Acta Biomed 2025; Vol. 96, N. 4: 16745 DOI: 10.23750/abm.v96i4.16745

Review

The role of the clinical research nurse in the context of clinical trials: A mini-review

Daniela Pais[1], Tiago Amado[2], Pedro Monteiro[3], Cláudio Santos[4]

[1]Investigation and Development Unit, ULS Coimbra, Coimbra, Portugal; [2]USF Mondego, ULS Coimbra, Coimbra, Portugal; [3]Department of Cardiology, ULS Coimbra, Coimbra, Portugal; [4]BIAL, Porto, Portugal

Abstract. *Background and aim:* Elucidate the role of clinical research nurses in the development of clinical trials. *Methods:* This study employs a theoretical-reflexive methodology, drawing upon an approach derived from the analysis of international publications. The study is structured by the researchers and informed by their experience gained through collaboration on multiple networks. *Results and discussion:* A clinical research nurse is a professional whose contributions and responsibilities ensure the quality of clinical research from inception to completion. They are involved in a number of key areas, including the evaluation and feasibility of research proposals, the negotiation of financial agreements, the implementation of trials, the supervision of trial sites, the conduct of clinical trials that involves patient recruitment, follow-up and education, informed consent process, data collection and product administration, and the management of participant expenses. *Conclusions:* The involvement of nurses in research teams facilitates a more efficacious approach to patient care. Despite the fact that the role of the clinical research nurse is present and recognised in multidisciplinary teams in clinical trials, the exact nature of the role remains unclear. It is of great importance to construct and promote the research nursing specialty. (www.actabiomedica.it)

Key words: nursing clinical research, nursing role, patient care team, nursing specialities, advanced practice nursing

Introduction

The ongoing advancement of clinical investigation on a global scale gives rise to the emergence of novel professional roles and competencies within the domain of nursing. This is of paramount importance in order to more accurately delineate and comprehend the contributions and responsibilities of nurses in the context of a clinical trial, given that these healthcare professionals are frequently the initial point of contact with research subjects, providing care and ensuring the proper execution of the trial protocol. In recent decades, the number of clinical trials (CT) has increased significantly. CT are defined as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc, thereby including Phase I to Phase IV trials" (1). Clinical research is defined as research conducted with human subjects or material of human origin, wherein the researcher engages in direct interaction with human subjects. CT are also appointed as part of clinical research and are at the heart of all medical advances. The primary objective of these trials is to determine the safety and efficacy of novel approaches to disease prevention, detection, and treatment (2). During a clinical trial, while funders provide opportunities, resources and management expertise, investigators guide

patient care and investigation, managing trial-specific and general medical issues (3). Analyzing the role of the CRN and comparing different contexts, there is a great disparity in the development of its functions: in the United States, the CRN operates in a highly regulated environment, with strong academic links; in the United Kingdom, it is part of the public structure of the National Health Service (NHS), which has well-defined and financed research structures; in the European Union, the scenario varies depending on the policies and health systems of each country; in low- and middle-income countries, financing and working conditions are, in largely limited, significantly impacting the existence or performance of CRNs. In terms of CRN experience, the first step is to complete a degree program in nursing, followed by further training in clinical research. This additional training may vary between countries, within the same country, or from institution to institution, and may take the form of short courses, postgraduate courses, or master's degrees depending on the requirements. The area of work, whether in a public, private or academic institution, can also influence the choice of a certain CRN profile. Although nurses are considered an integral and essential part of the clinical research team, there is no generally accepted and standardized definition of the role of the clinical trial nurse (4-8), but there are similar descriptions of the role in CT (9).

Methods

The objective of this narrative literature review was to clarify the role of clinical research nurses in the development of CT. This study employs a theoretical-reflective methodology based on an approach derived from the analysis of international publications. A comprehensive literature search was conducted using the databases Pubmed, Scopus and Google Scholar with the search terms "CLINICAL RESEARCH" OR "CLINICAL INVESTIGATION" AND "nurse". The search was not limited by study period, and the final selection was restricted to papers written in English. Additional papers were retrieved by manually searching the reference lists of each selected paper. The search was concluded on 29 November 2024.

Results and Discussion

The results were obtained through a comparison of evidence from several studies, which detected positive contributions and divergences between results, in order to approach the topic under study in a more in-depth, differentiated and enriching way. The researchers' day-to-day experiences also had weight in this analysis, contributing to a broader perspective and enriching the general interpretation of the topic. The interpretation of the results was based on the methodological rigor and robustness of the selected studies.

Definition of Clinical Research Nurse

The formation and advancement of interdisciplinary clinical research teams have facilitated the acquisition of novel professional competencies in nursing, thereby enhancing the role of the clinical research nurse (CRN). This has led to the emergence of a range of alternative designations, most commonly referred to as "Clinical Research Coordinator" or "Clinical Trial Coordinator." However, the term "clinical research nurse" remains the most prevalent (4,9). Clinical research nurses are registered nurses employed within research sites to facilitate and conduct any phase of a clinical trial (10,11). They are responsible for the care of research participants, ensuring that nursing care delivery aligns with the process of clinical research study implementation (4). The International Association of Clinical Research Nurses defines clinical research nursing as "the specialized practice of professional nursing focused on maintaining equilibrium between care of the research participant and fidelity to the research protocol" (12). The practice of research nursing or clinical research nursing is not a specialty recognized on a global scale. Even in countries with advanced nursing systems, such as the USA, its recognition by the national board of nursing did not occur until 2016 (13). In this context, three main roles of nurses in clinical research emerge: 1) the study nurse as the direct provider of care to research participants before, during and after participation in clinical research; 2) the nurse as study manager, coordinator or clinical trial nurse who works closely with the principal investigator who recruits research participants and oversees data management and

protocol compliance; 3) the investigator nurse who is the principal investigator in a clinical trial (13,14).

The responsibilities of Clinical Research Nurses

The duties of clinical research nurses in the context of CT typically encompass the recruitment and screening of participants, the assurance of informed consent, randomization, the collection and documentation of data, and the monitoring of participants (4,10,11). Nurses play an important role in the entire process of knowledge creation and translation, from concept development and basic scientific discovery to evaluation and dissemination research (4), as the involvement of clinical research nurses at the research site has been associated with improved quality of CT due to better communication with clinical staff and participants, increased recruitment to clinical trial arms, and improved patient compliance with protocols (11). The clinical trial coordinator, as a nursing professional, taking into account their technical and scientific competencies, provides care to the patient and ensures the correct implementation of the clinical trial protocol, as the care provided to research participants is driven by study requirements and the collection of research data, as well as clinical indications (4,13). Given the considerable autonomy and patient contact inherent to the role, the clinical research nurse is a pivotal figure in the field of medical research. However, the specific skill set required may vary depending on the nature of the study in question (10). By employing a clear and targeted language in their interactions with each participant, clinical research nurses are able to facilitate the enrollment of new patients in various clinical trial protocols. This approach enables them to promote learning and behavioral changes related to the management of the participants' illnesses. Consequently, the clinical research nurse develops procedures and skills as part of their daily role, including clinical observations, clinical measurements, specimen collection and preparation, documentation of research participant-reported outcomes, and parallel to that, interventions and study procedures may include the administration of investigational drugs, performance of an experimental or investigational surgical or radiological procedure, detailed clinical evaluation, or delivery of a psychosocial intervention (4,13). The clinical research nurse ensures that study objectives are met by coordinating research and care and managing the interface between study care and community services. The clinical research nurse balances the requirements of the study with the clinical needs of individual participants, promotes the ethical conduct of CT, and ensures the consistency, accuracy, and efficiency of data collection. In addition, the clinical research nurse manages study activities, monitors participants for events, supports and educates participants, upholds the principles of participant rights, patient safety, and continuity of care, improves participant recruitment, and assists individuals in making informed decisions about clinical trial participation.

Through collaboration with other patient care services (such as pharmacy, radiology, and laboratory), the clinical research nurse is able to integrate knowledge and skills to provide comprehensive care within the confines of the clinical research trial and discover new ways to manage the disease of the clinical research subject, including 1) communication with study sponsors; 2) training and supervision of nursing, medical, and new research team members; 3) responsibilities such as screening, recruitment, obtaining informed consent; 4) administration of the intervention being studied; 5) monitoring of participants; 6) laboratory work, data collection; 7) reporting of any adverse events; and 8) general management of the study, including maintenance of study records and resolution of data queries (4,14,15). In an area of work characterised by various responsibilities, roles and functions, a comprehensive literature review and analysis of authors' experience has identified key areas and specific activities for the clinical research nurse's daily work throughout the clinical trial. The following list comprises the key areas and specific activities that have been identified:

1. Evaluation, Feasibility and Financial Agreement
   - I. Ensure adequate human resources
   - II. Ensure adequate physical space, materials, and circuits
   - III. Regulatory support for study submissions
   - IV. Feasibility assessment, new protocols and financial aspects still in progress during the submission phase
   - V. Financial management in conjunction with financial services

2. Implementation – site supervision and clinical trial start
   I. Overall coordination of the clinical research team
   II. Preparation of source documents for guidance at each trial visit
   III. Training and education for multidisciplinary team
   IV. Protocol implementation
3. Clinical trial conduct - patient recruitment, follow-up and education, informed consent process, data collection, product management and participant cost management
   I. Work with researchers to recruit/identify patients
   II. Collaborate on informing patients about consent: objectives, type of treatment, number of visits to the research center, procedures at each visit, benefits and risks
   III. Participate in protocol follow-up
   IV. Patient and family education, including research product management and administration
   V. Assessment of vital signs - Physical assessments
   VI. Data collection and entry into platforms (CRF - Case Report Form)
   VII. Completion of Investigator Study File (ISF) and study records
   VIII. Telephone helpline with direct contact to the nursing team - Nursing Reference
   IX. Biological specimen collection and shipment
   X. Scheduling of consultations during the protocol period
   XI. Archiving, managing and updating documents
   XII. Work with financial services to reimburse patients for expenses
   XIII. Closing visit and file archiving
4. Clinical trial: from start to finish
   I. Clarification of doubts by the monitor and the international team
   II. Constant communication with the National Sponsor/International Sponsor
   III. Participation in sponsor monitoring visits, external audits and inspections
   IV. Event identification/monitoring of adverse reactions
   V. Collaborate with the principal investigator in the conduct of the clinical trial
   VI. Materials Management
   VII. Contribute to the development of internal quality procedures - Standard Operating Procedures (SOPs)
   VIII. Support and follow up on all phases of the clinical trial process
   IX. Report problems and protocol violations
   X. Protocol compliance monitoring

Conclusions

A research team comprising nurses, whose training is distinct from that of other healthcare professionals, will facilitate a more efficacious approach to patient care. This is achieved by fostering a relationship of greater trust, empathy, and proximity with each participant. Despite the presence and recognition of the clinical research nurse role in clinical trial multidisciplinary teams, the daily tasks associated with this role remain poorly defined, varying considerably depending on the specific clinical trial area or country in which the investigation is conducted. When nurses are responsible for teaching or programming protocol consultations, adherence to treatment or prevention plans, the quality of the data taken from the trials is demonstrably superior, as evidenced by the bibliography. It is therefore imperative to alter the paradigm of the current situation, in which nurses occupy a tertiary role in conducting trials. In the present context, the clinical research nurse's potential to play a pivotal role in conducting CT remains unfulfilled. Thus, it is important to construct and promote the nursing research specialty and to assess the potential added value of conducting CT by nurses.

Ethical Approval: Not applicable.

Conflict of Interest: Each author certifies that they have no commercial affiliations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might present a conflict of interest in relation to the submitted article.

Authors Contribution: Conceptualization: DP, TA. Original draft written by: DP, TA. Peer-reviewed manuscript: DP, PM, CS. All authors read, discussed, and approved the final version of the manuscript.

Declaration on the Use of AI: None.

Funding: No funding has been made available specifically for this project.

References

1. World Health Organization. Clinical trials. Geneva: World Health Organization; 2020 Jan 16 [cited 2024 Aug 1]. Available at: https://www.who.int/news-room/questions-and-answers/item/clinical-trials
2. National Institutes of Health. Nursing at the NIH Clinical Center - clinical research nurse roles. Maryland: National Institutes of Health; 2022 Oct 23 [cited 2023 Nov 23]. Available at: https://www.cc.nih.gov/nursing/careers/roles.html
3. Anker SD, Butler J, Khan MS, et al. Conducting clinical trials in heart failure during (and after) the COVID-19 pandemic: an expert consensus position paper from the Heart Failure Association (HFA) of the European Society of Cardiology (ESC) [published correction appears in Eur Heart J. 2021;42(18):1810. doi: 10.1093/eurheartj/ehab190]. Eur Heart J. 2020;41(22):2109-2117. doi:10.1093/eurheartj/ehaa461
4. Hastings CE, Fisher CA, McCabe MA, et al. Clinical research nursing: a critical resource in the national research enterprise. Nurs Outlook. 2012;60(3):149-156.e1563. doi: 10.1016/j.outlook.2011.10.003
5. Kukreja JB, Thompson IM Jr, Chapin BF. Organizing a clinical trial for the new investigator. Urol Oncol. 2019;37(5):336-339. doi: 10.1016/j.urolonc.2017.12.017
6. Búřilová P, Pokorná A. The role of the research nurse in clinical trials. Kontakt. 2017;19(3):e165-e170. doi: 10.1016/j.kontakt.2017.05.002
7. Wilkes L, Jackson D, Miranda C, Watson R. The role of clinical trial nurses: an Australian perspective. Collegian. 2012;19(4):239-246. doi: 10.1016/j.colegn.2012.02.005
8. Backman Lönn B, Hajdarevic S, Olofsson N, Hörnsten Å, Styrke J. Clarifying the role of clinical research nurses working in Sweden, using the Clinical Trial Nursing Questionnaire - Swedish version. Nurs Open. 2022;9(5):2434-2443. doi: 10.1002/nop2.1260
9. Hernon O, Dalton R, Dowling M. Clinical research nurses' expectations and realities of their role: a qualitative evidence synthesis. J Clin Nurs. 2020;29(5-6):667-683. doi: 10.1111/jocn.15128
10. Gibbs CL, Lowton K. The role of the clinical research nurse. Nurs Stand. 2012;26(27):37-40. doi: 10.7748/ns2012.03.26.27.37.c8986
11. International Association of Clinical Research Nurses. Enhancing clinical research quality and safety through specialized nursing practice: scope and standards of practice committee report. Mullica Hill: International Association of Clinical Research Nurses; 2012 [cited 2024 Nov 12]. Available at: https://iacrn.org/
12. Spilsbury K, Petherick E, Cullum N, Nelson A, Nixon J, Mason S. The role and potential contribution of clinical research nurses to clinical trials. J Clin Nurs. 2008;17(4):549-557. doi: 10.1111/j.1365-2702.2006.01872.x
13. Castro K, Bevans M, Miller-Davis C, et al. Validating the clinical research nursing domain of practice. Oncol Nurs Forum. 2011;38(2):E72-E80. doi: 10.1188/11.ONF.E72-E80
14. McCabe M, Behrens L, Browning S, Vessey J, Williams MJ. CE: original research: the clinical research nurse: exploring self-perceptions about the value of the role. Am J Nurs. 2019;119(8):24-32. doi: 10.1097/01.NAJ.0000577324.10524.c9
15. Poston RD, Buescher CR. The essential role of the clinical research nurse (CRN). Urol Nurs. 2010;30(1):55-77. doi: 10.7257/1053-816x.2010.30.1.55

Correspondence:
Daniela Pais
Affiliation of author: Investigation and Development Unit, ULS Coimbra, Coimbra, Portugal.
Vale Gemil nº19, 3040-322, Coimbra, Portugal
E-mail: danielapais24@gmail.com
ORCID: 0009-0007-8946-2613

Received: 27 December 2024
Accepted: 24 February 2025