Amsterdam Public Health

Amsterdam UMC University Medical Centers | VU Vrije Universiteit Amsterdam | University of Amsterdam

Quantitative research preparation – pilot study	Set-up & Conduct- Methods & Data Collection	
	VERSION	4.0

Aim

As suggested by an African proverb from the Ashanti people in Ghana "You never test the depth of a river with both feet", the main goal of pilot studies is to assess feasibility so as to avoid potentially disastrous consequences of embarking on a large study - which could potentially "drown" the whole research effort. (Thabane et al 2010)

Documentation

Criteria for success need to be developed before the start of the pilot in order to determine whether it is feasible to continue into the main study. If modifications to the protocol are needed, make sure to note the necessary changes in your electronic logbook.

Responsibilities

Executing researcher:

- Make sure each member of the project group considers the need of a pilot study;
- Clearly document decisions while undertaking the pilot study;
- Undertake a pilot study as you are performing the larger scale study.

Project leaders:

- Consider the need of a pilot study;
- Support the executing researcher in undertaking the pilot study.

Research assistant: N.a.

How To

In 2010, Thabane et al. published a tutorial on pilot studies. This handbook chapter was largely based on their work, please make sure to check the full article should you need additional information.

A pilot is usually conducted to test feasibility objectives, reasons for conducting a pilot study can be classified into 4 categories:

- Process: to test the feasibility of the separate steps of the study. For example; What are the anticipated number of participants? Are all medical files retrievable?
- Recourses: to test the time and budget problems that may occur. For example; Can all measurements be easily implemented? How long does it take to complete a questionnaire? Is the used software compatible with the data?
- Management: to test people and data management. For example; How long does a measurement take? How many measurements can be undertaken in one day? Are there any capacity issues?
- Scientific: to test the safety of treatments and the quality of the data. For example; Are all medical files retrievable? Have all the necessary details been registered in statuses? and is the quality of the data adequate?

Sample size of a pilot study

The sample size of a pilot study should be large enough to provide useful information about the aspects that are being assessed for feasibility (Thabane). Pilot studies may precede larger studies and may include a clear go/no go decision. The outcome of the pilot can be one of the following:

- Stop – target study not feasible
- Continue, but modify protocol – feasible with modifications
- Continue without modifications but monitor closely – feasible with close monitoring
- Continue without modifications – feasible as is

If the data are to be used for the target study, it is important that the population and in/exclusion criteria are the same. But beware that your decision to not change your protocol is not driven by your wish to include participants in the target study.

References

- Beurskens AJHM, de Vet HCW, Kant IJ. Dwalingen in de methodologie (Methodological erros). VIII. Pilot onderzoeken: zin en onzin (Pilot studies: Sense and nonsense). Ned T Geneesk., 1998; 142:2142-2145.
- Thabane L, MA J, Chu R, Cheng J, Ismaila A, Rios LP, Robson R, Thabane M, Giangregorio L, Goldsmith CH. A tutorial on pilot studies: the what, why and how. BMC Medical Research Methodology, 2010;10:1.

Audit questions

1. Are data being collected in this study?
    - If yes, was a pilot study conducted?
    - If no, why not?

LINKS

	Link

DOCUMENT HISTORY

Version	Status	Date	Name
4.0	Revision	02-11-20	Joske Nauta
3.0	Revision guideline	10AUG2016	EMGO
2.0	Revision format	12MAY2021	EMGO
1.1	Translated into English	01JAN2010	EMGO
1.0	Document created	14FEB2007	EMGO

DOCUMENT APPROVAL

Role	Name	Date
Project Leader	Dr. Seta Jahfari	12MAY2021