Editorial

Sample size estimation

The sample size is the number of participants or specimen required in a study and its estimation is important for both *in vivo* and *in vitro* studies. The sample size establishes the power and the impact of the study. The determined size should be optimum and has to be obtained by the scientific method. The arbitrary calculation with less or more can affect the study design and its significance. The larger size can lead to ethical concerns, time consumption, and financial wastage, and smaller sample size affects the effectiveness of the study.[1]

The sample size evaluation primarily depends on the study design and the outcome which is estimated prior to the start of the study. The determination varies with the statistical inference of the study which is done by either confidence interval technique (estimation) or test of significance procedure (hypothesis testing).

The factors affecting sample sizes are study design, method of sampling, and outcome measures – effect size, standard deviation, study power, and significance level.[2,3] The differences exist between the different types of study design alike description and analytical study. In general, the descriptive studies such as questionnaire and surveys require large sample size than analytical studies. All observational studies require more samples than the experimental studies. The estimation varies with the grouping, control, and population size in randomized clinical trials, observational and epidemiological studies. The studies of nonrandomized clinical study, multiple grouping, require more samples. The qualitative data outcome measures require more samples than the quantitative data.

The sample size for a study can be calculated from the standard deviation, significance, power, and effect size.[4,5] The standard deviation and effect size can be either determined from previous studies from literature or from pilot studies. The investigator's consideration on the effect of study plays a critical role in sample size estimation. If the investigator prefers to detect small effect size, it shall be better appreciated with an increased sample size.[6]

The significance level (type 1 error) and the power of the study are fixed before the study. The significance level is normally set at 0.05 or 0.01. For more accuracy, the significance level should be set at lower levels which increase the sample sizes. Anything more than these two levels can affect the study impact and should be done with caution unless it is essential for the study design. For appreciable inference, the power is normally set at 20% chance of missing difference or 80% chance of detecting a difference as statistically significant. This shall provide appreciable study impact.

Numerous methods are listed in literature to estimate the sample size. The researcher should adapt an effective, simple, and consistent system. Negligible errors in formula, grouping, statistical baseline values, study design, and the outcome measures can lead to faulty estimation with major impact on the external validity of the study. It is essential to consider all vital issues, more importantly the loss during follow-up. Nearly 10% of additional samples should be considered to the computed sample size for the follow-up loss.

The sample sizes are determined by nomograms, formulas, tables, and software.[7,8] There are published statistical tables, which provide the sample size for various situations. The statistical tables determine the sample sizes based on efficacy, confidence levels, and variability. It is an easier method comparatively but has assumptions and variability. Similar to the statistical tables, the nomograms determine the sample size with the effect size, standard difference, and confidence interval.

The formula for sample size estimation varies with the type of study designs. It is the more effective way in determining the sample size. It is cumbersome and difficult to the beginners and hence it is wise to take the help of a statistician before the start of the study. The easiest way to determine sample size is with the software. The sample size is determined by software using a target variance,

power of statistical test, and confidence interval. G*Power, PS, Russ Lenths power, Minitab, Stata, R package, PASS, and SampSize app are some of the software available to determine the sample size. Unlike using the complicated formulae, these software programs have made the calculation easier and simpler. A caution has to be ascertained during the use of these tools. Understanding of the research design and knowledge on common errors is mandatory. It is essential that these errors are controlled.

The studies in prosthodontics require more effective sample size estimations. It is necessary that all manuscripts either *in vivo* or *in vitro* have the sample size estimation. Many of the *in vitro* studies do not have effective determination and not stated clearly in the manuscript. If the earlier literature was used to determine, then it should effectively match in terms of materials, design, and standardization used in the study and it must be cited in the manuscript. A change of materials cannot be considered for sample size estimation. If no ideal study exist, it is always mandatory that a pilot study should be done to determine the effective sample size. Many studies lack clinical relevance due to inadequate sample size. This shall provide better impact, appreciation, and acceptance from the journals.

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