

## Conducting Clinical Trials to Support Evidence-Based Clinical Nursing Practice: Challenges and Recommendations

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### ABSTRACT:

Clinical trials are important for the development of health professions including nursing profession. Much of what health care providers practice in clinical settings is derived from evidence rooted in clinical trials. Despite nursing researchers employed clinical trials to generate evidence that can support nursing practice for many years, the significance of generated evidence is influenced by two key factors. First, the relevance of the studied topic to nursing profession. Second, the adherence of the study design to standards of clinical trials. This paper aims to discuss feasibility of generating evidence to support nursing practice based on clinical trials. The paper also presents recommendations to support the utilization of clinical trials in nursing research.

**KEY WORDS:** Nursing research, clinical trials, evidence-based practice, nursing intervention, scope of practice, study design, clinical practice, research method.

### INTRODUCTION

This paper presents a discussion on the feasibility of building nursing practices on evidence that is derived from clinical trials. The discussion debates two main concepts, the significance of the topics of the studies to nursing profession (relevance), and adherence of these studies to clinical trials guidelines (adherence).

Clinical trials are planned to observe the outcomes of the study participants in the context of experimental conditions controlled by researcher. This approach of scientific inquiry that aims to establish causal relationships between variables differ from descriptive research approach. In the latest, researchers aim to identify, describe, or explain variables and possible relationship among them without introducing interventions to influence to study participants. Hierarchies of evidence have always placed Clinical trial studies and their systematic reviews in a superior level as compared to other study methods. Clinical trials require randomization of the participants into intervention and placebo groups, thereby removing the selection bias that results from the imbalance of unknown confounding variables.(Umscheid, 2011).

Health sciences owe much to the clinical research method of randomized clinical trial (RCT), which plays a vital role in modern research and is considered to provide the best level of evidence-based practice due to reliability of results (Peterson, 2014). In fact, journals and organizations have endorsed several classification hierarchies for the level of scientific evidence, i.e. Canadian Task Force on the Periodic Health Examination's Levels of Evidence developed 1979, Levels of Evidence from Sackett in 1989, and Levels of Evidence for Therapeutic Studies, have placed clinical trials and their systematic reviews on the top of the scientific evidence hierarchy models (Burns 2011).

Clinical trials are usually led by a medical doctor, and have a research team that may include doctors, nurses, social workers, and other health care professionals Interventions in clinical trials may be in the form of medications medical devices, and procedures. They also include changes to participants' behavior like diet, exercise, or the model of care. Reasons for conducting clinical trials include evaluating interventions, finding ways to prevent the initial development of a disease, examining methods for identifying a condition or the risk factors for that condition, and exploring ways to improve the comfort and quality of life through supportive care for people with a chronic illness (Clinicaltrials.gov, 2018).

Despite the importance of clinical trials in generating evidence, nursing researchers should be vigilant when selecting clinical trial as a study method for two reasons, first, different study questions can be ideally answered by utilizing different study methods, second, clinical trials have rigorous guidelines that strict adherence to is imperative to generating quality evidence.

### NURSES' INTERVENTION SAND OTHER HEALTHCARE PROVIDERS' INTERVENTIONS

The scope of practice for registered nurses is well-documented in many international nursing associations. American Nursing Association (ANA), for example, issued ANA's Nursing Scope and Standards of Practice. Canadian Nursing Association issued framework for the practice of registered nurses in Canada 2015 and so forth in many countries. In addition, ANA has adopted Nursing Intervention Classification (NIC), which is gaining growing international recognition as an approach to nursing clinical documentation, communication of care across health settings, effectiveness research, and productivity

measurement(Nursing.uiowa.edu, 2018).Based on this classification, nursing intervention is defined as “any treatment, based upon clinical judgment and knowledge, that a nurse performs to enhance patient/client outcomes” (Butcher, et al 2018).Although the definition is appealing, it is broad enough to embrace many activities performed by nurses and does not set a cross line between nursing practice and non-nursing practice.

There are some factors that define the implementation of scope of practice including complexity of health care organization, multidisciplinary approach of care complexities, emergence of global health care emergencies, expectations of the patients, and expectations of the employers (McMahon, & Dluhy, 2017)(Stilos, et al 2007).In actual nursing clinical settings, a “grey zone” of practice arises in which nurses may find themselves welcomed to perform tasks that they may not be competent to perform, or wish to perform advanced or specialized tasks that they were not licensed or trained to perform at the general nurse level(Lillibridge et al, 2000). These situation of indistinctness of nursing roles are usually elaborated at the organizational level through organizational scope of nursing practice, nursing competencies, and nursing policies and procedures. This organization level definition of nursing scope of practice led to inter-organization inconsistencies of what constitute nursing interventions. A nursing intervention may be indorsed to be practiced by nurses in one hospital, while the same intervention is not allowed to be performed by the same level nurses in a neighboring hospital. Nursing scope of practice and related nursing interventions can be described as contextual and negotiable.

Nursing researchers should be vigilant when deciding to conduct studies using clinical trials design. The focus should be areas of nursing practice where quality evidence is lacking. Failing to do so, nursing researchers usually end up investing resources in studies that will not add quality evidence to nursing profession.

***Feasibility of conducting clinical trials to establish evidence for clinical nursing practice:***

The aim of nursing research process is to bring best possible evidence to improve health by improving nursing clinical practice. As the clinical practice is not limited to drugs or devices, all aspects of clinical practice can, and should be subject to be researched using appropriate research methodologies. In nursing profession, some clinical practices gained the credit as result of nurses’ intuition, opinion, or expertise without being adequately tested through rigorous scientific research(Turan, 2016). This approach of developing nursing practice puts nursing researchers before a crucial responsibility of bringing scientific evidence to adopt, modify, or abandon these practices.

Although there is an increased number of therapeutic clinical trials published in nursing journals, their methodological rigor and quality of reporting remain questionable(Hale & Griffiths, 2015).Chunhu (2014) reviewed methodological reporting of randomized trials in five leading Chinese nursing journals and concluded that the overall reporting was poor. Despite clinical trials reporting guidelines are gaining more popularity as tools that help both researchers and reviewers to improve the quality of conducting and reporting clinical trials, their utilization in nursing clinical trials is not up to the required standard. In fact, some nursing journals that review and publish clinical trials do not specifically support clinical trials guidelines, which potentially contribute to poor methodological quality of clinical trials.(Hale& Griffiths, 2015).

Some researchers conduct non-pharmacological clinical trials using methodological standards of the pharmacological clinical trials. Chaibi(2015) argued the feasibility of establishing a manipulative-therapy RCT with concealing the placebo intervention and maintaining the blinding throughout the study is impossible to achieve.

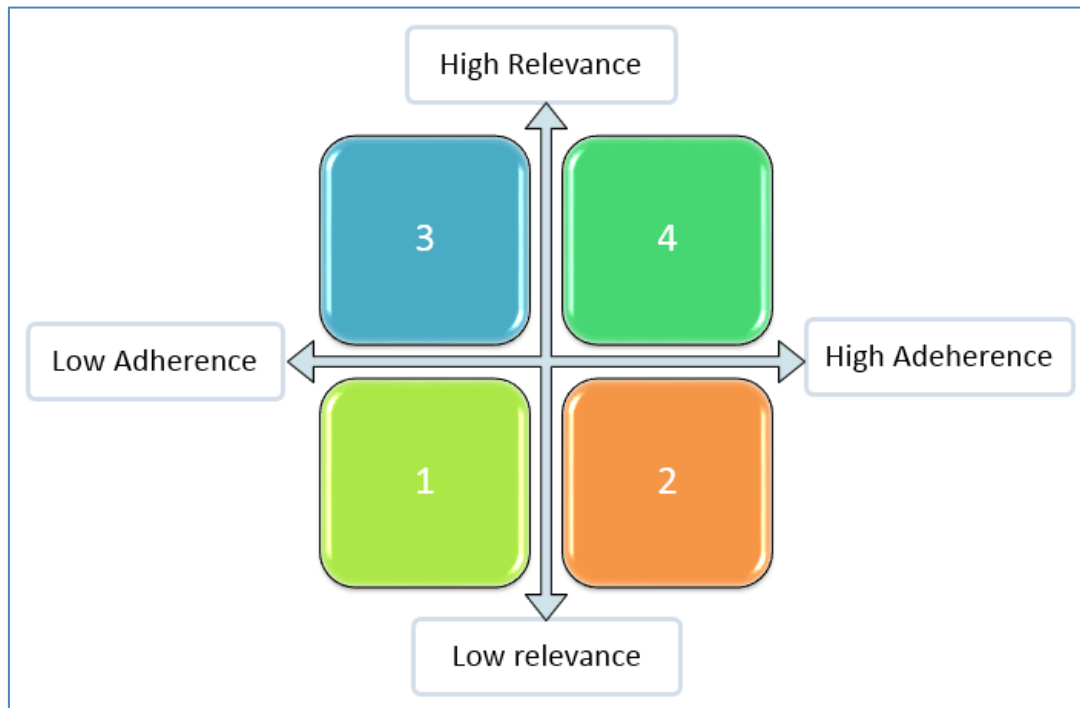
The same methodological challenges are observed in other clinical trials. Hsieh, et al, (2017) for example studied efficacy of cold application on pain during chest tube removal. Despite the research topic explicitly stated that it is “a randomized controlled trial conducted using CONSORT guidelines”, the blinding for both participants was not achieved.

Clinical trials conducted by nurses are not limited clinical interventions; it is established that some trials were conducted to test modalities of care (Légaré et al, 2015),nursing education and training methods (Crawford et al, 2015), and even economic evaluations(hakkaart, 2013).

***Nursing clinical trials relevance to nursing profession and adherence to clinical trials standards:***

It is the responsibility of all nursing research stakeholders to assess the need for conducting a clinical trial based on the “relevance to nursing profession” from one side, and on the “possibility of adhering to clinical trials guidelines” on the other side.

Diagram one presented below proposes model to assess nursing clinical trials against the two dimensions: relevance to nursing profession and adherence to clinical trials standards. According to this model, clinical trials can be put into four categories (quadrants), where the implication of clinical trials can be assessed against which quadrant clinical trials in nursing fall in.



**Diagram 1. A proposed model for assessing clinical trials based on relevance to the priorities of nursing profession, and adherence to clinical trial guidelines.**

Quadrant one represents clinical trials that are of no or low relevance to nursing profession, at the same time they show low possibility of adherence to clinical trials guidelines. This type of trials should be neither planned by nursing researchers nor endorsed by nursing journals. The implication maintaining this category of clinical trials may be harmful to the development of nursing profession. Clinical trials that fall under quadrant two are studies that despite their ability to comply with clinical trials guidelines, they are of low or no relevance to nursing profession. These clinical trials may be conducted as interdisciplinary approach under “health research” domain, rather than, “nursing research” domain, as they can contribute to improving health outcomes. Clinical trials that fall in quadrant three are trials that have the priority to be studied by nursing researchers; yet, they have low chance to adhere to clinical trials guidelines. In this category of clinical trials, researcher must deliberately take the decision not to use clinical trials methodology to research the topic as they usually end up generating findings that lack methodological rigor necessary to produce quality evidence. Despite the efforts that is invested in these type researches, the quality of generated evidence is questionable.

The fourth quadrant represents clinical trials that retain true methodological design and are relevant to nursing profession research priority. This category of clinical trials should be adopted and promoted by nursing researchers and nursing policy makers. Implication for utilizing clinical trials under this category would be of great significance to bring quality evidence to nursing practice and to refine the scope of nursing profession.

#### **Recommendations for improving quality of evidence generated from clinical trials in nursing:**

Generating evidence from research in general and from clinical trials in specific is not an easy mission. Although

most of the responsibility of conducting quality clinical trials goes to the researcher, all stakeholders should assume this responsibility. Generating quality evidence from research requires research stakeholders to deliberately coordinate their efforts to improve the quality of evidence generated from clinical trials (Hale & Griffiths, 2015). Recommendations to improve the quality of clinical trials are presented below.

#### **Nursing journals:**

1. Nursing Journals should explicitly endorse specific clinical trials reporting guidelines. It is not recommended that journals accept to review clinical trial studies that are not explicitly based on a clinical reporting guideline endorsed by the journal.
2. Journals should encourage reviewers to use clinical trials guidelines when reviewing the submitted researches.

#### **Nursing journals reviewers:**

1. Journals reviewers should strictly adhere to clinical trials guidelines endorsed by the journal.
2. Journal reviewers can improve researchers' capacity in compliance with clinical trials guidelines through feedback process.

#### **Nursing researchers:**

1. Purposefully choose not to conduct clinical trials when the topic is of no or little relevance to nursing profession, or when clinical trial is not the optimal design for conducting the study.
2. When researchers decide to conduct a clinical trial, they should take all necessary measures to adhere to the clinical trials guidelines, starting from planning phase.

#### **Readers (research users):**

1. Readers, are responsible for assessing the quality of research evidence.

2. Readers need to build their capacity for assessing clinical trials and critiquing their method.

## CONCLUSION

This paper presented a brief discussion on feasibility of building nursing practices on evidence derived from nursing clinical trials. It is obvious that in real practice there is no clear cut between nursing and non-nursing interventions, which is reflected on lacking of clear cut between nursing and non-nursing clinical trials. The discussion focused on the methodological challenges of using clinical trials in studying nursing interventions. There is a gap between clinical trial reporting guidelines requirements from one side and the actual clinical trial reports published in nursing journals from the other side. Implication for using clinical trials in nursing was discussed based on two criteria: relevance to nursing profession, and congruence with clinical trial design. Finally, a group of recommendations were proposed to improve quality of evidence generated from clinical trials.

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