

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 Ambroise Paré 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^[4].

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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^[6]. Also, there are different methods to answer questions include, mechanistic (devices), pharmacologic, biologic, procedure, or education^[8,9].

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^[8,14]. 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^[17] 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-

as, the number of nursing research using RCT designs is still a young and growing to compare with medical research^[24]. Also, these efforts to develop the best evidence reveal a large deficit in nursing intervention research to a large extent which results of a non-systematic review for nursing intervention^[25]. For this reason, the qualitative approach adopted by nurses which use the social sciences^[26].

In addition, in nursing research, the laboratory experiments not use frequently, although, social sciences researchers conducting laboratory experiments, especially in experimental psychology, this is due to laboratory experiments not appropriately to real-life clinical situations for nursing research^[27]. Also, the role of nurses is minor in scientific and clinical discussion in relative to the laboratory experiments^[28]. However, subjective information as a result of nursing clinical trials^[29].

So that, nursing intervention in nursing research is different from other therapeutic interventions. The nursing intervention provides direct treatments that a nurse performed it vicariously a client. However, nurse initiate treatments result from nursing diagnoses, in contrast, physician initiated treatments resulting from medical diagnoses, and from the inability of the patient to perform his daily essential function^[30]. Thus, nursing intervention only knows how to bring about change but does not know what effect this change will have, which is the main challenge of nursing intervention^[31].

In addition, nurses and doctors require different training and support to employee RCTs. The nursing role it is limited in RCTs due to fundamental differences between the practice of nursing and the practice of medicine^[31]. Nurses face conflicts in their roles to a recruiter, patient advocate, and clinician, so they need support to perceive that^[32]. Whereas, doctors benefit from support in relative to assessments of eligibility and equilibrium^[33]. On the other hand^[34], reported the replication of nursing intervention is a mysterious process, wherefore; therapeutic intervention is unique which cannot be observed, measured and copied to the benefit of other patients.

Actually, nursing intervention constitutes of complex elements which are difficult to identify the component of nursing and devise controls. Also, nurses do not treat patients, so, there is no role of relationship and causation in RCTs in nursing research. Therefore, these considered objections to using RCTs in nursing science^[31]. According to Medical Research Council, describe the complexity of nursing as a complex intervention which is an activity that constitutes of several component elements with the possibility for interactions between them, which produces a range of possible and variable outcomes (Medical Research Council, 2008)

These components that constitute the complexity intervention included behaviors, parameters of these behaviors, methods of organizing and delivering those behaviors, variation in the populations which give interventions, and the number and variability of possible results and the degree to which researchers and clinicians to allow flexibility in intervention fidelity^[35] (Medical Research Council, 2008). However, the complexity of component that constitutes intervention rises the problem in evaluation it which difficult because of problems of developing, identifying, documenting, and reproducing the intervention^[36].

In nursing research, the intervention studies have many limitations which lead to weaken the evidence that including,

unemployed random assignment, underdeveloped theoretical base, insufficient recruitment of sample size, presence confounding or extraneous variables^[4], lack of controls for researcher bias^[37], nonadherence to research protocols, economic and organizational obstacles^[38], and dilemmas in balance of validity (internal & external)^[39]. So, even if those clinical trials provide the best evidence, the reliability of the trial must be evaluated in all science^[4]. Also, presence evaluation and examination process it helps the researchers to choose a design and develop an intervention that minimizes potential bias and maximizes generalizability^[40].

So, to support nursing researchers define clearly the role in the research process, it is important to evaluate complexity of interventions, which include, development of the theoretical basis for an intervention, definition of components of the intervention, exploratory studies using a variety of methods, and definitive evaluative study^[36]. In addition to the previous process, to determine if the intervention is appropriate and feasible for conducting clinical trials, the researcher must have the rationale that support the test of intervention and focus on how to improve outcomes of the condition or disease; because the common mistake that researcher tested something that is already part of a standard of care^[9].

Moreover, the feasibility of conducting clinical trials it is critical to determine whether an intervention is appropriate for further testing. As well as, to assess the feasibility of intervention the researcher should focus on acceptability, demand, implementation, practicality, adaptation, integration, and expansion of intervention. Also, should focus and evaluate the technical and monetary feasibility, which depend on easily accessible, an environment supportive, and equipment needed that is important at the trial's outset^[9]. Besides that, review the outcomes of literature about the intervention on the population of interest and investigate about the pitfalls of the previous studies that help the researcher to refine the study design. Also, a pilot study can be helpful to ensure the feasibility of intervention^[9].

On the other hand,^[20] suggested to adopte and restructure the phases of pharmacological interventions in clinical trials and apply in nursing intervention, which helps to provide different information and to determine the feasibility, safety, efficacy, and effectiveness of new interventions. Also, he suggested a well-recognized path from phase 1 to faze 4 in nursing intervention to increase the credibility and strength of the results. The four phases include the acceptability of the intervention to patients, determine the amount of benefit from the intervention and environmental feasibility, randomization and overcome the potential for bias in study outcomes, and assess the effectiveness of interventions, respectively^[20].

The ultimate goal for many health organizations and institutions worldwide are underlining EBP which aims to improve healthcare systems through improving the outcomes of care, quality of care, patient safety, cost-effectiveness, elimination of unnecessary practices, and decrease complications Joint Commission 2013^[4].

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^[41]. 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 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^[42].

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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