

Introduction of a Pilot Study

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ABSTRACT

A pilot study investigates whether something is feasible, whether it should be followed by the researchers, and if so, how Pilot research, however, also has a unique design element; it is carried out on a smaller scale than the primary or full-size investigation. In other words, the pilot study is crucial for enhancing the effectiveness and quality of the main study. Additionally, it is carried out to examine the randomization and blinding process, evaluate recruitment potentials, increase researcher experience with the study methods or medications and interventions, and provide estimates for sample size calculation. The misconceptions and the ethical implications of a pilot study are the main topics of this paper. This review also introduces how to interpret the findings of a pilot research.

Keywords: Feasibility, Methodology, Pilot.

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INTRODUCTION

An effective research study with a pertinent experimental design and precise execution is necessary to get high-quality results. The main study, sometimes referred to as the full study or large-scale main trial, can be carried out to great advantage by first analyzing its viability. Often a smaller-scale study, a pilot study is the initial step in the overall research procedure and aids in the planning and adaptation of the primary study.^{1,2} To be more precise, the pilot or small-scale study frequently comes before the main trial in large-scale clinical investigations to assess the validity of the results. Before starting a pilot study, researchers must have a complete understanding of the experiment's objectives, research question, experimental design, and timetable. Through the pilot study, researchers learn about the processes involved in the major study, which helps in choosing the research method most suited for addressing the research topic in the main trial. Despite the advantages and significance of the pilot study, researchers frequently show little enthusiasm for it.

OBJECTIVES OF A PILOT STUDY

Feasibility of the Study Protocol

An evaluation of the inclusion and exclusion criteria for the participants, preparation of the drugs and intervention, storage and testing of the instruments used for measurements in the study, as well as training of researchers and research assistants, validates the feasibility of the study.³ The researcher, as well as the research assistants, must completely understand the purpose, method, and proceed additionally, the method's viability for data collecting needs to be evaluated.

Randomization and Blinding

A pilot study evaluates the effectiveness of the randomization and blinding.⁴⁻⁶ For instance, the precise preparation, storage,

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and delivery methods are evaluated to properly use the sealed opaque envelopes method, which is frequently used in clinical studies.⁷ Papers with random numbers are arranged according to the sequence of the assignments and placed inside an opaque envelope. These envelopes are kept in the pharmacy division and made available by the division when needed. Both the recipient and the provider must sign the document at the time of provision. According to the researcher's plans, the randomized groups' uniformity in terms of demographic traits, the appropriateness of blinding, and the participants' comprehension of randomization can all be evaluated. Additionally, the best strategy for informing patients about randomization and getting their agreement can be evaluated. Benger *et al.*'s³ study

Recruitment and Consent

The researcher finds the subjects and gets their permission to participate. The participants should be given enough time and information to make an informed choice and give their written consent. Following that, volunteers should be assessed to determine if they are appropriate for the trial. It is decided on the suitability of the consent form, recruiting rates, the amount of time it will take to get written consent, and the necessary number of researchers and research assistants. The recruiting rate is specifically correlated with the length of the study (duration) and its success or failure.⁸ The experimental

procedures can be changed to boost the recruitment rate as well. Vemulakonda and Jones found that observational cohort studies, in which carers chose the course of treatment, had greater recruitment rates than randomized clinical trials in their investigation of pediatric urological patients.⁹

Selection of the Most Appropriate Primary Outcome Measure

The major result that most accurately reflects the researchers' goals is difficult to choose. Additionally, the computation of the sample size is directly related to the main consequence. A sample size for each primary result is necessary if there are several primary outcomes needed. Mouton *et al.*¹⁰

Sample Size Calculation

Pilot research is essential to gather the basic data needed to determine the sample size for the primary outcome. Preliminary information is required for continuous outcomes, such as the mean and standard deviations for the control group. Preliminary information is needed for categorical outcomes, such as the conventional treatment's success rate.¹¹ To determine the sample size while choosing several primary outcomes, the preliminary data for each outcome must be gathered.

Effect Size and Sample Size Estimation

To determine the sample size for a study, a pilot study is often conducted first. However, it is important to exercise caution when estimating the sample size needed for the main experiment.^{2,11,12} The standardized effect size, or Cohen's *d*, is needed to calculate the sample size for the main trial. Unfortunately, the pilot studies estimated standardized effect size, which has a confidence interval, was determined from a sample of data. The confidence interval for the standardized effect size is quite large due to the small sample size, and the corresponding sample size likewise has a wide range. This could consequently result in mistakes being made when estimating the sample size or statistical power to be applied in the primary trial.¹²

Internal Pilot Study

Internal pilot research must be carefully designed at the main study's study design stage and included in the study method to be carried out. In addition, the researchers must take into account the fact that other than determining the sample size, adjustments in other categories related to the primary study cannot be made. The hypothesis that the main study and pilot study are independent of one another is another crucial factor to take into account. This hypothesis states that there is a modest higher risk of a type 1 error.¹

Analysis of a Pilot Study

The possibility of testing the hypothesis through the analysis of a pilot study is a matter of concern. The researchers must acknowledge that pilot studies are not for testing

hypotheses because the required power and sample size were not determined for the study.⁴ As a result, they must exercise caution when disclosing the findings of a pilot study. Furthermore, just because a pilot study reaches statistical significance does not mean that the major study or trial is not still necessary.¹³

How to Interpret the Results of a Pilot Study

There should be a list of prerequisites for a pilot study before it begins. The researcher determines whether to carry out the primary study as planned or to change the study design based on whether these requirements are met. In addition, findings from the pilot study are discussed in light of these circumstances. One of the following results² can be used to characterize typical pilot research outcomes:

- Termination of the study (cannot move forward with the main study).
- Ability to move forward with the main study after changing the study design.
- Absence of the need to change the research design but need for careful monitoring throughout the study processes.
- Ability to move forward without changing the study design.

Thabane *et al.*² provided a checklist for pilot studies using the CONSORT statement. A brief description is provided below: Must be noted that the study is a "pilot study" in the title.

In the introduction, the background for the main study and rationale for performing the pilot study should be written.

- The categories for evaluating the validity of the procedures and standards to be used in the primary study should be outlined in the techniques section, and the standards for validity should be developed.
- Participants' inclusion and exclusion criteria, specific administration and treatment procedures, descriptions of the primary and secondary outcomes, the process and justification used to choose the sample size, and techniques for acceptable statistical analysis should all be documented.
- The validity of the discussed points in the methodology part, as well as the points that need to be adjusted, are stated in the findings section, and solutions are sought.
- Additionally, a description of the baseline data and the participants' recruitment status is provided. Additionally presented is data on the major and secondary outcomes, including mean, standard deviation, 95% confidence interval, probabilities, etc.
- The key topic of discussion should be determining the viability of the main study. Standards and things from earlier lists are condensed here. There is a list of potential biases or experimental issues that may arise in the primary study.

Finally, depending on the results of the pilot study, it is assessed and explained whether or not a major study is possible.¹⁴



Summary

A pilot study provides important information for determining the sample size as well as for evaluating all other components of the primary study, eliminating the need for extra work from the researchers and participants as well as the waste of research resources. The elements mentioned in the text must be precisely defined before the pilot research begins and show a high level of completion for it to fulfill its purpose. Additionally, a pilot study yields useful data that may be used for the researcher's primary study as well as other studies of a similar nature. For this reason, it is critical to provide comprehensive information on the feasibility of the investigation.

Critique

Researchers frequently suggest that a pilot study should examine the "preliminary safety" of an intervention; however, because pilot studies typically involve small sample sizes, they are unable to provide useful information on safety except in rare circumstances, such as when a death occurs or repeatedly serious adverse events are reported. Suspected safety issues are often minor or infrequent for the majority of interventions suggested by NCCIH investigators, making them unlikely to be discovered in a small pilot trial. Group-specific rates with 95% confidence intervals for adverse events should be reported if any safety issues are found. Investigators cannot, however, conclude that the intervention is risk-free if no safety issues were revealed in the pilot trial. (NCCIH Research Framework).

CONCLUSION

A pilot study yields useful data that may be used for the researcher's primary study as well as other studies of a similar nature. For this reason, it is critical to provide comprehensive information on the feasibility of the investigation.

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