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EXPERIMENTAL AND QUASI-EXPERIMENTAL STUDY DESIGNS: DEFINITIONS AND CHALLENGES IN NURSING RESEARCH

DESENHOS DE ESTUDOS EXPERIMENTAIS E QUASE-EXPERIMENTAIS: DEFINIÇÕES E DESAFIOS NA PESQUISA EM ENFERMAGEM

DIBUJOS DE ESTUDIOS EXPERIMENTALES Y CASI EXPERIMENTALES: DEFINICIONES Y DESAFÍOS EN LA INVESTIGACIÓN DE ENFERMERÍA

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ABSTRACT

Objective: to discuss the experimental and semi-experimental applications designs and their applicability in nursing research. **Method:** informative article developed by searching information about the topic in electronic databases and books. **Results:** the experimental and semi-experimental applications designs are described, pointing its main features, similarities and differences, well as strategies used on these applications designs for the obtainment of applicable to the clinical practice. **Conclusion:** emphasizes the need of development of experimental and semi-experimental applications in the Nursing field, making evident the importance of building and validating of a knowledge corpus based itself on solid evidences. **Descriptors:** Clinical Trial; Nursing Research; Quantitative Analysis; Methods; Nursing.

RESUMO

Objetivo: discutir o desenho de estudos experimentais e quase-experimentais e sua aplicabilidade na pesquisa em enfermagem. **Método:** artigo informativo desenvolvido por meio de busca de informações sobre o tema em bases de dados eletrônicas e livros. **Resultados:** os desenhos experimentais e quase experimentais são descritos, apontando suas principais características, semelhanças e diferenças, bem como estratégias utilizadas nesses desenhos de pesquisa para obtenção de dados aplicáveis à prática clínica. **Conclusão:** ressalta-se a necessidade de desenvolvimento de estudos experimentais e quase-experimentais na área de Enfermagem, evidenciando a importância da construção e validação de um corpus de conhecimento próprio fundamentado em evidências sólidas. **Descritores:** Ensaio Clínico; Pesquisa em Enfermagem; Análise Quantitativa; Métodos; Enfermagem.

RESUMEN

Objetivo: discutir el diseño de estudios experimentales y cuasi-experimental y su aplicabilidad en la investigación de enfermería. **Método:** artículo informativo desarrollado por medio de la búsqueda de información sobre el tema en bases de datos electrónicas y libros. **Resultados:** los diseños experimentales y casi experimentales describen, señalando sus principales características, similitudes y diferencias, así como estrategias que se utilizan en estos diseños de investigación para la obtención de datos aplicables a la práctica clínica. **Conclusión:** la necesidad para el desarrollo de estudios experimentales y en parte en el área de enfermería experimental, destacando la importancia de la construcción y validación de un corpus de conocimiento basado en evidencia sólida. **Descriptores:** Ensayo Clínico; Investigación de Enfermería; Análisis cuantitativo; Métodos; Enfermería.

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INTRODUCTION

The speeding and remarkable changes in the health sector have imposed to the health professionals the challenge of attend them, and, at the same time, develop proposes to solution of individual, families and communities heath issues, in order to promote improvements to people's health and quality of life. In this sense, research constitutes in a tool capable to meet such demands, create new knowledge and promote the integration of innovations in health.

The health care related to costs and quality of care is also of growing concerns, imposing an even greater workload, influencing the quality of life at work. The demands that surround nurse's daily work require a constantly updated skills and abilities. The development of research, and consequently, generation of new knowledge, allow nurses to direct their practice results in consolidation of cost reducing and improvements of the professionals quality of life and helping the achievement of better results with patients, families and community.

The nursing research is the systematic process in which the profession reaches the potential to evolve technically and scientifically, and should be started as early as possible during the essential training for the formation of critical and reflective thinking.¹ Investigations developed through ordered methods produce the best health outcomes for individuals and society. As a vehicle for obtaining reliable data on topic relevant to the advancement of the profession, nursing researches direct professional practice to achieve excellence and quality of their actions.

In development of researches in nursing area, as in any other research area, the judicious care in the method of selection and the scientific rigor following the recommendations for each type of research is essential to produce the best evidence and best results in clinical practice. Thus, it is proposed to discuss the design of experimental and quasi-experimental studies and its applicability in nursing.

♦ Experimental studies

The experimental studies, also known as intervention studies, are those which the researcher in an intentional and controlled manner manipulates (deletion, addition or

modification) the exposure factor (intervention), in order to investigate the effects of the changes made.²⁻⁴ This type of research has the prospective character.⁴ It has been used experiment or true experiment terms to define the clinical trials of randomized controlled type.

To lead an experimental study is required: planning project, get updated references of the subject, seek grounds for a theory to plan intervention, elaborating and planning the performance of the intervention, establishing an observation system, testing the intervention, collecting and analyzing data, and spreading data.⁵

An experiment is a controlled test realized in order to demonstrate a known reality, to determinate if it is a true hypothesis or not, or assess whether something has not been tested has efficacy.^{6,7}

An experimental study may have as evaluation focus the individual (clinical trials) or a whole community (community trials). The kind of intervention can be classified as prophylactic or therapeutic. Furthermore, the experimental studies can be divided as controlled and uncontrolled. The controlled studies can be classified as randomized and nonrandomized.⁴

There are three properties related to a real experiment: randomization, control and manipulation.

The randomization determines the distribution of participants into groups: experimental and control group. In this kind of distribution, each individual has an equal or known probability of belonging to either group, eliminating trends related to attributes that may affect the study interest variable (dependent).^{6,8,9} The dependent variable can also be called "result" and the independent variable "predictive".¹⁰

The randomization of groups seeks to achieve comparability with regard to several variables (biological, psychological, social and other characteristics) and avoid the tendency of selection and mistaking. The differences observed between the groups, then, must be assigned to the realized intervention.^{4,9}

The randomization, however, does not guarantee the absence of tendency in the results obtained. Differences at random and reduced size of the number of participants can determine such problem.⁴ Uncertainty about the outcome of the intervention is

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called equipollence, which means that the choice of a particular evidence-based intervention is not possible, justifying the random allocation of subjects.^{9,11}

Control is a part of the group where the intervention will not be performed. This aims to establish a casual inference by comparison, as an isolated data does not infer whether variability was determined by intervention performed or by chance. The performance of the control group in relation to dependent variable is used to evaluate the results obtained in the experimental group. The use of control prevents changes in the results of the research due to external elements.³

In manipulation (intervention), occurs the researcher intervention in a group of subjects. Thus, the independent variable undergoes certain changes by the researcher and the results in the dependent variable are then evaluated by determining the validity of the treatment.³

A true experimental study allows researchers to control the effects of intrinsic and extrinsic variables that could threaten the internal validity of the results. These variables can be antecedents or intervenients. The antecedent variables include background events occurred before the research and that may affect the results. Minimizing the effects of background variables is given at the time of randomization of groups, when participants are randomly distributed and the effects of antecedent variables can also be allocated in the study groups. The intervenients variables are those that can interfere during the research, but it is not part of it and is not determined by the researcher.⁸

In true experiment is essential to pay attention to the different bias that may compromise the results: 1) selection bias (incomplete randomization or inadequate or that can promote systematic differences in experimental and control groups); 2) performance bias (systematic differences in attention given to the study participants besides the intervention of the target evaluation); 3) Exclusion bias (exclusion of participants with systematic differences); 4) Detection bias (differentiated measurement of outcomes).⁶

♦ Types of experimental designs

The *true experiment* design is one in which the study subjects are sent randomly to the experimental group or the control

group. The intervention is realized only in subjects in the experimental group. The evaluation of both groups in relation to behavior of the dependent variable is performed before (baseline data) and after the introduction of the desired intervention. The difference observed between the groups determine the connection between the dependent and independent variables.^{3,8,10,12}

The data obtained from true experiments also called randomized controlled trial are classified as evidence level II, producing high quality evidence.⁸

The rules for a true experiment include: 1) randomized sample of representative individuals of the population; 2) equivalence between the experimental and control groups; 3) complete control of the researcher regarding the treatment; 4) control of the group to receive the treatment and the group that will receive placebo; 5) control of the environment in which the study is conducted and; 6) precise measurement of results and comparison with the hypotheses developed.⁵ This type of research is suitable to demonstrate cause and effect relationships.^{5,13}

The *four Solomon groups* design aims at minimizing the possible effects of the test before the intervention on the results obtained in the post-intervention test. In this design, in addition to the intervention and control groups, two other groups are randomly distributed, one experimental and one control. Thus, the test before the intervention is carried out in an experimental group and in a control group. Intervention is applied in two groups and the test after the intervention applied to four groups. Thus, threats to internal validity are diminished when the effects of the test before on the test after the intervention are eliminated.^{8,10,12}

The *only after experimental* design type differs of true experiment by not applying test before the intervention in neither groups, in order to avoid effects of the test before on test results after the intervention. Just as in true experiment, there is randomization of participants in experimental and control groups, and the intervention is applied only to the experimental group.^{8,10}

When the researcher wants to handle two or more independent variables at the same time, it should be used *factorial research*

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model. In this design, the subjects are randomly distributed in different experimental groups and different interventions are applied to different groups. This type of application allows to evaluate not only the main effects (resulting from the manipulation of variables), but also the interaction effects, in other words, the combination of different interventions applied. This design evaluate the effect of multiple interventions, both individually and in various combinations.^{2,3}

The *crossed model* is so named “intra subject” for exposing the same subject to different interventions. They are considered experiments only when participants are randomly assigned to receive intervention and subjects act as control to themselves. This kind of design minimizes problems related to differences among the participants in the composition of experiment and control groups. In case of risk of cumulative effect of the intervention, this type of design should not be held.^{2,3,10} Finally, the so-called crossover model determines that different interventions are applied to the experimental groups, distributed in number equal to the number of interventions. After intervention completion in the different groups, it is defined a period called “wash out” to range between interventions. Subsequently, interventions are exchanged between the groups, determining different sequences of treatments.^{10,14}

The advantage of this design is that the subjects act as their own controls, which favors the control of confounding factors that threaten the internal validity of the research. Regarding the disadvantages, there is a long time required for carrying out the study, and therefore it is not suitable for research in acute care unit. In order to occur no interaction between the effects of each intervention, an adequate period of wash out between one of them should be applied.^{10,15}

◆ Features of control and experiment

For the experiment to be conducted properly, it is necessary to build a formal intervention protocol, which will detail the intervention to be applied to the experimental group.

On the other hand, the control must also be strictly fixed, and may be performed among this group: 1) no intervention; 2) an alternative performance of intervention; 3)

use of placebo or pseudo-intervention; 4) condition of attention in control, in which the members of the control group receive the attention of researchers, but not the active component of the intervention; 5) lower dose or less intensity of the intervention or just part of it; or 6) delayed intervention, when the members of the control group are sent to treatment at a future time.³

Another important issue relates to the masking or blinding, in other words, the application participants and members of research team, as well as those responsible for the evaluation of the results should not have knowledge about the distribution of the participants in experimental and control groups. Blinding is considered as important as randomization because it eliminates the confounding generated by co-interventions and reduces bias in the evaluation and allocation of outcomes.¹¹

As for the blinding, the study can be classified as: 1) blind, when participants are unaware of the allocation of subjects in groups; 2) double-blind, when participants and the research team are unaware of the allocation of subjects in groups; 3) triple-blind, when researchers, participants and responsible for analyzing and allocating the results ignore the distribution of subjects in groups;^{2,4} and 4) quad-blind, when in addition to the researchers, participants and members responsible for analysis and allocation of result, responsible for the final draft research report also ignores the allocation of subjects until the text is finalized.²

Blinding, in general, is an aspect difficult to apply for nursing, considering the types of intervention carried out by the professionals.³ The nursing interventions are defined as cognitive, verbal or physical activities with or for the benefit of individuals, families and communities, aimed at achieving a particular therapeutic purpose related to the health or welfare of these. Interventions may be defined as treatments, therapy, procedures or actions taken by health professionals for and with patients in a particular situation, to modify their condition to a desired health outcome that is beneficial to them.⁵

◆ Advantages and disadvantages of the experimental design

The main advantage of the experimental research regarding the observational

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research is the ability to identify cause and effect.^{3,8} For nursing, this is a significant aspect, it provides documentation that allows you to maintain or change the current practice.⁸

Other advantages include: 1) the possibility of accurately evaluate a variable in a group of individuals; 2) prospective design, in which data are collected in subsequent events to the research planning; 3) use of hypothetical-deductive reasoning that seeks to refute the hypothesis of researcher; 4) Potential to prevent bias when comparing two identical groups, except for the intervention; and 5) enables the inclusion of the research in future meta-analysis.⁶

This type of design is relevant for generating high-quality evidence and have the potential to avoid selection bias between experimental and control groups. Stands out security stands in the inference of causal relationships observed due to the use of control, manipulation, comparison and randomization.³

The disadvantage pointed out the impossibility of randomization and manipulation of certain variables, such as disease or health habits. The ethical issue must also be taken into consideration, which involves the manipulation of certain variables and difficulties to perform testing on some health services. It is noteworthy also the possibility of *Hawthorne effect*, i.e. participants' responses are modified only by knowing if participants in a research.^{3,16}

Added to the need to identify all the variables involved in a given phenomenon to conduct an experiment and. Thus, descriptive researches are still needed to identify different aspects in clinical practice, particularly in nursing.⁸

Other disadvantages include the generally high cost to conduct a true experiment, the small number of participants involved in researches and the short follow-up time that can mask the true effect of the intervention performed. It should be considered that surrogate outcomes can be highlighted at the expense of outcomes that are really important for patients.

♦ Quasi-experimental design

The quasi-experimental designs are so called because they did not include all the features of a true experiment, as a complete experimental control is not always

possible, especially concerning the randomization and application of intervention^{3,4,8,12} "Other controlled clinical trials" is another name given to clinical trials where randomization of participants did not occurred.⁶

The results of quasi-experimental researches do not have the same validity as those obtained in real experiments, since the absence of randomization of the subjects in the experiment and control groups cannot guarantee equivalence between the groups at baseline.³

The reasons for performing a quasi-experimental research results from the nature of the independent variable or profile of subjects. It can highlight some reasons for carrying out a quasi-experimental application: 1) there is a widespread view that there are already sufficient evidence of the benefits of certain interventions and establish a control group would be unethical; 2) the implementation of the intervention is already in progress; or 3) assignment to a control group is unacceptable to some subjects that could possibly be assigned to the control group.¹⁷ Thus, quasi-experimental studies may have compromised the internal validity. As a result, the relations of cause and effect have weakened confidence.

In quasi-experiments, the control group is commonly called the comparison group, since it does not meet the randomization requirements and cannot be equivalent to the experimental group.³

♦ Types of quasi-experimental designs

In nursing research are more common the design types: non-equivalent control group, non-equivalent control group only after design, time series stopped with the control group design, time series interrupted with a group design and counterbalanced design.

The *non-equivalent control group* design has the same characteristics of a true experiment, except for the randomization of participants in groups.^{3,12}

In the *non-equivalent control group only after* design it is assumed that the groups are equivalent and comparable before carried out the intervention. Thus, the confidence in the results lies with the robustness of pre-intervention comparison since evaluation is performed in groups only after the intervention.^{3,8,12}

The *time series stopped with the control group* design involves a single group. In this case, the phenomenon of interest is measured over time and at some point, intervention is inserted. The use of an extended period for data collection is to minimize threats to the validity of the data and the purpose of history (time tendency),^{3,8,12} however, in the time series interrupted with a group design, there are the experimental group and the control group. What characterizes this design is that the variable of interest is tested/measured repeatedly over a period of time, and at one moment of the time series the experimental group is exposed to the intervention and control group is not.¹⁰

In *counterbalanced* design, although the subjects were not randomized, all groups were exposed to intervention. It is the Latin square most used, i.e. four different operations are applied to four groups/different individuals. It is carried out post-test after each intervention in all groups/individuals. Importantly, in this design the number of interventions should be equal to the groups/individuals.¹⁰

Advantages and disadvantages of quasi-experimental designs

The advantages of quasi-experimental design fall mainly on its applicability, as a true experiment requires a rigor often impossible to be followed in certain situations in the context of nursing.^{3,12}

The main disadvantage is the reduced potential for widespread, with less conclusive results. Thus, the causal relationship cannot be made as safe way as in the true experiment.^{3,12} The validity of quasi-experimental designs is limited and there is great potential for bias.¹⁵

In this type of study, it is common the presence of competing hypotheses that could explain the results, because besides the intervention applied, other factors may be related to the outcome obtained, which weakens the causal relationship of intervention.³

The schematic representation of the experimental and semi-experimental applications is shown in Fig. 1.

Experimental study designs											
True experiment				Four Solomononic groups				Factorial research			
A	T	I	T	A	T	I	T	A	T	I ₁	T
A	T		T	A	T		T	A	T		I ₂
				A		I	T	A	T	I ₁	I ₂
				A			T	A	T	I ₂	I ₁
								A	T		T
Only After				Crossed				Crossover			
A		I	T	A	T	I ₁	I ₂	A	T	I _E	T
A			T	A	T	I ₂	I ₁	A	T	I _C	T
Quasi-experimental study designs											
Non-equivalent control group				Control group non-equivalent only after				Time series stopped			
NA	T	I	T	NA	I	T		NA	T	T	T
NA	T	I	T	NA	I	T			I	T	T
Time series interrupted with a group						Counterbalanced					
NA	T	T	T	I	T	T	T	NA	I ₁	T	I ₂
NA	T	T	T		T	T	T	NA	I ₂	T	I ₄
								NA	I ₃	T	I ₁
								NA	I ₄	T	I ₃
								NA	I ₁	T	I ₂
								NA	I ₂	T	I ₁

Fig. 1: Schematic representation of the experimental and quasi-experimental study designs.
Legend: NA There is no randomization of subjects. A = Groups/subjects randomly assigned. I = Exposed to intervention. I₁, I₂, I₃... = Exposed to a series of intervention. T = Observation of the group (pre-test and post-test). I_E = Experimental treatment. I_C = Control or reference treatment. W = Period of time that allows the effect of prior treatment to dispose (Wash Out).

♦ Evaluation of experimental and quasi-experimental studies

In order to systematize and improve the quality of the field of health research, standards and guidelines for conception, execution, analysis and interpretation of study designs, have been published by scientists and journal editors in recent decades.

In the case of intervention studies, the Consolidated Standards of Reporting Trials (CONSORT) is the instrument that has been most used and required by renowned journals to assess the validity of the study and applicability of the results obtained, in order to facilitate the full and transparent reporting of randomized controlled trials (RCTs). Therefore, to critically review the design of an intervention study from the CONSORT is obtained strengthen and improve of the conduct, interpretation and evaluation of results.^{18,19}

CONSORT characterizes by a checklist and a flowchart. The main checklist consists of 25 essential items to generate relevant and reliable information on RCT of two parallel groups of individuals, and refer to the content title, abstract, introduction, methods, results, discussion and other information. The most current version is 2010 and replaces 2001 and 1996 versions. All documents are available free of charge and in several languages on the CONSORT website.¹⁹

Thus, the CONSORT constitutes an important tool to improve the quality of reports of RCTs and avoid the omission of possible systematic errors that would compromise the validity and reliability of results to ensure the evaluation of the method and description in detail of the study. Consequently, it makes accurate and transparent design, execution, analysis and research results, contributing to the generation of the best evidence of the effects of interventions in health.

♦ Statistical analysis of experimental and quasi-experimental researches

Statistical analysis of experimental and quasi-experimental researches can be performed in two ways: among participants who underwent intervention by the end of the study and among all participants, regardless of whether they have participated until the end (intention to treat).^{4,6}

The analysis that considers the independent random groups of subjects' behavior during the research may underestimate the total effect of the intervention, but minimizes bias in the results.^{6,11}

Prior to the beginning of the study, should be given the sample size ("power"), i.e. the selected sample should be large enough for statistical significance in relation to the effect of the intervention. The probability of finding a true difference between the groups is known as "power" of the study.^{6,20,21}

The statistical power explores the relationship between four variables involved in statistical inference: sample size (N), significance (α), effect size in the population and statistical power (p-value). α is the probability of rejecting H_0 when it is true (type I error). The power of a statistical test of significance (1-B) is the probability, given the effect size in the population data, significance and sample size, to reject a false H_0 (type II error).^{20,21} Conventionally, is used $B = 0.2$, or 0.8 power. A power of 0.8 results in a ratio of B: α of 4:1 for the two types of risk.²⁰

Sometimes the significance of the null hypothesis test may provide insufficient information to interpretation of results.^{20,22} The p-value in an experimental study reports whether an effect exists or not, but cannot tell the size of the effect.²¹ However, the effect size tells the magnitude of the effect or association between two or more variables, more resistant to the influences of sample size.^{20,22}

One can use the statistical d Cohen to determine the effect size. This evaluates the magnitude of the difference between two or more groups. It must be calculated by the difference of the mean of two groups divided by the standard deviation of the population. To d were agreed values for small sized effect (0.2), medium (0.5) and large (0.8).^{20,22}

An experimental study seeks to identify the effect of a new intervention compared to a standard intervention or the absence of intervention.²³ For continuous outcomes, it is common to evaluate the effect of treatment by t test for two samples, which evaluates the difference between the average outcomes among individuals in the experimental group and the control

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subjects. When data distribution is skewed, not normal or too small, the nonparametric *Mann-Whitney U* test should be the choice,^{5,11,23-27} and the central tendency measure adopted is the median.^{24,25} These tests are very useful in experimental studies to allow evaluation of differences between the experimental and control groups.²⁷

Analysis of variance (ANOVA) should be used when it wants to evaluate the behavior of three or more independent variables; in the case of experimental studies the effects of the intervention on three or more groups. A result with statistical significance tells the investigator that there is difference between the groups, but does not say what the difference is. Thus, further analyzes (*post hoc*) should be conducted in order to identify what are the differences between the evaluated groups.^{5,24,27} In applying the analysis of variance, it is considered the variance within groups and the variance between groups. The variance within groups and between groups explains the total variance.⁵

When the conditions for completion of the analysis of variance are not met, it should be chosen for carrying out the nonparametric *Kruskal-Wallis* (analysis of variance by rank). Evaluates the difference between the presences of three or more independent groups.^{5,28,29} In case of repeated measures (one or more observations per cell), one may perform statistical analysis using the *two-way Friedman* ANOVA.⁵ The null hypothesis is that the samples come from the same population in both tests.⁵

If the outcome is dichotomous, the comparison of proportions between the groups can be made using the chi-square test.¹¹ The chi-square test should be applied when the dependent and independent variables are nominal or ordinal. The chi-square test calculates the expected number of observations in each cell of a table and compares with the actual number obtained. The greater the difference between the expected and observed values, the higher the probability of being identified statistical significance.²⁷

Linear regression analysis is used when it wants to explore the nature of the relationship between two continuous variables. It allows to investigate the change in a variable (response) corresponding to a change in another

variable (explanatory). Thus, it becomes possible to estimate the value of a response associated with a given value of the explanatory variable.²⁴ When studying an independent variable, it should decide for the simple linear regression. Already multiple regression analysis should be used if there is multiple independent variables.^{24,27} Multiple regression allows investigating the relationship among a group of different variables.²⁴

Multiple regression allows to investigate: 1) the degree of relationship between variables; 2) how relatively important are the predictor variables in explaining the dependent variable; 3) The influence of the addition of one or more variables in the equation resulting in increased multiple correlation; 4) the behavior of an independent variable in another context variable; 5) linear or non-linear relationship between the dependent and independent variables; 6) the prediction of the dependent variable from the comparison between non-identical sets of independent variables; 7) the estimated values of the dependent variable for subjects of a future sample; and 8) causal relationships between variables (path analysis or structural equation in special cases).³⁰

In multiple regression analysis type stepwise, the inclusion or exclusion of the following predictors in the equation is made statistically. It can be performed in three ways: each predictor is added progressively (forward); predictors are all initially included and excluded one by one (backward); or predictors are included in the equation blocks (block wise).³⁰

The Pearson correlation coefficient measures the linear relationship between two variables, pointing its magnitude (strength) and direction (positive or same direction, or negative meaning opposite directions). A non-parametric alternative is the Spearman correlation coefficient in which the data are arranged in positions in both groups and subsequently evaluated the relationship between them.^{3,5,8,24} This option is valid when the assumptions of the Pearson correlation coefficient are not verified or when the data are nominal or ordinal.⁸

The tests most commonly used in experimental studies are presented in Figure 2.^{6,24}

Apply in the study design phase		
Effect size (<i>d</i> Cohen)	It must be calculated during the research planning in order to determine the sample size required for the study has the desired statistical power.	
Apply in evaluating of the results		
Parametric test	Non-parametric test	Test objective
-----	Chi-square test	Test the null hypothesis that the proportion of a given variable in two or more independent samples is the same.
---	McNemar Test	Test the null hypothesis in a paired sample of the estimated proportions are equal.
t test with two independent samples	Mann-Whitney U test	Comparison of two independent samples of the same population.
t test with one sample (paired)	Wilcoxon test	Test the null hypothesis that between two measurements the average difference is zero, comparing two sets of observations in a single sample.
Analysis of variance (ANOVA): F test	Analysis of variance (ANOVA) by rank: Kruskall-Wallis test	Compares three or more sets of observations carried out on a sample. Tests the influence and interaction between two different covariates.
Simple linear regression	---	It shows whether there is relationship between two quantitative variables, indicating a predictive value from another.
Multiple regression	---	It shows whether there is relationship between a dependent variable and two or more predictor variables.
Pearson Correlation Coefficient	Spearman Correlation Coefficient	Evaluates the correlation between two variables.

Figure 2. Statistical tests that can be applied to experimental studies.

In experimental studies with dichotomous outcomes, other measures may also be used to compare the results identified in the intervention and control groups. They are measures that can estimate the size of the difference in an outcome in groups submitted to different interventions.

It can be estimated the size of the treatment effect. One way to obtain this estimate is through Absolute Risk Reduction (ARR), which corresponds to the difference in risk between the control (Rc) and the intervention group (RI). ARR is expressed by the formula $ARR = Rc - RI$. Another way is by means of Relative Risk (RR), which refers to the ratio between the risk of the intervention and the risk group in the

control group. In this case, the RR is obtained by the formula $RR = RI/RC$.⁴

It can also perform this analysis by Risk Relative Reduction (RRR), which is the reduction of events in the intervention group (RI) compared to controls (RC), which is represented by the formula $RRR = 1 - RI/RC \times 100\%$ or $RRR = (1-RR) \times 100\%$.⁴

Another assessment that can be made is the number needed to treat (NNT), which expresses the inverse of the absolute risk reduction, i.e. it refers to the number of patients to be treated aiming at preventing the occurrence of additional adverse event. NTT is expressed by the formula $NNT = 1/RAR$ or $NNT = 1/(RC - RI)$.⁴

The Odds Ratio, it is a proportionality measured association type obtained by the

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ratio between the cross-product distributions of table cells 2x2. Thus, in the case of rare events of interest, the OR has the property of approaching the RR. It is represented by the formula $OR = a.d/b.c$.⁴

It emphasizes the importance of follow-up duration in the research because the intervention should be measured by time sufficiently able to identify the effect of the intervention on the outcome of interest.⁶

♦ **Intervention studies and implications for nursing**

Nursing interventions can be defined as: 1) a single act (application of heat or cold); 2) a series of actions in a given moment in time (answers to the family on the birth of a baby); 3) a series of actions over time (implementation of a protocol of care for a newly diagnosed patient with hypertension); or 4) a series of actions developed collaboratively with other health professionals (conduct a membership program to healthy food in a community).⁵

Some nursing interventions can also be directed to health professionals (permanent/continuing education), the environment (changes in the nursing team composition) or in the care (change in the care model).⁵

Some objectives of the interventions include risk reduction, prevention, treatment, resolution or management of a health problem. Some interventions have multiple objectives and multiple outcomes. The desirable outcome can vary according to the desired purpose and may include absence, solving and successful management of the problem or non-developing of complications.⁵

There are variations on nursing interventions between and among nursing, including terminology and operationalization. Actually, a same intervention can be differently applied by the same nurse each time. Concerning different nurses, there is even less consistency. The lack of clarity about how an intervention should be applied highlights the importance and the need to conduct intervention studies in nursing in different clinical settings.⁵

The true experiment is based on the positivist logical, which strategy is accumulating facts to discover laws.^{5,13} Because nursing philosophy and theoretical basis are not consistent with this approach,

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few researchers in nursing hold this perspective.

Human studies require changes in the design, which weakens the power of design and threatens its validity.¹³

The needs of individuals, the difficulties of recruiting a sufficient number of subjects, in addition to differences in comorbidities, access to health services and support, education, among others complicates the activity of constructing equivalent groups. Another problem occurs when health workers, family members or others than the researcher, are responsible for implementing the intervention. The intervention itself must sometimes be adjusted to meet the demands of the participants or the usual treatment has variations, which can compromise the comparison of results. It added to the time required to manifest certain outcomes, which can make long the observation period, or the measure of an intermediary outcome is mandatory and often questionable in some situations.⁵

CONCLUSION

The designs of experimental and quasi-experimental researches are the most appropriate when studying a relationship of cause and effect. Due to the characteristics of the interventions carried out in Nursing field it is much more usual to carry out quasi-experimental research in the area.

The relevance of this research design is based on the assessment of the evidence produced and the possibility of wide application in clinical practice. It emphasizes the need for greater investment in experimental research and quasi-experimental research in Nursing.

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