Application of the Consolidated Standards of Reporting Trials (CONSORT) Statement Guideline in Nursing Studies: Analytical Review

تطبيق دليل المعايير التوجيهية الموحدة للإبلاغ عن التجارب السريرية في الدراسات التمريضية: مراجعة تحليلية

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الخلاصة:

خلفية البحث: تعتبر التجارب العشوائية المسيطر عليها (RCT)، والتي تسمى أيضا بالتجارب السريرية العشوائية، المصادر الأكثر شهره للأدلة والتي توفر أفضل دليل لفعالية التدخلات التمريضية اثناء فترة الممارسة القائمة على الأدلة (EBP)، ومع ذلك، في الأدبيات التمريضية، لم يتم تقييم جودة الإبلاغ عن التجارب العشوائية المنضبطة وكانت التحديات العملية و المفهومية لحركة التمريض القائم على الادلة. إن الأدلة العلمية المحدودة المتاحة حول فعالية العديد من ممارسات التمريض هي أحد الشواغل الخطيرة. تطلب الممارسة القائمة على الادلة أن يتم توليف أدلة الدراسة من التجارب السريرية العشوائية وغيرها من أشكال دراسات التداخل التي لا تزال محدودة في التمريض. من ناحية أخرى، التقييمات الشاملة والتحليلات الوصفية والمراجعات المنهجية التي يتم إجراؤها في ابحاث التمريض هي أيضا محدودة بالمقارنة مع التخصصات الأخرى، مثل علم النفس والطب وقد تكاد ان تكون منعدمة.

الاهداف: تهدف هذه المراجعة التحليلية إلى تطبيق إعلان بيان المعايير الموحدة للإبلاغ عن التجارب (CONSORT) على الابحاث التمريضية، ومدى ملائمة التقارير المنشورة بالتزامها بالبيان وكيف يتأثر محتوى التجارب العشوائية المسيطر عليها باعتماد CONSORT على جودة الإبلاغ التجارب العشوائية المسيطر عليها.

المنهجية: تمت مراجعة للأدب استنادا إلى دراسات ومراجعات سابقة مستمدة من ناشرين دوليين مثل قواعد بيانات (Scopus, PubMed, Medline) المتعلقة بالمبادئ التوجيهية الموحدة للمعايير الموحدة للإبلاغ عن التجارب (CONSORT). وقد تم جمع البيانات في الفترة من 24 / تشرين الثاني / 2020 إلى 10 / شباط / 2021. كما استخدمت كلمات رئيسية مثل CONSORT، ودراسات التمريض، والممارسة القائمة على الأدلة، وممارسة التمريض القائمة على الأدلة، والتجارب عشوائية منضبطة، فضلا عن المقالات التي نشرتها المكتبة الوطنية للطب، والتي قدمت بيانات صحيحة وموثقة من البحوث العالمية وعلم الأوبئة. تم جمع هذه الدراسات وتصفيتها وفقًا لمعايير محددة.

النتائج: استنتجت الدراسة ان ممارسة التمريض القائمة على الأدلة تستند الى أدلة قوية على افتراض ان التمريض (قائم على العلم) في رعاية المرضى وينبغي دعمه بأدلة سليمة، من المهم ان يستخدم أخصائيو التمريض بيان consort لمراجعة ونشر واستخدام تقاريرهم عن التمريض السريري وجمع افضل الأدلة لدعم ممارساتهم التمريضية السريرية وصنع القرار.

الاستنتاج: ان ممارسة التمريض القائمة على الأدلة (EBNP) تستند إلى أدلة قوية على أن افتراض أن رعاية المرضى يمكن دعمها بأدلة سليمة، ومن المهم أن يستخدم أخصائيو التمريض بيان CONSORT لمراجعة ونشر واستخدام التقارير حول التقنيات السريرية التمريضية وجمع أفضل الأدلة لإبلاغ ممارستهم السريرية للاستخدام وصنع القرار.

التوصيات: لتحسين جودة الإبلاغ عن التجارب السريرة في دراسات التمريض، يجب على الباحثين استشارة المشرفين وخبراء الإحصاء الحيوي في وقت مبكر عند صياغة بروتوكول الدراسة. تحديد النتائج الأولية والثانوية مسبقا، ويفضل أن يكون ذلك في بروتوكول منشور. استخدم قوائم مرجعية كافية للإبلاغ، مثل المعايير الموحدة لتجارب الإبلاغ، وتعزيز الإبلاغ عن الدراسات الرصدية في علم الأوبئة (STROBE).

الكلمات المفتاحية: بيان CONSORT، دليل، دراسات التمريض، ممارسات التمريض القائم على الأدلة.

ABSTRACT:

Background: Randomized Controlled Trials (RCTs), also called randomized clinical trials, are regarded as the most reputable source of evidence that provides the best guide of the effectiveness of nursing interventions during the Evidence-Based Practice (EBP) period and, however, yet in the nursing literature, has not been evaluated the quality of reporting RCT. Practical and conceptual challenges to the EBP nursing movement have been. The limited available scientific evidence on the efficacy of many nursing practices is one of the serious concerns. EBP requests that study evidence from RCTs and other forms of intervention studies that are still limited in nursing be synthesized. On the other hand, comprehensive evaluations, meta-analyses, and systematic reviews that are performed in nursing are also that limited when compared to other disciplines, such as psychology and medicine.

Aims of the study: The study aimed at applying the declaration of the Consolidated Standards of Reporting Trials (CONSORT) statement to nursing and healthcare provider studies and adequacy of the published reports adhere to the statement and how the content of the published RCTs is being influenced by the adoption of CONSORT on the quality of reporting RCT.

Methodology: Analytical review of literature based on previous studies and reviews derived from international publishers such as (Scopus, PubMed, and Medline) databases concerning Consolidated Standards of Reporting Trials (CONSORT) Statement Guideline. The collection of data was conducted from 24 November 2020 to 10 February 2021. These studies were collected and filtered according to the specific criteria. Also, was used keywords such as CONSORT, nursing studies, evidence-based practice, evidence-based nursing practice, randomized controlled trial, as well as the articles by the National Library of Medicine, which provided valid and documented data from global research and epidemiology.

Conclusion: Evidence-based practice (EBP) is rooted in solid evidence that the assumption (science-based nursing) in patient care should be supported by sound evidence. It is important that nursing professionals use the CONSORT statement to review, publish, and utilize their reports of nursing clinical and gather the best evidence to support their clinical practice of use and their decision-making.

Recommendations: The authors should consult supervisors and biostatisticians experts early when formulating the study and analysis protocol to improve the quality of reporting the trials in nursing studies. Determine primary and secondary outcomes in advance, preferably in a published protocol. Use adequate checklists reporting, e.g., Consolidated Standards of Reporting Trials (CONSORT), Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).
Keywords: CONSORT statement, Guideline, Nursing Studies, Evidence-based nursing.

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INTRODUCTION

Evidence-based practice: Scientific research indicates that advancement in evidence-based nursing has strengthened health care systems and outcomes. The experts agree that nurses worldwide should play a major role in building such evidence to accelerate its implementation through working with interdisciplinary health care teams [(1)].

David Sackett and colleagues at McMaster University in Ontario coined the term evidence-based practice (EBP) in the early 1990s [(2)] and was popularized and can be defined as Integration of the best research evidence with clinical expertise and patient and/or family preferences and values in the delivery of quality, safe, and cost-effective health care [(3)].

From a nursing perspective, Scott and McSherry's (2009) and Melnyk and his colleagues (2010), as well as the Honor Society of Nursing and Sigma Theta Tau International (STTI), supports the publish of knowledge to enhance practice in nursing that defined evidence-based practice in a way that is specific to nursing. A patient advocate is one of the roles that are exclusive to nurses. Therefore evidence-based nursing (EBN) is described as an integration of the strongest available evidence, nursing expertise, and the values and preferences of the individuals, families, and communities who are served [(2, 4)].

To improve the comprehension of the evidence-based nursing practice (EBNP), the advantage and challenges of EBP are identified. A framework is provided for developing clinical questions that can guide research-based evidence that can be used in practice. Important benefits of evidence-based practice are enhanced patient and family outcomes, nursing agencies, patients, and healthcare agencies [(5, 6)].

Why should we be so interested in using evidence in nursing practice? Haven't we always sought for the best evidence and used it when looking for answers to clinical questions? Unfortunately, we have not [(7)].

The natural next question is what is evidence that should be interpreted into practice? In the United States, in a text published in (USPSTF, 1989) [(13)], the U.S. Preventive Services Task Force (USPSTF/Task Force) classifies the evidence quality as follows:

Level I: Evidence obtained from at least one properly designed randomized controlled trial (e.g., large multi-site randomized controlled trial).

Level II-1: Evidence obtained from well-designed controlled trials without randomization (e.g., quasi-experimental).

Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

Level II-3: Evidence obtained from multiple time series with or without intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence.

Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Thus, much of the evidence that it is used as healthcare providers' guides should be coming from randomized control studies and little evidence from the expert committees and opinion of authorities. (USPSTF/Task Force) represents one of the initiatives to strengthen the use of professional practice standards by governmental and/national organizations to include

the medical experts and other stakeholder groups and enhance the scientific foundation and their abilities. Guidelines established through studies rather than that depend on theory and expertise are much more likely to follow empirical findings than evidence supported by theory and knowledge. Efforts are made to integrate the intensity of quality of evidence recommendations, to help make that link explicit and transparent, and to ensure that the review of evidence is objective, comprehensive, and attentive to the quality of nursing studies [14].

AIM OF THE STUDY

To move up the implementation of evidence-based practice in nursing studies and healthcare provider studies. To apply CONSORT statement to the reports published on the science of nursing.

METHODLOGY

Analytical review of literatures based on previous studies and reviews derived from international publishers such as (Scopus, PubMed, and Medline) databases concerning Consolidated Standards of Reporting Trials (CONSORT) Statement Guideline. Data collection was conducted from 24 November 2020 to 10 February 2021. These studies were collected and filtered according to the specific criteria. Also, was used keywords such as CONSORT, nursing studies, evidence-based practice, evidence-based nursing practice, randomized controlled trial, as well as the articles by the National Library of Medicine, which provided valid and documented data from global research and epidemiology.

RESULTS:

Table (1): CONSORT statement checklist of information should be included in reporting a randomized trial*

Section/Topic	Item No.	Checklist item
Title and abstract		
	1a	Identification as a randomized trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)
Introduction		
Background and objectives	2a	Scientific background and explanation of the rationale
	2b	Specific objectives or hypotheses
Methods		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
	6a	Completely defined pre-specified primary and secondary outcome

Outcomes		measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
Randomization		
Sequence generation	8a	The method used to generate the random allocation sequence.
	8b	Type of randomization; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	The mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions.
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes), and how
	11b	If relevant, a description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses
Results		
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned received intended treatment and were analyzed for the primary outcome
	13b	For each group, losses, and exclusions after randomization, together with reasons
Recruitment	14a	Dates defining the periods of recruitment and follow-up
	14b	Why the trial ended or was stopped
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
Numbers analyzed	16	For each group, the number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary	18	Results of any other analyses performed, including subgroup analyses

analyses		and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19	All-important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
Discussion		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, the multiplicity of analyses
Generalizability	21	Generalizability (external validity, applicability) of the trial findings
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
Important information		
Registration	23	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available
Funding	25	Sources of funding and other support (such as the supply of drugs), the role of funders

*Strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, recommend reading CONSORT extensions for randomized cluster trials, no inferiority and equivalence trials, no pharmacologic treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: For those and for up-to-date references relevant to this checklist, see www.consort-statement.org.

Table 1 shows the CONSORT statement that used globally to improve the reporting of randomized controlled trials (20). It is a protocol created by a community of researchers to detect, record, and explain problems that serve the additional purpose of informing, helping in the readability of study trials, allowing outcomes to be detected and assessed comprehensively (21). The CONSORT statement, published in 1996, spurred partly by methodological research and revised in 2010, is consisted of 25 items in the checklist form (Table 1)

Figure (1): the progress through the phases of a parallel randomized trial of two groups (that is, enrolment, intervention allocation, follow-up, and data analysis).

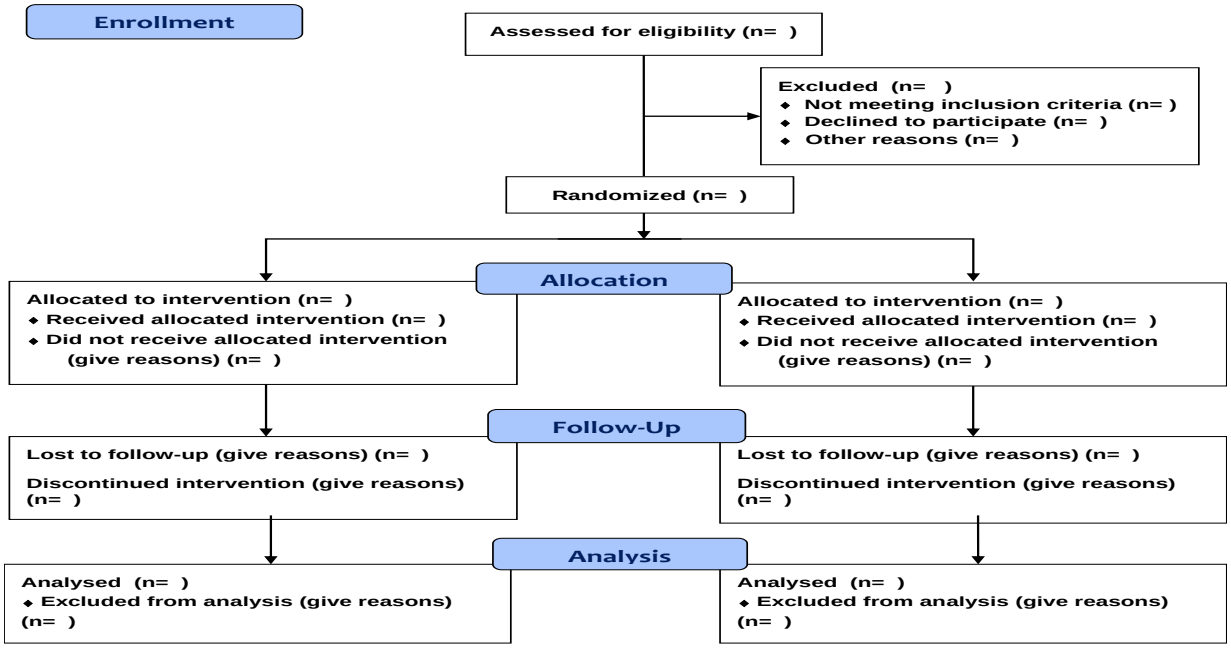

Figure (1) Flow chart of the progress through the phases of a parallel randomized trial of two groups (that is, enrolment, intervention allocation, follow-up, and data analysis) and available at: http://www.consort-statement.org/consort-statement/flow-diagram.

Figure 1 shows the checklist, reporting registration, assignment, follow-up, and analysis of patients participating in the RCT, the CONSORT statement also includes a flow chart that provides the reader with information on how to conduct the experiment (Figure.1).

DISCUSSION

Evidence-based practice: A practice that is based on evidence is an objective for the nursing profession and each practicing nurse. Some nursing practices are currently evidence-based, but many interventions need more study to produce essential knowledge for practical changes. Some clinical agencies support the EBP process, and others do not support it [(8)]. Although significant efforts have been made to support the activities of EBP in nursing, there are more barriers that must be overcome before evidence-based nursing practice (EBNP) can be established in nursing practice [(9)]. And so, there are conceptual, theoretical, and practical challenges to the implementation of the nursing movement towards evidence-based practice. One of the major challenges that many faces concerning knowledge that is present in clinical practice are a limitation in the current availability of study results, EBP requests that study evidence from randomized control trials (RCT) and other forms of intervention studies that which are still limited in nursing be synthesized. It is to be noted that the meta-analyses and systematic reviews that are performed in nursing are also limited when compared to other disciplines, e.g., psychology and medicine [(10)].

Another issue is the fact that evidence of empirical is based on data of population and then applied to individual patients in practice. There are also several approaches and various values to arrive at a response to any specific research question that may be somewhat different for individuals with other different responses and experiences. Additional studies are needed to enhance the use of evidence-based guidelines that can also provide better results for particular patients [(11, 12)].

The reason for the use heavily of data from RCTs is because these findings offer evidence supporting the cause and effect of which the outcome (efficacy) interventions, including interventions used predominantly by nurses, are invaluable [(15)]. More importantly, RCTs control and environment enhance the internal validity of the sample by randomly allocating participants to groups and manipulating the independent variable (intervention). Blinding aims to minimize appearance bias, this is often used in RCTs [(16)]. Therefore, studies that are unable to eliminate or little to eliminate bias may lead to false conclusions and pose inherent risks to the usefulness and validity of results.

Randomized Controlled Trials results must include comprehensive information on the design, how random assignments, blinding, data management, analyses, and interpretations are conducted to allow nurse scientists to accurately evaluate and apply the findings of randomized controlled studies [(1)]. It is much more to the responsibility of researchers when it comes to reporting EBP on clinical trials than in terms of conducting clinical trials; more so, physicians have to provide correct and up to patient treatment [(17)].

CONSORT statement: Randomized Controlled Trials, in the era of evidence-based practice, may be offered the best evidence of the nursing interventions' efficacy. Yet, the quality of RCTs reporting in the kinds of literatures of nursing hasn't been evaluated [(18)].

To prove effectiveness, the monitoring and randomization of studies is the pinnacle of clinical research when conducted, administered, carried out, and recorded correctly. To accurately assess the trial, readers of the published report need complete, clear, and interpreting information on its method and the study results. Unfortunately, evaluation

attempts often fail because the authors of several trials report neglected to provide clear and complete descriptions of this important information [19].

The CONSORT statement that used globally to improve the reporting of randomized controlled trials [20]. It is a protocol created by a community of researchers to detect, record, and explain problems that serve the additional purpose of informing, helping in the readability of study trials, allowing outcomes to be detected and assessed comprehensively [21]. The CONSORT statement, published in 1996, spurred partly by methodological research and revised in 2010, is consisted of 25 items in the checklist form (Table 1) and a flow chart (Figure. 1).

Thus, it has the characteristics of a helpful research tool, making it possible for investigators and clinical nurses to perform an RCT and provide an accurate decision on the evidence presented. In addition, she/he will be able to determine the overall quality of randomized controlled trials additionally to studying the design. In order to make the review can be made easier to understand, the CONSORT checklist has been divided into six sections, according to the components of the paper or parts of the article [22]:

1. **Title and abstract:** title should be informative, identify the study as a randomized control trial, be brief, concise, and should contain the randomized word and avoid abbreviations. The abstract should be organized to include: research problem, design of the trial, methods, objectives, the key results or arguments, and conclusions.
2. **Introduction:** should be included; scientific background information, a brief review of the literature, generates interest, explanation of the rationale for the trial, and the study hypothesis or specific objectives, all of which were reported clearly and objectively.
3. **Method:** It should explain what it did and how did it? And reported carefully as follows: description design of trial; the changes that occur during trial commencement, with obvious reasons; participants eligibility criteria, with an explanation of the justification for these criteria; settings and locations how and where the data were collected; comprehensive description of the intervention with enough details, which allows results to be re-procedure; report how was calculated of sample size; comprehensive description and explanation of the methods used for the random allocation in the trial groups, enrolled participants, and evaluators blinding after assignment; and appropriate used statistical methods for analysis.
4. **Results:** It should be evaluated the effects of the initial intervention for each group, the number of participants who were received intended treatment, assessment losses, and exclusions after randomization should also be reported for each group, and the reasons must be clearly defined; should be reported post-intervention assessment and follow up periods; determining the recruitment periods; the methods of statistical used and estimated effect size to obtain the primary and secondary outcome values, results for each group should be reported such as confidence interval (95%).
5. **Discussion:** It should be presented: limitations of the trial, addressing sources of potential bias, weaknesses, and inaccuracies of methodological; generalizability, applicability, and interpretation of findings, balancing benefits and harms, considering other relevant evidence.
6. **Other important information:** the RCT must be registered and provided with the name of the trial registry and registration number; should be available the full trial protocol; the sources of funding, and different types of support and should be highlighted the role of the funders.

Additionally, to the checklist, reporting registration, assignment, follow-up, and analysis of patients participating in the RCT, the CONSORT statement also includes a flow chart that provides the reader with information on how to conduct the experiment (Figure.1). Most importantly, the clinical nurse should be analyses the presence and quality flow chart in the trial being evaluated, as it provides a broad view of how the experiment was conducted, as well as briefly reporting on the method used [23].

CONCLUSION

Evidence-based Nursing practice (EBNP) is grounded on solid evidence that the assumption that patient care can be supported by sound evidence. It is important that nursing professionals use the CONSORT statement to review, publish, and utilize reports on nursing clinical techniques and gather the best evidence to inform their clinical practitioner of use and their decision-maker.

RECOMMENDATIONS

The authors should consult supervisors and biostatisticians experts early when formulating the study and analysis protocol to improve the quality of reporting the trials in nursing studies. Determine primary and secondary outcomes in advance, preferably in a published protocol. Use adequate checklists reporting, e.g., Consolidated Standards of Reporting Trials (CONSORT) [(24)], Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) [(25)].

REFERENCES:

1. Correa-de-Araujo R. Evidence-Based Practice in the United States: Challenges, Progress, and Future Directions. *Health Care Women Int*. 2016; 37(1):2–22.
2. Thoma A, Eaves FF. A brief history of evidence-based medicine (EBM) and the contributions of Dr David Sackett. *Aesthetic Surg. J*. 2015; 35(8): N P 261–3.
3. Potter PA, Perry AG, Stockert PA, Hall AM. Fundamentals of Nursing [Internet]. 10 ed. Elsevier Evolve. River port Lane: Elsevier Health Sciences; 2021. 96 p. Available from: http://ebooks.elsevier.com/.
4. Mentzer K. Levels of Evidence - Evidence-Based Practice for Health Professionals [Internet]. Northern Virginia Community College. 2020. Available from: https://libguides.nvcc.edu/c.php?g=361218&p=2439383.
5. Melnyk BM, Gallagher-Ford L, Zellefrow C, Tucker S, Van Dromme L, Thomas BK. Outcomes From the First Helene Fuld Health Trust National Institute for Evidence-Based Practice in Nursing and Healthcare Invitational Expert Forum. Worldviews Evidence-Based Nurs. 2018; 15(1):5–15.
6. Mackey A, Bassendowski S. The History of Evidence-Based Practice in Nursing Education and Practice. *J Prof Nurs*. 2017; 33(1):51–5.
7. Pane DN, Fikri M EL, Ritonga HM, A. Nursing Theorists and Their work. Vol. 53, *Journal of Chemical Information and Modeling*. 2018. 1689–1699 p.
8. Grove SK, Gray JR. Understanding Nursing Research: Building an Evidence-Based Practice. 7 ed. *Journal of Clinical Nursing*. River port Lane: Elsevier Health Sciences; 2019. 481 p.
9. Nieswiadomy RM, Bailey C. Foundations of nursing research. 7th ed. Hudson Street, NY, NY: Pearson; 2018. 19–20 p.
10. Gray JR, Grove SK, Sutherland S, A. The practice of nursing research: Appraisal, synthesis, and generation of evidence. 8th ed. St. Louis, MO: Elsevier Saunders: Elsevier Health Sciences; 2017.
11. Cochrane Collaboration. Cochrane: Our health evidence [Internet]. Retrieved November 19. 2017. Available from: http://www.cochrane.org/evidence.
12. CNC CNC. Cochrane Nursing Care (CNC) [Internet]. Retrieved November 30. 2017. Available from: https://nursing.cochrane.org/resources.
13. USPSTF/Task Force. U.S. Preventive Services Task Force. Guide to clinical preventive services: Report U.S. Preventive Services Task Force. *DIANE Publishing*; 1989. 24 p.

14. Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow CD, Teutsch SM, et al. REPRINT OF: Current Methods of the U.S. Preventive Services Task Force: A Review of the Process. *Am J Prev. Med* [Internet]. 2020; 58(3):316–31. Available from: https://doi.org/10.1016/j.amepre.2020.01.001.

15. Black AT, Balneaves LG, Garossino C, Puyat JH, Qian H. Promoting evidence-based practice through a research training program for point-of-care clinicians. *J Nurs Adm*. 2015; 45(1):14–20.

16. Deaton A, Cartwright N. Understanding and misunderstanding randomized controlled trials. *Soc. Sci. Med* [Internet]. 2018; 210(1997):2–21. Available from: https://geekymedics.com/understanding-an-ecg/.

17. Hsieh PL, Chen SH. Effectiveness of an evidence-based practice educational intervention among school nurses. *Int. J Environ Res Public Health*. 2020; 17(11):1–10.

18. Smith BA, Lee HJ, Lee JH, Choi M, Jones DE, Bausell RB, et al. quality of reporting Randomized Controlled Trials (RCTs) in the nursing literature: Application of the Consolidated Standards of Reporting Trials (CONSORT). Nurs Outlook. 2008; 56(1).

19. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomized trials. *Int. J Surg.* [Internet]. 2011; 9(8):672–7. Available from: http://dx.doi.org/10.1016/j.ijsu.2011.09.004.

20. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomized trials. *Int. J Surg.* [Internet]. 2012; 10(1):28–55. Available from: http://dx.doi.org/10.1016/j.ijsu.2011.10.001.

21. Falci SGM, Marques LS. Consort: When and how to use it. Dental Press J Orthod. 2015; 20(3):13–5.

22. Cuschieri S. The CONSORT statement. *Saudi J Anaesth*. 2019; 13(5):S 27–30.

23. Samargandi OA, Koziarz A, Makhdoum A, Mirdad L. Can We Trust the Conclusion No Significant Difference in Plastic Surgery Trials? *Aesthetic Plast Surg*. [Internet]. 2021; Available from: https://doi.org/10.1007/s00266-020-02097-z.

24. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomized trials. *BMJ*. 2010; 340:1–28.

25. Von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Lancet. 2007; 370(9596):1453–7.