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INTRODUCTION

Research approach and research design are two terms that are frequently used interchange ably, however, research design is a broader plan to conduct a study, and research approach is an important element of the research design, which governs it. A research design is the framework or guide used for the planning, implementation and analysis of a study. It is a systematic plan of what is to be done, how it will be done and how the data will be analysed. Research design basically provides an outline of how the research will be carried out and the methods that will be used. It includes the descriptions of the research approaches, dependent and independent variables, sampling design and a planned format for data collection, analysis and presentation.

It is a methodology for answering research questions or hypotheses that may arise. Different types of questions or hypotheses demand different types of research designs, so it is important to have a broad preparation and understanding of the different types of research designs available. In addition, as a single research design may fall short of answering all the research questions or hypotheses, investigators may use a combination of different research designs.

DEFINITIONS

The research design is the master plan specifying the methods and procedures for collecting and analysing the needed information in a research study.

Research design can be defined as a blueprint to conduct a research study, which involves the description of research approach, study setting, sampling size, sampling technique, tools and method of data collection and analysis to answer specific research questions or for testing research hypotheses.

Research design is a plan of how, when and where data are to be collected and analysed. Research design is the researcher's overall plan for answering the research questions or testing the research hypotheses

ELEMENTS OF RESEARCH DESIGN

Research design is also known as a blueprint that researchers select to carry out their research study; sometimes research design is used interchangeably with the term methodology. Re

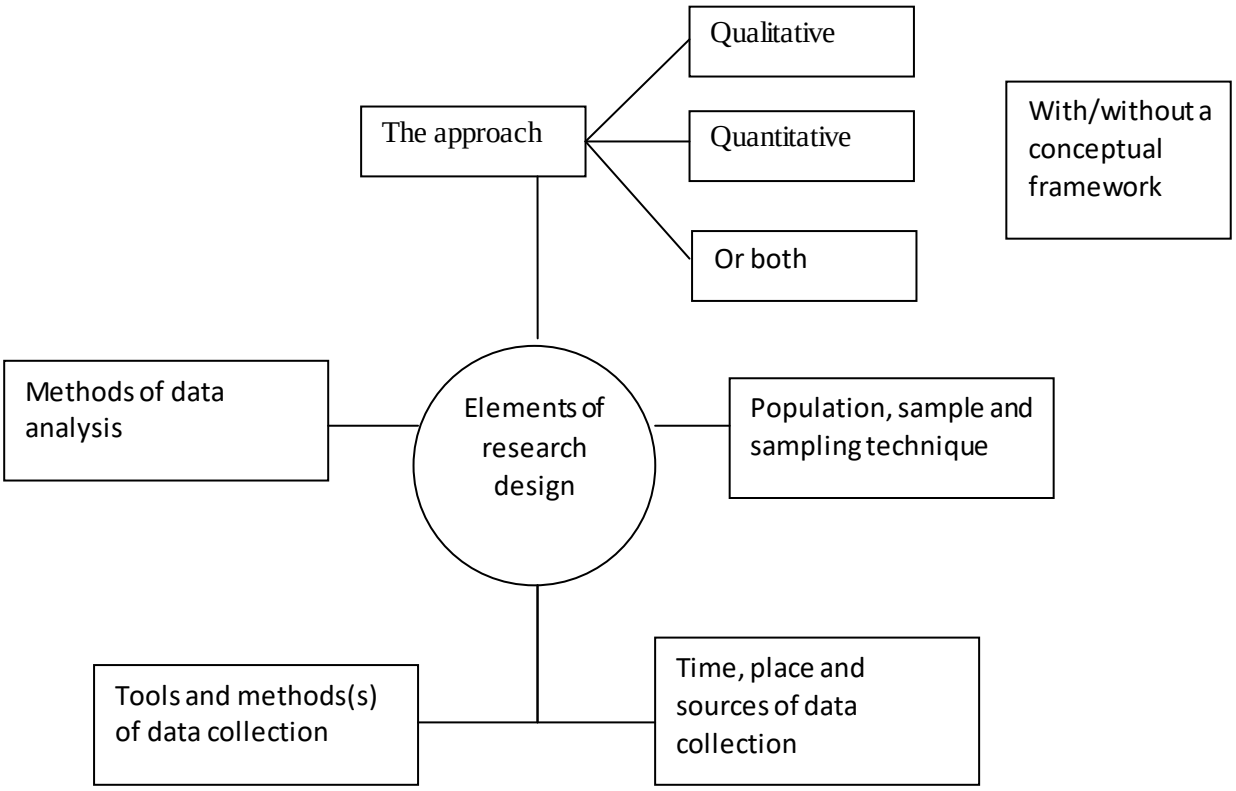
searchers often describe a design using a concise notation that enables us to summarize complex design structure efficiently in simple form. However, broadly speaking, research design includes six major elements (Fig. 7.1) as discussed below.

The Approach

It involves the description of the plan to investigate the phenomenon under study in a tired (quantitative), unstructured (qualitative) or a combination of the two methods quantitative-qualitative integrated approach). Therefore, the approach helps to decide about presence or absence of randomization, as well as manipulation and control over variables. In addition, it also helps to identify the presence or absence of control groups for comparison The approach of research study depends on several factors, but primarily on the nature of phenomenon under study. At this stage of the research study, conceptual framework may or may not be incorporated.

Population, Sample and Sampling Technique

Research design also provides the researcher with directions about population, sample and sampling technique that will be used for the research study. For example, in an ethnographic qualitative research design, a researcher gets the directive that the population will be a specific cultural group and the study will include a small sample selected through a non-probability sampling technique.



Elements of research design

The Time, Place and Sources of Data Collection

Time (specifying days, months and years of study), location (study setting and the sources of the requisite data are the other important constituents essential to ensure effective planning to conduct a research study.

Tools and Methods of Data Collection

This element of research design involves the description of different tools and methods of data collection, for example questionnaires, interviews, direct observation or any other meth ods that suit the particular approach of the research as well as nature of the phenomenon under study

Methods of Data Analysis

A research design must also include the description of the methods of data analysis either quantitative or qualitative data analysis techniques that helps the researcher to collect the relevant data, which later can be analysed as per the research design plan. Without a formal plan

of data analysis, a researcher may collect irrelevant data, which can later become difficult to analyse

SELECTION OF RESEARCH DESIGN

Research designs are plans and the procedures for research that span the decisions from broad assumptions to detailed methods of data collection and analysis. To meet the aims and objectives of a study, researchers must select the most appropriate design. The selection of a research design largely depends on the nature of the research problem, the resources available (cost, time, expertise of the researcher), accessibility of subjects and research ethics. However, the main factors that affect the selection of research design are as follows.

Factors Affecting Selection of Research Design

The selection of research design may be influenced by several factors of which some of the important ones are listed below.

• **Nature of the research problem:** This is the most important factor, which helps the re searcher to decide about the selection of a research design Based on the nature of research problem or phenomenon, researchers decide whether it should be investigated through a quantitative or qualitative study design. For example, a researcher is interested in assessing experiences of the patients who remain on mechanical ventilation. The nature of phenomenon in the given example is qualitative in nature, therefore, a researcher has to choose a most suitable qualitative study design to study this problem.

- **Purpose of the study**: Study may be conducted for the purpose of prediction, description, exploration or correlation of the research variables. Therefore, the purpose of the research study helps the researcher to choose a suitable research design. For example, a researcher old-age homes. In this instance, a researcher has to choose one of the experiential wants to predict the effect of music therapy on depression among elderly people residing Search designs to study this research problem. the researchers' knowledge and experience because they avoid using those designs

- **Researcher's knowledge and experience**: Selection of research design is largely influenced where in they lack confidence, relevant knowledge or experience, Hence the awareness of and expertise in existing research designs are important factors pertaining to the resources For example, a researcher lacks the knowledge and experience in conducting the qualitative research, in that case, he may use a study tool (e.g. Liker's scale) to quantify the qualitative phenomenon and try to study it using a most suitable quantitative study design
- **Researcher's interest and motivation** Interest and motivation levels help researchers decide about the particular research design(s) Motivated researchers always analyse most aspects of research design before selecting one or a combination, while casual and callous researchers may choose research design(s) that may lead to failure.
- **Research ethics and principles:** The incorporation and application of ethical and legal principles in the research design are essential. This includes moral obligations, such as respect for participants and their rights, informed consent and protection from harm including any adverse effects to educational progress, health and well-being. Selection of a research design is significantly influenced by the ethics of the research study.

For example, a researcher may be willing to conduct a research study through a particular experimental approach, but problems of ethical approval may stop the researcher from doing so and the researcher may have to settle for another available possible research design.

- **Subjects/participants:** The number and availability of study subjects may influence the selection of research design. For example, if only few subjects are involved in study and an in-depth data is required, a qualitative research design (such as case study design) may be chosen in such instance. But in case of a large sample, the researcher may opt for a quantitative research design.
- **Resources:** No research can be conducted without resources, such as money, equipment facilities and support from colleagues, However, some studies require more resources, compared to others. Therefore, the selection of a research design may be affected by the availability of resources for the research study. For example, randomized controlled to also require more resources because of randomization and mandatory control group comparison. Therefore, sometimes because of resource constraints, a researcher has compromise with non-randomized controlled trials or non-randomized uncontrolled trial designs.

- **Time**: Time is also a major deciding factor for the selection of research design. For example a researcher needs more time to conduct longitudinal studies, while cross-sectional studies may be conducted in shorter time. Therefore, time is also a significant contribution in selection of a research design.
- **Possible control of extraneous variables**: An efficient design can maximize results, decrease errors and control pre-existing or impaired conditions that may affect the outcome of the study. The maximized efforts of the researcher should maximize control. Therefore possible control over the extraneous variables may affect the selection of a research design For example, a researcher wants to conduct a study through true experimental design, but because of inability to control selected extraneous variables, other similar design has to be opted for, such as quasi-experimental or pre-experimental research design.
- Users of the study findings: A research design also involves various methods of data col lection and data analysis. Therefore, while choosing a research design, researcher must bat research design is as appropriate as possible for the users of the study findings so that maximum advantage of the results can be obtained.

VALIDITY OF RESEARCH DESIGNS

There are two important criteria for evaluating the trustworthiness, credibility and dependability of the research results: internal and external validity.

Internal Validity

It validates whether the independent variables actually made a difference. Did the intervention or treatment lead to the results, or are the results a response to the other factors (extraneous/confounding variables)? The high internal validity refers to the differences observed between experiential and control groups that are related to the intervention tested in the trial and not because of any other confounding factor(s).

Campbell and Stanley (1963) used the term internal validity to refer to the extent to which it is possible to make an inference that the independent variable is truly influencing the dependent variable. In the internal validity, the independent variable is responsible for variation in

dependent variable. Internal validity demands a tighter control over study to maximize the effectiveness of the results.

Internal validity is helpful in making the inference that the independent variable influences the dependent variable. So, internal validity answers the question, 'Is the connection between the independent variable and dependent variable clear to make causal inferences?' Is an independent variable, in fact, responsible for variation in the dependent variable? Or, 'did the treatment cause the effect? If the experiment can clearly establish that the treatment caused an effect, the experiment has internal validity. For example, consider a study of the effect of guided imagery on the pain perception among chronic cancer pain. In this study, the guided imagery is an independent variable and pain is a dependent variable. It follows the principle of cause and effect. Experiments will have a high degree of internal validity if they involve randomization of different groups, which enables the researcher to rule out competing explanations.

According to Campbell and Stanley (1966), six major extraneous variables have been identified that can jeopardize the internal validity. They are known as threats to the internal validity and are as follows:

- **History:** The threat of history occurs when some event besides the experimental treatment occurs during the course of study, and this event even influences dependent variables. For example, you are conducting a health teaching programme on the importance of breast self Examination (BSE), while recently a famous film actress is diagnosed to be suffering from r cancer. It catches media attention. Medical experts are interviewed and the importance of BSE is supported. All major television channels and newspapers start reporting on the importance of BSE. While you find that the BSE activity has improved, you an are searcher may not be able to conclude if the change in behaviour the result of your teaching programme or is a result of the diagnosis of the affliction of the movie actress and the subsequent media coverage.
- **Maturation of subjects:** When experimental research is carried on for along period of time over a group of subjects, there may be changes in the subjects in different ways, like in

children there is increase in height, weight and so on. So maturation is a threat to internal validity. For example, a researcher is interested in assessing the effect of particular nutritional protocol on the weight and height of malnourished children. If this experiment is conducted for a very long period, it is difficult to make out whether the effect on weight and height is due to maturation or nutritional protocol.

- **Testing:** It refers to the effect of taking a pre-test on the subjects' performance post-test. The effect of taking a pre-test may sensitize an individual and improve the score of the post-test Individuals generally score higher when they take test a second time regardless of the treatment
- **Instrumentation change**: Another threat related to measurement is that of instrumentation. This bias reflects changes in measuring instruments or methods of measurements between two points of data collection. Instruments like thermometer, sphygmomanometer, weighing scale, tape measure and so on should be checked for their accuracy at regular intervals; the same instruments should be used throughout the study to minimize the instrument-related error of the internal validity.
- **Mortality Mortality** is the loss or dropout of study subjects during the course of study. IF the subjects who remain in the study or join later are not similar to those who dropped out the results could be affected. The longer the period of the study, the more are the chances of subject mortality. For example, a researcher conducting a longitudinal study wherein a subject who participated in the first round of the data collection may not be available for the second or subsequent rounds of data collection
- **Selection bias:** If the subjects are not selected randomly for participation in groups, then there is a possibility that the groups that will be compared may not be equivalent. The effect on the dependent variable may be due to some other factors. For example, if two different classes are used to test the effects of two types of lecture methods or if subjects are selected in a non-random way, the effect on the dependent variables could be because of other confounders/heterogeneity factors rather than the types of lecture methods. In experimental research studies, the chances of selection bias are minimized by using randomization of subjects in different groups.

External Validity

It refers to the extent to which the results can be generalized to a large population. External validity shows under what conditions and in which type of subjects the same results can be expected to be replicated, or whether the same intervention will work in another setting and with different subjects.

External validity explores the generation beyond specific experiment(s) to check if the results and findings are the same with other settings or with other subject population, but with related variables. For example, the Newton's law of gravitation is applicable universally, irrespective of whether it is an American or an Indian apple. The external validity is ensured by choosing study sampling using random sample selection techniques. The factors that may affect external validity are Hawthorne effect, experimental effect, reactive effect of pre-test, novelty effect, people, place and time

- **Hawthorne effect**: Subjects may behave in a particular manner because they are aware of hem being observed and this is called the Hawthorne effect. Subjects have the knowledge the they are involved in research study, thus affecting the result. For example, a researcher conducting an observational study on hand hygiene compliance among nurses working Is critical care units. In this instance, if the researcher opts for direct observation of hand hygiene compliance among nurses and if nurses know that they are being observed, they may change their hand-washing behaviour.
- **Experimental effect:** Experimental effect is a threat to study results when researcher's characteristics, mannerisms, or behaviour may influence subject behaviour. Examples of researcher's characteristics or behaviour are facial expressions, clothes, age, gender, body built and so on. Thus, the way researcher dresses up or the researcher's gender can influence the way in which respondents answer research questions.
- **Reactive effect of pre-test:** The reactive effect of the pre-test occurs when subjects have been sensitized to the treatment because of taking a pre-test. People might not respond to the treatment in the manner they finally do if they had not received the pre-test. For example, a researcher wants to conduct a study to assess the effect of a health education programme on

the awareness of HIV/AIDS among people. In this instance, researcher conducts a pre-test to collect baseline data before health education. This pre-test may sensitize the subjects to learn about the HIV/AIDS irrespective of whether the health education is provided or not to the subjects.

- **Novelty effect**: When a treatment is new, subjects and researcher might behave in different ways. They may be enthusiastic about new methods of doing things. Once treatment is more familiar and as the novelty wears off, results might differ.
- **People:** For example, people of a specific race, such as whites, have high prevalence of coronary artery disease compared to blacks. Therefore, a generalization made for whites will not be applicable for blacks. Hence, this is a threat to external validity.
- **Place:** For example, the people living at high altitudes have high haemoglobin (Hb) levels because at higher altitudes there is low oxygen availability, due to which there is more production of red blood cells (RBCs). However, the Hb level of the people living on the plains is lower in comparison, so a generalization for people of hilly areas is not applicable for people living on plains.
- **Time:** If a research was carried out on a community in 1990 and then again in 2000, the results of these two researches would be different. Therefore, older results cannot be generalized over periods of time as societies and circumstances constantly change.

TYPES OF RESEARCH DESIGN

There is an inconstancy in the terminologies used for research design in biomedical and nursing research because nurses initially developed their research knowledge from social science disciplines. Table 7.1 presents the terminologies used for research design in nursing and biomedical literature. Furthermore, there is a lack of consensus on the uniform classification of karch designs; each author has his or her an own style of classifying the research designs.

Quantitative Research Design Terminologies Used in Nursing Versus Biomedical Literature

Terms Used in Nursing Research	**Terms Used in Biomedical Research**
Randomized controlled trials	True experimental research design
Non-randomized controlled trials	Quasi-experimental research design
Observational study design	Non-experimental research design

Case-control study design	Retrospective study design
Cohort study design	Prospective study design
Cross-sectional/cross-sectional descriptive study design	Descriptive study design
Case series	-
Case report	-

The following discussion presents the most practical and simplified classification, which is practised by most prestigious research institutions and eminent research scholars. Generally research designs are classified into three broad categories and several subtypes.

- **Quantitative research designs** (classification and main features are depicted in Table 7.2)
- **Qualitative research designs** (classification and main features are depicted in Table 73)
- **Mixed methods research designs** (classification and main features are depicted in Table 74)

EXPERIMENTAL RESEARCH DESIGNS

Experimentation is the most scientifically sophisticated research method. It is defined as observation under controlled conditions'. Experimental research differs from non-experimental design in one important aspect. The researcher using an experimental design is an active agent rather than a passive observer.

Experimental research designs are concerned with examination of the effect of independent variable on the dependent variable, where the independent variable is manipulated through treatment or intervention(s), and the effect of these interventions is observed on the dependent variable. All the experimental researches have a common characteristic, that is, manipulation of independent variable, but a true experiment/RCT also consists of the principles of randomization and control. The application of control is difficult when studies are conducted in natural settings on human subjects. Therefore, in nursing, it is not generally feasible to conduct RCTS and nurses primarily depend on quasi-experimental and non-experimental research design to generate the research evidence.

According to Riley, experimental research design is a hypothesis of causal relationships among variables. Ideally, in the experimental design, the investigator throws in a sharp relief of explanatory variables in which he or she is interested controlling and manipulating the independent variable, observing its effect on the dependent variable and minimizing the effect of extraneous variables, which might confound his powerful design for testing or her results. Experimental research design is further classified into true experimental de signs and quasi-experimental design. Clinical psychology research literature also mention

Types of Quantitative Research Designs

Types of Research Designs	**Main Features**
True experimental design/randomized controlled trial Basic true experimental designs • Post-test-only control design . • Pre-test-post-test control group design • Solomon four group design Specific true experimental designs • Parallel group design • Split body design • Factorial design • Randomized block design • Crossover design • Latin square design	Most scientific design, popularly known as RCT, where researcher manipulates independent variables to observe the effect on dependent variables, in the presence of randomization and control group for comparison Use of allocation concealment and blinding may also be used to prevent the selection, performance and measurement bias.
Quasi-experimental design/non-randomized controlled trial • Non-randomized control group design • Non-equivalent control group post-test-only design . • Time series non-equivalent control group design Time series with withdrawn and re-	It is a weak experimental design where researcher manipulates independent variables to observe the effect on dependent variables without presence of randomization and even sometimes control group for comparison. Thus, it is often called as non-randomized controlled trials or controlled trials without randomization.

instituted treatment design • Time series design • One-group pre-test-post-test design	
Correlational research design • Cohort research design • Prospective cohort design • Historical cohort design • Ambispective cohort design • Case-control research design • Nested case-control design • Analytical cross-sectional design	Correlational research design involves examination of relationship between two or more variables in a natural setting without manipulation or control (cause and effect relationship). Cohort: Observing a cohort (exposed and unexposed groups) prospectively from cause to effect. Case-control: Observing cases and controls retrospectively from effect to cause Analytical cross-sectional: Observing relationship in two or more naturally occurring variables by observing at a single point of time in cases and controls
Descriptive research design • Univariate descriptive design • Prevalence studies/cross-sectional descriptive design • Incidence studies/longitudinal descriptive design • Comparative descriptive design	Descriptive research design involve accurate description of characteristics of individual situation or group and the frequency with which a certain phenomenon occurs in natural setting without imposing any control or manipulation When observations are described and compared in two more different groups, it is termed as comparative descriptive design:
Exploratory research design: It is used when topic of research is new and helps to operationally define the problem and generate	Exploratory research design is the most primitive research design, which is used to study a phenomenon that is not well

hypothesis, it may also be used to study qualitative phenomenon.	understood to operationally define problem, generate hypothesis and improve a research design.
Survey research design: It is used to obtain Information about prevalence, distribution and interrelations of phenomenon in a population political opinion polls, customer survey. health survey and so on.	Survey research design provides a superficial information on what people do, eat, seek health care and so on, which is collected through face-to-face interview, questionnaire, telephonic or electronic interviews. It provides extensive rather than intensive results.

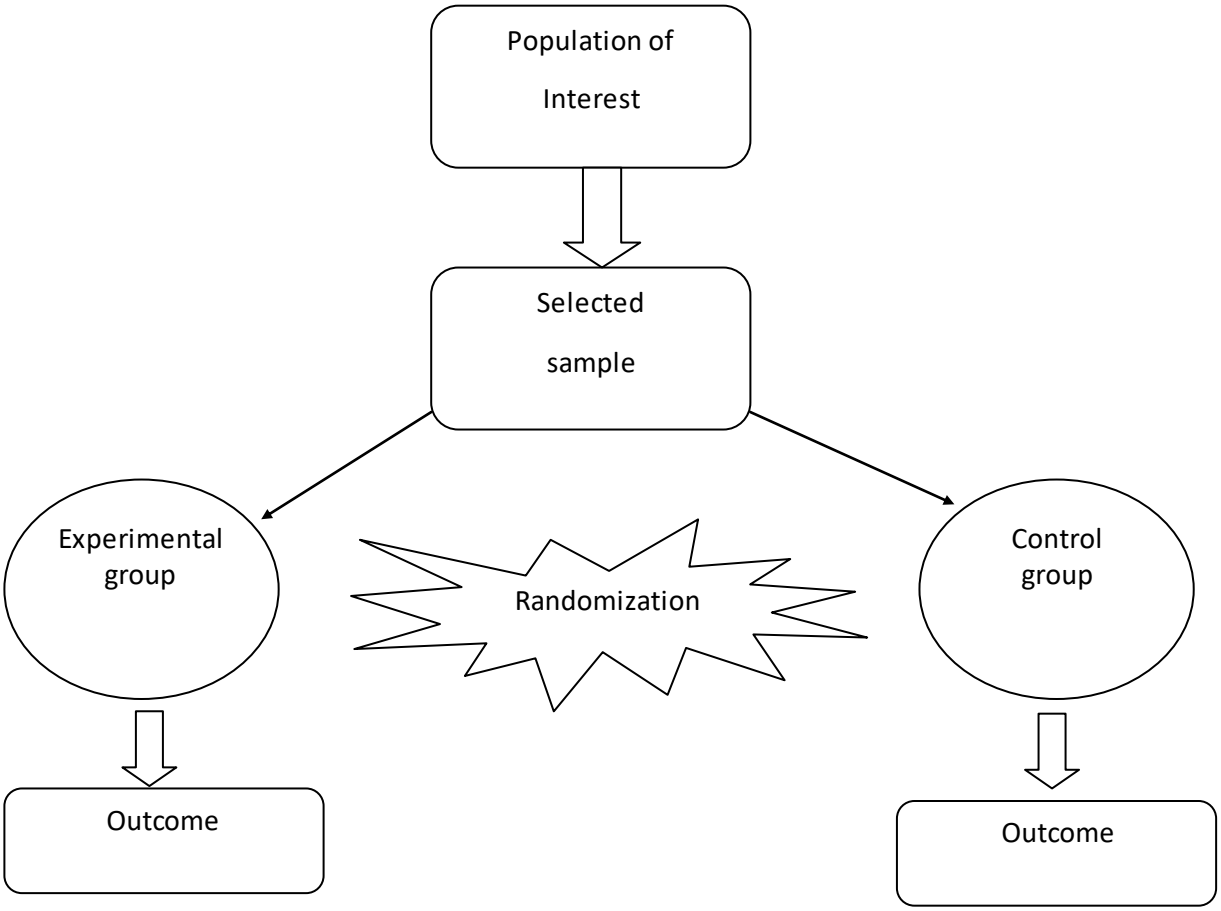
TRUE EXPERIMENTAL DESIGN

True experimental research designs are also known as Randomized Controlled Trial (RCT) in biomedical literature, in which researchers have complete control over the extraneous variables and can predict confidently that the observed effect on the dependable variable is only due to the manipulation of the independent variable.

Nursing as youngest profession is in increasing need of true experimental research/RCT to justify its practices on sound evidence. The RCTS are considered as the gold standard to generate high-level evidence. There are number of authors pointing out that there is a scarcity of evidence generated through the RCTS. However, recently there is an increasing trend among nurses conducting more RCTS. There are several reasons for lack of RCTS in nursing such as lack of experience, education and understanding of ICT as a method of research among nurses and partially due to nature of some of the nursing interventions because it is difficult to neatly pack them like a tablet or capsule. There are a number of confounding variables involved in RCTs conducted in natural setting, especially for nursing interventions. The process of RCTs and outcome measurement becomes difficult with several confounding variables. The planning, implementation and successful completion of an RCT can be demanding in terms of time, skills and resources. There are also problems in relation to recruitment, consent, attrition, implementation of intervention and contamination.

- The RCT is a random allocation of subjects to intervention groups so that all participants have equal chance of being allocated to each intervention group. These are the most straightforward of studies to design and interpret. They are often considered to be the gold standard of clinical and epidemiological studies. This is because if they are conducted properly, it is often possible to be fairly sure that the results are correct, at least for the type of patients who took part in the study.
- The intervention to be tested is called an experiment and the group receiving intervention is called as an experimental group. The other intervention is regarded as the standard of comparison or control and the group of participants who receive it is called the control group. The control can be a conventional practice, a placebo or no intervention at all.
- RCTS are considered to be the most rigorous scientific methods of determining whether a cause effect relationship exists between an intervention and outcome. For this reason, they are often used in medicine, especially when new or alternative interventions are being compared to usual standard care. Additionally, they are frequently used to assess the cost-effectiveness of an intervention.
- The RCTs are quantitative, comparative and controlled experiments in which a group of investigators study two or more interventions in a series of participants allocated randomly to each intervention group.
    - **Experiments**: Investigators can influence number, type and regime of interventions
    - **Quantitative**: Measure events rather than interpret them in natural city
    - **Comparative**: Compare two or more interventions,
- RCT helps to prevent selection bias by distributing the features of participants, which might influence the result randomly between the groups so that any discrepancy in the result can be detailed only by the treatment. Furthermore, it is an effective method to balance confounding factors between treatment groups and can eliminate the influence of confounding variables. Thus, RCT is considered as the most scientifically rigorous method of hypothesis testing presently available and is also considered as the gold standard trial for estimating the effectiveness of interventions. The initial RCTs conducted in medicine demonstrated inconsistencies and bias.

Consequently, a panel of experts (clinical trial researchers, medical journal editors, epidemiologists and methodologists) developed guidelines to assess the quality of RCTS report. This group developed consolidated Standard Reporting of Trials (CONSORT)-2010. The current guidelines include a checklist (Appendix XIII) and flow diagram (Appendix XIV) might be used by nurses to develop, report and critically appraise published RCTs.



Basic structure of randomized controlled trial (RCT)

Essential Characteristics of True Experimental Research Design

A true experimental research/RCT must essentially consist of the following three characteristics manipulation, control and randomization (Fig. 7.2).

Manipulation

Manipulation refers to conscious control of the independent variable by the researcher cough treatment or intervention(s) to observe its effect on dependent variable. In other Words, it is a conscious act by the researcher, where he/she varies the independent variable and observes the effect that manipulation has on the dependent variable of interest.

For example, a researcher is conducting a study on the efficacy of chlorhexidine mouth Washy on the prevention of ventilator-associated pneumonia (VAP) among patients admitted in this example, chlorhexidine mouthwash is the independent variable, which is manipulated by the researcher and is used as an intervention for the experimental group, while the control group is kept deprived of it to observe its effect on the incidence of VAP.

In another example, suppose we hypothesize that gentle massage is effective as a pain-relief measure for elderly nursing home residents. Providing gentle massage to elderly in experimental group and withholding for others in control group is considered manipulation of independent variables, where the effect of this manipulation is observed on the pain level in both the groups.

Independent variable	Gentle massage (As manipulation, which can be given to some patients and withholding it from others in control group.)
Dependent variable	Pain level

Control

Control is another essential element of true experimental design. Control refers to the use of control group for comparison

The subjects in the control and experimental groups are generally similar in numbers and characteristics, but the subjects in the control group receive no intervention or an alternative intervention. The experimental group receives the planned treatment or intervention, and a comparison is made with the control group to observe the effect of this treatment or intervention. Fundamentally, controls are classed as (i) negative control in which subjects in control group

neither receive any placebo nor any other type of treatment or intervention; (ii) clear control: the subjects in this type of control receive placebo and (iii) positive control: where the subjects in control group receive existing traditional intervention or an alternative intervention. Generally, in healthcare and nursing research, it is not practically and ethically feasible to keep a control group deprived of interventions; however, existing conventional method of interventions may be compared with experimental interventions. Therefore, possibilities for the counterfactual control group in experiential nursing research studies may include the following:

- An alternative intervention: It is also known as positive control, where subjects in control group receive other treatment or intervention, which may be already tested to be effective For example, a researcher is conducting a study on effectiveness of povidone iodine versus hydrogen peroxide in prevention of pin site infection among patients with external skeletal fixator.
- Standard method of care: This is the most commonly used control in nursing studies, while researchers use existing intervention in the control group. For example, a researcher wanted to assess the effectiveness of closed endotracheal/ tracheostomy suctioning technique where existing open suctioning method is used as a standard control.
- A placebo or pseudo-intervention presumed to have no therapeutic value. It is also known as a dear control in which a placebo is used in control group, Placebo is a commonly used control in biomedical studies to assess the efficacy of drugs. However, it is not conveniently used in nursing studies because it is very difficult to design a pseudo nursing intervention, which has no therapeutic effect.
- Different doses or intensities of intervention/treatment: In dose-response effect studies, experimental group participants receive richer and more intensive and longer intervention com- pared to control group to test whether larger doses are associated with larger benefits or smaller doses will suffice for the purpose.
- Wait-list control group: The participants in control group are delayed with treatment till the effect of intervention is compared between experimental and wait-list control group. However, eventually every subject in study receives the treatment.

Randomization

Randomization is a very powerful tool to ensure internal validity in the true experimental research/RCT. It is generally confused with random sampling techniques, which is a method of sample selection from a study population. However, randomization is a process of random al location of subjects in experimental and control groups or two different experimental groups, where every subject has an equal chance of being assigned to experimental or control group. This is also known as random assignment of subjects, which involves the placement of study subjects on a random basis in experimental and control groups or two different experimental groups. Random assignment of subjects in experimental or control group eliminates the chances of selection bias in the study. Randomization also ensures balance of known and unknown confounders, and makes experimental and control groups homogenous and as balanced as possible. Thus, randomization is used in RCT to minimize the threat of internal validity of the study and to eliminate the effect of extraneous variables on dependent variables. Through randomization, on an average, the characteristics of the subjects in experimental and control groups are similar, thus influence of extraneous variables on dependent variables is eliminated by dispersing the variability of the subject characteristics equally in both the groups.

Methods of Randomization

Practically, randomization is achieved by random allocation of subjects in experimental and control groups, which can be done by using opaque envelopes, flipping of coin, random allocation tables or computer-based random number generators (http://www.graphpad. com/quickcalcs/index.cfm). A good randomization method must have three basic characteristics, that is (i) unpredictability: every participant has to have similar option of getting any of the intervention, which cannot be predicted by person allocating the interventions; (ii) balance: the intervention and control group must be of the same size and characteristics; (iii) simplicity: it should be easy for an investigator to implement it. Following are com monly used methods of randomization in RCT:

1. **Simple Randomization**: It is a simple and convenient method of randomization. It can be carried out using following techniques:

a) Flip of a coin for each subject: If the coin lands on its 'head', subjects are assigned to first group/experiential arm and with 'tail' subjects are assigned to second experimental

b) Shuffled deck of cards: If even number appears, subjects are assigned to treatment group and in case of odd number, subjects are assigned to control group.arm/placebo/control group.

c) Throwing a dice: If number comes below and equal to 3, subjects will be assigned to experiential group and if dice number comes above 3, subjects are assigned to control group.

d) A random table (see sample random Table 7.5, a complete random table is given in Appendix-X) or a computer-generated random table (http://www.randomizer.org/form htm) may be used to facilitate the randomization process. In this method, blind-folded subjects choose a number from a table of numbers horizontally (row) or vertically (columns) till a requisite number is reached for both experimental and control groups

Simple randomization using a random table is a simple, convenient and reliable method of randomization in two arm trials (experimental vs. control). In large size RCT, it can be trusted to assign nearly similar number of subjects in both experiential and control groups However, in small size trials it can lead to a problem of imbalance in the number of subjects assigned to experiential and control groups, and imbalanced randomization can lead to reduction in the statistical power of the trials. An example of a simple randomization procedure is presented in Table 7.6.

2. Block Randomization: The simple randomization has inherent problem, which means there are chances that unequal number of subjects may be assigned to each arm of the study especially in smaller trials, which could decrease the power to detect statistically significant differences between groups. Therefore, block randomization is used as an alternative randomization technique to eliminate the chances of bias and ensure the balance in allocation of equal number of subjects to each arm of trial. However, a weakness of block randomization is that the allocation of subjects may be predictable and could result in selection bias, if investigator is not blinded and block size is fixed. The block size is determined as multiple of the number of groups. For example, for two treatment groups, block size of either 4, 6 or 8 may be used. Small size blocks provide better control to keep the balance on equality of subjects assigned to each

group of trial, but it increases chances of heterogeneity between groups in terms of selected covariates such as one group may have more number of subjects with comorbidity (e.g hypertension, diabetes, cancer and so on). Such covariate heterogeneity could result in bias and can reduce the power of the study. Therefore, sample size and covariates must be balanced when block randomization is used. Example: Consider two treatments arms: A and B. In this instance, the block size could be 2 x 2 = 4,

Some of the probable allocations for treatment within every block are as follows: (1) AABB, (2) BBAA, (3) ABAB, (4) BABA,(5) ABBA and (6) BAAB.

The block size depends on the total number of treatments. The block size should be at least X2 of the number of treatments. The chances of selection bias may be minimized by using the random block sizes. The block randomization may also be computed using free web site source such as https://www.sealedenvelope.com/simple-randomiser/v1/lists.

3**. Stratified Randomization:** In block randomization, there are chances of covariate (base line characteristics) heterogeneity among experimental groups, which can be controlled through use of stratified randomization. In this method, following steps are used for randomization:

a) First, specific confounders (baseline characteristics/covariates) are identified, which may unnecessarily influence the dependent variable(s). For example, age and gender could be cofounders and may affect the outcome of an intervention

b) Second, separate strata are generated as per identified covariates/combination of covariates and thereafter participants are assigned to each of their respective strata of covariate. For example, age and gender may affect the recovery of a rehabilitation intervention among total knee replacement (TKR) patients. Thus, patients are first assigned into these following strata, that is (6) males <60 years. (ii) males >60 years, (iii) females <60 years and (iv) females >60 years.

c) Third, after all participants are identified and assigned to respective strata, simple randomization is used to assign the participants to experimental and control groups from each block/strata

In small size trials, it is a simple and useful technique to ensure homogeneity of participants in experimental and control groups, but it is not convenient when several covariates need to be controlled in a trial. Furthermore, it is not a popular method of randomization in nursing and biomedical trials because all the participants and their baseline characteristics have to be identified before they are assigned into experimental groups, which is practically not possible in healthcare settings because all the patients cannot be available at a single point of time

4. Covariate Adaptive Randomization: Covariate adaptive randomization is also known as the minimization, which is used as an alternative method of randomization to effectively control the covariates in arms of clinical trials, where stratified randomization is not practically possible to use. In this method, every new patient is assigned to an arm of the experiment based on specific baseline characteristics of subject and previously assigned participants in the different arms of the trial. The balance of confounders/potential covariates is main trained in each arm by changing the way the next subject is assigned to an experimental arm Following free online web resources may also be used to generate the randomization for clinical trials: http://www.graphpad.com/quickcalcs/index.cfm.

Allocation Concealment

Allocation concealment is used to prevent selection bias in RCTS, where allocation sequence is concealed from the individual who assigns the participants to the experimental interventions until assignment occurs. Therefore, the individual who is randomizing the participants will not be able to know about the sequentially coming next allocation to the participants. Thus, after the random numbers are generated for randomization of the subjects to the experimental and control groups, the individuals who assign the participants are provided with sequentially numbered, sealed/opaque envelopes or coded identical containers prepared by an independent central agency. Allocation concealment ensures that it is not possible for investigators to know the allocation sequence in advance and it is universally recommended as it can be used even for unblinded trials. Allocation concealment is different from blinding as it helps in preventing the selection bias, whereas blinding helps in prevention of placebo effect and measurement bias. The risk of different types of bias in research is presented.

Blinding

Terms blinding and masking are synonymously used in clinical trials, which means the methods that help to ensure that individuals do not know which treatment or intervention is being administered in trial. Blinding is used to prevent the placebo effect, performance and detection bias in the trials (Box 7.1). It could be at three levels that treatment or intervention is unknown to (i) the research participant, (ii) the individual(s) who administer the treatment or intervention and (iii) the individual(s) who assess the outcomes.

Open trial: The open trial is opposite to the blind trials, where all the research participants, persons who administer the intervention and individuals who assess the outcome know about it. Therefore, open trials are open to challenge for bias and do nothing to reduce the placebo effect. Thus, blinding is strongly recommended in the trials to generate more reliable results.

Single-blind trial: In a single-blind trial, the researcher knows the details of the treatment but the research participants do not. As the participants do not know which treatment is being administered the new treatment or another treatment), there might be no placebo effect.

Double-blind trial: In double-blind trial neither the research participants nor the persons who administer the intervention have the knowledge of the participants receiving the treatment and those that are getting placebo. The double-blind trials are preferred, as they tend to give the most accurate results by preventing placebo effect, as well as performance bias.

Triple-blind trial: (i) The participants, (ii) the investigators who administer treatment and (ii) the individuals who assess the outcome of experiment are blinded from knowledge of participants receiving interventions and placebo. Thus, placebo bias, performance bias and measurement bias are prevented.

RISK OF BIAS IN RESEARCH

Bias: Bias is a systematic error occurring during research process due to flaws in design, sampling techniques, data collection, analysis and publication, which can distort validity of study results.

Types of Bias	Meanings	Interventions
Response bias	Participants themselves report for the trials or selection of sample by non-random sampling techniques.	• Random sampling techniques
Selection bias	Participants are allocated to groups without randomization and lack of homogeneity between selected groups.	• Randomization of subjects • Allocation concealment
Recall bias	Patients who are aware about their allocation in experimental and/ or control group may affect their report of symptoms.	• Blinding of research participants
Performance bias	The participant and research personnel are aware of treatment/placebo. This could lead to do better care/intervention for experimental group.	• Blinding of research personnel • Blinding of outcome assessors
Detection bias	When phenomenon is more likely to be observed for one group of subjects.	
Attrition bias	Withdrawal of participants from the study, which may	• Intensive follow-up • Participant motivation • Intention-to-treat analysis

Reporting bias	lead to incomplete outcome of data from the trial. • Publication bias: Positive results are more likely to be published as compared to negative results. • Outcome bias: Selective outcome reporting of outcome due to intended interest of industry.	• Publication bias is assessed by plotting the identified studies on 'flannel plot', used in systematic review and meta-analysis.

Use of Placebo in True Experimental Research

The idea of receiving a new treatment can itself make some people feel better, this is called placebo effect. If some subjects in an experiment have high expectations of a new drug or other form of treatment being tested, this can affect the results of the study. To overcome possible suggestive effect of the new intervention, a placebo is used. Placebo is a substance that has no pharmacological or therapeutic property, which can be administered to the control group. It is assumed that in any of the medical interventions, there are placebo effects some extent, including effect of therapeutic setting, perception of the therapist by the patient and credibility of medication itself (colour, size, shape, test, etc.). Therefore, generally a placebo intervention is designed to overcome this placebo effect, for example the use of placebo in an RCT comparing the effectiveness of a methocaine gel with a similar resembling placebo gel in the management of procedural pain in neonates. However, it is often not possible to design a placebo to match many nursing interventions, especially psychosocial interventions such as counselling. For this reason, use of placebo is uncommon in RCTs conducted in nursing, and most of the RCTs are conducted to test the best-known (usual practised) intervention against the new interventions.

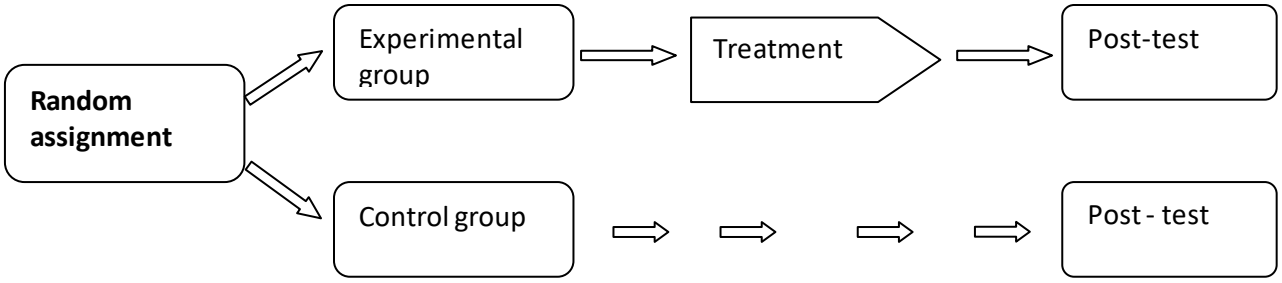
Types of True Experimental Designs

Following designs are commonly used in true experimental research or RCT.

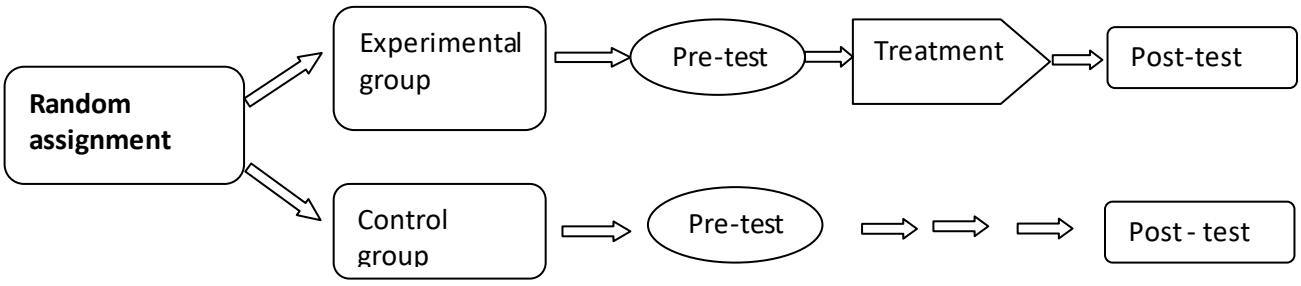
BASIC TRUE EXPERIMENTAL DESIGNS

POST-TEST-ONLY CONTROL DESIGN Composed of two randomly assigned groups, that experimental and control, but neither of which is pre-tested before the implementation of treatment on the experimental group. In addition, while treatment is implemented on experimental group only, post-test observation is carried out on both the groups to assess effect of manipulation (Fig. 7.3). This design can be helpful in situations where it is not possible to pre-test the subjects. For example, to study the effect of an educational interventional related to urinary incontinence on the subsequent help-seeking behaviour of older adults

PRE-TEST-POST-TEST-ONLY DESIGN In this research design, subjects are randomly assigned to either the experimental or the control group. Effect of the dependent variable on both the groups is seen before the treatment (pre-test). Later, the treatment is implemented in experimental group only, and after-treatment observation of dependent variable is made on both the group to examine the effect of the manipulation of independent variable on the dependent variables



Schematic diagram of post-test only design

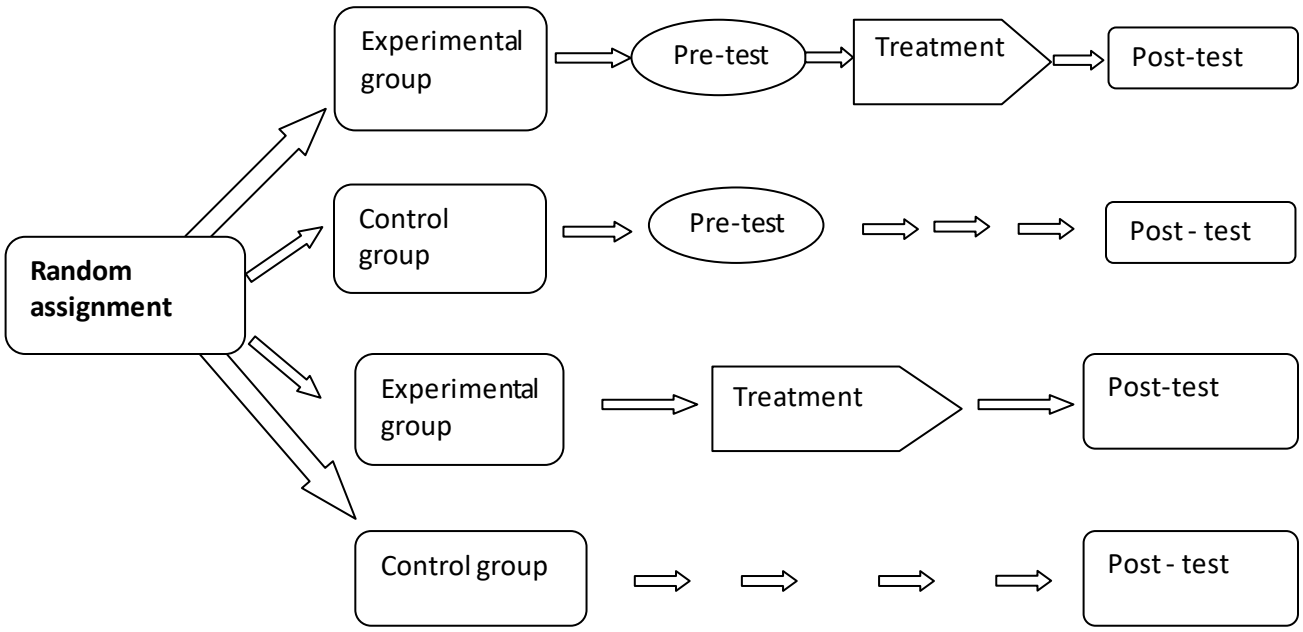


Schematic diagram of pre-test-post-test only design

For example, such a design could be used for an experimental study to assess the effectiveness of cognitive behavioural therapy interventions in reduction of stress among patients with breast cancer'.

SOLOMON FOUR-GROUP DESIGN There are two experimental groups (experimental group 1 and experimental group 2) and two control groups (control group 1 and control group 2). Initially, the investigator randomly assigns subjects to the four groups. Out of the four groups, only experimental group 1 and control group 1 receive the pre-test, followed by the treatment to the experimental groups 1 and 2. Finally, all the four groups receive post-test, where the effects of the dependent variables of the study are observed and comparison is made between the four groups to assess the effect of independent variable (experimental treatment) on the dependent variable. In this study design, experimental group 2 was observed at one occasion, and that score should be similar to averaged scores of those in experimental and control groups. To estimate the amount of change in experimental and control groups 2, the average test scores of experimental and control groups 1 are used as baseline (Fig. 7.5).

The Solomon four-group design is believed to be the most prestigious experimental research design because it minimizes the threat to internal and external validity. This design not only controls all of the threats to internal validity but also the reactive effects of the pre-tests. Any differences between the experimental and the control groups can be more confidently attributed to the experimental treatment. Unfortunately, this research design requires a large sample and statistical analysis, and therefore, it is not commonly used by nursing and c healthcare researchers.



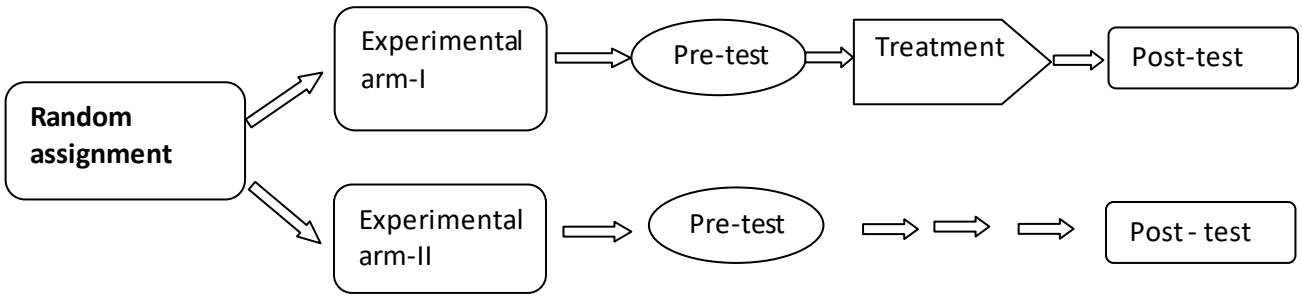
Schematic diagram of Solomon four-group design

SPECIFIC TRUE EXPERIMENTAL DESIGNS

PARALLEL GROUP DESIGN In this study design, two or more treatments/interventions are compared, where participants are randomized in different experimental arms, and after implementing the different interventions, the outcome is assessed and compared in two more experimental groups (Fig. 7.6). For example, 'A randomized controlled trial on efficacy of continuous versus bolus nasogastric feeding on prevention of enteral feeding associated problems among critically ill patients (Kaur & Sharma, 2016). In this instance, participants are randomized in two experimental arms; then they are exposed to respective intervention and the intended outcome is measured and compared between both the experimental arms.

SPLIT BODY DESIGN In this design, the body is divided into left and right half, and one side serves as an experimental arm and another side is used as a control arm (Fig. 7.7). For example, RCT on efficacy of moist ice pack application in prevention and reduction of pain, bruise and hematoma at subcutaneous LMWH injection site (Sharma, Mehra, Wander, & Saini, 2015). In this example, patient's right side abdomen is used as an experimental arm, where moist ice pack is applied at subcutaneous site after low molecular heparin injection administration and left side

is used as control. Wherever it is possible split body design is considered as the most robust design in clinical research, as experimental and control are truly homogenous in this design.



Schematic diagram of parallel group design

FACTORIAL DESIGN In factorial design, a researcher manipulates two or more independent variables simultaneously to observe their effects on the dependent variables. This de sign is useful when there are more than two independent variables called factors to be tested. For example, a researcher wants to observe the effects of two different protocols of mouth care on prevention of VAP when performed at different frequencies in a day (Fig. 7,8). This design also facilitates the testing of several hypotheses at a single time. Typical factorial design incorporates 2 x 2 or 2 x 3 factorial, but it can be in any combination. The first number (a) refers to the independent variables or the types of experimental treatment, and the second number (B) refers to the level or frequency of the treatment.

Frequency of mouth care	**Protocols of mouth care**	
	Chlorhexidine(α_1)	Saline(α_2)
4 hourly(β_1)	α_1….. β_1	α_2…….β_1
6 hourly(β_2)	α_1….. β_2	α_2…….β_2
8 hourly (β_3)	α_1…… β_3	α_2…….β_3

Schematic diagram of factorial design

RANDOMIZED BLOCK DESIGN Control of inherent differences between experimental subjects and differences in experimental conditions is one of the difficult problems faced by re searchers in biological sciences. When there are a large number of experimental comparison groups, the randomized block design is used to bring homogeneity among different selected groups. This is a simple method to reduce the variability among the treatment groups by a more homogeneous combination of the subjects through randomized block design. For ex ample, a researcher wants to examine the effects of three different anti-hypertensive drugs on patients with hypertension. In this example, to ensure the homogeneity among the subjects under treatment, a researcher randomly places the subjects in homogeneous groups (blocks) such as patients with primary hypertension, diabetic patients with hypertension and renal patients with hypertension (Fig. 7.9).

This design looks similar to a factorial design in structure, but out of two factors one is not experimentally manipulated; like in the given example there are two factors: type of anti hypertensive drugs and type of patients with hypertension, where only the type of drug is manipulated and type of patients with hypertension is simply grouped in different blocks with similar characteristics to ensure homogeneity.

Type of antihypertensive drugs	**BLOCKS**		
	Patients with primary hypertension (I)	**Diabetic patients with hypertension (II)**	**Renal patients with hypertension (III)**
A	A,I	A,II	A,III
B	B,I	B,II	B,III
C	C,I	C,II	C,III

Schematic diagram of randomized block design

CROSSOVER DESIGN In this design, subjects are exposed to more than one treatment, where subjects are randomly assigned to different orders of treatment (Fig. 7.10). It is also known as repeat measures design. This design is more efficient in establishing the highest possible

similarity among subjects exposed to different conditions, where groups compared obviously have equal distribution of characteristics. Though crossover design is considered as an extremely powerful research design, sometimes it is not effective because when subjects are exposed to two different conditions their responses to the second condition may be influenced by their experience in the first condition. To avoid this issue, a washout period is recommended, so the effect of previous intervention is worn off and another intervention can be used. For example, when we compare the effectiveness of the chlorhexidine and saline mouthcare protocol, first we administer the chlorhexidine mouth care protocol on group I and saline mouth care protocol on the subjects of group II. Later, the treatment is swapped, where group I receives the saline mouth care and group II receives chlorhexidine. In such studies subjects serve as their own control.

Groups	**Protocols of mouth care**	
Group I	Chlorhexidine(α_1)	Saline(α_2)
Group II	Saline(α_2)	Chlorhexidine(α_1)

Schematic diagram of crossover design

LATIN SQUARE DESIGN Latin square design different from randomized complete block is signs in that the experimental units are grouped in blocks in two different ways, "that is by rows and columns. Therefore, two different sources of variation can be isolated. Latin square design is primarily used in agriculture field. However, it can be used in the field of health sciences. For example, a nurse scientist is investigating efficacy of four different creams in treatment of dermatitis. In Latin square design, each patient will receive every product. To use Latin square design, the researcher will take first four patients as the rows of the Latin square and the order position of four different creams application as column of the Latin square; next four patients will become part of next Latin square and thus every patient will receive each product application. It is more complex form of a crossover design, where every patient receives each of the products. A restriction in the assignment of treatments in a Latin square is that each treatment can occur only once in each row and column so that each row and each column is like a complete block. A requirement of the Latin square is that the number of treatments, rows, and number of replications, columns, must be equal; therefore, the total number of experimental units must be a perfect square. For example, if there are four treatments, there must be four replicates, or four

rows and four columns. This is a 4 x 4 Latin square that gives a total of 16 experimental units. Because of this restriction, Latin square experiments can become large and unmanageable very readily. Additionally, if the number of treatments is too small, there are too few degrees of freedom (df) for error so that the most common squares are in the range of 5 x 5-8 X 8. As two sources of variation are isolated in rows and columns, the mean square of error will be smaller than the mean square of the same data analysed as either completely randomized or randomized complete block design. The advantages of Latin square design are that it helps in controlling more variation than completely randomized (CR) or randomized complete block (RCB) designs because of its two-way stratification, results in a smaller mean square of error and the data analysis is simple with this design even with instance of missing plots. However, it does have some disadvantages such as in this design the num ber of treatments is limited to the number of replicates, which seldom exceeds 10, and if it has less than 5 treatments, the df for controlling random variation is relatively large and the df for error is small. An example of Latin square design with four treatments (ABCD) is presented in Fig. 7.11, where numbers in upper left corner are plot number for each row and letters are the treatments followed.

Advantages and Disadvantages of True Experimental Design

ADVANTAGES

- RCTS are considered the most powerful designs to establish the causal relationship between independent and dependent variables.
- For the purpose of research as an explanation, causal relationship may be established among the variables by experimentation, especially in studies involving physical obo where the variables are more easily controlled than that in human studies.
- In these studies, the controlled environment in which the study is conducted can yield a greater degree of purity in observation.
- Conditions not found in a natural setting can be created in an experimental setting where the independent variable is manipulated by investigator.

- In the RCT, we can often create conditions in a short period of time that may take years to occur naturally. For example, in genetic studies, we can breed strains in very small time which would take a long time to occur naturally.
- Randomized experiment designs completely remove any accusations of conscious or conscious bias from the researcher and practically guarantee external validity.
- RCTs completely remove effect of extraneous variables.

DISADVANTAGES

• Sometimes, the results of laboratory-based RCT cannot be replicated in studies conducted on human beings due to ethical problems.

• For certain research problems, because of the danger to physical and psychological health of the human subjects, it is not possible to conduct experiments on human beings.

• Many of the human variables neither have valid measurable criteria nor instruments to measure them. For example, patient welfare or level of wellness cannot be measured on any scale or by any instrument. In these situations, if a refined experimental design is used, there may be a mismatch of research design and the variable measuring instruments

• The RCTs conducted in natural settings such as hospitals or community; it becomes difficult to impose control over extraneous variables.

Experiments are often impractical when the effect of independent variable may require lengthy period of time before it can emerge as a response on the criterion measures. This situation exists for many variables in nursing. One of the main drawbacks in conducting experiments on the effects of nursing care on acutely ill, hospitalised patients is that the patients are discharged from hospitals in such short periods of time that there is little op opportunity to study the effect as they occur. Only by a difficult and costly procedure, these discharged patients can be followed up in their homes to observe the experimental results. However, it is not always possible because of several constraints.

Another disadvantage of the randomized controlled research design is that it is very difficult to get cooperation from the study participants because it may involve medical or surgical treatment

or intervention, which may make the prospective subjects reluctant to participate in research study.

• Because the sample size for experiments involving human beings is often kept small there is a question as to how representative the findings of such studies can be. If the target population is diverse, if the extraneous variables are numerous or if these extraneous variables can exert spurious influence on dependent variables when uncontrolled, question arises as to whether a small number of study subjects can provide meaningful results for a large population, even if they have been carefully selected and the conditions are kept intact during study

Although theoretically randomized controlled experimental designs can yield insight into the causes of certain phenomena, in research involving human beings, these phenomena are usually so complex and driven by such a plurality of causes that the simple experimental approach does not help. A more complex, multivariate and non-linear approach is required, which may only be possible with great difficulties through experimental approach

The limitations inherent in the randomized controlled experimental approach are greatest when the experimental subjects are human beings As most conceivable patient care studies involve humans, the use of the randomized controlled experimental approach in such research is limited. However, the quasi-experimental designs could be more feasible on human subjects especially in nursing intervention trials

QUASI-EXPERIMENTAL RESEARCH DESIGN

Quasi-experimental research design also called as non-randomized controlled trial involves the manipulation of independent variable to observe the effect on dependent variable, but it lacks randomization of participants in experimental groups, which is one of the essential characteristics of the RCT. In addition, some of the quasi-experiments even lack a control group for comparison.

In other words, quasi-experimental designs have an element of manipulation but lack the randomization and sometimes even the control group for comparison which are essential properties of the RCTS. Quasi-experimental designs are generally used to establish the causality (effect of independent variable on dependent variable) in situations where researchers are not able to randomly assign the subjects to groups or for various reasons in certain situations cannot have a control group for comparison in an experimental study

Main Characteristics

• Manipulation of the independent variables to observe the effects on the dependent variables.

• Lacks randomization of participants to experimental groups, which is one of the essential characteristics of the RCT and sometimes even control group for comparison. Quasi-independent variables are used instead of true independent variables where independent variables are not manipulated in a completely controlled situation.

Types of Quasi-Experimental Designs

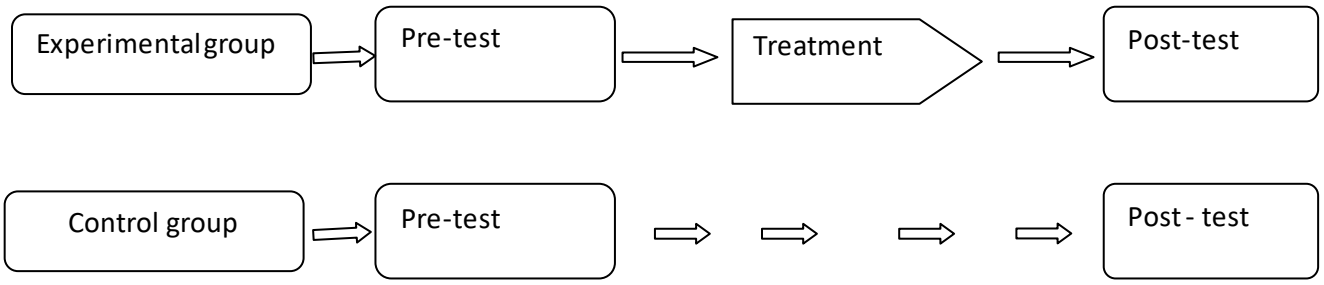
Quasi-experimental designs may be of several types, but some of the most frequently used designs are discussed in this chapter.

Non-Randomized Control Group Design

It is also known as the non-equivalent control group pre-test-post-test design. This design is identical to the pre-test-post-test control group design except that there is no random assignment of subjects in experimental and control groups. In this design, experimental and control groups are selected without randomization, and dependent variables are observed in expert mental, as well as control groups before the intervention. Later, the experimental group receives treatment and after that post-test observation of dependent variables is carried out for both the groups to assess the effect of treatment on experimental group

For example, a quasi-experimental study was planned to assess the effect of older people's involvement in social services on their loneliness among elderly residing in selected old-age homes in New Delhi. In this study, randomization was not possible, so a researcher used on old-age home residents as experimental group and for comparative purpose residents of another old-

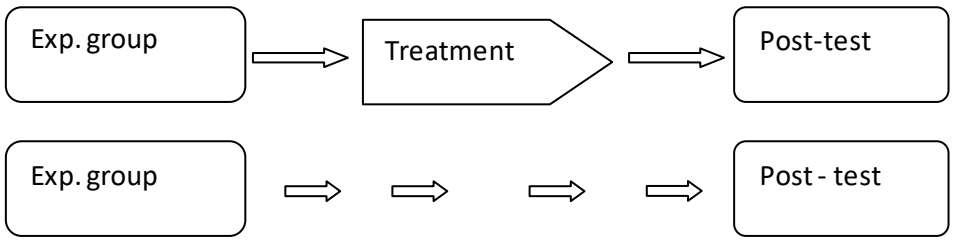
age home were used as control group. The baseline loneliness score was assessed in both the groups, and intervention (their involvement in social services) was implement in experimental group and after the implementation of intervention outcome variables were assessed in both the groups.



Schematic diagram of non randomized control group design

Non-Equivalent Control Group Post-Test-Only Design

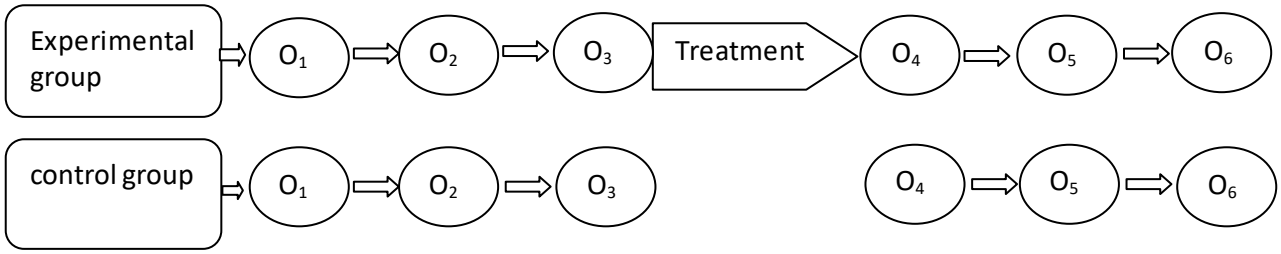
This design involves two non-randomized groups, that is experimental and control, but neither of which is pre-tested before the implementation of treatment on the experimental group In addition, while treatment is implemented only on the experimental group, post-test observation is carried out on both the groups to assess the effect of manipulation (Fig. 7.13) This design can be helpful in situations where it is not possible to pre-test the subjects. For example, to study the effect of an educational intervention related to self-care abilities among diabetic patients residing in rural areas, where randomization was not possible, so diabetic patients of one village were used as an experimental group and for comparison diabetic patients of another village were used as a control group.



Schematic diagram of non-equivalent control group post-test-only design

Time Series Non-Equivalent Control Group Design

In time series non-equivalent control group design, an investigator makes series of observations in an experimental and a control group before implementation of intervention in the experimental group and again series of observation of outcome variables is made in both experimental and control groups (Fig. 7.14). For example, a study is carried out to assess the effect of VAP prevention bundle on VAP-related morbidity and mortality among critically ill patients admitted on selected ICUs of a tertiary care hospital. In this example, an investigator recruits patients of a selected ICU as an experimental group and patients of another similar ICU in the same hospital or another hospital are used as a control group. Before intervention is implemented in an experimental group, several monthly VAP-related morbidity and mortality data are collected in both selected ICUS (experimental and control group) and after intervention again monthly morbidity and mortality related to VAP are collected in both the groups for the comparison.

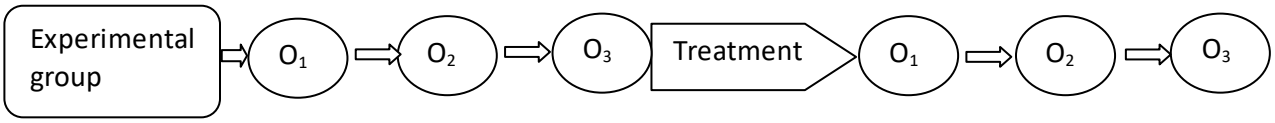


Schematic diagram of time series non-equivalent control group design

Time Series Design

Time series design involves only a single experimental group without a control group for the comparison. In this design, an investigator makes series of observations in experimental group before implementation of intervention, and again series of observations of outcome variables are made in the group after implementation of intervention (Fig. 7.15). This design is useful when the investigator wants to measure the effects of a treatment over a long period of time. For example, a researcher may evaluate pain levels of a group of patients having lower back pain. After assessing for pain as long as 3 weeks, participants are educated about special exercises to manage the pain. Then weekly pain level would be evaluated for next 3 weeks. In another example, evaluating a child's academic performance on a weekly basis, bringing out a new

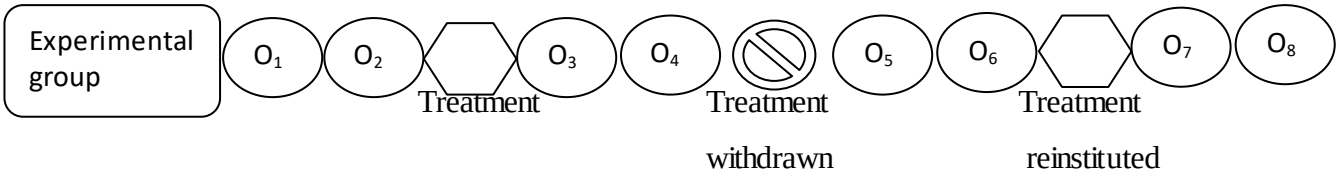
teaching method, and then again evaluating the academic performance on a weekly basis for few weeks to assess the constant long-term effect of the intervention.



Schematic diagram of time series design

Time Series Design With Withdrawn and Reinstitution Treatment Design

In this design, an investigator would continue to carry out observation of variables and implement short-term intervention and again carry out outcome variable observations and then administer new intervention and then again observe the outcome variables. Then again an investigator would administer new treatment and observe the outcome variable to compare the effect of different interventions (Fig. 7.16). For example, an investigator carries out a study to assess the effectiveness of detergent versus phenolic disinfectants versus glutaraldehyde disinfectant in reducing flora count for surgical ICU floor moping at tertiary care hospital. In this example, investigator first carries out culture samples during different shifts and then gets floor moped with detergent and then again takes culture samples during different shifts and then implements the floor moping by phenolic disinfectants followed by culture sample during different shifts and consequently the floor moping by glutaraldehyde disinfectant, which is followed by the culture samples to assess the flora count on ICU floor. In between two interventions, there could be a wash period to eliminate the risk of residual effect of previous intervention, which is a major disadvantage of this design.



Schematic diagram of time series design with withdrawn and reinstitution treatment design

One-Group Pre-test-Post-test Design

It is considered as a very weak quasi-experimental research design where participants are recruited in the experimental group. A pre-test observation of the dependent variables is made before implementation of the treatment in the selected experimental group, the treatment is administered, and finally a post-test observation of dependent variables is carried out to as assess the effect of treatment on the selected group (Fig. 7.17).

This design measures the effect on the experimental group based on their state before the beginning of the experiment (pre-test) and the difference achieved at the end of the experiment (post-test). There is no control group in this design.

For example, a study on the effect of interventions on the stress-coping resources of associate degree nursing students'. In this study, a pre-test and post-test design was used to examine three groups in nursing programmes. Each group completed the instrument Coping Resources Inventory for Stress (CRIS)-at the beginning and at the end of the first-year of nursing course. The modified curriculum group received interventions for the development of stress-coping resources in their initial nursing course, the second group experienced self-directed interventions and the third group received no intervention. This study conclude measured that curriculum intervention for first year degree nursing students resulted in a increase of stress monitoring and tension-control coping resources.

Advantages and Disadvantages of Quasi-Experimental Design

Advantages

- Quasi-experimental designs are more frequently used because they are more practical and feasible to conduct research studies in nursing, where in the absence of a large sample size, randomization and/or availability of control groups are not always possible.
- This design is more suitable for real-world natural setting than true experimental research design
- It allows researchers to evaluate the impact of quasi-independent variables rally occurring under naturally occurring conditions.

- It may be able to establish causal relationship, wherein some of the hypotheses are practically answered through this design only.

Disadvantages

- It is considered as a weak experimental design to establish causal relationship between independent and dependent variables because it controls no threat to internal validity.
- Lack of randomization increases the risk selection bias; there is poor control over confounding variables, which could negatively affect the study results.
- There is no control over extraneous variables influencing the dependent variables.
- The absence of a control group or a lack of control over the research setting makes the results of this design less reliable and weak for the establishment of causal relationship between independent and dependent variables.

NON-EXPERIMENTAL RESEARCH DESIGNS

Non-experimental research design is also known as observational research design in biomedical research literature, which is one of the broad categories of research designs in which the researcher observes the phenomena as they occur naturally and no external variables are introduced. It is a research design in which neither the variables are deliberately manipulated nor is the setting controlled. In non-experimental research, researchers collect data without making changes or introducing treatments. Data obtained are analysed and the results may lead to the formation of hypothesis that can then be tested experimentally. Within a quantitative framework, the observations are represented by numbers that can be statistically analysed. Data in non-experimental research are generally collected through the use of questionnaires, interviews, observations, literature reviews and critical-incident technique.

Need of Non-Experimental Design

Non-experimental research design is frequently used by the nurse researchers. Some of the study situations where only non-experimental designs can be used to conduct a study are as follows:

- The studies in which the independent variables cannot be manipulated.
- The studies in which it is unethical to manipulate the independent variable, that is manipulation may cause physical or psychological harm to subjects.
- The studies or research situations where it is not practically possible to conduct experiments.
- Descriptive type studies that do not require any experimental approaches.

Types of Non-Experimental Research Designs

There is a lack of uniformity in classification of the non-experimental research designs, However, following classification of the non-experimental research designs is the most suit able to improve the understanding about the non-experimental research designs. Following classification of non-experimental research is presented in hierarchical levels of evidence (beginning with higher level of evidence of non-experimental research design to lower level of evidence designs).

- **Correlational research designs**
    - Cohort research design
        - Prospective cohort design
        - Historical cohort design
        - Ambispective cohort design
    - Case-control research design
    - Nested case-control design
    - Analytical cross-sectional design
- **Descriptive research designs**
    - Univariate descriptive design
        - Prevalence studies/ cross-sectional descriptive design
        - Incidence studies/longitudinal descriptive design
    - Comparative descriptive design
- Exploratory research design
- Survey research design

Correlational Research Designs

This is a non-experimental design where researcher examines the relationship between two or more variables in a natural setting without manipulation of independent variable. In other words, it is a research design where researchers study the relationship of two or more variables without any intervention. For example, this design was used for a study on the effect of smoking on lung cancer among people in New Delhi' Correlational design is used to examine the relationship or association between two variables, that is naturally occurring independent and dependent variables. Correlational research designs could be cross-sectional (data are collected at particular point of time) or longitudinal (data are collected over an extended period). Furthermore, correlational research design could be prospective (researcher observes phenomenon from cause to effect) or retrospective (backward approach, where researcher observes phenomenon from effect to cause)

MAIN FEATURES

- In correlational studies, the researchers examine the strength of relationships between variables by determining how change in one variable is correlated with change in the other variable.
- Generally, correlational studies have independent and dependent variables, but the effect of independent variable is observed on dependent variable without manipulating he dependent variable
- In some correlational studies, identification of the independent and dependent variables is difficult, however, in most correlational studies, the independent variable is identified, which, without any intervention, influences the dependent variable. For example, this de sign was used in an investigation of the study habits and visual acuity among school children studying in selected schools in the city of Ludhiana'. In this study, study habits are the independent variable, while visual acuity is the dependent variable.
- Magnitude and direction of relationship of independent and dependent variables are measured by using the correlation coefficient statistical measure, where results range between – 1 and +1. Negative results of correlation coefficient signify negative correlation of independent (-1: perfect negative correlation) and dependent variables, while positive results show positive relationship of independent and dependent variables (+1: perfect positive

correlation). However, a zero result of correlation coefficient indicates no relationship between independent and dependent variables. Other statistical methods can also be used to find out the statistical relationship between two or more naturally occurring independent and dependent variables.

- Theoretically, a positive relationship means increase in one variable leads to the increase in the other variable. While negative relationship means increase in one variable leads to decrease in the other variable or vice versa. For example, a study was conducted to examine the effect of age on physical performance and correlation coefficient results were found to be -0.80. This indicates that there is a negative correlation between age and physical performance, which means that physical performance decreases as age increases.
- In epidemiological language, these studies are known as a cause and an effect study, where cause and effect relationship is investigated in natural settings without imposing experimental interventions. This cause and effect relationship can be investigated either in forward manner, that is from cause to effect (prospective) or backward manner, that is from effect to cause (retrospective).

TYPES OF CORRELATIONAL RESEARCH DESIGN

Three basic correlational research designs are discussed in this chapter: cohort research design, case-control research design and analytical cross-sectional research design.

COHORT RESEARCH DESIGN A cohort is a group of people who have something in common and who remain a part of a group over an extended time. In health care, the subjects in cohort studies are selected by some defining characteristic (or characteristics) suspected of being a precursor to or risk factor for a disease or health effect. In this design, a longitudinal approach is used to investigate the occurrence of a disease in a cohort (group with similar characteristics for a time period) with existing presumed causes comparing with homogenous controls. For example, a researcher longitudinally observes a homogenous cohort of smokers and non smokers for the developmental of lung cancer. Some of the specific characteristics of cohort study design are as follows:

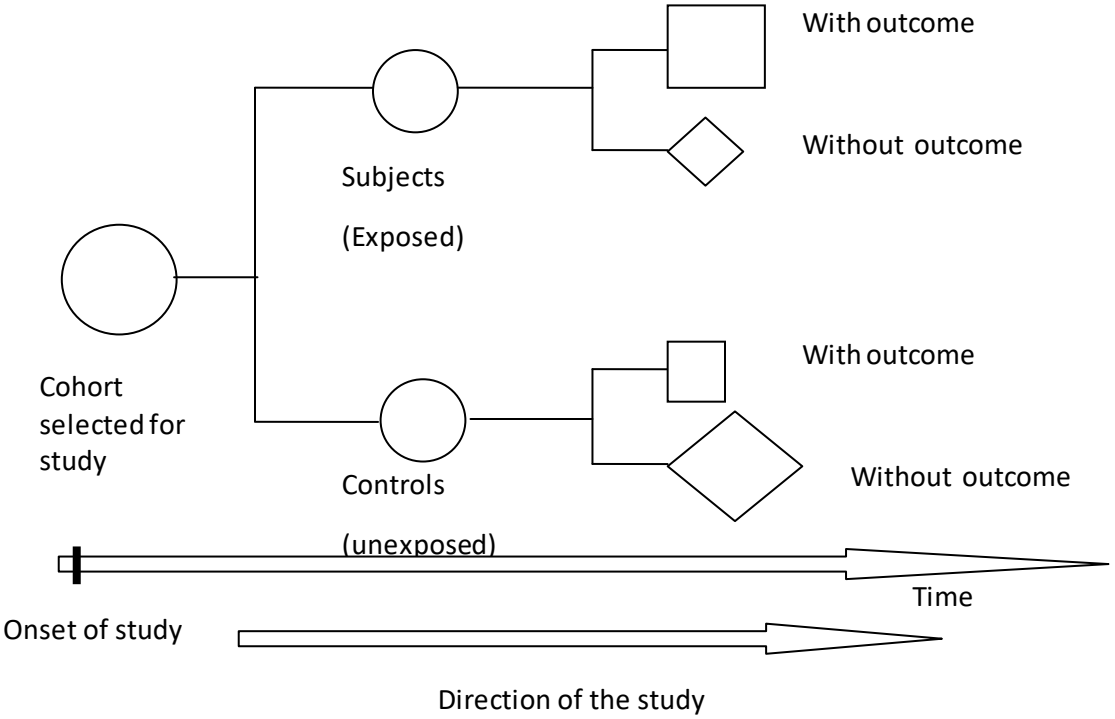
- Cohort studies, also called incidence studies, are designed to measure the exposure and outcome in the context of time.
- In this study design, individual subjects are followed over time to measure the exposure when it happens (in real-time or historical); then they measure the outcome at a point in time after exposure. Because the outcome is measured exactly or approximately when happens, the incidence of the new cases can be determined in cohort studies.
- The strength of this design is the ability to demonstrate the temporal order of the exposure and outcome-a necessary criterion to determine causality.
- While case-control studies are limited to odd ratios for measuring association between exposures and outcomes, cohort studies allow the use of risk differences, risk ratios and odd ratios for evaluating associations. The concept of risk is meaningful because the outcome or disorder is measured as incidence.
- The cohort studies could be prospective, retrospective or ambispective. The retrospective cohort study design differs from the case-control study design, whereas in retrospective cohort study, the subjects chosen are at high risk for outcome, naturally including those with or without the outcome; however, in the case-control studies, subjects are purposively chosen those with the outcome; then a group of control without the disorder from same setting to compare the history of exposure with cause.

The main disadvantage of cohort studies is that they tend to be very expensive and time consuming. The study is substantively weakened with high attrition of subjects between measurement points. Considerable resources and staff time are typically needed to maximize retention rates and subsequently the validity of the study sample. This design is also inefficient for rare outcome and for those with a very long latency period (time from exposure to outcome).

Prospective Cohort Design A prospective cohort study is an observational longitudinal study where a cohort (a group of subjects with similar characteristics) is followed over a time period, but cohorts differ in certain factors under study to determine how these factors affect the rate of certain dependent outcomes (Fig. 7.18). For example, a researcher may follow a cohort of

middle-aged nurses who vary in terms of body mass index, to the hypothesis that the 15-year incidence rate of coronary artery disease will be highest among the obese nurses, followed by overweight and the healthy weight.

The prospective cohort studies are helpful in determining the etiology of different diseases and disorders. The important features of the cohort prospective study are that the subjects with homogenous characteristics are enrolled in the cohort and a specific intended independent variable is observed in subjects longitudinally for time period to determine the effect of hypothesized risk factor on the causation of particular disease or disorder. For example, a researcher might follow a cohort of middle-aged shopkeepers who vary in terms of smoking habits, to test the hypothesis that the 20-year incidence rate of lung cancer will be highest among heavy smokers, followed by moderate smokers and then non-smokers. Other examples of research studies with prospective cohort design are presented in Box 7.2

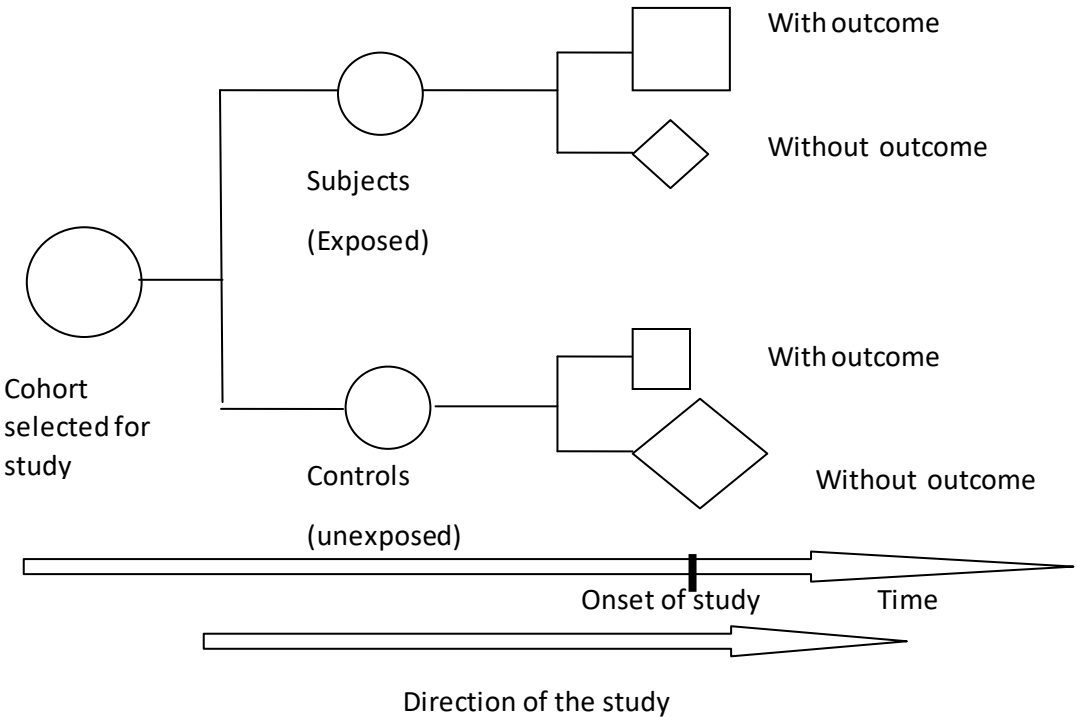


Schematic diagram of prospective cohort design

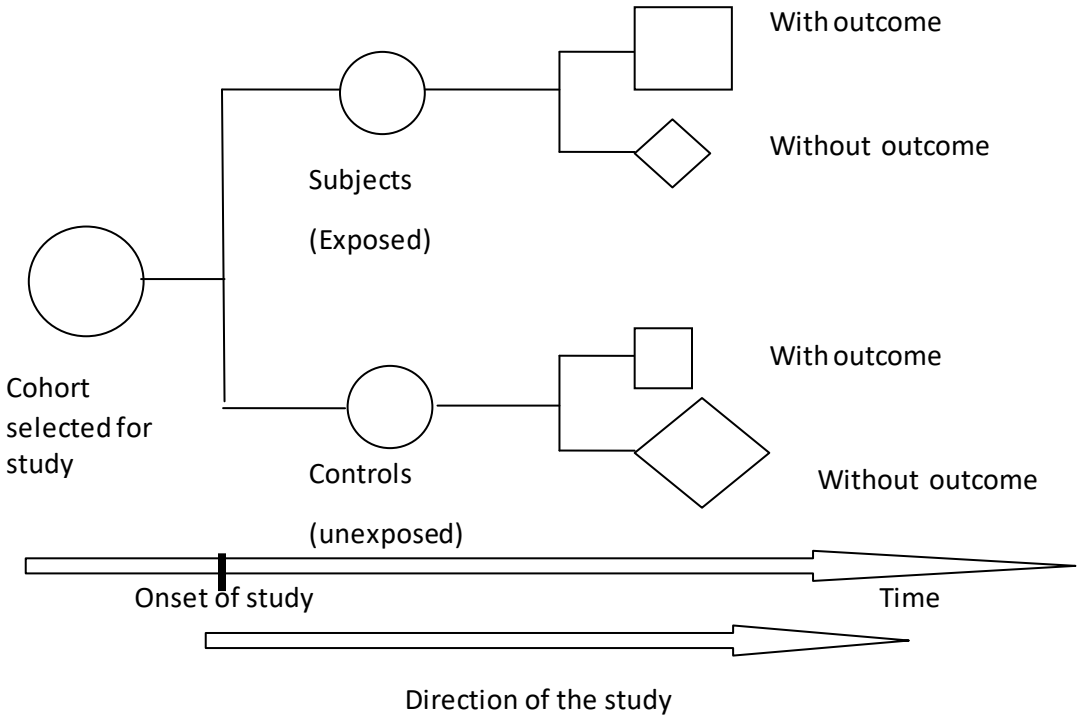
Historical Cohort Design The historical cohort design is also known as retrospective cohort design, where one can also undertake a cohort study by using information collected in the past

and then kept in records or file. In the case of a retrospective cohort study, an investigator collects data from past records and does not follow up with patients as is the case with a prospective study. Thus, in retrospective cohort study, all the events-exposure, latent period and subsequent outcome (e.g. development of disease) have already occurred in the past; researcher merely collects the data now, and establishes the risk of developing a disease if exposed to a particular risk factor (Fig. 7.19). Historical or retrospective cohort study design differs from the case-control study design, whereas in historical/retrospective cohort study, the subjects chosen are at high risk for outcome, naturally including those with or without the outcome; however, in the case-control studies, subjects are purposively chosen those with the outcome; then a group of control without the disorder from same setting to compare the history of exposure with cause.

For example, one researcher wanted to assess study outcomes in men with prostate cancer treated with a specific type of radiation therapy. He plans to evaluate existing records to look at survival and tumour recurrence in 1607 men who were treated between 2009 and 2016 and had at least four prostate-specific antigen measurements after radiation. This approach to a Study is possible if the records on follow-up are complete and adequately detailed and if the investigators can ascertain the current status of the patients. In retrospective cohort studies, a risk ratio or odd ratio gives an assessment of relative risk of a disease or disorder.



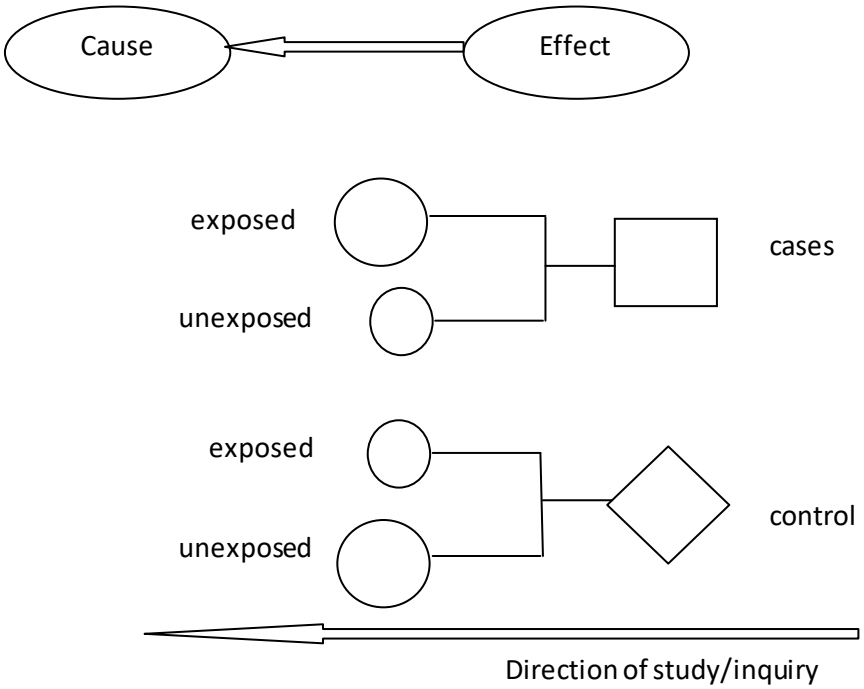
Ambispective Cohort Design The ambispective cohort study design moves both forward and backward in time. With this design, the exposure is measured twice-historical and in real time during the study period. The design allows a more precise measure of exposure in terms of time. It can be determined if the exposure is of longer or shorter terms or variable with respect to coming and going (Fig. 7.20). For example, a study about hip replacement (outcome in the future) can start with adults aged 20-40 years, and their current and future physical activity (contemporary exposure), as well as their school and other historical records can be measured to determine their childhood experience with organized sports-type, intensity and duration



Schematic diagram of ambispective cohort design

In another example of an ambispective cohort study: 'an ambispective cohort study of the natural history of HIV infection among former unsafe commercial blood and plasma donors (Zhang, 2008), in which HIV/AIDS cases were found, who were confirmed prior to 24 July 2006 being former commercial blood and plasma donors. Then data regarding infection, incidence, death and influencing factors were collected and analysed. Other examples of research studies with ambispective design are presented in Box 7.3.

CASE-CONTROL RESEARCH DESIGN A design in which the researcher studies the current phenomenon by seeking information from past is also known as a retrospective research de sign. In this design, the researcher links the present phenomenon with the past events. In other words, the researcher has a backward approach to study a phenomenon, where he/she moves from effect to identify the cause (Fig. 7.21).



Schematic diagram of case-control design

In case-control studies, causes of a disease are investigated after the occurrence of a disease. For example, a researcher investigates the history of smoking in patients diagnosed with lung cancer. Some of the specific characteristics of case-control study design are as follows:

• This study design uses true exposure and outcome measures that are anchored in measured time. The study begins with the outcome measure and relies on participant's memories or medical records to go back to measure the potential exposure.

A unique feature of this design is that individuals with the outcome of interest (case) are compared to individuals who do not have the outcome but were risk for it (control) to determine difference in past exposure to the potential cause of the health phenomenon.

The unit of analysis in case-control studies is the individual, and in this design only one measure of association between exposure and outcome is appropriate, that is odd ratio.

Case-control studies are specially valuable for studying rare or emerging diseases.

This type of design begins with selecting the cases after operationally defining the cases. The operational definition should not be too narrow or too broad because too narrow operational definition of case makes it difficult to choose the sufficient size sample in given period and too broad definition seriously minimizes the validity of study results. Therefore, a balance must be ensured in operational definition of cases to avoid the aforementioned problems

• In this study design, cases and controls are identified from either clinical or general population sources. The clinical sources such as hospitals and medical clinics are convenient sources to obtain cases, but it must be ensured that when cases are taken from a hospital then control also must be identified from same or similar hospital, which did have that specific disease manifestations. For example, if cases of lung cancer are selected from hospital A, control treated in hospital-A for illness other than cancer should be chosen. However, patients with illness too similar to lung cancer such as emphysema should be avoided as controls due to similar disease aetiology.

• The cases may also be chosen from community setting through disease registry other previous cross-sectional surveys. For these cases, controls should be chosen from the same neighbourhood, community or region. Friends, relatives and co-workers of cases can also be used as controls

It must be ensured that whenever possible and practical, controls should be similar to cases in important outcome-relevant characteristics such as age, gender, occupation, med cal history, residence and so on.

The potential weakness of case-control studies is an inability to calculate incidence of pin silence of the outcome, Incidence is impossible to measure because the study travels bangle time, so cases cannot be measured as they emerge. Similarly, the extent to which the sample represents the population of individuals with the outcome cannot be established because the sample was purposively selected to include a large proportion of cases. Another weakness of the case-control design is uncertainty about the true temporal order of exposure and outcome due to potential weakness of available historical data. In addition, the quality of data in this study design largely depends on the past memories of the study subjects and sincerity, and capability of person collecting the data. The examples of research studies with case-control design are presented in Box 7.4.

NESTED CASE-CONTROL DESIGN A nested case-control study is a modified design of standard case-control study design, in which exposure of interest is assessed in cases and selected controls (who has not developed the disease/condition but they are from the risk set of participants and they match to the cases on selected characteristics such as age, family history, etc.) only

This design is used when exposure of interest is rare, or expensive to assess or difficult to measure. For example, an investigator is interested to assess the association of colon cancer (cases/effect) and gene expression (cause). The research included total target population in risk were 92,370 and out of them some 2376 developed colon cancer. In this instance, it is not cost-effective to carryout genetic assay test in all 92,370 people. Therefore, in this design investigator carries out genetic assay test in all the cases and in only selected controls from risk set of participants, who has selected matched characteristics with cases such as age, family history and so on. The nested case-control is considered as more efficient than standard case-control because cases are compared with selected matched controls, where as in standard case-control studies, cases are compared with controls selected without matching. However, it is less efficient than the cohort design because in cohort studies all the participants in cohort care assessed for the exposure of interest and all the exposed and unexposed participants are longitudinally followed to assess the development of disease/condition, but cohort design may not be cost effective and feasible in certain situations.

ANALYTICAL CROSS-SECTIONAL DESIGN Descriptive cross-sectional study involves single group of subjects with purpose to identify, assesses and describes a phenomenon by collecting data at single point of time. For example, a descriptive cross-sectional study to assess the prevalence of anxiety at first day of clinical posting among nursing students studying in selected nursing institutes of Kerala and Tamil Nadu. Descriptive cross-sectional studies only describe the characteristics of a phenomenon or describe the prevalence of a health outcome in a specific population. Prevalence can be assessed at either one point in time (point prevalence) or over a defined period of time (period prevalence).

However, analytical cross-sectional studies begin with population, where two groups, who are exposed and who are not exposed to risk factors, are taken and among them presence or absence of a condition or disease is assessed and compared at a particular one point in time. The comparison is done between proportion of exposed participants who are having condition (risk even in exposed group) with the proportion of non-exposed participants who are having condition (risk even in non-exposed group) and then relative risk (RR) and odd ratio (OR) may be computed to draw the statistical inferences about cause effect relationship.

Descriptive Research Designs

The purpose of descriptive studies is to observe, describe and document aspects of a situation as it naturally occurs, and sometimes to serve as a starting point for hypothesis generation or theory development

MAIN FEATURES

- Descriptive designs are used to observe, document and describe a phenomenon occurring in its natural setting without any manipulation or control.
- The descriptive studies are designed to gain more information about characteristics within a particular field of inquiry.
- Descriptive studies provide an impression of a situation as it occurs in a natural setting.

- Descriptive studies do not involve the manipulation of variables and variables are studied, as they exist in the real world.
- Descriptive design may be used to develop theories, identify problems with current practices, justify current practices, make judgements or determine other practices in similar situations.
- In descriptive studies, bias is prevented through operational definitions of variables, large sample size, random sampling techniques, valid and reliable research tools and formal data collection methods.
- Descriptive designs include identification of a phenomenon of interest, identifying the variables within the phenomenon, developing operational definitions of the variables and describing the variables. The description of variables leads to an interpretation of the theoretical meaning of the findings and the development of hypotheses.

TYPES OF DESCRIPTIVE RESEARCH DESIGN

Two basic descriptive research designs are discussed in this chapter: univariate descriptive sign, comparative descriptive design.

UNIVARIATE DESCRIPTIVE DESIGN Univariate descriptive designs are undertaken to des scribe the frequency of occurrence of a phenomenon. This design does not necessarily focus on the study of a single variable; there may be one or more variables involved in the study

For example, a researcher is interested in assessing the treatment-seeking pathway of patient suffering from rheumatoid arthritis. In this study, the researcher may describe the frequency different symptoms experienced by the patients and the type of treatment they received during the course of disease and so on. There are multiple variables in this research study.

The basic purpose of the study is to only describe each of the variables without internet to establish any relationship between those variables. This design is mainly used to identify on and describe the perception, awareness, behaviour, attitude, knowledge, practice and socio-cultural of people. For example, this design was used for 'a descriptive study of the perceived socio cultural factors of female feticide among women in selected rural and urban communities of district Jaipur, Rajasthan',

There are mainly two types of descriptive studies in the field of epidemiology: incidence and prevalence studies.

Prevalence studies are carried out to estimate prevalence rate of some phenomenon such as a disease (eg breast cancer) or a behaviour (eg. alcoholism) at a particular point of time. The descriptive prevalence studies are also termed as descriptive cross-sectional or cross-sectional studies in epidemiological or biomedical research literature because data are obtained from a population at risk of the condition at a particular point of time, means the researcher takes a snapshot of the population at risk to determine the extent to which the condition of interest is present in the given population. For example, descriptive cross-sectional study on the prevalence of depression among elderly people residing in Chandigarh. The formula used for a calculating point prevalence (PR) is

$$= \frac{\textbf{Number of cases with the condition or disease at a given point in time}}{\textbf{Number in the population at risk of being a case}} \times k$$

where k is the number of people for whom we want to have the prevalence rate estimated (e.g. per 100 or per 1000 population).

The numerator is the number of cases with the particular condition as identified in study and denominator is the size of the sample.

For example, 'a descriptive study of the prevalence of pin-site infection among patients with external skeletal fixation admitted in orthopedic ward of a tertiary care hospital'. Suppose, there were 92 patients were found positive with pin-site infection out of the sample of 600 patients. Thus, [(92 = 600) x 100 = 15.3%] 15.3% will be point prevalence of pin-site infection in selected tertiary care hospital.

Incidence studies are carried out to estimate the frequency of developing new cases. The descriptive incidence studies are also termed as descriptive longitudinal studies because at outset researcher has to estimate who are at risk to develop a particular condition and who are free of the condition before observation is started and how many of them develop the particular condition in a given time as new cases. For example, 'a descriptive study on incidence of burnout

among critical care nurses working in ICU of selected tertiary care hospital at Hyderabad'. The formula for an incidence rate (IR) is

$$= \frac{number\ of\ new\ cases\ with\ the\ condition\ or\ disease\ over\ a\ given\ time\ period}{Number\ in\ the\ population\ at\ risk\ of\ being\ a\ case(free\ of\ condition\ at\ th\ onset} \times k$$

where k is the number of people for whom we want to have the incidence rate estimated (e.g. per 100 or per 1000 population)

The numerator is the number of new cases with the particular condition as identified in study and denominator is the total target population in study at risk of being a case (free of condition at the outset).

In aforementioned example, investigator identifies that out of total 300 nurses working in ICUS, 220 were found free of burnout at the outset of study and then he observes the nurses for a year and found that 48 of them were found to develop burnout as a new case. Thus, incidence of burnout among nurses working in ICU of the selected hospital will be [(48 + 220) x 100 = 21.8%].

In nursing research, descriptive design is widely used to observe and describe a variety of phenomenon. Other examples of research studies with descriptive design are presented in Box 75

COMPARATIVE DESCRIPTIVE DESIGN Comparative design involves comparing and contrasting two or more samples of study subjects on one or more variables, often at a single point of time. This design is used to compare two distinct groups on the basis of selected attributes such as knowledge level, perceptions and attitudes, physical or psychological symptoms; and so on. For example, 'a comparative study on health problems among rural and urban older people in district Bikaner, Rajasthan'. Other examples of research studies with comparative design are presented in Box 7.6.

Exploratory Design

Exploratory research design is most primitive research design, which is used to study a phenomenon, which is not well understood to operationally define problem, generate hypothesis and improve a research design. It is used when topic of research is new and helps to operation ally define the problem and generate hypothesis. Furthermore, exploratory design is used to identify, explore and describe the existing phenomenon and its related factors. In other words, it is not only a simple description or the frequency of occurrence of a phenomenon but also in depth exploration and a study of its related factors to improve further understanding about less understood phenomenon. For example, an exploratory study to assess the multifactorial dimensions of falls and home safety measures for elderly people living in selected communities in the city of Ludhiana. Other examples of research studies with exploratory design are presented in Box 7.7.

Exploratory research design is primarily used under qualitative research designs, but in nursing research literature is also found to be used under quantitative non-experimental research designs, therefore, for practical purposes, it is discussed under quantitative research designs in this textbook.

Survey Research Design

A survey is a research design used to collect information from different subjects within a given population having same characteristics of interest. If a survey is conducted on a sample of population, it is called sample survey, and if the entire population is involved, it is called a population survey, such as census, and so on.

It provides superficial information on what people do, eat, seek health care and so on, which is collected through face-to-face interview questionnaire telephonic or electronic inter views. It provides extensive rather than intensive results. Survey is used to obtain information about prevalence, distribution and interrelations of phenomenon in a population such as political opinion polls, customer survey and health survey. A survey helps to collect wide range of data from a given population, such as actions, attitudes, opinions, perceptions, behaviours, awareness

practices and so on. Survey could be descriptive, exploratory, comparative, or correlational depending on the nature of phenomenon under study

MAIN FEATURES

• Survey research is a process of gathering current required data from the subjects so that new information can be obtained. The best feature of the survey research is that it enables the investigators to easily collect current information about whatever it is they wish to study.

• In survey research, information is collected from a mix of subjects who represent the total population in the characteristics being studied.

• Survey research is a mode of enquiry that relies heavily upon the validity of verbal reports. Surveys can be descriptive, exploratory, comparative and correlational, depending upon the nature of phenomenon being studied.

• Survey data can be collected in a number of ways. The most common method is questioning The information is obtained directly from the respondents by self-reporting questionnaires, however, face-to-face interview method may also be used. A carefully developed questionnaire or interview schedule is essential for data collection, which must be reliable and valid

• Personal interviews are regarded as the most useful method of collecting survey data because of the quality of information that can be obtained. An in-depth response is possible in an interview as relatively few people refuse to express their views on a given subject in an interview.

TYPES OF THE SURVEY

• Depending on the nature of phenomenon under study: Based on the nature of phenomenon under study, surveys are classified as descriptive, exploratory, comparative and correlational surveys.

Descriptive survey: It is undertaken to describe the frequency occurrence phenomenon rather than to study relationships.

• Exploratory survey. It is the survey of a phenomenon, which is very less understood and helps to operationally define the problem and generate hypothesis.

Comparative survey: Comparing and contrasting the existence of a certain phenomenon in two or more groups is done by comparative surveys.

• Correlational survey: It is a study of the relationship between two or more variables in a natural setting without manipulation or control.

Based on methods of data collection: Based on the method of data collection, survey researches can be classified as written, oral and electronic surveys.

• Written survey: In a written survey, data are collected with the help of written, structured tools, such as questionnaires, opinionnaires and so on.

• Oral survey: Data in an oral survey are collected by using face-to-face or telephonic con versation or oral interview with respondents.

Electronic survey: When data are collected by using electronic means such as electro mail messages (e-mails), web forms, mobile short message services (SMS) and s it is known as electronic survey, Computer-assisted telephone interviewing (CATI), a new technology to assist in data collection, is also used for survey research. It is a tool of data collection for computer literate subject, who can privately provide information, but it involves more cost and is not feasible to use in illiterate/subject without computer and Internet facility.

Some of the research designs are used as adjunct designs in combination with standard basic designs, which are presented in with description and relevant examples

Research Designs Used in Combination With Other Standard Designs

Cross-sectional	This design involves observation of sample variables at a specific point in time. In biomedical literature, prevalence studies are termed as cross-sectional

research design	studies. This design is also used in combination with designs where data are collected at a specific point in time. For example, descriptive cross-sectional study, exploratory cross-sectional study and so on. Examples of research problems with combination design: • Breast-feeding practices and newborn care in rural areas: a descriptive cross-sectional study (Madhu, Choudary, & Masthi, 2009). • Exploratory cross-sectional study on factors associated with pre-hospital management of pain (Siriwardena Shaw, & Bouliotis, 2010).
Longitudinal research design	It involves repeated observations of sample variables over extended period of time, which may vary from few months to many decades. It is often a type of non-experimental or observational research, but it can also be used as longitudinal RCT. It is often used in psychology to observe the development trends of a person In sociology, cultural changes or life events are observed through life span or generation. The longitudinal studies could be classified as: • Trend studies: In trend studies, a phenomenon is observed for a long to examine pattern' and rate of changes to make prediction of future direction of changes. • Panel studies: In panel studies, same people are observed over a long period to observe patter of changes, as well as reasons of changes. Thus, it is more informative than trend studies • Follow-up studies: Clinical follow-up study design is commonly used in health sciences, which is undertaken to determine the subsequent states of subject(s) with a specified condition or for those who have received a specific intervention. Furthermore, in clinical follow-up studies patients with specific condition are monitored systematically to establish how their illness progresses and what influences prognosis. For example, what is the prognosis of a patient reported with anterior lumber cord injury, how likely is it that he will be able to walk? These questions can be answered through clinical follow-up studies

	Longitudinal is also used in combination with other observational and experimental studies, when variables are observed for over extended period of time. For example, a descriptive longitudinal study, an exploratory longitudinal study, a longitudinal cohort study and a longitudinal nested case-control study. Examples of research problems with combination design . Life situation of patients with an implantable cardioverter defibrillator a descriptive longitudinal study (Flemme et al., 2001). Attraction and retention of high-IQ students in nursing: an exploratory longitudinal study (Sharma et al., 2017) The effect of social networks on the relation between Alzheimer disease pathology and level of cognitive function in old people: a longitudinal cohort study (Bennett, Schneider, Tang, Arnold, & Wilson, 2006). Both high and low levels of blood vitamin D are associated with a higher prostate cancer risk a longitudinal, nested case-control study in the Nordic countries (Tuohimaa et al.2004).

Research Designs Used in Combination With Other Standard Designs (cont.)

Prospective research design	Prospective studies start with presumed cause to effect. It is often longitudinal in approach, where investigator first identifies the cause and then observes the subjects for longer period to assess the effect of presumed cause. Prospective design is also used in combination with other experimental and non-experimental studies, when study starts with presumed cause and moves towards effect and data are collected for relatively longer period. For example, prospective double-blind RCT, prospective descriptive study and prospective exploratory study. Examples of research problems with combination design: • Azathioprine combined with Prednisone in the treatment of idiopathic pulmonary fibrosis: a prospective double-blind, randomized, placebo-

	controlled clinical trial (Raghu et al, 1991). • Outcomes of intended home births in nurse-midwifery practice: a prospective descriptive study (Murphy & Fullerton, 1998). • Risk factors for death rattle in terminally ill cancer patients: a prospective exploratory study (Morita, Tsunoda, Inoue, & Chihara, 2000).
Retrospective research design	In this design, investigator uses backward approach to study a phenomenon, where he/she moves from effect to identify cause. Investigator first locates the cases affected with condition and then tries to identify the cause of problem. For example, 'a descriptive retrospective study on substance-abuse related high risk factors among traumatic head injury patients admitted in neurosurgery ICU of a tertiary care hospital at Ludhiana, Punjab'. In this study, investigator first approaches head injury patients and then tries to identify the number of head injury that occurred under the influence of substance abuse. The case-control studies are retrospective in approach, therefore, in nursing literature term voce abuse retrospective design is also used for case-control studies. Furthermore, retrospective design is also used in combination with some of the non-experimental studies when study starts with effect and moves backward to identify and cause. For example, descriptive retrospective study, Examples of research problems with combination design: • A descriptive retrospective study of bladder cancer at a hospital in Iran (Yavari, Sadrolheti, Mohagheghi, & Mehrazin, 2009).

Advantages and Disadvantages of Non-Experimental Research Design

Advantages

- Non-experimental research designs tend to be closest to real-life situations. Unlike many research designs are tied experimental studies, correlational, comparative or descriptive criticized for their artificiality.
- Non-experimental research designs are most suitable for the nursing research studies fact, these research designs are extremely useful to enhance your understanding about existing real-world settings around us.
- Numerous human characteristics are inherently not subject to experimental manipulation (e.g. blood type, personality, health beliefs, medical diagnosis and so on); therefore, the effects of these characteristics on other phenomena cannot be studied experimentally
- There are many variables that could technically be manipulated, but manipulation is forbidden on ethical grounds. In such cases, it is fair to carry out non-experimental research.
- There are many research situations in which it is simply not practical to conduct a true experiment. Constraints might involve insufficient time, lack of administrative approval, shortages of funds, excessively inconvenient and so on. In such cases, non-experimental researches are most suitable.

Disadvantages

- The major disadvantage of non-experimental researches is that the results obtained and the relationship between the dependent and independent variables can never be absolutely clear and error-free. The sheer presence of a relationship-a strong one among variables is not sufficient to certify the result that one variable induced the other.
- Non-experimental studies are conducted for comparative purposes using non-randomly selected groups, which may not be homogeneous and tend to be dissimilar in different traits or characteristics that may affect the authenticity and generalizability of the study results.

SPECIFIC QUANTITATIVE RESEARCH

The quantitative studies are broadly classified under true experimental, quasi-experimental and non-experimental research designs. However, there are certain category of researches, which vary in study purposes rather than designs; therefore, they are presented separately under this heading. Some of specific quantitative researches discussed under this heading are clinical trials, evaluation research, outcome research, operational research, methodological studies, secondary data analysis and meta-analysis.

Clinical Trials

Clinical trial is a systematic investigation in the field of medicine to evaluate the safety and efficacy of new drugs and medical devices in human subjects. Preclinical (animal) testing of drug/device is done before its clinical trials to obtain information on quality and non clinical safety of the drug/device on living tissue. In addition, approval of health authority [Drug Controller General of India (DCGI) in India] and Institute Ethical Committee must be obtained before starting the clinical trials. Human clinical trials include the following five sequential phases:

- Phase 0: It is the first stage of clinical trial on human subjects, where a new drug is tested in microdoses (1/100 of test dose) in 10-15 people with a purpose to understand about pharmacokinetics (how drug proceeds in body), bioavailability (proportion of drug reaches to circulation to have active effect) and how drug affects body.
- Phase I: The phase I trial is carried out with the aim to know the most optimum dose of new drug with least side effects. Phase I trials are non-randomized, uncontrolled, open trials conducted on 15-30 healthy volunteers or people with a disease/condition, where investigator administers low dose of drug to few patients and subsequently dose is increased in other patients until desired effect of observed or side effects become too severe to tolerate. The phase I trials are carried out to test safety and tolerability of new drug

- Phase II: If drug is found safe enough in phase I, then it is tested to assess the efficacy and safety of new drug in phase II trial. Phase II trials are also non-randomized uncontrolled trials conducted on 100 or more patients with specific targeted disease condition, who are administered with specific doses of new drug and then they are observed for how well drug works (efficacy) and which side effects they experience (safety).
- Phase III: This trial involves testing of new drug for efficacy and safety by comparing with current drug in use (standard-of-care) through RCTs' approach involving several hundreds of patients with specific disease. Patients are closely observed for adverse drug reaction and trial is stopped if adverse drug reactions are too severe or one group of patients has better results. Phase III trials are required to be completed before ob taining approval of health authority (DCGI in India) to use the new drug in general public.
- Phase IV: Phase IV test, a new drug, is approved by health authority of a country (DCGI in India and FDA in the United States) on several thousand patients to assess safety, the short-lived and long-lasting adverse drug reactions. Phase IV trials are randomized, dou ble blind, placebo-controlled trials where investigator also gets opportunity to assess rare side effects and use of drug in treatment in other conditions.

Evaluation Research

Evaluation research studies are an applied form of research design, which involves the judgement about how well a specific programme, practice, procedure or policy is working. Evaluation research primarily focuses on developing information needed by decision-makers about whether to adapt, modify or abandon a programme, practice, procedure or policy. Evaluation studies may also be used to determine the effectiveness or value of processes, personnel, equipment and the material used in a particular setting

In the era of evidence-based practice and client-centred care, evaluation research assumes great importance. Nurses can evaluate their practices by reflecting on what they do. The evaluation studies are generally carried out when the researcher wants to find out that how and to what extent the objectives of a particular activity have been or are being met. For example, Sharma (2012) carried out an evaluation study to assess the effectiveness of Anganwari Scheme on

nutritional level of beneficiary children in selected villages of district sikar, Rajasthan, where researcher evaluates that how far the predetermined aims and objectives of the particular scheme are achieved.

The aim of the evaluation studies is to improve the particular activity, it makes sense that the original aims and objectives of an activity provide the benchmark against which effectiveness or success is evaluated

The evaluation research is not similar to audit. The evaluation research uses original aims and objectives as benchmark to assess the effectiveness of particular activity. However on the other hand is a cyclic process that involves setting standards for practice, monitoring that practice, comparing actual practice with the standards set, if necessary making change to practice and then re-monitoring practice to see if agreed standards are attained. Evaluation research could be either formative evaluation (process analyses) or summative evaluation (outcome analyses) research.

- Formative evaluation research refers to the assessment of a programme as it is being implemented; the focus is on the evaluation process of a programme rather than the outcome. It is also known as process or implementation analyses, which provide descriptive information about the process by which a programme gets implemented and how it actually functions. Process analysis was designed to address to answer specific questions, such as What were superiority or inferiority of programme compared to traditional practices? Does the programme implantation happened the way it was intended by designers? What were barriers experienced during implantation of programme? What were the significant good and bad experiences of beneficiaries and implementation staff?
- Summative evaluation refers to the assessment of the outcome of a programme that is con ducted after the completion of the programme. It is also known as outcome analyses, which focus on whether a programme or policy was able to meet the intended aims and objectives. For example, a programme is designed to encourage institutional delivery among tribal women from hilly region of Uttarakhand. In outcome analysis, the investigator collects the data about what percentage of tribal women, who had institutional delivery after the implementation of specific programme, when actually number of institutional delivery increased and so on. The investigator may also compare the data with available pre-programme implementations data on institutional delivery among tribal women.

The main limitation of evaluation studies lies in the fact that they are aimed at understanding specific practice, programme, policy or event. Their contribution to knowledge, in general, and research methodology, in particular, remains a secondary objective.

Outcome Research

Outcome research involves the evaluation of care practices and systems in place. Outcome research looks like overlapping with evaluation research, but evaluation research topically focuses on a specific new programme or policy, whereas outcome research is a more global assessment of nursing and healthcare services in place.

It is used in nursing to develop evidence-based practice and to improve nursing services. It is a research that is planned to assess or record the end result of healthcare services. These studies are conducted in response to the increasing demand from public to justify care practices and systems that improve patient treatment outcome and reduce costs of care. The focus of the outcome research is predominantly on patients' health status and cost of care, but recently there is growing interest among nurses and related personnel to study patient outcomes in relation to nursing care.

Outcome research aims to document effectiveness of healthcare services by a global assessment of nursing and healthcare services. The policy-makers, insurers, and public demand improved patient outcomes and costs. This research methodology is the result of demands by the professional standards review organizations for quality assessment and quality assurance of nursing care. Outcome research essentially justifies existing care practices and systems in place. Focus on health status and costs associated with medical care studies in relation to nursing care have resulted in better patient outcomes.

Operational Research

Operational research is an advanced level analytical technique to make best use of available resources. Operational research is relatively new method of research. Morse and Kimball de fine that operational research is a quantitative approach and describe it as a scientific method of providing executive departments with a quantitative basis for decisions regarding the operations under control.

Operational research uses application of scientific methods for making decisions especially in scarce resource organizations. Thus, it provides the rational basis for decision-making in a complex human organization to develop new knowledge about institutions, programmes use of facilities and personnel to improve working efficiency of an organization.

Operational research is the application of scientific method of investigation to study or complex human organizations and services for the purpose of generating information better decision for progressive improvement in organization or service. Development of operational research involves the following six steps or phases:

1. Observe the problem environment in an organization/services.
2. Analyse and define the problem.
3. Develop a model.
4. Select appropriate data input.
5. Provide a solution and test its reasonableness.
6. Implement the solution,

The main objectives of operational research are to develop new knowledge about institution, programmes, use of facilities and personnel to improve working efficiency of an organization. Operational research is a very essential tool for nursing discipline in India because there is serious need to improve the nursing services at primary, secondary and tertiary level of resource scare public healthcare organization. The operational research can offer better understanding about issues pertaining to nursing services through quantitative measurements tools and a practical solution may be identified to improve the quality of nursing services. Furthermore, it may be helpful in effectively designing a hospital or ward for an efficient flow of man and material, constructing communication systems at low cost, computerizing patient information storage for efficiency and so on.

Methodological research

Methodological research design is used for the development and evaluation of data collection instruments, scales or techniques. It is popularly known as psychometrics, which focus on developing and evaluating the instruments for objective measurement of skills, knowledge, abilities, attitude, personality traits, educational achievements, a disease condition, disorder manifestation, nursing care outcome and so on.

Traditionally, nurses used the tools/instruments of measurements for assessing different health-related phenomenon, which were developed in the fields of psychology and sociology. However, gradually nurses realized the need and actively developed several valid and reliable instruments for the measurement of different health-related attributes pertaining to nursing care, nursing education and nursing research. The Journal of Nursing Measurements is devoted to the publication of information on instruments and approaches for measurement of variables.

Therefore, psychometric/ methodological studies are conducted to develop, validate, test and evaluate the research instruments and methods. Basically, a methodological research includes the following steps; however, these steps require sound, specified and exhaustive literature review to identify the theories and understand the construct.

- Defining the behaviour or construct to measure
- Formulating the items for tool.
- Developing instruments for users and respondents.
- Testing the reliability and validity of research tool.

For example, a researcher may conduct 'a methodological study to develop a pressure sore risk assessment tool for patients admitted in orthopaedic wards.

Secondary Data Analysis

Secondary data analysis is a research design in which the data collected by one researcher is re-analysed by another researcher, usually to test new hypotheses. Sometimes researchers collect lots of data in a study, out of which some of the data are left unused or unanalysed that are later taken up and utilized by another researcher, which is called the secondary data analysis research.

In this research design, researchers analyse data collected in previous studies, but they may have a new research question or may test new hypotheses. These studies are considered as most convenient, time-saving and cost-effective because data collection is what is usually considered as the most difficult, time-consuming and costly affair in a research activity.

A secondary analysis can be performed with both quantitative and qualitative data.

Meta-Analysis

Quantitatively combining and integrating the findings of the multiple research studies on a particular topic is known as meta-analysis. In other words, it is a method of integrating quantitative research findings statistically, In 1976, Glass coined the term meta-analysis, it indicates the analysis of analysis.

A meta-analysis statistically merges the outcomes of various studies that hint a research hypothesis that is shared. Just as individual studies summarize data collected from many participants to answer a specific research question (le each participant is a separate data point in the analysis), a meta-analysis summarizes data from several individual studies t concern a specific research question (i.e. each study is a separate data point in the analysis

Meta-analysis is considered as the statistical analysis of a large amount of analysed results from individual studies for the purpose of integrating the findings. It is believed that the findings from each study individually may not be effective or powerful enough to influence decisions affecting clinical practices. However, when results of the several similar studies are analysed together, the finding of such studies may be more effective or powerful. For example, delayed breastfeeding initiation and infant survival: a meta-analysis (Smith et al., 2017).

Systematic review and meta-analysis are not synonymous; a systematic review is carried out to answer a defined research question by collecting and narratively summarizing all the available empirical evidences on that topic that fit pre-specific eligibility criteria, whereas a meta-analysis is the use of statistical methods to summarize the results of these studies. The initial process of systematic review and meta-analysis remains same, but if identified studies are very heterogeneous, it is most appropriate to summarize the data narratively (systematic review) and

not to attempt a statistical summary (meta-analysis). However, they are used in combination in the research practices, for example:

"Comparison of outpatient and home-based exercise training programmes for COPD: a systematic review and meta-analysis'.

"Coping behaviour of the people with cancer diagnosis: a systematic review and meta analysis'.

Steps in Conducting a Meta-Analysis

A well-designed systematic review and meta-analysis will include the following:

- Clearly stated research question considering PICO and precisely identified objectives the systematic review and meta-analysis.
- Well pre-defined eligibility criteria for study selection and explicit reproducible search methodology
- A precise evaluation of study quality and risk bias of the selected studies.
- Systematic plan of presentation, summarization and synthesis of findings of selected studies

In addition, before starting the systematic review and/meta-analysis ensure that it has not been already done to avoid the duplication and wastage of time and resources.

A well-designed systematic review and meta-analysis includes the following steps:

1. Formulate the research question: A clear, specific and answerable question is essential for successful review and meta-analysis. Consider use of PICO (problem/patient/person, intervention, control and outcome) to formulate research question. For example, P: adults 218 years, both genders; It mindfulness mediation, C placebo/cognitive behavioural therapy, O: panic symptoms score.
2. Register meta-analysis: The registration of systematic review and meta-analysis will help others to know about this ongoing systematic review and meta-analysis to avoid duplication. Systematic review and meta-analysis may be registered on following networks: http://www.erd.york.ac.uk/PROSPERO/ by Cochrane Collaboration: http://www.cochrane.org/cochrane-reviews

3. Conduct literature search (locate and select studies): Literature involves the following components

   Identify the key search terms, and relevant database sources such as CINHAL, PubMed/Medline, EMBASE, Google scholar, Cochrane Library and so on.

   Specify inclusion and exclusion criteria: Specifying methodology, for example, will in cloud only RCTS or RCT and quasi-experimental studies both. Specifying clinical c ria, for example, including studies only panic disorder but not on mild and moderate anxiety

   Determine search strategy: Use Boolean operators (see Chapter 5, page no. 125-126 d)

   Select the relevant articles needed for meta-analysis; PRISMA (Preferred Items for Systematic Reviews and Meta-Analyses) flow chart may be used for select the relevant studies (Appendix XV). However, if you are doing Cochrane Collaboration, you have to follow their guidelines. Use reference management software (eg, RefMan, EndNote, Mendeley) to manage searches and also make writing final paper easier.

   Data extraction: Have a well-designed form in hand to obtain all relevant information from each of the included studies. Generally, it includes information about basic information of study, characteristics of participants, methodology (sample size, study de sign, randomization, blinding, participants' allocation, intervention, outcome variables, etc.) and main findings.

4. Critically assesses the quality each searched study: Appropriates of design of study, risk bias quality of intervention, choice of outcome measures, statistics used, quality of reporting (consensus reporting guidelines for different study designs proposed by EQUATO: http://:www.equator-network.org/ may be used to assess reporting quality), generalize ability must be evaluated to assess the quality of study. Although there is no consensus on objective criteria to assess the study quality, however, GRADE (grading, recommendations, assessment, development and evaluation) criteria may be used to assess the quality of each study (https://gradepro.org/).

5. Determine the heterogeneity in selected studies: It is most critical step of meta-analysis and heterogeneity of studies can be estimated with x statistics (high p value suggests homogeneity) or

I statistics (score 25%: low heterogeneity, 50% moderate hetero geneity: 75% high heterogeneity). If identified studies are very heterogeneous in the scope of population, intervention and outcome, then it is most appropriate to summarize the data narratively (systematic review) and not to attempt a statistical summary (meta-analysis).

6. Estimate the summary effect size and construct forest plot: If selected studies are found homos venous, then study findings are pooled to arrive at summary estimates using fixed-effect on random-effect meta-analysis model and forest plot is constructed. Meta-analysis involves risk ratio and odd ratio as most measures of effect for dichotomous data and standardized mean difference (SMD) estimation for continuous data. Studies are reported using ant MA flow chart (Appendix XV), The results of meta-analyses are often presented in plot, where each study is shown with its effect size and the corresponding 95% confidence interval (Fig. 7:22).

7. Assess for publication bias and run a funnel plot: After identifying heterogeneity, summary effect estimates and forest plot, it is essential to assess publication bias in studies. Publication bias means if the meta-analysis has or has not omitted studies that should have been included as studies with large sample size and positive results are more likely to be pub listed and identified in search as compared to studies with smaller sample size with equivocal or negative results, Publication bias may be estimated by plotting effect estimate of studies on x-axis and either sample size or effect measure variability (variance or standard deviation) on y-axis of plot and if the plot resembles flannel, which means meta-analysis is free from publication bias.

8. Interpret the result and draw and the conclusion: Finally, forest plot also known as blobbogram in interpreted and conclusion is drawn based on intended objectives of the meta-analysis

Software also may be used for conducting systematic review and meta-analysis such as a paid software: Comprehensive Meta-Analysis (https://www.meta-analysis.com/), and a free software: Review Manager (RevMan) from the Cochrane Collaboration (http://ims cochrane.org/revman).

Ecological Studies

Ecological studies are epidemiological research design, which compares measurements in groups rather than individuals. For example, 'an ecological study of tuberculosis transmission in California' (Myers, Westen house, Flood, & Riley, 2006), In this study, investigator collects the case reports of TB cases from Department of Health and their socio-economic data from census and computed the statistical results to find out the association between ecological factors and rates of tuberculosis within California. The unit of measurement in ecological studies are groups (regions/states/counties) rather than individual. The variables/measures could be aggregate measures (mean or proportion, e.g. mean per capita income, proportion of alcoholics, etc.), environment measures (physical characteristics of living places such as air pollution, air temperature, humidity, etc.) and global measures (e.g. population density, specific existing law and so on) and data are primarily collected from secondary sources such as population disease registry, vital stats records, large survey reports and census. Ecological study designs are classified based on method of exposure measurement (exploratory and analytic) and method of grouping-based in place (multiple group design), based on time (time-trend design) and based on both place and time (mixed design). The details of ecological design are presented

The major of problem of conducting ecological studies include lack of adequate secondary data, migration of people across regions, ecologic bias, problems of confounder control temporal ambiguity and collinearity,

QUALITATIVE RESEARCH DESIGNS

Qualitative research approaches have somewhat short and less well-defined plans. In qualitative research study design, elements typically evolve over the course of the project. As one study unfolds, decisions are made in the field about how best to obtain information and from whom; how to schedule data collection; and how long each data collection session should last

Qualitative research as emergent design: The design for a qualitative study is emergent in nature, that is a design that emerges as the researcher makes ongoing decisions while reflecting on what has already been learnt. It has been mentioned by the eminent re searchers and thinkers that an emergent design in qualitative studies is not the result of researchers' sloppiness or laziness of not having a design in place before the commencement of the study, but rather it is their desire to

base the enquiry on the realities and view points of those under study-realities and viewpoints that are not known or understood at the outset.

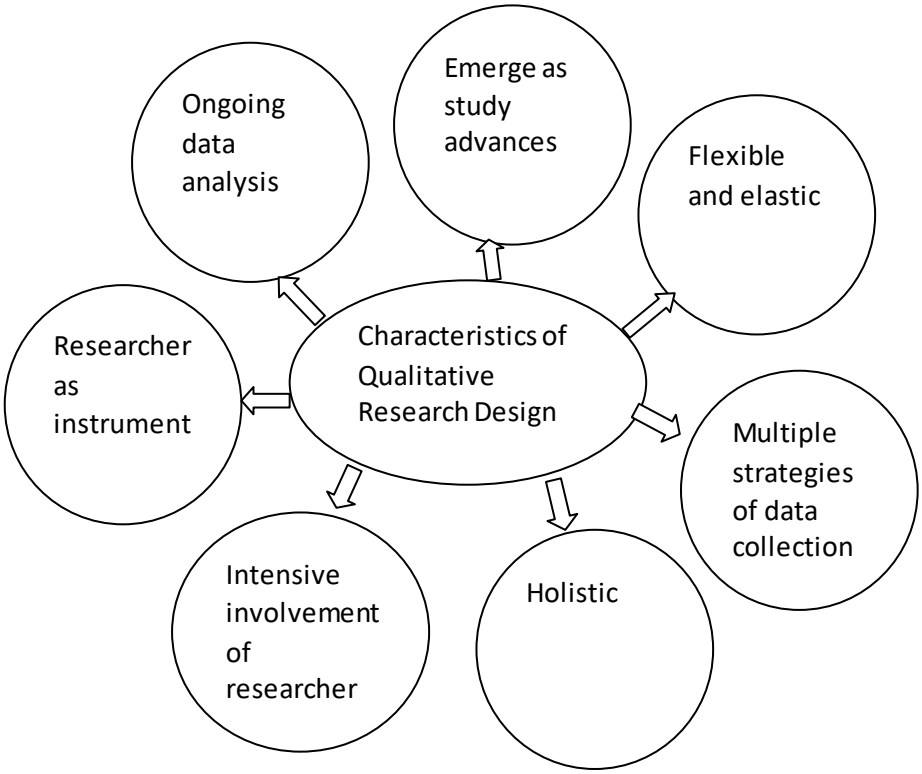
Importance of Qualitative Research Designs

- Qualitative methodologies contribute a great deal in nursing studies, as it is a discipline that is building a knowledge base in the process of clarifying how nursing sciences should be developed, therefore, nursing scientists have appreciated this contribution
- Qualitative research methods enable researchers to study social and cultural phenomena, so they also contribute to the social sciences.
- Qualitative research is an inductive approach for discovering or expanding knowledge. In this, it includes researcher's involvement in the identification of meaning or relevance of a particular phenomenon to the individual. Qualitative strategies are useful for exploring facts and developing concepts about an area of interest that has received little research attention.

Characteristics of Qualitative Research Design

A number of different disciplines have been guided by qualitative enquiry, and each one of them has produced research methods that best suit its discipline. Some of the general characteristics of qualitative research design tend to apply across most disciplines. Qualitative research designs basically have the following characteristics (Fig. 7.23).

- Emerge as study advances: Generally, it is believed that qualitative research designs
- Flexible and elastic: They are flexible and elastic, and can be adjusted to the information emerge as study advances being gathered during data collection
- Multiple strategies of data collection (triangulation): Qualitative designs typically merge the various strategies of data collection
- Holistic They tend be holistic, striving for an understanding of the whole.
- Intense researcher's involvement: They require intense involvement of the researcher, that is commitment for longer periods in the field of study. Sometimes qualitative research designs also require the researchers to become research instruments for data
- Ongoing data analysis: Qualitative research design requires data analysis for the formation of subsequent strategies and to determine when further field work should be done.



Characteristics of qualitative research design

Phases of the Qualitative Research Design

The exact form of a qualitative study design cannot be known and specified in advance. The naturalistic enquiry processes go through three broad phases when the researcher is in the field. The three main phases of qualitative research designs are as follows:

- Orientation and overview phase: This is the first phase of qualitative research de n At this stage, the researchers only presume the type of knowledge that is expected to be obtained by conducting this particular qualitative study. However, they are not familiar with phenomenon that will drive the enquiry forward. Therefore, initially researchers get an overview of the salient features of interest. This orientation and overview phase enables them to plan further for the research study.
- Focused exploration: This is the second phase in qualitative research design. The salient aspects of the phenomenon are more focused in this phase, and then an in-depth explain ration of the salient aspects of the phenomenon is carried out. In this phase, a variety of people related to the field are invited to participate in the study and questions are asked from them to gather more information about phenomenon. Questions are asked based on the understanding developed during the first phase of the design. Therefore, at this stage of the

design, focus is on exploration of the salient aspects of the phenomenon under study. Confirmation and closure: This is the third and final phase of the qualitative design E forts are undertaken to establish that the findings gathered are trustworthy, The qualitative researchers re-group and discuss their understanding with the participants of the study Therefore, the qualitative researchers confirm their findings by analysing and discussing with study participants about the authenticity and correctness of their findings, and then finally the study is closed.

Main Types of Qualitative Data Collection

Those who are not familiar with qualitative methodology may be surprised by the sheer vol ume of data and the detailed level of analysis that result even when research is confined to a small number of subjects. Following are the three main methods of data collection

1. Written depiction by participants	People were expected to write down detail of their understanding of phenomenon
2 Observation	Detailed observations of both verbal and non-verbal behaviours
3. Interactive interviewing	People were asked to verbally mention their understanding of the event

Types of Qualitative Research Designs

In this chapter, the main qualitative research designs discussed are phenomenological research, ethnography research, grounded theory, historical research and action research. The brief discussion of main types, meaning and description of qualitative research design may be perused

Main Types of Qualitative Research Designs

Qualitative Research Design Categories	Definitions and Narrations
Phenomenological	Details the structure of experiences as they present themselves to

research	awareness, without recourse to assumptions, theory or deduction from other methods.
Ethnographie research	Concentrates on the sociology of meaning through close field observation of socio-cultural phenomena. Basically, the ethnographer checks on a community
Grounded theory	Theory is developed inductively from a corpus of data gathered by a participant-observer
Historical research	Systematic accumulation and objective measurement of data relating to earlier occurrences to measure hypotheses pertaining to causes, effects or trends of these events which might facilitate in explaining present events and anticipate future events.
Action research	Action research is a form of applied research that tries to empower people through a process that constructs and uses knowledge. It tries to find practical solutions to problems existing in the framework of an organization. It increases understanding of how change in one's actions or practices can mutually benefit nurses within an organization
Case study	Trying to concentrate on a phenomenon by checking in depth an individual case example, The case can be a group, an individual an event or an institution

Phenomenological Research

Phenomenology is a movement in philosophy that has been adapted by certain sociologists to raise an understanding of the relationship between states of individual consciousness and social life. As an approach within sociology, phenomenology attempts to uncover how human awareness is implicated in the production of social action social situation and social world. The aim of phenomenological approach to qualitative research is to trace out precisely the lived experiences of people and generate theories or models of phenomena being studied

According to GWF Hegel, Phenomenology is an approach to philosophy that begins with an exploration of a phenomenon (what presenting itself to us in conscious experience), logical, ontological, and metaphysical spirit that is behind phenomenon. This is called as a "dialectical phenomenology".

According to Edmun Husserl, Phenomenology is an approach to philosophy that takes the perceptive experience of phenomenon (what present itself to us in phenomenological reflection) as its origin and attempts to distillate from it the main traits of experiences and the essence of what we experience', as it is shown diagrammatically in Fig. 7.24.

CHARACTERISTICS OF THE PHENOMENOLOGICAL APPROACH

- Phenomenology tends to withstand the acceptance of those circumstances servable, and is a grand system erected in speculative thinking.
- Phenomenology tends to oppose naturalism, that is objectivism and positivism.
- Positively speaking, phenomenology tends to justify knowledge with reference to awareness of a substance itself, as disclosed in the most comprehensive, distinct and suitable way for something of its kind.
- Phenomenology tends to seize/grasp that enquiry ought to emphasize upon 'encountering as it is directed at objective and correlative upon objectives as they are encountered.

- The data collection issues in phenomenology are shown in Table 7.9. The primary sources of data collection are the real-life situations of the individuals being studied, where in-depth interviews, that is semi structured, audio taped interviews with participants are the most common means. Furthermore, emerging themes are frequently validated with participants because their meanings of that lived experience are central to phenomenon logical study. People who have recently had the experience are selected as participants.

Data Collection Issues in Phenomenology

Issues	Phenomenology Researches
Methods of data collection	Primarily in-depth interviews, sometimes diaries or other written material
Units of data collection	Individual subject
Data collection points	Mainly cross-sectional
Length of time for data collection	Typically moderate
Data recording	Interview notes and/or audiotape recording
Salient features	Bracketing one's view, building rapport, encouraging candour, listening while preparing what to ask next, keeping discussion on 'track, and handling emotions

For example, a recently diagnosed HIV patient or a woman who has had a stillborn baby in last 3 months can be interviewed for a study of psychological impacts of these medical conditions. Bracketing is a technique used by the researchers to assist the participants in describing lived experiences, while at the same time setting aside their own personal feelings. Statements that would be helpful in eliciting a participant's description should be a part of such an interview. The researcher must use intuition to develop an awareness of the lived experiences without forcing prior expectations or knowledge into the process. Then after classifying, the researcher attempts to reduce categories until overlap, vagueness and irrelevancy are eliminated. The final listing of categories should reflect the lived experience captured in a coherent, meaningful manner.

Data analysis: The process of analysis involves the difficult task of contrasting and com paring the final data to determine what pattern, themes, or threads emerge. In the final analysis, a wise researcher seeks further knowledge about that lived experience in a concise manner. If the knowledge is to be of relevance to other researchers, it must be understandable and clear, detailing the relationship that exists.

TYPES OF THE PHENOMENOLOGICAL RESEARCH

There are basically four types of the phenomenological researches, as discussed below.

1. Realistic phenomenological research: It focuses on gathering the universal abstract of various types of information, including human actions, motives and results.

2. Constitutive phenomenological research: This includes the philosophy of natural sciences. This procedure entangles suspending acceptance of the pre-given position of conscious life as something that exists in the world, and is carried out to obtain an ultimate intersubjective grounding for the world and the positive sciences of it. For example, social beliefs, positions and practices.

3. Existential phenomenological research: This is concerned with topics, such as actions, conflicts, desires, finitude, oppression and death.

4. Hermeneutial phenomenological research: It utilizes vital experiences as a device for better consideration of the political, social, cultural or historical aspect in which those experiences hap pen. Hermeneutic enquiry almost always concentrates on interpretation and meaning: how historically and socially conditioned individuals portray their world within a given context.

Ethnographic Research

Ethnography, associated with the field of anthropology, is a branch of human enquiry, which concentrates on the culture of a group of people with an effort to interpret their worldview. Ethnographic studies are involved in the collection and analysis of data about cultural groups Ethnography is basically classified into two types: macro- and microethnography, Macroeth nography is a study of broadly defined culture, while microethnography is a study of more narrow aspects of a culture.

Ethnographic research is a method of conducting enquiry of a life process by studying in dividuals, artefacts or documents in their natural setting. It includes both anthropology and historical forms of research. In healthcare research, ethnography provides access to health beliefs and healthcare practices in particular cultural or subcultural group. Therefore, ethno graphic enquiry facilitates understanding about cultural behaviour and practices affecting health of people.

In nursing, several qualitative nursing phenomena are studied by using ethnographic research. However, Madeleine Leininger has coined the phrase ethno-nursing research, which is defined as the study and analysis of the local or indigenous people's view points, beliefs, and practices about the nursing care behaviour and process of designated cultures'.

CHARACTERISTICS OF THE ETHNOGRAPHIC RESEARCH

- Ethnographers learn about cultural groups in which they are interested through the extensive fieldwork.
- Ethnographic research is a labour-intensive and time-consuming endeavour, where even months or years of fieldwork can be involved.
- A certain level of intimacy with cultural group members is required to study culture. Intimacy can develop over time and by working together directly with those cultural group members who are active participants.
- Researchers use themselves as instruments in these ethnography studies, where they spend time with group members to collect data through informal interactions and observations rather than using a formal tool for data collection.
- Information on three major aspects of cultural life is sought in the ethnography studies: cultural behaviour (what members of culture do), cultural artefacts (what members of the culture make and use) and cultural speech (what people in cultural group say).
- Ethnographers rely on various sources of data collection such as in-depth interviews, record analyses and observation of physical evidence (photographs, diaries, letters, etc.).

For example: 'An ethnographic or ethno-nursing study focusing on blood donation beliefs of women living in rural areas of district Imphal-East, Manipur'.

Grounded Theory

Grounded theory is an inductive technique developed for health-related topics by Gloser and Strauss (1967). It emerged from the discipline of sociology. The term grounded theory means that the theory developed from the research is 'grounded' or has its roots in the data from which it was derived.

Grounded theory has become an important research method for the study of nursing theories of phenomena relevant to nurses. It is an approach to study social process and social structures. It is different from other methods because of its specific access to theory development. As per grounded theory, there should be an ongoing interplay between data collection and data analysis. The main focus is on developing social experience, the social and psycho logical stages and phases that characterize a particular event or episode.

Martin and Jurner (1986) have mentioned that 'Grounded theory an inductive theory discovery methodology that allows the researcher to develop a theoretical account of the general features of a topic while simultaneously grounding the account in the empirical observation or data'.

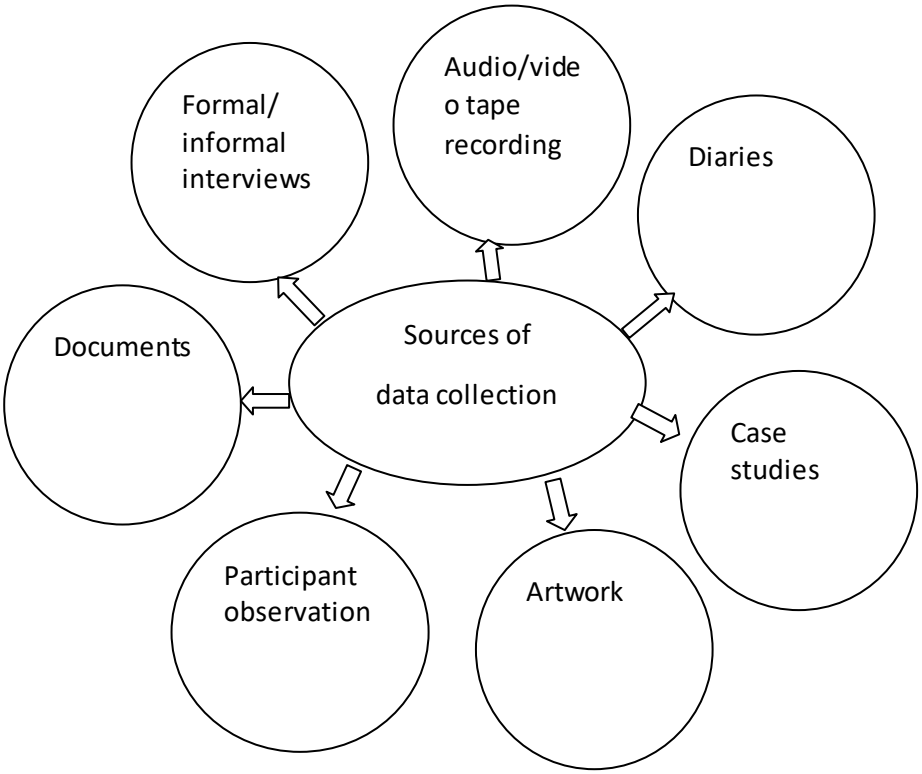
CHARACTERISTICS OF THE GROUNDED THEORY

Overview and phases of grounded theory: Grounded theory begins with a research situt ation. Within that situation, the task of researcher is to understand what is happening there (core variable), and how the players manage their role. After each hour of data collection the researcher notes down key issues, this is known as note taking Constant comparison lies at the heart of the process. First, the researcher compares one interview (or other data to another (or other comparative data). From this comparison, a theory emerges. Research ers compare the initial data to the theory, and the results of this comparison are written in the margin of the notes taken as 'codes'. The researcher's task is to identify categories and their properties from these codes. In the researcher codes, there may be link between categories or a core category may emerge (a category which appears central to study/ es proceeding to this step provides the researcher with a final theory. The researcher W further notes about this theory, which is called

memoing. If this process saturates at ever time for sorting. Researcher groups memos, line-by-line, and sequences them in whatever mostly overlapping phases (as shown in Fig. 7.25),

order will make his/her theory clearer. Over time a grounded theory works through the method is frequently considered to be an inductive means of developing theory (from the tant methodological technique in grounded theory is constant comparison. Although this Methodology: The steps of the grounded theory research occur simultaneously. An impor data actually gathered), in reality a combined inductive and deductive process is utilized (deductive means what is expected to be found in social life). For example, a community health nurse is using grounded theory methodology to study scapegoating in dysfunctional families. The nurse limits the study to those families that have children (under 10). Observation for the purpose of collecting data occurs primarily in the homes of the participants. Family interaction and communication patterns are assessed through observation and interviews as well as through role-playing (manipulation) and observation of family members in their work or school environment. As data collection proceeds, nurses begin to form some hypotheses regarding scape goating activity. During this process, the nurse began to categorize the data and code it; coding helped her in thinking and conception of the families. To verify the theory, the nurse plans to study other dysfunctional families who are scapegoating.

- Sources of data collection: For data collection, the researcher will use all his/her senses. There is a lot to be learned just by observing; some of it is evident within minutes of entering a situation. Sources of data collection vary with the focus of enquiry, the purpose of investigation and guidelines suggested by research approach being utilized. The data col lection issues for grounded theory are shown in Table 7.10.
- Some possible sources that could be used in collecting data relevant to the life processes have been shown in Fig. 7.26.



Sources of data collection in grounded theory

- Data analysis: Typically, grounded theory research projects in nursing studies tend to have a sample of 25-50 people, and are conducted by in-depth interviews, data collection notes, typed interview transcripts, or video-taped/audio-taped conversations that contain multiple pieces of data to be stored and analysed. The process is initiated by coding and categorizing the data. There are several types of coding: open, axial, and selective coding
  - Open coding: It is the part of the analysis related to categorizing, identifying, naming and describing phenomenon as found in the text. Essentially, each paragraph, line, sentence and so on are read in search of the answer to the repeated question, What is this about? What is being referred to here?
  - These labels can refer to anything like hospitals, information gathering, friendship, social loss, etc. Part of the analysis process is to identify the more general categories that these things are a part of, such as institutes, work activities, social relations, social out comes and so on. For example, with regard to friendship, we might ask about its duration, its closeness or its importance to each party. It is important to have a fairly abstract category in addition to every concern, as the abstract categories help to generate general theory. Take pain, for example, the researcher views pain as having different properties, like intensity (it varies from a little to a lot), consequences (when it hurts a lot, we do not want

to get out of our beds, do not feel like doing anything), agents of pain relief (drug), duration of pain relief (could be temporary) and effectiveness (could be partial).

- One can see that this sort of analysis has a very emic cast to it; even though most ground ed theories believe they are theorizing about how the world is rather than how respondents see it, coding can be done very formally and systematically or quite informally. In this it is done informally. As the codes are developed, it is useful to write memos known as code notes that discuss the codes. These memos become source for later development into reports.
- **Axial coding**: It is the process of connecting codes (properties and categories) to each other through deductive and inductive thinking. To simplify this process, besides looking at other kinds of relations, grounded theorists point out causal relationship and fit things into a main frame of generic relationship. It seems obvious from the previous example that phenomenon of interest is pain, causal condition is arthritis, the action strategy is taking drugs, and the consequence is pain relief. Note that grounded theorists do not show much interest in the consequences of the phenomenon itself.
- Selective coding: Selective coding is the act of selecting one category as the core category and connecting all categories to that category. The main idea is to find out a single storyline around which everything else is draped. It is about finding the driver that impels the story forward.

TYPES OF THE GROUNDED THEORY

There are mainly two types of grounded theories.

- **substantive theory**: It is grounded in data on a specific substantive area, such as postpartum depression.
- **Formal theory:** Substantive theory serves as a springboard for developing a higher, more abstract level of theory from a complicated substantive grounded theory study regarding a particular phenomenon. Kearney (1998) used an interesting analogy to differentiate substantive theory (custom-tailored clothing) and formal theory (ready-to wear clothing).

For example: A grounded theory study was conducted by a group of researchers, which looked at how parents coped with difficult times when caring for a chronically ill child. They audio taped interviews of 30 families who used their clinic. The following is a brief statement of theory that came from their research: "The families of chronically ill children establish specific ways of coping to meet the requirements of all their members. If support is available, equilibrium is achieved. If needs increase dramatically or support changes, there is lack of equilibrium'. Some more examples of the grounded theory research design are presented in Box 7.11.

Historical Research Design

The systematic collection and critical evaluation of data relating to past occurrences of a particular phenomenon is also a tradition that relies primarily on qualitative data. Historical research is undertaken to answer questions concerning causes, effects or trends relating to past events that may shed light on present behaviour or practices.

CHARACTERISTICS OF HISTORICAL RESEARCH DESIGN

- It is important not to confuse historical research with a review of literature about historical events. Historical research involves the careful study and analysis of data about past events.
- Historical research is a critical investigation of events, their development, experiences of the past, the careful weighing of evidence of the validity of courses of information from the past, and the interpretation of the weighed evidence.
- The purpose is to gain a clearer understanding of the impact of the past on present and future events related to the life process. It involves detailed analysis of what has been written or done and is used to describe, explain or interpret these events.
- Generally, historical research involves the review of written materials, but may include oral documentation as well.
- Historical research typically relies on available data. Data for historical research are usually in the form of written narrative records of the past, diaries, letters, newspapers, minutes of meetings, reports and so on.

- The results of the historical research studies contribute to a clearer understanding of past, present or future events as they relate to nursing, healthcare and the life process, For ample, a nurse investigator may be interested in studying the professional nurse's role as an advocate for pregnant women since the Second World War. Knowledge of how the advocate's role has been fulfilled in the past may provide nurses with helpful information regarding how that role might best be carried out today.
- Historical method of research also covers categories, such as historical, legal, documentary, bibliographical, biographical, ideational, institutional and organizational.
- Important existing data sources for nurse researchers are hospital records, nursing charts, physicians, order sheets and care plan statements. They all constitute rich data sources Records are an economical and convenient source of information.

STEPS OF HISTORICAL RESEARCH

Use of the historical research approach is highlighted by discrete steps.

FIRST STEP: DATA COLLECTION Comprehensive gathering of data is undertaken. Historical sources of data are usually classified into two main categories.

- **Primary sources**: Primary sources are first-hand information that include
  - Remains or relics associated with persons, groups, periods or events.
  - Fossils, skeletons, tools, weapons, utensils, clothing, buildings, furniture, pictures, paintings, coins and art objects are examples of the remains that were not deliberately intended for use in transmitting information or to be used as records.
  - Oral or written testimony or the records kept and written by actual participants in an event, or actual witnesses of the same. These sources are consciously produced for the purpose of transmitting information to be used in the future.
  - Documents classified as primary sources are constitutions, characters, laws, court rulings, official records, autobiographic letters, diaries contracts, deeds, wills, licenses declaration, certificate, bills, receipts, newspapers, magazines, advertisements, maps, inscriptions, diagrams, books, pamphlets, films, pictures, paintings, recordings research reports,

- **Secondary sources:** These are the reports of people who related the testimony he an actual witness of an event or actual participants in the same. The writer n are secondary source was not on the scene of the event. Secondary sources of data usually of limited worth because of the usual errors that result when information is encyclopedia, passed on from one person to another. For example, most of the history books and

SECOND STEP: CRITICISM OF THE DATA The second step necessitates a comprehensive re view of gathered materials. This is an arduous task requiring a sense of scepticism about the accuracy of the documents in question. Christy (1975) describes the analytic process of document review as a two-pronged activity.

- **External criticism**: The establishment of validity by determining the authenticity of the source.
  - External criticism is covered basically with the authenticity and genuineness of the data. It is a preliminary and preparatory step, providing data to be used in the second phase known as internal criticism.
  - External criticism primarily deals with data relating to form and appearance rather than meaning of contents, while internal criticism weighs the testimony of document in relation to truth
  - The nurse ascertained that all the documents were original. First-hand oral and written accounts were accepted as valid. Signatures and date on materials were carefully reviewed; when each document selected for review clearly met the criteria for authenticity, it was accepted as appropriate for further analysis and interpretation
- **Internal criticism**: The determination of reliability by correctly interpreting the contents of the document.
  - The use of original, authentic sources; awareness of one's own biases, the substantiation of the document in question by another collaborating source are a few of the safeguards used to ensure that interpretations are correct.
  - To ensure reliability, the nurse examined each document to make sure that the meaning of facts and statement was clearly understood. This process entailed seeking collaboration

from individuals who may have witnessed the events in question as well as deter mining the meaning of words, phrases and colloquialisms unique to that time period.

- After the authenticity or genuineness of a historical document or relic has been established, the next question is to establish the validity of its contents or to determine the accuracy and value of the statement made.
- In performing internal criticism, historians must make several determinations, which require historical knowledge beyond perusal of the materials in question.
- Evidence bearing on the accuracy of historical data might include one of the following
    1. Comparison with other people's accounts of the same event to determine degree of agreement
    2. Knowledge of time at which the document was produced.
    3. Knowledge of the points of view or biases of the written and oral documents.
    4. Knowledge of the degree of competence of the writer to record events authoritatively and accurately.

THIRD STEP: PRESENTATION OF THE FACTS After evaluating the authenticity and accuracy of historical data, the researcher must bring the material together to analyse it and to test the research hypotheses.

- Historical researchers must be extremely careful at this point since the analysis of historical data involves logical processes rather than statistical ones, and, therefore, the possibility of subjectivity arises.
- Historical composition is a synthetic and constructive process that involves the mechanical problems of documentation, the logical problem of arrangement of topics and subtopics, and the philosophical problem of interpretation
- The earlier practice in historical writing presented a strictly chronological type of organization. Such organization involved a series of events broken up into short time units. The writing used to be in the form of calendar and dates, events and names. The chapters were marked off by a period of a few months or a few years, depending upon the changes of some important nature or occurrence of some significant events.

- The organization of historical material can also be done in topical, thematic or functional arrangement
- A well-written history of education provides information on the conditions of education in the past. Even the stories written in the past show purpose and meaning of education in historical times, and provide background for better understanding of current educational problems
- The writing of history demands careful avoidance of the following factors.
    - Over signifying facts.
    - Overgeneralizations from insufficient evidence.
    - Failure to distinguish between significant and trivial facts
    - Tendency to use secondary data.
    - Tendency to accept statements as essentially authentic when several observers agree.
    - Personal bias.
    - A dull and colourless style.
    - Failure to interpret words and expressions in the light of their usage in earlier times
- Determining the interrelationship among facts and the meaning of the data gathered, reviewed, and recorded is the final step in historical research. The three steps identified are central to discovering the truth about the past and how it can relate to nursing and health care provided today. For example, a nurse researcher is interested in examining the influence of early Western nurse leaders in Indian nursing from 1890 to 1950; a historical research approach would be appropriate in generating the evidence. The nurse researcher could interview descendents, review professional documents, read diaries and letters, and examine photographs, among other sources.
    - Scrutiny of these materials should assist in the construction of the story of facts regarding these leaders. Ultimately, the nurse researcher would synthesize the material and make a determination regarding the contribution of these leaders to nursing and healthcare as well as suggestions for future change.

    - Another example of historical research is that researchers have done intensive analysis of the image of professional nurses through the examination of various document

Documents examined have included film clips, novels, newspaper clippings magazine articles, among others.

- Intensive examination of these historical materials has allowed the nurse researcher to identify varying images during different time periods. The result of this analysis has been a systematic evaluation of image problems currently existing within the profession. Some more examples of historical research design are presented in Box 7.12.

AREAS OF HISTORICAL STUDY

- **Periods**: Historical studies often focus on events and developments that occurred during particular block of time in the past. Historical researcher gives these periods of time names to allow the organization of ideas and the classificatory generalization to be used by these historical researchers. The names given to a period can vary with geographical location as can the dates of the start and end of a particular period. Centuries and decades are commonly used periods, and the time they represent depends on the dating system used. Most periods are constructed retrospectively and so reflect value judgement made about the past. The way periods are constructed and the names are given to them can affect the way they are viewed and studied.
- **Geographical locations:** Particular geographical locations can form the basis of historical study, for example continents, countries and cities.
- **Military history**: Military history concentrates on the study of conflicts that have happened in human society. This includes examining the wars, battles, military strategies and weaponry. In addition, the effect of these events on the society and health may also be examined.

METHODS AND TOOLS USED IN HISTORICAL RESEARCH

- **Contemporaneous corroboration:** Contemporaneous corroboration is further support provided by the existing evidence about the past events. It is a powerful method generally used by the historical researcher to establish facts beyond their limited lifespan.

- **Photography:** A methodological tool for the collection of all known information about individuals in a given period.
- **Historical revisionism:** Traditionally used in a completely natural sense to describe the work or idea of historian who has revised a previously accepted view of a particular topic.
- **Change log:** Log or record of changes made to a project, such as a website or software project.
- Human evolution: Process of change and development or evolution by which human beings emerged as distinctively special.
- **Social change:** Changes in the nature, the social institutions, the social behaviour, or the social relations of a society or community of people. For example, "The historical evolution and political/moral contents of technological instruments in obstetric surveillance and diagnosis, and the use of those instruments by nurses,' signify social change.

Action Research

Action research is a form of applied research that tries to empower people through a process that constructs and uses knowledge. It tries to find practical solutions to problems existing in the framework of an organization. It increases understanding of how change in one's actions or practices can mutually benefit nurses within an organization. Changes are planned, which can be locally implemented in a particular organizational setup, and, therefore, are not universally applicable.

A branch of action research known as participatory action research (PAR) emerged in 1940s. It was started by Kurt Lewin, a social psychologist, and is closely related to critical research. The problem is researched, changed and re-researched within the research by the participants and researchers. It is actively co-researched by those who are hoped to be helped. Taking action through planning and fact-finding brings about future and organizational change

DATA COLLECTION METHODS

Action research involves the following methods of data collection.

- Interview

- Observation
- Storytelling
- Socio-drama
- Drawing and painting
- Plays and skits
- Other creative ways, like explore lives, tell stories, and recognize own strengths.

IMPORTANCE OF ACTION RESEARCH IN NURSING

Research has the ability to exert power, especially if research involves collaboration between study participants and the researcher. The research process can improve nursing practice and nursing researchers. The habit of thinking, ability to work harmoniously with others and professional spirit will improve. Nursing knowledge, actions and consciousness will benefit from action research, as it will help to recognize strengths and areas of improvement.

Action research is of particular importance to the nursing field, especially in the Indian setup, as its objectives are as follows:

- To solve a problem by enriching the field of application of a discipline
- To collaborate with several disciplines for solving the problem
- To study the individual cases without the objective to generalize
- To recognize that other variables are constantly changing
- To try to say how things can be changed
- To report in common language

For example, in the Indian nursing colleges, foreign nursing practices are taught, but when the nursing students go to the hospital, they find insufficient infrastructure for the nursing practices taught to them. In this situation, action research may help to bridge the gap of theory and nursing practices in our own scenario. Examples of the action research design are presented in Box 7.13.

Case Study

- Case studies are in-depth examination of people, places or institutions. Robson defines case study as the development of detailed, intensive knowledge about a single 'case' or a small number of related cases. This strategy is of particular interest if researcher wishes to gain a rich understanding of the context of the research and its processes. While H. Odum defines that case study method is a technique by which individual factor whether it be an institute or just an episode in the life of an individual or a group is analysed in its relationship to any other in the group.
- Case study is often used when the selected case might offer insight into a unique situation or when researcher wants to know more about a particular phenomenon within a real-life context. Using case study methodology, researchers are able to maintain the richness and complexity of the concept of interest while simultaneously highlighting specific details.
- Based on the purpose of carrying out case studies, they are classified into three major types, that is descriptive, exploratory and explanatory case studies. north
    - Descriptive case studies allow researchers to describe characteristics, features and qualities of a yet unstudied person, institution or situation.
    - Exploratory case studies offer an opportunity to clarify key concepts, ask more relevant questions and better understand a concept of interest, often as a prelude to understand a large study of the issue.
    - Explanatory case studies can be used as pilot studies in the development of a conceptual framework, which can serve to organize the data collection in large study. Explanatory case studies give new or refined meaning to previously explored concepts, while the researcher holds extent to theories and prior assumptions in abeyance. Each type of case study uses multiple data sources and data collection methods to obtain a broad view of the phenomenon. For example, a researcher is interested in end of-life issues of the terminally ill cancer patient. The researcher may conduct a case interviewing the terminally ill patient with cancer or nurses working in hospice. In case studies, data collection might be both qualitative and quantitative. For example, in case study, researcher may obtain the pain on a numerical pain measurement scale, respiration rate during pain (quantitative) and/or may ask patient to describe person's experience of pain and discomfort (qualitative).

- In nursing sciences, case study methodology is used since a long time for in-depth study of a single patient or a group of patients to generate knowledge for solving nursing problems of patients suffering with specific disease conditions. For example, 'How nurses and pregnant women manage pain during delivery process'? Basically case studies are considered as qualitative research studies, however, they could be either quantitative or qualitative research study based on the purpose of the study and phenomenon under study. Some other examples of case study research design are presented in Box 7.14
- Case study data are collected by observation or by the personal interview method. Generally, analysis in case study design does not involve sophisticated quantitative and statistical techniques. In case studies, the stress is more on the qualitative analysis of collected data.

MIXED METHOD RESEARCH DESIGNS

Mixed method research approaches have been continuously used by the investigators in all the spheres of research without realizing its use. However, since last two decades mixed method research designs have methodologically evolved and now recognized as systematic approach to study a complex phenomenon. Nursing research deals with several complex phenomena, which cannot be answered completely by quantitative or qualitative research methods alone. Therefore, increasing use of mixed method research has been observed in nursing research.

Mixed method research is either a concurrently or sequentially merged approach o is to collection, analysis and interpretation using both quantitative and qualitative methods understand a research question more comprehensively.

Mixed method research is an integrated approach to answer a research question, where quantitative and qualitative research methods are mixed at data collection, data analysis and data interpretation to obtain better understanding of phenomenon and to provide a complete answer to a research question than either approach alone.

Uses of Mixed Method Research Designs

These are inherent strengths and weaknesses of each quantitative and qualitative research designs. Thus, mixed method research can be useful to overcome the weakness of one de sign by using other in combination Mixed method research designs are helpful to answer a research question more comprehensively and completely, which cannot be answered by qualitative and quantitative designs alone Based on the work of Greene, Caracelli, and Graham (1989) and Bryman (2006), following uses of mixed method research designs have been identified:

- In mixed method research, quantitative and qualitative research act as supplementary and complimentary to each other for overcoming the weakness of one by using other in combination
- Mixed method researches are helpful in enhancing comprehensiveness and completeness of a study results.
- Mixed method research provides better understanding and explanation for unexpected study results generated with quantitative and qualitative method alone.
- Mixed method research also helps in instrument and taxonomy/theory development.
- Mixed method research improves the credibility and usefulness of the data.

Types of Mixed Method Research Designs

There is a lack of consistency in terminologies and classifications used for mixed method research designs in different disciplines. Tashakkori and Teddlie (2003) found 40 different types of mixed methods designs in the literature, whereas Creswell and Plano (2003) have summarized the 15 different classifications of mixed method research, out of which 3 nurse researchers have provided classification with different terminologies, that is Morse (1991) classified as (1) simultaneous triangulation and (ii) sequential triangulation; Sandelowski (2001) classified as (1) sequential, (ii) concurrent, (iii) iterative and (iv) sandwich, whereas Morse and Niehaus (2009) classified as (1) mixed method simultaneous design, (ii) mixed method sequential design, (iii) complex mixed method design: (a) qualitative-driven complex method design, (b) quantitative-driven complex mix method design and (c) multiple method research design. Literature also mentions that the mixed method research designs could be fixed (which is defined at outset) or emergent (which gradually evolves with pro cess of research) in nature. Latest classification has been given by Creswell (2015). Although authors have used different features and terminologies,

there are actually more similarities than differences in these classifications. Therefore, based on these similarities a parsimonious and functional classification of mixed method research has been provided for nursing and health research:

1. Convergent design: It is also known as concurrent triangulation design, which involves collection and analysis of quantitative and qualitative data separately at same time with equal weight age, where data are merged only at the time of interpretation/discussion to compare and contrast quantitative and qualitative results to enhance understanding of a phenomenon (Fig. 7.27), The convergent design is used for conformation, validation and elucidation of quantitative results with qualitative findings to develop a more complete understanding of a phenomenon.

For example, a researcher might use convergent design to understand the nurses' attitude towards the care of HIV/AIDS patients. The researcher may survey the nurses' attitude towards the care of HIV/AIDS patients and also conduct a focused group discussion (FGD) with nurses at the same time. The researcher analyses survey data quantitatively and FGD qualitatively and then merges the two data set results for comparing and contrasting the attitude of nurses towards care of HIV/AIDS patients.

The convergent design has several variants (slight variations in the primary design), some of the most commonly documented variants are (1) convergent parallel variant, (ii) data transformation variant and (i) data validation variant.

a) The convergent parallel variant involves a separate but concurrent data collection and data analysis, and independent results are then synthesized or compared during the interpretation/discussion of results (Fig. 7.28).

b) Data transformation variant includes a separate but concurrent data collection analysis; however, qualitative data are transformed into quantitative data before t are merged at the time of interpretation for comparing and contrasting the lea (Fig. 7.29)

c) Data validation variant has a feature that open-ended questions are included in and quantitative instrument and qualitative results generated from these open-ended questions are used for validation of quantitative results at the time of data interpretation

2. Explanatory sequential design: The explanatory sequential design is an emergent type mixed method research design, which is conducted in two distinct interactive phases. The first quantitative phase of study is implemented, where quantitative data are collected and analysed, which is followed by qualitative data collection and data analysis phase. The second qualitative phase is built on the specific quantitative results, which requires additional explanation to improve overall understanding of phenomenon. Based on the unexplained critical quantitative results, investigator designs specific qualitative question, sampling and data collection protocol and then collect and analyse qualitative data to get insight into unexplained quantitative results to improve overall understanding of a phenomenon. Final report is written as a separate quantitative section followed by qualitative section, with as discussion that to what extent and way qualitative results helped to explain specific unexplained quantitative results (Fig. 7.31). For example, an investigator found in quantitative study results that a group of specific ethnic background nurses have a very poor attitude score for care of HIV/AIDS patients. In this instance, a qualitative phase may be planned by the investigator to explain why a group of specific ethnic background nurses have very poor attitude score; he develops a specific qualitative question, carries out focused group discussion with a sample form specific ethnic background nurses and analyses the qualitative results to obtain insight into why nurses feel so.

This is a straightforward and simple design to use, but requires lengthy time to conduct both quantitative and qualitative phases and faces difficulty in obtaining ethical permissions because of tentative plan of qualitative phase in the absence of exact details of study objectives and participants for qualitative phase until the quantitative phase is completed Two variants of explanatory sequential design have been documented in literature td follow-up explanatory variant and participant selection variant.

a) The follow-up explanatory variant involves first phase of quantitative data collection and analysis with more weight age followed by qualitative data collection and analysis in supportive role to understand unexplained quantitative phenomenon more clearly where interpretations are made based on quantitative data analysis and qualitative data analysis.

b) The participant selection variant includes first phase of quantitative data collection and analysis in service to the second qualitative phase, which has more weight age. This variant is used to identify basic characteristics of a large group to purposefully select the participants for the second dominant qualitative phase of the study.

3. Exploratory sequential design: The exploratory sequential design is also an emergent type mixed method research design, which is conducted in two distinct interactive phases, also referred as instrument development design or quantitative follow-up design. The first phase includes qualitative data collection and data analysis, which help to develop an instrument or taxonomy/theoretical model/classification to be tested during second quantitative phase of data collection and data analysis. This design is also used to understand an unknown phenomenon, and to generalize qualitative results generated on small sample to a larger population through quantitative phase of data collection and analysis. The final report is developed based on interpretation and discussion of qualitative and quantitative results (Fig. 7.32).

Exploratory sequential design has two variants, that is instrument development model and ther ry development model.

a) The instrument development model involves first phase of qualitative data collection d data analysis to develop an instrument to collect data quantitatively during Fast quantitative phase, which has more weight age. The instrument developed during qualitative phase is statistically tested for validity and reliability during second quantitative phase of this design (Fig. 7.33). This design is commonly used by nurses to develop measurement instruments to be used for nursing practice, nursing education and nursing research.

b) The taxonomy/theory development model includes first phase of qualitative data collection classification of disease or disorder, which is the tested in second quantitative phase of qualitative and data analysis, which have higher weight age to develop as taxonomy/theory/this design

4. Embedded design: In this design, investigator combines the collection and analysis of both quantitative and qualitative data within a traditional quantitative research design or qualitative research design (Fig. 7.35). Embedded design is used when it believed that one type of design is not sufficient to answer a question completely. Further, in embedded experimental mixed methods design, qualitative method is embedded in predominant experimental quantitative design to improve the participants recruitment procedures, to examine process of an intervention and reaction of participants to intervention

Embedded design has two variants, that is 'embedded experimental model and embedded correlational model.

a) Embedded experimental model is a most commonly used embedded design, in which qualitative data collection is embedded within the primary experimental or quasi experimental research design before, during or after the intervention

Before intervention embedding helps to effectively design the intervention, develops a measurement instrument for experimental data collection and to know basic details of participants to improve the participants' recruitment procedures in experiment The embedding of qualitative data collection during and after intervention helps the researcher to examine the process of intervention and participants' experiences and feedback about experiment.

b) Embedded correlational model is another variant of embedded mixed method design, where qualitative data are embedded into correlational quantitative design to help ex plain how naturally occurring independent variables are effecting the dependent variables (Fig. 7.37). For example, an investigator embedded the qualitative in-depth interview in a correlational study to assess relationship of ethnicity and depression in North Indian population to understand the reason of variation of depression in different ethnic groups.

Advantages and Disadvantages of Mixed Method Research Designs

Advantages

- In mixed method research, qualitative data are helpful in understanding the quantitative data more clearly. Thus, it provides more complete knowledge to guide the nursing theory and practices.
- Mixed method research encompasses the strengths of both qualitative and quantitative research designs, thus evidence generated have higher validity and acceptability An unexplained data generated through quantitative data can be further examined through subsequent qualitative data in mixed method research.
- Embedded experimental mixed method design helps to effectively plan an intervention improve recruitment process, examine intervention process and understand the participants' experience with intervention
- Embedded correlational research design helps not only to understand how much a naturally occurring independent variable is affecting dependent variable but also helps tº understand reason of this effect
- Mixed method research also contributes for instrument and taxonomy/theory/classification development, which is a need of nursing discipline more than any other discipline.
- In mixed method research, an investigator gets an opportunity to use the strengths of one research design to overcome the weaknesses of another design.
- Mixed method research provides stronger evidence through corroboration and convergence of results.
- Mixed method research designs also help to generalize the findings generated through qualitative research for small size population to large population.

Disadvantages

- Mixed method research is a time-consuming and more expensive process
- It is difficult for one researcher to handle both quantitative and qualitative data collection and data analysis in a single study.

- There is limited knowledge and expertise to use different mixed method designs among nurse researchers.
- There is difficulty in obtaining ethical permissions because of tentative plan of qualitative phase in the absence of exact details of study objectives and participants for qualitative phase until the quantitative phase is completed.
- Methodologies of mixed method research designs are still evolving, and there is a lack of consensus in terminologies and classification of mixed method research designs, which creates confusion among researchers.
- There are some of the issues of mixed method research such as problem of mixing paradigm, effective transformation of qualitative data in quantitative form and interpretation of conflicting results are still to be resolved by research methodologists.