

Research Process, Study Variables, Statistical Validations, and Sampling Methods in Public Health Related Research: An Update

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Abstract Scientific research is a systematic process that involves a research question, appropriate methodology, participant selection, collection of data, processing/analysis of the data using statistical applications, and finally deriving conclusions. Most public health research-related study conclusions are utilized to the betterment of the people and therefore such research is considered as evidence upon which health-related decisions are taken by the governments. In this review, we discuss the most influential aspects of the research including the research process, study variables, statistical validations, and sampling methods.

Keywords: *research, process, methodology, statistical applications, validations, sampling methods*

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1. Introduction

The research proposal is a document that is prepared by an individual who envisages conducting it. A research proposal consists of all the necessary details of a research project that is intended to be carried out. It generally serves as a blueprint for research and is intended to gain the confidence of the sponsors, institutional review boards,

and other stakeholders in the research. The three important elements which are needed to be satisfied while writing a research proposal include what do you want to achieve (answer to a research problem), why is this research being conducted (purpose), and how do you want to do it (methodology).

The essential components of a research proposal in the serial order include the title, the abstract, introduction, objectives, variables, hypothesis/research question, and methodology as shown in [Table 1 \[1,2\]](#).

Table 1

Research component	Function	Applications
Title	The research title must be able to convey the motive of the research. It should not be either too long or too short. It must be as clear as possible and deliver the core idea regarding the purpose of the research/result. Attracts the reader's attention	Depicts the scope and area/subject of research
Abstract	This should have a brief description of the research question, purpose of research/hypothesis, and the methodology. It is a mini version of the complete research proposal which contains important aspects like the method used, subjects recruited, among others	The abstracts convey the summary of the research work that includes the context/background, methods, results, and conclusions
Introduction	This section tries to justify the study, or elaborate the rationale of the study systematically by briefing the background literature on the area of research that may converge to the aims of the research	Identifies the research background and potential research gap that justifies the importance of the current research
Literature Review	This involves searching for the research related available up to now. The researcher evaluates it critically and gains knowledge. This helps the researcher to improve the understanding of the topic and come out with newer ideas, and assumptions. A thorough literature review helps a researcher to make significant research contributions including novel discoveries	Identifies the available pieces of evidence, either accepts the previous standpoint or negates the available evidence. Potentially fills the research gap.

Research component	Function	Applications
Objectives	This section justifies the reason for the conduction of research by interpreting the potential goals that may be achieved.	General objectives: Probably identifies the main goal of the study Specific objectives: To get an answer to the research question that was framed by the researcher
Variables	The elements of research may interfere with the study results. The variables are generally measurable (dependant variables)	Independent variables: These may include the predisposing factors, risk factors, and others Dependent variables: The changes which are inevitable, i.e. the outcome, effect, result, and others Confounding variables: Unexpected, ignored, and probably unforeseen factors that may interfere with the results Background variables: These include demographic factors like age, sex, and others
Research Hypothesis	This section delineates the potential predictions/assumptions regarding the results of a study. Such a statement which is made only after an extensive review of the literature and prior knowledge, expertise, and creativity of the researcher	Helps to identify and predict research failure and progress
Methodology	This section describes how the proposed research will be conducted. The most important aspect of research is its reproducibility. The methods need to be detailed enough for another researcher, or the same researcher to reproduce	Study design: which type of study; descriptive, observational, analytical, experimental, etc. Study subjects: experimental animals, humans, selection/inclusion criteria, exclusion criteria, ensuring internal and external validity, the inclusion of control group Sample size: This should consider the external validity, not too little or not too many, cost-effectiveness, vulnerable population, etc. Interventions: Caution with clinical trials of unapproved drugs/medical products Ethical concerns: Most important aspects that need to be addressed in the methodology section. Informed consent is a must

The titles can be descriptive, declarative, and interrogative. The descriptive titles reveal the important elements of research that may include the subjects involved. Such titles however do not reveal the results and conclusions. The declarative titles may include the findings of the study and conclusive evidence. The interrogative titles appear to be inquisitive to the readers and include a research question within the title, however, they are least preferred [3].

Titles may also be compound in nature wherein the main title is followed by a subtitle that may be separated by a colon (:). Compound titles provide the readers with some specific elements of the research like the geographical areas researched, among others [4]. Journal articles with inappropriate titles may be at threat to being ignored by the readers and therefore may receive less attention [5]. The titles should preferably be informative and concise [6].

The need for a research proposal germinates from the necessity of an individual to prove his/her ability to carry out work or a project in a well-planned procedure. This will enforce the confidence of the peers in the researcher. The research proposals may be invited or unsolicited, wherein the researcher submits them for approval from a sponsoring body. Traditionally, most research proposals are based on academic requirements, which are necessary to acquire degrees like undergraduate, postgraduate, or doctoral degrees [7].

2. Design and Format of Research Proposals

To develop a research proposal, a researcher must be motivated. There are several basic requirements involved in the development of a research proposal. These include formulating the working topic, defining the research title, identifying the purpose of research, and the potentially interested parties concerning the area of research, performing pilot/preliminary work, cornering a research question and working out a clear plan as shown in Figure 1 [8].

A research proposal is a concise document that delineates the most significant elements of the research that includes the title of the research, introduction, background information, problem statement, hypothesis, aims, and objectives, the methodology that includes details of the study period, design, sampling methods, methods of data analysis, ethical clearances, financial considerations like the budget, sponsors, and references as shown in Figure 2.

Currently, there are scarce recommendations and guidelines regarding the preparation of a quality research proposal. The most important aspect before preparing a research proposal is the careful review of the literature. This allows the researcher to understand the current knowledge, identify the gaps, and build on it [9].

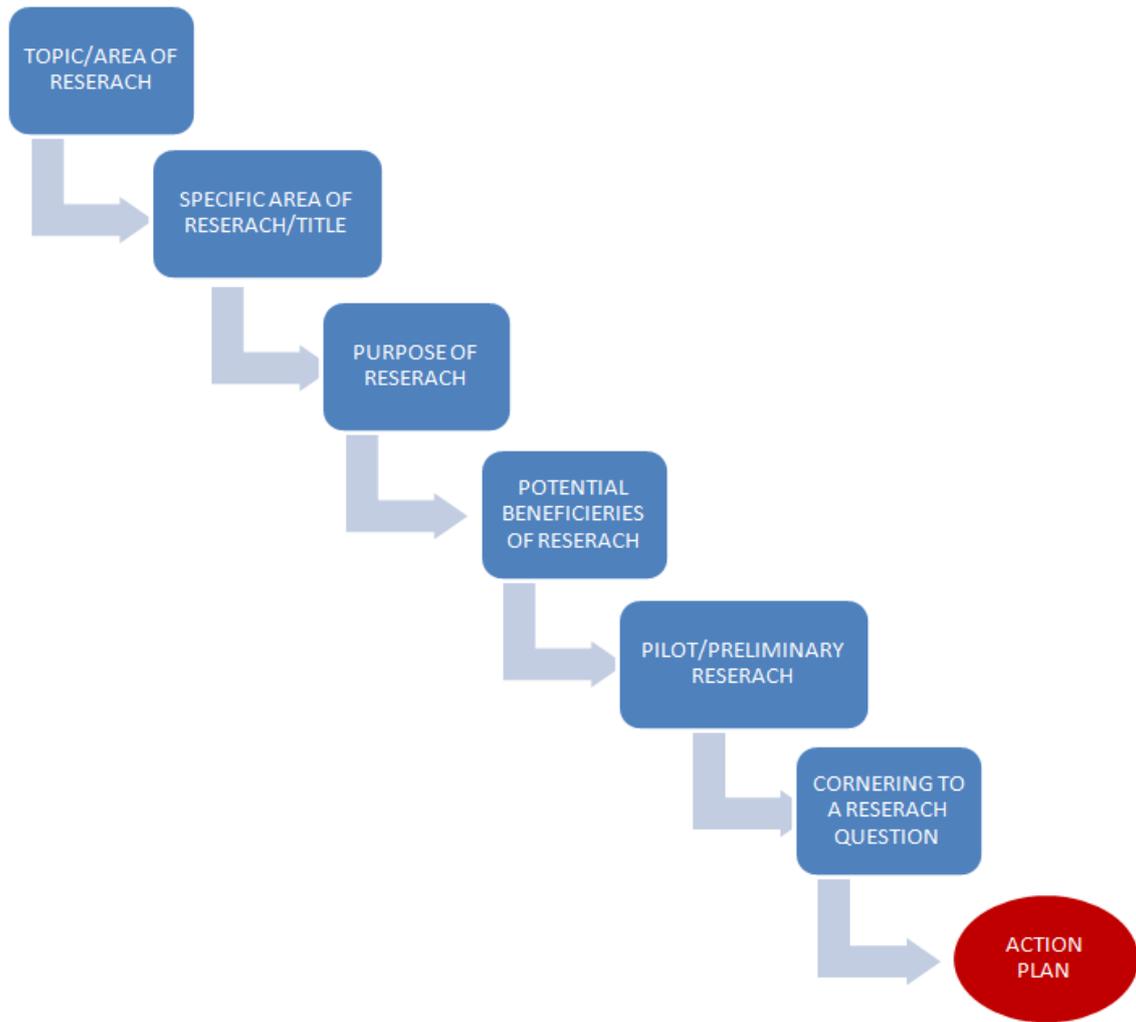


Figure 1. Diagrammatic representation of the steps involved in the development of a research plan

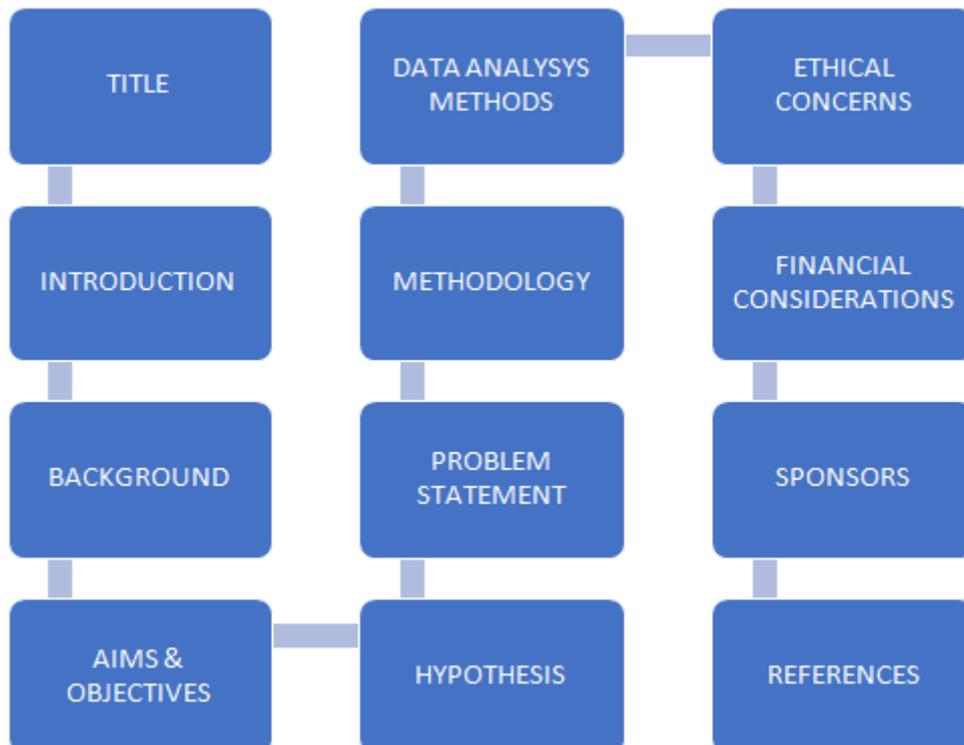


Figure 2. Diagrammatic representation of the elements of a research proposal

3. Study Variables that Interfere with Research Results and Observations

A variable is an element, aspect, or factor of investigation in research that is bound to changes. The variables included in the study that vary or change depending on certain research/experimental factors are called dependant variables. The dependent variables are generally associated with the study participants and are usually perceived as effects enforced by the changes in independent variables. However, the independent variables are those aspects that don't change based on the experimental reasons and alterations in the other variables included in the study. In most instances, the independent variable is potentially the cause for changes in the dependant variables.

The independent variables are also called exploratory, predictor, and right-hand-side variables. They may be experimental variables (drug composition in a clinical trial) and subject variables (gender, education, income, etc.) wherein the former ones are manipulated by the researcher whereas the latter cannot be changed.

A variable that could influence both the dependent and independent variables is called a confounder variable. A confounding variable may be considered as an extra variable that influences the research result unexpectedly. The confounding variable is related to both the dependent and independent variables. The interference of a confounding variable/s may result in bias and increased variance.

The confounding variables in a research study may cause either underestimation or overestimation of the research hypothesis. The effects of the confounding

variables on the study may be neutralized by choosing random sampling, selection of subjects of different categories, and counterbalancing by dividing study subjects into groups based on specific conditions [10,11]. In a research study that attempts to find the cause-and-effect association, the confounding variables may influence the outcome, which is rather completely unexpected as shown in Figure 3.

3.1. Measurement Variables

A variable that is measured usually in numbers is called a measurement variable. The measurement variables represent the quantitative assessment of the research parameters like the activities of blood urea, and creatinine to estimate the kidney function, height of a subject, and others. The measurement variables can be of various types that include nominal variables (name, sex, etc.), ordinal variables (very satisfied, satisfied, etc.), interval variable (time, temperature, etc.), and ratio variables (multiple-choice questions, survey questionnaires, etc.) [12].

3.2. Types and Effects of Variables

The confounding variable may show two types of effects on the study. In the positive confounding, the researcher notices a significant correlation/association negating the null hypothesis. The negative confounding ignores the association and supports the null hypothesis. Also, the confounding variables can be controlled by using measures like randomization, matching, and statistical control as shown in Figure 4 [10].

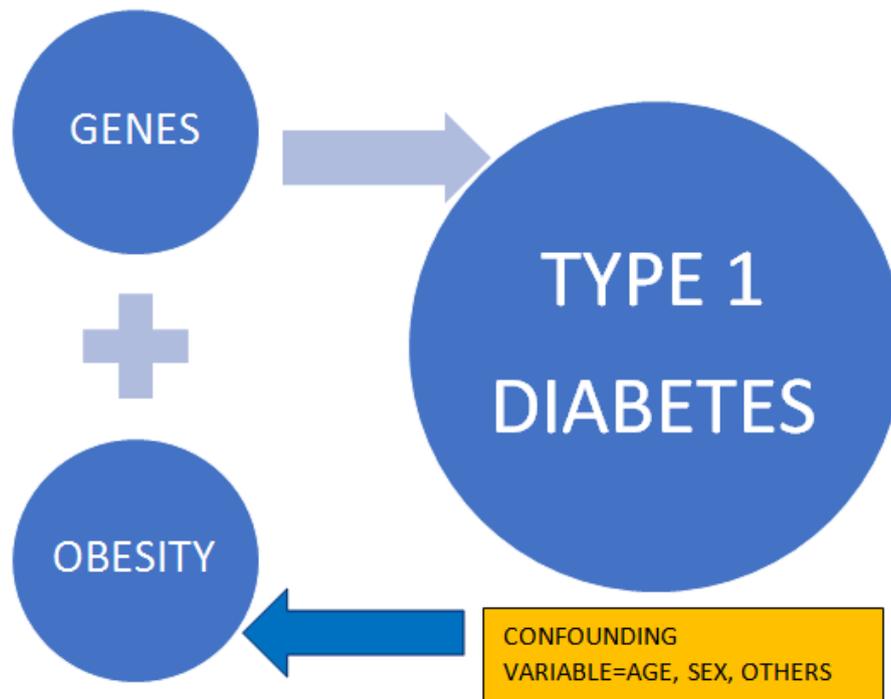


Figure 3. Confounding variables and their effect

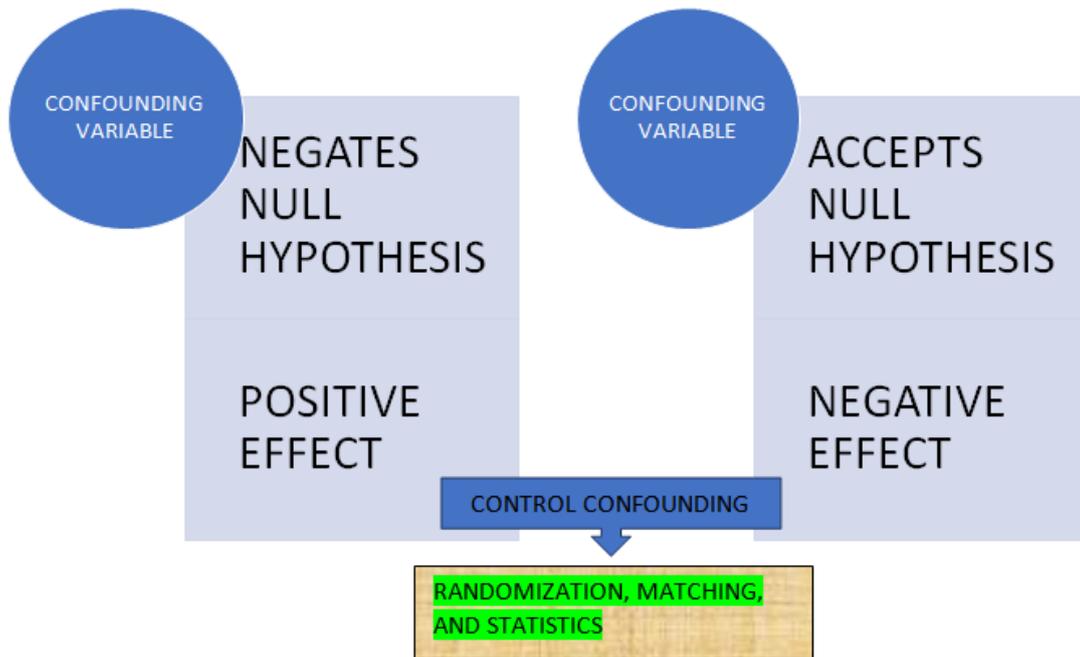


Figure 4. Types of confounding effects

3.3. Control of Confounding Variables

The unmeasured variables that influence the study variables and falsely implicate cause (independent variable) and effect (dependent variable) relationships are designated as confounding variables. The researchers pursuing the study should carefully assess the potential role of confounding variables that consequently influence the validity of research results. The confounding variables are generally extraneous in origin and may be related both to dependent and independent variables. The effects of confounding variables influence the internal validity of the research. Therefore, researchers must take care of these variables and control their influence to increase the strength and validity of the study results [13,14,15]. Methods to minimize the effects of confounding variables on the research studies are discussed further in later sections.

3.3.1. Randomization

Most clinical trials use this process to remove bias, and this includes two groups, one taking the drug and the other receiving the placebo/blank.

3.3.2. Matching

The importance of the study can be obtained, and the confounding variables are identified and neutralized by using the matched studies that include the case-control studies.

3.3.3. Statistical Control

Using multivariate analyses will neutralize the effect of confounding variables. There are a few statistical methods that can be used to minimize the effects of the confounding variables [11]. This includes stratification and standardization of the study groups to fix the level of confounders [16,17]. The Analysis of Covariance (ANCOVA), linear regression, and logistic regression are multivariate statistical applications when used to analyze the results could improve the strength of the study [16].

4. Types and Characters of Study Validity

The validity of study results increasingly depends on various aspects that include bias. Moreover, study bias can be of different types including selection bias, information bias, and confounding bias. Therefore, a deep understanding of the factors that influence study validity is important while conducting research [18]. The study validity includes both internal and external validity. The internal validity ensures neutralization of confounding factors, and the external validity confirms rationalization of study results on generalized terms [19]. The activities of confounding factors assume increased significance in studies related to public health where the cause and effect are considered while screening people and managing and treating patients [20,21,22,23].

A statistical spatial model was recently proposed to confirm the association of disease with the incidence in a particular geographical region. The researchers must assess the spatial variability and associated confounding factors during epidemiological surveillance studies to increase the study validity [24,25,26]. Host variables those influence the microbiota-related studies that attempt to relate gut microbiota with human disease must be carefully considered [27]. Different types of study validity are discussed in the following sections.

4.1. Content Validity

Content validity refers to the ability of an instrument to measure/function in ways it was designated to do. Content validity enables us to accept the results of the instrument and make decisions regarding the interpretation of the results [28]. Since most instruments/machines are used in the treatment of patients, it is important that these are validated. In a previous study, the Innovative dementia-oriented Assessment (IdA®) instrument was checked at the scale-level (S-CVI) and item-level (I-CVI), for its

reliability in analyzing the abnormal behavior of the dementia patients [29]. **Example:** Instrument, and method validation for reliability, validity, and completeness.

4.2. Criterion Validity

Also called criterion-related validity, it is a measure that can predict the outcome for another one and can be compared to the gold standard. Criterion-related validity is performed by testing a novel measurement method and comparing it with the standard method or an independent criterion. This is also called concurrent validity which is done simultaneously (present), in the past, or in the future [30]. **Example:** Validating the responses of the subjects in relation to a voting process.

4.3. Construct Validity

Construct validity is like external validity. Construct validity refers to the extent to which the research results can be generalized. It helps the researcher to validate the reliability of the questionnaire to test the research hypothesis in generating the study results. There are two types of construct validities that include convergent and discriminant construct validities. The former helps the researcher to test the relatedness between the construct and a related measure. The discriminant construct validity conveys the relatedness between the construct and unrelated measure [31]. **Example:** Measuring the emotional maturity of the children in relation to the educational program.

5. Types of Sampling Methods

Sampling is a process of identifying a defined number of subjects from a large population to be recruited into a research study [31,32]. Good knowledge of sampling methods is essential to conduct quality research [33,34,35,36]. A study sample is a representation of a specific number of individuals from a large population. Sampling is a prerogative and because not all individuals participate in a research study, sample defines the representative study group that defines the characteristics of a given population as shown in Figure 5.

There are different types of sampling methods that include probability, and non-probability sampling.

5.1. Probability Sample

The probability sampling method is routinely used in quantitative research where each person in the representative population is given an equal chance of being included in the study. It is divided into four types that include simple random sampling, systematic sampling, stratified sampling, and cluster sampling.

5.1.1. Simple Random Sample

Simple random sampling gives equal chance for everyone in the population to get selected. It may use the random number generator for selecting the study participants.

5.1.2. Systematic Sample

Systematic sampling allows the researcher to select the study subjects based on the pre-defined order (1, 3, 5, 7, 9...), after assigning the potential subjects a serial number (1-100).

5.1.3. Stratified Sample

Stratified sampling is used when the population from which the sample must be taken is represented by varied characteristics. The population is separated into groups/strata based on the characteristics like age, sex, and others. Later, by using either the simple random or systematic method, the samples are selected from each group.

5.1.4. Cluster Sample

Cluster sampling involves the creation of groups of the representative population consisting of mixed characters. Since the group has mixed characteristics, each group can be considered as a sample, or a sample can be generated by using simple random/systematic sampling techniques.

5.2. Non-probability Sample

In a non-probability sampling method, the subjects are selected on a non-random criterion. Here the subjects do not have an equal chance to get selected. The non-probability sampling method, although, appears to be cheap, and easy to do, results in selection bias. Such type of sampling method is routinely used in exploratory, and qualitative research. It is suitable to perform a pilot study that is performed to understand the qualities of a small group of subjects. The non-probability sampling is of four types that include convenience sampling, voluntary response sampling, purposive sampling, and snowball sampling.

5.2.1. Convenience Sample

This sample includes only those subjects who are easily available for the researcher and has no pre-defined criteria. Although it is an inexpensive method, the results generated from studies including convenience sampling may not reflect the character of the population, and therefore, results cannot be generalized.

5.2.2. Voluntary Response Sample

In this a type of sampling method, the subjects themselves volunteer to participate in the study. Such type of sampling method is like convenience sampling and leaves enough room for bias.

5.2.3. Purposive Sample

In this sampling method, the researcher selects the sample based on his/her judgment. Elucidating the characteristics (opinions/experiences) of the specific population group. An example of such a sampling method is the handicapped group's opinion on the facilities at an educational institute.

5.2.4. Snowball Sample

This type of sampling method is done to find the appropriate study participants based on the recommendations of the already participating subjects [37].

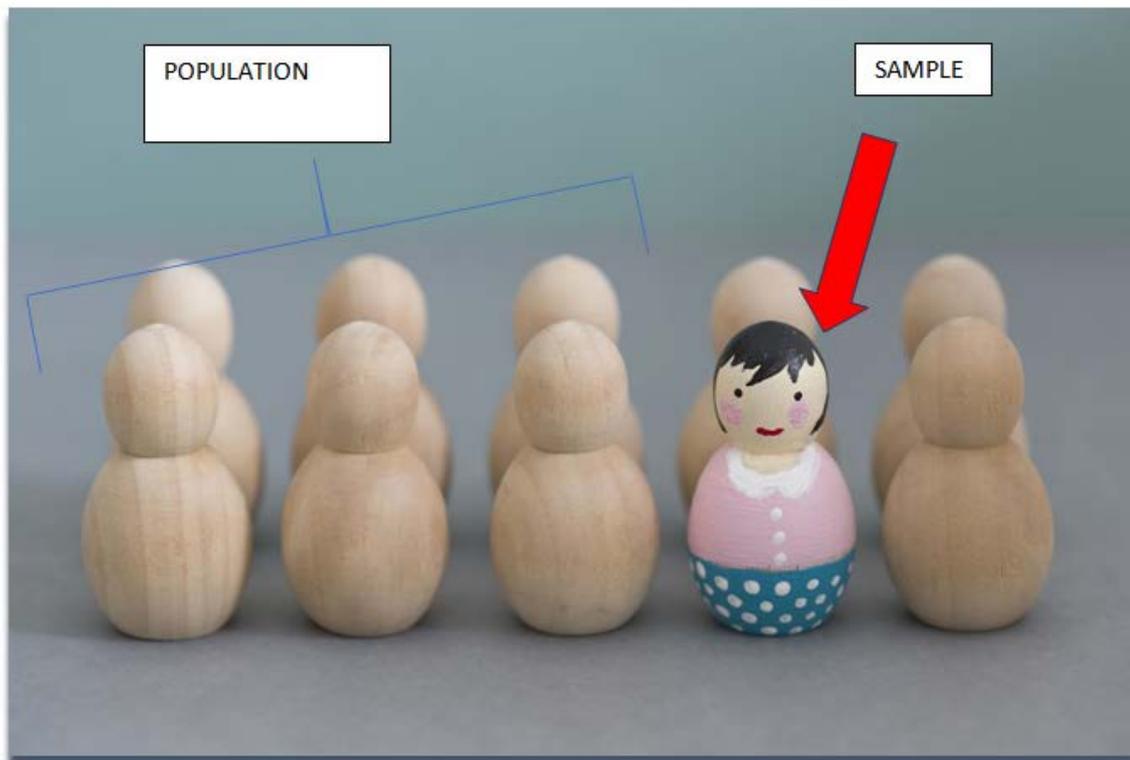


Figure 5. Representation of a sample from the population

6. Conclusions

Research is a tedious process that is generally envisaged by the investigators to find out a solution to a problem. However, research activity involves scrupulous planning and financial support in the form of funding. The research studies, especially in the health sector include human participants and therefore it may potentially be plagued by bias and other confounding factors. Also, the research results derived conclusions are translated into human applications. This puts increased importance on the validity of the study results, and their generalizability and external validity. Considering the significance of the research conclusions, researchers and other people involved in research processes are required to have a basic and good knowledge of the research process, roles of confounding variables, cause for bias, study validity, and sampling methods as discussed in brief in this review.

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