Do Randomized Controlled Nursing Trials Have a Pragmatic or Explanatory Attitude? Findings From the Pragmatic–Explanatory Continuum Indicator Summary (PRECIS) Tool Exercise

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ABSTRACT

Background: Randomized controlled trials (RCTs) may be categorized as either effectiveness trials or efficacy trials, which may be categorized by the Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) tool. However, no data regarding the application of the PRECIS tool in a cluster of RCTs belonging to a specific discipline such as nursing are available.

Purpose: The principal aim of this study was to assess the prevailing nature (pragmatic vs. explanatory) of a cluster of clinical nursing RCTs. Evaluating the suitability of the PRECIS in the analysis of nursing RCTs was the secondary aim.

Methods: All nursing RCTs published in 2010 were identified through a systematic review and extracted in full-text form. An explanatory–pragmatic (E–P) group consisting of 11 researchers trained in the use of the PRECIS tool evaluated each RCT in terms of 10 domains, respectively scored on a scale ranging from 5 (*pragmatic*) to 1 (*explanatory*). The E–P group further scored the feasibility of the PRECIS tool using a numerical rating scale (0 = *not at all*, 10 = *entirely feasible*).

Results: Along the pragmatic–explanatory continuum, assuming 50 as the highest degree of pragmatism and 10 as the highest degree of explanatory, the evaluation of nursing RCTs returned an average of 31.1 (median = 31, *SD* = 7.18, range = 13–44). On the pragmatic–explanatory continuum, the evaluated nursing RCTs tended to be pragmatic, which seems to be consistent with the purposes of the nursing discipline. The feasibility of the PRECIS tool in the evaluation of nursing trials as perceived by the E–P Group was, on average, 7.09 (*SD* = 1.09, 95% CI [6.35, 7.82]).

Conclusions/Implications for Practice: Applying the PRECIS tool is perceived to be highly feasible in the critical appraisal of a cluster of RCTs in a specific discipline such as nursing.

KEY WORDS:
explanatory, pragmatic, PRECIS tool, nursing discipline, randomized controlled trials.

Introduction

Randomized controlled trials (RCTs) may be categorized as either effectiveness trials or efficacy trials. Schwartz and Lellouch (1967) classified RCTs into the two categories of "pragmatic" trials and "explanatory" trials, with the former used to establish the validity of an intervention in practical application and help users decide between care options (for decision making) and the latter used to test causal research hypotheses (if and how an intervention works) under ideal and controlled conditions (Thorpe et al., 2009).

During the period of 2005–2008, an international group developed the Pragmatic–Explanatory Continuum Indicator Summary (PRECIS) to help researchers assess the degree to which design decisions align with trial aims (decision making vs. explanatory). The tool is composed of 10 domains, with each domain associated with a score between 1 and 5 that expresses the extent to which the nature of a trial is pragmatic (5) or explanatory (1; see Table 1; Koppenaal, Linmans, Knottnerus, & Spigt, 2011).

The PRECIS tool has been validated with positive results in an analysis of individual trials (Thorpe et al., 2009), in refining the RCT design, and in the evaluation of RCTs included in systematic reviews (Koppenaal et al., 2011). However, no data regarding the application of the PRECIS tool in a cluster

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TABLE 1.
Summary of the 10 PRECIS Tool and Scores

Domain (D)	Description	Score (From 1 to 5)	
		1 = *Extreme Explanatory*[a]	5 = *Extreme Pragmatic*[a]
1	Eligibility criteria for trial participants	Stepwise selection criteria are applied (e.g., including those high-risk, highly responsive study individuals who show high compliance).	All interested participants are enrolled.
2	Extent of flexibility in application of the experimental intervention	Inflexible experimental intervention, with strict instructions for every element.	Highly flexible instructions on how to apply the experimental intervention are allowed.
3	Degree of practitioner expertise in applying and monitoring the experimental intervention	The experimental intervention is applied only by expert practitioners documented as having applied that intervention with high rates of success and low rates of complications.	The experimental intervention typically is applied by the full range of practitioners and in the full range of clinical settings.
4	Extent of flexibility in application of the comparison intervention(s)	Restricted flexibility of the comparison intervention. A placebo may be used rather than the best alternative management strategy as the comparison.	''Usual practice'' or the best available alternative management strategy.
5	Degree of practitioner expertise in applying and monitoring the comparison Intervention (s)	Practitioner expertise in applying the comparison intervention(s) is standardized.	The comparison intervention is typically applied by the full range of practitioners and in the full range of clinical settings.
6	Intensity of follow-up of trial participants	Individuals are followed with more frequent visits and more extensive data collection than would occur in routine practice.	No formal follow-up visits.
7	Nature of the primary outcome	Outcome is known to be a direct and immediate consequence of the intervention.	Primary outcome is an objectively measured, clinically meaningful outcome to the study participants.
8	Intensity of measurements of participants' compliance to study protocol and whether compliance improving strategies are used	Study participant compliance with the intervention is monitored closely.	Unobtrusive (or no) measurement of compliance, and no special strategies to maintain or improve compliance are adopted.
9	Intensity of measurements of practitioners' adherence to study protocol and whether adherence-improving strategies are used	Close monitoring of how well the participating clinicians and centers are adhering.	Unobtrusive (or no) measurement of practitioner adherence and no special strategies to maintain or improve it are adopted.
10	Specification and scope of analysis of primary outcome	An intention-to-treat analysis is usually performed.	Analysis attempts to determine if the intervention works under the usual conditions.

Note. PRECIS = Pragmatic–Explanatory Continuum Indicator Summary.
[a]Examples of criteria were reported in the table. We aimed to include the full criteria in the PRECIS Tool (please see Thorpe et al., 2009).

of RCTs (Thorpe et al., 2009) belonging to a specific discipline such as nursing are available. A discipline is distinguished by a domain of inquiry that represents a shared belief among its members regarding its reasons for being. Thus, each discipline has a specific area of study, and knowledge development proceeds from identified philosophies, scientific perspectives, and study designs (Polifroni & Welch, 1999). Analyzing RCTs in a specific discipline may serve three purposes:

(a) plot discipline-related research attitudes on the pragmatic–explanatory continuum, (b) evaluate the consistency of these attitudes with the purpose(s) of the discipline, and (c) identify emerging trends on the basis of serial assessments. The principal aim of this study was to evaluate a cluster of nursing RCTs to assess their prevailing nature (pragmatic vs. explanatory). To evaluate the feasibility of PRECIS for the evaluation of RCTs in the discipline of nursing was the secondary aim.

Methods

Study Design

A systematic review of the RCTs published in the field of adult and older clinical nursing care in 2010 and their evaluation with the PRECIS tool was performed.

Data Collection

A review of the literature that included all adult and older clinical nursing RCTs published in 2010 in PubMed-indexed journals was performed using the MeSH terms "nursing" and "randomized controlled trial." The limits applied were humans, English, Italian, and all adult (19+ years old). To adhere to the distinction between nursing and midwifery in Europe (World Health Organization, 2011) and the different educational pathways for pediatric care and adult/older nursing care in Italy, RCTs performed in the fields of pediatric and midwifery were excluded. In addition, aiming to evaluate clinical trials exclusively, those developed in the field of nursing education and not including patients were also excluded. The index of the articles included/excluded is available upon request from the authors.

One hundred four qualified RCTs emerged. Independent evaluation by two researchers (A. P. and M. G. B.) identified 68 articles (65.3%) to be included and 36 (34.7%) to be excluded (nursing education, n = 14; midwifery, n = 12; pediatric, n = 7; not RCTs, n = 3).

The 11 researchers who formed the explanatory–pragmatic (E–P) group for this research received 8 hours of training on the E–P trial and on the PRECIS tool by an epidemiologist. Interrater concordance in the evaluation of the trials with the PRECIS tool was assured by dividing the group into pairs, each of which independently assessed one trial. Concordance between pairs was high in all domains (average, Spearman > .90). To avoid misinterpretations of Domain 10 ("Specification and scope of analysis of primary outcome"), a score was attributed only when the article reported the analysis undertaken for the principal outcome (intention-to-treat or per-protocol analysis).

E–P group members received an average of six qualified RCTs in printed format. Members were asked to complete their analytical evaluation of all assigned RCTs using the PRECIS tool within 1 month. Each trial was then reassessed by a third E–P group member who was blinded to the given scores. Discrepancies were discussed with a third member until a complete consensus was achieved.

The feasibility of the PRECIS as a tool for evaluating nursing RCTs was evaluated by E–P group members using a short questionnaire with a numerical rating scale that ranged from 0 (*not feasible at all*) to 10 (*entirely feasible*) for each domain.

Data Analysis

Data analysis was performed in SPSS version 18 (SPSS, Inc., Chicago, IL, USA). In accordance with the principal aim of the study, the scores obtained in each RCT domain were summed, and means, standard deviations (*SD*s), and confidence intervals (95% CI), were calculated. The average score was calculated along the pragmatic–explanatory continuum, assuming 50 as the highest degree of pragmatism (score of 5 in 10 domains) and 10 as the highest degree of explanatory (score of 1 in 10 domains). In addition, the score was transformed into a percentage, with 0% representing an extremely explanatory study and 100% representing an extremely pragmatic study. A visual representation of the means obtained in each domain was then reported in a wheel (Thorpe et al., 2009).

In accordance with the secondary aim of this study, the feasibility of using the PRECIS tool to evaluate nursing RCTs was evaluated by calculating means, *SDs*, and 95% CI of the score attributed by E–P group members in each domain.

Results

Using the PRECIS tool to evaluate nursing RCTs earned an average score of 31.1 (median = 31, *SD* = 7.18, range = 13–44) and of 62.2% on the percentage scale (median = 62%, *SD* = 14%, range = 26%–88%). Data on each domain as evaluated with the PRECIS tool are reported in Table 2. Figure 1 presents the complete PRECIS wheel.

The average score given by E–P group members for PRECIS feasibility was numerical rating scale of 7.09 (*SD* = 1.09) and 95% CI [6.35, 7.82]. Table 2 shows the data on the perceived feasibility of each domain.

Discussion

This was the first study to use the PRECIS tool to evaluate the research attitudes of RCTs published in a specific discipline. Because no assessment of a cluster of RCTs belonging to a specific discipline has been performed (Thorpe et al., 2009), the findings may not be compared with other similar studies.

Nursing is recognized as a discipline focusing on "the study of caring in the human health experience" (Polifroni & Welch, 1999). Despite the highly complex and contextualized nature of this discipline, which inhibits the undertaking of trials (Richards & Hamers, 2009), we identified a number of RCTs published in 2010.

In general, our evaluation of the PRECIS tool indicated that clinical nursing RCTs tend toward a pragmatic attitude. This

TABLE 2.

Nursing RCTs Published in 2010 as Evaluated With the PRECIS Tools and its Feasibility as Perceived by Members of the E–P Group

Domain		*n*	%	Clinical Nursing RCT Evaluation With the PRECIS Tool (From 1 to 5)[a]			PRECIS Tool Feasibility as Perceived by the E–P Group (From 0 to 10)[b]		
				M	*SD*	95% CI	*M*	*SD*	95% CI
1	Eligibility criteria for trial participants	68	100	2.96	1.29	[2.64, 3.27]	8.55	0.93	[7.92, 9.17]
2	Extent of flexibility in application of the experimental intervention	68	100	2.50	1.17	[2.21, 2.79]	7.64	1.92	[6.35, 8.92]
3	Degree of practitioner expertise in applying and monitoring the experimental intervention	68	100	2.93	1.40	[2.58, 3.27]	8.00	1.18	[7.21, 8.79]
4	Extent of flexibility in application of the comparison intervention(s)	68	100	3.88	1.20	[3.59, 4.17]	6.91	1.75	[5.73, 8.09]
5	Degree of practitioner expertise in applying and monitoring the comparison intervention(s)	68	100	4.00	1.28	[3.69, 4.31]	7.09	1.44	[6.12, 8.06]
6	Intensity of follow-up of trial participants	68	100	2.72	1.26	[2.41, 3.02]	7.27	1.61	[6.19, 8.36]
7	Nature of the primary outcome	68	100	3.24	1.16	[2.95, 3.52]	7.27	2.28	[5.74, 8.81]
8	Intensity of measurements of participants' compliance to study protocol and whether compliance improving strategies are used	68	100	3.34	1.37	[3.00, 3.67]	6.91	1.70	[5.77, 8.05]
9	Intensity of measurements of practitioners' adherence to study protocol and whether adherence-improving strategies are used	68	100	3.85	1.35	[3.53, 4.18]	6.42	1.69	[5.32, 7.59]
10	Specification and scope of analysis of primary outcome[c]	24	35.3	4.83	0.81	[4.49, 5.18]	4.82	3.12	[2.72, 6.92]

Note. RCTs = randomized controlled trials; PRECIS = Pragmatic–Explanatory Continuum Indicator Summary; E–P = Explanatory–Pragmatic Group; NRS = numerical rating scale.
[a]Clinical nursing RCTs' evaluation with PRECIS tool: from 1 = *extreme explanatory* to 5 = *extreme pragmatic*.
[b]PRECIS tool feasibility as perceived by the E–P Group: NRS from 0 (*none*) to 10 (*maximum*).
[c]RCTs for which it was possible to evaluate the domain using the PRECIS tool.

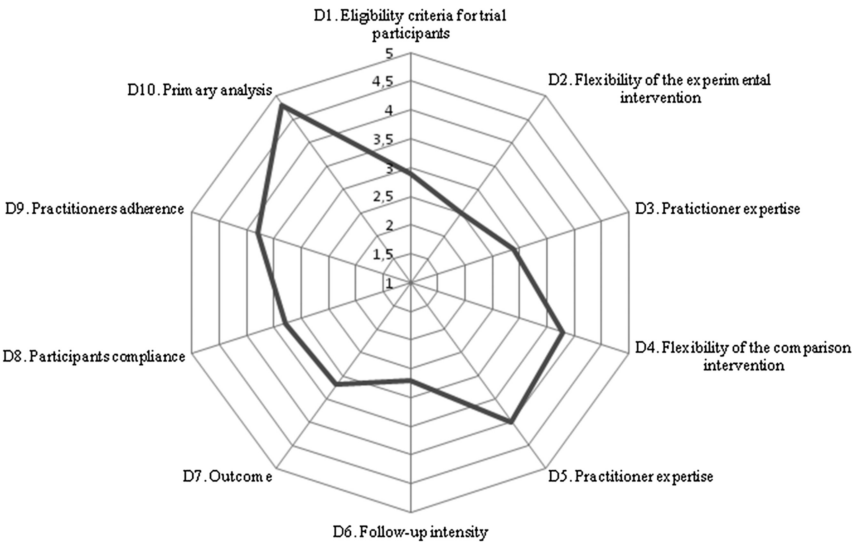

Figure 1. A complete PRECIS wheel reporting E–P Group domain ratings (1 = *extreme explanatory*, 5 = *extreme pragmatic*) of clinical nursing RCTs published in 2010. RCTs = randomized controlled trials; PRECIS = Pragmatic–Explanatory Continuum Indicator Summary.

finding seems to be consistent with the nursing discipline, which (a) is an applied science, (b) delivers interventions that are often complex and multidimensional and mirror the real world of nursing practice, (c) focuses on providing information that facilitates nurses' decision making, and (d) aims to influence patient outcomes in a real environment. Moreover, as recently argued by Hallberg (2008), the nursing discipline needs greater explanatory power to determine the effectiveness of its interventions: knowledge is needed to establish not just whether an intervention works but also why, for whom, and in what circumstances.

In terms of domain scores, the lowest average score was obtained in D2. This indicates that nursing RCTs tend to be explanatory in this domain, offering specific instructions and not allowing flexibility in terms of how to apply an experimental intervention (Thorpe et al., 2009). The highest average score was obtained in D5. This indicates that, in the context of nursing RCTs, comparison interventions are typically applied by the full range of practitioners and in the full range of clinical settings regardless of their expertise and with only ordinary attention given to dosage setting and side effects (Thorpe et al., 2009).

Regarding the extent of intradomain variations, a discrete homogeneity emerged (*SD* = 0.81–1.40). This finding seems to suggest that nursing researchers make similar decisions in the realms of RCT planning, implementation, and reporting. Only 35% of the RCTs were evaluated for D10, with a lower PRECIS tool feasibility perceived by the E–P Group in this domain. This finding suggests that improvements are needed in terms of how RCTs are reported and that journals should define clear guidelines for authors.

Conclusions and Implications for Research

Despite the several limitations of the study (duration of only 1 year, used only a single database, and excluded studies that applied RCTs in the pediatric and midwifery fields), the use of the PRECIS tool was perceived as highly feasible in our critical appraisal of a cluster of RCTs in adult and older nursing care studies. The PRECIS tool is a valid instrument for evaluating clinical RCTs, and this evaluation suggests that the research attitude is pragmatic. A regular assessment of RCTs using the PRECIS tool (e.g., on a yearly basis), published in a specific discipline or in a subdiscipline, may enable trend analysis and offer a basis for discussion on knowledge development. However, further efforts should be undertaken in the evaluation of RCTs that involve multiple disciplines and that may have different attitudes.

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