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REVISIONES

Evaluation of randomized clinical essays developed by nurses according to the consort declaration criteria

Evaluación de los Ensayos Clínicos Aleatorios desarrollados por enfermeras según los criterios de la Declaración CONSORT

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ABSTRACT:

Objective: Evaluate if the Randomized Clinical Trials (RCTs) carried out by nurses in the last seven years fulfill the methodological rigor established by the CONSORT declaration criteria.
Methods: Nursing journals literature integral review; sixty-six RCTs carried out by nurses and published in 11 indexed journals within recognized data bases were analyzed and where their title, key words or design allowed them to be recognized as a randomized clinical essay. A 48 item instrument was realized to evaluate the characteristics of the 66 published RCTs. Such instrument is divides in two segments: the first one evaluates general information in the articles, and the second one includes the CONSORT Declaration characteristics.
Results: The 57.6% of RCTs used an equivalent control group, 87.9% used randomized sampling, 28.8% blind, 54.5% presented flow chart, groups.
Conclusions: In general, the RCTs published by nursing in the last seven years do not fulfill the CONSORT Declaration criteria. These findings present an opportunity area so nursing journals publishers request from the authors the most attachment to the methodological rigor in their articles, according to the CONSORT Declaration criteria.

Keywords: Evaluation; Clinical Trial; Nursing Research.

RESUMEN:
Objetivo: Evaluar si los Ensayos Clínicos Aleatorizados (ECAS) realizados por enfermeras en los últimos siete años, cumplen con la rigurosidad metodológica establecida por los criterios de la Declaración CONSORT.
Métodos: Revisión integrativa de la literatura de revistas de enfermería, se analizaron 66 ECAS realizados por enfermeras y publicados en 11 revistas indizadas en bases de datos reconocidas, en cuyo título, palabras clave o diseño se reconocieran como un ensayo clínico aleatorio. Se realizó un instrumento de 48 ítems para evaluar las características de los 66 ECAS publicados. Dicho instrumento está dividido en dos segmentos: el primero evalúa información general de los artículos y el segundo incluye las características de la Declaración CONSORT.
Resultados: El 57.6% de los ECAS utilizaron grupo control equivalente, 87.9% utilizó muestreo aleatorio, 28.8% enmascaramiento, 54.5% presentaron diagrama de flujo, 83% realizaron aleatorización, 57.6% describen las intervenciones empleadas a los grupos de estudio.
Conclusiones: De forma general, los ECAS publicados por enfermería en los últimos siete años no cumplen con los criterios de la Declaración CONSORT. Estos hallazgos representan un área de oportunidad para que editores de revistas de enfermería soliciten a los autores mayor apego a la rigurosidad metodológica en sus artículos de acuerdo a los criterios de la Declaración CONSORT.

Palabras clave: Evaluación; Ensayo Clínico; Investigación en Enfermería.

INTRODUCTION

Randomized clinical trials (RCTs) are controlled experiments that regularly are used to evaluate treatment or interventions security and efficiency[1]. Well designed and correctly executed, RCTs provide the best evidence of the sanitary interventions effect[2]. However, the methodological rigor in executing a controlled experiment with parallel groups is not always performed. Diverse groups of researchers have interested on identifying which are the systematic procedures to carry on this experimentation and on obtaining reliable results and perform replicas in other contexts or populations[3]. Scientific studies quality evaluation can be considered as essential to the production process and the health scientific literature selection[4]. The most representative guide, Consolidated Norms for Clinical Essays Publications (CONSORT), was published in 1996 aiming to unify criteria to publish RCTs. CONSORT Declaration criteria have been constantly modified to polish design methodological details and procedures through a check list and a flow chart. The list has 25 specific items to communicate results or evaluate reports about RCTs of two or more parallel groups[5,6].

Regarding the published literature, there is no recent work evaluating if the RCTs carried out in certain disciplines fulfill the CONSORT Declaration criteria; it seems it is implied that the published essays have been evaluated by an editorial committee based on the CONSORT criteria. The evaluation performed to the essays published in the Revista Española de Anestesiología y Reanimación (Spaniard Journal on Anesthesiology and Re-animation) concluded on the lack of relevant data about the essays performance as well as a low methodological quality according to the actual criteria[7]; similar results report that the evaluation of RCTs published in Chile bio-medical journals have serious deficiencies but it is difficult to know if those inconsistencies are due to incomplete reports or to poor methodological designs.[8]

The presence of these methodological weaknesses is well known by the scientific journals editors, who point out that RCTs biases limit the available information and condition knowledge, affecting particularly to evidence-based medicine.[9]

In the case of the Nursing Science, RCTs represent one of the best scientific evidence for better caring procedures in communities, families, hospitals and independent

practice as well.[10,11] Nursing publications with an experimental design, however, are minimum, so it is appropriate them would be evaluated with the rigor stated by the CONSORT declaration criteria.

There are no published works evaluating the RCTs developed by nursing; a study carried out the analysis of 358 nursing studies published in Mexican journals and identified that 14% of the published articles designs are experimental. The authors don't specify the methodological characteristics of this 14% nor tell if they are RCTs, only point out methodological weaknesses in general like no randomized sampling, small samples, instruments which reliability is unknown and statistical tests wrongly employed.[12]

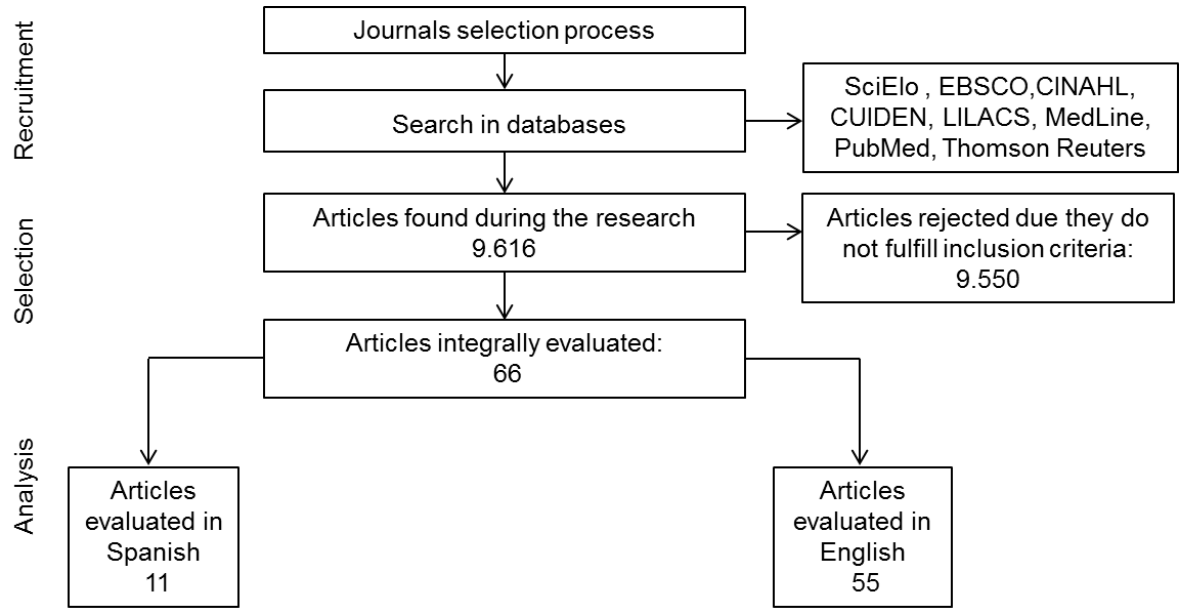
At the face of the evidence published actually, the following purpose may be stated: To evaluate if the RCTs performed by nurses in the last seven years fulfill the methodological rigor established by the CONSORT declaration criteria.

METHODOLOGY

This is an integral review of the nursing journals literature through the virtual library in the Meritorious Autonomous University of Puebla. The searching criteria were as follows: indexed journals (in databases SciElo, EBSCO, CINAHL, CUIDEN, LILACS, Medline, PubMed and Thomson Reuters), research articles published from 2008 first semester to 2014 second semester; in Spanish, English and Portuguese languages; articles which title, key words or design allow them to be recognized as a randomized clinical essay.

Eighty seven journals were analyzed in the determined period. Results rendered 9616 articles from which 66 researches were selected as they fulfill the inclusion criteria; they were located in 11 journals. To notice the selection criteria, go to Figure 1.

Figure 1. Selection process flow chart



A 48 item instrument was carried out to evaluate the characteristics of the 66 RCTs published. Such instrument is divided in two segments: the first one evaluated the articles general information (six items) and the second includes the CONSORT Declaration characteristics. The instrument was pilot tested and the final review was performed within a 90 days period. Each articles was reviewed twice by different researchers to compare results and diminish biases. This procedure was done by the complete reading of the articles, focusing attention on the reagents the instrument evaluated.

Ethical considerations. This work protocol and procedures were evaluated for its registry in the Pre-Grade Investigation Coordination of the Meritorious Autonomous University of Puebla, Mexico under the reference number A-2015-0111-CIP. Statistical analysis. The results analysis was performed with descriptive statistics (frequencies and percentages) through de SPSS program, version 21.

RESULTS

Sixty six nursing RCTs published within the 2008 to 2014 in indexed journals in Spanish and English were analyzed. Those analyzed RCTs came from Spain (6), Colombia (3), México (3), Brazil (2), Turkey (2), USA (30), South Korea (2), Australia (2), Iran (6), China (2), Canada (1), Portugal (1), Netherlands (1) and some that don't specify their origin (5).

The descriptive findings were: 34 RCTs (51.5%) present a nursing sciences PhD as first author; an MD for 13 RCTs (19.7%), one publication for each a specialist and a graduate (1.5% respectively), while 17 RCTs (25.7%) mention nothing about it.

Places where RCTs were performed show that 38 (57.6%) come from universities, 22 (33.3%) from health institutions, while the remaining 6 (9%) are divided from research clinics and institutes. Regarding collaboration, 25 RCTs (37.9%) are multidisciplinary, and the rest are performed exclusively by nursing professionals.

The main theme prevalent was clinic in 46 RCTs (69.7%), education in 17 RCTs (25.8%), and the family theme among other themes in 3 RCTs (4.5%).

The findings regarding the CONSORT Declaration criteria are shown in the following table.

Table 1. Criteria results: CONSORT Declaration. Puebla, México, 2014.

CONSORT Declaration Criteria			
Section		**Results**	
		fr	**%**
Clinical essay identification in the title	Yes	28	42.4
	Not	38	57.6
IMRyD Format	Yes	51	77.3
	Not	15	27.7
Related background or studies	Yes	64	97
	Not	2	3
Objectives	Yes	60	90.9
	Not	40	9.1
Researching purpose	Yes	60	9.1
	Not	40	90.9
Design type (parallel, factorial or Pharmacologica)	Yes	15	22.7
	Not	51	77.3
Changes after initiating the essay	Yes	5	7.6
	Not	61	92.4
Interventions detailed	Yes	50	75.8
	Not	16	24.2
Answer variables identified	Yes	54	81.8
	Not	12	18.2
Sample size calculated	Yes	6	9.1
	Not	60	90.1
Intermediate measurement of variables	Yes	22	33.3
	Not	44	66.7
Mechanism for implementing the randomized selection sequence	Yes	14	21.2
	Not	52	78.8
Statistics analysis	PS*	13	19.7
	NPS†	3	4.5
	PS/NPS‡	15	22.7
	MVS§	24	36.4
	DS¶	11	16
Additional analysis (subgroups and adjusted)	Yes	55	83.3
	Not	11	16.7
Flow chart with number of participants for each group	Yes	31	47
	Not	35	53
Mention the number of excluded participants	Yes	31	47
	Not	35	53

Mention recruitment dates and follow-up of participants	Yes Not	29 57	43.9 56.1
Indicate external cause for ending or interrupting the study	Yes Not	39 27	59.1 40.9
Include socio-demographic and clinical data about the study population	Yes Not	53 13	80.3 19.7
Detail the number of participants in each analysis	Yes Not	53 13	80.3 19.7
Mention results for the control and intervention groups	Yes Not	56 10	84.8 15.2
Mention Confidence Intervals ≥95%	Yes Not	56 10	84.8 15.2
Calculate the size of absolute effect	Yes Not	17 49	25.8 74.2
Calculate the size of relative effect	Yes Not	4 62	6.1 93.9
Show results of another analysis	Yes Not	4 62	6.1 93.9
Indicate there have provoke harm or damage to the study participants	Yes Not	27 39	40.9 59.1
Point out the study limitations	Yes Not	10 56	15.2 84.8
Mention the possibility to generalize their study results (extreme validity)	Yes Not	45 21	68.2 31.8
Apply an interpretation consistent with their results	Yes Not	34 32	51.5 48.5
Present a registry number	Yes Not	49 17	74.2 25.8
Present a registry number from an ethics committee	Yes Not	13 53	19.7 80.3
Mention the informed consent	Yes Not	42 24	84 16
Mention a pilot-test	Yes Not	16 50	24.2 75.8
Were financed	Yes Not	9 57	13.6 86.4

IMRyD Format= Introduction, Methodology, Results, and Discussion
PS*= Parametric statistics; NPS†=Non Parametric statistics; PS/NPS‡= Parametric statistics/non parametric statistics; MVS§= Multivariate statistics; DS¶= Descriptive statistics.

Table II. Main characteristics of the Randomized Clinical Essays analyzed. Puebla, México, 2014

Characteristics	Fulfilled		Not-fulfilled	
	%	fx	%	fx
Randomization	89.3%	59	10.6%	7
Parallel groups	83.3%	55	16.7%	11
Control group(s) interventions description	57.6%	38	42.4%	28
Blind	28.8%	19	71.2%	47
Flow chart	54.5%	36	45.5%	30

DISCUSSION

General characteristics of the study

The present study aimed to evaluate if the RCTs performed by nurses in the last seven years fulfill the methodological rigor established by the CONSORT Declaration criteria.

Authorship. Half of the RCTs analyzed have as first author a doctor in sciences, which is congruent due the upbringing of this academic degree, which main objective is facilitate the transition from knowledge to practice through variables manipulation. [13]

Themes. The prevalent theme was clinic; is seems logic to think that this type of design has more feasibility in hospitals than in community or family interventions. This finding is similar to that reported by García Rodríguez[12] where the most used variables were clinical type, indicating that the evaluations included in RCTs have a clear interest and repercussion on the hospital environment patients.[14] However, a larger presence is required specially in indexed journals publication and with a good impact factor, since RCTs publications by nurses are scarce, and the figure of the nurse in clinical essays is not clearly described and remains as an unknown entity for most of the professionals working in a hospital.[11]

Researchers. Most of the RCTs in this study do not include other disciplines different from nursing; the figures coincide with the findings of García Rodríguez, where the minority of articles show no multi-disciplinary collaboration, but the situation is similar in other disciplines.[7,8] In this sense we believe that to afford the study problems in RCTs, researchers necessarily must pertain to diverse disciplines that might contribute to clarify the research phenomenon.

Title and Abstract. Most of the evaluated works didn't facilitate the search since in the title and abstract they could be identified as a randomized clinical essay as is set out by the CONSORT Declaration. However, they could be included because in the methodological section were mentioned as RCTs. If you wish to make a systematic review or meta-analysis of a particular theme that had been approached as a randomized clinical essay, the simple situation of not mention this in the title could be an exclusion motive, even though the RCE is well structured.

Background. One of the guidelines evaluated in any research work is the reference to previous studies and in our evaluation, most of the articles do so; it is clear that the articles that don't show background in their research lack the power to make neutral conjectures when comparing their parallel groups and thus in these articles the results

don't give the certainty that the interventions or treatments are reliable; situations that can be notice not only in nursing discipline but is well known in the published reports in other types of journals.[9]

*Pilot test.*Just a minority RCTs report applying a pilot test, which is backed by the García Rodríguez and Abeille Mora's report where most of the experimental studies don't express a previous training or omit it,[12,15] however, this result must be considered with reserve because is possible that the pilot test was not necessary due the instruments have already been validated with previous studies or the researchers are experts and they simply didn't mention it.

Financing. In the case of financing (equipment or material), most RCTs didn't specify their financing source.[7] This situation allows for subjectivity, possibly they are researches which are financed by the researchers themselves; anyhow, the budget line is not clear.

Methodological aspects.

Participants selection. Most of the analyzed articles present selection criteria, diminishing confounding variables. However, in a bit more than the half of the sample, the elimination criteria are not mentioned, coinciding with the scores performed by Gonzalez Barahona[16] who mentions that not detail exclusion criteria represents a bias that influences the results external validity.

Equivalence and randomization. More than half of the analyzed RCTs show the basal-demographic characteristics and these results accord with Manriquez' report[8] about 66 RCTs where 80.3% clearly informed on the demographic characteristics; this fact facilitates locating if the groups are equivalent, apparently showing a correct randomization. In our evaluation, however, most of the RCTs don't mention the method used to generate the randomized designation sequence and they don't guarantee knowing if the groups are equivalent. This results are similar to García Alamino's report[7] where he mentions that the exposition to treatment or interventions maybe were not comparable.

Interventions. Most of the analyzed RCTs detail the interventions and specify they have a response variable after the intervention; this allows to know which were the changes from the statistic point of view were obtained. Other similar studies, however, found that in the analyzed studies the process and the analysis were not detailed.[7,8]

Sample size. It has been evident now that most works don't clarify the method to calculate the sample size[8] such is the case of our study; this situation diminishes the statistical power and may lead to a wrong conclusion that there are no differences between parallel groups and highlighting the type I or alpha error. Since a small sample size gives reliable answers to the stated questions or the study hypothesis that need to be proven. On the other hand a large sample size may make the study hard to handle, waste much time and effort and is essential for producing useful research results.[17]

The principal variable measurements number. Most RCTs didn't carry out an intermediate measurement of the variables, since most of them were designed under a test re-test model. It would be important to have a comparison between each one of these variables in order to observe the phenomenon evolution, have more control over

the variable being manipulated and watch for changes as they evolve; but this depends on several facts, both the study design and the financing to carry out repeated measurements model.

Blind. In experiments, the blind or masked interventions are important to avoid biases and make more accurate comparisons. In our review most of the RCTs don't mention blind, and as a consequence it is possible that comparisons between parallel groups are, deliberately or unwittingly, impartial inducing a sample contamination that involves a bias in the final analysis; this agrees with Manriquez and Flores Pineda,[14] who found that the way the studies participants were masked is not clearly specified.

Flow chart. The study progression was not schematically showed in more than half of the researchers. As is mentioned in the CONSORT Declaration, show it allows to observe the way in which the sample wears through the subjects loss in order to keep the statistical power, or if there was intention of treatment, or to understand the results analysis. The reviewed literature does not make evident the evaluation of this parameter from the CONSORT in the analysis of RCTs in other studies.

Ethics considerations. More than half of the RCTs evaluated don't mention having used a written informed consent. Getting a signed paper, however, is not a guarantee that the participant has understand the research objectives;[19] this situation could give the RCE more credibility if the protocol had been registered and evaluated by an ethics committee, since this committee's responsibility is to assure the rights, security, and welfare of the possible participants in the essay;[18] most of the evaluated works, however, don't mention such a registry and this situation must be required by journals specially in this kind of designs.

Limitations. Most of the evaluated essays don't mention the limitations occurred during their development; without these data, carrying out improved replicas of protocols is not allowed, since some factors acting as impediment and reduce the clinical applicability of the study might be allowed to be established.[19]

CONCLUSION

In a general form, the RCTs published by nursing in the last seven years don't fulfill the CONSORT Declaration criteria. The results might be considered as methodological limitations in design and statistics that contribute nothing to present a reliable evidence.

This must be considered just now that the nursing work with experimental designs is recent. If the RCTs are performed with the pertinent statistical reliability and with quality in their procedures, they might represent a clear scientific evidence in the future of nursing interventions.

This findings represent an opportunity area for nursing journals editors to require from the authors more adherence to the methodological rigor in their articles according to the CONSORT declaration criteria.

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