COMMENTARY

Feasibility Studies: What They Are, How They Are Done, and What We Can Learn From Them

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Nursing clinical research is a growing field, and as more nurses become engaged in conducting clinical research, feasibility studies may be their first encounter. Understanding what they are, how to conduct them, and the importance of properly reporting their outcomes is vital to the continued advancement of nursing science.

Many interventions, practices, and processes exist in the nursing field that are grounded in evidence; however, problems that do not appear to be linked to any strong evidence are encountered in daily practice. Nurses are left questioning, "Why do we do it this way?" or "Is there a better way to provide this intervention?" Sometimes these questions may be answered by performing a literature search and realizing that a novel approach exists to implement into their practice; however, if the literature search does not yield any results for an evidence-based practice change, then conducting research could be the next step. Conducting a large, well-designed study can be overwhelming and expensive and may require funding; it also may not be the appropriate first step in the research process (Morris & Rosenbloom, 2017). A feasibility study may be the appropriate first step to help identify whether a larger research study is warranted.

A feasibility study is often a critical step to be taken prior to conducting a larger study. The primary aim of a feasibility study is to assess the feasibility of conducting future conclusive randomized, controlled trials (RCTs) (Eldridge et al., 2016a). Feasibility studies do not have a primary focus on effectiveness or efficacy (Eldridge et al., 2016a); they can be viewed as a dry run to identify problems that may hinder or prevent success of a subsequent larger trial (Conn, Algase, Rawl, Zerwic, & Wyman, 2010). Feasibility studies can demonstrate that a research design is achievable and that recruitment for an anticipated larger study is possible (Morris & Rosenbloom, 2017). They also can supply data that often are required to receive funding and support for a larger RCT to demonstrate that the study approach is feasible and to make a case that the proposed study will answer the question that is being posed (Morris & Rosenbloom, 2017). They also permit testing of sampling strategies, intervention content, delivery methods, data collection, and analysis (Conn et al., 2010). The article "Nurse-Delivered Symptom Assessment for Individuals With Advanced Lung Cancer" (Flannery et al., 2018) provides an example of how a nurse took a clinical question and moved it into the research arena by conducting a feasibility study to assess an intervention strategy.

A feasibility study's focus is not on efficacy or effectiveness, but the publication of the findings is beneficial and important to the development of science and must follow high standards, just as definitive trials do (Conn et al., 2010; Eldridge et al., 2016a). The Consolidated Standards of Reporting Trials (CONSORT) statement, last updated in 2010, is a guideline designed to improve the transparency and quality of the reporting of RCTs (Eldridge et al., 2016a). Eldridge et al. (2016a) presented an extension to that statement for randomized pilot and feasibility trials conducted in advance of a future definitive RCT. The development was motivated by the increasing number of studies that were described as pilot or feasibility studies and by research that identified weaknesses in the way they were being

KEYWORDS feasibility studies; clinical research; nursing science; evidence-based practice

***ONF*, *45*(5), 572–574.**

DOI 10.1188/18.ONF.572-574

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conducted and in their reporting (Eldridge et al., 2016b). Eldridge et al. (2016b) recognized that, although much of the information to be reported in these trials was similar to RCTs, key differences also were seen, and the CONSORT standards and checklists needed to be adapted to assist in improving the reporting of pilot and feasibility studies (Eldridge et al., 2016a). When conducting and reporting a feasibility study, of importance is that the guidelines, flowchart, and checklists provided in the 2016 extension of the CONSORT 2010 statement are used by the researcher to promote transparency and to improve the quality and standardization of the reporting (Eldridge et al., 2016a).

Many terms are used interchangeably to describe preliminary studies that are done before a larger study, but consensus is growing in the field of research that distinctions among them should be recognized and more consistently used (Morris & Rosenbloom, 2017). The rationale for needing increased consistency in usage is because the way terms are defined determines the necessary components of the study (Eldridge et al., 2016b; Morris & Rosenbloom, 2017). For example, the terms *feasibility studies*, *pilot studies*, *pilot RCTs*, *pilot trials*, and *pilot work* are used by many authors to reference a study done in advance of a future definitive RCT and whose primary aim is to assess feasibility (Eldridge et al., 2016b; Morris & Rosenbloom, 2017). This can be confusing when reading and searching the literature. Eldridge et al. (2016b) proposed the following definitions, which may be helpful when reading articles or when a researcher is deciding on which type of study to perform:

- Feasibility study: Research conducted to determine whether something can or should be done and, if so, how
- Randomized pilot study: A small-scale feasibility study, conducted with randomization of participants, that evaluates the practicability of carrying out all or part of an intervention and other processes to be undertaken in a future larger study; may or may not include alternative approaches
- Nonrandomized pilot study: A small-scale feasibility study, conducted without randomization of participants, that evaluates the practicability of carrying out all or part of an intervention—and, possibly, other processes—to be undertaken in a future larger study
- Feasibility study that is not a pilot study: A feasibility study that does not incorporate the intervention or other processes to be undertaken in a future trial but may address the development of interventions or processes

Regardless of the type of feasibility study that will be done, they all start the same way, with a question or a problem that a clinician has come up with, followed by a literature search. After that, the researcher must identify gaps in knowledge and in the literature, followed by revision and refinement of the original question into a specific research question. Next, the reasons for conducting the preliminary research need to be considered and then the form it should take determined. The focus of feasibility studies can be on any aspect of research, including the following (Morris & Rosenbloom, 2007):

- Processes: Informed consent procedures, recruitment approaches, nonadherence
- Resources: Budget allocation, equipment, data collection time, time requirements
- Management: Data management, ease of data entry, overall study feasibility, and reporting procedures
- Science: Treatment safety, dose levels and responses, and variance of treatment effect

After the focus and form are decided, the researcher must design the study, collaborate with stakeholders, carry out the study, and analyze the results. Finally, the researcher must relate the findings to plans for a future study and disseminate the findings.

The publication of feasibility studies provides important information to the scientific community. The results of feasibility studies focus on the value of outcomes for subsequent studies rather than on specific findings (Morris & Rosenbloom, 2017). These studies can provide detailed information that often is omitted from reports of large-scale trials because of space considerations, such as changes to the protocol or other modifications that were done because of findings during the pilot (Conn et al., 2010). Often, a larger trial does not happen after the pilot study is completed for one reason or another, so publication of the pilot results may be the only publicly available record that the intervention was tested (Conn et al., 2010). Flannery et al. (2018) reported that although delivering the intervention with fidelity was possible, the feasibility findings did not warrant intervention replication. This is an important finding to report because it will prevent additional researchers from wasting their time and resources testing that same intervention and process. So, even though these findings did not support the plan to conduct a future larger study, they still provide vital information concerning this vulnerable

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population. This article provides detailed information on how the feasibility study was designed and conducted, allowing future researchers to change the approach and test different interventions and delivery to this population to promote their well-being.

Feasibility studies are extremely important to advance the science of nursing because they allow for the planning of subsequent larger trials. Nurses often think of ideas and solutions to everyday clinical problems and issues but are challenged to move that idea into a full-scale study. Taking that idea or solution and conducting a feasibility study may be a first step into the area of research for many nurses.

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No financial relationships to disclose.

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