tings. Those subjects who were randomized to receive the alternative intervention (passive range-of-motion exercise) represented an attention control group. They were also required to attend three sessions a week for ten weeks in the research setting, and received the same amount of attention and montoring as the intervention group.

It is generally advisable to exclude certain individuals from participating in a clinical trial. These individuals may have characteristics or a living situation that will influence their level of adherence. For example, subjects may live too far away from the research setting, may be planning to move before the end of the trial, or may live elsewhere for part of the year. Subjects with cognitive impairment or those addicted to drugs or alcohol are usually inappropriate study candidates.

Prospective subjects must be thoroughly informed about the clinical trial, specifically, the purpose of the study, procedures, randomization process, intervention being examined, control intervention(s), number of visits required, duration of the trial, and any follow-up visits. The better informed subjects are, the better adherers they tend to be.[13] It's important that subjects understand, as clearly as possible, what they are committing to, and certainly, that they have a right to withdraw at any time. In the stroke study, subjects were informed that a total of 30 exercise sessions were required, generally over ten weeks. If a session was missed, the missed session was added on until 30 sessions were completed. Prior to signing the informed consent form, subjects were told that they could not miss more than three sessions for vacation. Given that the intervention period was only ten weeks, subjects were able to anticipate whether or not they could keep this commitment.

When subjects visit the research setting, an optimal experience promotes adherence. Research staff must be friendly, courteous, and cognizant of subject needs. It is essential that subjects feel comfortable discussing study-related concerns with staff members. The environment should be pleasant, appointment times convenient, and waiting time short. When subjects are required to adhere to interventions outside of the research setting, some additional methods will help maintain subject adherence: time devoted to counseling and responding to questions during appointments; self-recording of intervention (medication or dietary intake, exercise sessions, etc.), educational hand-outs; staff phone calls at pre-determined intervals; mailed reminders; contracts with subjects; and involvement of family members.

When an intervention is carried out in the research setting, adherence is implied when subjects keep their appointments. However, when subjects are responsible for adhering to an intervention outside of the research setting, it is critical to integrate suitable methods for monitoring adherence. A single measure of adherence often doesn't present a complete picture, and all measures of adherence are subject to inaccuracies. Examples of adherence measures are: pill counts in drug trials; electronic monitoring devices (e.g., medication dispensing caps or heart rate monitors); laboratory determinations of medication level; physiologic response (e.g., reduction in resting heart rate or an increase in aerobic exercise capacity with exercise training); interview or recording keeping (e.g., 24 hour recall or 7-day food record). Measurement of adherence should be as frequent as feasible for better accuracy. Furthermore, when subjects are aware that adherence is monitored, they will generally be better adherers.

## CONCLUSION

When investigating a clinical phenomenon, it is often necessary to first describe the characteristics, e.g., frequency of occurance, prevalence, degree and variance, quality of the phenomenon. Next, it is necessary to explore what factors are related to the phenomenon and to determine the measurable associations between phenomena. Finally, when a problem is identified and examined in a specific clinical population, interventions must be developed and tested. In randomized clinical trials, the efficacy of new interventions is examined and compared with that of alternative or standard interventions. The results of well-designed clinical trials provide the highest level of evidence upon which to base sound clinical practice.

In this paper, successful strategies for the develop-