EDITORIAL

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Pragmatic Clinical Trials

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The traditional approach in nursing science is to focus on research from randomized controlled trials (RCTs). RCT research design is scientifically robust, readily accepted, and historically verified. However, RCT research is also slow and expensive and rarely produces findings that are easily put into practice. Traditional RCTs study the effects of treatments delivered to carefully selected populations under ideal conditions. As RCTs rarely happen in typical clinical settings, the findings are often not feasible for real-world uptake. This makes it difficult to translate results into everyday clinical practice. Thus, if we limit nursing research strictly to this approach, we will see significant limitations to our ability to rapidly influence nursing practice. If we want more evidence-based practice in nursing, we need more nursing practice-based research evidence.

One way to ensure that research results can be translated into effective practice guidelines that will be accepted and implemented in routine clinical care is to conduct pragmatic clinical trials (PCTs). PCTs are designed for the primary purpose of informing decision-makers regarding the comparative balance of benefits, burdens, and risks of an intervention [1]. The purpose of this editorial is to briefly describe key characteristics of PCTs and advocate the increased use of PCTs in nursing research.

Some of the key characteristics of PCTs are that they (1) are designed to improve practice; (2) utilize key stakeholder input from multiple levels, such as patients, providers, administrators; and (3) are conducted in settings where everyday care happens. A PCT is more practical because it is designed to identify interventions that can achieve success in realistic, typical, functioning health care settings. Specifically, PCT research design (1) has broad inclusion and few exclusion criteria, enhancing the generalizability of findings; (2) engages health care providers integral to the setting but who may have little research experience, such as practicing nurses, in delivering the interventions; (3) delivers interventions in a way similar to usual care and incorporates them into a typical health care workflow; and (4) collects data in the context of routine clinical care, usually from the electronic health care records [2].

PCTs are not an abandonment of the scientific methods of RCTs. No clinical trial is completely explanatory (RCT) or pragmatic (PCT). RCTs and PCTs exist on a continuum and focus on different questions (e.g. 'Can an intervention work under ideal conditions?' or 'Does an intervention work under usual conditions?'). To assist nursing researchers with determining if their study is more RCT or PCT, the PRagmatic Explanatory Continuum Indicator Summary (PRECIS-2 Tool) can be used to assess a research study across nine domains: eligibility, recruitment, setting, organization, flexi-

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bility in intervention delivery, flexibility in intervention adherence, follow-up, primary outcomes, and primary analysis [3,4]. By using the PRECIS-2 nurse researchers can determine the approach along the explanatory-pragmatic continuum that is most appropriate for answering their research question. As no trial is completely explanatory or pragmatic, nurse researchers can also ask themselves how their research can adapt to be more pragmatic.

While RCT design is scientifically robust, readily accepted, and historically verified, limiting ourselves too strictly to this approach will result in significant limitations to our collective progress. Using PCT principles to design nursing research studies generates results that are more actionable, patient-centered, and relevant. PCT research output is actionable because it is designed around pragmatic and realistic clinical settings and is focused on implementation. A PCT's alignment of goals and measures around individuals' goals of care and its pragmatic adaptation to non-response to interventions ensure a patient-centered process and results. The PCT data and results, along with adherence to practical settings and goals, produce results that are understandable, relatable, and relevant to health care decision-makers and policy proponents.

Given that, it is important that we nurses advance those techniques that most closely connect our scientific thinking with our clinical activity. Embracing and increasing our use of PCT design concepts in nursing research can support this connection. By doing this, we enhance the significance of our findings, the ease of translating our research into practice, and our ability to continually improve outcomes for all.

CONFLICTS OF INTEREST

The authors declared no conflict of interest.

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Please contact the corresponding author for data availability.

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