
✓ Barriers and facilitators as identified by authors
3. *What does the literature reveal about self-care of the skin in people with spinal cord injury?*
✓ Individuals, families, health professionals, researchers, and government entities
4. *How has self-care of the skin performed in people with spinal cord injury?*
✓ Care networks (primary, secondary and tertiary)
5. *How do health professionals involved in the care/rehabilitation process contribute to the self-care of the skin of people with spinal cord injury?*
✓ Multi-profession actuation and individual actuation
6. *How do family members/caregivers involved in this process contribute to the self-care of the skin of people with spinal cord injury?*
✓ Support types

Stage 2: Identifying relevant studies

At this stage, team discussions established the eligibility criteria, electronic databases, descriptors and keywords, and search strategies.

Eligibilitycriteria

Inclusion will meet the following criteria: empirical and theoretical studies, published in English, Spanish or Portuguese, in the period from January 2007 to January 2017. Original articles about qualitative (e.g., randomized controlled trials, case–control studies, prospective or retrospective cohort studies, or quasi-experimental studies) and quantitative research, experience reports, literature reviews, integrative, systematic with or without meta-analysis and scope review; guidelines, booklets, protocols, theses and dissertations published in the databases selected for the study; and relevant studies on the subject that are in the list of references of the publications will be included. We will exclude publications whose subject does not match our research question, duplicate works,research not freely available in the databases,publications in which the inclusion criteria are not defined, review letters, reviews, editorials, books, book chapters, newsletters, and summaries in annals of events.

Databases

The identification of studies relevant to this review will be achieved by searching electronic databases of the published literature, which will include the following:Latin American and Caribbean Health Sciences (LILACS);Spanish Bibliographic Index on Health Sciences(IBECS); BDENF (Nursing Database); Cumulative Index to Nursing and Allied (CINAHL); SCOPUS; Medical Literature Analysis and Retrieval System Online (PUBMED/MEDLINE); Web of Science; the Cochrane Library; and the Scientific Electronic Library Online (SciELO).To capture all relevant information, we will also search a variety of grey literature sources, includingGoogle Scholar, OpenGrey, PROQUEST,Capes Bank of dissertations and theses and The Brazilian Ministry of Health. We will also hand-search all reference lists of the included studies to identify additional studies of relevance.

Search strategy

To construct the search strategies, we used the PICo strategy. In addition to guiding the development of the research question, the PICo strategy allows the best available scientific information to be accurately located by the professional or researcher. Considering the research questions mentioned above, the literature search of articles was guided by PICo: “P” population (people with spinal cord injury), “I” phenomenon of interest (self-care; skin), and “C” context (rehabilitation). [12]

The search was guided by the Boolean operators AND and OR, as needed. A librarian led the refinement of our database search strategies during this stage. Each search result was documented, and the references were imported into separate folders using Mendeley Desktop1.15.2 reference management software.

The following descriptors, keywords and their combinations were used to construct the strategies: *"Spinal Cord Trauma", "Spinal Cord Traumas", "Spinal Cord Injury", "Spinal Cord Injuries", "Spinal Cord Disease", "Spinal Cord Diseases", "Spinal Cord Disorders", "Spinal Cord Disorder", "Spinal Paraplegia", "Spinal Paraplegias","Paraplegia", "Paraplegias", "Tetraplegia", "Tetraplegias","Quadriplegia","Quadriplegias", "Skin", "Skin care", "Hygiene", "Skin Ulcer","Skin Ulcers","Pressure Ulcers", "Pressure Ulcer", "Decubitus Ulcers", "Decubitus Ulcer", "Bedsores", "Bedsore", "Sore pressure", "Pressure Sore", "Pressure Sores", "Self Care", "Self Care (Rehabilitation)", "Daily Living Activities", "Daily Living Activity", "Rehabilitation"*,and*"habilitation".*

Stage 3: Study selection

The review process will consist of two levels of screening: (1) a title and abstract review and (2) a full-text review. For the first level of screening, the titles and abstracts of articles retrieved in the search willbe read and analysed by two independent investigators to identify potentially eligible articles. In the second step, the two investigators will then each independently assess the full-text articles to determine whether they meet the inclusion/exclusion criteria. Any discordant full-text articles will be reviewed a second time, and further disagreements about study eligibility at the full-text review stage will be resolved through discussion with a third investigator until full consensus is obtained. Scoping reviews do not allow articles to be excluded according to methodological quality criteria; thus, the items included in this review not were submitted to an evaluation of methodological quality.

To include studies from the list of references, three experts in the area of rehabilitation and disability at the national and international levels will be consulted. To organize the data,a PRISMA flow diagram will be used.

Stage 4: Charting the data

A data collection instrument will be developed by the research team to confirm study relevance and to extract study characteristics, covering questions related to the research proposal (type of publication, language, country, and year); the researcher (name and place of work); and the article (journal, title, year and place of the research, methodology, sample, interventions, analysis, the results and conclusions). Based on a preliminary analysis, we will develop categories and priorities, which will guide the extraction and mapping of data.Bibliographies Management Software (Mendeley Desktop1.15.2) will assist the organization.

Stage 5: Collating, summarizing and reporting the results

In our scoping review, we will describe key categories, such as the target populations, dominant action areas, intervention characteristics, and types of questions posed.This review of the research about intervention effectiveness will also provide suggestions for future research. Potential gaps inskin self-care actions will be identified. This study will present the results in the form of tables and graphs.

Stage 6: A consultation exercise

Arksey; O'malley[11] and Levacet al.[14] suggest that the consultation stage provides opportunities for stakeholder involvement, providing insights beyond what is reported in the literature. To address the study's patient-centric approach and the interests of stakeholders, particularly people with spinal cord injury,our study will consist of two stages: (1) consultations with experts in the area of rehabilitation and disability (3 stages), who will be responsible for the analysis of the list of references relevant to the research, and (2) recorded interviews with patients or caregivers in which information about their daily skin care practices is requested to clarify possible research gaps found in the study (Box 3).

Box 2. Consultations with stakeholders composed of experts and patients.

Consultant stakeholders		Intervention proposal
Experts in the area of rehabilitation and disability	Doctor Nurse Physiotherapist Psychologist Social Worker Nutritionist	Responsible for the analysis of the list of references and inclusion of studies relevant to the research
Patient-centric	People with spinal cord injury Family or caregiver	***Semi-structured interview guide:*** What do you need to know about skin care in your daily routine? Describe how you perform skin care in your daily life. If you were to find any skin changes, what would you do? How would you care for an injury? What are your difficulties (barriers) in performing routine skin care? What are the benefits or reasons for performing skin care in your daily routine?

DISSEMINATION AND ETHICS

The research protocols aim to guide the researcher in the construction of a research methodthatencompasses the following points: importance of the theme - literature review; the issue of study, sample selection, study design, and study conduction strategy; and data analysis, ethical considerations and administrative responsibilities.[15]

In recent years, the publication of revision protocols has been increasing, since process transparency is considered a quality criterion for review, facilitating their subsequent publication in high-impact journals. The review will have relevance to a variety of audiences, including researchers and health professionals who are interested in better understanding the practical applications of self-care in a rehabilitation context, the impacts of this rehabilitation and how to build an evidence base for this work in future.

Corroborating this fact, several studies of protocols of revision of scope in the health area have beenconducted. Halas et al.[3] performed a scoping review protocol to systematically review published review articles specific to tobacco control and primary prevention over the last 10 years. Goertzen et al.[16] described a protocol for a scoping review of reviews (SRR) that aims to map a decade of research focused on physical activity interventions within the domain of primary prevention. Additionally, Colquhoun et al.[17] performed a study protocol for a scoping review on rehabilitation. Jolley et al.[12] outlined a scoping review protocol to systematically review published and unpublished literature, implemented and evaluated in various care settings, specifically for patient-centred quality indicators.

Since the scoping review methodology consists of reviewing and collecting data from publicly available materials, this study does not require ethical approval.Our protocol for systematically conducting a scoping review of published review articles, specifically about skin self-care among people with spinal cord injury over the last 10 years, has been presented. This is an innovative approach that offers a viable way to synthesize a wide range of research literature specific to self-care strategies for the skin of people with spinal cord injury, identifying specific potential trends and gaps. The scoping review will undertake a secondary analysisof previously collected data and does not require ethical approval; however, the ethical precepts of copyright were respected.

CONCLUSIONS

Caring for the injured spinal cord must be continued throughout the life trajectory. The need for improvements in care in this setting has strong impacts on the prevention of complications and other health problems that may require changes in the quality of life of these people.

The development of new products and technologies helps the health team and supports and subsidizes safer, effective and practical care for those who live with daily permanent care needs.

The elaboration of this protocol and others that may arise from this example will contribute to improvement in the planning and self-care of the injured person. Likewise, this protocol will certainly enable the scientific community to present concrete stepsthatare capable of presenting strong evidence related to the subject it is intended to investigate.

Contributors: DKSL conceived of the conception, developed the research question and study methods and contributed meaningfully to the drafting and editing; she has also approved the final manuscript. SDS, NSK, CPV, ADT, SGRL, MMM and KSAH aided in developing the research question and study methods, contributed meaningfully to the drafting and editing, and approved the final manuscript.

Competing interests: None declared.

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Data sharing statement: No additional data available.

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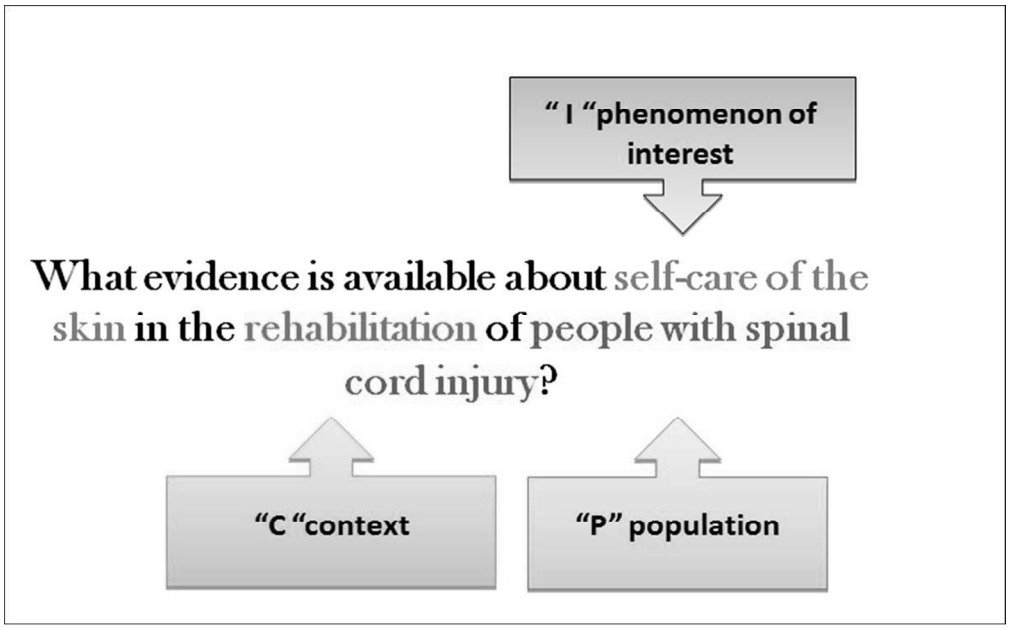

Guiding research question- PICostrategy (adapted from Briggs13).

203x126mm (300 x 300 DPI)

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Protocol for a scoping review of Skin Self-care of people with spinal cord injury

Section and topic	Item No	Checklist item	Page Number
ADMINISTRATIVE INFORMATION			
Title:			1
Identification	1a	Identify the report as a protocol of a systematic review	
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 (such as PROSPERO) and registration number	N/A
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	1, 12
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	12
Sponsor	5b	Provide name for the review funder and/or sponsor	12
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	12
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	2-5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	5-9

Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	7
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	8
Study records:			8-10
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	8-9
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	8-9
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6(box1)
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	6 (box1)/10(box2)
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	10-11
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	8
	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 (such as I^2, Kendall's τ)	N/A
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	9
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as 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 (such as GRADE)	N/A

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page Number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	N/A
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	5
Funding	4	Sources and types of financial, material, and other support	12
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 12
	5b	Name and contact information for the trial sponsor	12
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	6-12
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	9,12
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-5
	6b	Explanation for choice of comparators	3

Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	3-4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5-6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6-7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	N/A
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	N/A
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9-10 (Box 2)

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	N/A
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	N/A
Methods: Assignment of interventions (for controlled trials)			
Allocation:			N/A
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	5-8
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	9-10

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	9
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	9-10
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	9
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	9
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	10-11

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	9-10
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	N/A
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	N/A, 10
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	12
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	12
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	N/A
	31b	Authorship eligibility guidelines and any intended use of professional writers	12
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Protocol for a scoping review of Skin Self-care of people with spinal cord injury

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Protocol for a scoping review of Skin Self-care of people with spinal cord injury

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ABSTRACT

Introduction In recent years, increasing methodological references have been used in scientific research; these are points of support in the search for evidence, formulation and elaboration of instruments, scales, guideline and protocols. However, significant variability currently exists in scoping review conduct and reporting, thus limiting the potential of the methodology to advance research and practice about skin self-care of people with spinal cord injury (SCI). Our objective was to perform a scoping review protocol within the health rehabilitation context of people with SCI, focusing on skin self-care. **Methods and analysis** The protocol was developed by using the scoping review methodological framework proposed by Arksey and O'Malley and further refined by the Joanna Briggs Institute, incorporating insights from more recent innovations in scoping review methodology. Sensitive searches of 13 electronic databases from 2007 to 2017 will be supplemented by grey literature searches. Two reviewers using a tool developed for this scoping review will screen eligible studies. **Ethics and dissemination** The scoping review will undertake a secondary analysis of previously collected data and does not require ethical approval; however, the ethical precepts of copyright will be respected. The results will facilitate a better understanding of the practical health rehabilitation context of people with SCI, the impacts of these rehabilitations and how to build an evidence base for this work in the future.

Key-words: Spinal Cord Injury; Self-care; Skin; Rehabilitation

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is a novel review approach to cover a vast volume of literature on a broad topic, thus offering a map of research about the skin self-care of people with spinal cord injury (SCI).

- The search strategy includes 10 electronic databases with peer-reviewed literature and a broad range of grey literature sources.

- Stakeholders will be consulted and engaged throughout the study review process. The experts in the area of rehabilitation will be responsible for analyzing and judging the relevant references for the research. Patients and caregivers will provide information and clarification beyond what is reported in the literature about their daily skin care practices.

- The elaboration of this protocol will contribute to improvements in the planning and self-care of the people with SCI and will enable the scientific community to present concrete steps capable of presenting strong evidence related to the subject it is intended to investigate.

BACKGROUND

In recent years, scientific research has used more methodological references, which can support the search for evidence and the formulation and/or elaboration of instruments, scales, guides and protocols.

In the health area, the use of these methodological references has promoted and disseminated studies and research capable of adding new tools and evidence, which have subsidized behaviours and have provided quality, safety and effectiveness in the diagnosis, prognosis, care and therapy of patients. Evaluating health care from a patient-centred approach has promoted safe and quality care.[1 2]

Scoping review methodology is particularly useful for examining a broadly covered topic to comprehensively and systematically map the literature and identify key concepts, theories, evidence, or research gaps. Unlike systematic reviews or meta-analyses, scoping reviews do not narrow the parameters of the review to research trials

or require quality assessment. Nonetheless, this type of review is rigorous and methodical in its approach to examining the extent, range and nature of research activity in a particular field while encompassing both empirical and conceptual research with broadly framed questions. [1 2 3] In this sense, it is understood that this reference methodology can subsidize the elaboration of an instrument/tool that is capable of assisting in the self-care of a patient with spinal cord injury (SCI).

The World Health Organization (WHO) defines SCI as any injury to the structures of the spinal canal, medullary cone and equine tail that causes motor, sensory, autonomic or psychoactive changes. Because of the injury, the functions performed by the spinal cord are interrupted, causing serious and significant disabilities in various aspects of life of the patient.[4] Traumatic events usually cause the incidence levels of SCI, including increasing numbers of car and motorcycle accidents and urban violence. Epidemiological data have estimated an annual global incidence of 40 to 80 cases per million population.[5] In Brazil, approximately 7,000 occurrences of people with SCI per year were verified.[6]

Decreased physical mobility, sensitivity deficits, genitourinary and gastrointestinal repercussions, and circulatory changes make the spinal cord vulnerable to a series of serious complications and further limit the rehabilitation and social insertion processes.[7] Among the complications, the impairment of the skin structure, the limitation of active movement, the loss of tactile and/or thermal sensitivity and long-term permanence in the same position are highlighted.[8]

Recently, the prevalence of pressure injury in individuals with SCI has increased. The prevalence rates of pressure injury vary between 25 and 50% of veterans with SCI. Pressure injury not only pose a significant medical burden but are also associated with high costs of care. A value of $1.3 billion was projected to be the annual cost of treating pressure injury in the SCI population.[9]

The preventive skin care activities taught to people with SCI during rehabilitation include daily skin inspection, wheelchair pressure relief (WPR) every 30 minutes, establishing and adhering to turning and sitting tolerance, hygiene, nutrition, and equipment maintenance.[8]

The search for new technologies for the care of the skin of people with SCI has been a challenge for health professionals. Krishnan et al. [10] evaluated the validity of the Spinal Cord Injury Pressure Ulcer Scale (SCIPUS) during acute care and inpatient rehabilitation following SCI by determining critical cutoff points and assessing the

ability to predict risk of pressure ulceration. The authors demonstrated that SCIPUS can prevent the occurrence of pressure ulceration in the acute period (2 to 3 days), however, it was unable to predict over a longer term (5 to 21 days).

Of note, individual with SCI usually presents a deficit of self-care and is considered dependent for basic daily activities.[6 11] Thus, continuing efforts to develop new technologies that support self-managed care are an important prevention strategy.

We believe that a scoping review may contribute to the development of a self-care tool for patients with SCI, because the method will help us map the evidence from the available research and relevant literature to inform the development of new technologies in health aimed at supporting the management of self-care practices, thereby improving participation in daily life for individuals.

Protocol development is an important component of the standard construction of scoping reviews because it increases the transparency of the method and allows readers to judge the validity and reliability and use the research appropriately.[2] Our objective is to perform a scoping review protocol within the health rehabilitation context of people with spinal cord injury, focusing on skin self-care.

METHODS

The scoping review is an ideal methodology for mapping key concepts within a research area, identifying main sources and types of evidence available, and identifying gaps in the existing research. Scoping reviews are different from systematic reviews, which attempt to answer a specific research question by collating all empirical evidence that fits prespecified eligibility criteria.[12]

This methodological study aims to present a protocol for a scoping review about self-care practices with the skin of people with SCI. Our protocol was developed using the scoping review methodological framework proposed by Arksey and O'Malley[12] and further refined by the Joanna Briggs Institute.[13] The approach describes 6 methodological stages: (1) identification of the research question, (2) identification of relevant studies (search for relevant studies), (3) selection of studies, (4) data extraction, (5) interpretation, summarization and dissemination of results, and (6) consultation with stakeholders (optional).

Stage 1: Identifying the research questions

The first stage of this study is the development of one or more research

questions. Thus, to construct the guiding research question, we used an adaptation of the PICO strategy (P: patient, I: intervention, C: comparison, O: outcomes), with "P" being the population (people with spinal cord injury), "I" the phenomenon of interest (self-care; skin injury), and "C" the context (rehabilitation) (Figure 1). The PICO strategy can provide potential readers with a significant amount of information about the focus, scope and applicability of a review to fit their needs.[14]

Figure 1. Guiding research question - PICO strategy (adapted from Briggs[14]).

Insert figure 1

In the sequence, using an interactive process that involved team discussions as we became more familiar with the literature, new issues were established. The research questions developed were defined according to Box 1.

Box 1. Research questions and operational definitions.

Research questions and operational definitions
1. *What evidence is available in the literature that can support the self-care of people with SCI?*
✓ Support networks, health education, and health technologies
2. *What barriers and facilitators to implementing strategies of self-care are available to people with SCI?*
✓ Barriers and facilitators as identified by authors
3. *What does the literature reveal about of the involvement of health professionals, researchers, and government entities in self-care skin strategies in people with SCI?*
✓ Research and public policies
4. *How is self-care of the skin provided in care networks for people with SCI?*
✓ Care networks (primary, secondary and tertiary)
5. *How do health professionals involved in the care/rehabilitation process contribute to the self-care of the skin of people with SCI?*

- ✓ Multi-profession actuation and individual actuation
- **6.** *How do family members/caregivers involved in this process contribute to the self-care of the skin of people with SCI?*
- ✓ Support types

Stage 2: Identifying relevant studies

At this stage, team discussions established the eligibility criteria, electronic databases, descriptors and keywords, and search strategies.

Eligibility criteria

Inclusion will meet the following criteria: empirical and theoretical studies, published in English, Spanish or Portuguese, in the period from January 2007 to January 2017. Original articles about qualitative (e.g. case–control studies, prospective or retrospective cohort studies, or quasi-experimental studies) and quantitative research, experience reports, literature reviews, integrative, systematic with or without meta-analysis and scope review; guidelines, booklets, protocols, theses and dissertations published in the databases selected for the study; and relevant studies on the subject that are in the list of references of the publications will be included.

Databases

The identification of studies relevant to this review will be achieved by searching electronic databases of the published literature, which will include the following: Latin American and Caribbean Health Sciences (LILACS); Spanish Bibliographic Index on Health Sciences (IBECS); BDENF (Nursing Database); Cumulative Index to Nursing and Allied (CINAHL); SCOPUS; Medical Literature Analysis and Retrieval System Online (PUBMED/MEDLINE); Web of Science; the Cochrane Library; and the Scientific Electronic Library Online (SciELO). To capture all relevant information, we will also search a variety of grey literature sources, including Google Scholar, Open Grey, PROQUEST, Capes Bank of dissertations and theses and The Brazilian Ministry of Health. We will also hand-search all reference lists of the included studies to identify additional studies of relevance.

Search strategy

To construct the search strategies, we used the PICO strategy. In addition to guiding the development of the research question, the PICO strategy allows the best available scientific information to be accurately located by the professional or researcher. Considering the research questions mentioned above, the literature search of articles was guided by PICO: "P" population (people with SCI), "I" phenomenon of interest (self-care; skin injury), and "C" context (rehabilitation). [13]

The search was guided by the Boolean operators AND and OR, as needed. A librarian led the refinement of our database search strategies during this stage. Each search result was documented, and the references were imported into separate folders using Mendeley Desktop1.15.2 reference management software.

The following descriptors, keywords and their combinations were used to construct the strategies: *"Spinal Cord Trauma", "Spinal Cord Traumas", "Spinal Cord Injury", "Spinal Cord Injuries", "Spinal Cord Disease", "Spinal Cord Diseases", "Spinal Cord Disorders", "Spinal Cord Disorder", "Spinal Paraplegia", "Spinal Paraplegias", "Paraplegia", "Paraplegias", "Tetraplegia", "Tetraplegias", "Quadriplegia", "Quadriplegias", "Skin", "Skin care", "Hygiene", "Skin Ulcer", "Skin Ulcers", "Pressure Ulcers", "Pressure Ulcer", "Decubitus Ulcers", "Decubitus Ulcer", "Bedsores", "Bedsore", "Sore pressure", "Pressure Sore", "Pressure Sores", "Pressure Injury", "Pressure Injuries", Self-Care", "Self-Care (Rehabilitation)", "Daily Living Activities", "Daily Living Activity", "Rehabilitation"*, and *"habilitation"*.

Stage 3: Study selection

The review process will consist of two levels of screening: (1) a title and abstract review and (2) a full-text review. For the first level of screening, the titles and abstracts of articles retrieved in the search will be read and analysed by two independent investigators to identify potentially eligible articles. In the second step, the two investigators will then each independently assess the full-text articles to determine whether they meet the inclusion/exclusion criteria. Any discordant full-text articles will be reviewed a second time, and further disagreements about study eligibility at the full-text review stage will be resolved through discussion with a third investigator until full consensus is obtained. Scoping reviews do not allow articles to be excluded according to methodological quality criteria; thus, the items included in this review not were submitted to an evaluation of methodological quality.

To include studies from the list of references, three experts in the area of

rehabilitation and disability at the national and international levels will be consulted. To organize the data, a PRISMA flow diagram will be used.

Stage 4: Charting the data

A data collection instrument will be developed by the research team to confirm study relevance and to extract study characteristics, covering questions related to the research proposal (type of publication, language, country, and year); the researcher (name and place of work); and the article (journal, title, year and place of the research, methodology, sample, interventions, analysis, the results and conclusions). Based on a preliminary analysis, we will develop categories and priorities, which will guide the extraction and mapping of data. Bibliographies Management Software (Mendeley Desktop1.15.2) will assist the organization.

Stage 5: Collating, summarizing and reporting the results

In our scoping review, we will describe key categories, such as the target populations, dominant action areas, intervention characteristics, and types of questions posed. This review of the research about intervention effectiveness will also provide suggestions for future research. Potential gaps in skin self-care actions will be identified. The data collected will be stored in the electronic database of Excel 2010. The results of this study will be presented in a descriptive way in tables and graphs.

Stage 6: A consultation exercise

Arksey; O'malley[12] and Levacet al.[15] suggest that the consultation stage provides opportunities for stakeholder involvement, providing insights beyond what is reported in the literature. To address the study's patient-centric approach and the interests of stakeholders, particularly people with SCI, our study will consist of two stages: (1) consultations with experts in the area of rehabilitation and disability (3 stages), who will be responsible for the analysis of the list of references relevant to the research, and (2) recorded interviews with patients or caregivers in which information about their daily skin care practices is requested to clarify possible research gaps found in the study (Box 2).

Box 2. Consultations with stakeholders composed of experts and patients.

Consultant stakeholders		Intervention proposal
Experts in the area of rehabilitation and disability	Doctor Nurse Physical therapists Psychologist Social Worker Nutritionist	Responsible for the analysis of the list of references and inclusion of studies relevant to the research
Patient-centric	People with spinal cord injury Family or caregiver	***Semi-structured interview guide:*** What do you need to know about skin care in your daily routine? Describe how you perform skin care in your daily life. If you were to find any skin changes, what would you do? How would you care for an injury? What are your difficulties (barriers) in performing routine skin care? What are the benefits or reasons for performing skin care in your daily routine?

DISSEMINATION AND ETHICS

The research protocols aim to guide the researcher in the construction of a research method that encompasses the following points: importance of the theme - literature review; the issue of study, sample selection, study design, and study conduction strategy; and data analysis, ethical considerations and administrative responsibilities.[16]

In recent years, the publication of revision protocols has been increasing, since process transparency is considered a quality criterion for review, facilitating their subsequent publication in high-impact journals. The review will have relevance to a variety of audiences, including researchers and health professionals who are interested in better understanding the practical applications of self-care in a rehabilitation context, the impacts of this rehabilitation and how to build an evidence base for this work in future.

Corroborating this fact, several studies of protocols of revision of scope in the health area have been conducted. Halas et al.[3] performed a scoping review protocol to systematically review published review articles specific to tobacco control and primary prevention over the last 10 years. Goertzen et al.[17] described a protocol for a scoping review of reviews (SRR) that aims to map a decade of research focused on physical activity interventions within the domain of primary prevention. Additionally, Colquhoun et al.[18] performed a study protocol for a scoping review on rehabilitation. Jolley et al.[13] outlined a scoping review protocol to systematically review published and unpublished literature, implemented and evaluated in various care settings, specifically for patient-centred quality indicators.

Since the scoping review methodology consists of reviewing and collecting data from publicly available materials, this study does not require ethical approval. Our protocol for systematically conducting a scoping review of published review articles, specifically about skin self-care among people with SCI over the last 10 years, has been presented. This is an innovative approach that offers a viable way to synthesize a wide range of research literature specific to self-care strategies for the skin of people with SCI, identifying specific potential trends and gaps. The scoping review will undertake a secondary analysis of previously collected data and does not require ethical approval; however, the ethical precepts of copyright were respected.

CONCLUSIONS

Caring for the injured spinal cord must be continued throughout the life trajectory. The need for improvements in care in this setting has strong impacts on the prevention of complications and other health problems that may require changes in the quality of life of these people.

The development of new products and technologies helps the health team and supports and subsidizes safer, effective and practical care for those who live with daily permanent care needs.

The elaboration of this protocol and others that may arise from this example will contribute to improvement in the planning and self-care of the individual with SCI. Likewise, this protocol will certainly enable the scientific community to present concrete steps that are capable of presenting strong evidence related to the subject it is intended to investigate.

Contributors: DKSL conceived of the conception, developed the research question, study methods, contributed meaningfully to the drafting and editing, and approved the final manuscript. SDS, NSK, CPV, ADT, SGRL, MMM and KSAH aided in developing the research question and study methods, contributed meaningfully to the drafting and editing, and approved the final manuscript.

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Data sharing statement: No additional data available.

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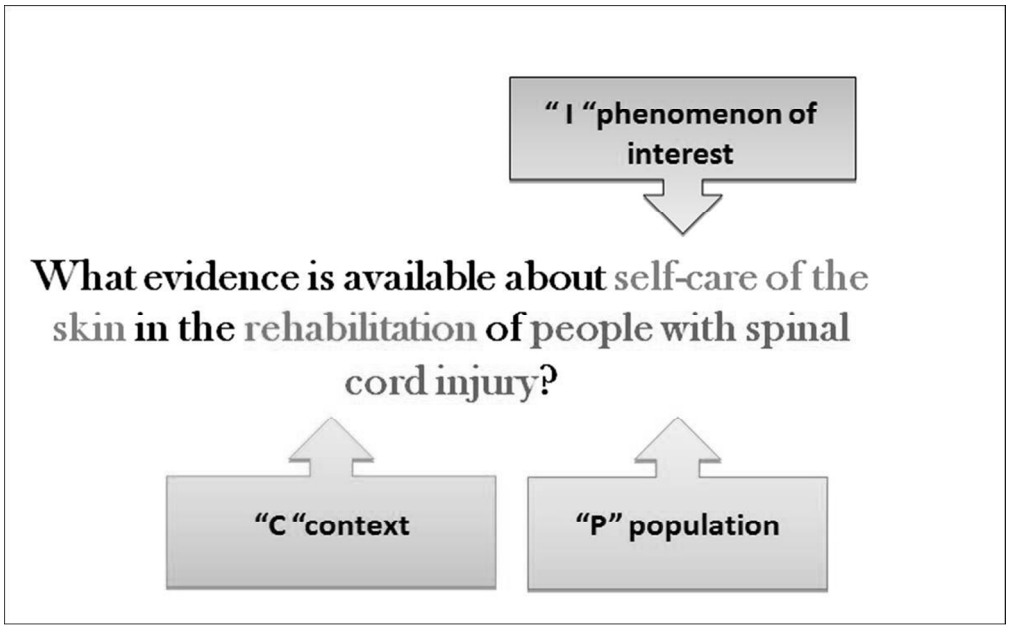

Guiding research question- PICostrategy (adapted from Briggs13).

203x126mm (300 x 300 DPI)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page Number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	N/A
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	5
Funding	4	Sources and types of financial, material, and other support	12
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 12
	5b	Name and contact information for the trial sponsor	12
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	6-12
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	9,12
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-5
	6b	Explanation for choice of comparators	3

Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	3-4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5-6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6-7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	N/A
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	N/A
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9-10 (Box 2)

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	N/A
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	N/A
Methods: Assignment of interventions (for controlled trials)			
Allocation:			N/A
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	5-8
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	9-10

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	9
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	9-10
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	9
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	9
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	10-11

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	9-10
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	N/A
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	N/A, 10
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	12
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	12
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	N/A
	31b	Authorship eligibility guidelines and any intended use of professional writers	12
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Protocol for a scoping review of Skin Self-care of people with spinal cord injury

Section and topic	Item No	Checklist item	Page Number
ADMINISTRATIVE INFORMATION			
Title:			1
Identification	1a	Identify the report as a protocol of a systematic review	
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 (such as PROSPERO) and registration number	N/A
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	1, 12
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	12
Sponsor	5b	Provide name for the review funder and/or sponsor	12
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	12
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	2-5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	5-9

Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	7
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	8
Study records:			8-10
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	8-9
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	8-9
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6(box1)
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	6 (box1)/10(box2)
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	10-11
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	8
	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 (such as I^2, Kendall's τ)	N/A
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	9
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as 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 (such as GRADE)	N/A

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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