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ORIGINAL ARTICLE

Study characteristics impacted the pragmatism of randomized controlled trial published in nursing: a meta-epidemiological study

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Abstract

Objectives: The objective of this study was to examine the impact of study characteristics on the score of the pragmatism/explanatory continuum of randomized controlled trials (RCTs) published in nursing journals using the PRagmatic Explanatory Continuum Indicator Summary (PRECIS)-2 tool.

Study Design and Setting: RCTs concerning five themes of nursing care indexed in the PubMed and CINAHL databases published from 2002 to 2005 and 2012 to 2015 were selected by title/abstract. A sample of 400 was randomly selected and evaluated with the PRECIS-2 tool and reading grid.

Results: The median PRECIS score was 32 of a possible 45 [28; 36] corresponding to a medium level of pragmatism. Studies with "*medication*" as an intervention had a more explanatory PRECIS score than studies with other intervention types ($P = 0.015$). Studies with "*placebo*" and "*no usual care*" as comparators had a more explanatory PRECIS score ($P = 0.0027$). The pragmatism/explanatory level was unaffected by impact factor ($P = 0.42$), h-index of the first and last author ($P = 0.27$ and $P = 0.25$, respectively), funding ($P = 0.32$), blinding ($P = 0.41$), sample size ($P = 0.22$), and time ($P = 0.11$).

Conclusion: This study highlights the pragmatism/explanatory level of nursing RCTs, the impact of the field of the article, and the comparator type on the pragmatism of these studies. Further studies are needed to confirm the astonishing result that blinding resulted in no significant difference in the PRECIS score.

Keywords: Pragmatism; Methodology; Nursing; Randomized controlled trials; PRECIS-2 tool; Applicability; Knowledge transfer

1. Background

The scientific nursing literature is extensive (with 230 nursing journals indexed on Web of Science database). The number of randomized controlled trials (RCTs) in nursing science has doubled since 2000 (from 127 items in 2000 to 331 items in 2017 indexed in PubMed database). The research-to-practice gap is a worldwide challenge to stakeholders, including health actors (health policy experts, caregivers, patients, families, and society). Over 85% of biomedical research investments are wasted because of the poor transferability of research results to practice [1]. To address this problem of implementation, results must not only be valid and reliable but also conducted in a way that ensures that they are directly applicable to the real-world conditions in which practice is carried out.

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Availability of data and material: All data generated and analyzed during this present study are included in this published article and its supplementary information files.

Authors' contributions: Study planification design and methodology were carried out by F.D., H.C., J.M.T., and P.Y.A. The calibration exercise was performed by F.D., F.F., and N.B., and the reading of full-text articles was completed by F.D. The statistical analysis was performed by P.Y.A., F.F., and N.B. Manuscript writing was completed by F.D., P.Y.A., H.C., and J.M.T. All coauthors have read and validated the final version of the manuscript.

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What is new?

Key findings

- These results highlight, for the first time, the medium level of pragmatism of nursing randomized controlled trials (RCTs) and the impact of the field of the article and type of comparator on it.

What this adds to what was known?

- With the number of RCTs doubling since 2000, questions concerning the use of research results in practice are crucial for quality of care.
- Identification of the pragmatism/explanatory level of nursing RCTs, as well as factors affecting it, can help to guide the improvement of quality of care.
- No study has yet evaluated the impact of study characteristics on the pragmatism/explanatory level of nursing RCTs.

What is the implication and what should change now?

- Sharing a free and accessible tool to evaluate the pragmatism/explanatory level of RCTs can help nursing researchers, clinical nurses, and health policymakers to identify the applicability of research results to practice.

This issue was described as early as 1967 by Schwartz and Lellouch who created two concepts to account for the real considerations of practice in studies: explanatory and pragmatic [2]. Explanatory trials aim to understand mechanisms of the interventions studied under ideal circumstances, whereas, pragmatic trials address the question of ''which treatment is preferable?'' Pragmatic trials are designed to determine the effect of an intervention in the usual care setting in which it will be applied. Design characteristics that are of importance in pragmatic trials include exclusion criteria and the care organization and settings of care [2–4]. Pragmatic measures and trials are needed to promote evidence-based practice [5], as clinicians require useful data collected under similar conditions, with similar materials, at a similar cost [6].

Tools available to evaluate the pragmatism/explanatory level of RCTs include i) the ASPECT-R tool (A Study Pragmatic-Explanatory Characterization Tool-Rating) created by Alphs et al., with six items scored from 0 (very explanatory) to 6 (very pragmatic) [7]; ii) a binary tool created by Gartlehner et al. comprised seven items [8]; and iii) the PRagmatic Explanatory Continuum Indicator Summary (PRECIS)-1 tool, which comprised 10 items, designed by Loudon et al. [9]. A number of studies have measured the pragmatic level of RCTs using the PRECIS-1 tool either a priori [10] or retrospectively on one [11,12] or several studies [13,14]. The PRECIS-1 tool was updated in 2015 to the PRECIS-2 tool, making the previous version and its adaptations out-dated. To date, only three studies have used the PRECIS-2 tool to estimate the pragmatism level of reviews [3,15,16].

The pragmatism level of nursing RCTs was evaluated in 2014 with the PRECIS-1 tool on a sample of 68 RCTs in the field of adult and elderly clinical nursing care. The results of this study showed that nursing RCTs tended to be pragmatic [14]. Importantly, knowing the characteristics of such studies that may affect the pragmatism/explanatory level, for example, the intervention type studied, impact factor, and sample size might be valuable to improve the transferability of nursing research. Indeed, having access to such information would allow for increased value and reduced waste of nursing research and draws the authors' attention to these characteristics when they design their studies. In addition, clinical nurses could easily identify pragmatic research to transfer into their practice. However, it is unknown how the study characteristics of these articles, such as the intervention type studied, the impact factor and the sample size, affected their pragmatism/explanatory level.

We thus aimed to examine the impact of the study characteristics on the pragmatism/explanatory level in RCTs published in nursing journals with the PRECIS-2 tool.

2. Methods

2.1. Search strategy and selection of reports

We identified all English-language reports of RCTs that included patients or caregivers indexed in PubMed and CINAHL and were published in nursing journals using the following keywords: ''therapeutics without drugs'', ''medication'', ''medical device'', ''care practice'', and ''therapeutic patient education''. The keywords were chosen to explore all major fields of nursing practice. In particular, ''therapeutics without drugs'' was included to capture nursing practice not performed in a prescription role, such as relational care, hypnosis, yoga, and meditation therapy, as the influence of these practices on wellness and satisfaction with patient care is significant.

Articles published during two periods, January 2002 to December 2005 and January 2012 to December 2015, were extracted to investigate the effect of time on the pragmatism/explanatory level of studies. These periods were chosen because the PRECIS-1 tool had already been created and several articles asserting the necessity of studies with high pragmatism were published between these two periods.

2.2. Eligibility criteria

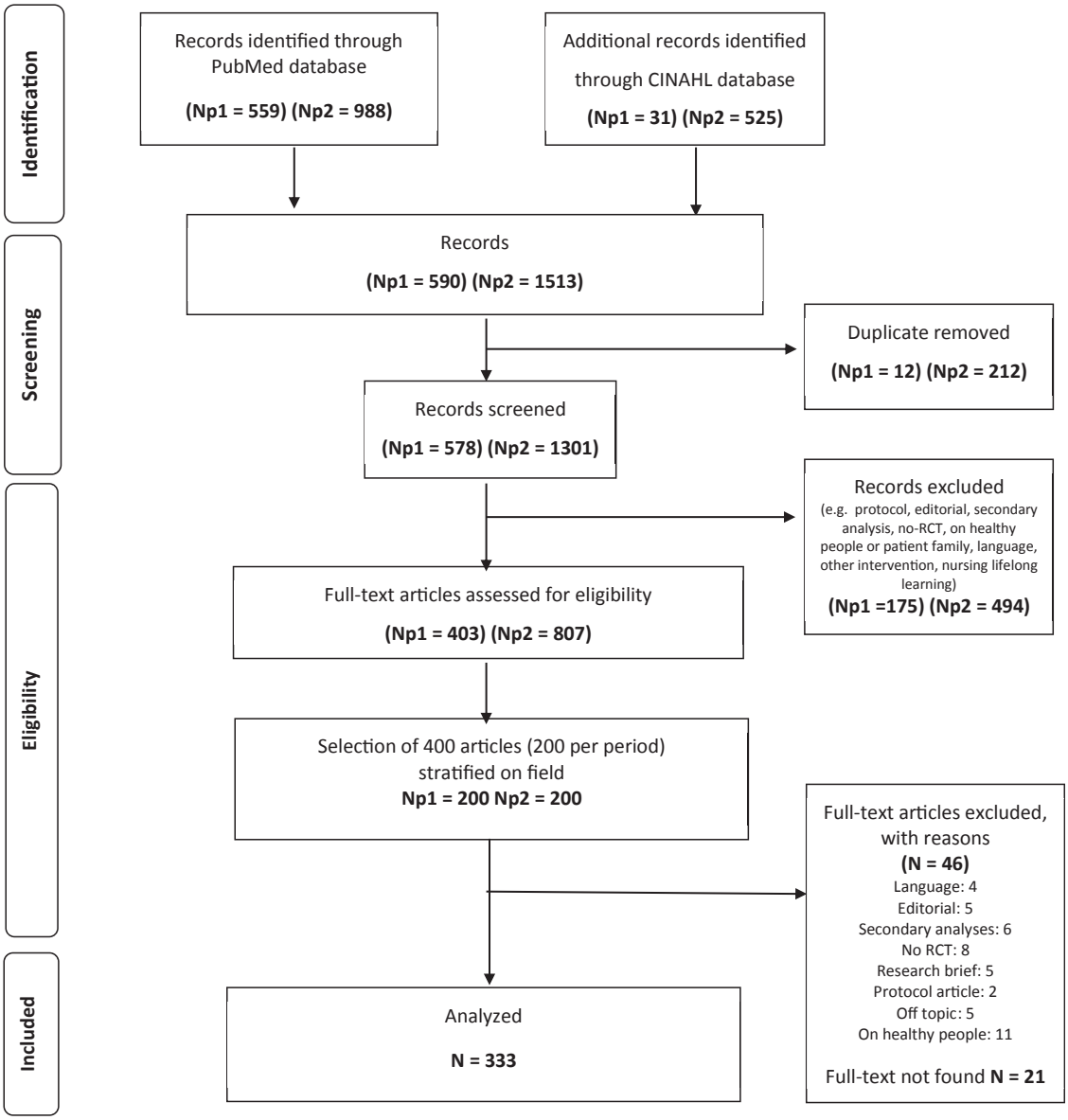
We collected the electronic records in a Zotero data file. Two reviewers (F.D. and H.C.) screened each report

by title and abstract to access relevant studies. Inclusion criteria were articles of RCTs concerning therapeutics without drugs, medications, medical devices, care practice, and therapeutic patient education, published during the periods from 2002 to 2005 and 2012 to 2015, in English. We excluded articles of observational studies, studies on patients' families, editorial and protocol trials, secondary analysis trials, report brief, RCTs on healthy people, and nursing continuing education. We randomly selected a sample of 400 articles (200 per period) using R-3.3.1 software, with stratification by intervention type: therapeutics without drugs, medication, medical device, care practice, and therapeutic patient education (Fig. 1).

2.3. Data collection

A read grid was created on Microsoft Access Software 2016 to assess the pragmatism of the RCTs.

Extracted data included features of the selected studies (year of publication, impact factor, *h*-index of first and last authors, funding, field, type of comparator groups, blinding, and sample size). We chose these variables because they are accessible, common, and factual.



Np1: Articles published in January 2002 to December 2005; Np2: Articles published in January 2012 to December 2015

Fig. 1. Flow diagram. Articles inclusion process and justification for excluded articles.

We used the PRECIS-2 tool to evaluate the pragmatism/explanatory level of RCTs in the nursing literature. The UK National Institute for Health Research Randomized Trials Methods website listed the PRECIS-1 tool as one of eight "*useful papers*" for trial designers, which has been used by authors prospectively and retrospectively [13] to assess the pragmatic level of RCTs. As already mentioned, the PRECIS-2 tool (Fig. 2) is an updated version of the PRECIS-1 tool, in which the number of domains was reduced from 10 to 9 [9,17]. Loudon et al. [18] evaluated the validity and reliability of the PRECIS-2 tool and confirmed its good inter-rater reliability and modest discriminant validity.

Each item of the PRECIS-2 tool is evaluated using a Likert scale from 1 to 5. A grade of 1 means the item is very explanatory and a grade of 5 means it is very pragmatic. As recommend by Loudon et al. [9] in the PRECIS-2 toolkit, a grade of 3 was given if an item was missing or not applicable (e.g., no follow-up required, adherence to treatment is not applicable to the intervention studied because the patient was unconscious). A score of 3 was given only in these cases. A PRECIS score ranging from 9 to 45 was produced by summing each item score (nine domains each with a score from 1 to 5) [14,19] for each RCT included, similarly to the studies of Koppenaal et al. and Palese et al.. We considered an overall score of 9 to 22 to be slightly pragmatic, 23 to 34 to be mediumly pragmatic, and 35 and above to be very pragmatic.

2.4. Screening process

The full text of all articles was read by one reviewer (F.D.). A calibration exercise was conducted by three independent reviewers (F.D., F.F., N.B.) on a set of 10 articles. Samples of articles were read and pooled for scoring comparisons. The inter-rater reliability was 0.70 [0.51; 0.81]. This calibration exercise allowed the reader reviewer to check for correct comprehension of and scoring with the PRECIS-2 tool.

2.5. Statistical analysis

2.5.1. Sample size

Statistical analysis was performed using R-3.3.1 software (http://www.R-project.org).

Based on the study results of Palese et al., the sample size was calculated to detect a difference of five points between the mean PRECIS score of the two period groups with a standard deviation of 15, an alpha risk of 0.05, and a power of 0.8, meaning a minimum of 142 articles for each group were needed. We selected 400 articles (200 for each period) with stratification by intervention type to anticipate poor indexing of the articles in the PubMed and CINAHL database.

2.5.2. Analysis

A descriptive analysis of the total PRECIS score was performed. The median [interquartile ranges] PRECIS score and that of each item are reported. Associations

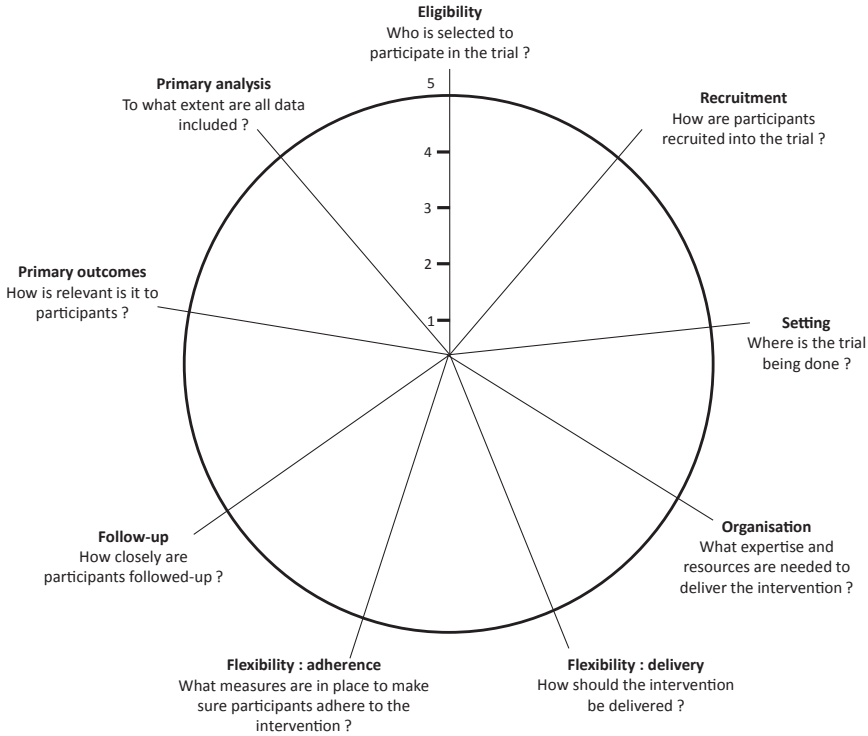


Fig. 2. PRECIS-2 tool by Loudon et al. Wheel of nine items to assess the pragmatism/explanatory level of randomized controlled trials.

between the PRECIS score and qualitative variables were assessed using Kruskal-Wallis tests. Spearman correlation tests were used to compare the distribution of the PRECIS scores with quantitative variables.

Each PRECIS item score was turned into a binary variable before analysis. Items with a grade <3 were classified as explanatory and those >3 as pragmatic. A grade of 3 indicated an item was not applicable or missing (excluded from analysis). These analyses were performed using Wilcoxon-Mann-Whitney tests for quantitative variables and chi-square tests (or Fisher's exact tests, as applicable) for qualitative variables.

3. Results

3.1. Description of articles read

All steps of the selection process and the number of articles included in each step are summarized in Fig. 1. Sixty-seven of the 400 articles in our sample were not considered meet the inclusion criteria after a full reading. References of the articles read are available in Additional File 1 (web-only material) and their characteristics are included in Table 1. The articles were published in 152 different nursing journals with one to twenty-one articles included per journal.

3.2. PRECIS score

The overall median [IQR] PRECIS score was 32 [28; 36] of 45, indicating a medium level of pragmatism.

The PRECIS score appeared to be affected by two characteristics of the studies (Table 2). Intervention type was shown to have a significant impact on the PRECIS score ($P = 0.015$): studies with "*medication*" as an intervention had a more explanatory PRECIS score than those with other intervention types. Moreover, there was a significant difference concerning comparator types, with a median PRECIS score showing more explanatory aspects for studies using "*placebo*" and "*no usual care*" comparators ($P = 0.0027$).

The pragmatism/explanatory level was unaffected by impact factor ($P = 0.42$), *h*-index of the first and last author ($P = 0.27$ and $P = 0.25$, respectively), type of funding ($P = 0.32$), blinding ($P = 0.41$), sample size ($P = 0.22$), and time ($P = 0.11$).

3.3. PRECIS items

The results by PRECIS item showed significant differences. The PRECIS items of Eligibility ($P = 0.019$), Recruitment ($P = 0.039$), Setting ($P = 0.013$), and Adherence Flexibility ($P = 0.001$) were more explanatory in studies with "*medication*" interventions than those with the other intervention types. Moreover, studies concerning "*therapeutics without drugs*" were more pragmatic than other intervention types for the PRECIS item of Primary Outcomes ($P = 0.001$).

The type of comparator significantly affected the score of Adherence Flexibility, with trials having no comparator being the most pragmatic ($P = 0.024$).

4. Discussion

This study assessed the pragmatism/explanatory level in a sample of 333 RCTs published in nursing journals grouped by five intervention types. Our results show a medium level of pragmatism in nursing trials. Moreover, our study suggests that "*intervention type*" and "*comparator type*" affect the pragmatism level of RCTs published in nursing journals.

As the PRECIS-1 tool was updated in 2015, it is difficult to compare overall findings to other reports that rated studies using an earlier version of the tool. However, the 2014 study of Palese et al. [14] reported a median PRECIS score of nursing RCTs of 31/50 and concluded that nursing RCTs tended to be pragmatic. Our study, using the PRECIS-2 tool, extends the investigation of the pragmatism/explanatory level of nursing RCTs. Moreover, we analyzed 333 articles across five intervention types for all ages, whereas that of Palese et al. [14] only analyzed 68 articles from 1 year in one field (adult and elderly nursing care).

Research results must be valid, reliable, and adapted to real-life conditions before they can be transferred to practice. The research-to-practice gap is a worldwide challenge that could be better addressed by pragmatic clinical trials. The bench-to-bedside concept is built on collaboration and comprehension between research and nursing practice in an "exchange" format (both entities regularly discuss nursing research needs for practice) [20]. Although clinicians must have applicable research results, research entities are more focused on the internal validity of trials than their applicability to practice, despite the publication of guides to identify pragmatic research [21]. Furthermore, the need for pragmatic research contrasts with research reality, which is focused on population or disease features (e.g., genetic, pharmacological modeling, computerized system decision-making). These aspects do not promote the design of pragmatic studies [22,23] and can increase research waste [24]. We found that studies concerning "*therapeutics without drugs*" have a higher pragmatic score for the item "*primary outcome*" than studies with other interventions. This can be explained by the fact that the main purpose of these articles is to improve quality of life and wellness of the patient rather than to demonstrate biological efficacy. Here, we showed these practices to be investigated in clinical nursing research with a medium level of pragmatism (32/45). These practices are easily transferable to nursing practice and improve both the well-being and quality of life of hospitalized patients. The

Table 1. Characteristics of articles read

Item description					
				n	%
Periods	2002-2005			159	47.74%
	2012-2015			174	52.25%
Impact factor	Med = 1.66	[1.21; 2.10]	[0; 1.2]	69	20.70%
			[1.2; 1.6]	65	19.51%
			[1.6; 2.1]	89	26.72%
			[2.1; 3.8]	68	33.07%
h-index first author	Med = 4	[1; 8]	[0; 1]	73	21.92%
			[1; 4]	83	24.92%
			[4; 8]	68	20.42%
			[8; 113]	74	22.22%
h-index last author	Med = 6.5	[2; 16]	[0; 2]	69	20.70%
			[2; 6]	64	19.21%
			[6; 16]	74	22.22%
			[16; 95]	70	21.02%
Funding	Public			94	28.22%
	Private			71	21.32%
	Both			26	7.80%
	Without funding			119	35.73%
Intervention type	Medication			41	12.31%
	Therapeutics without drugs			160	48.04%
	Medical device			22	6.60%
	Care practice			26	7.80%
	Therapeutic patient education			84	25.22%
Comparator	Placebo			38	11.41%
	Usual practice			188	56.45%
	Other intervention[a]			53	15.91%
	Without intervention			49	14.71%
Blind	Simple			74	22.22%
	Double			41	12.31%
	No			218	65.46%
Sample sizes	Med = 68	[41; 122]	[4; 41]	84	25.22%
			[41; 68]	82	24.62%
			[68; 122]	82	24.62%
			[122; 4,904]	83	24.62%

[a] Other interventions signifies interventions tested other than those used in usual practice.

relevance of pragmatic studies has been highlighted in the evaluation of complementary and alternative therapies [25], in contrast to other fields for which there is an absence of evidence [26]. Moreover, our findings show no-change in the PRECIS score over time. It will be informative to more intensively explore these surprising findings in future trials considering nursing research history and its evolution. Another remarkable result is that blinding resulted in no significant difference in the PRECIS score. Indeed, blinding contributes to ensuring internal validity and reliability of study results, but it may distance the study design from real-life care settings. Further studies are needed to evaluate the impact of blinding.

Our study had several strengths. First, the PRECIS-2 tool is available at no-cost, making it easy to reproduce our methodology. We chose the PRECIS-2 tool because the PRECIS-1 tool has been cited more than 700 times, with the updated version cited 118 times as of July 01, 2018. Although other tools exist, such as the ASPECT-R tool [7] and a binary tool [8], the PRECIS-2 tool is the most cited and reliable tool available to retrospectively evaluate the pragmatism/explanatory level of RCTs [27].

Table 2. PRECIS score by features

Item	Item description	PRECIS score		ρ	*P*
		Median	Interquartile ranges		
Periods	2002-2005	33	[28; 36]		0.11
	2012-2015	31.5	[27; 35.75]		
Impact factor				ρ = 0.047	0.42
h-index first author				ρ = −0.062	0.27
h-index last author				ρ = −0.067	0.25
Funding	Public	30.5	[28; 35]		0.32
	Private	34	[29.5; 36]		
	Both	39.5	[28; 34.75]		
	Without funding	32	[29; 37.5]		
Intervention type	Medication	29	[26; 33]		0.015[a]
	Therapeutics without drug	32	[28; 36]		
	Medical device	32	[27.2; 35]		
	Care practice	33	[29; 38.75]		
	Therapeutic patient education	33	[28; 36]		
Comparator	Placebo	29	[25.25; 34]		0.0027[a]
	Usual practice	32	[28.75; 36]		
	Other intervention	29	[27; 34]		
	Without intervention	34	[29; 37]		
Blind	Simple	32.5	[28.25; 36]		0.41
	Double	31	[26; 34]		
	No	32	[28; 36]		
Sample sizes				ρ = 0.066	0.22

[a] *P* value < 0.05.

Second, our study used two large databases for biomedical and health care practitioners, representing a substantial panel of published international nursing studies. Furthermore, our results came from reading the full text of 400 articles. Finally, we investigated several intervention types, representing major fields of nursing practice, including therapeutics without drugs, such as hypnosis and meditation. Nevertheless, our study had one main limitation: the full text of the studies was read by only one reviewer. However, the selection, based on the title and abstract, was performed by two reviewers and a calibration exercise was conducted with three independent reviewers on a set of 10 articles to assess inter-rater reliability. The retrospective use of PRECIS-2 may be another limitation of this study. Indeed, the information published in articles can be limited compared with the information available in the study protocol or study report. However, the information in published articles is the only information available to clinicians. It was also important to have this view in the measurement of the pragmatism/explanatory level of the articles. Moreover, this study attributed an identical weight to each of the nine domains, when in fact they might carry a different importance for pragmatism or explanatory tendencies. However, this question was not the scope of this study and will have to be to addressed in future studies.

5. Conclusion

In conclusion, this study highlights the pragmatism/explanatory level of nursing RCTs, as well as the impact of the field of the article and comparator type on the pragmatism of these studies. This effort must be continued to improve the quality of care of patients.

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Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jclinepi.2019.07.017.

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