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Randomized controlled trials in nursing conducted by Latin American research teams: A scoping review

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Abstract

Introductio: Randomized controlled trials (RCTs) are the cornerstone of systematic reviews and other evidence synthesis. RCT identification remains challenging because of limitations in their indexation in major databases and potential language bias. Scientific production in Latin American nursing is steadily increasing, but little is known about its design or main features. We aimed to identify the extent of evidence from RCTs in nursing conducted by Latin American research teams and evaluate their main characteristics, including potential risk of bias.

Design: Scoping review with risk of bias assessment.

Methods: We conducted a scoping review including a comprehensive electronic search in five relevant databases. We completed a descriptive data analysis and a risk of bias assessment of eligible studies using Cochrane's guidance.

Results: We identified 1784 references of which 47 were RCTs published in 40 journals. Twenty (42.6%) RCTs were published in journals in English. Chronic diseases were the most common health conditions studied (29.7%). Fifteen (31.9%) RCTs had a high risk of bias. Thirty (75%) journals were included in the Journal Citation Report (JCR) catalog and 5 (16.7%) were journals classified under nursing category. Twenty-one (52.5%) journals explicitly required CONSORT checklist recommendations for RCTs reporting.

Conclusion: Publication of RCTs in nursing by Latin American authors has increased. Most journals where RCTs are published are in English and not specific to nursing. Searches in journals of other disciplines may be necessary to facilitate identification of RCTs in nursing. CONSORT statements need to be actively promoted to facilitate rigorous methodology and reporting of RCTs.

Clinical Relevance Statement: This study highlights the need for an increased research focus on RCTs in nursing in Latin America, and the importance of enhancing the reporting quality of these studies to support evidence-based nursing practice.

KEYWORDS
evidence-based, nursing, nursing, randomized controlled trials, scoping review

INTRODUCTION

Randomized controlled trials (RCTs) are considered to be atop the evidence hierarchy, owing to their rigorous methodology. RCTs provide evidence of the relationship between therapeutic interventions, drugs, devices, or medical techniques, and outcomes in terms of cause and effect (Bonfill et al., 2013; Dickersin et al., 1994; Sibbald & Roland, 1998). RCTs contribute to the development of systematic reviews and other evidence syntheses, which together form the basis of evidence-based recommendations and clinical practice guidelines (Sackett et al., n.d.; Villanueva et al., 2018).

Identifying RCTs in literature searches remains a significant challenge. The term "randomized controlled trial" was included in major databases, e.g., MEDLINE and EMBASE, in the 1990s, which hampers efforts to identify RCTs published previously. In addition, journals that publish in languages other than English are underrepresented in the major scientific databases, which may add language and other types of biases when identifying RCTs (Martí et al., 1999; McKibbon et al., 2009; Villanueva et al., 2018). Furthermore, RCTs do not always adequately report methodology, which hampers indexing and identification efforts (Arevalo-Rodriguez et al., 2018; Cullum, 1997; Gutarra-Vilchez et al., 2016; Loezar et al., 2018; Martí et al., 1999; Sanclemente et al., 2015; Villanueva et al., 2018).

Nursing, as the evidence-based (EB) practice model suggests, must rely its practice on the best available scientific evidence (Cullum, 1997; Melnyk, 2019; Pearson et al., 2006), including RCTs. The current state of scientific production in nursing has increased substantially worldwide (Achury-Saldaña et al., 2022; Baldi et al., 2014; Hodgson et al., 2014; Kokol & Blažun Vošner, 2019; Munday et al., 2020; Pham et al., 2021). In Latin America, nursing research tends to rely on qualitative, cross-sectional, or descriptive methodological designs – only a small proportion of studies are experimental – this may be due to the cost and resources needed for RCTs (Achury-Saldaña et al., 2022; Cullum, 1997; Iribarren et al., 2018; Mendoza-Parra et al., 2009).

Previous work has identified and ascertained the quality of nursing RCTs in the United States (U.S.), Spain and Australia (Adams et al., 2018; Guo et al., 2014; Medina-Aedo et al., 2022; Munday et al., 2020; Pham et al., 2021). To our knowledge, no study has done so for nursing RCTs conducted by Latin American research teams.

We aimed to identify the characteristics and the current state of publication of RCTs in nursing in Spanish-speaking Latin American countries. In addition, we explored appropriate methods and strategies for identifying this body of evidence for evidence synthesis studies.

DESIGN

Scoping review is a comprehensive and descriptive approach to evidence synthesis, facilitating the exploration of a specific body of literature (Munn et al., 2018). In the context of this review, the scoping review methodology provides the tools to ascertain the extent of available evidence pertaining to RCTs in nursing in Latin America. We performed a systematic and extensive search of RCTs following the Joanna Briggs Institute (JBI) methodology for scoping reviews (Peters et al., 2020 in Aromataris E, Munn Z (editors)).

MATERIALS AND METHODS

Search strategy

In order to identify eligible studies, we performed an electronic search in five databases: MEDLINE (PubMed), Cumulative Index for Nursing and Allied health Literature, (CINAHL complete, through EBSCO host), Cochrane Central Register of Controlled Trials (CENTRAL), SciELO through Web of Science (WOS), and *Literatura Latinoamericana y del Caribe en Ciencias de la Salud* (LILACS, through Bireme), from inception up to December 2022 (updated search) (Appendix S1). Our search strategies were developed individually for each database under the supervision of an experienced researcher from the Iberoamerican Cochrane Center (CCIb).

The eligibility criteria for the identified studies included:

- Randomized controlled trial based on the definition provided by Cochrane (J. P. Higgins et al., n.d., Chapter 3).
- Trials involving only human subjects (randomization units could be individuals, groups, organs, or body parts).
- Prospective trials.
- Trials comparing two or more interventions or treatments (one of which could be a control/placebo or no treatment group).
- Treatment allocation should be randomized and/or blinded to participants, research staff, or outcome assessors.
- Studies with a first or corresponding author affiliated with a Latin American institution from a Spanish-speaking country (universities, hospitals, research institutes, etc.).
- Studies led by nurses or in which the intervention was related to the nursing field.
- Interventions in any population or setting (hospital, community centers, primary care, residential, or long-term centers).
- We excluded quasi-experimental studies.

Evidence screening and selection and data extraction

Studies

We entered the results of the electronic searches into Rayyan (Ouzzani et al., 2016), for screening, duplicate removal, and selection of eligible studies. The selection was performed in two steps: an initial screening of titles and abstracts and a second assessment of full text of the articles. Two independent researchers (ETM, MMA) carried out both steps in duplicate, and we resolved disagreements by consensus or, if necessary, by a third reviewer.

Two reviewers (ETM, CSC) independently extracted: citation; author name, year of publication, study title, journal name, objective and type of study, study timeline, participants characteristics, and missing follow up information.

Journals

To assess the characteristics of the journals that published eligible RCTs, CSC and MMA reviewed the Journal Citation Reports™ (JCR) (Thomson Reuters, 2022) and *Matriz de informacion para el analisis de revistas* (MIAR) (Equipo MIAR, 2021), collecting the following: country, language of publication, indexing databases, impact factor, heath category, quartile, and open access publication status. Additionally, we explored whether the authors' guidelines of the journals required adherence to the Consolidated Standards of Reporting Trials (CONSORT) checklist for RCTs design, aiming to determine the explicit compliance with the CONSORT guidelines (Schulz et al., 2010).

Risk of bias assessment

Two reviewers (ETM, CSC) performed the risk of bias assessment for all eligible RCTs using five domains of the Collaboration ROB-1 (Risk of bias) tool (J. P. T. Higgins et al., 2011); sequence randomization, sequence concealment, blinding of personnel and/or participants, blinding of outcome assessment, and reporting reasons for missing data. We considered the percentage of missing data or drop-outs for all intervention groups, and we classified overall risk as high, low, or unclear.

Data analysis

We performed a descriptive analysis using the SPSS© statistical package (v.25). We used measures of central tendency and dispersion to describe quantitative variables, and relative and absolute frequencies and percentages to describe qualitative variables.

Ethical considerations

This study did not involve private patient data and not require ethics committee approval.

RESULTS

Number of RCTs selected

This review was conducted between June 2021 (protocol and initial search) and December 2022 (updated search). The comprehensive electronic search initially retrieved 1784 references. After removing duplicates ($n=73$), in the first screening process, we identified 52 eligible RCTs and selected 47 nursing RCTs for final inclusion (Appendix S2) that were published between 2005 and 2022. These RCTs were published in 40 journals (see PRISMA-ScR chart in Figure 1).

Characteristics of the identified journals

Forty journals and one open research publishing platform published the identified nursing RCTs. Of these journals, 27.5% ($n=11$) were from Spanish-speaking Latin American countries, mostly from Colombia (36.4%, $n=4$ of 11), Mexico 27.3% ($n=3$ of 11), Chile 18.2% ($n=2$ of 11), Bolivia 9.1% ($n=1$ of 11), and Peru 9.1% ($n=1$ of 11).

Regarding the language of publication of the journals, 52.5% ($n=21$) published in English, 22.5% ($n=9$) in Spanish, and the remaining 25.0% ($n=10$) were multilingual. Journals publishing in English were predominantly from the United States, Europe, and Brazil; none were from Spanish-speaking Latin American countries. Among journals publishing in English ($n=21$), all of them were indexed in Scopus ($n=21$), 95.2% ($n=20$) in JCR, and 66.7% ($n=14$) in both Medline and CINAHL.

Seventy-five percent ($n=30$) of all journals were cataloged in the Journal Citation Reports™ (JCR), of which 16.7% ($n=5$) were included under JCR Nursing category. Twenty-seven percent ($n=11$) were open access and 2.1% ($n=1$) were inactive at the time of analysis. The database indexing the largest number of journals was Scopus (92.5%, $n=37$) followed by CINAHL (57.5%, $n=23$) and MEDLINE (45.0%, $n=18$).

A total of 52.5% ($n=21$) of the journals explicitly stated in their author guidelines that the CONSORT checklist should be used when reporting RCTs. Journals general characteristics by country are available in Table 1.

Characteristics of selected RCTs

The first two nursing RCTs were published in 2005 in journals that are still active, *Anales de Pediatría* and the British Medical Journal. One evaluated the effectiveness of amniotic fluid aspiration from babies' stomachs to reduce nausea and vomiting. The other determined whether a centralized telephone intervention reduced death or admission for worsening heart failure incidence in outpatients. The mean number of nursing RCTs published between 2005 and 2022 was 2.6 articles per year, with an increase over time of 5.6 per year in the las 3 years (2020–2022). Figure 2 shows this dramatic

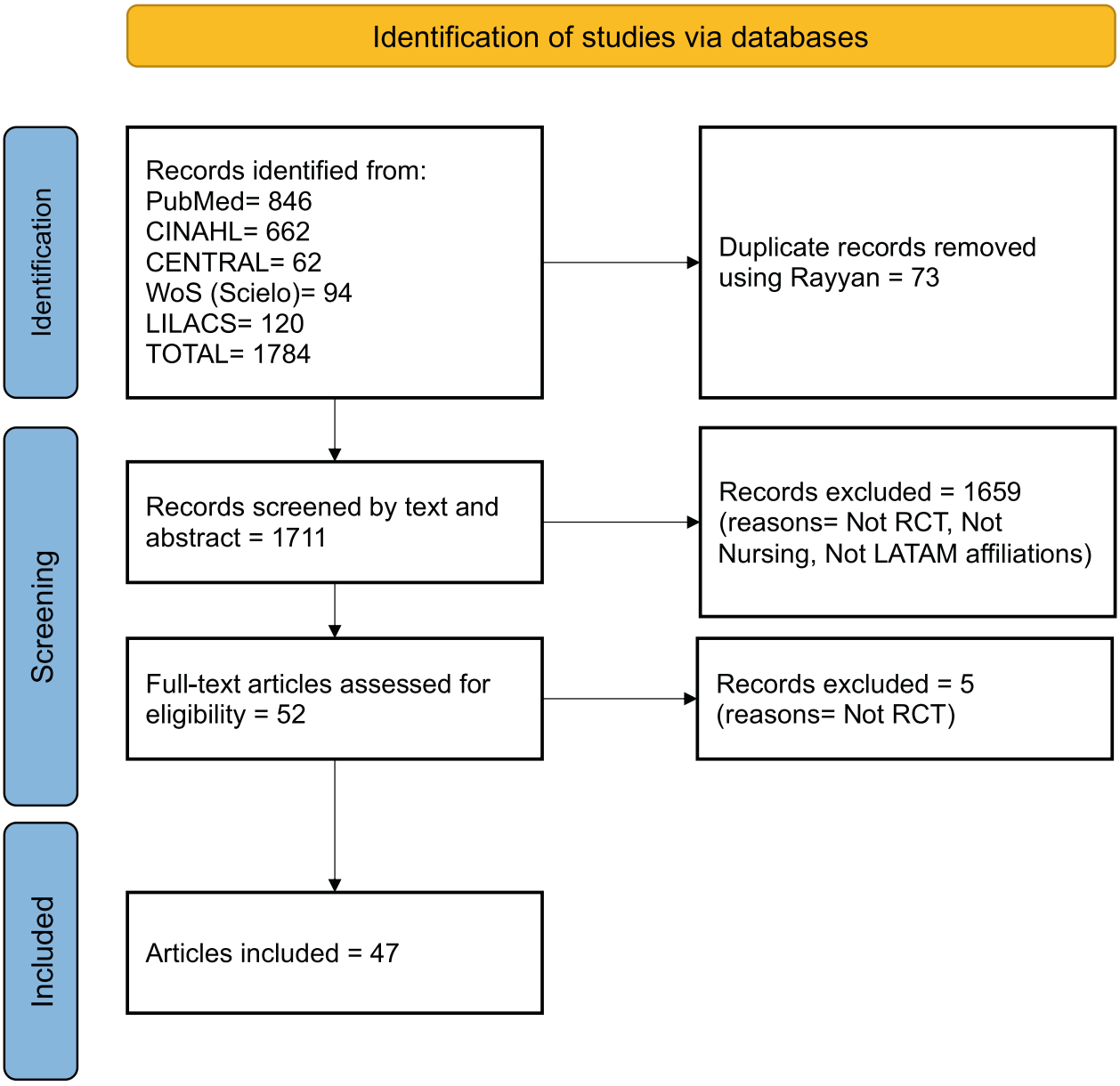

FIGURE 1 PRISMA-ScR flowchart for the process of identifying and selecting the included studies.

change from 2017 to 2019 period to 2020–2022. The number of RCTs published in English-language journals has also increased, reaching a peak of 53.0% ($n=9$) in the period 2020–2022.

Regarding the country affiliation of the first author, 43.0% ($n=20$) were from Colombia, 34.0% ($n=16$) were from Mexico, 8.5% ($n=4$) were from Argentina, 8.5% ($n=4$) were from Chile, and 6% ($n=3$) were from Peru. More than two-thirds of the identified RCTs were unicentric trials (68.1%, $n=32$). The most common settings for conducting RCTs were hospitals (59.6%, $n=28$), schools and universities (17.0%, $n=8$), and primary care/community centers (14.9%, $n=7$). The proportion of women in these trials was 62.2% ($n=7380$) of the total number of participants. The mean age of participants was 45.4 years; however, this information was reported in 57.4% ($n=27$) of the trials.

Out of the analyzed RCTs, 33 (70.2%) reported duration of study, with a mean length of duration of 0.61 year (SD = 0.83). Mean time between the study's end (end of recruitment) and publication was 2.84 years (SD = 1.35), and this data was available for 68.0% ($n=32$) of the trials.

More than half (55.3%, $n=26$) of the RCTs used educational interventions. These interventions aimed to address various health conditions, with a predominant focus on chronic diseases (29.7% $n=14$) (e.g., type 2 diabetes mellitus, arterial hypertension, heart failure, and chronic kidney disease), followed by pregnancy issues (12.7%, $n=6$). In 95.7% ($n=45$) of the studies the comparison group was explicitly identifiable. Among these, 82.2% ($n=37$ of 45) consisted of standard care or placebo control groups, while 17.7% ($n=8$ of 45) involved other interventions (e.g., intervention with less intensity,

TABLE 1 Characteristics of journals by country of publication ($n = 40$).

Country	*n* (%)[a]	Language *n* (%)[b]			Indexation *n* (%)[b]						Included in JCR, *n* (%)[b]	CONSORT adherence, *n* (%)[b]
		English	Spanish	Multi-language	SCIE	SCOPUS	EMBASE	CINAHL	Medline	DIALNET		
Bolivia	1 (2.5)			1 (100)								
Brazil	3 (7.5)	2 (66.7)		1 (33.3)	2 (66.7)	3 (100)	2 (66.7)	2 (66.7)	3 (100)	1 (33.3)	2 (66.7)	2 (66.7)
Chile	2 (5.0)		1 (50.0)	1 (50.0)	1 (50.0)	1 (50.0)			1 (50.0)		2 (100)	1 (50.0)
Colombia	4 (10.0)		3 (75.0)	1 (25.0)		3 (75.0)		3 (75.0)		3 (75.0)	1 (25.0)	3 (75.0)
England	6 (15.0)	6 (100)			5 (83.3)	6 (100)	5 (83.3)	4 (66.7)	4 (66.7)	2 (33.3)	5 (83.3)	(33.3)[c]
Ireland	1 (2.5)	1 (100)				1 (100)		1 (100)			1 (100)	1 (100)
Italy	1 (2.5)	1 (100)			1 (100)	1 (100)	1 (100)		1 (100)		1 (100)	1 (100)
Mexico	3 (7.5)		1 (33.3)	2 (66.7)	1 (33.3)	3 (100)	2 (66.7)		1 (33.3)	1 (33.3)	2 (66.7)	1 (33.3)[d]
Netherlands	1 (2.5)	1 (100)			1 (100)	1 (100)	1 (100)	1 (100)			1 (100)	1 (100)
New Zealand	1 (2.5)	1 (100)			1 (100)	1 (100)	1 (100)		1 (100)		1 (100)	1 (100)
Peru	1 (2.5)		1 (100)			1 (100)					1 (100)	1 (100)
Spain	5 (12.5)		2 (40.0)	3 (60.0)	1 (20.0)	5 (100)	3 (60.0)	3 (60.0)	1 (20.0)	5 (100)	2 (40.0)	2 (40.0)
Switzerland	2 (5.0)	1 (50.0)		1 (50.0)	1 (50.0)	2 (100)	2 (100)	1 (50.0)			2 (100)	1 (50.0)
USA	9 (22.5)	8 (88.9)	1 (11.1)		9 (100)	9 (100)	3 (33.3)	8 (88.9)	6 (66.7)	3 (33.3)	9 (100)	4 (44.4)

[a]Percentage per total of journals, $n = 40$.

[b]Percentage per country, see first column.

[c]We did not find guidance for authors for two of the six journals.

[d]We did not find guidance for authors for two of the six journals.

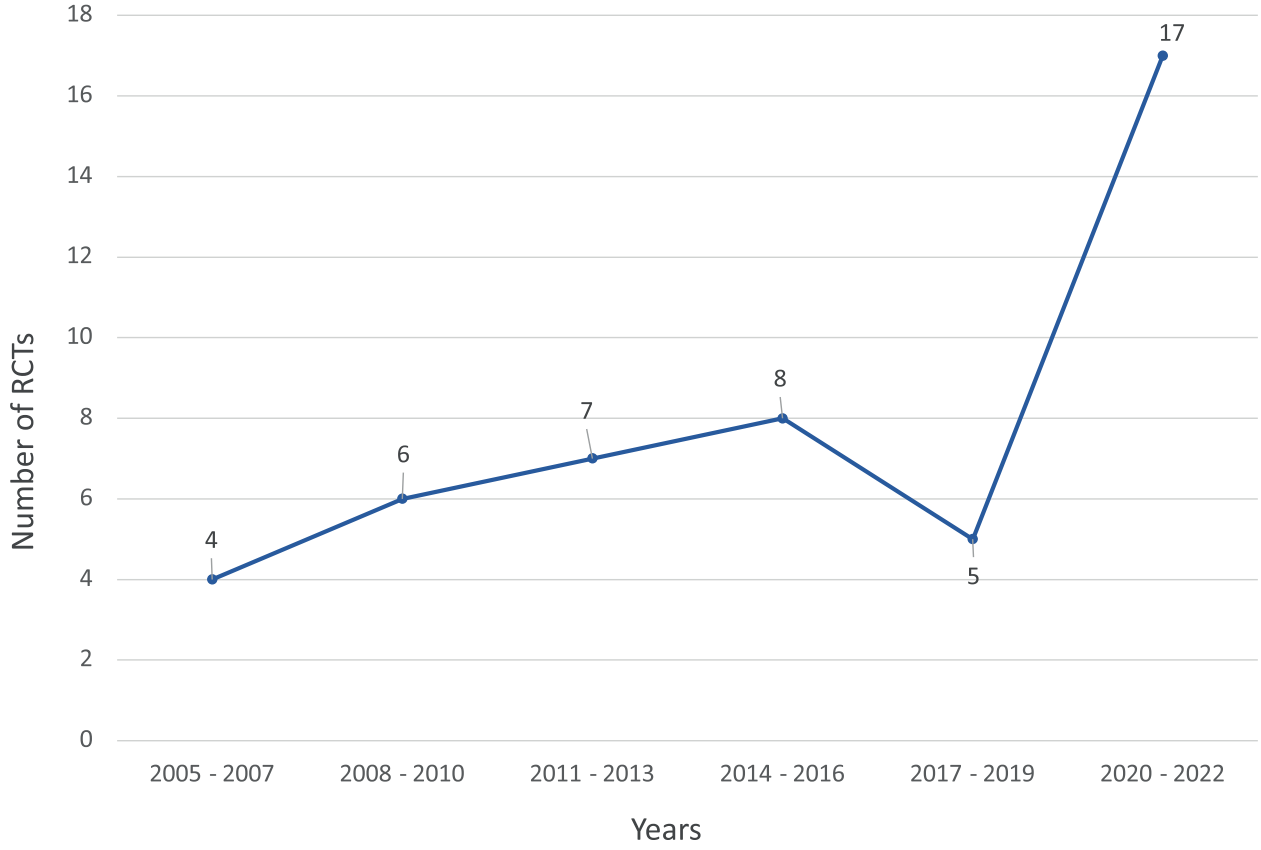

FIGURE 2 Number of RCTs published between 2005 and 2022 in 3-year intervals.

intervention performed by different professionals, intervention with alternative devices) (Table 2).

Conflict of interest reported by the RCTs

Seventeen (36.2%) trials did not mention any conflict of interest, of those that did (63.8%, $n=30$) all reported nothing to disclose. Sixty-two percent ($n=29$) of the RCTs clearly reported the type of funding they received. Of these, 96.6% ($n=28$) obtained funding from public sources, with government research funding being the primary contributor (Table 3).

Risk of bias assessment

Among the analyzed trials, a total of 31.9% ($n=15$) exhibited a high overall risk of bias, while 23.4% ($n=11$) had a low risk of bias. The criterion with the highest risk of bias was the blinging of participants/staff accounting for 25.5% ($n=12$) of all RCTs. Missing data reported presented a 2.1% high risk of bias ($n=1$).

In the RCTs deemed to have high risk of bias, the sequence generation and concealment was judged as unclear in 60% ($n=9$ of 15). Furthermore, blinding of participants/staff and blinding of outcome assessment were evaluated as unclear in nearly half (46.7%, $n=7$ of 15) of these studies. Thirty-three percent ($n=5$ of 15) did not implement blinding measures for participants, staff nor outcome evaluators. Details of this assessment are presented in Figure 3.

DISCUSSION

We identified a total of 47 RCTs published across 40 journals over a period of 17 years, representing research conducted in five Latin American Spanish-speaking countries. We ascertained the country of origin based on the affiliation of the first author. Hospitals served as the primary setting for more than half of these trials with funding mostly from public sources. Nearly one-third of the RCTs exhibited a high risk of bias mainly stemming from lack of blinding of participants or staff.

A significant proportion of journals were these RCTs are published focused on medical fields others than nursing, as per categorization in the JCR. Over half of the journals published in English, suggesting a preference for international journals among Latin American authors. This trend is in line with previous related research, highlighting the broader reach and readership that international journals may afford (Mendoza-Parra et al., 2009; Villanueva et al., 2018).

Less than one-fifth of the journals were classified within the nursing category of JCR. This finding stresses the need for

TABLE 2 Characteristics of the RCTs identified ($n = 47$).

Category			n	%
N participants			11,874	100
Women			7380	62.2
Men			4494	37.8
		Mean	SD	Range
Age (years)		46,5	17,2	15–75
Duration of RCTs (years)		0,61	0,83	0–3
			n	%
Type of study				
Unicentric			32	68.1
Multicenter			15	31.9
Setting				
Hospital			28	59.6
School/university			8	17.0
Community center /primary care			7	14.9
Patient Home			3	6.4
Day center			1	2.1
Type of intervention				
Educational			26	55.3
Other type[a]			8	17.0
Devices/equipment			6	12.8
Rehabilitation			5	10.6
Medication/Drug			2	4.3
Comparison				
In a control group	Standard care		34	72.3
	Placebo		3	6.4
	Not reported		2	4.3
Other intervention			8	17.0

[a]Include multicomponent intervention, nursing procedures, and alternative therapies.

TABLE 3 Conflicts of interest and type of funding reported in the RCTs ($n = 47$).

Category	n	%
Conflict of interest		
Reported conflict	0	0
Reported no conflict	30	63.8
Not reported	17	36.2
Type of funding		
Reported public funding	28	59.6
Reported private funding	1	2.1
Not reported	18	38.2

comprehensive search strategies that include diverse databases when identifying nursing RCTs (Loezar et al., 2018; Villanueva et al., 2018). We covered the most common databases, e.g., CENTRAL and PubMed; CINAHL for nursing; and SciELO (via the WoS database) and LILACS, for publications from Latin American journals and authors.

Among the identified journals, only 45% were indexed in MEDLINE, one of the most relevant databases in the biomedical field. It is therefore important to employ comprehensive search strategies for identifying RCTs studies in nursing.

Although we did not analyze the impact factor of journals where the identified RCTs are published, Latin American authors tended to publish their research in international journals, likely driven by the higher impact factor and broader readership associated with such publications (Loezar et al., 2018; Medina-Aedo et al., 2022). Over time, there has been an increase in the publication of nursing RCTs in English-language journals, with approximately one-fifth of all trials published within the last 3 years. This result, in line with previous research on Spanish nursing research teams (Medina-Aedo et al., 2022), emphasize the appeal of English-language journals due to their wider readership and higher impact factor (Loezar et al., 2018; Mendoza-Parra et al., 2009; Villanueva et al., 2018). Nonetheless, our review was limited to electronic databases, thus potentially excluding local or international journals that are not indexed. Therefore, as other authors have noted (Armstrong et al., 2005; Hopewell et al., 2007; Pardo-Hernandez et al., 2017), future research may benefit from incorporating handsearching of local journals to ensure a comprehensive identification of scientific evidence in nursing from non-English speaking countries.

Forty-seven percent of the total number of identified journals did not explicitly state adhering to the CONSORT recommendations for reporting RCTs. This lack of compliance may result in suboptimal reporting of published RCTs (Adams et al., 2018; Arevalo-Rodriguez et al., 2018). Consequently, incorporating the CONSORT checklist as a requirement for RCT publication by journals can enhance the quality and transparency of research, thereby facilitating critical appraisal of this type of study design (Blanco et al., 2018; Turner et al., 2012).

Our findings revealed an average of approximately three RCTs published per year, lower than that reported for Spanish authors which were seven RCTs per year (Medina-Aedo et al., 2022) and other disciplines and in high-income countries (Arevalo-Rodriguez et al., 2018; Gonella et al., 2019; Turrillas et al., 2017). This finding may be explained by political environments, implementation costs, inadequate research training, and poor infrastructure, all of which may disproportionately affect nurses (Aguilera, 2021; Gyawali et al., 2020; Iribarren et al., 2018). It is encouraging to note that the publication of nursing RCTs by Latin American authors, has reached a peak in recent years, consistent with the overall trend of increasing of RCTs publication (Baldi et al., 2014; Vinkers et al., 2021).

Our review highlights the usefulness of electronic searches across multiple databases in identifying RCTs conducted by Latin American research teams, and it is possible that in the future the integration of artificial intelligence will improve the effectiveness of identifying RCTs in electronic searches (Gutarra-Vilchez et al., 2016; Marshall et al., 2018; Martí et al., 1999). Nonetheless, it is still advisable to supplement electronic searches with manual searches of non-indexed

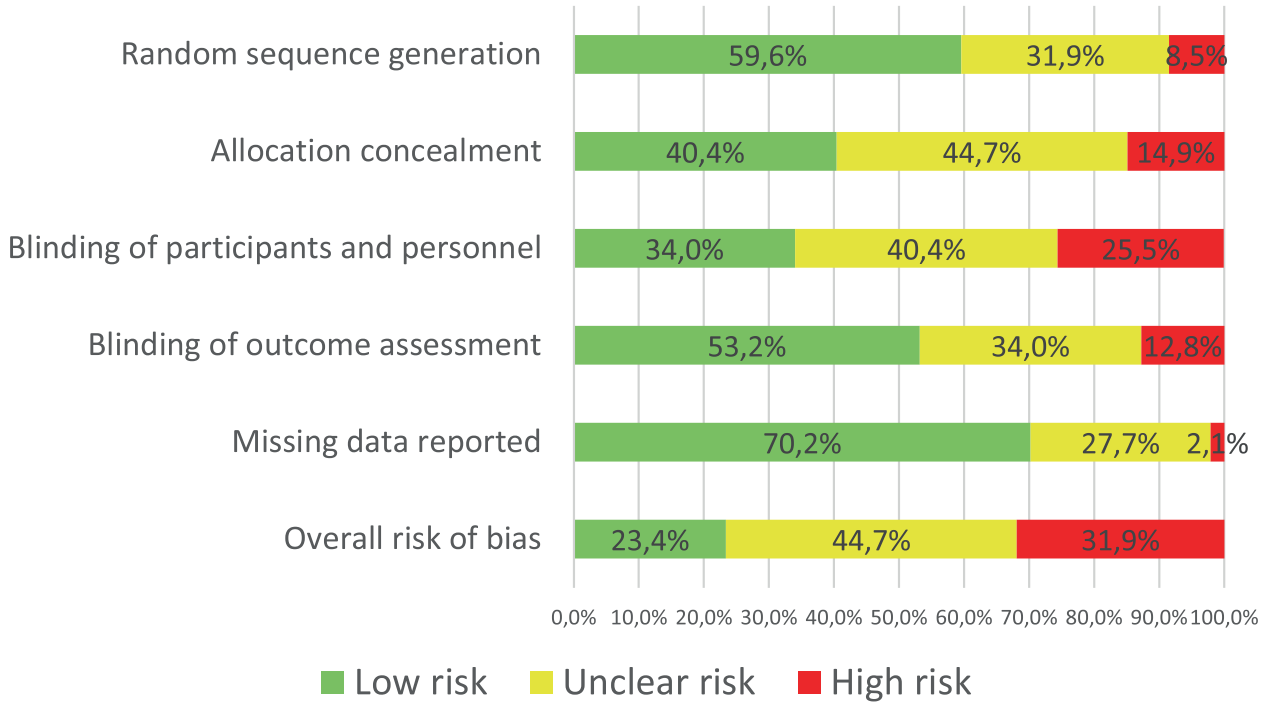

FIGURE 3 Risk of bias assessment of selected studies ($n = 47$).

journals to ensure a comprehensive inclusion of all relevant RCTs (Hopewell et al., 2007). Manual searches complement this work and facilitate the detection of trials published in non-indexed journals. Previous projects, such as those undertaken by the Iberoamerican Cochrane Centre, have successfully increased the visibility of RCTs published in non-indexed journals by adding this body of evidence to BADERI (Database of Iberoamerican Clinical Trials and Journals, by its initials in Spanish) (Arevalo-Rodriguez et al., 2018; Gutarra-Vilchez et al., 2016; Loezar et al., 2018; Martí et al., 1999; Medina-Aedo et al., 2022; Pardo-Hernandez et al., 2017; Sanclemente et al., 2015; Turrillas et al., 2017; Villanueva et al., 2018).

Nurses play a significant role in clinical research, as they are well-positioned to lead and propose clinical trials aimed at enhancing healthcare delivery. Furthermore, nurses can collaborate with other healthcare professionals in clinical trials (E.g., trials assessing the effectiveness of drugs or medical devices) under different roles allowing active participation and the expansion of evidence-based nursing practices (Grady & Edgerly, 2009). Within the Latin American context, evidence-based nursing has gained prominence. Although the relatively modest annual publication rate of RCTs in nursing, the observed upward trend in the publications over time is an encouraging sign of the ongoing commitment to nursing research. This positive trend is likely to motivate research funders to create more opportunities for supporting the development of RCTs in nursing. Simultaneously, it is likely to inspire nursing researchers to continue designing and conducting high-quality RCTs and probably even prompt them to explore international collaboration and networking opportunities within the nursing community, thereby contributing to address healthcare priorities in Latin America.

Strengths of our review include the implementation of a comprehensive search strategy in five databases and the utilization of a double screening process to enhance accuracy and maximize the inclusion of RCTs. Our study also had limitations, we did not apply country or regional filters in the databases, and we did not search in gray literature or handsearched journals not indexed in the main databases; this is the scope of future work. Future studies may explore compliance with the CONSORT checklist, as it remains uncertain whether authors adhere to this recommendation and whether their reporting is satisfactory (Adams et al., 2018).

CONCLUSION

The number of the RCTs in nursing published by authors affiliated with Latin American countries is low. Authors prefer journals published in English and that may not necessarily focus and on nursing. To ensure a comprehensive identification on nursing RCTs, it is essential to develop search strategies beyond nursing-specific journals. Handsearching journals not indexed in the main databases may further enhance the identification of RCTs in nursing in this region. Adherence to the CONSORT checklist as a requirement for publication may improve RCT reporting.

CLINICAL RESOURCES

Iberoamerican RCTs identification Project (Iberoamerican Cochrane Centre): https://es.cochrane.org/es/proyecto-de-identificacion-de-ensayos-clinicos-iberoamericanos.

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CONFLICT OF INTEREST STATEMENT

Nothing to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

Appendix S1.

Appendix S2.

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