

Why do a pilot study?

When to carry out a pilot study

A pilot, or feasibility study, is a small experiment designed to test logistics and gather information prior to a larger study, in order to improve the latter's quality and efficiency. A pilot study can reveal deficiencies in the design of a proposed experiment or procedure and these can then be addressed before time and resources are expended on large scale studies. Animal experiments are not usually carried out in isolation, but are part of a programme of research. A good research strategy requires careful planning and a pilot study will often be a part of this strategy.

A pilot study is normally small in comparison with the main experiment and therefore can provide only limited information on the sources and magnitude of variation of response measures. It is unlikely, for example, that a pilot study alone can provide adequate data on variability for a power analysis to estimate the number of animals to include in a well designed experiment. A systematic review of the literature or even a single publication is a more appropriate source of information on variability. The pilot study may, however, provide vital information on the severity of proposed procedures or treatments.

Logistical issues which may be revealed by a pilot study

A pilot study may address a number of logistical issues. As part of the research strategy the following factors can be resolved prior to the main study:

- Check that the instructions given to investigators (e.g. randomisation procedures) are comprehensible;
- Check that investigators and technicians are sufficiently skilled in the procedures;
- Check the correct operation of equipment;
- Check that the experimental animal can perform a task (physical or cognitive)
- Check the reliability and validity of results
- Detect a floor or ceiling effect (e.g. if a task is too difficult or too easy there will be skewed results)
- Assess whether the level of intervention is appropriate (e.g. the dose of a drug);
- Identify adverse effects (pain, suffering, distress or lasting harm) caused by the procedure, and the effectiveness of actions to reduce them (e.g. analgesia dose rate and schedule);
- Define early humane endpoints.

What to do with the data / information

The information obtained on logistical issues should be incorporated into the main study design. As the purpose of a pilot study is to assess the feasibility of an experiment it is very rarely sensible to present more than summary statistics of the data. In fact, the data might be irrelevant if problems with the methods are discovered.

If a pilot study does not lead to modification of materials or procedures then the data might be suitable for incorporation into the main study. The sampling strategy used to select subjects, and the possibility of changes over time should be carefully considered before incorporating pilot data. Even if the pilot data are not used in this way, and even if the final design differs markedly from the pilot, it is useful to include information on the pilot study in any publications or reports arising from the main experiment as this can inform the design of future experiments.

It may be necessary to carry out a second pilot study to assess the revised main study or in some cases the main study may have to be abandoned.

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Further information

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