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An Introduction To Epidemiological Study Designs

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Abstract

Epidemiology describes the distribution, frequency, risk of disease and the pattern of health related events in a population. .In this article, an attempt is made to describe various types of the Epidemiological studies such as Descriptive Studies (Case Report Study, Case Series Study , and Ecological Study) ; Analytical studies (Cross Sectional Study, Case Control Study and Cohort Study) and Experimental studies (Controlled Clinical Trial ,Field trial and Community trial). Each study design has its strengths and weaknesses, and the choice of design depends on the research question, feasibility, ethical considerations, and available resources. Combining multiple study designs can provide a more comprehensive understanding of the factors influencing health and disease in population.

Key words: Descriptive Studies, Analytical studies, Experimental studies

Introduction:

Public health is one of the main subjects of preventive medicine and is mainly concerned with the prevention of occurrence of many diseases in the human population. H**owever, i**t varies from clinical medicines that focus on the prevention of the disease rather than treatment, and in emphasis at the population level rather than the individual subjects. Epidemiology is the division of public health that strives to determine the disease causing factors, which enable and facilitate in the prevention of occurrence of the disease.

The term epidemiology is derived from the three Greek words such as epi, means "on or upon and ," demos, means "people," and logos, means "the study of." In fact ,there are several definitions in medical literature to describe the term epidemiology.

Cates (1982) described the term Epidemiology, in the following dimensions

a) "*a quantitative discipline built on a working knowledge of probability, statistics, and sound research methods" (Cates,1982,p.174);*

b) " *a method of causal reasoning based on developing and testing hypotheses pertaining to occurrence and prevention of morbidity and mortality" (Cates,1982,p.174) and*

c) "*a tool for public health action to promote and protect the public health based on science, causal reasoning, and a dose of practical common sense"* (Cates,1982,p.174).

Last (1995) also defined the term Epidemiology *"as the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to control of health problems*."

Epidemiology also describes the distribution, frequency, risk of disease and the pattern of health related events in a population. Furthermore, Descriptive epidemiology is the main subject of epidemiology which explains the main characteristics, of the distribution of the diseases while Analytic epidemiology describes Why and How a disease occur.

Epidemiological investigations can be categorized into two major types observational and experimental. They are basic approaches are concern with assessment of exposure in relation with the specific outcome. Generally , the selection of suitable study design is a very important step in epidemiological research since each study design will have its own advantages and disadvantages.

Table 2.1

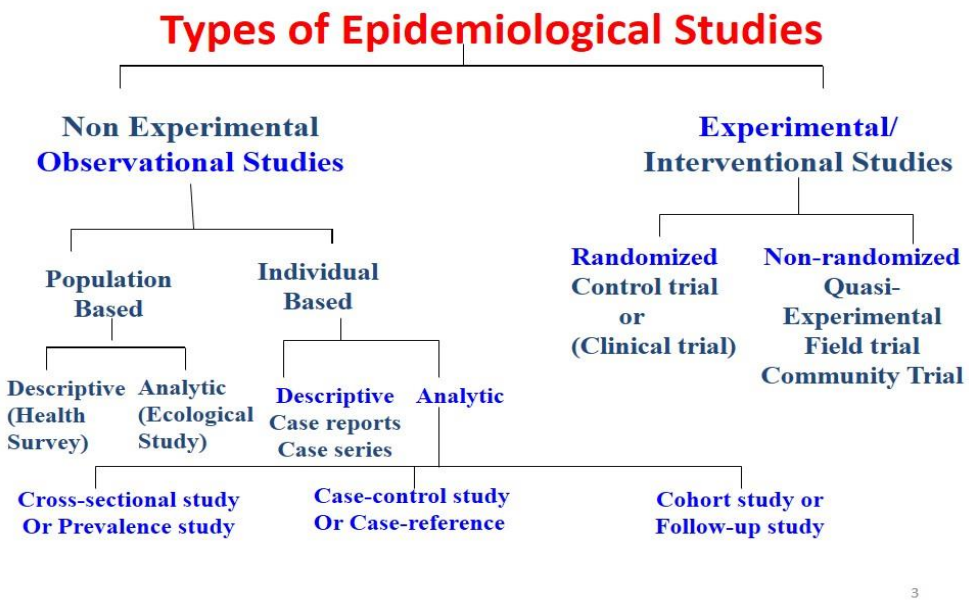
Epidemiological study designs (Pearce, 2012; Tu and Greenwood, 2012 ; Rothman , Greenland , and Lash, 2008)

Study design	Type of study	Other names	Level of study
I. Observational studies			
Case Report Study	Descriptive studies		Individuals
Case Series Study	Descriptive studies		Groups /Populations
Ecological studies	Descriptive studies	Correlational method	Populations
Cross sectional studies	Analytical studies	Prevalence method	Individuals
Case-control studies	Analytical studies	Case-reference method	Individuals
Cohort studies	Analytical studies	Follow-up method	Individuals

II. Experimental studies		Intervention method	
Randomized controlled trials		Clinical trials method	Individuals
Cluster randomized controlled trials			Groups
Field trials			
Community trials		Community intervention studies	Communities/ Populations

Figure 2.1

Types of epidemiological studies (Study Designs, 2011)



Above figure 1, shows the classification of epidemiological studies. Observational studies are most important and basic techniques in research . For instance, in Observational studies the investigator measures the exposure and outcome, but do not manipulate or intervene. The Observational studies can be either Descriptive or Analytical studies. The subjects or cases of the study selected at individuals, groups or population level. The study design can be cross-sectional or longitudinal study and moreover ,basing timing of data collection, they can be prospective study, retrospective study, and combination of both. Descriptive studies play a very important role in medical research and provide description of the prevalence, history, and determinants of a disease or health condition in a population. They may conduct as small and large scale study and help in formulation of hypothesis.

Descriptive studies can be divided into two main groups such as studies which deal at individual level, such as case series report, and cross sectional studies. Studies which deal at population level such as ecological studies. Descriptive study consist of two major groups: those that deal with individuals and those that relate to population. Studies that include only individuals are case report, the case series, and surveillance, whereas ecological correlation studies investigate the populations. Analytical studies in epidemiology analyses the association between the health condition and other variables of a disease. In experimental studies, involve the modification of a variable in one or more groups of population, such as clinical trials and Community trials.

.1.1 Case Report Study

Case reports are descriptive studies, and provide detailed written information. They are profiles or report of an individual patient and provide information about the signs, symptoms, medical phenomena and treatment for the disease or health condition. Case reports have wide applications and integral part of medical and social science research .They explain and interpret individual case. Generally case reports on various diseases are published in medical journals. Case reports are useful to know about public health and interface between clinical medicine and other fields (Nissen and Wynn, 2014, p.264.).

Generally Case reports include main heads such as background, introduction, case report, discussion and summary. Case representation includes relevant details of the case or subject in a comprehensive manner in chronological order. In discussion, it includes what and how the study case is different, how the current diagnosis and treatment process differ from previous reports. The unusual findings of the case report may help in the formation of a new hypothesis and help in understanding the causes and the phenomena of the disease (Nissen and Wynn, 2014, p.264; Nissen and Wynn, 2012, p.87).

In medical sciences, Case report is the publishable item in journal or a book, and a magazine.They enable the identification of new diseases or health conditions, adverse and beneficial effects of health conditions also. They allow the study of mechanisms, and play a significant role in medical education. In contemporary research, case reporting is a blend of a quantitative approach and qualitative research. It includes the methodology of patient-centered reporting and scientific inferences. In case reporting, the quantitative and qualitative approaches are applied in evaluation of policies and programs, business, and many other fields (Jenicek, 2008, p.149; Nissen and Wynn, 2012, p.87).

The major advantages of case reports **(**Nissen and Wynn, 2014, **p.264; Nissen and Wynn, 2012, p.87)**.

a) These studies enable the recognition of new trends and rare disease manifestations.
b) These studies help in identification of new clinical issues and may result in the formation of hypotheses (Chan.
c) In medicine, reports help in the detection of adverse effects of new drugs and potential uses.
d) They are easy and inexpensive to implement and conduct.

e) They give data on new disease or new treatments strategies.
f) They are useful instrument in communicating "clinical experience"
g) They facilitate hypothesis formation.

The major disadvantages of case reports **(**Nissen and Wynn, 2014, p.264; Nissen and Wynn, 2012, p.87).

a) Case study report cannot be generalized and easily cannot apply to study other cases.
b) Case study reports have the low level of evidence.
c) The reports may be subjected to bias in the selection of the subjects.
d) These studies do not depend upon systematic studies.
e) They are retrospective in nature.
f) The reports are based on the availability, accuracy and reliability of the data, records and other information.

1.2 . Case Series

A case series is also referred as a clinical series in medical research. Case series is defined as "*a collection of patients with common characteristics used to describe some clinical, pathophysiological or operational aspects of a disease, treatment or diagnostic procedure*s (Porta, 2008 p. 33 ; Abu-Zidan, Abbas and Hefny, 2013).They a series of report on patients with a known exposure and outcome. In simple terms, Case Series are collection of case reports and act as register of cases. They have a high sensitivity for detecting novelty and therefore remain as one of the cornerstones of medical progress; they also provide many new ideas in medicine (Vandenbroucke, 2001; Bhandari and Chan, 2011). They may be may be consecutive or non-consecutive.

Case Series design has an historical significance in epidemiological studies, especially in the identification of an epidemic. Case series is advantageous over the case report and enable the formulation of a new and useful hypothesis. However, the main disadvantage of this test is, it cannot be applied for testing the occurrence of a valid statistical association between the variables. Case series are liable for selection bias as they do not represent a wide population, information bias, confounding, low internal .validity, and intervening effects like placebo effect, Hawthorne effect (Bhandari and Chan, 2011).

1.3 Ecological Study

Ecological Study is an observational study and also referred as Ecological Correlational Study. These studies observe the association between exposures and outcomes in populations or group level rather than in individuals ((Levin, 2006, p.106). They are widely used in epidemiologic research and health planning and also to assess the prevalence and incidence of the disease or health condition in the population (Morgenstern , 1982, p.1336 ; Morgenstern, 1995, p. 61). It provides the association between exposure and outcome in the

form of correlation coefficient "*r"* the correlation coefficient "r" gives the degree of linear the relationship is between the exposure and outcome variables of the study (Grimes, and Schultz, 2002, p.146).

An ecological study design is applied to monitor public health, so that population health programs and strategies may be devised and implemented (Levin, 2003, p.60). They enable to compare large-scale comparisons such as comparisons between two regions, and two countries. They help to study the association between population-level exposure to risk factors and disease and enable to understand the effect of risk factors on the population (Levin, 2003, p.60). Ecological Studies are of three types such as a) Geographical, b) Longitudinal; and c) Migration (Morgenstern , 1982, p.1336 ; Morgenstern, 1995, p. 61) and moreover, they provide aggregate measures, environmental measures, or global measures (Morgenstern , 1995, p.62) provides the ecologic inferences about effects on group or population.

The main advantages of an ecological studies are a) They are easy to conduct and implement, and inexpensive in nature .b) They help in the formulation of new hypotheses.and c)They enable to identify new risk factors for the disease or health condition.

The main disadvantages of ecological studies are a)These studies are unable to regulate for confounding factors which is known as 'ecological fallacy'. (Pearce ,2000, p.326). The 'ecological fallacy', means that two variables are said to be correlated but their relationship is affected by confounding factors (Piantadosi , Byar , and Green 1988, p.893),b)The usage of average exposure levels covers more complex associations with the disease.and c) The study is targeted at a population level. So, the results of the study may not represent an association at individual level (Susser ,1994, p.830)

II Analytical studies

2.1. Cross Sectional Study

Cross-sectional Study is the most common design in epidemiology and also referred as Prevalence Study, Transversal study method or naturalistic sampling method. It is a good research design in social sciences and medical research. This is a method of descriptive study or analytic study, or both and is an observational study method. It provides a snapshot of a defined population at a particular point in timeline or time interval. They depend upon the observations made on various groups and compared at one time. There will be no manipulation of variables by the investigator and are used to describe the characteristics which are observed in a group. This method provides only information and it does not answer why.

In epidemiological studies, this study design implemented and useful in many ways such as a) To know the prevalence and etiology of disease b) To know the prevalence of risk factors, exposure for the disease or health condition c) To know the disease surveillance; d) To asses the health status of the population; and e) they work as adjunct tools in health planning, and assessment of healthcare programs.

In precise, this method includes the collection of data (i.e subject) form defined population without respect to disease condition, at one defined point in time or time interval. The extensive cross-sectional studies can be conducted with the help of routinely collected data which facilitate low cost to the investigator. The collected data in Cross-sectional Studies is useful in proposing a hypotheses.

At the same time , routinely collected data does not answer which variable will be the cause and which variable will be the effect in the study.

The four types of cross-sectional study designs such as

a) Exposed and have the disease; b) Exposed, and do not have the disease;

c) Not exposed, and with disease, and d) Not exposed, and do not have the disease

They can be utilized for different population basing upon on information on both exposure and disease. The Cross-sectional Studies describe the prevalence risk ratio (PRR) (i.e. absolute risks and relative risks) and odds ratio, that enable charactering points such as prevalence of a particular health condition in the population (Schmidt and Kohlmann, 2008,p.166).

The main advantages of Cross-sectional design are such as a) These studies are simple depictive of the population ; b) They can be conducted rapidly and efficiently with low cost (Sedgwick, 2014) ; c) This method permits the study of several diseases, health conditions, risk factors and exposures for diseases; d) It is useful to assess the multiple outcomes (Sedgwick, 2014); e) This method uses the individualized data for the study; and f) This method is very useful in the evaluation of a disease burden on the population, health planning and prioritizing health problems in Health Planning at Population level(Levin, 2006).

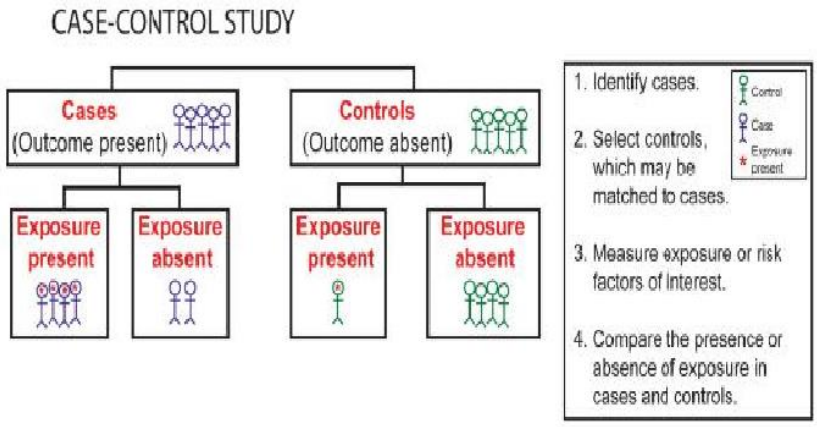
The main disadvantages of Cross-sectional design are such as ,This method is inefficient in studying etiology of the disease considering the temporal sequence between exposure and outcome of disease is unknown; This method is inefficient in studying a diseases with low prevalence . There is a high respondent bias in methodology ; It does not assess the incidence of the disease (Hennekens, Buring and Mayrent, 1987). This method is not advisable to study rare disease. There is less authentication of confounding factors. The main Limitations of the Cross-sectional Studies are that, it only assesses the prevalence of exposure and outcome for a disease. It is only applicable for chronic diseases, which appear at a moderate level in the given population. Sometimes this method might over-represent factors affecting incidence and duration of disease. It can mislead protective risk factors of the disease (Levin, 2006).

2. 2 Case Control Study

In Bio-medical literature, the Case control studies are a form of observational studies and also described as "Retrospective or backwards studies", “Case - control design” and "Case-referent studies"(Song and Chung, 2010, p.11). This process emphasizes on differences between disease exposed and non-exposed cases. Case control approach emphasizes on prior exposures of disease and hence it moves form effect to cause. This is widely used method and a primary strategy in infectious disease epidemiology, chronic disease epidemiology and enables more statistical efficiency in study of rare disease.

Figure 2.2

CASE CONTROL STUDY (Song and Chung, 2010, p.11).



(Above diagram is accessed from Song and Chung, 2010, p.11)

The control design study include the main steps such as identification of cases, choosing controls which may be matched controls , assessment of exposure and comparsion of with and without exposure among the cases and controls (Song and Chung, 2010,p.11).

Table 2.2

Analysis of Case-Control Study (Song and Chung, 2010, p.4). :

Exposure to disease or health condition	Number of cases	Number of controls
yes	A	B
No	C	D

The exposure odds ratio (OR) is equal to the prevalence ratio when a disease is rare. Let us assume A and B are the number of cases and controls who are having exposure to disease while C and D number of cases and controls who are not having exposure to disease respectively. The Exposure odds ratio (OR)'s can be calculated as follows

Odds of being exposed among the cases in the study = A/C
Odds of being exposed among the controls in the study = B/D
Exposure odds ratio = (A/C)/ (B/D) = (A*D)/ (B*C)

The major advantages of the Case-Control Study (Song and Chung, 2010, p.3) are a).This research design is relatively rapid to implement, very informative, relatively inexpensive and requires comparatively less number of cases. b).This is very useful design in studying rare diseases and many potential exposures. c).This method requires less time conduct the study as disease has been already manifested

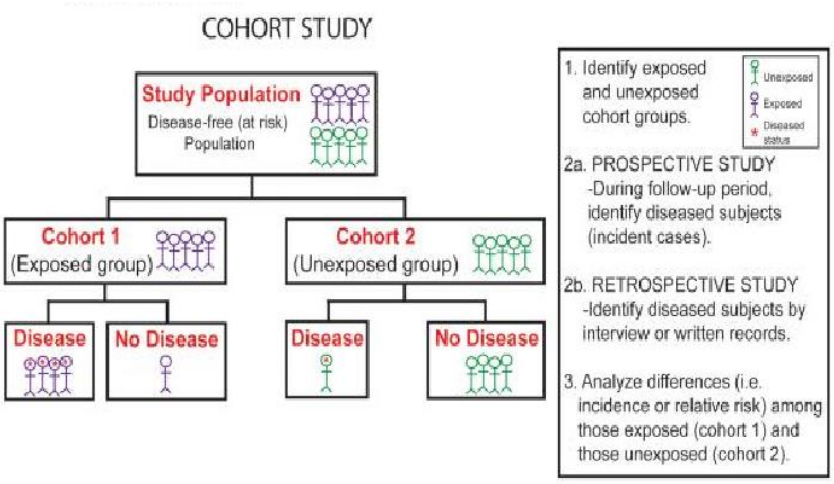
The major disadvantages of the Case-Control Study are a) In this method, the absolute frequency, attributable risk and individuals at-risk of a disease cannot be evaluated. b) It is not possible to compare disease rates in various studies due to lack of absolute risks, and estimate the attributable risk .c) This method is subjected to selection bias in identifying the cases, controls and also subjected to recall bias. d) The status of a disease condition in the study may influence the selection of subjects. And e) It is difficult to interpret the exposure-outcome relationship in the study.

2.3 Cohort Studies

Etymologically, the word "cohort" is derived from the Latin word *cohors* which means a group of individuals with a similar statistical characteristic such as age and gender. In Ancient Roman societies, the term "cohort" is used to describe the military unit. The term "cohort" has been imbibed into the subject of epidemiology to describe a group of individuals followed over a defined period of time (Morabia 2004, p.10).

Figure 2.3

Cohort study (Song and Chung, 2010, p.11).



(Above diagram is retrieved from Song and Chung, 2010, p.11)

Cohort Studies are longitudinal studies .They can be prospective or retrospective in nature and utilized in various fields such as medicine, social science, science, and many applied branches in the analysis of risk factors and relative risk. The prospective and retrospective cohort studies help in the assessment of outcome in exposed and unexposed group (Euser et al., 2009). Prospective cohort studies are implemented from the present to future in timeline and are devised with unique methods for exposure data collection. The prospective cohort studies may be carried for the long follow-up period and inefficient for inspecting latency period of a disease and is liable to a maximum loss to follow-up rate (Song and Chung, 2010). The Retrospective cohort design is also referred to as historical cohort studies and is implemented at current time and inspects past history to assess the medical events or outcomes (Song and Chung, 2010). Depending upon the events like exposure status and outcome data which are assessed in the past, can be reestablished for analysis. The Retrospective cohort studies are highly efficient, less cost and less time consumption than prospective cohort studies.

A key characteristic of a cohort study is that the study begins with identification of the subjects and their exposure to risk factors is measured. Usually the prevalence of the disease or death over a definite period of time, is assessed and with regard to the exposure status. Cohort Studies can also be described as clinical study design and maximum it explains about the life histories of sections of the populations (Porta, 2008).

The major advantages of Cohort Studies are: a) It is useful to find out incidence rate and risk of the disease in the population.b) This method enables to assessment of exposure and can deal with modifications in exposure to disease.c) It enables to establish cause – effect of variables in the study.d) This method enables to study the rare exposures (Song and Chung, 2010,p.15).e) The methodology minimizes selection and information bias in the study than case-control study. f) The exposure to the disease is evaluated before the onset of the disease and hence it can be unbiased in terms of progression and development of the disease. g) Cohort Studies help in procuring prospective information about fatal diseases in the population. h) This method enables to measure Incidence rate of the disease in the exposed and unexposed groups of the study (Song and Chung, 2010, p.15). i)This method enables to determine the temporal sequence and also to know the natural history of the disease. J) This method studies the multiple outcomes for any one exposure.and k)Results in Cohort Studies are more conclusive than case-control study results.

The major disadvantages of Cohort Studies are such as

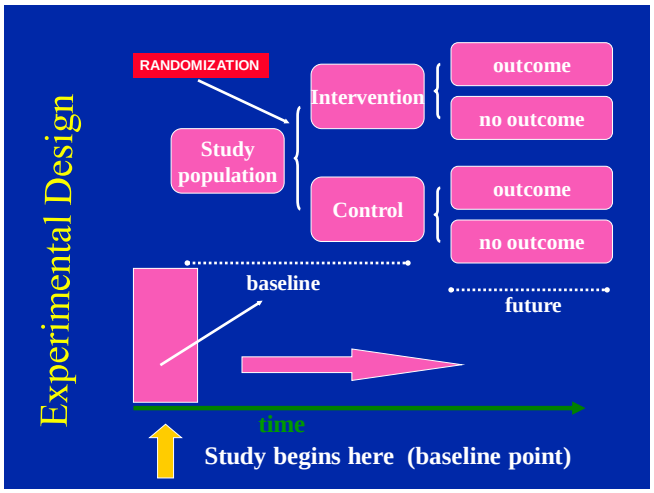
a) The Cohort Studies are expensive, requires large sample and time consuming for data collection (Song and Chung, 2010, p.15) .b) The modifications in disease diagnostic criteria and exposure status over a period of time may influence the classification of the persons with regard to disease exposure status. c) The Cohort Studies could not be statistically significant. As the outcomes of the study may be influenced by information bias (Song and Chung, 2010, p.15).

3. Experimental studies

The experimental studies are placed at the top of the pyramid of research designs, because they are almost most nearly similar to controlled laboratory experimental methodology. In the controlled laboratory experiments , researcher control all the important variables such as independent and dependent variables, of the experiment. The main focus method is that the researcher regulates the assignment of the exposure and permits the cases to vary only for the objective of hypothesis testing. Figure 2.4 depicts the general outline procedure of experimental design in research. The main features of Experimental Studies are formulation of hypothesis, recruiting subjects depending on criteria, obtaining informed consent from participants. randomly allocate willing participants to receive interventions of the experiment .The investigator monitor the study groups of the experiment for the outcome of the experiment . At the end of the experiment, investigator compares the rates of the outcome among the different groups.

Figure 2.4

Experimental designs (Experimental and observational studies,2015)

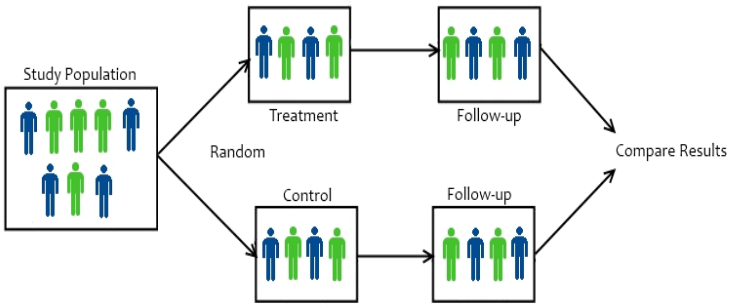


3.1 Controlled Clinical Trial

Controlled Clinical Trial : They are also known as “Randomized controlled trials, "Randomized clinical trial" "Randomized comparative trial" and clinical trials. Randomized controlled clinical trial (RCT) studies are prospective, analytical, and experimental in nature. They are implemented in clinical environment and utilize primary data. Randomized designs can be referred as “a comparative study in which study subjects are assigned by a formal chance mechanism between two or more intervention strategies (Noel, Weiss, Thomas ,and Koepsell , 2014, p.280). This design is applied mainly in clinical research and other research areas.

Figure 2.5

Randomised Controlled Trials (Batt, 2014)



They are regarded as gold standard and powerful tool in clinical and medical studies. . Because of Randomization in this method, every individual have equal opportunity of being assigned to the intervention without any bias (Rajagopalan ,Priyadarshini and Srikanth, 2013**,**p.31). The types randomization such as a) simple, b) block, c) stratified and d) unequal randomization are used to avoid bias (Rajagopalan ,Priyadarshini and Srikanth, 2013**,**p.31)..

Table 2.3
Randomized Controlled Trials (Rajagopalan ,Priyadarshini and Srikanth, 2013**,**p.33).

S.no	**Type of trial**
1	RCT Trials Such as Diagnostic, Therapeutic, Prophylactic, AND Regimens, (Rajagopalan ,Priyadarshini and Srikanth, 2013**,**p.33).
2	Randomized Controlled Field Trial .
3	Preventive :These trials are preventive in nature by reducing risk with preventive measures like vaccination.
4	Risk Factor trials.
5	Cessation experiments .
6	Trial of etiologic agents .
7	Evaluation of health system .

Table 2.4
Randomized controlled trials steps(Rajagopalan ,Priyadarshini and Srikanth, 2013**,**p.33).

s.no	step	Description
1	protocol	Stating the Rationale of the study. Describing the Aims and objectives and, Research questions of study. Determining the study design: data analysis, and data discharge. Ethics issues concerned with study and taking patient consent, Documentation of the study.
2	Select participants	Selection of representative sample of the population through randomization, which is the main features of Randomized controlled trials.
3	Measure baseline variables	
4	Randomize	To avoid confounding variables
5	Blinding the intervention	To avoid biased assessment of outcome of variable
6	Follow subjects	It should adherence to the protocol of the study and Lost to follow up.
7	Measure outcome	Analysis of Positive results/Negative results of the study and their importance and consequences.

The main advantages of randomized designs (Rajagopalan ,Priyadarshini and Srikanth, 2013**,**p.33) are a) Identical distribution of baseline features in comparison groups.b) Most of randomized designs are just like experiment . c) They are effective method to control selection bias and confounding bias . d) There are unbias confounder variables in the study.e) They enable to estimate risk directly.f) There is chance of blinding.g) Randomization in this method enables the statistical analysis and h) They enable the comparison of multiple outcomes of study.

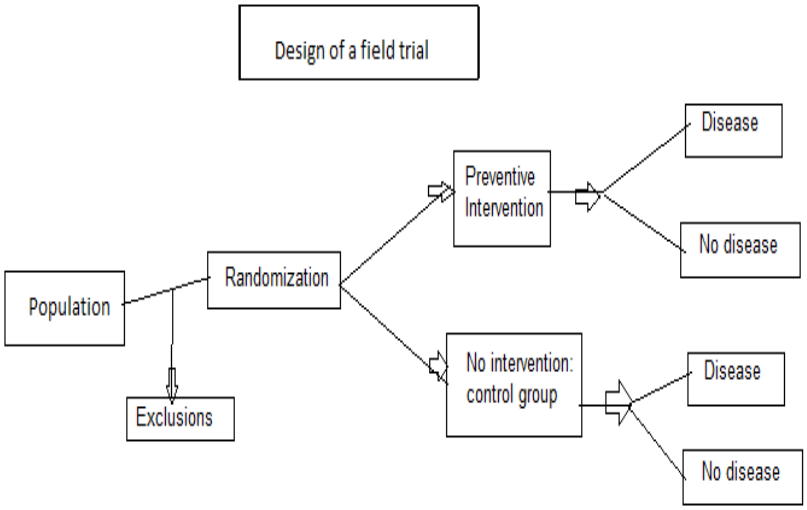
The main disadvantages of randomized designs (Rajagopalan ,Priyadarshini and Srikanth, 2013**,**p.33) a) There are limitations on types of interventions in randomized designs, b) This methodology is expensive in terms of time and finance. c) Randomized designs are not advisable for rare outcomes, d) Randomized designs are not advisable for outcomes need extensive follow-up.and e) There are issues of ethics , inclusion/exclusion and withdrawal issues.

3.2 Field trial

They are the general methods for studying new techniques and new products in various fields such as pharmaceutical research and medicine. Field trial can be referred as investigation of exposure in wild. This method includes individuals who are healthy and disease free. They are presumed to be at risk of the disease. The data collection for the study will take place in the field in non-institutionalized individuals in the general population (Bonita, Beaglehole and Kjellström, 2008). They are similar to lab experiments. It is used to evaluate interventions which reduce exposure (Bonita, Beaglehole and Kjellström, 2008). They are logistically complicated and more expensive in nature.

Figure 2.6

Field trial Design (Bonita, Beaglehole and Kjellström, 2008)



3.3 Community trial

Community trials, are also known as community interventions studies and they play key role in the evaluation of public health (Gortmaker et al., 1999). They are prospective preventive and experimental in nature (Hsieh, 2008).This design, studies the entire community rather individuals. They study and treat the whole communities as experimental units. Communities such as cities or states are taken as treatment groups. The experimental interventions are allocated to each and every number of communities. This character makes Community trials, distinguished from clinical trials which are assigned to patients in a clinical environment. The methodology of Community trials is almost controlled clinical trials except for experimental unit (Hsieh, 2008). In Community Trials, the Intervention and control of variables will vary with age, gender and unmeasured variables. Normally, the duration of Community Trials is more than clinical Trials. The method also requires informed consent from participants of the study for collection of data and relevant information.

There are four different community intervention designs such as a) single community design, b)two -community design, c) one-to-many and d) many-to-many design to be used in community trials. The disease prevalence of health condition is assessed before and after intervention in a single community design. In two -community design, one community will be exposed to intervention while other community acts as control. In one-to-many community intervention design, there are many control communities for intervention community. There are many intervention communities and many control communities observed in many-to-many design. Randomization method is applied for the allocation of the community in the intervention or the control group. The outcomes of these trials can be assessed with regard to the four phases of evaluation a) formative, b) process, c) impact and d) outcome (Friis and Sellers, 2009, p.355). The pre test outcome and post test results are compared. The end-point may be assessed by longitudinal change method or repeated cross-sectional survey method (Donner and Klar, 1996, p.435).

The net change is calculated as $\{(I_1 - I_0) / I_0\} - \{(R_1 - R_0)/ R_0\}$

or

$$\text{as } (I_1/I_0\} / \{R_1 / R_0\} - 1.$$

The community trial studies show short follow-up periods with large sample sizes. The intervention frequency and duration should be adequate. The short follow-up may results in to insufficient information while too long follow-up lead to high attrition

The main advantageous of this method (Friis and Sellers, 2009, p.355) are a) This method is more advantageous than individual intervention.b) Estimates realistic effects of exposure in incidence of disease in the community (Friis and Sellers, 2009, p.355). c) The interventions are made in natural field conditions. The main disadvantageous of this method are a) Loss of effect due to shifting (Friis and Sellers, 2009, p.355), b)

Secular trends in prevalence of incidence of disease. c) Blinding, and double blinding cannot be utilized (Friis and Sellers, 2009, p.355) and d) This method suffers from selection bias and controls in the community may also receive intervention.

Conclusion:

Epidemiological studies play a crucial role in identifying risk factors, understanding disease patterns, and informing public health interventions. There are several types of epidemiological study designs, each with its strengths and limitations. Case-control studies are efficient for studying rare diseases and can provide estimates of the association between exposures and outcomes. However, they are prone to recall bias and cannot establish causality. Cohort studies are useful for studying multiple outcomes and establishing temporal relationships between exposures and outcomes. They can also calculate incidence rates and relative risks. However, they are resource-intensive and can be affected by loss to follow-up. Ecological studies are useful for generating hypotheses and identifying patterns at a population level. However, they are susceptible to the ecological fallacy, where associations observed at the group level may not apply to individuals. RCTs are widely used in clinical research but can also be applied in epidemiology to evaluate preventive interventions or health policies. Combining multiple study designs can provide a more comprehensive understanding of the factors influencing health and disease in populations.

References

ABU-ZIDAN, F., ABBAS, A. AND HEFNY, A. (2013). Clinical "case series": a concept analysis. *African Health Sciences*, 12(4),p.557-562.

BONITA, R., BEAGLEHOLE, R. AND KJELLSTRÖM, T. (2008). *Epidemiología básica*. Washington, D.C.:

BHANDARI, M. AND CHAN, K. (2011). Three-minute critical appraisal of a case series article. *Indian Journal of Orthopaedics*, 45(2), p.103.

CABÁN-MARTINEZ, A. J. AND GARCÍA-BELTRÁN, W. F. (2012). **Advancing medicine one research note at a time: the educational value in clinical case reports. *BMC Research Notes*, 5(1), p.293.**

Cates, W.J. (1982). Epidemiology: Applying principles to clinical practice. *Contemporary Obstetrics /Gynecology*. 20(2): p.147-161.

DONNER, A. AND KLAR, N. (1996). Statistical considerations in the design and analysis of community intervention trials. *Journal of Clinical Epidemiology*, 49(4), p.435-439.

EUSER, A. M., ZOCCALI, C., JAGER, K. J. AND DEKKER, F. W. (2009). Cohort Studies: Prospective versus Retrospective. *Nephron Clinical Practice*, 113(3), p.c214-c217.

Experimental and observational studies,(2015). [Figure] at:http://www.pitt.edu/~super1/lecture/lec19101/043.htm (Accessed on 31.01.15)

FRIIS, R. H. AND SELLERS, T. A.. (2009). *Epidemiology for public health practice*. Sudbury, Mass.: Jones and Bartlett Publishers.

GORTMAKER, S. L., CHEUNG, L. W. Y., PETERSON, K. E., CHOMITZ, G., CRADLE, J. H., DART, H., FOX, M. K., BULLOCK, R. B., SOBOL, A. M., COLDITZ, G., FIELD, A. E. AND LAIRD, N.. (1999). Impact of a School-Based Interdisciplinary Intervention on Diet and Physical Activity Among Urban Primary School Children. *Archives of Pediatrics & Adolescent Medicine*, 153(9), p.975.

GRIMES, D. A. AND SCHULZ, K. F. (2002). Descriptive studies: what they can and cannot do. *The Lancet*, 359(9301), pp.145-149.

HENNEKENS, C. H., BURING, J. E. AND MAYRENT, S. L. (1987). *Epidemiology in medicine*. Philadelphia: Lippincott Williams & Wilkins.

Last, J.M. (ed.) (1995). A dictionary of epidemiology. New York, Oxford University Press.

LEVIN, K. A. (2006). Study Design VI - Ecological Studies. *Evidence-Based Dentistry*, 7(4), pp.108-108.

LEVIN, K. A. (2006). Study design III: Cross-sectional studies. *Evidence-Based Dentistry*, 7(1), p.24-25.

MARCH, S., TORRES, E., RAMOS, M., RIPOLL, J., GARCÍA, A., BULILETE, O., MEDINA, D., VIDAL, C., CABEZA, E., LLULL, M., ZABALETA-DEL-OLMO, E., ARANDA, J. M., SASTRE, S. AND LLOBERA, J. (2015). Adult community health-promoting interventions in Primary Health Care: A systematic review. *Preventive Medicine*.

MARSHALL, W. E., PIATKOWSKI, D. P. AND GARRICK, N. W. (2014). Community design, street networks, and public health. *Journal of Transport & Health*, 1(4), p.326-340.

MORGENSTERN, H. (1995). Ecologic Studies in Epidemiology: Concepts, Principles, and Methods.*Annual Review of Public Health*, 16(1), p.61-81.

MORGENSTERN, H. (1982). Uses of ecologic analysis in epidemiologic research. *Am J Public Health*, 72(12), p.1336-1344.

NISSEN, T. AND WYNN, R. (2014). The clinical case report: a review of its merits and limitations.*BMC Research Notes*, 7(1), p.264.

NISSEN, T. AND WYNN, R. (2012). The recent history of the clinical case report: a narrative review.*JRSM Short Reports*, 3(12), pp.87-87.

PEARCE, N. (2012). Classification of epidemiological study designs. *International Journal of Epidemiology*, 41(2), p.393-397.

PEARCE, N. (2000). The ecological fallacy strikes back. *Journal of Epidemiology & Community Health*, 54(5), p.326-327.

PORTA, M. S. (2008). *A dictionary of epidemiology*. Oxford: Oxford University Press.

SEDGWICK, P.. (2011). The ecological fallacy. *BMJ*, 343(jul27 1), p.d4670-d4670.

SEDGWICK, P. (2014). Cross sectional studies: advantages and disadvantages. *BMJ*, 348(mar26 2), p.g2276-g2276.

SONG, J. W. AND CHUNG, K. C. (2010). Observational Studies: Cohort and Case-Control Studies. *Plastic and Reconstructive Surgery*, 126(6), p.2234-2242.

STUDY DESIGN VI ECOLOGICAL STUDIES (2006). *Evidence-Based Dentistry*, 7(4), p.114-114.

STUDY DESIGNS (2011). [Figure] at: http://howmed.net/community-medicine/study-designs/ (Accessed on 31.01.15)

SUSSER, M. The logic in ecological: I. The logic of analysis. *Am J Public Health*, 84(5), p.825-829.

TU, Y. AND GREENWOOD, D. C. (2012). *Modern methods for epidemiology*. Dordrecht: Springer.

VANDENBROUCKE, J. P.. (2001). In Defense of Case Reports and Case Series. *Annals of Internal Medicine*, 134(4), p.330.

VANDENBROUCKE, J. P. AND PEARCE, N. (2012). Case-control studies: basic concepts. *International Journal of Epidemiology*, 41(5), p.1480-1489.