

**Inputs for Power Analysis:
Planned Pilot Studies**

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Learning Objectives

Define a planned pilot study.

Recognize the benefits of a planned pilot.

Recognize the risks of a planned pilot.

Understand the difference between planned pilot studies and internal pilot studies.

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A planned pilot is a rehearsal of the actual study, with a similar design

A **planned pilot** precedes the actual study.

A **planned pilot** demonstrates feasibility of

1. the protocol,
2. recruitment and retention, and
3. the measurement process.

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A planned pilot can provide a preview of the actual study, when sufficiently similar

A **planned pilot** may (or may not) provide useful estimates of standard deviations and correlations.

A **planned pilot** may (or may not) provide useful estimates of means.

A **planned pilot** can support the credibility of the protocol in a grant proposal.

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Data collected in a pilot is *not* included in the final data analysis

Unlike internal pilot data, hypothesis testing should be done **only** on data collected after the end of the pilot, **excluding** pilot data.

If you omitted a planned pilot, then the beginning of your study become an unplanned pilot and corrupts your study.

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Planned pilot data has limitations when it comes to hypothesis testing

Researchers **may** conduct separate hypothesis tests in pilot.

Unlike internal pilot data, planned pilot data is **not** used in hypothesis testing in the final study.

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Researchers may only test hypotheses in a pilot study separate from the primary analysis

Inappropriate use of pilot data creates bias and increases Type I error.

Many interim analysis papers address the problem.

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A common, inappropriate use of pilot data involves the following process

1. Testing hypotheses using pilot data
2. Interpreting the p-values
3. Collecting more data
4. Combining pilot data with subsequent study data
5. Testing hypotheses again

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Investigators usually plan sequences of studies

As a result, power analyses based on pilot data may be optimistic or pessimistic.

Optimistic power chooses sample size too small; pessimistic power chooses sample size too big.

Bias is highly likely if the pilot analyses lead to changes in the analysis of the pooled data (Taylor & Muller, 1996).

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If the first study is non-significant, scientists may plan a larger study in an attempt to achieve significance

Power calculations are likely pessimistic, resulting in too large a sample size.

Pessimistic power chooses sample size too big.

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If the first study is significant, scientists may attempt to replicate the result

Power calculations are likely optimistic, resulting in too small a sample size.

Optimistic power chooses sample size too small.

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Pilot study data are used to generate estimates, which are in turn used to calculate power and sample size

Data observed in pilot studies come from random sampling.

Taylor and Muller, 1996
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Any value based on data collected using random sampling is also random in nature

Values of means, standard deviations and correlations from pilot studies are random; are **statistical estimates**.

Power and sample size values are also **statistical estimates** when based on (random) estimates from pilot studies.

Taylor and Muller, 1996
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Due to random inputs, power and sample size values have statistical uncertainty

Confidence bounds for power (statistical) **estimates** can account for variability.

Confidence bounds provide a range of estimates likely to contain the true value.

Taking the pilot estimates far too seriously is a chronic problem.

Taylor and Muller, 1996
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Risks with a planned pilot

Putting too much weight on pilot data can lead to counterproductive changes to the actual study.

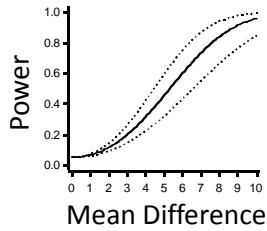
In the worst, case, useful research is abandoned.

If the protocol is known to work, then a pilot delays the research (not common).

Putting too little weight on the pilot feasibility can doom the actual study to problems or failure.

Taylor and Muller, 1996
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Power as a function of mean difference for observed variance estimate (black line) and 95% confidence limits (dotted lines) (Taylor & Muller, 1995).



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REVIEW OF LEARNING OBJECTIVES

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Why conduct a planned pilot study?

- To refine a protocol.
- To demonstrate feasibility, especially of recruitment and retention.
- To provide estimates for some inputs of power and sample size analysis for a grant proposal.
- To find bugs in protocol needing to be fixed.

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In a sentence or two, explain the difference between planned and internal pilot studies

Unlike internal pilot data, planned pilot data is used for grant writing but **not** for hypothesis testing.

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Questions?

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