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REVIEW AND CLINICAL RESEARCH PROTOCOLS

PROTOCOLOS DE REVISÃO E DE PESQUISA CLÍNICA

PROTOCOLOS DE REVISIÓN Y DE INVESTIGACIÓN CLÍNICA

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In recent years, global science has witnessed an exponential expansion in the volume of published scientific articles. This scenario, driven by increasing pressures for research productivity and publication, has also been accompanied by a rise in the number of scientific article retractions, defined as the formal withdrawal of an already published article. Such retractions may occur due to the detection of honest errors or, more frequently, as a result of researcher misconduct, that is, the intentional violation of the principles of research honesty and integrity, including data fabrication, manipulation, or falsification; plagiarism; duplicate publication; and unethical research practices. These issues undermine the credibility of science, clinical decision-making, and the formulation of public policies[1].

This scenario has posed increasing challenges for researchers, organizations responsible for developing and promoting guidelines for different types of studies, and scientific journals committed to publication quality. Methodological rigor, transparency, reproducibility, and scientific integrity are globally valued principles that underpin trust in research. In this context, the development and prior dissemination of research protocols, whether for review studies or clinical research, constitute essential steps that prospectively outline the research plan, guide methodological decisions, reduce biases and potential errors, and promote transparency throughout the research process[2-3].

Review and clinical research protocols should be developed at the initial stage of research planning, prior to data collection. They systematically describe a comprehensive and up-to-date review of the literature, the study rationale, objectives, the steps guiding the methodology, data analysis, and ethical considerations, depending on the type of study. By prospectively outlining what will be conducted, the protocol serves as a reference framework, enabling all members of the research team to clearly understand the study. Another relevant aspect to consider is the publication of research protocols in open access and subjected to peer review. In addition to preventing duplication and research waste, the relevance of a protocol is also associated with the prevention of methodological biases. Therefore, a protocol should not be understood merely as a normative requirement of a guideline, but as a foundational document for the scientific integrity of the proposed study[3-4].

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A robust protocol should include essential elements that ensure clarity and methodological consistency. These elements include the study rationale and theoretical framework, the formulation of objectives, and a detailed description of the methodology, encompassing the research question, eligibility criteria, participants and recruitment strategies, definition of outcomes and variables, hypotheses, data collection procedures, data analysis methods, and ethical considerations. The components of a protocol may vary depending on the type of study, whether a systematic review, a scoping review, or a clinical research protocol. Therefore, it is essential to follow the specific guidelines applicable to each study design[3,5].

It is recommended that research protocols be registered on open-access platforms. Prospective registration consists of submitting information about a research protocol to a registry platform prior to the initiation of the study. Prospective registration of clinical trials, as well as systematic and scoping reviews, is essential for scientific transparency, helping to prevent duplication of studies and the waste of time and resources. Registration platforms and available options vary according to the type of study and should follow specific recommendations[3,6].

Registries typically include only minimal datasets; therefore, the publication of protocols containing all relevant elements is strongly encouraged. Research has shown that studies with both registration and a published protocol are more likely to result in the publication of the complete study in indexed journals with higher impact factors. This has also been associated with smaller discrepancies between published articles, registry records, and published protocols regarding methodological planning. Another relevant aspect is the inclusion of registration information and the appropriate citation of the published protocol, whether it is used as a methodological reference or when the final article is published, as the absence of protocol citation hinders the verification of methodological consistency[2-4].

The publication of research protocols in indexed, peer-reviewed journals, making them accessible for consultation and citation, represents an essential practice for promoting transparency, reproducibility, bias reduction, and for ensuring methodological rigor and scientific integrity. Furthermore, citing research protocols, whether for review studies or clinical research, acknowledges the intellectual contribution of researchers in the methodological development of studies and fosters a more open, collaborative, and reproducible science.

In this context, by encouraging the development, prospective registration, and publication of research protocols, the *Online Brazilian Journal of Nursing* plays a significant role in consolidating practices guided by transparency and methodological rigor. By publishing research protocols, the journal reinforces its commitment to open science, the strengthening of scientific integrity, and the quality of scholarly output in nursing and health.

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