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The Conduct of Clinical Trials: Lessons Learned

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Key Words
Clinical Trials

A clinical trial is a prospective comparison in human subjects of the effectiveness of an intervention or treatment as opposed to a control condition. A clinical trial follows the principles of a planned experimental design. Three essential conditions of a true experiment must be met: 1) an independent variable is manipulated by the investigator who observes the effect on dependent variables; 2) a comparison (or control) group is used; and 3) subjects are randomly assigned to either the experimental or the comparison group (or condition).[1] Randomized clinical trials provide the only reliable basis for evaluating the efficacy and safety of new treatments. They are designed to determine the best treatment of future patients with a given problem or condition. Therefore, the results of clinical trials have the potential for directly influencing nursing and medical practice.[2] When the results of similar trials are evaluated, clinical practice guidelines may be developed. Well-designed clinical trials represent the highest level of scientific inquiry, and therefore, provide the best evidence for sound clinical practice.

Compared to exploratory research, designed to describe phenomona, relatively few clinical trials have been conducted by nurse researchers. Cullum[3] conducted a selective search of the literature from 1966 to 1994 and identified 522 papers and 20 systematic reviews related to nursing. Considering the time span, this represents a low number of clinical trials.[2] The purpose of this paper is to encourage the conduct of clinical trials by nurse researchers and to share some insights from the literature and from these authors' experiences.

Assuring Internal Validity

Internal validity addresses the basic concern of whether a study satisfactorily answers the posed question of investigation. For example, does therapy "X" result in significant benefit to patients with a specified condition, disease state or set of symptoms? A successful clinical trial addresses a clear question in a manner that poses few, if any, alternative hypotheses to the source of treatment outcome. To accomplish this, several factors need to be considered before the study is undertaken.

Randomization to treatment groups is the classical solution to acieving "equality" of group assignment. Randomization to treatment groups is most effective in achieving equalization if the following conditions are met: 1) The overall sample size is adequate, so that fundamental subject characteristics are similar in both

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