Amsterdam Public Health

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

Quantitative research – Sampling – Sample size and power calculations	Set-up & Conduct- Methods & Data Collection	
	VERSION	4.0

Aim
To calculate sample size and/or power when applicable.

Requirements
Documentation of sample size and/or power and how these are calculated.
A reader has to be able to reproduce your calculations

Documentation
The following variables are required for calculating sample size:

- Significance (α)
- Power (b)
- Relevant effect
- Standard deviation (SD) of individual changes
- Outcome of sample size calculation.
- The assumptions made in your calculations.

Responsibilities
Executing researcher:

- To make sure sample size and/or power are calculated.

Project leaders:

- To calculate the sample size and/or power for the study, potentially in consultation with a statistician.

Research assistant: N.a.

Why
Sample size calculations are usually performed to determine the number of participants needed to detect a clinically relevant treatment effect. Pre-study calculation of the required sample size is warranted in the majority of quantitative studies. Also in objective research sample size calculations or power calculations can be of use, to determine how many cases or controls you need or how large the groups must be to detect meaningful differences.
Calculating the sample size in the design stage of the study is increasingly becoming a requirement for grant applications and when seeking ethical committee approval for a research project.

How To
Most importantly is to contact our biostatisticians for assistance. See 'Inleiding in de toegepaste biostatistiek' of Prof. dr. Jos Twisk for more information.
There are numerous formulas for calculating sample size and/or power [Cohen, 1998]. The differences correspond to differences in study design. From a statistical point of view, a lot of power calculations should come with critical notes. This is due to the fact that it is often difficult to provide true estimates of the parameters required for each formula. On the other hand, a sample size calculation is required for most grant applications to allow people to complete the necessary parameter values one way or the other. Here you can find an overview of calculation methods.

The calculation of sample size requires several components:

- the type 1 error (alpha) / false positive results: the probability of falsely rejecting H0 and detecting a statistically significant difference when the groups in reality are not different.
- the type 2 error (beta) / false negative results: the probability of falsely accepting H0 and not detecting a statistically significant difference when a specified difference between the groups in reality exists.
- power (1-beta): the probability of correctly rejecting H0 and detecting a statistically significant difference when a specified difference between the groups in reality exists.
- the smallest effect of interest: the minimal difference between the groups that is considered biologically plausible and clinically relevant.
- the variability / variance: the variability of the outcome measure.

The null hypothesis (H0) hypothesizes that the groups that are being compared are not different. The alternative hypothesis (Ha or H1) hypothesizes that the groups are different.

It should be noted that the routine of null hypothesis significance testing is increasingly criticized. See De Boer et al for a gentle introduction.

References

- Cohen J. Statistical power analyses for the behavioral sciences. Hillsdale, New Jersey: Lawrence Erlbaum, 2nd edn., 1988.
- De Boer MR, van Grootel LE, Bouter LM. Stop met het onkritische gebruik van nulhypothesen. Huisarts en Wetenschap 2018;61: DOI:10.1007/s12445-018-0255-4.
- Twisk J. Inleiding in de toegepaste biostatistiek. Amsterdam: Reed Business, 2nd edn., 2010.
- Noordzij M. Sample size calculations: basic principles and common pitfalls. Neprhology Dialysis Transplantation 2010; 25(5)1388-1392 https://academic.oup.com/ndt/article/25/5/1388/1842407

Audit questions

1. Has a power calculation been undertaken for each of your primary outcome measures?
    a. If so, has the measurement level of the outcomes been taken into consideration?
    b. If not, why not?
2. In the event of equivalence research, did you take the particular requirements imposed on the power calculations by this design into account?
3. Did the analysis investigate whether the power calculations in the protocol are based on realistic assumptions?
    a. If not, did you record this (in articles and reports)?
4. If the actual sample size was smaller than that calculated in advance, how was this dealt with in the analysis?

LINKS

	Link
Amsterdam UMC Biostatistics assistance for researchers	https://www.amsterdamumc.org/research/support/about/methodological-and-statistical-support.htm
OpenEpi	https://www.openepi.com/Menu/OE_Menu.htm

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DOCUMENT HISTORY

Version	Status	Date	Name
4.0	Revision	8DEC2020	Laura van Dongen, Prof. dr. Hans van der Wouden
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2.0	Revision format	12MAY2015	EMGO
1.1	Translation into English and updated	01JAN2010	EMGO
1.0	Minor textual amendments	01MAY2005	EMGO

DOCUMENT APPROVAL

Role	Name	Date
Project Leader	Dr. Seta Jahfari	16MAY2021