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A Clinical Case Presentation - A Review Study

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ABSTRACT

Clinical case presentation is essential feature in medical science as it works as a guideline for new researchers. It includes each and every aspect related to patients. There are different type of clinical researches which is based on the work done in particular disease. The purpose of clinical research is to discover answers to questions through the application of scientific procedures. Clinical Research test, how will new approaches and interventions work in people, these approaches can be medical, behavioral or management oriented. The clinical study helps to prevent, screening, diagnose, manage and answer scientific questions about diseases. A clinical case presentation is a case report of symptoms scientific diagnosis treatments and follow up of an individual patient. Finally, the case report should be connected to existing literature, mentioning the message that the case conveys. The review should narrow down to the source of confusion or main challenge in the case.

Key words: *Scientific, Procedures, Screening, Literature.*

INTRODUCTION

Clinical Research is the foundation of improvements in patient care. All attempts at improving patient care, development of new drugs and intervention or finding new screening and diagnostic tests involve testing on human volunteers both sick persons and healthy individuals, who willingly participate altruistically even after knowing the risk, they are submitting themselves in study. A clinical trial is a research study that tests a new medical Treatment or a new way of using an existing treatment to see if it will be a better way to prevent and screen for diagnose or treat a disease.[1]

A well-functioning ethics committee is expected to ensure this, but there is much more that the participants are entitled to expect. They rightly expect that the society benefits to the maximum by their sacrifices in voluntarily and altruistically undergoing clinical trials. This is possible only if the trials are conducted in scientifically correct manner and all the findings of the trials are correctly recorded, truthfully analyzed and honestly reported, this is often not done.

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Purpose of clinical research

The purpose of clinical research is to discover answers to questions through the application of scientific procedures.[2] Clinical researches test how well new approaches and interventions work in people, these approaches can be medical, behavioral or management oriented. Each study helps to prevent, screen for, diagnose, manage and answer specific scientific questions about diseases.

Types of clinical trials (based on purpose)

1. Prevention Trials
2. Diagnostic Trials

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3. Treatment Trials
4. Quality Of Life Trials

1) Prevention Trials

In this trial only prevention will be taken. It includes medicine, vitamins, vaccines, minerals and life style modification.

2) Diagnostic Trials

This kind of trial is the best way for diagnose some diseases and health condition.

3) Treatment Trials

To know about new management or treatment by using new drug combination by experiment.

Ex. In surgery and radiation therapy testing.

4) Quality of life trials

In this clinical trials, chronic illness patients were live probably and comfortable like standard of life style should become more comfortable.

Methods of clinical research

1) *Ayurvedic* method

In modern era clinical researches done for establishing new facts, correcting or modifying them and to validate old principles by using modern parameters. There is ample proof that appropriate research was done even at the original *Ayurvedic Samhita* were written. *Acharya Charaka* says that after obtaining all knowledge the sages acted on the textual method, experimental on it and attend long life, that is what the researchers do and is expected from researchers.

Management of health and treatment of diseases is the main objective, through various principles, practices and procedures were mentioned. They can be used to treat or eradicate various diseases. Conducting clinical trials with integral approach considering *Ayurvedic* as well as modern parameters.

Approach of *Ayurvedic* method

- *Ayurvedic* methods are based on inductive and deductive methods.
- Individualized approaches are important for outcome of therapy.
- In *Ayurvedic* drug action is explained with holistic approach and not only the basis of active principle.
- In *Ayurveda* examination known as *Pareeksha* and inspired from philosophical term *Pramana*, which refers to evidence.[3]
- *Ayurvedic* approaches towards reversal of pathology that is 'disease modifying method'.
- *Ayurveda* from years together also taking about utility of observation of animal for understanding pathophysiological concept of *Ayurveda* e.g., Gait of *Kaphaprakruti* is compared with the elephant.[4]
- Intensive documentation of available *Ayurvedic* treatments in different region in India and their standardization is more important than standardization of drug.etc

2) Modern method

In modern methods, observations, experimentation or investigation or any other systemic method to determine nature and cause and effect relationship of phenomena are actual procedure of research in development of scientific knowledge.

Approach of modern methods

- Group observations are done in modern methods.
- Randomization is necessary for trials.
- Contemporary research is based on 95% confidence limit.
- Significance to quantitative research given.
- Contemporary research is aimed to find out active principles and bioassays are done.
- Drug disease models are explored in modern research methods. Etc.

A clinical trial produces data that could reveal quantitative differences between two or more interventions; statistical analyses are used to determine whether such differences are true, result from chance, or are the same as no treatment (placebo).

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Data from a clinical trial accumulate gradually over the trial duration, extending from months to years. Accordingly, results for participants recruited early in the study become available for analysis while subjects are still being assigned to treatment groups in the trial.

Types of clinical trials

Clinical research is a branch of healthcare science that determines the safety and effectiveness of medications, device, diagnostic products and treatment regimens intended for human use.[5] These are mainly divided in two types-

Experimental / Interventional Studies

The hallmark of the experimental study is that the allocation or assignment of individual is under control of investigator and thus can be randomized. The key is that the investigator controls the assignment of the exposure or of the treatment.

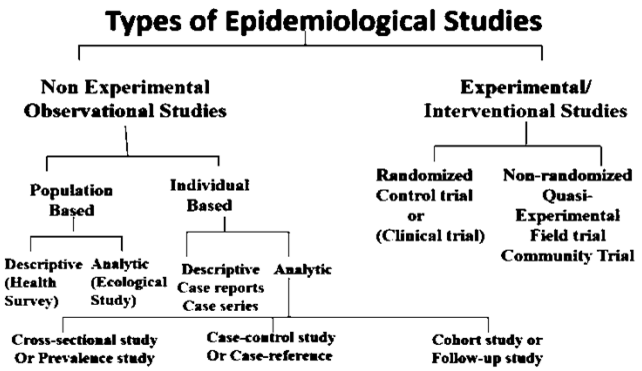
Within this category, two principal types exist:

1) Randomized control trial (RCT) or clinical trials

These are prospective studies that measure the effectiveness of a new intervention or treatment. Randomization avoids bias by eliminating baseline differences in risk between trial and control groups.

2) Non- Randomized Trial / Quasi - experimental field trial / Community trials

Non randomized trials are a type of clinical trial in which the participants are not assigned by chance to different trial groups. In these trials, some method short of true randomization is used to assign the exposer.



Non-Exeperimental / Observational Studies

Observational study is a method of assessment that is used by a researcher who, at best, identifies, observes, records, classifies and analyses relevant information in a study without interfering with the course of event. The allocation or assignment of factor is not under control of investigator. Observational research dominates the literature.

Observational studies, two major types exist:

Individual Based

Individual based studies are divided into two types-

- Descriptive
- Analytic

1) Descriptive Studies

A descriptive study does not try to quantify the relationship but tries to give us a picture what is happening in a population. Descriptive studies includes i.e., Case report and case series.

- **Case Reports -** A description of single case, typically describing the manifestation, clinical course and prognosis of that case (Anocdotal evidence). For example, a clinician, reported benign hepatocellular adenomas, a rare tumor, in women who had taken oral contraceptive pills.
- **Case-series -** A case series is a type of medical research study that tracks subjects with a known exposure, such as patient who have received a similar treatment, or examine their medical records for exposure and outcome. Case series usually contain demographic information about the patients, for example age, gender, ethnic origin.

2) Analytic Studies

An analytic study attempts to quantify the relationship between two factors, that is, the effect of an intervention or exposure on an outcome in a comparison group as well as in intervention or exposed group. Analytic studies further divided into 3 major types :

a) Cross Sectional Study / Prevalence Study

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b) Case Control Study / Case Reference

c) Cohort Study / Follow Up Study

- **Cross-Sectional Study / Prevalence Study**

The term cross sectional study usually refers to studies at the individual level. A cross-sectional study is a descriptive study in which data on exposure status and outcome status are obtained at essentially the same point in time. Cross sectional studies can be thought of as providing a "snapshot" of frequency and characteristics of a disease in a population at a particular point in time. This kind of data can be used to assess the prevalence of acute and chronic conditions in a population. For example, assume that a cross sectional study finds obesity to be more I common among women with than without arthritis. Was it the extra weight load on joints that lead to arthritis.

- **Case Control Study / Case Reference**

A case control study starts with an outcome, such as disease, and then looks backward in time for exposures that might have caused the outcome. In contrast, a cohort study moves from exposer to outcome. The case control study has traditionally been viewed as an inferior alternative to the cohort study. For example, to know the etiology of ovarian cancer, investigators define a group with ovarian cancer and a group without ovarian cancer, the outcome, the investigators then ascertain the prevalence of exposure to a risk factor – e.g., oral contraceptives, or ovulation-induction drugs- in both groups.

- **Cohort Study / Follow Up Study**

The term cohort was originally used to describe a 300-600 men unit in the Roman army; ten cohort formed a legion. A cohort study consists of bands or groups of persons, marching forward in time from an exposer to one or more outcomes. Depending on the time when the cohort study is initiated relative to occurrence of the disease to be studied three are used:

- In a prospective / concurrent cohort study, participants are grouped on the basis of past or current exposer and are followed into the future in order to observe the outcomes of interest.
- In a retrospective / historical cohort study, both the exposer and outcome have already occurred when the study begins.
- An ambidirectional cohort study has both prospective and retrospective components.[6]

Population Based - these are often relied on the combination of data originating from different sources. These are major divided into two types:

1) Health Survey

The ongoing systematic collection, analysis and interpretation of health data essential to the planning, implementation and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know.

Surveillance, another type of descriptive study, can be thought of as watchfulness over a community, with feedback to the community about the results, an important element.

2) Ecological Study

Classical ecological studies examine the rates of disease in relation to a factor described on a population level. Thus, "the units of analysis are populations or group of people rather than individual." The measure of association between exposer and outcome is the correlation coefficient r, which indicates how linear the relation between exposer and outcome is as an example, the death rates from coronary artery disease may corelate with per capita sales of cigarette.[7]

Phases of clinical trials

Good clinical practice trials conducted in a series of steps called "phases." Each phase has a different purpose and helps researchers answer different questions.[8]

Phase 0 (Human Microdosing)

This phase is also called as principal phase. It is conducted in 10-15 persons for two weeks.

- Small dose of drug should be given for testing.
- No information for drug safety and efficacy of data.

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- Main aim to know about pharmacodynamics and pharmacokinetics.

Phase 1 (Human Pharmacology)

It is conducted in 10 – 100 persons for 1 year. Generally it is done health volunteers safety and desires sick patients.

The following information is collected in phase one trial-

- Drug dose - The amount of drug safer for patient without adverse effect.
- Without severe side effect how much amount of drug should be given.
- How much amount of drug is required for how many times.
- Which route of drug administration is best.

Phase 2 (Therapeutic Exploratory Trials)

It is conducted in 100 - 300 persons for 2 years. In this phase we know that whether drug is effective to reduce symptoms of particular disease.

Phase 3 (Therapeutic Confirmatory Trials)

It is conducted in 300 - 3000 persons for 1 to 4 year. In this phase effectiveness and side effects of drug in particular groups will be seen. This phase designed to see the efficacy, effectiveness and safety of drug.

Phase 4 (Post Marking Trials)

It is conducted in more than 1000 persons for long term i.e., 12 to 15 years. (After approval of FDA). Actually, it is first testing of drug. It is also called as post marketing surveillance trial. It any side effect of drug will be seen then drug should not be sold and prohibited. Pre-clinical phase to phase 4includes 12-18 years.

Bias in research

Bias is a systematic inconsistency in research that contaminates the primary comparison. There are several Forms of bias, and there are specific methods of minimizing them in different study designs.[9] Bias is any trend or deviation from the truth in data collection, data analysis, interpretation and publication cation which can lead to false conclusions. Bias can occur either intentionally or unintentionally. In intention to introduce bias into one's research is immoral. Nevertheless, considering the possible consequences of a biased research, it is almost equally irresponsible to conduct and publish biased research unintentionally.

Types of Bias

a) Selection Bias

b) Measurements Bias

c) Design Bias

d) Attrition Bias

e) Statistical Bias

f) Recall Bias

g) Lead Time Bias

h) Response Bias

1) **Selection Bias -** Selection bias is the bias introduced by the selection of individuals, groups, or data for analysis in such a way that proper randomization is not achieved, thereby failing to ensure that the sample obtained is representative of the population intended to be analyzed.

2) **Measurements Bias -** Measurement bias refers to any systematic or non-random error that occurs in the collection of data in a study. Another broad term for this type of bias is "detection bias".

3) **Design Bias -** Design bias occurs when the research design, survey questions, and research method is influenced by the preferences of the researcher rather than its suitability to the research work. Furthermore, design bias occurs when personal experiences of researcher influence the choice of the research question and methodology.

4) **Attrition Bias -** Attrition bias is a type of selection bias due to systematic differences between study groups in the number and the way participants are lost from a study.

5) **Statistical Bias -** Statistical bias is a systematic tendency which causes differences between results and facts. The bias exists in numbers of the

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process of data analysis, including the source of the data, the estimator chosen, and the ways the data was analyzed.

6) **Recall Bias -** Recall bias is a type of information bias where people do not remember previous events, memories, or details. It is related to recency bias, where we tend to remember things that have happened more recently better.

7) **Lead Time Bias -** Lead time bias happens when survival time appears longer because diagnosis was done earlier (for instance, by screening), irrespective of whether the patient lived longer. Lead time is duration of time between detection of a disease (by screening or based on a new experimental criteria) and its usual clinical presentation and diagnosis (based on traditional criteria).

8) **Response Bias -** Response bias is a general term for a wide range of tendencies for participants to respond inaccurately or falsely to questions. These biases are prevalent in research involving participant self-report, such as structured interviews or surveys. Response biases can have a large impact on the validity of questionnaires or surveys.

Error in Research

Error is defined as the difference between the true value of measurement and the recorded value of a measurement. There are many sources of error in collecting data. Error can be described as random or systematic. Power is the ability to correctly reject a null hypothesis that is indeed false.[9]

These error are generally produced by one or more of the following :

a) Type 1 error

b) Type 2 error

c) Type 3 error

- **Type 1 Error / Alpha Error -** A type 1 error occur when in research, we reject the null hypothesis and erroneously state that the study found significant differences when there indeed was no difference. In other words, it is equivalent to saying that the groups or variable differ when, in fact, they do not or having false positive.

- **Type 2 Error -** A type 2 error occur when we declare no differences or associations between study group when, in fact, there was. When we wrongly conclude that there is no difference in treatment effects. Also called as False-negative error. As with type 1 errors, type 2 errors in certain causes problems.

- **Type 3 Error -** A type 3 error is where you correctly reject the null hypothesis, but it is rejected for the wrong reason. Type 3 errors as giving the right answer to the wrong question.

Randomized Controlled Trial (RCT)

A study in which people are allocated at Random (by chance alone) to receive one of several clinical interventions. One of these Is the interventions is standard of comparison or control. The control may be a standard practice, A placebo (sugar pill), or no intervention at all.[10]

A randomized controlled trial (RCT) is a form of clinical trial, or scientific procedure Used in the testing of the efficacy of medicines or medical procedures. It is widely Considered the most reliable form of scientific evidence because it is the best-known Design for - eliminating the variety of biases that regularly compromise the validity of Medical research. A randomized controlled trial (RCT) is a form of clinical trial, or Scientific procedure used in the testing of the efficacy of medicines or medical Procedures.

Types of trials - Randomized trials are employed to test efficacy while avoiding These factors. Trials may be open, blind or double-blind.

Open trial

In an open trial, the researcher knows the full details of the treatment, and so does the patient. These trials are open to challenge for bias, and they do nothing to reduce the Placebo effect. However, sometimes they are unavoidable, particularly in relation to surgical techniques.

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Blind trials

Single-blind trial

In a single-blind trial, the researcher knows the details of the Treatment but the patient does not. Because the patient does not know which treatment Is being administered (the new treatment or another treatment) there should be no Placebo effect.

Double-blind trial

In a double-blind trial, one researcher allocates a series of Numbers to new treatment' or 'old treatment'. The second researcher is told the Numbers, but not what they have been allocated to. Since the second researcher does not Know, they cannot possibly tell the patient, directly or otherwise, and cannot give in to patient pressure to give them the new treatment. In this system, there is also often a more Realistic distribution of sexes and ages of patients. Therefore double-blind (or Randomized) trials are preferred, as they tend to give the most accurate results.

Triple-blind trial

Some randomized controlled trials are considered triple-blinded. Although the meaning of this may vary according to the exact study design. The most Common meaning is that the subject, researcher and person administering the treatment (often a pharmacist) are blinded to what is being given. Alternately, it may mean that the Patient, researcher and statistician are blinded, these additional precautions are often in Place with the more commonly accepted term double blind trials", and thus the term "triple-blinded" is infrequently used, However, it connotes an additional layer of security to prevent undue influence of study results by anyone directly involved with the study.

Good Clinical Practices (GCP)

Good Clinical Practice (GCP) is defined as a standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provide assurance that the data and reported results are credible and accurate and that right, integrity and confidentiality of trial subjects are protected.

Prior to an actual set of guidelines to follow for good clinical practice, clinical studies were dangerous and could result in serous disease, or possibly death.

Declaration of Helsinki

In 1964, the World Medical Association established Recommendations guiding medical doctors in biomedical research involving human subjects. These guidelines influenced national legislation, but there was no set standard between nations.

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials. GCP provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are respected and protected. It was finalized in 1996 and became effective in 1997, but was not enforced by law at that time.[2]

Survey Research: Definition, Examples and Methods

Survey Research is defined as the process of conducting research using surveys that researchers send to survey respondents. The data collected from surveys is then statistically analyzed to draw meaningful research conclusions.

The traditional definition of survey research is a quantitative method for collecting information from a pool of respondents by asking multiple survey questions. This research type includes the recruitment of individuals collection, and analysis of data. It's useful for researchers who aim to communicate new features or trends to their respondents.[11]

Survey Research Methods -

Survey research methods can be derived based on two critical factors: Survey research tool and time involved in conducting research.

There are three main survey research methods, divided based on the medium of conducting survey research:

- **Online/ Email:** Online survey research is one of the most popular survey research methods today. The cost involved in online survey research is extremely

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minimal, and the responses gathered are highly accurate.

- **Phone:** Survey research conducted over the telephone (CATI survey) can be useful in collecting data from a more extensive section of the target population. There are chances that the money invested in phone surveys will be higher than other mediums, and the time required will be higher.
- **Face-to-face:** Researchers conduct face-to-face in-depth interviews in situations where there is a complicated problem to solve. The response rate for this method is the highest, but it can be costly.

Based on the time taken, survey research can be classified into two methods:

- **Longitudinal survey research:** Longitudinal survey research involves conducting survey research over a continuum of time and spread across years and decades. The data collected using this survey research method from one time period to another is qualitative or quantitative. Respondent behaviour, preferences, and attitudes are continuously observed over time to analyse reasons for a change in behaviour or preferences.
- **Cross-sectional survey research:** Researchers conduct a cross-sectional survey to collect insights from a target audience at a particular time interval. This survey research method is implemented in various sectors such as retail, education, healthcare, SME businesses, etc. Cross-sectional studies can either be descriptive or analytical. It is quick and helps researchers collect information in a brief period. Researchers rely on the cross-sectional survey research method in situations where descriptive analysis of a subject is required.

Qualitative Research Methods: Types & Examples

Qualitative research is defined as a clinical research method that focuses on obtaining data through open-ended and conversational communication. The great contribution of qualitative research is the culturally specific and contextually rich data it Produces.[12]

This method is about "what" people think and "why" they think so. Qualitative research is based on the disciplines of social sciences like psychology, sociology, and anthropology. Therefore, the qualitative research methods allow for in-depth and further probing and questioning of respondents based on their responses. The interviewer/researcher also tries to understand their motivation and feelings.

Types of qualitative research methods

Qualitative research methods are designed in a manner that help reveal the behaviour and perception of a target audience with reference to a particular topic. There are different types of qualitative research methods like an in-depth interview, focus groups, ethnographic research, content analysis, case study research that are usually used.

One-on-one interview

Conducting in-depth interviews is one of the most common qualitative research methods. It is a personal interview that is carried out with one respondent at a time. This is purely a conversational method and invites opportunities to get details in depth from the respondent.

One of the advantages of this method provides a great opportunity to gather precise data about what people believe and what their motivations are.

Focus groups

A focus group is also one of the commonly used qualitative research methods, used in data collection. A focus group usually includes a limited number of respondents (6-10) from within your target market.

The main aim of the focus group is to find answers to the "why" "what" and "how" questions. One advantage of focus groups is, you don't necessarily need to interact with the group in person. Nowadays focus groups can be sent an online survey on various devices and responses can be collected at the click of a button.

Ethnographic research

Ethnographic research is the most in-depth observational method that studies people in their naturally occurring environment.

This method requires the researchers to adapt to the target audiences' environments which could be anywhere from an organization to a city or any remote

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location. Here geographical constraints can be an issue while collecting data.

This research design aims to understand the cultures, challenges, motivations, and settings that occur.

Case study research

The case study method has evolved over the past few years and developed into a valuable qual research method. As the name suggests it is used for explaining an organization or an entity.

This type of research method is used within a number of areas like education, social sciences and similar. This method may look difficult to operate, however, it is one of the simplest ways of conducting research as it involves a deep dive and thorough understanding of the data collection methods and inferring the data.

Record Keeping

This method makes use of the already existing reliable documents and similar sources of information as the data source. This data can be used in new research. This is similar to going to a library. There one can go over books and other reference material to collect relevant data that can likely be used in the research.

Process of observation

Qualitative Observation is a process of research that uses subjective methodologies to gather systematic information or data. Since, the focus on qualitative observation is the research process of using subjective methodologies to gather information or data. Qualitative observation is primarily used to equate quality differences.

Qualitative observation deals with the 5 major sensory organs and their functioning - sight, smell, touch, taste, and hearing.

Qualitative Research: Data Collection and Analysis

A. Qualitative data collection

Qualitative data collection allows collecting data that is non-numeric and helps us to explore how decisions are made and provide us with detailed insight. For reaching such conclusions the data that is collected should be holistic, rich, and nuanced and findings to emerge through careful analysis.

Whatever method a researcher chooses for collecting qualitative data, one aspect is very clear the process will generate a large amount of data. In addition to the variety of methods available, there are also different methods of collecting and recording the data.

B. Qualitative data analysis

Qualitative data analysis such as notes, videos, audio recordings images, and text documents. One of the most used methods for qualitative data analysis is text analysis.

Text analysis is a data analysis method that is distinctly different from all other qualitative research methods, where researchers analyse the social life of the participants in the research study and decode the words, actions, etc.

DISCUSSION

Clinical case presentation is one of the most important issues related to patience and clinician. It explains each and every information related to patience. It can be act as a guideline for new researchers who works on same disease. There are lots of factors responsible for good clinical practice and many guidelines were given for it. In major view the main points are the study design, material and method, subjective and objective parameters, statically data of subjective and objective parameters, results, discussion, conclusion and references. The time duration and amount of patience in clinical case presentation is one of the important features in research.

The case presentation is a rapid short communication between busy clinician who may not have proper time or resources to conduct any large-scale researches. Finally, the case reports should be connected to the existing literature, mentioning the message that the case conveys. The most common regions for publishing a case is an unexpected association between disease or symptoms and unexpected event in the course observing or treating a patient, finding that shed new light on the possible pathogenesis of a disease or an adverse effect, unique rare features of a diseases and unique therapeutic approaches towards the diseased.

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CONCLUSION

The conclusion is intended to help the reader understand why the research should matter to them. A conclusion is not merely a summary of the main topics covered or a rest statement of the research problem, but a synthesis of key points and if applicable where he/she recommend new areas for future research.

Well written conclusion provides with important opportunities to demonstrate to the reader for understanding of the research problem these includes-

1. Presenting the last word on the issues the raised in the paper.
2. Summarizing the thoughts and conveying the large significance of the study.
3. Identifying how a gap in the literature has been addressed.
4. Demonstrating the importance of the ideas.
5. Introducing possible new or expanded way of thinking about the research problem.

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