Clinical Trials as Evidence-Based Practice in Nursing Research

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Abstract

The clinical trials rapidly grew and contributed valuable knowledge to the medical field to provide the evidence and good practice in health sciences. The clinical trials are the most important with high level and best evidence. The high priority for nursing research especially in clinical trials to develop nursing interventions which demonstrate the connection between nursing actions and patient outcomes. The number of nursing research using Randomized Clinical Trial (RCT) designs is still a young and growing to compare with medical research, nursing intervention in nursing research is different from other therapeutic interventions, and nurses and doctors require different training and support to employee RCTs. Also, the nursing role it is limited in RCTs due to fundamental differences between the practice of nursing and the practice of medicine. Nursing intervention constitutes of complex elements which are difficult to identify the component of nursing and devise controls. Furthermore, the feasibility of intervention the researcher should focus on acceptability, demand, implementation, practicality, adaptation, integration, and expansion of intervention. Increasing understanding nurse educators and academic of the Evidence-Based Practice (EBP) in nursing could enhance nursing students’ clinical practice ability and help them to make effective and wise decisions. Also, the link between academia and the clinical field it is important, which is the knowledge from the practical issues guide the researcher to plan and ensure that research clinically applicable in-patient care.

Keywords: Clinical trials; Randomized clinical trial; Nursing research; Evidence-based practice

Introduction

Clinical Trials as Evidence-Based Practice in Nursing Research: The first clinical trial conducted by AmbroiseParè in 1537 was transformed from traditional practices by using the egg yolks, rose oil, and turpentine to prevent the infection of battlefield wounds[1]. The revolution of the clinical trial continued, in 1754 James Lind was the first the author of control groups in a clinical trial; he used the citrus fruits against scurvy[2]. Then clinical trials rapidly grew and contributed valuable knowledge to the medical field to provide the evidence and good practice in health sciences[3].

On the other hand, there are different levels of evidence to determine clinical practice based on research which is Evidence-Based Practice (EBP) or other reliable evidence[4] reported the evidence rating scale which sort based on the quality of design, validity, and applicability to patient care. As well as, different levels and types of evidence it ultimately answers different clinical questions. The evidence-rating system included six level of evidence, level (A) for meta-analysis of multiple controlled studies or meta-synthesis of qualitative studies; level (B) for well-designed clinical trials either randomized or nonrandomized; level (C) for qualitative studies, descriptive or correlation studies, integrative reviews, or systematic reviews; level (D) for peer-reviewed professional organizational standards; level (E) for theory-based evidence from expert opinion or multiple case reports; and the last level is level (F) for manufacturers’ recommendations only[5].


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Therefore, clinical trials are the most important with high level and best evidence[5]. Clinical trials defined according to National Institute of Health (NIH) is prospective assigned one or more subjects to interventions which focus on human beings, thus evaluate and expect health-related biomedical or behavioral outcome of intervention effect in subjects. In order, prevent, detect, diagnose, or treat diseases[5]. Also, there are different methods to answer questions include, mechanistic (devices), pharmacologic, biologic, procedure, or education[5,9].

The point of clinical trials as is obvious from the definition, clinical trials must utilize intervention techniques which employ one or more intervention. Also, key elements of clinical trials are availability of control over threats to internal and external validity, availability of comparison group to compare the intervention, and availability of random assignment to either the interventional or comparison group[14,15]. Often experimental studies refer to the term of clinical trials which describe true experimental design or a quasi-experimental design[14].

According to key elements of clinical trials the type of design is determined either Randomized Clinical Trial (RCT) or randomized trial (Quasi-Experimental Study). As well as, these differences of designs in experimental studies it is to adapt with the limitations of settings specifically natural settings, difficult in random assignment to treatment, impractical, or unethical study design[15]. On the other hand, Randomized Clinical Trial (RCT), Randomized Controlled Trial (RCT), and true experiment it is used interchangeably which indicates the same meaning of availability of control over extraneous variables, comparison group, and random assignment for the group(Centre for Evidence-Based Medicine [CEBM], 2016).

In addition, different designs can be used to evaluate quality improvement interventions and to found causal relationships within a population of interest. Besides that, the choice of design depends on the purpose, question[16], and other elements mentioned. However, there are many important questions unanswered in the management of patients care in different health specialties. Therefore, clinical trials prerequisite to answering possible questions that help to take a decision in clinical practice that guides to provide high-quality of healthcare[21]. Recently, the essential way to provide high-quality of healthcare by using what the most policies and guidelines in clinical practice recommend through the best and up to date evidence that helps to guide choices about patient care[18].

However, nurses are the largest health professionals in the health care system (American Association of Colleges of Nursing, 2016). The nurse’s work within patient-centered care framework through assessing patients’ health collaboration with health care disciplines team, planning, implementing, evaluating, and making decisions on interventions[19].

Uncertainty about nurses’ knowledge to improve their caring, it is the problem that faces many nurses[20]. So, the Evidence-Based Practice (EBP) is a common in health care that is helping to make a decision on intervention in nursing care to promote the highest quality of care for patients, families, and community[21]. In addition, they have a significant part in health and social care challenges about global health concerns[22], and the high priority for nursing research especially in clinical trials to develop nursing interventions which demonstrate the connection between nursing actions and patient outcomes[23]. Where-
In nursing research, the clinical trials can be used to establish EBP platform. As well as, nursing practice changed from tradition to scientific based, that provide high-quality and systematic services which are the main important issues for healthcare policymakers, practitioners, and researchers. Further, clinical trials provide valuable research data, which is as EBP delegate and guide nurses, in order to obtain and do the effective nursing interventions for the patient. Moreover, increasing understanding nurse educators and academic of the EBP in nursing could enhance nursing students’ clinical practice ability and help them to make effective and wise decisions. Also, the link between academia and the clinical field is important, which is the knowledge from the practical issues guide the researcher to plan and ensure that research clinically applicable in-patient care.

In contrast, other types of research design it increases the body of nursing knowledge. The results from cross-sectional studies or descriptive studies it is useful to evaluate the aspects of nursing care and development the proper interventions or protocols through transform the results and systematically study the outcome of the intervention or implementation. Also, appraising the current nursing practices it provides useful knowledge.

Conclusion

Worldwide, the fundamental and substantial issue of patient care is the clinical effectiveness of interventions that achieved by EBP. It is considered one of the standards of professional performance and competencies that nurses should possess, which evaluate the effectiveness of care and the level of competency for nurses by utilizes and incorporates research outcomes into practice to improve care. Also, the clinical trials can generate nursing knowledge. In addition, the value and credibility of clinical trials support strategies into practice, and the growing acknowledgment of quantitative techniques and statistical analysis of the clinical trials for nursing interventions is helping to improve the situation. Despite there is a difference in role and complexity between nursing intervention in nursing research and other discipline interventions, but the clinical trials growing and evaluating the intervention, through the process to examine the complex interventions by development, feasibility / piloting, evaluation, and implementation the interventions.

Also, availability of guideline for doing clinical trials it is helpful to provide robust and valid intervention such as Consolidated Standards of Reporting Trials (CONSORT) guideline, which gives direction that plan, manage, deliver and receive nursing care. Also, the implication of clinical trials increases the understanding of inputs and outputs from complex intervention and guide to the implementation process.
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