Recruitment and retention of participants to clinical trials is critical to the outcome and success of clinical trial research. Clinical trials in nursing research have become more prevalent in the past decade, particularly as more intervention-level studies are implemented (Burns & Grove, 1997). Clinical trials have provided validity to examinations of outcomes of nursing interventions for testing theory-based practice (Tyzenhouse, 1981; Woods, 1990).

Clinical trials in nursing fall into two categories—preventive and therapeutic (Talbot, 1995). Preventive trials examine the efficacy of a specific treatment in reducing risks associated with a disease. Therapeutic trials examine outcomes of specific interventions or treatments, such as symptom relief, risk reduction, or relapse prevention. The most common types of clinical trials are drug studies that test the efficacy of medications.

An advantage of clinical trials is that they establish a relationship between treatment and clinical outcomes. Clinical trials most often require randomization, which involves placement of subjects in groups on a random basis, giving every subject an equal chance of being assigned and eliminating selection bias (Polit & Hungler, 1999). This method helps reduce threats to internal and external validity (Talbot, 1995). Disadvantages of clinical trials include expense and ethical considerations related to treatments for which risks have not yet been documented (Talbot).

A number of factors may affect participation in clinical trials. Pilot studies are critical and usually required prior to the implementation of large clinical trials. The pilot study allows

**Purpose/Objectives:** To present barriers and strategies related to successful clinical trial participation and integrate them into a model for successful trial participation.

**Data Sources:** The proposed model was developed based on a literature review related to clinical trial participation, review of empirical studies related to clinical trials, and experiences with subject participation.

**Data Synthesis:** Successful clinical trial participation depends on study design, participant factors, issues related to ethnic diversity, the informed consent process, and physician factors.

**Conclusions:** Clinical trial participation is critical for all disciplines. However, nurses either are researchers or co-investigators with physicians on clinical trials, and it is critical for them to understand specific barriers and success strategies for patient participation. Future studies need to be conducted related to participation in nursing clinical trial research. These study results will facilitate successful nursing clinical trials.

**Implications for Nursing Practice:** This model can be used in implementation of clinical trials across disciplines prior to and during enrollment of patients into studies.

**Key Points . . .**

- Successful clinical trial participation can be increased when barriers and issues are identified.
- Success in overcoming barriers related to subject recruitment, retention, and compliance could result in decreased costs and increase the power of the study.
- Successful clinical trials depend on study design, participant factors, issues related to ethnic diversity, the informed consent process, and physician factors.
- The model for successful participation identifies strategies that can be used across disciplines by nurses and healthcare providers to facilitate successful accrual and increased satisfaction of patients, nurses, and physicians.

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