This article will focus on the processes that require attention before data collection is initiated. The processes include the design of data collection tools or instruments and estimation of the number of subjects required to produce reliable and generalizable results to be used by other clinicians. The importance of designing or evaluating data collection tools during the initial stages of the development of research protocols cannot be underestimated.

As with the previous two articles in the series, this article is a continuation of the examination of the data analysis for an intervention study for subjects diagnosed with breast cancer in a support group (Coward, 2003). Coward’s study will be reviewed using the first two steps of the six-step process presented in Table 1. Issues related to identification of limitations also will be discussed, because limitations should be identified and noted throughout the research process—not just at the end. The primary objective of Coward’s study was to pilot a support group intervention that promotes self-transcendence perspectives in women diagnosed with breast cancer. The second objective was to assess whether changes in well-being would occur over time between patients participating in support groups and those not participating.

Ideally, all researchers should meet with a statistician at least three times (sometimes more often) during the study process. The first meeting is to perform a sample-size estimation, often referred to as a power analysis. The second meeting is to design a data collection tool or evaluate the strengths and limitations of using an established tool. The third meeting and subsequent meetings take place throughout the process of data summarization. Researchers should keep in mind that data analysis is a process—not a one-time analysis of data. It requires ongoing discussions between researchers and statisticians to ensure clarity and understanding of the questions being asked.

Estimate the Sample Size

The pilot study enrolled 41 subjects, all diagnosed with breast cancer. The study design incorporated two groups: the experimental group (support group participants, n = 22) and the control group (did not participate in support group activities, n = 17). The author did not report a power analysis or sample-size estimation, which is common. Many trials, especially pilot studies, do not have sufficient information available to calculate estimated sample sizes required when designing research projects. In fact, one of the key roles of pilot studies is to obtain preliminary information to justify the need (and expense) for larger studies.

Assess the Appropriateness of the Design of the Data Collection Tool

Data collection tools serve two very important roles. First, they force researchers to identify all (or almost all) of the data elements required to address primary and secondary objectives. Second, researchers and statisticians can determine how data should be collected.