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How many are enough? Crucial role of sample size in research

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When one starts to do the research, it usually begins with a question. The question can be: "How many patients or participants or observations need to be included in the research?" For a robust study design there should be an appropriate sample size. The sample must be representative of the population.[1] When researchers submit a research proposal for the ethical clearance and approval from Institutional Review Committee (IRC) or Institutional Review Board (IRB), the review committee/ board often expect an explicit justification of the sample size in methodology section of the research proposal document. When sample size calculation is not mentioned, reviewers may wonder whether the sample size was adequate or not. An increasing number of academic journals request evidence of sample size calculation or specific requirements to be provided in the methodology section of a manuscript, and the calculation can be part of a checklist before submission of the original research article to the journals. Although sample size calculation is requested as part of the methodology section of an original article, this requirement has not increased the reporting of sample size remarkably.[2,3] Some journals may directly reject the submission of the original article if researcher fails to mention the sample size calculation. The statistical knowledge is increasing among the medical faculties. Despite many available resources on sample size calculation, the sample size calculation may be challenging for the medical students and faculties.

Sample size calculation involves several statistical terms. At the time of planning, the researcher must establish a justifiable level of statistical significance, the chances of detecting a difference of given magnitude between the groups compared (the power), the targeted difference (effect size), and the variability of the data for quantitative data. Most academic journals do not place limitations on the sample sizes.[4,5] The minimum sample should be 10% to 25% of size of the population depending on size of study population.[6] The sample size is inversely proportional to the size of study population, the larger size of population requires lower percentage of sample size and smaller population size requires the larger percentage of sample size. A more uniform or homogenous population needs a smaller sample than a diverse or heterogeneous population. Less sample size is required when the stratified random sampling technique is used compared to other sampling techniques. A sample size may be small, especially when investigating rare diseases or when the sampling technique is complicated and costly. However, too small sample size makes it challenging to reproduce the results, risks inconclusive or misleading results and can be unethical. It may produce high false negatives, which in turn undermine the scientific impact of the research. The larger sample sizes may give more reliable results with greater precision and power, but they also cost more time and money.[7] On the other hand, choosing too large sample size may be unethical, when human subjects are exposed to risks and wastes of resources. Moreover, too large sample size may lead the statistical significance even if the effect is not of practical or clinical importance (false positives).[1,4]

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Sample size is crucial in the research. Researchers should calculate an appropriate sample size to ensure that it reflects the population, minimizes error, and adequately addresses the research question. Researchers should not emphasise making the sample sizes large, rather they should focus on choosing an appropriate sample size that achieves precision, reliability and sufficient power. Appropriate sample size helps the statistical test to detect true positives result, comprehensively reporting the analysis techniques and interpreting the results in terms of p-values and generalisability of findings. Hence, the sample size calculation is important for striking a balance between risk and benefit.[4]

For the sample size calculation, it should be calculated based on statistical analysis. The type of analysis should be related to the study design and study objective. If a comparison between two or more groups is required after estimating the value of outcome variable in the population, the calculated sample size should be adjusted, in order to account for the types of statistical tests to be used in the comparison. This ensures that the final sample size is appropriately suited to the study's main objective.

If there is an intervention in the research or to find the difference between two or more groups, the effect size must be determined, in order to calculate the sample size. The effect size is defined as the minimum effect an intervention must have in order to be considered clinically or practically significant. This is a challenging step in sample size calculation.

A 95% confidence level indicates that the sample mean will not differ by more than a certain value from the true population mean in 95% of the repeatedly withdrawn samples from the same population. The margin of error is a measure of the precision of an estimate. The smaller the allowed margin of error, the larger the precision of our estimates and the larger the sample size.

The standard deviation and the prevalence / proportion of dependent variable can be obtained from the previous published studies. If the previous published study reference is not available, it may be obtained from the hospital record for similar study period. If there is no information regarding the standard deviation, the researchers can conduct a pilot study to estimate the value of standard deviation and if the value of the prevalence / proportion of dependent variable is unknown, it is best to use a value of 0.5 which gives a maximum sample size.

If the population is limited, the sample size can be adjusted for the finite population size. The size of a finite population can be obtained from a database or records, and is included in the sample size calculation.

All the participants may not be willing to participate in the research, which entails the possibility of a low response rate. A large difference between the calculated sample size and the number of participants in the study affects the generalisability of the results. Hence the dropout or noncompliance rate may be added to calculate the final sample size.

Sample size calculation can be done manually or may take help of the statistical software. For example, G Power, OpenEpi12 and the online calculator are commonly used for the sample size calculations in the health research. Sample Size Calculators are the tools for power and the calculations in the studies with dichotomous or continuous variables. The software offered by these tools varies in terms of the type of interface and the mathematical formula or assumptions used for the calculation. Most of the sample size calculation software packages include the option to select the required statistical test related to the response or outcome variable, with each test requiring a different sample size.

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