

Randomized clinical trials on the Intensive Care Unit conducted by nurses in Brazil

RESUMO | Objetivo: caracterizar os ensaios clínicos randomizados realizados em unidade de terapia intensiva desenvolvidos por enfermeiros no Brasil. Método: trata-se de um estudo descritivo, de natureza quantitativa, com coleta de dados realizada mediante o acesso ao website de Registro Brasileiro de Ensaios Clínicos, no qual foram incluídos os ensaios cadastrados por enfermeiros. A análise ocorreu de forma descritiva a partir do software R. Resultados: a amostra do estudo foi composta por 33 ensaios clínicos. Predominaram os ensaios referentes à especialidade da enfermagem em neonatologia, que representou 16 (48,5%) dos estudos analisados. A maioria das intervenções testadas foram procedimentos de enfermagem, encontradas em 17 (51,5%) estudos. Observou-se predominância do mascaramento aberto, em 19 (57,6%) estudos e a maioria dos autores encontrava-se na docência, em 26 (48,1%) dos estudos. Conclusão: sugere-se que sejam realizados outros estudos que abordem a caracterização de ensaios clínicos realizados por outras categorias profissionais no setor em questão.

Descritores: Assistência de Enfermagem; Ensaios Clínicos Randomizados; Unidade de Terapia Intensiva; Bacharelado em Enfermagem; Prática Clínica Baseada em Evidências.

ABSTRACT | Objective: to characterize the randomized clinical trials carried out in an intensive care unit developed by nurses in Brazil. Method: this is a descriptive, quantitative study, with data collection performed by accessing the website of the Brazilian Registry of Clinical Trials, which included trials registered by nurses. The analysis detected descriptively using the R software. Results: the study sample consisted of 33 clinical trials. The trials referring to the specialty of nursing in neonatology predominated, representing 16 (48.5%) of the studies involved. Most of the interventions tested were nursing procedures, found in 17 (51.5%) studies. There was a predominance of open masking in 19 (57.6%) studies and most authors were in teaching, in 26 (48.1%) of the studies. Conclusion: it is necessary to carry out other studies that address the characterization of tests carried out by other professional categories in the sector in question.

Keywords: Nursing Care; Randomized Clinical Trials; Intensive Care Unit; Bachelor of Nursing; Evidence-Based Clinical Practice.

RESUMEN | Objetivo: caracterizar los ensayos clínicos aleatorizados realizados en una unidad de cuidados intensivos desarrollados por enfermeras en Brasil. Método: se trata de un estudio descriptivo, cuantitativo, con recolección de datos mediante el acceso a la página web del Registro Brasileño de Ensayos Clínicos, que incluyó ensayos registrados por enfermeras. El análisis se detectó de forma descriptiva mediante el software R. Resultados: la muestra de estudio estuvo formada por 33 ensayos clínicos. Predominaron los ensayos referidos a la especialidad de enfermería en neonatología, representando 16 (48,5%) de los estudios involucrados. La mayoría de las intervenciones probadas fueron procedimientos de enfermería, encontrados en 17 (51,5%) estudios. Hubo predominio del enmascaramiento abierto en 19 (57,6%) estudios y la mayoría de los autores estaban en la docencia, en 26 (48,1%) de los estudios. Conclusión: es necesario realizar otros estudios que aborden la caracterización de pruebas realizadas por otras categorías profesionales del sector en cuestión.

Palabras claves: Atención de Enfermería.; Ensayos Clínicos Aleatorizados; Unidad de Terapia Intensiva; Licenciatura en Enfermería; Práctica Clínica Basada en Evidencias.

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INTRODUCTION

The intensive care unit (ICU) is a hospital sector established for patients who are in a serious condition or at risk, whether clinical or surgical, who need assistance through intensive care. Among the professionals working in the sector in question, the nurse stands out. 1 One of the minimum requirements for the functioning of the ICU sector is the performance of the nursing professional, who must be present in this sector in at least one for every eight beds or fraction, in each shift. 2

The nursing professional who works in the ICU performs functions in care, management, training and continuing education that are consistent with the care of patients who are critically ill and at risk of death, for whom rapid decision-making is required. 3

The care provided in the ICU is considered complex, since the care provided and decision-making reflect on mortality. In this context, it is emphasized that the nursing professional working in the ICU needs to be trained, needs technical and scientific skills, in addition to constant improvement, in order to develop care with safety and quality. 3-4

Furthermore, the nurse's performance based on scientific evidence provides a greater probability of better clinical results. Among the types of study that provide Evidence-Based Practice (EBP), the randomized clinical trial (RCT) is highlighted. 5 This makes it possible to analyze the cause-effect relationship, with minimal bias and determinants that cause confusion. 6 In this context, the randomized clinical trial stands out as the gold standard of intervention studies and is regarded as the type of study with the highest standard of reliability, intended for the analysis of the effect, both of treatment and intervention. 7-8

In view of the above, it is pointed out that the characterization of the

RCTs already carried out is relevant, since such characterization can help in pointing out gaps that can be addressed in the production of future studies, given that it highlights data from the method used, location of the studies, as well as pointing out populations and contexts studied. Therefore, the present study aimed to characterize the randomized clinical trials carried out in an intensive care unit developed by nurses in Brazil.

METHOD

This is a cross-sectional, descriptive study of a quantitative nature, carried out through access to the website of the Brazilian Registry of Clinical Trials (ReBEC - Registro Brasileiro de Ensaios Clínicos) of the Ministry of Health, Pan American Health Organization, and Oswaldo Cruz Foundation. The aforementioned website has free and available access, in which the registry of randomized clinical trials (RCTs) performed with human beings in Brazil takes place.

It is worth mentioning that, in order to publish randomized clinical trials in scientific journals, it is mandatory to register the study with the randomized clinical trials registry platform, which, in Brazil, is the ReBEC option.

Randomized clinical trials registered with ReBEC made up the study population. The inclusion criteria established were that the registration was performed by a nursing professional and that the RCT took place in Brazil. The professional category of the author who registered at ReBEC was verified through access to the Lattes curriculum. The exclusion criterion was the study is interrupted or canceled.

It was observed that 321 studies met the inclusion criteria, of which 288 were excluded because they were not tests carried out in the ICU sector, thus 33 studies constituted the sample.

An instrument for data collection

developed for this study was used, which had 20 questions, in which the following variables were considered, referring to information about research and researcher data: year it took place, region and state, study sector, nursing specialty, recruitment situation, intervention studied, health condition, type of allocation, number of arms, type of masking, public evaluated, number of participants, gender of participants, author affiliation, author's title, and professional practice of the author.

Access was made to each record available at Rebec to fill in the instrument's questions and the data were descriptively analyzed using the R software, version 4.0.1.

The study was carried out with information in the public domain, therefore, there was no need for submission and consideration to the ethics and research committee with human beings.

RESULTS

There was an increase in the number of studies over the years and the majority, which corresponded to eight (24.3%) studies, took place in 2018. Figure 1 details the number of clinical trials per year.

Regarding geographic location, 16 (48.5%) were from the Southeast region, seven (21.2%) from the South region, seven (21.2%) from the Northeast region, and three (9.0%) from the Midwest. Regarding the distribution by state, eight (24.2%) were from Minas Gerais, six (18.2%) from the state of São Paulo, five (15.1%) from the state of Ceará, four (12.1%) from the state of Paraná, three (9.0%) from the state of Rio Grande do Sul, two (6.0%) from the state of Rio de Janeiro, two (6.0%) from the state of Goiás, one (3.0%) from the Federal District, one (3.0%) from Bahia and one (3.0%) from Alagoas.

Regarding the sector, 15 (45.5%) were from the adult intensive care unit (ICU) and 18 (54.5%) were from the

Neonatal ICU sector. Regarding the nursing specialty in which the study was registered at Rebec, 16 (48.5%) were in Neonatology, nine (27.3%) Intensive Care, two (6.0%) Cardiology, two (6.0%) Integrative Practices, one (3.0%) Surgical, one (3.0%) Stomatotherapy, one (3.0%) Adult Health, and one (3.0%) Urgency and Emergency.

Regarding the situation of recruitment, 15 (45.5%) studies had this stage in progress, in 14 (42.4%) the recruitment was completed, and in four (12.1%) had not been started.

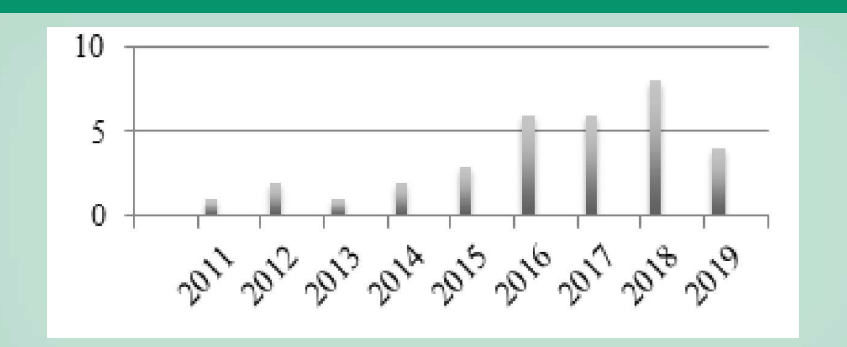
Regarding the interventions studied, most addressed nursing procedures, found in 22 (66.7%) studies, as detailed in table 1.

Regarding the investigated outcome, among 26 health conditions found, prematurity and pain stood out, researched in four (12.1%) and three (9.0%) studies, respectively, as detailed in table 2.

Regarding the focus of the study, 18 (54.4%) focused on prevention, 12 (36.3%) on treatment, two (6.0%) on diagnosis and one (3.0%) on prognosis. Regarding the type of allocation, 30 (91.0%) studies were randomized controlled and, regarding the number of arms, 26 (78.8%) had two arms, four (12.1%) used three arms and three (9.0%) were single-arm studies. With regard to the type of blinding, open masking corresponded to 19 (57.6%) of the studies, in seven (21.2%) the blinding was double-blind, in four (12.1%) single-blind, two (6.0%) triple-blind and one (3.0%) did not provide this information.

As for the time interval between pre and post measurements, 16 (48.5%) studies did not present this information. However, the most frequent intervals were those ranging from one to six hours, found in five (15.1%) studies. Intervals of one to five days were used in four (12.1%) studies; while those of seven and 15 days were used in three (9.0%) of the studies, each. The three-

Figure 1- Clinical trials carried out in Intensive Care Units, registered by nurses at Rebec, per year, Pesqueira-PE, Brazil, 2020. (N=33)



Source: Prepared by the authors (2021)

Table 1- Interventions studied in Randomized Clinical Trials registered at Rebec by nurses, Pesqueira-PE, Brazil, 2020. (N=33)

Interventions studied	n (%)
Peripherally Inserted Central Venous Catheter	4 (12,0%)
Dressing	4 (12,0%)
Health education	3 (9,0%)
Mechanical restraint in bed	2 (6,0%)
Intraoperative care	2 (6,0%)
Cardiopulmonary resuscitation	1 (3,0%)
Invasive mechanical ventilation	1 (3,0%)
Oral hygiene	1 (3,0%)
Bed bath	1 (3,0%)
Non-invasive monitoring	1 (3,0%)
Medication administration	1 (3,0%)
Gastric catheterization/probing	1 (3,0%)
Positioning the Patient in the Bed	1 (3,0%)
Use of semipermeable membrane	1 (3,0%)
Cryotherapy	1 (3,0%)
Colostrum Administration	1 (3,0%)
Breast Milk Administration	1 (3,0%)
Use of nose protector	1 (3,0%)
Applying a bundle	1 (3,0%)
Sleep promotion and sensory correction	1 (3,0%)
Kangaroo Method	1 (3,0%)
Music therapy	1 (3,0%)
Bach Flower Remedies	1 (3,0%)

Source: Prepared by the authors (2021)

-month and five-minute intervals were observed in one (3.0%) study each.

Regarding the population evaluated, 15 (45.4%) were newborns, 14

(42.4%) were adult patients in general, two (6.0%) were mothers of newborns and two (6.0%) were from the Nursing team. Regarding the number of participants in the analyzed studies, the minimum number was 18 participants and the maximum was 1034 participants, 14 (42.4%) had a sample of 51 to 100 participants; 10 (30.3%) from 101 to 300; eight (24.2%) up to 50 participants, and in one (3.0%) study the sample was 1000.

Regarding the gender of the participants, 31 (94.0%) studies did not present specificity, and in two (6.0%) exclusively female participants were studied. Regarding the author's affiliation, 15 (42.5%) studies were affiliated to federal universities, 10 (30.4%) to state universities, five (15.1%) to private education institutions, two (6.0%) to public hospitals, and one (3.0%) to the research institution. Regarding the author's title, 20 (60.6%) were doctors, of these two (6.0%) had postdoctoral degrees, 11 (33.4%) were masters, of these six (18.1%) were studying for a doctorate, and two (6.0%) were specialists. Regarding the author's professional practice, 10 (18.5%) were in care, 18 (33.4%) in research, and 26 (48.1%) in teaching.

DISCUSSION

There was a predominance of randomized clinical trials developed in the area of neonatology. This finding differs from a review of trials funded and published by the UK Health Technology Assessment Programme, which observed a predominance of trials in the mental health area. 9 Due to the complexity of care for newborns, it is necessary that professionals who provide care to the public use the best evidence-based care. Therefore, the existence of trials that test interventions in neonatology is relevant. However, there is a need to increase investment to carry out studies that include other

Table 2- Health condition studied in Randomized Clinical Trials registered at Rebec by nurses, Pesqueira-PE, Brazil, 2020. (N=33)

Health Condition	n(%)
Prematurity	4 (12,1%)
Pain	3 (9,0%)
Delirium	1 (3,0%)
Cardiovascular disease*	1 (3,0%)
Psychological stress	1 (3,0%)
Diseases of the respiratory system*	1 (3,0%)
Stress and anxiety/cardiovascular disease	1 (3,0%)
Wounds and Injuries	2 (6,0%)
Peri-intraventricular hemorrhage	1 (3,0%)
Hyperthermia	1 (3,0%)
Primary bloodstream infection	1 (3,0%)
Chronic kidney failure	1 (3,0%)
Thrombosis	1 (3,0%)
Dry eye	1 (3,0%)
Oxy-hemodynamic changes.	1 (3,0%)
Knowledge, Skill and Attitude	1 (3,0%)
Alarms in Mechanical Fans	1 (3,0%)
Maternal behavior	1 (3,0%)
Sleep quality	1 (3,0%)
Thermoregulation	1 (3,0%)
PICC Complications**	1 (3,0%)
PICC placement **	1 (3,0%)
Knowledge of professionals	1 (3,0%)
Enteral tube measurement	1 (3,0%)
Surgical wound infection	1 (3,0%)
Disruption, occlusion, traction, and displacement	1(3,0%)

*Not detailed information on Rebec. **Peripherally inserted central catheter
Source: Prepared by the authors (2021)

types of ICUs.

Regarding research tasks, dry them with nursing procedures. As a result of a study carried out in the United States, there was a predominance (81%) of different clinical trials for COVID-19 that investigated pharmacological intervention. 10 It is noteworthy that improving the quality of care for the patient requires the development of research that provides a scientific basis for the interventions performed by the professional nurse in the act of caring. Therefore, it

is important to develop clinical studies in order to test and evaluate nursing interventions, both newly emerged and those that have been carried out for years empirically, so that the acquired results help to change the clinical practice according to themselves.

Regarding the type of allocation, the randomized controlled type predominated. This finding is similar to research that characterized experimental studies on COVID-19, whose results show a predominance of this

type of allocation. 11 Such findings are relevant since randomization allows a greater chance of homogeneity between the groups that are compared and, therefore, it is relevant for the quality of the results that show the relationship between cause and effect.

Regarding the type of masking, it is highlighted that most studies adopted open masking, which does not coincide with the systematic review study on the characteristics of randomized clinical trials on surgery carried out in New York, whose results indicate that 47.9% of the studies were blinded. 12 When considering that blinding reduces the chance that the researcher and participant's own interpretation tendency will occur, there is a need for more intervention studies to have this characteristic that gives methodological robustness to the research.

Regarding the region, most studies were carried out in the Southeast, which corroborates the integrative review study carried out in Brazil, on scientific production on biomedical technologies and patient safety in the ICU sector,

which identified that most studies were found to come from the same region. 13 These findings may be related to the regional pioneering spirit in research and implementation of master's

and doctoral courses, as well as the differentiated investment made by the states that make up this region.

Regarding the number of participants recruited for the studies, it is noteworthy that there was a predominance of 51 to 100 participants, which differs from the study carried out in the United States regarding the characterization of clinical trials that evaluate treatments for COVID-19, of which the minority of studies (26.4%) recruited this number. 10 Such divergence can possibly be explained due to the analyzed outcomes, since pharmacological interventions may require a larger sample size.

Regarding the affiliation of the authors, it predominated in the Federal Universities. This fact can be justified by the scientific, technological and innovation development in Brazil, which is highly related to universities, especially public ones, which also account for most of the vacancies offered for training researchers.

The limitation of the study consisted in the possibility of not registering all clinical trials carried out in an intensive care unit (ICU), on the platform used for data collection. In addition, the delimitation of the analysis of clinical trials carried out by Nursing profes-

sionals was established, so that it does not contemplate the reality of clinical trials developed by other professionals working in the ICU sector.

The characterization of randomized clinical trials already carried out by nurses in the ICU sector is important, considering that the characterization of studies can highlight gaps that can be addressed in future studies.

CONCLUSION

Randomized clinical trials carried out by nurses in Brazil, in the ICU sector, had a quantitative growth from 2011 to 2018, they were mostly carried out in the area of neonatology, in which the predominant public investigated was newborns. There was a predominance of open blinding, carried out in studies with two arms and a randomized controlled design, in which recruitment was in progress. Most studies focused on prevention, tested interventions related to nursing procedures, mainly on dressings and care with central venous catheters, and were from the Southeast region. The authors were predominantly professors with a doctorate degree and affiliation to Federal Universities.

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