

Randomized clinical trials on nursing procedures recorded by nurses in Brazil: bibliometric study

Ensaaios clínicos randomizados sobre procedimentos de enfermagem registrados por enfermeiros no Brasil: estudo bibliométrico

Ensayos clínicos aleatorios sobre procedimientos de enfermería registrados por enfermeros en Brasil: un estudio bibliométrico

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Abstract

Objective: To characterize the Randomized Clinical Trials on Nursing procedures registered by nurses in Brazil. **Methods:** Bibliometric study, which took place through access to the digital platform of the Brazilian Registry of Clinical Trials between the years 2010-2021, in which 65 trials registered by nurses were included. Data analysis occurred with the aid of the software R. **Results:** There was an increase in records about nursing procedures over the years, in which most of the research came from the southeast region, by professionals with PhD degree, linked to public institutions, and on the population studied there was a predominance of patients. Most studies were conducted in secondary care, with emphasis on venous and arterial puncture. **Conclusion:** The characterization of randomized clinical trials on nursing procedures can contribute to highlight the advances and gaps in the conduct of these professionals in health care. There is a growth in the development of randomized clinical trials over the years, so its incorporation into clinical practice still represents a challenge.

Descriptors: Randomized Controlled Trials as Subject; Nursing care; Clinical Nursing Research.

Whats is already known on this?

There are gaps in the characterization of randomized clinical trials on nursing procedures. Furthermore, there is a low production of Randomized Clinical Trials in the area of nursing.

What this study adds?

It contributes to evaluate the scientific evidence of Randomized Clinical Trials produced by nursing professionals, applied in health care in their clinical practice.



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Resumo

Objetivo: Caracterizar os Ensaios Clínicos Randomizados sobre procedimentos de Enfermagem registrados por enfermeiros no Brasil. **Métodos:** Estudo bibliométrico, que aconteceu por meio do acesso à plataforma digital de Registro Brasileiro de Ensaios Clínicos entre os anos de 2010 e 2021, no qual foram incluídos 65 ensaios registrados por enfermeiros. A análise dos dados ocorreu com auxílio do software R. **Resultados:** Constatou-se aumento dos registros acerca dos procedimentos de enfermagem ao longo dos anos, em que a maioria das pesquisas foi oriunda da região Sudeste, por profissionais com titulação de doutor, vinculados a instituições públicas, e sobre a população estudada ocorreu predominância de pacientes. A maior parte dos estudos foi realizada na atenção secundária, com ênfase no procedimento de punção venosa e arterial. **Conclusão:** A caracterização dos ensaios clínicos randomizados sobre procedimentos de enfermagem pode contribuir para evidenciar os avanços e as lacunas das condutas desses profissionais na assistência à saúde. Verifica-se o crescimento no desenvolvimento de ensaios clínicos randomizados com o passar dos anos, no entanto sua incorporação à prática clínica ainda representa um desafio.

Descritores: Ensaios Clínicos Controlados Aleatórios como Assunto; Cuidados de Enfermagem; Pesquisa em Enfermagem Clínica.

Resumen

Objetivo: Caracterizar Ensayos Clínicos Aleatorios sobre procedimientos de Enfermería registrados por enfermeros en Brasil. **Métodos:** Estudio bibliométrico, realizado a través del acceso a la plataforma digital del Registro Brasileño de Ensayos Clínicos entre los años 2010-2021, en el que fueron incluidos 65 ensayos registrados por enfermeros. El análisis de los datos se realizó con la ayuda del software R. **Resultados:** Hubo un aumento de los registros sobre los procedimientos de enfermería a lo largo de los años, en los que la mayoría de las investigaciones fueron de la región sureste, por profesionales con título de doctorado, vinculados a instituciones públicas, y en la población estudiada hubo predominio de pacientes. La mayoría de los estudios se realizaron en atención secundaria, con énfasis en punción venosa y punción arterial. **Conclusión:** La caracterización de ensayos clínicos aleatorios sobre procedimientos de enfermería puede ayudar a evidenciar los avances y lagunas en la actuación de estos profesionales en el cuidado de la salud. Ha habido un crecimiento en el desarrollo de ensayos clínicos aleatorios a lo largo de los años, sin embargo, su incorporación a la práctica clínica aún representa un desafío.

Descriptores: Ensayos Clínicos Controlados Aleatorios como Asunto; Atención de Enfermería; Investigación en Enfermería Clínica.

INTRODUCTION

Nursing aims to respond to the needs of human beings in the scenarios of health promotion, protection and rehabilitation, in which it develops activities in multiple sectors, such as hospital care, primary care service, emergency network, home and specialized clinics. To improve care, nurses need perceptions beyond technique to expand their professional practice, in which knowledge through scientific evidence is essential during care delivery.⁽¹⁾

Over the years, there have been advances in the incorporation of scientific evidence in nursing care, reflecting the progression from empirical to scientific knowledge, which help to care for the individual, family, community, training, teaching, and the growth and operationalization of instruments of conduct suitable for the performance of the professional and his team.⁽²⁻³⁾

In this scenario, Evidence-Based Practice (EBP) is a fundamental approach to assist the promotion and/or updating of conducts, support the clinical analysis and decision-making of nurses, and maximize the effectiveness of health actions. The concept emerged in the 1990s derived from medicine, although today its methods cover the other areas of health. The use of EBP by health workers results in improvements in health care, in which they seek safe and systematic ways to effectively promote care delivery.⁽⁴⁻⁵⁾

The EBP methodology consists of subsequent stages ranging from the identification of a problem, thorough research of the available evidence, implementation in practice and evaluation of the results achieved. Thus, by incorporating scientific evidence, the nurses enhance the execution of reliable and safe interventions to improve health care through the systematic use of the most relevant clinical foundations.⁽⁴⁻⁶⁾

Randomized Clinical Trials (RCTs) stand out among the study designs used to incorporate new evidence and evaluate the effectiveness of health interventions. They consist of primary and experimental studies that analyze the cause of health actions. The methodological robustness of RCTs, characterized by the randomization of the allocation of interventions, which consists of randomly distributing healthy patients or volunteers in different intervention groups for comparison, provide greater safety and effectiveness in the analysis of the results of the interventions studied.⁽⁷⁾

However, there are factors that hinder the use of EBP in clinical nursing practice, such as the scarcity of studies in the area, encouragement to conduct intervention research and care practices that are still based on empirical knowledge. Thus, it can be seen that the use of EBP is relevant for the advancement

of scientific evidence in nursing, since clinical studies can support and evaluate nursing interventions in their applicability⁽⁸⁻⁹⁾.

In order to enhance the transparency and dissemination of clinical studies in humans, in 2010 the national repository of Brazilian Clinical Trials Registries (ReBEC) was created, which aims to meet national and regional information needs and give transparency to studies. The registration of clinical trials reduces the risk of bias in research, enables changes in clinical practice and identification of gaps that can enable new studies⁽¹⁰⁾.

Most bibliometric studies on the production of research in the nursing area are aimed at specific proposals, which do not include clinical practice focused on nursing procedures. Thus, the present study aimed to characterize the Randomized Clinical Trials on Nursing procedures registered by nurses in Brazil.

METHODS

This was a descriptive bibliometric study, which consists of evaluating the development and growth of scientific production in specific areas of the literature, through the application of quantitative methods⁽¹¹⁾. The research took place through access to the ReBEC platform (Brazilian Registry of Clinical Trials), which is part of the project of the Pan American Health Organization (PAHO), the Oswaldo Cruz Foundation (FIOCRUZ) and the Ministry of Health (MH). It records the Randomized Clinical Trials (RCTs) performed in humans in Brazil, which has free and open access.

The study consisted of 4,999 RCT, produced in Brazil between the years 2010 to 2021 of the ReBEC platform, the time frame occurred from the year 2010 due to the year of development of the platform. Of these, only 220 were related to the area of nursing.

The inclusion criteria were RCTs produced in Brazil, registered by nurses and referring to nursing procedures. The verification of professional graduation was analyzed through the *Lattes* curriculum of the author responsible for registering on the platform. Studies given as interrupted or canceled were excluded. Thus, after reading the title and abstract, 155 records were excluded and 65 RCTs related to nursing procedures published by professionals from Brazil were obtained for the final sample.

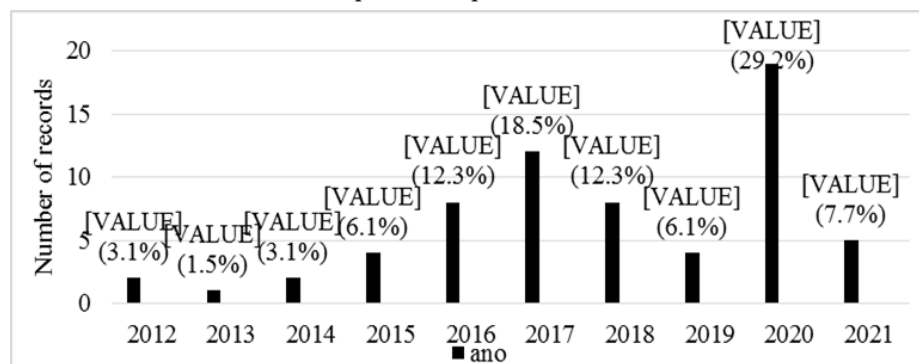
Data collection occurred through the use of an instrument created for the research, which consisted of the variables about the characteristics of the professionals who registered the RCT (affiliation, graduation, state and region), characteristics of the participants (evaluated public and minimum and maximum age), and characteristics of the RCT methodological design (nursing procedure, nursing area, level of care, recruitment situation, year of recruitment, number of arms, type of masking, focus of the study and type of allocation)

The analysis of the data obtained occurred with the aid of the R software, version 3.1.2. Thus, submission to the Ethics and Research Committee with Human Beings was not necessary, as the research was conducted with secondary data in the public domain.

RESULTS

Progress was observed in relation to the number of records published on the platform over the years, with emphasis on 2020 with 29.2% (n=19) of the registered RCTs, according to figure 1.

Figure 1. Temporal distribution of Randomized Clinical Trials on nursing procedures performed by nurses in Brazil. Pesqueira, Pesqueira, Brazil, 2022.



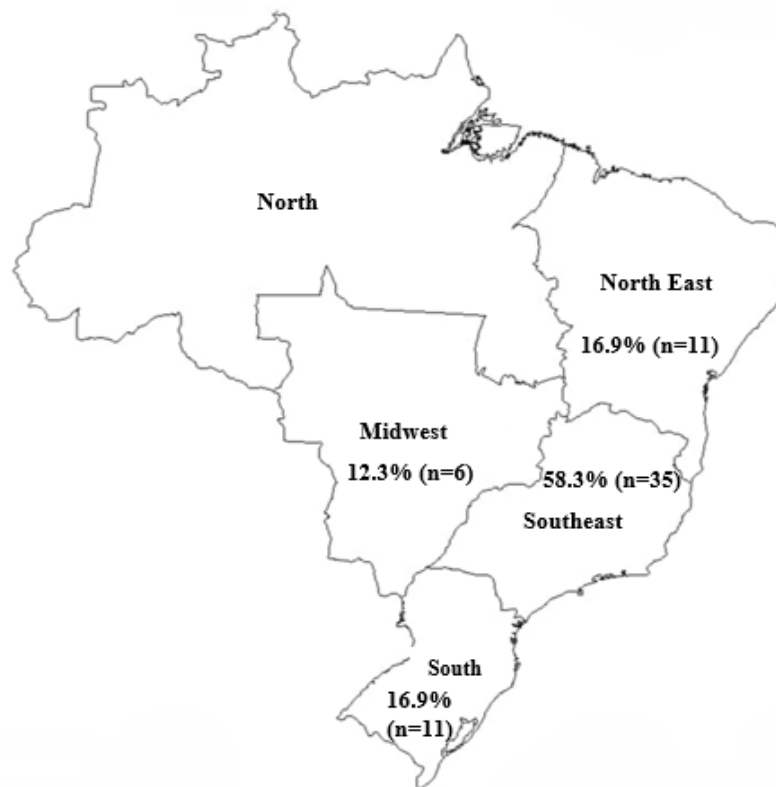
Source: authors (2022).

Regarding the geographical location of development of RCTs, there was a predominance of studies carried out in the Southeast region in 53.7% of the records, according to figure 2. Regarding the level of care in which the research was developed, 32.3% (n=21) were in secondary care, 30.8% (n=20) tertiary care, 10.8% (n=7) in primary care and 1.5% (n=1) included studies of pre-hospital care. In 24.6% (n=16) RCT did not indicate the scope of development in the registry.

Most of the researchers were affiliated with institutions of the public network, of a Federal or State nature. With regard to the academic background of the authors, it stands out with a PhD, in 72.3% (n=47), 21.5% (n=14) master's degree, 1.5% (n=1) with specialization in residency, and 1.5% (n=1) graduated in nursing.

Regarding the nursing areas, a predominance of 32.3% (n=21) was obtained in the area without nursing specialties, followed by the following areas: neonatal 27.7% (n=18), 13.8% (n=9) were part of alternative therapy, 9.2% (n=6) in immunization, 6.2% (n=4) in pediatrics, 4.6% (n=3) in education, 3.1% (n=2) in oncology and 1.5% (n=1) in obstetrics and urgency and emergency. Regarding the recruitment situation, 36.9% (n=24) were in progress, 33.8% (n=22) were completed, 15.4% (n=10) were under data analysis to initiate recruitment and 13.8% (n=9) had not yet been recruited.

Figure 2. Geographical description of Randomized Clinical Trials conducted by nurses in Brazil. Pesqueira, Pernambuco, Brazil, 2022.

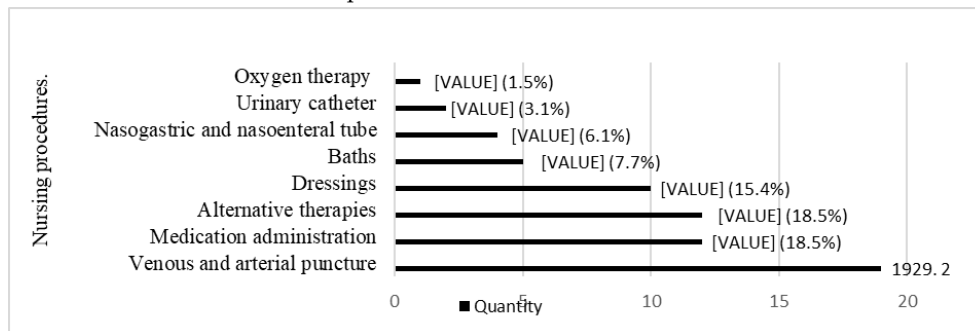


Source: authors (2022).

Regarding the evaluated public, it was observed that the majority 92.3% (n=60) were patients and 7.7% (n=5) were students and nursing workers, with a minimum age of 0 and maximum of 100 years. Regarding the nursing procedures investigated, it was found that venous and arterial puncture was the most analyzed in the studies, with 29.2% (n=19), followed by administration of medications and alternative therapies, with 18.5% (n=12) according to figure 3.

Regarding the focus of the studies, 46.1% (n=30) were focused on treatment, 35.4% (n=23) on prevention, 3.1% (n=2) on diagnosis and prognosis, and 12.3% (n=8) were classified as others. Regarding the number of arms, 76.9% (n=50) had two arms, 16.9% (n=11) used three arms. Regarding the type of masking, 44.6% (n=29) corresponded to the open type, in 26.1% (n=17) masking was single blind, in 21.5% (n=14) double blind and 7.7% (n=5) unspecified. As for the type of allocation, 96.9% (n=63) were from randomized controlled trials.

Figure 3. Distribution of Randomized Clinical Trials related to nursing procedures performed by nurses in Brazil. Pesqueira, Pernambuco, Brazil, 2022.



Source: authors (2022).

DISCUSSION

Based on the results, it was observed that the amount of RCTs over the years increased, with emphasis on 2020, the year when the World Health Organization declared the state of the COVID-19 pandemic.⁽¹²⁾ This finding contributes to highlight the performance of nursing with the increase of EBP even in the pandemic situation, which is an essential element for the advancement of scientific evidence in the health area.

A study conducted in South Korea found the importance of nurses knowing and applying EBP at the health care level, for this, the author mentions that continuing education can be a fundamental factor to improve the individual performance of professionals on EBP.⁽¹³⁾ From the progress of EBP, nursing professionals can improve their conducts that guide clinical practice in order to promote improvements in the quality of health and safety of their patients.

However, a study on teaching strategies for evidence-based practice in nursing addressed, through an integrative review, the deficiency of EBP implementation during graduation, where the main strategies for teaching EBP found used the traditional teaching model as lectures.⁽¹⁴⁾ The use of EBP since graduation can stimulate nursing students to acquire critical thinking, which can expand the effectiveness of EBP and enhance decision-making during its practice.

Regarding the region, most of the research was conducted in the southeast region, which corroborates with a study on Randomized Clinical Trials about the Intensive Care Unit in Brazil⁽¹⁵⁾, in which most of the trials were from the same region. These data may be related to the fact that it is a region with large concentrations of research centers and a high number of researchers, especially with more investments to carry out clinical trials.

Regarding the authors' affiliation, it was found that most of the studies were by authors affiliated with Federal and State public institutions, which coincides with studies carried out in Brazil on RCT, where it was showed the relevance of universities and public institutes for scientific advancement and for the training of researchers⁽¹⁵⁻¹⁶⁾.

In nursing procedures, clinical trials on venous and arterial puncture showed a higher number of records. In this perspective, a study by a specialist in the United States showed that the majority of hospitalized patients receive intravenous therapy.⁽¹⁷⁾ As this is an invasive procedure, which results from the use of a sterile mechanism inserted inside blood vessels, observational research carried out in a hospital in Peru identified an incidence of inflammation in the blood vessel of 53% due to puncture.⁽¹⁸⁾

For this reason, it is necessary to conduct infection control and the knowledge and skills of the nursing professional to avoid risks.⁽¹⁹⁾ Thus, it points out the importance of having scientific evidence on the venous and arterial puncture procedure in order to minimize risks and preserve patient safety.

In the administration of medicines, a cross-sectional study carried out in a regional hospital in Australia identified that of the doses of medicines administered, nursing professionals made a mistake during the application and preparation of more than half of the prescribed medicines.⁽²⁰⁾ Therefore, risk management strategies must be implemented, such as the development of research related to the theme. Medicine administration is an important procedure conducted by the nursing team, in which professionals must improve their knowledge about the safest techniques based on scientific evidence, in order to reduce errors during the procedure.

Regarding alternative therapies, a study carried out in Indonesia on nurses' knowledge and attitudes towards complementary therapies for adult cancer patients showed that the scarcity of reliable sources of information, such as scientific research, present obstacles for professionals to improve their knowledge, in which nurses develop their practice through personal experiences.⁽²¹⁾

With this, quality research on the efficacy and safety of alternative therapies proves to be scarce.⁽²²⁾ Thus, the enhancement of knowledge and reliability about alternative therapies is relevant to carry out more scientific research with emphasis on RCTs to increase the level of evidence of these practices.

In dressings, a study carried out in a university hospital in the center west on nurses' level of knowledge about dressings reported the professionals' deficit of critical thinking regarding the procedure performed, which can lead to delay in treatment. In addition, the authors showed that professionals did not rely on scientific evidence to expand their knowledge.⁽²³⁾ As improvement strategies, the training of nurses with the use of EBP during graduation and in continuing education can be a fundamental element to stimulate improvements during the procedure.

As for the focus of the study, most were about treatment, similar to a study done in New York about the definition of contemporary randomized controlled trials of cardiovascular interventions, which showed the predominance of trials to also evaluate the effect of treatment.⁽²⁴⁾ These clinical studies carried out with the perspective of treatments contribute to the advancement of scientific evidence, in which from their results they can develop innovation techniques for improvements in health care conducts.

Regarding the type of masking, the open type predominated, which differs from a study carried out in New York on the definition of Randomized Clinical Trials related to the surgical area, in which most trials had blinding.⁽²⁵⁾ Blinding of studies can minimize the chances of the researchers' and research subjects' own interpretations, to reduce bias both in carrying out the intervention and in analyzing the data.⁽²⁶⁾ It can be considered that masking in clinical trials is important and increases the reach of reliable results.

Regarding the types of allocation, most of the records were from randomized trials. A study on the efficacy and effectiveness of Randomized Clinical Trials reported the importance of randomization, in which it has an essential methodological tool, through the random organization of research participants, which expands the variety of the sample and improves the effectiveness of the study.⁽²⁷⁾ Thus, the randomization of studies is important for scientific evidence, since comparisons enhance the results.

CONCLUSION

There was an increase in the number of records about nursing procedures over the years, in which most of the research came from the southeast region, by professionals with PhD degrees in the area, linked to Federal and/or State institutions. In relation to the studied population that received the interventions, there was a predominance of patients. In addition, studies were conducted in secondary care, in an area without nursing specialty, with emphasis on venous and arterial puncture procedure, treatment focus and open masking.

The study was limited by the number of records found on the ReBEC platform regarding nursing procedures performed by nurses, which may be related to the non-identification of nurses' participation in other study groups, in which they may have participated directly or indirectly in other studies. In addition, certain variables (time interval between measurements and study phase) were not possible to perform the evaluation, as they had incomplete or unspecified data in the records.

This research is relevant because it addresses the characterization of randomized clinical trials on nursing procedures performed by nurses, which contributes to highlight the advances and gaps in the conduct of these professionals in health care in Brazil. Thus, more research related to the theme is suggested, in order to enhance EBP in the various areas of nursing about the praxis of care.

Thus, it is worth reflecting on the challenges in nursing performance in the adequacy and modification of clinical practice through EBP, which despite advances over the years, it is noted that some professionals still have difficulty associating the scientific evidence available with their clinical practice. Therefore, it is essential to transmit to nurses the relevance of scientific research in their professional practice.

CONTRIBUTIONS

Contributed to the conception or design of the study/research: Silva TJP, Silva CRD. Contributed to data collection: Silva TJP, Silva CRD. Contributed to the analysis and/or interpretation of data: Silva TJP, Silva CRD. Contributed to article writing or critical review: Silva TJP, Silva PCC, Silva CRD, Neto

NMG, Alexandre ACS, Guedes JMS, Carvalho MC. Final approval of the version to be published: Silva TJP, Silva PCC, Silva CRD, Neto NMG, Alexandre ACS, Guedes JMS, Carvalho MC.

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