SUPPLEMENTARY FILES

Supplementary file 1. Details of sampling methods.

The sample subjects in the study should be representative of the population upon whom the inference has to be drawn and be in adequate numbers to detect a valid difference, should one exist. Sample size calculation is often performed after a pilot study or may be guided by outcomes measured in a previous similar study, called the index or parent article. When basing the sample size calculations on a parent article, students must ensure that the outcome variables under consideration are exactly the same as the primary outcome variable of the current thesis. Scientifically speaking, sample size should be calculated for primary as well as important secondary objectives. Many online sample size calculators are available which are easy to use e.g. clincalc.com, statulator.com, raosoft.com, openepi.com which also guide operators on how to calculate the sample size based upon their research design. Some common errors noted in dissertations with respect to sample size calculations include:

- Not mentioning the basis of sample size calculations at all. Mere mention of the sample size is not adequate.
- Many students consider an outcome variable of the parent article which is significantly different from outcome variables of the current project for calculation of power of the study.
- Some students document faulty or unrealistic assumptions in order to bring down sample size to manageable proportions
- Very commonly students draw conclusions on objectives even though the sample size is underpowered to detect a significant difference for the particular objective being discussed. It is of concern when this is the primary objective of their study.

Normally a study should have minimum power of 80%, and after primary analysis of data, various post hoc power analysis methods can measure it. These may be found on the websites which students use for sample size calculations in the first place. Higher the sample size, more will be the power of the study to answer the research question and more reliable will be the result. Study participants in excessive numbers may make the study more expensive and a waste of resources.

There are different ways of picking up subjects from a population for purpose of research which is called sampling. There are mainly two types of sampling methods.

Probability sampling involves random selection of subjects, but in a manner that every individual of the population has some known probability of inclusion in the sample. This sample is also likely to resemble the population from which it is drawn.

Probability sampling may be,

- Simple random sampling: This is easy to apply when small numbers are involved but needs a full list of members of the target population.
- Cluster sampling: The entire population is divided into clusters or groups and then all individuals in one cluster may be taken as the sample.
- Systematic sampling: This method fixes an interval to select members from a sampling frame, e.g. every 10^{th} member may be chosen.
- Stratified random sampling: Involves subgrouping the population into non-overlapping groups or strata from which the sample is obtained.

Non-probability sampling: Here the chances of a subject of being selected is unknown and this may therefore result in a selection bias. However, practically for many thesis projects, probability sampling is not practical, feasible, or ethical therefore non probability sampling techniques are employed.

- Convenience sampling: As the name suggests, it is as per convenience of the investigator. It is commonly used in clinical thesis research where patients as and when meet the inclusion criteria, are recruited into the study.
- Purposive sampling: This is similar to convenience sampling but here researchers rely on their own judgment when choosing members of the population for their survey/study.
- Snowball sampling: The initial respondents are chosen by any sampling method but then the additional subjects are obtained by information provided by the initial respondents.
- Quota sampling: The investigator may desire a certain composition and mix of his population. This method ensures that the characteristics of his sample will be representative of the population to the exact extent as the investigator desires.

Interim analysis and stopping rule

Interim analysis is usually not very relevant for a post graduate thesis however if some trial recruits subjects over a long period of time or if an intervention is resulting in particularly adverse or favourable outcomes, an interim analysis is mandated. The study may need to be terminated early for ethical reasons in such cases. The analysis will help keep the trial free of any conflicts of interest. Considerations of cost, resource utilisation, and meaningfulness of the study are often answered after an interim analysis. An interim power analysis may suggest changes in sample size or even the study design. When reporting an interim analysis in the thesis, authors report whether the analysis was sought by the data monitoring committee or it was a self-initiated analysis. Frequency of data monitoring by researchers and what reasons triggered the interim analysis or whether such an analysis was planned in the protocol itself, before the start of the trial. They should mention the statistical tools used. This will be important if any formal stopping rule is applied. When an interim analysis is performed on initial or limited data, the implementation of the stopping rule requires more stringent *P* values, as compared to later analyses. The later the analysis, the stopping *P* values may be nearer to the nominal levels of significance. Although rarely performed in a dissertation, this information is often not included even in published trials that report stopping earlier than planned.