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**TÍTULO:** El cálculo del tamaño de la muestra en la investigación científica.

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**RESUMEN:** Este artículo proporciona una visión general de los enfoques comunes y los factores que afectan la determinación del tamaño de la muestra en varios diseños de estudio, incluyendo estudios experimentales, observacionales, cualitativos y de encuesta. Se discute la metodología utilizada para determinar el tamaño de muestra, junto con los desafíos, limitaciones e importancia de informar la determinación del tamaño de muestra en los estudios de investigación y proporciona pautas para hacerlo. El artículo concluye con la necesidad de que los investigadores consideren cuidadosamente la determinación del tamaño de muestra al diseñar estudios para garantizar resultados válidos y confiables. El artículo proporciona un recurso útil para investigadores y profesionales involucrados en el diseño e implementación de estudios.

**PALABRAS CLAVES:** estadísticas, tamaño de muestra, investigación científica.

**TITLE:** Sample size calculation in scientific research.

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**ABSTRACT:** This article provides an overview of common approaches and factors that affect sample size determination in various study designs, including experimental, observational, qualitative, and survey studies. The methodology used to determine sample size is discussed, along with the challenges, limitations, and importance of reporting sample size determination in research studies and provides guidelines for doing so. The article concludes with the need for researchers to carefully consider sample size determination when designing studies to ensure valid and reliable results. The article provides a useful resource for researchers and practitioners involved in study design and implementation.

**KEY WORDS:** statistics, sample size, scientific research.

## **INTRODUCTION.**

Sample size is an important concept in statistics and research methodology that refers to the number of observations or participants in a study. In scientific studies, researchers typically collect a sample of data from a larger population in order to make inferences or draw conclusions about that population. The size of the sample can have a significant impact on the accuracy and reliability of the study's findings, as well as on the statistical power of the analysis; therefore, choosing an appropriate sample size is crucial to ensure that the results of a study are valid and generalizable to the larger population. Sample size is an essential consideration in scientific research because it affects the accuracy, precision, and generalizability of the study's findings.

A larger sample size typically provides more accurate results because it reduces the impact of random variation or error. This is because larger samples tend to have a more representative distribution of the population, and any random variations are more likely to cancel out. This means that the results are more likely to reflect the true nature of the population being studied.

Sample size also affects the precision of the study's findings. A larger sample size leads to narrower confidence intervals around the estimate of the population parameter, providing more precise estimates of the effects of an intervention or relationship between variables.

The generalizability of the study's findings is influenced by the sample size. A larger sample size increases the likelihood that the results can be generalized to the larger population from which the sample was drawn, improving the external validity of the study.

It is crucial to carefully determine an appropriate sample size for a study, considering factors such as the research question, study design, available resources, and variability in the population being studied. Failure to select an appropriate sample size can result in inaccurate or misleading results, limiting the usefulness of the study's findings.

Determining an appropriate sample size for a study is a critical step in the research process. Some of the key issues related to sample size determination include:

- Accuracy: An important consideration when determining sample size is ensuring that the sample is large enough to accurately represent the population being studied. A larger sample size can reduce the margin of error and increase the precision of estimates.
- Statistical power: The statistical power of a study refers to its ability to detect a significant difference or effect if one exists. A larger sample size generally results in greater statistical power, which can increase the chances of detecting a significant effect.
- Cost: Collecting data can be expensive and time-consuming, so it is important to consider the cost of obtaining a larger sample size. Researchers need to balance the benefits of a larger sample size against the costs of collecting that data.
- Representativeness: It is important to ensure that the sample is representative of the population being studied. If the sample is not representative, the findings may not be generalizable to the larger population.
- Ethical considerations: Researchers must ensure that their sample size is large enough to avoid ethical concerns related to harm or exploitation of participants, while still being small enough to respect their autonomy and minimize the burden on them.

In summary, determining an appropriate sample size involves balancing various factors such as accuracy, statistical power, cost, representativeness, and ethical considerations to ensure that the study produces valid and reliable results.

Sample size determination is an important aspect of research design and planning, because it directly affects the statistical power, precision, and generalizability of study results. Inadequate sample sizes can lead to inaccurate or inconclusive findings, while excessively large sample sizes can be costly and time-consuming without providing any additional benefits.

Overall, sample size determination is a crucial step in the research process, and researchers should carefully consider the above factors when deciding on the appropriate sample size for their study. It involves several statistical concepts that are important to understand when designing a study. Some of the key concepts include:

- Power: Power is the probability of rejecting the null hypothesis when it is false. In other words, it is the ability of a study to detect a true effect if one exists. The desired power level of a study depends on factors such as the research question, the effect size, and the significance level.
- Effect size: The effect size is a measure of the magnitude of the difference between groups or the strength of an association between variables. It is typically expressed as a standardized difference or correlation coefficient. The effect size is an important factor in determining the sample size because larger effect sizes require smaller sample sizes to achieve a given level of power.
- Significance level: The significance level, also known as alpha, is the probability of rejecting the null hypothesis when it is actually true. It is typically set at 0.05, meaning that if the p-value of a test is less than 0.05, the null hypothesis is rejected. The significance level is also an important factor in determining the sample size because higher significance levels require larger sample sizes to achieve a given level of power.

- Variability: Variability refers to the amount of spread or dispersion in the data. In general, greater variability requires larger sample sizes to achieve a given level of power.
- Type I and Type II errors: Type I error is the probability of rejecting the null hypothesis when it is true, while Type II error is the probability of accepting the null hypothesis when it is false. Both errors are important to consider when determining the sample size because increasing the power of a study to reduce Type II error will also increase the risk of Type I error.
- Sampling design: The sampling design refers to the method used to select participants for the study. The sample size calculation will depend on the sampling design, such as simple random sampling or stratified sampling.

These statistical concepts are interrelated and must be carefully considered when determining the appropriate sample size for a study. The goal is to achieve adequate power to detect the desired effect size while minimizing the risk of Type I and Type II errors.

This article on sample size in scientific research aims to provide a comprehensive overview of the current knowledge and best practices related to sample size determination. The objectives are focused on:

- Summarizing the importance of sample size in scientific research, including the impact of sample size on statistical power, accuracy, and generalizability of findings.
- Reviewing the existing literature on sample size determination in various fields of research, including the methods and techniques used for determining sample size, as well as the factors that influence sample size determination.
- Discussing the advantages and limitations of different methods for determining sample size, including statistical power analysis, effect size estimation, and sample size calculation based on precision or accuracy requirements.

- Highlighting the ethical considerations involved in sample size determination, such as the potential risks and benefits to participants, and the need to ensure adequate representation of diverse populations.
- Providing practical guidance on how to determine an appropriate sample size for a given research question, including considerations of study design, data collection methods, and statistical analysis techniques.

Overall, this article aims to provide a comprehensive and up-to-date overview of the key issues related to sample size determination, with the goal of guiding researchers towards more accurate and reliable results.

## **DEVELOPMENT.**

### **Methodology.**

To identify relevant articles on sample size determination, the search strategy included the following steps:

- Define the research question: The first step was to clearly define the research question or topic of interest. "What are the best methods for determining sample size in scientific research?"
- Identify relevant keywords: The next step was to identify relevant keywords and phrases related to the research question. These included terms such as "sample size," "power analysis," "precision," "effect size," "statistical significance," and "research methodology".
- Search databases: Using a combination of relevant keywords, search relevant academic databases. These databases allow to search for articles related to the research question.
- Filter results: Once retrieved a list of articles, there was a filter of the results by relevance, date, and publication type. It was also used citation tracking tools to identify related articles and authors.

- Review articles: After filtering, followed a review of the articles and the selection of those that are most relevant to the research question. The abstracts and the full text of the articles were read to determine whether they provide useful information on sample size determination.

By using this search strategy that involves identifying relevant keywords and searching academic databases, it was possible to identify relevant articles on sample size determination and ensure that it is used the best available evidence to guide the research.

To identify relevant articles on sample size determination, it was searched a variety of academic databases that cover a wide range of disciplines. They included:

- PubMed: This database provides access to over 30 million citations from biomedical and life science journals.
- Scopus: Scopus is a multidisciplinary database that covers over 22,000 journals in the social sciences, life sciences, and physical sciences.
- Web of Science: This database includes over 20,000 scholarly journals in the sciences, social sciences, and arts and humanities. It is particularly useful for tracking citations and identifying related articles.
- PsycINFO: This database provides access to over 4 million citations and abstracts of scholarly articles in the field of psychology and related disciplines.
- Google Scholar: This search engine provides access to scholarly literature across a wide range of disciplines. It can be particularly useful for identifying grey literature and other sources that may not be included in traditional databases.

Other databases were also useful, such as Education Research Complete for educational research and IEEE Xplore Digital Library for computer science and engineering. It was used a combination of databases to ensure that most of relevant articles were identified.

Inclusion and exclusion criteria are important for identifying relevant articles on sample size determination. These criteria can help to ensure that the articles selected for review are appropriate for the research question and meet certain quality standards. The inclusion and exclusion criteria for identifying relevant articles on sample size determination for this article included:

**Inclusion Criteria:**

- Articles published in peer-reviewed journals.
- Articles that specifically address sample size determination in scientific research.
- Articles that include a description of the methods or techniques used to determine sample size.
- Articles that discuss the impact of sample size on statistical power, accuracy, and generalizability of findings.
- Articles that discuss the advantages and limitations of different methods for determining sample size.
- Articles that provide practical guidance on how to determine an appropriate sample size for a given research question.

**Exclusion Criteria:**

- Articles that do not focus on sample size determination in scientific research.
- Articles that do not provide a description of the methods or techniques used to determine sample size.
- Articles that only briefly mention sample size without providing substantive discussion or analysis.
- Articles that are not published in peer-reviewed journals.

This article on sample size determination aimed to include a sufficient number of articles to provide a comprehensive and balanced overview of the current state of knowledge on the topic. It included articles that represent a range of perspectives, methods, and disciplines to provide a well-rounded and informative review of the topic. It is important to note that the quality of the articles is more important



than the quantity. This article prioritizes articles that are methodologically rigorous, well-designed, and relevant to sample size determination.

### **Common approaches for sample size determination.**

Some of the most common approaches (Perneger, 1998; Hoenig & Heisey, 2001; Feise, 2002; Faul et al., 2009; Konietschke et al., 2012; Schönbrodt & Perugini, 2013; Hsieh & Wang, 2017; Li et al., 2017; Gamboa, 2018; Park & Kim, 2019) for determining sample size in different study designs are:

- Experimental studies: In experimental studies, the sample size calculation depends on the type of hypothesis being tested, the significance level, power, effect size, and variability. Commonly used approaches for calculating sample size in experimental studies include power analysis, sample size tables, and simulations.
- Observational studies: In observational studies, the sample size calculation depends on the type of study design, the population size, the expected prevalence or incidence of the outcome, the desired precision or margin of error, and the level of confidence. Commonly used approaches for calculating sample size in observational studies include formulae for cross-sectional studies, cohort studies, case-control studies, and nested case-control studies.
- Qualitative studies: In qualitative studies, the sample size calculation is not based on statistical power or significance levels but rather on theoretical saturation, which refers to the point at which no new information or themes emerge from the data. The sample size is usually determined by data collection methods, data analysis techniques, and the research question's scope.
- Survey studies: In survey studies, the sample size calculation depends on the desired level of precision, the expected response rate, the margin of error, the design effect, and the population size. Commonly used approaches for calculating sample size in survey studies include sample size calculators, sample size formulas, and sample size tables.

In general, the determination of sample size requires careful consideration of the study's objectives, research questions, study design, and statistical analysis plan. The sample size should be sufficient to ensure that the study has enough power to detect a significant effect or relationship between variables while minimizing the risk of type I and type II errors.

### ***Experimental studies.***

Here is a general approach to sample size calculation for experimental studies:

- Determine the research question: Define the primary research question and identify the primary outcome measure or dependent variable.
- Choose the significance level: Determine the level of significance ( $\alpha$ ) that reflects the acceptable probability of rejecting the null hypothesis when it is true. The most common level of significance is 0.05, which indicates a 5% chance of rejecting the null hypothesis when it is actually true.
- Determine the statistical power: Choose the desired level of statistical power ( $1 - \beta$ ), which reflects the probability of rejecting the null hypothesis when the alternative hypothesis is true. The most commonly used level of statistical power is 0.80, which indicates an 80% chance of detecting a statistically significant effect if one exists.
- Choose the effect size: Estimate the effect size, which reflects the magnitude of the difference between the treatment and control groups. The effect size can be obtained from previous studies or pilot data or estimated based on a clinically meaningful difference.
- Determine the allocation ratio: Determine the allocation ratio, which reflects the number of participants assigned to the treatment group relative to the control group. The most commonly used allocation ratio is 1:1, where an equal number of participants are assigned to the treatment and control groups.

- Calculate the sample size: Use a sample size formula to calculate the sample size needed to achieve the desired level of statistical power with the chosen level of significance and effect size. The most commonly used formula for calculating sample size in experimental studies is:

$$n = (2 \times (Z_{\alpha/2} + Z_{\beta})^2 \times SD^2) / (d^2)$$

where:

$n$  = sample size  $Z_{\alpha/2}$  = the standard normal deviate corresponding to the chosen level of significance  $Z_{\beta}$  = the standard normal deviate corresponding to the desired level of statistical power  $SD$  = the standard deviation of the dependent variable  $d$  = the effect size.

The formula  $n = \frac{Z^2 pqN}{(e^2 (N-1) + Z^2 pq)}$  is used to calculate the sample size for a finite population correction factor in a simple random sampling design. This formula is used when the population size ( $N$ ) is known, and the goal is to estimate a proportion ( $p$ ) or mean of the population with a certain level of precision ( $e$ ) and confidence level ( $Z$ ).

In this formula,  $n$  is the required sample size,  $Z$  is the standard normal distribution critical value for a given level of confidence,  $p$  is the estimated proportion of the population with a given characteristic,  $q$  is the complementary probability to  $p$  (i.e.,  $q=1-p$ ), and  $e$  is the desired margin of error.

The finite population correction factor is used to adjust the sample size calculation when the population size is relatively small compared to the sample size. The correction factor takes into account the fact that sampling without replacement from a finite population can affect the precision of the estimate compared to sampling with replacement from an infinite population.

- Adjust for attrition: Adjust the sample size for potential attrition or dropout during the study period. This can be done by increasing the sample size by a percentage that reflects the expected attrition rate.

In conclusion, sample size calculation for experimental studies involves determining the research question, choosing the significance level and statistical power, estimating the effect size, and using a

sample size formula to calculate the number of participants needed to achieve the desired level of precision and power.

### ***Observational studies.***

Observational studies include a range of study designs, such as cohort studies, case-control studies, cross-sectional studies, and nested case-control studies. The sample size calculation for observational studies depends on the study design and the research question. Here, we will discuss the sample size calculation for three common observational study designs, with references from peer-reviewed journals.

### ***Cross-sectional studies.***

Cross-sectional studies aim to estimate the prevalence or distribution of a particular disease or condition in a population at a specific point in time. The sample size calculation for cross-sectional studies depends on the expected prevalence or proportion of the outcome, the desired precision, the level of confidence, and the population size. A common formula for calculating the sample size for cross-sectional studies is:

$$n = (Z^2 \times P \times (1-P)) / d^2$$

- n: the sample size needed to estimate the prevalence or proportion of the outcome with the desired level of precision and confidence.
- Z: the standard normal deviate (Z-score) that corresponds to the desired level of confidence. For example, if the desired confidence level is 95%, the corresponding Z-score is 1.96.
- P: the expected prevalence or proportion of the outcome in the population. This is usually estimated from previous studies or pilot data. It represents the proportion of individuals in the population who have the outcome of interest.
- (1-P): the complement of P, which represents the proportion of individuals in the population who do not have the outcome of interest.

- $d$ : the desired margin of error or precision. It represents the maximum difference between the estimated prevalence or proportion in the sample and the true prevalence or proportion in the population.

The formula assumes that the prevalence or proportion of the outcome follows a binomial distribution, and that the sample is drawn from a larger population using simple random sampling. If the population size is small, a finite population correction factor can be applied to adjust the sample size formula.

For example, in a cross-sectional study that aimed to estimate the prevalence of depression in a rural community in Ethiopia, the researchers used a sample size formula based on the expected prevalence, margin of error, and confidence level to calculate the sample size. They determined that a sample size of 384 was needed to estimate the prevalence of depression with a 5% margin of error and 95% confidence level (Mekonnen et al., 2019).

### ***Cohort studies.***

Cohort studies follow a group of individuals over time to assess the incidence or risk of a particular outcome. The sample size calculation for cohort studies depends on the expected incidence or risk of the outcome, the desired power, the level of significance, and the follow-up time. A common formula for calculating the sample size for cohort studies is:

$$n = (Z_{\alpha/2} + Z_{\beta})^2 \times (P_1(1-P_1) + P_2(1-P_2)) / (P_1 - P_2)^2$$

- $n$ : The required sample size.
- $Z_{\alpha/2}$ : The Z-score associated with the desired level of significance (e.g., 1.96 for a 95% significance level).
- $Z_{\beta}$ : The Z-score associated with the desired power (e.g., 0.84 for 80% power).
- $P_1$ : The expected incidence or risk of the outcome in the exposed group.
- $P_2$ : The expected incidence or risk of the outcome in the unexposed group.

The formula assumes that the incidence or risk of the outcome is binary (i.e., either the outcome occurs, or it does not occur), and that the exposure is also binary (i.e., either the individuals are exposed or unexposed).

The first part of the formula,  $(Z_{\alpha/2} + Z_{\beta})^2$ , is a function of the desired level of significance and power, and represents the variability that can be tolerated in the estimates. The second part of the formula,  $(P_1(1-P_1) + P_2(1-P_2)) / (P_1 - P_2)^2$ , represents the difference in the incidence or risk of the outcome between the exposed and unexposed groups that the study aims to detect.

In summary, the sample size calculation for cohort studies takes into account the desired level of significance, power, and the expected incidence or risk of the outcome in the exposed and unexposed groups and aims to provide an adequate sample size to detect a difference between the groups.

For example, in a prospective cohort study that aimed to assess the relationship between dietary intake and breast cancer risk in Iranian women, the researchers used a sample size formula based on the expected incidence, level of significance, and power to calculate the sample size. They determined that a sample size of 4800 was needed to detect a 15% reduction in breast cancer risk with 80% power and a 5% significance level (Ravanshad et al., 2019).

### ***Case-control studies.***

Case-control studies compare the exposure history of individuals with a particular disease or outcome (cases) to those without the disease (controls). The sample size calculation for case-control studies depends on the expected prevalence or proportion of the exposure, the desired power, the level of significance, and the ratio of cases to controls. A common formula for calculating the sample size for case-control studies is:

$$n = (Z_{\alpha/2} + Z_{\beta})^2 \times [(P_1(1-P_1) / P_2(1-P_2))]$$

- n: The required sample size (the number of cases and controls combined).

- $Z_{\alpha/2}$ : The Z-score associated with the desired level of significance ( $\alpha$ ), which is usually set to 0.05 for a two-tailed test.  $Z_{\alpha/2}$  represents the number of standard errors from the mean of a normal distribution that corresponds to the desired level of significance.
- $Z_{\beta}$ : The Z-score associated with the desired power ( $1-\beta$ ), which is usually set to 0.80 or 0.90.  $Z_{\beta}$  represents the number of standard errors from the mean of a normal distribution that corresponds to the desired power.
- $P_1$ : The expected prevalence or proportion of exposure in the cases.
- $P_2$ : The expected prevalence or proportion of exposure in the controls.

The formula assumes that the exposure is dichotomous (i.e., present or absent) and that the cases and controls are sampled independently from the same population.

The numerator of the formula,  $(Z_{\alpha/2} + Z_{\beta})^2$ , represents the variance of the estimate, which depends on the level of significance and power. The denominator,  $[(P_1(1-P_1) / P_2(1-P_2))]$ , represents the effect size or the difference in exposure prevalence between cases and controls. The larger the effect size, the smaller the required sample size. Note that the formula assumes that the cases and controls are sampled in a 1:1 ratio. If the ratio is different, a modification factor can be applied to adjust the sample size calculation.

For example, in a case-control study that aimed to investigate the association between occupational exposure to electromagnetic fields and childhood leukemia, the researchers used a sample size formula based on the expected exposure prevalence, level of significance, and power to calculate the sample size. They determined that a sample size of 200 cases and 400 controls was needed to detect a 2-fold increase in the risk of leukemia associated with electromagnetic fields exposure with 80% power and a 5% significance level (Kheifets et al., 2010).

***Qualitative studies.***

Sample size calculation for qualitative studies is often determined by the concept of data saturation. Data saturation is the point at which no new information is being generated and collected from the participants. Therefore, researchers generally aim to reach data saturation in qualitative studies.

The sample size calculation for qualitative studies depends on the research question, research design, and the target population. In qualitative research, researchers often use purposive sampling, which involves selecting participants who have specific characteristics or experiences related to the research question.

To calculate the sample size for qualitative studies, researchers typically use a criterion known as theoretical saturation. Theoretical saturation refers to the point at which the data collected is sufficient to achieve a complete understanding of the phenomenon under investigation; for instance, in a study examining the experience of individuals living with chronic illness, the researchers may continue data collection until no new themes or categories are emerging from the data, and they feel confident that they have achieved theoretical saturation.

The sample size calculation for qualitative studies is not typically based on statistical power calculations. Instead, the goal is to select a sample size that is adequate for the research question and design to reach data saturation. Researchers often use a range of 10-30 participants in their studies, but this can vary depending on the study's goals, the complexity of the phenomenon being studied, and the richness of the data.

Therefore, the sample size calculation for qualitative studies involves determining the number of participants required to achieve theoretical saturation or data saturation. Researchers should use their judgment and consider factors such as feasibility, resource availability, and the nature of the study to determine the appropriate sample size.



***Survey studies.***

Sample size calculation is an important aspect of survey research, as it ensures that the sample is representative of the population being studied, and that the study is adequately powered to detect significant differences or associations between variables. The sample size for survey studies depends on several factors, such as the size of the population, the desired level of precision, and the expected response rate. Here are the steps to calculate sample size for survey studies:

- Determine the population size: The first step in calculating the sample size for a survey is to determine the size of the population being studied. This could be the entire population, or a subset of the population.
- Determine the level of precision: The level of precision refers to how close the sample estimate is expected to be to the true population parameter. The level of precision is usually expressed as a margin of error, which is the range within which the true population value is expected to lie with a certain degree of confidence. The level of precision is often expressed as a percentage or proportion, such as +/- 3%, or 0.05.
- Determine the desired level of confidence: The level of confidence refers to the degree of certainty with which the sample estimate can be generalized to the population. The most common level of confidence used in survey research is 95%.
- Determine the expected response rate: The expected response rate refers to the proportion of the sample that is expected to respond to the survey. The response rate can vary depending on the survey method, the nature of the questions, and the population being studied.
- Use a sample size calculator: Once the population size, level of precision, level of confidence, and expected response rate have been determined, a sample size calculator can be used to calculate the sample size. There are several sample size calculators available online, which allow researchers to input the relevant variables and determine the appropriate sample size.

- Adjust for design effect: The design effect refers to the extent to which the sample design increases the variance of the estimates beyond what would be expected from a simple random sample. The design effect is often greater in surveys that use complex sampling designs or stratified sampling. To adjust for the design effect, the calculated sample size should be multiplied by the design effect factor.
- In summary, sample size calculation for survey studies involves determining the population size, level of precision, level of confidence, expected response rate, and adjusting for the design effect. Sample size calculators can be used to simplify the process and ensure that the sample is representative of the population and adequately powered to detect significant differences or associations.

### **Factors affecting sample size determination.**

Several factors can affect the determination of the sample size, including:

- Effect size: The effect size is the magnitude of the difference or association between variables of interest. A larger effect size requires a smaller sample size to achieve statistical significance.
- Type I and Type II errors: Type I error refers to rejecting the null hypothesis when it is actually true, while type II error refers to accepting the null hypothesis when it is actually false. Controlling for these errors requires an appropriate sample size to detect a significant difference or association between variables.
- Variability: The variability of the population being studied affects the sample size. A population with high variability requires a larger sample size to achieve statistical significance than a population with low variability.
- Statistical power: Statistical power is the probability of rejecting the null hypothesis when it is actually false. A higher statistical power requires a larger sample size.

- Confidence level: The confidence level determines the level of certainty that the true population parameter lies within a given interval. A higher confidence level requires a larger sample size.
- Research design: The research design can affect the sample size determination, such as the number of groups being compared, or the type of statistical analysis used.
- Population size: The population size affects the sample size determination when sampling without replacement from a finite population. A larger population size requires a larger sample size to achieve the same level of precision.
- Resources: Resources such as time, budget, and personnel can affect sample size determination. A larger sample size requires more resources for recruitment, data collection, and analysis.

In conclusion, determining an appropriate sample size requires considering several factors, such as the effect size, type I and type II errors, variability, statistical power, confidence level, research design, population size, and resources. Researchers need to carefully consider these factors to ensure that the sample size is adequate to achieve the study's research objectives.

In addition, researchers should consult statistical experts and use appropriate statistical software to calculate the sample size. Here are some software options for sample size calculation:

- G\*Power: This is a free and user-friendly software that allows you to calculate sample size and power for various statistical tests, including t-tests, ANOVA, regression, and correlation. It also provides a graphical user interface that can be helpful for those who are not familiar with programming.
- R: R is a free and open-source programming language that can be used for statistical computing and graphics. It has many packages that allow you to calculate sample size for different types of analyses, such as power analysis, sample size determination for survival analysis, and cluster randomized trials.

- SAS: SAS is a proprietary software suite that is commonly used in clinical research and other fields. It provides many functions for calculating sample size and power for different types of analyses.
- Stata: Stata is a proprietary statistical software that provides a user-friendly interface for sample size calculation. It has built-in functions for power analysis and sample size determination for different types of designs.
- PASS: PASS (Power Analysis and Sample Size) is a proprietary software that provides a comprehensive suite of tools for sample size calculation and power analysis. It has a user-friendly interface and supports a wide range of statistical tests and designs.
- Catamu: It is an Excel book that allows the user to input multiple data and use it in decision-making to calculate sample sizes.
- Researchers should also conduct sensitivity analyses to explore the robustness of their sample size calculations under different scenarios. Finally, researchers should clearly document their sample size calculations and assumptions in their research protocol to ensure transparency and reproducibility.

### **Reporting of sample size determination.**

Reporting sample size determination in research articles is important for several reasons:

- Reproducibility: Reporting sample size determination allows other researchers to reproduce the study and verify the findings. It enables them to understand the study design, the statistical analysis, and the conclusions drawn from the data.
- Transparency: Reporting sample size determination demonstrates transparency and accountability in the research process. It allows readers to evaluate the adequacy of the sample size and the power of the study to detect a significant effect. It also allows readers to assess the potential risk of bias or error in the study.

- Scientific rigor: Reporting sample size determination is essential for ensuring scientific rigor and validity. An inadequate or inappropriate sample size can lead to inaccurate or misleading conclusions and may undermine the credibility of the study.
- Ethical considerations: Reporting sample size determination is also important from an ethical perspective. An inadequate sample size may lead to inconclusive results, or may require the recruitment of additional participants, which can be time-consuming and costly. Reporting sample size determination helps ensure that the study is conducted in an efficient and ethical manner, with minimal harm to participants.

Reporting sample size determination is critical for ensuring transparency, reproducibility, scientific rigor, and ethical considerations in research. It is therefore essential that researchers report their sample size calculations and assumptions clearly and thoroughly in their research articles.

### **Guidelines for reporting sample size determination.**

The following are some general guidelines for reporting sample size determination in research articles:

- Explain the rationale for the sample size: Provide a clear and concise rationale for the sample size determination, including the research question, the study design, and the statistical analysis. Explain why the sample size is appropriate for the research question and the study objectives.
- Specify the statistical methods used: Specify the statistical methods used to determine the sample size, including the type of statistical test, the significance level, the power, and the effect size. Describe the assumptions made about the population and the variability of the data.
- Provide the sample size calculation: Provide the sample size calculation, including the formula used, the variables and parameters used in the calculation, and the resulting sample size. Provide a justification for the chosen values of the variables and parameters.
- Describe the sampling method: Describe the sampling method used to select the study participants, including the sampling frame, the sampling technique, and the sample size allocation.

- Report the sample characteristics: Report the characteristics of the study sample, including the sample size, the demographic characteristics, and any relevant clinical or other characteristics.
- Discuss any limitations: Discuss any limitations of the sample size determination, such as assumptions made about the population or the variability of the data, and the potential impact of these limitations on the study results.
- Interpret the results: Interpret the study results in light of the sample size determination, including the statistical significance of the findings, the effect size, and the statistical power.

In general, the reporting of sample size determination should be clear, transparent, and comprehensive. It should enable readers to understand the rationale and methodology of the sample size determination, and to evaluate the adequacy and validity of the study results.

### **Challenges and limitations.**

Sample size determination can be challenging and subject to limitations. Some of the challenges and limitations include:

- Uncertainty of parameters: Sample size determination often depends on estimates of various parameters such as effect size, standard deviation, and correlation coefficient. These estimates may be uncertain, and inaccurate estimates can lead to inadequate or excessive sample sizes.
- Cost and feasibility: Larger sample sizes are often more accurate, but they can be more costly and time-consuming to collect. This can limit the feasibility of conducting larger studies.
- Ethical considerations: The recruitment of larger sample sizes may raise ethical concerns, particularly if the research involves vulnerable populations or if the study requires invasive or risky procedures.
- Generalizability: Sample size determination assumes that the study sample is representative of the population of interest. However, the sample may not be representative, which can limit the generalizability of the study findings.

- Study design: Sample size determination depends on the study design and statistical analysis. Different study designs and statistical tests may require different sample sizes, and the choice of design and analysis can affect the accuracy and precision of the sample size determination.
- Type of outcome measures: Sample size determination can be affected by the type of outcome measures used in the study. For example, studies with binary outcomes require larger sample sizes than studies with continuous outcomes.
- Variability of the data: The variability of the data can affect the accuracy and precision of the sample size determination. If the data is highly variable, larger sample sizes may be needed to achieve a certain level of precision.

In summary, sample size determination is subject to several challenges and limitations. These challenges and limitations highlight the importance of careful planning and consideration when determining sample size in research studies. It is important to consider the study design, statistical analysis, ethical considerations, and other factors that may affect the accuracy and precision of the sample size determination.

Sample size calculations are essential in research studies as they determine the minimum number of participants needed to obtain statistically significant results. However, these calculations are based on certain assumptions and uncertainties, which may affect the accuracy of the results.

Assumptions:

- Effect size: The effect size is a measure of the magnitude of the difference between two groups or the strength of the relationship between two variables. Sample size calculations are based on assumptions regarding the effect size. If the effect size is overestimated, the sample size may be too small, leading to insufficient power to detect the effect. Conversely, if the effect size is underestimated, the sample size may be too large, leading to unnecessary costs and time.

- Level of significance: The level of significance is the probability of rejecting the null hypothesis when it is true. It is typically set at 0.05 or 0.01. Sample size calculations assume a specific level of significance, and changing this level can affect the required sample size.
- Variability: Variability refers to the degree to which scores in a sample differ from each other. Sample size calculations are based on assumptions regarding the variability of the population. If the variability is overestimated, the sample size may be too small, leading to insufficient power to detect the effect. Conversely, if the variability is underestimated, the sample size may be too large, leading to unnecessary costs and time.

#### Uncertainties:

- Sample size: The sample size calculation itself may be subject to uncertainty. The formula used to calculate the sample size assumes that the population standard deviation is known, which is often not the case. In these instances, researchers must estimate the standard deviation based on previous research or pilot studies, which can lead to uncertainty in the sample size calculation.
- Nonresponse rate: Nonresponse rate refers to the proportion of participants who decline to participate in the study. Sample size calculations assume a specific nonresponse rate, which may not reflect the actual nonresponse rate. If the nonresponse rate is higher than expected, the sample size may be too small, leading to insufficient power to detect the effect.
- Missing data: Missing data can affect the accuracy of sample size calculations. If there is a high rate of missing data, the sample size may be too small, leading to insufficient power to detect the effect.

In conclusion, sample size calculations are essential in research studies, but they are based on assumptions and uncertainties that may affect the accuracy of the results. Researchers should carefully consider these factors when calculating sample sizes and interpreting the results of their studies.



## CONCLUSIONS.

Sample size calculations are used in research studies to determine the minimum number of participants needed to obtain statistically significant results. However, the accuracy of these calculations is based on certain assumptions and uncertainties. Assumptions include the effect size, level of significance, and variability. Uncertainties include the sample size, nonresponse rate, and missing data. It is important for researchers to carefully consider these factors when calculating sample sizes and interpreting the results of their studies.

To determine the appropriate sample size for their studies, researchers can follow these general recommendations:

- Define the research question and hypotheses: Before calculating sample size, researchers need to define the research question and hypotheses of their study. This will help them determine the type of statistical analysis they will use and the effect size that is relevant to their research.
- Choose the level of significance: Researchers need to choose the level of significance (alpha level) that they will use in their study. The most commonly used levels are 0.05 or 0.01, but the level of significance may depend on the research area or the type of study being conducted.
- Determine the effect size: Researchers need to estimate the effect size of their study. This can be done through a literature review or pilot study. The effect size is a measure of the strength of the relationship between two variables or the magnitude of the difference between two groups.
- Consider the variability: Researchers need to consider the variability of the population being studied. This can be estimated through a pilot study or by using previous research in the area. The variability will affect the precision of the sample size calculation.
- Choose the power: Researchers need to choose the desired power of their study. Power refers to the ability of the study to detect a significant difference if one exists. A power of 0.80 is commonly used, but the power level may depend on the research area or the type of study being conducted.

- Use a sample size calculator: Researchers can use online or software-based sample size calculators to estimate the minimum sample size required for their study. These calculators require information on the level of significance, effect size, variability, and power.
- Consider practical issues: Researchers need to consider practical issues such as the availability of participants, the resources needed to collect the data, and ethical considerations. It may not always be feasible to recruit a sample size that meets the theoretical requirements of the study.

In summary, determining the appropriate sample size for a study requires careful consideration of the research question, level of significance, effect size, variability, power, and practical issues. Researchers can use online or software-based sample size calculators to estimate the minimum sample size required for their study.

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