

who underwent a similar exercise testing protocol. In addition, the exercise training program was administered to six stroke patients to examine the appropriateness of the exercise methods and to determine the overall change in aerobic capacity. Beyond the intent of these pilot studies, a wealth of key information was revealed, such as: transportation issues for stroke patients; the need for adaptations made to the bicycle ergometer; and staffing requirements to conduct exercise testing and training. Through this pilot work, exercise testing and training methods were validated and refined, and support for the purpose of the clinical trial was obtained.

Selection of Collaborators

It is impossible to conduct a clinical trial without the expertise and assistance of collaborators. Collaborators are interested in working together toward a common goal. They typically serve in the capacity of coinvestigators and have unique expertise to offer the project. It is wise to involve collaborators early in the research project, at the time of the initial inception of the study, if possible. Collaborators should be involved in all decision-making, including the determination of the study design and procedures.

Physicians, clinical psychologists, nutritionists, and members of other disciplines often serve as collaborators in clinical trials where a nurse researcher is the principal investigator. There are many reasons for including members of other disciplines. Physician expertise is important when a particular clinical population is studied. Physicians may provide access to this clinical population, a clinical setting, staff or equipment necessary to conduct the study. For example, the physician coinvestigator on the stroke clinical trial (described above) is an internist and pulmonary specialist. He has an interest in respiratory muscle dysfunction, as observed in some stroke patients. His unique contribution was expertise in metabolic exercise testing. He provided the laboratory space, equipment, and physician supervision for the conduct of the exercise tests. In addition, the co-principal investigator of this project is a clinical psychologist. Her interest was the effect of aerobic exercise training on psychological and cognitive function in post-stroke patients. There-

fore, the purpose and aims of the study were expanded, and additional measures added.

Collaborators may have goals that are not identical to the principal investigator's goals, but are parallel. It is often possible to merge the interest areas of collaborators and add breadth to the project. When selling an idea to a potential collaborator, it is essential to choose individuals who have the following characteristics: 1) have a unique contribution to offer the project; 2) have interest in the project, and will provide the time necessary for preparation (writing the proposal), implementation (conduct of the study), analysis, and dissemination (writing publications); and 3) will work together as a member of a team.

Research Team Meetings

The research team includes the collaborators (investigators), research staff members (recruiters and data collectors), and consultants. The larger the clinical trial, in terms of sample size and outcome variables, there is the greater likelihood for a large research team. Communication among all members of the team is key for a well-orchestrated clinical trial. One of the best ways to insure communication is to schedule a regular meeting of all team members (either weekly or bi-weekly). This meeting time should be mandatory for all members, and other study activities should be scheduled around it. At times, the investigators may not be involved with the day-to-day study procedures, and the team meeting serves to inform all members about the key issues and progress of the study. In addition, the screening forms for potential subjects can be reviewed and a decisions made about appropriate study candidates. The regular team meeting helps to limit phone calls to investigators on a daily basis, and insures that all members share and hear the same information.

Subject Recruitment

Most clinical trials require the use of multiple strategies for subject recruitment. The plan for recruitment of subjects must be delineated while writing the proposal, so that adequate funds are allocated within the budget. Some recruitment strategies cost little or nothing, while other strategies are expensive.