**Competencies and scope of practice of clinical research nurses in clinical trials: a scoping review protocol.**

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**ABSTRACT**

**Introduction**

Clinical trials (CTs) are critical to the advancement of medical knowledge, serving as both pivotal gatekeepers and bottlenecks in medical progress. Conducting cancer studies in clinical trial centers (CTCs) demands a significant time investment, involving a range of clinical and non-clinical tasks. This process requires specialized knowledge and skills across scientific, ethical, and regulatory domains, which can be challenging for healthcare professionals who are primarily focused on daily clinical duties. The clinical trial multidisciplinary team, including clinical research nurses (CRNs), supports the principal investigator (PI) in fulfilling their responsibilities as the trial sponsor. CRNs play a crucial role in this process, ensuring the safety of participants and the quality of research.The nursing workforce in clinical trials, particularly oncology CRNs, has evolved into a specialized practice recognized by the American Nurses Association (ANA). Despite this recognition, there is a lack of clear and consistent understanding of the specific characteristics and roles of CRNs.

**Aim**

To conduct a scoping review to comprehensively analyze the role of CRNs

**Methodology**

The scoping review will follow the JBI approach.

**Inclusion criteria**

The scoping review will include studies that involve CRNs (P) competencies and roles (C) in the conduct of clinical trial protocols (C).

**Search strategy**

A comprehensive search strategy will be employed inMEDLINE (PubMed), CINAHL (EBSCO), Web of Science (Clarivate), and PsycINFO (Ovid). The sources to be explored for unpublished research and gray literature include ProQuest Dissertations and Theses, OpenGrey, and the websites of national CRNs organizations.

**INTRODUCTION**

Clinical trials (CTs) serve as pivotal gatekeepers and bottlenecks influencing medical progress(Wu et al., 2022). Conducting cancer studies in clinical trial centers (CTCs) requires a large time commitment that includes both clinical and non-clinical tasks. It requires specialized knowledge and diverse abilities in scientific, ethical, and regulatory domains, which may be difficult for professionals whose primary focus is on their daily clinical duties(Pontrelli et al., 2021). The clinical trial multidisciplinary team supports the principal investigator (PI) in fulfilling its responsibilities as sponsor for the trial. The team will usually include clinical research coordinators (CRCs), clinical research nurses (CRNs) and clinical research associates (CRAs). CRNs play a critical role in the trial process(Portier, 2020),(Good et al., 2013). The nursing workforce, specializing in clinical nursing research, bears the complex responsibility of ensuring participants' clinical safety and maintaining research quality(Menzies et al., 2020). The evolution of clinical trials nursing into a specialized practice recognized by the American Nurses Association (ANA)(American Nurses Association & International Association of Clinical Research Nurses, 2016) signifies the increased impact of oncology CRNs in multicenter international trials (Hong et al., 2021). However, the characteristics of CRNs is still unclear. The National Institutes of Health Clinical Center (NIHCC) has outlined the nursing role in clinical trials as having two main responsibilities: providing nursing services for the trials and overseeing and carrying out the trials on behalf of the primary investigator (Kunhunny & Salmon, 2017). Conversely, the UK Clinical Research Collaboration (UKCRC) defined CRNs as nurses whose main focus is conducting research in a clinical environment (UKCRC, 2006). Due to the absence of clear and consistent characteristics of CRNs, the struggle in identifying their roles may result in a lack of self-confidence and feelings of isolation among CRNs (Faulkner-Gurstein et al., 2019). This situation is not beneficial for the growth of CRNs. This study seeks to undertake a scoping review to carefully analyze the role of CRNs in order to summarize the existing conceptual distinctions.

**MATERIALS AND METHODS**

**Methodology**

This scoping review will follow the Joanna Briggs Institute guidelines and use the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) 2020 framework to guide the selection and review process (Page et al., 2021; Peters et al., 2020). The primary research question for this scoping review is: “What is the current state of literature on the role of Clinical Research Nurses? To explore this broad question, several secondary research questions have been developed to address specific aspects of CRNs’ competencies, roles, and barriers. These secondary questions include:

* **RQ1**: What are the core competences of CRNs?
* **RQ2**: What is the scope of practice for CRNs?
* **RQ3**: What obstacles are linked to the position of CRNs?
* **RQ4**: What is the current employment status of CRNs worldwide?
* **RQ5**: What geographical contexts have examined the role of CRNs?
* **RQ6**: What clinical and organizational settings have contributed to the development and implementation of the CRN role?
* **RQ7**: What outcomes have been used to evaluate the impact of CRNs?
* **RQ8**: What emerging themes or sub-topics have been identified through data mining techniques?
* **RQ9**: Is there a temporal pattern in the thematic focus of the literature, and are there emerging themes tied to specific periods of publication?

This elaboration ensures that the review will capture the complexity and diversity of the literature related to the CRN role, while remaining faithful to the original scope and intent of the protocol.

**Criteria for inclusion**

Participants  
This scoping review will encompass research that incorporate CRNs in clinical trial protocols worldwide, regardless of age, gender, or race. We will incorporate CRNs based on the definition provided by the International Association of Clinical Research Nurses (American Nurses Association & International Association of Clinical Research Nurses, 2016) (IACRN) and engage in direct patient care during clinical trials. ‘Clinical Research Nursing is the specialized practice of professional nursing focused on maintaining equilibrium between care of the research participant and fidelity to the research protocol. This specialty practice incorporates human subject protection; care coordination and continuity; contribution to clinical science; clinical practice; and study management throughout a variety of professional roles, practice settings, and clinical specialties.’

Concept

The focus of this scoping review will be on the competence and scope of practice of CRNs. Competencies encompass a range of skills and knowledge. These competencies also include practice tasks that are uniquely carried out by CRNs. The scope of practice encompasses the areas of duty of CRNs who operate in the field of clinical trials, without any limitations.

Context  
This scoping review will include studies completed in clinical trial centers, metropolitan areas, and suburban districts (worldwide context) where CRNs are employed. The primary emphasis is on investigating the provision of healthcare research services for both adult and pediatric populations. A clinical trials unit is responsible for the comprehensive oversight of the design, recruiting, data management, publicity, and analysis of randomized controlled trials or other meticulously planned investigations, regardless of the disease or area being studied.

**Type of sources**

This scoping review will examine both quantitative and qualitative study designs. We will evaluate dissertations, theses, and websites of CRNs organizations (materials such as expert opinions and

position-statements).  
  
  
**Search strategry**

The search strategy will endeavor to locate both published and unpublished studies. This evaluation will employ a three-step search method. A preliminary search of MEDLINE (PubMed) and CINAHL (EBSCO) will be conducted in August 2024 to locate relevant papers. This will be followed by an examination of the keywords in the title and abstract, as well as the index terms used to characterize the article. Subsequently, a secondary search will be conducted across all relevant databases using the indicated keywords and index terms. During the third search, we will carefully analyze the reference lists of all the reports and papers that were included following the full-text screening. This analysis aims to find any additional studies that may be relevant to our research. Table I provides a comprehensive search strategy proposal for PubMed.

Table I. Elaborate search methodology in MEDLINE.

|  |  |
| --- | --- |
| #1 | "scope of practice"[MeSH Terms] OR "nurse s role"[MeSH Terms] OR "professional competence"[MeSH Terms] OR "clinical competence"[MeSH Terms] OR "competenc\*"[Text Word] OR "role"[Text Word] OR "barrier\*"[Text Word] OR "professional identity"[Text Word] OR "responsibilit\*"[Text Word] |
| #2 | "clinical nursing research"[MeSH Terms] OR "clinical research nurse\*"[Title/Abstract] OR "research nurse\*"[Title/Abstract] OR "clinical trial nurse\*"[Title/Abstract] OR "research nurse coordinator\*"[Title/Abstract] |
| #3 | #1 AND #2 |

All articles published in any language will be included. Only studies published from 1990 to the present will be considered. The databases that will be queried include MEDLINE (PubMed), CINAHL (EBSCO), Web of Science (Clarivate), and PsycINFO (Ovid). The sources to be explored for unpublished research and gray literature include ProQuest Dissertations and Theses, OpenGrey, and the websites of national CRNs organizations such as the International Association of Clinical Research Nurses (IACRN). Only websites in English, Italian, and French that are actively maintained in 2024 will be included in the narrowed organization website search.

**Selection of studies**

After conducting the search, all identified records will be gathered and uploaded into Zotero. Any duplicate records will be eliminated. Two impartial reviewers will screen the titles and abstracts to assess them based on the inclusion criteria. The complete text of chosen papers will be obtained and thoroughly evaluated using the specified criteria for inclusion. Papers that do not match the above criteria will be omitted from the final scoping review report. The reasons for their exclusion will be detailed in an appendix. The complete findings of the search will be documented in the final report and displayed in a flow diagram following the guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Scoping Reviews (PRISMA-ScR)(Tricco et al., 2018). Any conflicts that develop between the reviewers will be handled through discussion or with the involvement of the last author.

**Data extraction**

Two independent reviewers will extract data from the papers included in the scoping review using a data extraction tool created by the reviewers. The extracted data will encompass the following precise particulars: participants, concept, and context. An extraction tool in draft form is given (see to Appendix I). It will be altered and edited as required while gathering data from each document that is included. Protocol amendments will provide a thorough explanation of the modifications. Any conflicts that develop among the reviewers will be handled through deliberation or under the guidance of the senior author. The authors of the studies will be contacted to solicit any missing or supplementary data, if necessary.

**Data analysis and presentation**

The collected data will be displayed in tables or graphs in a manner that best aligns with the purpose and extent of this scoping review. The tables and graphs will present data on the distribution of studies based on the year or period of publication, countries of origin, participants, and the setting. Furthermore, the evolution of the scope of practice and competencies will be documented. The process of synthesizing the textual data from the research will involve three distinct steps: first, identifying the findings; second, grouping the findings together; and last, categorizing the groups. The tables or graphically depicted results will be accompanied by a narrative summary that explains how the results are relevant to the review objective and questions. The implications of the findings will be examined in relation to both practical applications and further study.

Following the data extraction process, the main results will be used to perform a Latent Dirichlet Allocation (LDA) in R (R Core Team, 2023), after a preliminary description of the lexicometric characteristics of the textual corpus. Given the substantial volume of literature identified, LDA has been selected to facilitate the identification of recurrent themes across the included studies through a systematic, reproducible approach capable of managing large, unstructured textual data (Caruso et al., 2024; Chauhan & Shah, 2022). To determine the optimal number of topics, the *ldatuning* package (Moor, 2023) will be applied, which calculates the most appropriate number of topics based on four widely used metrics (Arun et al., 2010; Cao et al., 2009; Deveaud et al., 2014; Griffiths & Steyvers, 2004).

Once the topics are generated, we will examine the most frequent words and word clouds associated with each topic to support the interpretative labeling of the thematic structures identified. Based on this evaluation, the most representative topics summarizing the included literature will be defined and described (and presented in Supplementary Files).

To strengthen the validity and robustness of the LDA results, Multiple Correspondence Analysis (MCA and k-means clustering will be conducted as complementary techniques for model validation (Hjellbrekke, 2019). This step will allow us to explore how the topics identified through LDA relate to key study variables, such as year of publication, country, and study design, by visualizing their distribution in a multidimensional space. MCA will help assess whether the identified topics show meaningful patterns or separations based on these variables, supporting the coherence of the topic model.

Additionally, k-means clustering will be applied to identify potential subtopic groupings within the dataset, providing further insight into the thematic structure of the literature and its associations with the characteristics of the included studies. The combined use of these complementary techniques will enhance the interpretative depth and methodological rigor of the analysis. A detailed description of the procedures applied for LDA, MCA, and k-means clustering will be provided in a Supplementary File. This approach aligns with the exploratory purpose of scoping reviews, which aim to identify research trends, gaps, and future directions rather than to synthesize findings quantitatively (Pollock et al., 2023).

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Appendix I. Data extraction form

|  |  |
| --- | --- |
| Study details | |
| Author(s) [Year] |  |
| Type of study |  |
| Aim(s) |  |
| Country(ies) |  |
| Participants (Including the definition on CRN) |  |
| Context |  |
| Concept (and relevant data) | |
| CRNs Role |  |
| CRNs Competencies |  |
| CRNs Barriers |  |
| CRNs Work Status |  |