Conducting Pilot and Feasibility Studies

Diane G. Cope, PhD, ARNP, BC, AOCNP®

Planning a well-designed research study can be tedious and laborious work. However, this process is critical and ultimately can produce valid, reliable study findings. Designing a large-scale randomized, controlled trial (RCT)—the gold standard in quantitative research—can be even more challenging. Even the most well-planned study potentially can result in issues with research procedures and design, such as recruitment, retention, or methodology. One strategy that may facilitate sound study design is the completion of a pilot or feasibility study prior to the initiation of a larger-scale trial. This article will discuss pilot and feasibility studies, their advantages and disadvantages, and implications for oncology nursing research.

Defining Pilot and Feasibility Studies

The terms *pilot study* and *feasibility study* often are used interchangeably (Arain, Campbell, Cooper, & Lancaster, 2010; Leon, Davis, & Kraemer, 2011; Thabane et al., 2010). Although some goals and procedures overlap, pilot studies and feasibility studies also have unique characteristics.

A pilot study is a miniature or trial run of a full-scale study. A feasibility study generally is done to evaluate interventions for clinical intervention research (Tickle-Degnen, 2013). A pilot study may be performed to test the feasibility of techniques, methods, questionnaires, and interviews and how they function together in a study.

A feasibility study is performed to evaluate individual critical components that are necessary for the large-scale study, such as participant recruitment, ability to execute the intervention, and accuracy of the intervention protocol (Arain et al., 2010; Tickle-Degnen, 2013).

Advantages of Conducting a Pilot or Feasibility Study

A pilot or feasibility study could be viewed as a burden or an added step in conducting a large-scale study. Although conducting these types of studies cannot guarantee avoiding all problematic issues for the main study, the benefits can outweigh the added effort and increase the likelihood of success. Advantages of conducting a pilot or feasibility study include the following (Polit & Beck, 2011; van Teijlingen & Hundley, 2002).

- Assess the adequacy of study methods and procedures.
- Develop and assess the adequacy and quality of research instruments and questionnaires.
- Assess participant recruitment strategies.
- Identify potential participant retention problems.
- Assess the research protocol for realistic execution.
- Assess the strength of key variable relationships.
- Identify confounding variables that should be controlled.
- Assess the effectiveness of sampling techniques.
- Determine study resources, such as training materials, research staff, project costs, and study budget planning.
- Assess outcome variability to estimate study sample size.
- Assess proposed data analysis.
- Assess preliminary evidence and its justification for a larger-scale study.
- Provide evidence to funding agencies proving that the study is feasible and worthy of research funding.

Disadvantages of Conducting a Pilot or Feasibility Study

Although many advantages of performing a pilot or feasibility study are evident, limitations exist. One limitation is that pilot and feasibility studies are not capable of calculating sample size or response rates because they typically are based on a small sample size. Another limitation is the appropriateness of including data from the pilot or feasibility study in the main study (van Teijlingen & Hundley, 2002).

If problems with the research tool or methodology were identified in the preliminary study, data could be flawed and contaminate the main study. Using the pilot or feasibility study, participants in the main study also may present limitations in data analysis. Participants previously exposed to the intervention may be more proficient in the main study or may be less compliant with the protocol because the intervention already has been completed. Research funds potentially may be affected if the pilot or feasibility study identifies major problems that no longer can be changed with existing funds.

Implications for Oncology Nursing Research

Pilot and feasibility studies are fitting for oncology nursing research. As oncology nurse researchers continue to develop and test interventions to

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address a multitude of symptoms experienced by patients with cancer across the care continuum, pilot and feasibility studies offer cost and time efficiency in planning large-scale RCTs. In reviewing the past 10 years of published research in the *Oncology Nursing Forum (ONF)*, approximately 50 pilot studies have been published. The majority of these studies were pilot studies assessing various interventions for multiple types of cancer.

In this issue of *ONF*, Yoon, Grundmann, Williams, and Carriere (2015) conducted a feasibility study assessing an acupuncture intervention to improve appetite and decrease weight loss in patients with gastrointestinal cancers. The authors concluded that the acupuncture intervention, completed by seven patients, was feasible, well-accepted, and safe without any reported side effects. Acupuncture did appear to improve appetite and decrease weight loss. The authors found that because of the small sample size and lack of control group, statistical significance of effectiveness was not determined, which is a known feasibility study characteristic and limitation.

Conclusion

Pilot and feasibility studies can offer many advantages to researchers who design and conduct large-scale RCTs. These types of studies are fitting for oncology nursing and the quest for effective interventions to improve symptom management and quality of life for patients with cancer. In addition, as seen in *ONF*, researchers should publish pilot and feasibility studies that have been conducted, whether outcomes are positive or negative, to share research experiences as a learning process for other researchers.

Diane G. Cope, PhD, ARNP, BC, AOCNP®, is an oncology nurse practitioner at the Florida Cancer Specialists and Research Institute in Fort Myers. No financial relationships to disclose. Cope can be reached at dgcope@comcast.net, with copy to editor at ONFEditor@ons.org.

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Methods & Meanings

Methods & Meanings comments and provides background on the methodology used in one of the studies reported in the that month's issue of *Oncology Nursing Forum*. For more information, contact Associate Editor Diane G. Cope, PhD, ARNP, BC, AOCNP®, at dgcope@comcast.net.