

VIVÊNCIA DE ACADÊMICOS DE ENFERMAGEM NA OPERACIONALIZAÇÃO DE ENSAIO CLÍNICO RANDOMIZADO: RELATO DE EXPERIÊNCIA

EXPERIENCE OF NURSING ACADEMICS IN THE RANDOMIZED CLINICAL TEST OPERATION: CASE STUDIES

LA EXPERIENCIA DE ACADÉMICOS DE ENFERMERÍA EN EL FUNCIONAMIENTO DE ENSAYO CLÍNICO RANDOMIZADO: ESTUDIOS DE CASO

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RESUMO

Objetivo: Relatar a experiência e atividades de acadêmicos de enfermagem na operacionalização de um ensaio clínico randomizado. **Métodos:** Trata-se de um estudo descritivo na modalidade de relato de experiência, no qual relatou-se a experiência e atividades de acadêmicos de enfermagem na operacionalização de um ensaio clínico randomizado conduzido em pacientes criticamente enfermos, internados na unidade de terapia intensiva de um hospital filantrópico do norte de Minas Gerais, Brasil. **Resultados:** As funções dos acadêmicos foram realizar a alocação das intervenções que os pacientes recebiam, mediante uma lista randomizada e aleatorizada; coletar dados sob a supervisão de um dos pesquisadores e digitar os dados em programa estatístico. O método empregado é considerado ideal, pois possibilita que os acadêmicos e profissionais de enfermagem reflitam sobre a prática de enfermagem científica e não intuitiva, ao se testar e validar cientificamente intervenções que são implementadas no cotidiano da enfermagem, muitas vezes de maneira empírica. **Conclusão:** A experiência na operacionalização desse tipo de estudo, por acadêmicos de enfermagem, contribui para formação profissional, ao proporcionar o desenvolvimento do pensamento crítico, com vista à resolução de problemas presentes na prática clínica de enfermagem.

Descritores: Ensaio clínico controlado; Enfermagem; Pesquisa em enfermagem clínica; Aprendizagem baseada em problemas.

ABSTRACT

Objective: To report the experience and activities of nursing students in the operationalization of a randomized clinical test. **Methods:** This is a case study, descriptive, in which the experience and activities of nursing students in the operationalization of a randomized clinical test conducted in critically ill patients hospitalized in the intensive care unit of a philanthropic hospital in the north of Minas Gerais, Brazil. **Results:** The functions of the academics were to perform the allocation of the interventions that the patients received through a randomized and aleatory list; it collected data under the supervision of one of the researchers and enter the data into a statistical program. The method applied is ideal, since it allows nursing academics and professionals to reflect on a scientific and non-intuitive nursing practice, by scientifically testing and validating interventions implemented in the daily routine of nursing, often empirically. **Conclusion:** The experience in the operationalization of this type of study by nursing undergraduates contributes to professional training by providing the development of critical thinking, in order to solve problems present in clinical nursing practice.

Descriptors: Controlled clinical test; Nursing; Clinical nursing research; Problem-based learning.

RESUMEN

Objetivo: Presentar la experiencia y las actividades de los estudiantes de enfermería en la operación de una prueba clínica aleatorizada. **Métodos:** Se trata de un estudio de caso, descriptivo, en el cual la experiencia y las actividades de los estudiantes en la operacionalización de un teste clínico randomizado realizado en pacientes criticamente enfermos ingresados en la unidad de cuidados intensivos de un hospital filantrópico en el norte de Minas Gerais, Brasil. **Resultados:** Las funciones de los académicos fueron realizar la asignación de las intervenciones que los pacientes recibían mediante una lista aleatorizada; recoger datos bajo la supervisión de uno de los investigadores e introducir los datos en el programa estadístico. El método empleado es considerado ideal, ya que posibilita a los académicos y profesionales de enfermería reflexionar acerca de una práctica de enfermería científica y no intuitiva, al probar y validar científicamente las intervenciones que se implementan en el cotidiano de la enfermería, muchas veces de forma empírica. **Conclusión:** La experiencia en la operacionalización de este tipo de estudio por académicos de enfermería contribuye a la formación profesional al proporcionar el desarrollo del pensamiento crítico, con miras a la resolución de problemas presentes en la práctica clínica de enfermería.

Descritores: Prueba clínica controlada; Enfermería; Investigación en enfermería clínica; Aprendizaje basada en problemas.

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INTRODUCTION

Building knowledge must be based on a permanent dialog between all participants in the process of teaching and learning, being inside or outside the academic physical place; thereby, providing a link between the theoretical and the practical⁽¹⁾.

Health research is the source producing the construction, an activity that seeks new scientific discoveries, contributing to the quality of new studies, in addition to its implementation, tends to result in the incorporation of new knowledge in health care. In this sense, the interventions to be implemented in clinical practice should be based on research, on scientific evidences⁽²⁻⁴⁾.

It stands out in the development of strong scientific evidence, clinical research. It is recent, characterized by advances of good clinical practice, consolidated in the United States in 1988, by the Food and Drug Administration (FDA), which provides standards, guidelines, and scientific ethics, for the progress in the clinical study^(3,5). In Brazil, there after being approved the Resolution of the National Health Council (CNS) 196/96, revised in 2012, with the CNS Resolution 466/12, which regulates the researches with human beings throughout the national territory.

Clinical study, clinical research, or clinical tests are synonyms and investigations with healthy or ill human beings are involved⁽³⁾. It is a systematic study that follows methods in which the results may generate new knowledge about procedures, medications, or interventions that improve the health of people^(3,6-8).

In clinical studies, an interest group that is using a new therapy (intervention group) is monitored and compared with others that make use of an already standardized therapy in clinical practice or a placebo (control group). The randomized clinical trial (RCT) is considered the most reliable method to analyze the effect of a treatment or intervention⁽⁷⁾.

The allocation of research subjects in the groups of RCT can be carried out at random or non-random⁽⁶⁾. The randomization allows comparisons of treatments are not affected by selection, consciously or not, the participants with a specific characteristic for a particular treatment. Thus, this strategy reduces the chance of bias or trends and, consequently, selection bias sources⁽⁹⁾.

As well as in various areas of knowledge in nursing, there is a lack of this type of study, especially given the recent field of action, which

has hampered the decision making in clinical practice⁽⁷⁾. The absence of sufficiently strong scientific evidence can influence in a restricted clinical trial with respect to a particular situation, as the effectiveness of certain medicines or what the best intervention to be applied. In addition, it is essential the development of randomized clinical trials that allow to evaluate an intervention in relation to its effectiveness, safety and cost-benefit^(2,4).

It is noteworthy that the clinical study is still little explored and approached in the undergraduate nursing course. In Brazil, the first studies began in the decade of 80, involving the definition of a particular problem, the search, and critical evaluation of the evidence available, implementing evidence in practice and the evaluation of the obtained results, being that the majority of the studies are available in the international literature^(4,7).

In the field of nursing, it has been developed an RCT, whose goal is to evaluate the effect of nursing interventions (artificial tears in gel and liquid artificial tears) in the prevention of dry eye, in patients hospitalized in general Intensive Care Unit (ICU) for adults of a philanthropic hospital in the north of Minas Gerais, Brazil.

Dry Eye is a syndrome that is related to the deficiency in the production of tear or the increase in its evaporation, thus influencing the keep of corneal surface⁽¹⁰⁾. According to the NANDA International, Inc. (NANDA-I)⁽¹¹⁾, the concept of the nursing diagnosis of risk for dry eye is "the risk of ocular discomfort and damage to the cornea and conjunctive, due to the reduced quantity or quality of tears to moisten the eye".

Patients hospitalized in the ICU may present conditions of high risk for the development of dry eye, since, in most cases, these are sedated, in coma, with mechanical ventilation (MV); in use of various medicines and eye protection mechanisms involved⁽¹²⁻¹³⁾. It is emphasized that, due to the prioritization of assistance to the physiological systems considered vital as the cardiovascular, neurological, and respiratory, eye care is usually treated secondarily⁽¹²⁾.

A recent study⁽¹²⁾ pointed out that the dry eye is a common problem in patients hospitalized in ICUs for adults, presenting an incidence of 53%. In this way, the specific care for the prevention of the dry eye are of paramount importance;

because it may reduce the probability of discomforts and ocular alterations in critically ill patients, both during hospitalization and after discharge from the ICU.

Justified this case studies, since, even though the clinical research, in general, being not very well known and understood by nursing professionals, believes it to be essential that discussions on the topic, since undergraduation, should be encouraged. In addition, it is intended to help stimulate the understanding about the randomized RCT and its importance for growth and strengthening of nursing practice based on strong scientific evidence.

In the face of our experience in RCT and, for this type of study being relevant to be incremented in nursing, the objective is, in the present study, to report the experience and activities of nursing students in the operationalization of an RCT, highlighting the importance of this type of design.

METHODS

It is a descriptive study in the case studies modality. This type of study allows recognizing deeply the experience described, more than being a precise narrative about a certain activity. In addition, it provides a reflection about the content approached⁽¹⁴⁾.

The experience to be reported is related to an RCT developed by a team of research with funding from the National Council for Scientific and Technological Development (CNPq). There were part of the team, a student of doctorate, a researcher and three scientific initiation students from a Nursing undergraduate course of the north of Minas Gerais, Brazil.

The collection of data of the present study was carried out in the period between 14th January 2016 and 14th March 2017, in a philanthropic hospital of tertiary care. With 275 beds, this is classified as large size. The hospital has active participation in the system of urgency from the north of Minas Gerais, being a reference for clinical urgencies, trauma and surgical procedures, as well as for the achievement of elective surgeries. Currently, there are made available to the community, 10 intensive care beds for elderly people.

The selection of the academics for participation in the study occurred before starting the field research. This was followed by some criteria, such as obtain good academic performance, discipline, commitment,

manifestation of the desire and preparedness to participate in the project. They were enrolled in the fourth period of the Undergraduate Nursing Course and devoted to the study a weekly schedule of 20 hours.

The functions performed by the academics were the control and allocation of interventions that each patient received by means of a randomized and aleatory list; data collection under the supervision of one of the researchers and typing the data into a statistical program.

Highlights that, in gathering data, in addition to the socio-demographic and clinical variables, for evaluation of the lacrimal volume, there was used in the test of Schirmer I. This consists of the installation of a strip of Whatman, number 41 or 50, with five millimeters (mm) in width and 35 mm in length, with the bent tip (approximately 5 mm), attached to the bottom of the lower eyelid bag in the temporal portion (outer corner of lower eyelid). After five minutes, the bind was removed, measured and noted the extent of the wetted part. For corneal evaluation, there was installed a drop of fluorescein in each eye of the patient, and after one to two minutes under low light conditions, the cornea was examined with the aid of an ophthalmoscope with cobalt blue light filter and magnifying glass, for better visualization of possible corneal alterations⁽¹⁰⁾.

This study, that was part of the case study, complies with the Resolution 466/12, which regulates research with human beings. The project was forwarded to the Research Ethics Committee of the Federal University of Minas Gerais, and obtained a favorable opinion under the protocol CAAE -50711915.8.0000.5149.

RESULTS AND DISCUSSION

After the selection of the academics, there were laid down some steps of empowerment. At first, the training consisted in prior reading of articles and texts about the themes, theoretical explanation about dry eye, ocular evaluation, and about the research design of randomized clinical trial. The training of academics by professor researcher was vital, because it allowed for the approximation of the members with the theme to be approached, since many did not know, in addition to the deepening of their own study design, since this is explored and approached in a superficial way in undergraduate nursing course.

In the second step, there have been discussions in relation to instruments of data

collection, on which occasion were worked the variables that comprised it, the clinical tests (test of fluorescein and Schirmer test I) that were made during the evaluation of the eye, as well as training for handling the statistical program in which the data were entered. For this study, we chose to work with the software Epi Info, version 3.5.1, due to be of easy management and by providing, after the double typing, checking the consistency of information. It is evident that it is necessary for the generation of any data, to be trusted, for which this may assist in correct decision making on the part of other professionals^(8,15).

This step made opportune the standardization of information among the team, in addition to the approximation, understanding and familiarization with the working tools that were used throughout the study.

Completed the training of academics, began training with teams of professionals from the hospital where the study was conducted. There were trained four teams, so that each one was composed by a nurse and five nursing technicians who work in shift, in the modality 12 hours on duty and 36 hours of play, totaling four nurses and 20 nursing technicians. The trainings occurred in two consecutive days, during the exchanges of duty. These were ministered by professor researcher with the aid of the academics. The training consisted in the explanation of the problem of study; inclusion criteria for participation of patients in the study; informed consent, once the nurses collaborated, approached the family to obtain the consent; and the way of application of each one of the interventions by nursing technicians.

The stage of training the team was essential for the formation of the bond between academics and the teacher researcher, and the professionals who work in intensive practice of the study place, enabling you to ensure the credibility of the study, membership and participation (since this was voluntary) in each of the assigned roles.

Started the study itself, after the acquisition of the informed consent by nurses, the same came into contact through an information center, which was created by academics with the aid of a phone application, and that did not count with the participation and presence of the Teacher Researcher, due to the masking of study. Via the central unit, the academics informed the nurses, in respect of

which intervention would be implemented by nursing technicians.

Because this is a double-blind RCT, in which the researcher and the patient do not have knowledge of the intervention that is being implemented⁽¹⁶⁾, in this study, the randomized and aleatory list with the interventions was sent directly by a statistical from another state, academics and these were responsible to allocate each patient according to the chart drawn. This strategy is essential to avoid possible biases, since the knowledge of intervention being implemented can tendency the result found during the assessment in relation to the presence or absence of the outcome. On the other hand, selection bias, by allocating the participant in some of the interventions due to its clinical profile, taking into account the hypothesis that intervention may be more effective to solve the problem.

Collaboration in the step above allowed that students to develop the perception of the need for planning and organization related to the methodological rigor of the study type. Furthermore, in line with the National Curricular Guidelines for nursing undergraduate course, allowed the intellectual improvement and capacity building in the pursuit of professional autonomy.

After the nurses receive the notification, through the central information, of which intervention would be implemented, the same was, then, separated by the same and conditioned in a manila envelope, with the aim to also keep the masking of the intervention.

The role of nursing technicians was to administer the intervention, according to randomization, in two moments of the day: at 08:00 o'clock in the morning and at 20:00 hours in the evening, during five consecutive days. The certification of completion of the procedure by the technicians was performed by means of a data collection tool, in which the same should check if whether or not has been implemented care in the shifts mentioned above and if there was any shortcoming, which would lead to the loss and exit of the patient from the study.

It was observed that, despite the physical exhaustion and often psychological, due to multiple demands and situations that the professionals who work in the ICU are exposed, the participation and involvement in the study was an opportunity to enable and act in a type of research still unknown to many and of great

relevance to nursing. Such felt valued, because they knew the importance of their role, both for conduction of the study, regarding the implementation of care to be provided. In addition, it was noticeable the recognition of other professional categories in relation to the study that was being developed.

Daily, during five consecutive days, the professor researcher, with the aid of one of the students, came to the hospital for completion of data collection and evaluation of the eye. For evaluation of the lacrimal volume, there was used the test of Schirmer I and, for identification of the presence or absence of lesions of the cornea, the fluorescein test. After collection, the data were doubly entered into Epi Info, version 3.5.1.

The participation of academics in the step of data collection provided clinical experience and a greater knowledge of the hospital area, mainly on the profile of patients under intensive care. It may be noted that this is an area requiring from professionals responsibility, agility, dexterity, fast clinical reasoning, and ability to take immediate decisions. In the ICUs, it assists patients affected by serious organic weaknesses or at risk of developing them, and they quickly change the profile of clinical stability.

To teach concepts and ideas by appropriation or apprehension of this, on the part of the learners, demand the creation and the exercise of a serious discipline. Thus, the teachers should be able to perceive, understand, and analyze and monitor the changes that occur in the course of the teaching-learning process⁽¹⁷⁻¹⁸⁾. From the cognitive practice and scientific research, students form subject increasingly critical, get specific knowledge, and structured on a subject need^(15, 18).

The experience points to the importance of conducting this type of study by the nurses; and enrollment of nursing students, due to the influence of extracurricular experience in improving academic and professional training. The method employed is considered ideal, having in view that enables the nursing professionals and academics to reflect on a scientific nursing practice and not intuitive when testing and validating scientifically interventions that are implemented in the daily routine of nursing, very often empirically.

CONCLUSION

The experience, during the undergraduate nursing course in clinical research, was of vital

importance. The moments of discussions about the theme and the participation in the implementation of the various stages of the study provided to academics who acquire new knowledge, which, probably, would not covered in depth during academic formation. This tends to impact on a future professional practice of higher quality, providing a basis for developing scientific research with healthy design, contributing to the growth and strengthening of nursing as a science.

Highlights the opportunity to participate in a study in which the practical care is tested and validated scientifically with consequent positive results in nursing care, to implement, in clinical practice, care based on strong scientific evidence.

It should be noted that, despite the design being complex and difficult to manage, the nurse is able to plan and carry out a study of this size. The insertion of academics in this type of research is important because it affects the development of a professional even more critical and able to seek solutions to the various problems present in the daily practice of nursing.

Finally, these new knowledges are indispensable in the face of current technological advances that require constant training and technical-scientific improvement, so that the professionals develop competencies and are able to carry the theoretical scientific knowledge for the care practice.

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