Research Design and Methodology (PRA7101)

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Lecture One

Course Content

Course Content

- Introduction to Research Methodology
- Research Philosophy, Ethics, and Environmental Aspects
- Formulating Research Questions and Hypotheses
- Research Design and Data Collection Methods
- Variable Identification and Bias Awareness
- Validation, Replication and Reproducibility
- Research Funding and Proposal Evaluation
- Experimental Designs in Pharmaceutical Formulation
- Preclinical Research Designs
- Meta-Analysis Studies – Techniques and Interpretation
- Effective Research Documentation and Data Compilation
- Scientific Presentation and Publication Ethics

Lecture 1

Introduction to Research Methodology

Lecture 1

Intended Learning Outcomes (ILOs)

By the end of the lecture, you will be able to

- ❑ Define research.
- ❑ Discuss the objectives of research.
- ❑ Enumerate the motives behind conducting research.
- ❑ Define and discuss different types of research.
- ❑ Differentiate between research methods and methodology.
- ❑ Enumerate the importance of research methodology.
- ❑ Discuss different types of research methodology.
- ❑ Discuss different steps in the process of research.


Iterative Process
Systematic Approach
Peer Review
Objective and Unbiased
Research
Logical and Critical Thinking
Empirical Evidence
Transparency
Replicability
WHAT IS
RESEARCH?

What is the meaning of Research?

What is Research?

The word 'Research' is comprised of two words:

Re + Search

It means to **search again**.

It is a systematic investigation or activity to gain new knowledge of already existing facts.

What is the meaning of Research?

Research is considered to be the more ***formal , systematic intensive process of carrying on the scientific method of analysis.*** *It involves a more systematic structure of investigation , usually resulting in some sort of formal record of procedures & a report of results or conclusion.*

(John W Best)

What is the meaning of Research?

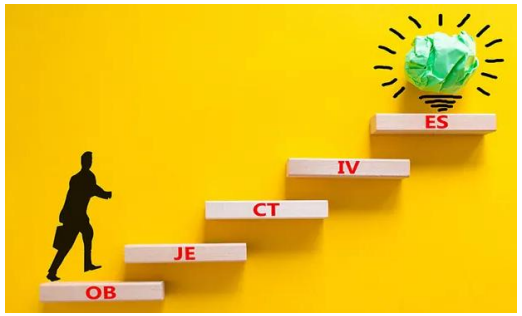
*"Research is a systematic effort to **gain new knowledge**."*

Redman & Mori

*"Research comprises defining and redefining problems, formulating hypothesis or **suggested solutions, collecting, organizing and evaluating data, making deductions and reaching conclusions** and at **last careful testing the conclusions** to determine whether they fit the formulated hypothesis."*

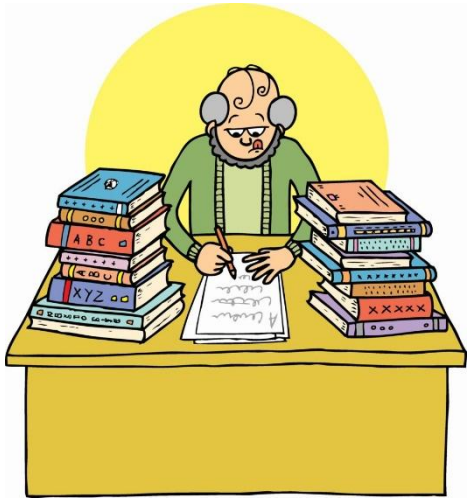
Clifford Woody

What are the objectives of Research?



Objectives of Research

What are the objectives of Research?



Objectives of Research

- Purpose of research is to **discover answers to questions** through the application of scientific procedure.
- Main aim of research is to **find the truth** which is hidden and which has not been discovered as yet.

Objectives of Research can be grouped under following items:

1. To **gain familiarity** with a phenomenon or to **achieve new insights** into it.
2. To **portray accurately the characteristics of a particular individual situation or a group.**
3. To determine the **frequency** with which something occurs or **with which it is associated with something else.**
4. To **test a hypothesis** of a casual relationship between variables.
   (Such studies are known as hypothesis-testing research studies)

What are your motivations to do research?

Research Motivation

What are your motivations to do research?

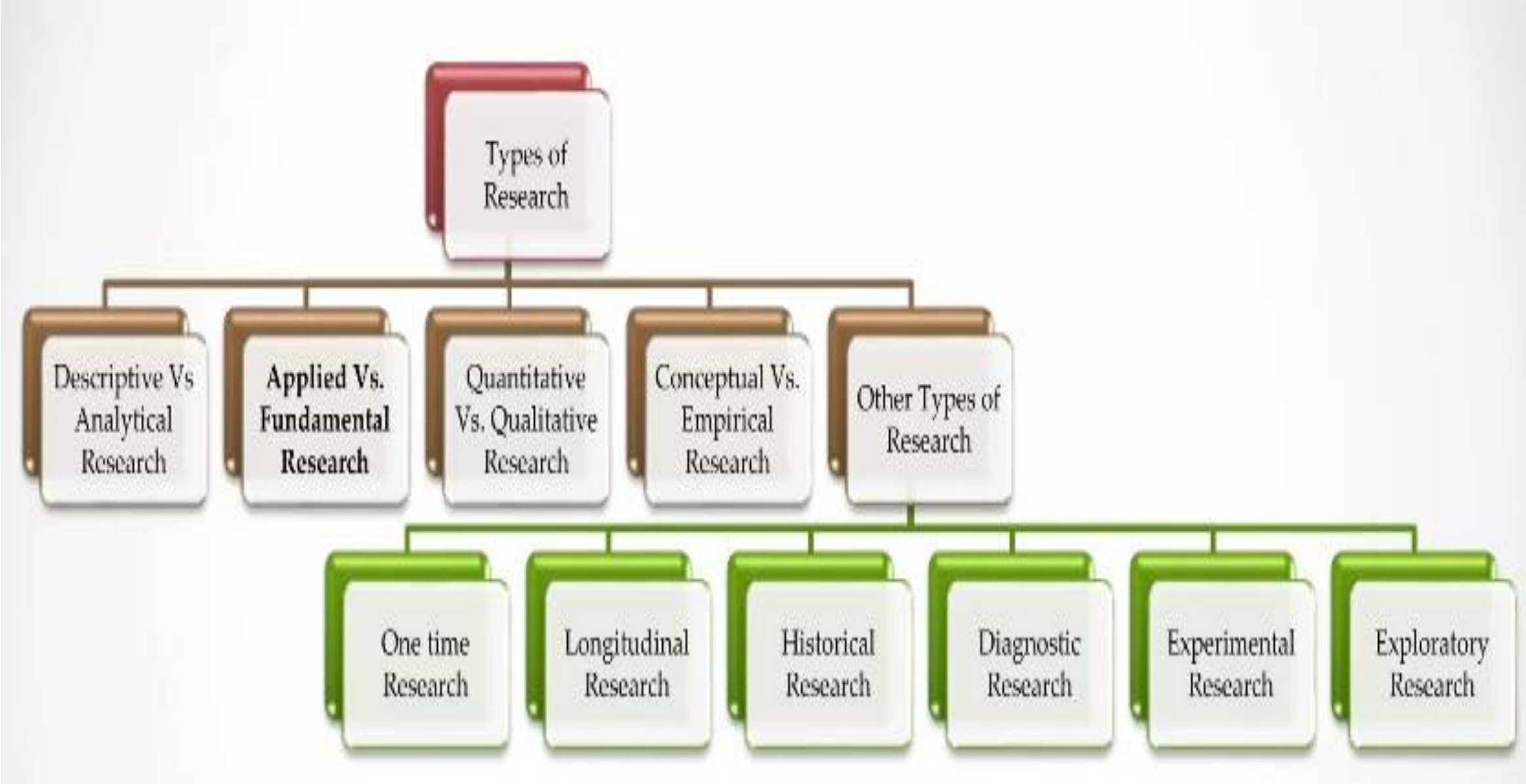
Research Motivation

1. Desire to get ***a research degree*** along with its benefits.
2. Desire to face the challenge in ***solving the unsolved Problem***.
3. Desire to get intellectual joy from ***doing some creative work.***
4. Desire to be of ***service to Society***.
5. Desire to get respectability.

Types of Research

What are the types of research?

Research Types

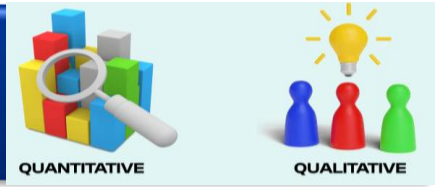


What are the types of research?

Research Types

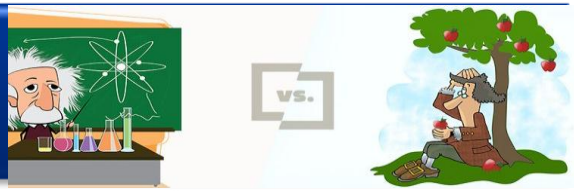
Applied vs fundamental.

Qualitative vs Quantitative



Descriptive vs analytical

Conceptual vs empirical

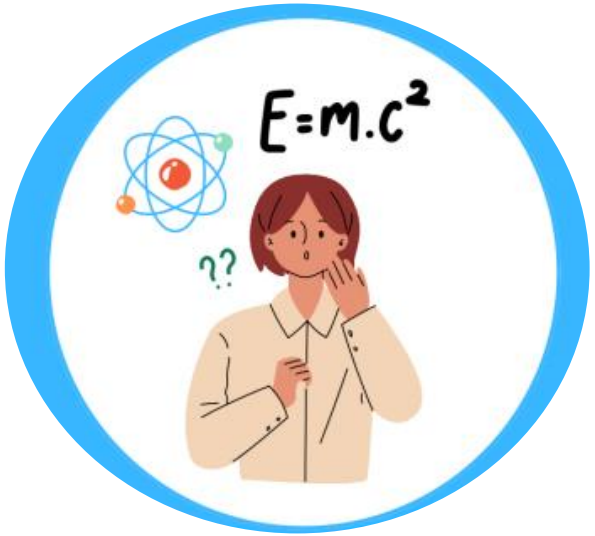


What are the types of research?

Research Types

Applied vs fundamental (basic)

Based on the utility of the content or the nature of the subject matter of research



Fundamental Research is mainly concerned with Generalization and with the formulation of a theory.
It is also known as pure research.
e.g.:- Pure Mathematics

Its utility is universal.

Applied Research aims at finding a solution for an immediate problem facing a society or an organization.
e.g.:- Marketing Research

Its utility is limited.

What are the types of research?

Research Types

Qualitative vs Quantitative

Based on the nature of information

Quantitative Research is based on the measurement of **quantity or amount.**

Qualitative Research is especially important in the **behavioral sciences** where the aim is to discover the underlying motives of human behavior.
e.g.:- Motivation research.

What are the types of research?

Research Types

Descriptive vs analytical

DESCRIPTIVE RESEARCH

Descriptive Research observes and describes the characteristics and behaviors of a subject or group without manipulating variables.

ANALYTICAL RESEARCH

Analytical Research is a systematic method of analyzing data to uncover patterns & gain insights into a specific phenomenon or problem.

What are the types of research?

Research Types

Conceptual vs empirical

Conceptual Research is that related to **some abstract ideas for theory.**
It is generally used by philosophers and thinkers to **develop the new concepts or to interpret existing ones**.

Empirical Research **is a way of learning through direct observation or experience. Instead of relying on theories or ideas alone.**
It is **data-based research** coming up with conclusions which are capable of been variable of observation and experiment.

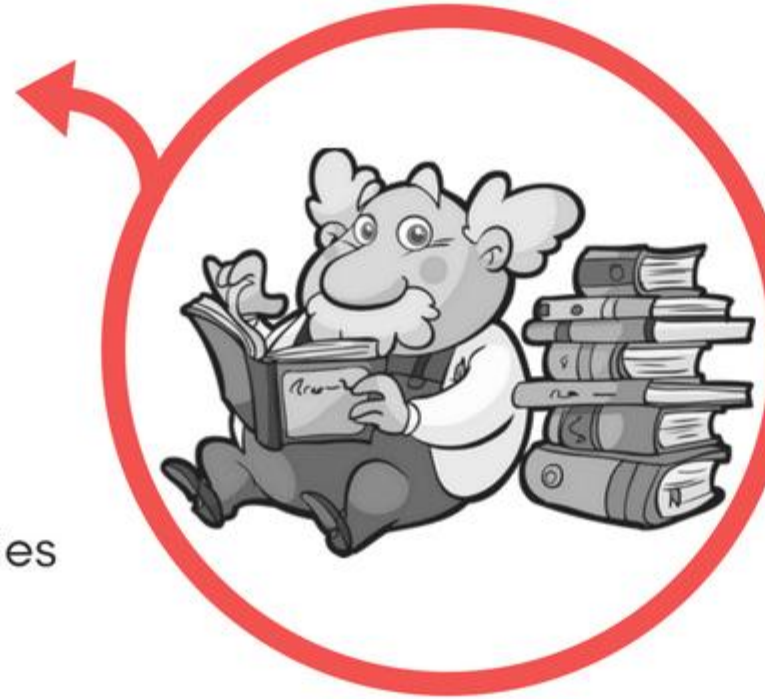
What are the types of research?

Research Types

Conceptual vs empirical

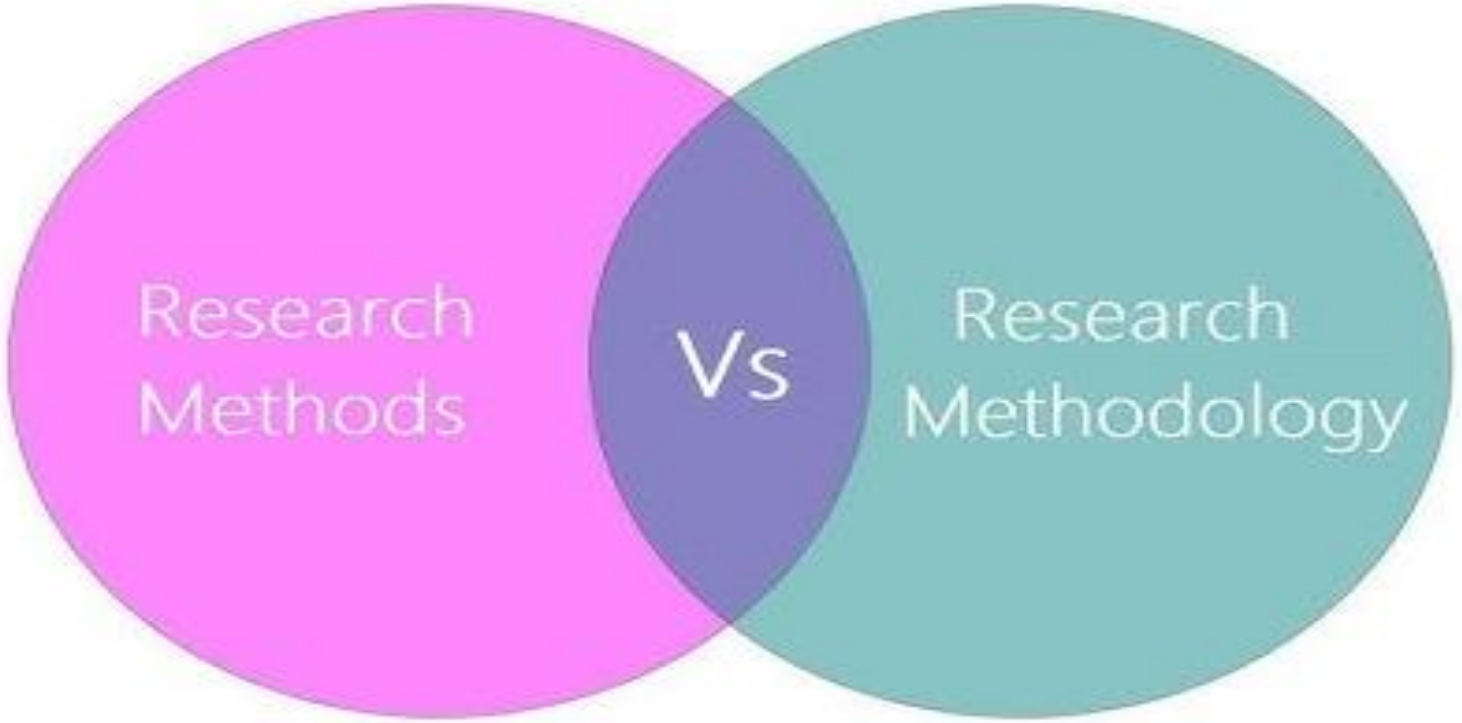
Are you into conceptual or empirical research?

Developing new concepts or theories like Aristotle!



Experimenting to test theories or form basis for new theories like Edison!

Differences Between Research Methods & Research Methodology



Research methodology is different from a research method, although both terms are often confused and sometimes used interchangeably.

What is research methods ?

Research methods

- Methods refers to ***specific techniques or approaches*** **used to achieve objectives in research or problem-solving.**
- It focuses on the ***execution of tasks***.
- Research methods are the ***tools used to gather data.***

Research methods refer to the ***specific techniques, procedures, and tools used by researchers to collect, analyze, and interpret data, for instance surveys, questionnaires, interviews***, etc.

What is research methodology ?

Research Methodology

- Methodology provides the ***broader framework that guides the selection and application of methods.***
- It includes ***overall research design and rationale***.

It **includes all the important aspects of research,** including ***research design, data collection methods, data analysis methods, and the overall framework*** within which the research is conducted.

What is research methodology ?

Research Methodology

What is the difference between methodology and methods ?

Methodology vs Method

When we talk of research methodology, we not only talk of the research methods but also ***consider the logic behind the methods we use in the context of our research study*** and explain ***why we are using a particular method*** and why we are not using others, so that **research results are capable of being evaluated by the researcher himself or by other**

What is the difference between methodology and methods ?

Methodology vs Method

For example, in a study investigating the effects of a new drug on blood pressure, **what are the research methods and methodology.**

The **research method** might involve **a randomized controlled trial with a specific protocol for administering the drug and monitoring blood pressure.**

The **research methodology** would encompass the ***study's overall design***, including the **rationale for selecting a randomized controlled trial as the most appropriate means to address the research question.**

Methodology pertains to the methods or rules used to execute a specific research study and the underlying principles, theories, and values that inform a particular research approach

Why is research methodology important ?

Importance of Research methodology

Having a good research methodology has the following advantages:

- Helps other researchers who may want to ***replicate your research***.
- You can easily ***answer any questions*** about your research if they arise at a later stage.
- ***Provides a framework and guidelines*** for researchers to clearly define research questions, hypotheses, and objectives.
- It helps researchers to ***identify the most appropriate research design, sampling technique, and data collection and analysis methods***.

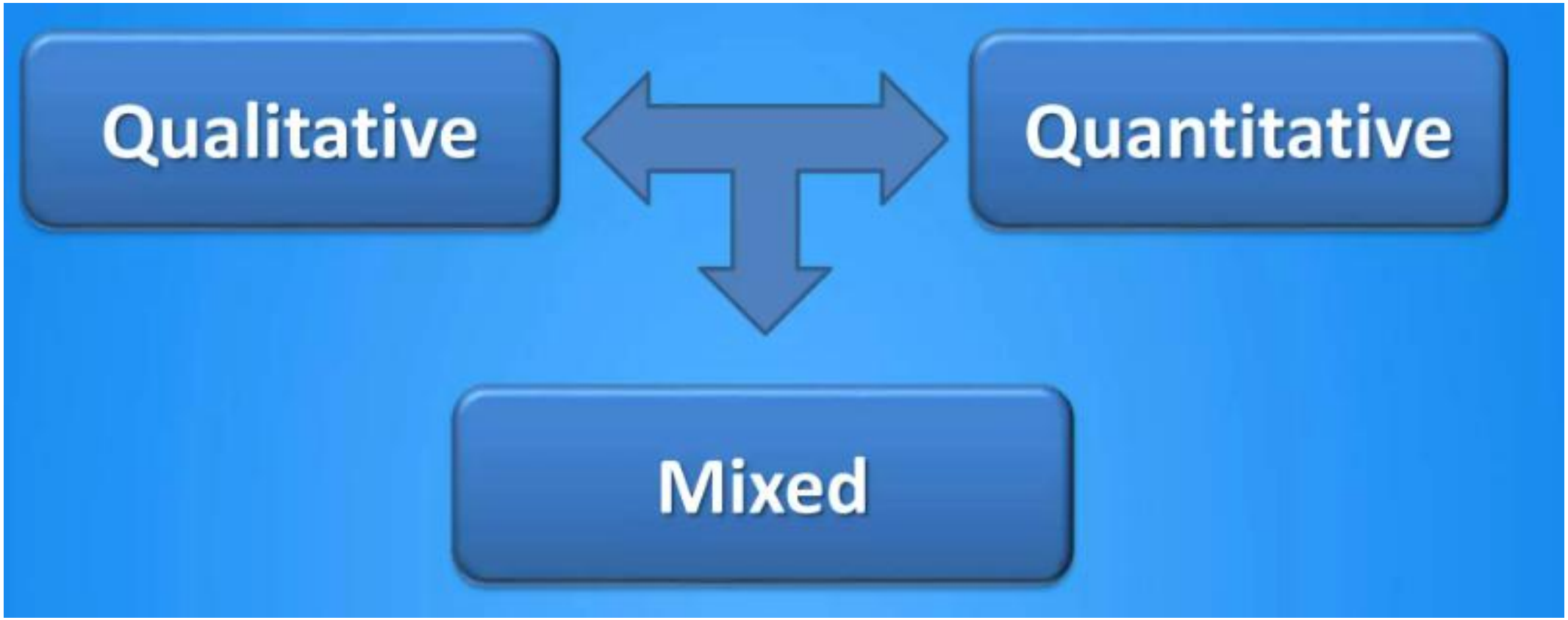
Why is research methodology important ?

Importance of Research methodology

Having a good research methodology has the following advantages:

- ***Ensure that their findings are valid and reliable and free from biases and errors***.
- ***Ensure that ethical guidelines are followed*** while conducting research.
- Helps researchers in ***planning their research efficiently***, by ensuring optimum usage of their time and resources.

Types of Research methodology



Types research methodology

Types of Research methodology

There are three types of research methodology based on the type of research and the data required

Quantitative research methodology focuses on ***measuring and testing numerical data***.

This approach is good for reaching a ***large number of people in a short amount of time.***

This type of research helps in testing the **causal relationships between variables**, **making predictions**, and **generalizing results to wider populations**.

Types research methodology

Types of Research methodology

Quantitative research methodology

Tile: Study of Pharmacokinetic Profile of a Novel Extended-Release Formulation of Oxycodone

Methods:

A crossover study design was used, where 24 participants received both the new formulation and a standard formulation.

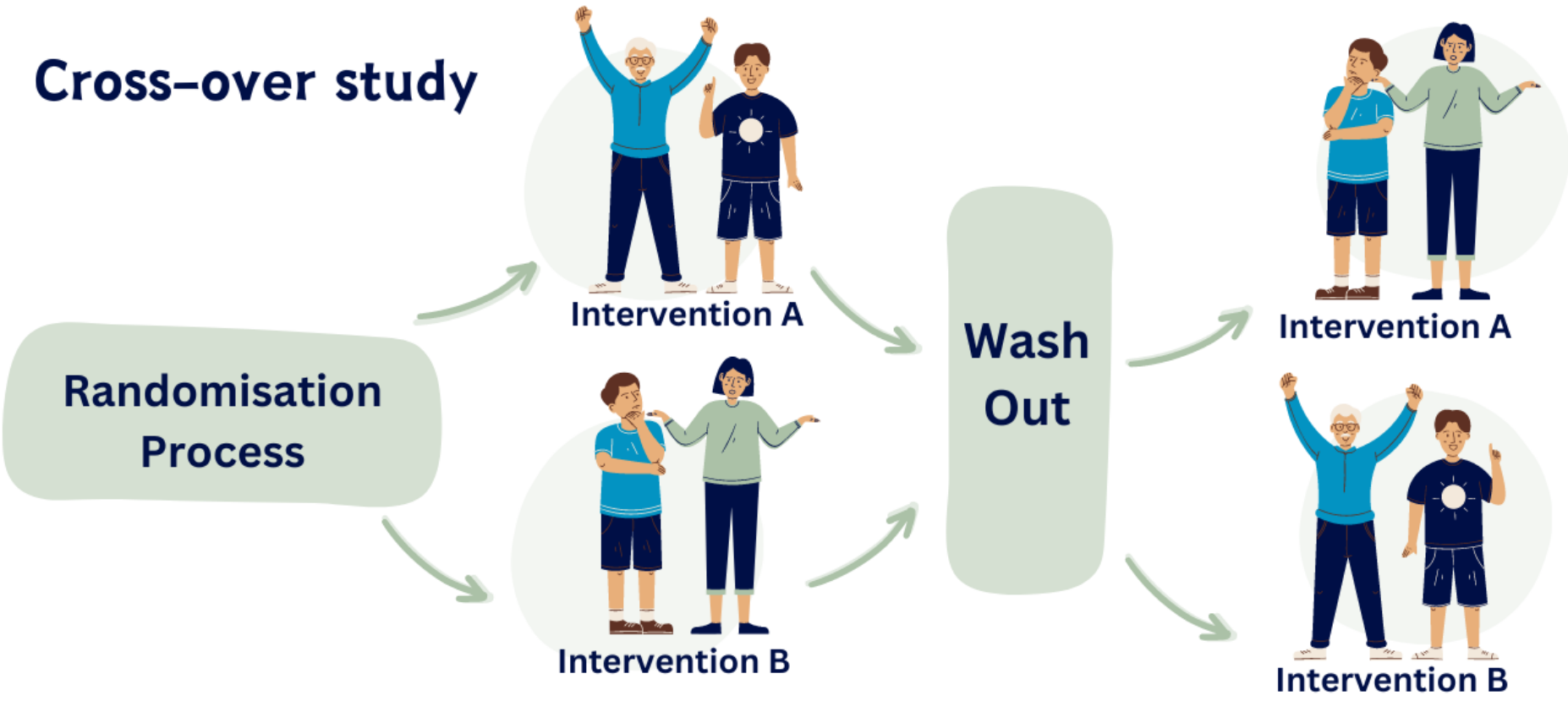
Blood samples were collected at various time points, and pharmacokinetic parameters (Cmax, Tmax, AUC) were calculated using non-compartmental analysis.

Types research methodology

Types of Research methodology

Quantitative research methodology

How to conduct a cross over study?



Types research methodology

Types of Research methodology

Qualitative research methodology

Qualitative research methodology examines the ***opinions, behaviors, and experiences of people.***

- It collects and ***analyzes words and textual data***.
- This research methodology requires ***fewer participants but is still more time-consuming because the time spent per participant is quite large.***
- This method is used in ***exploratory research*** where the ***research problem being investigated is not clearly defined.***

Types research methodology

Types of Research methodology

Qualitative research methodology

- **Title**: Exploring the Role of Pharmacists in Patient Education: A Qualitative Approach
- **Objective**: To investigate how pharmacists communicate medication information to patients and the challenges they face.
- **Methodology**: Focus group discussions were held ***with 15 pharmacists, and transcripts were analyzed to identify barriers and facilitators to effective communication, as well as strategies used to enhance patient understanding.***

Types research methodology

Types of Research methodology

Mixed research methodology

Mixed-method research methodology uses the characteristics of ***both quantitative and qualitative research methodologies*** in the same study.

This method allows researchers to **validate their findings, verify if the results observed using both methods are complementary, and explain any unexpected results** obtained from one method by using the other method.

Types research methodology

Types of Research methodology

Mixed research methodology

Title: Exploring the Role of Pharmacists in Chronic Disease Management: A Mixed-Methods Study

Objective: To identify the roles pharmacists, play in managing chronic diseases and the effectiveness of their interventions.

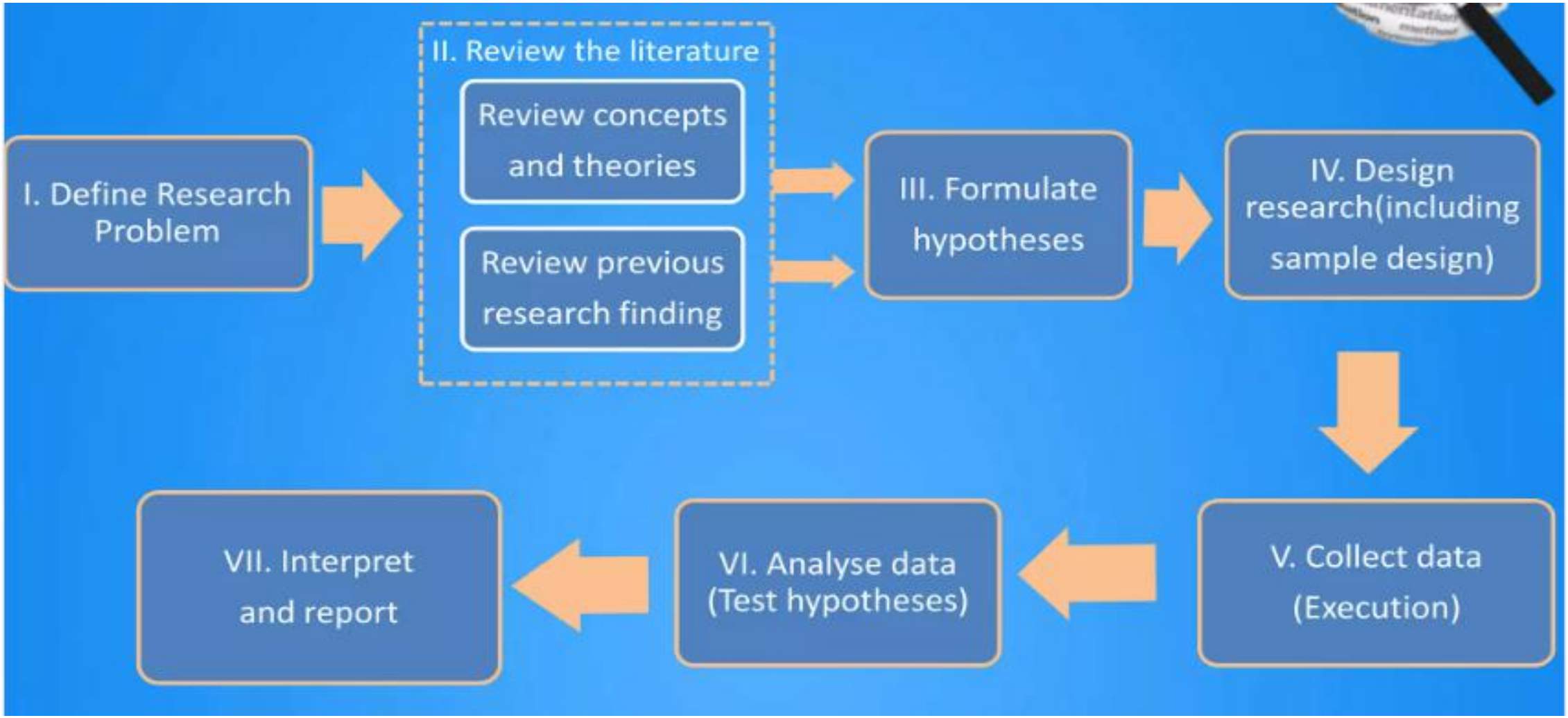
Methodology:

1. **Quantitative**: Surveys distributed to 300 pharmacists to **quantify the types of interventions they provide and their frequency.**
2. **Qualitative**: Focus groups with 20 pharmacists to **discuss their experiences, challenges, and perceived impacts of their interventions on patient outcomes.**
3. **Outcome**: **The study combined numerical data on pharmacist interventions with qualitative insights into the challenges faced in practice**.

What are the steps of research process?

Research Process

Research process consists of series of actions or steps necessary to effectively carry out research and the desired sequencing of these steps.



What are the steps of research process?

Research Process

(1) Formulating the research problem.

(2) Extensive literature survey

(3) Developing the hypothesis

(4) Preparing the research design

(5) Determining sample design

(6) Collecting the data

(7) Execution of the project

(8) Analysis of data

(9) Hypothesis testing

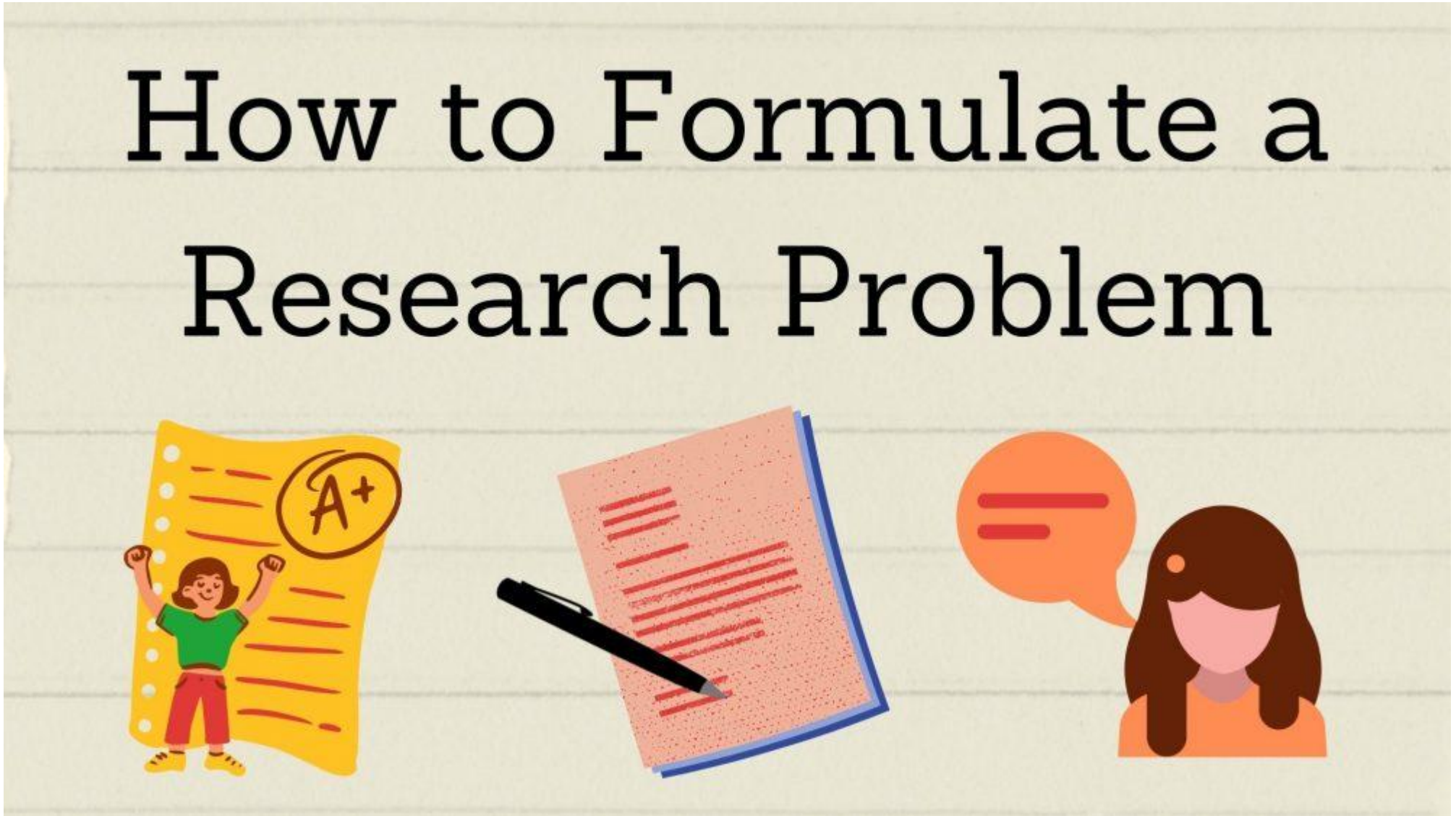
(10) Generalizations and interpretation

(11) Preparation of the report or presentation of the results

How to formulate Research problem?

Research Process

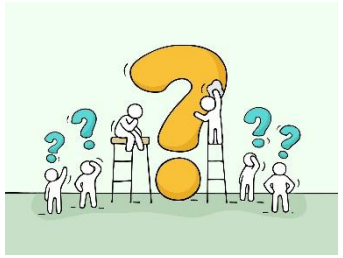
(1)Formulating the research problem.



What are the steps of research process?

Research Process

(1)Formulating the research problem.



Define research problem.

A research problem, in general, refers to ***some difficulty which a researcher experiences*** in the context of either a theoretical or practical situation and wants to obtain a solution for the same.

- The research problem undertaken for study must be **carefully selected**.
- Help may be taken from a **research guide** in this connection.

What are the steps of research process?

Research Process

(1)Formulating the research problem.

Ask yourself one key question:

Where do your interests lie?

What are the steps of research process?

Research Process

(1)Formulating the research problem.

When you select your research problem, consider:

1. Your interest
2. Your capacity
3. Relevance
4. Your level of expertise
5. Availability of data
6. Research Ethics.

What are the steps of research process?

Research Process

(2) Literature review

What are the steps of research process?

Research Process

(2) Literature review

- Once the problem is formulated, a ***summary*** of it should be written down.
- It is compulsory for a research worker writing a thesis for MSc or PhD degree ***to write a synopsis of the topic and submit it to the necessary Committee or the Research Board for approval.***
- At this juncture, the researcher should undertake an ***extensive literature survey*** related to the problem.

What are the steps of research process?

Research Process

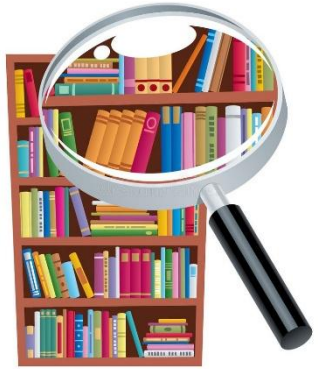
(2) Literature review

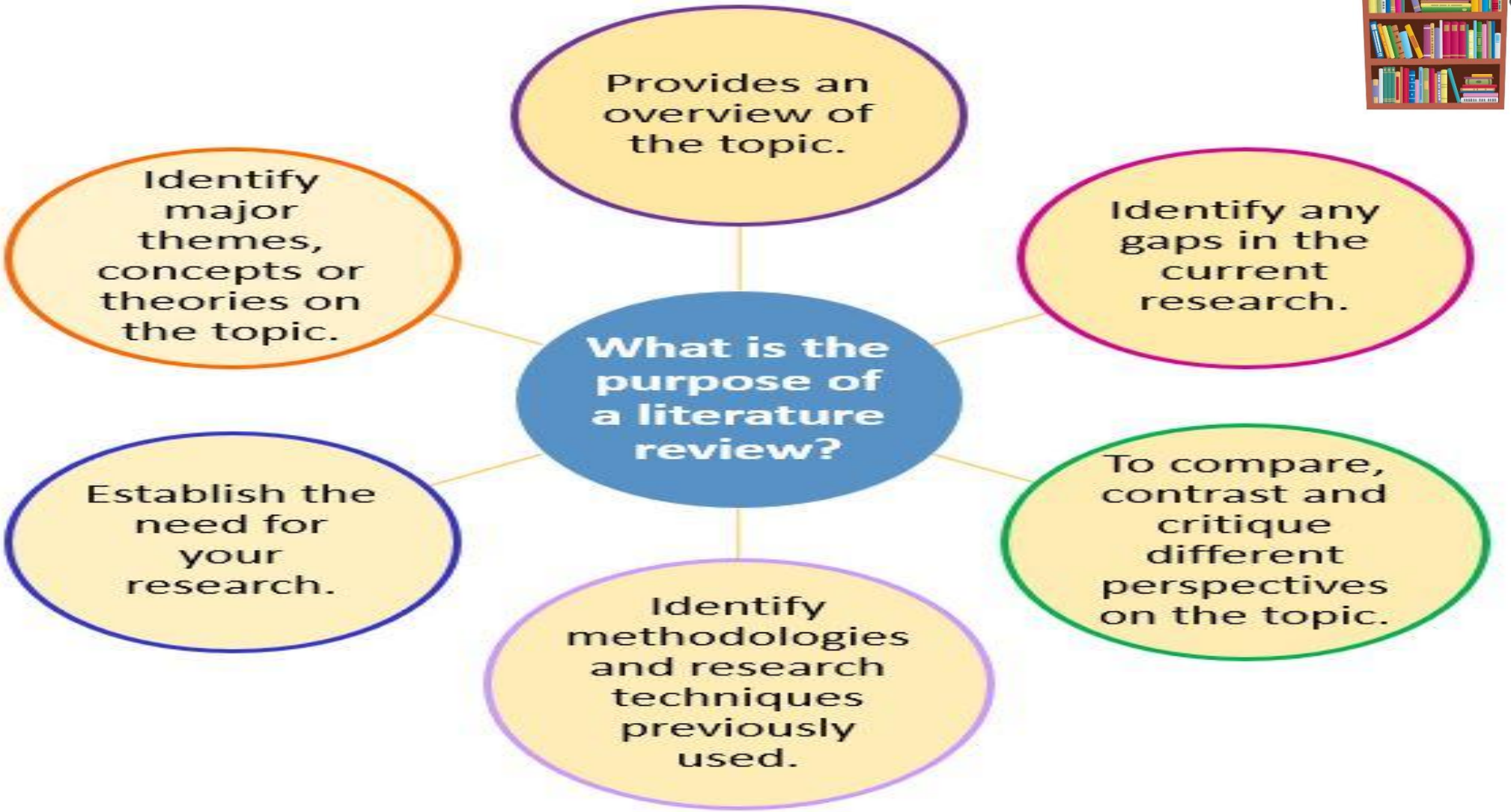
How to write a literature review?

What are the steps of research process?

Research Process

(2) Literature review





What are the steps of research process?

Research Process

(2) Literature review

Sources of Literature

Books
- Text books
- Monographs
- Edited collections

Journal Articles
- Academic journals
- Conference Proceedings

Indexing and Abstracting journal search engines
- Pubmed
- Google Scholar

Past Dissertations

Vital statistics
- Census
- Government Records
- Surveillance system
- Surveys

International organization documents
- e.g. (WHO,UNICEF)

Media
- Newspaper
- Magazine

Internet

In this process, it should be remembered that one source will lead to another.

What are the steps of research process?

Research Process

(2) Literature review

Some useful websites

- Medline - Major bibliographic database for biomedical sciences
- Embase - An extensive biomedical and pharmaceutical database from Elsevier.
- PubMed Central - is the National Library of Medicine's database of free, full-text medical articles made available by contributing publishers.
- ScienceDirect - is a part of Elsevier, a publisher of scientific, technical and medical information provider. It is an online collection of published scientific research, including over 2500 journals and 6000 books
- Proquest – database for biomedical sciences
- Medscape - is a part of the WebMD Health Professional Network. It aims to make it easier for physicians and healthcare professionals to access clinical reference sources, to stay abreast of the latest clinical information
- And many more.....

What are the steps of research process?

Research Process

Literature Review

It is a measure of the frequency with which the "average article" in a journal has been cited in a particular year or period.

- Impact Factor was developed by Eugene Garfield as a **quantitative method for comparing journals**.
- He, together with Irving H. Sher, proposed IF in 1955 to rank journals according to the **journal citation.**
- Impact Factor is calculated **after 3 years** of the journal's launch.
- **New journals should not be expected to have IF from day 1.**

What are the steps of research process?

Research Process

(2) Literature review

Journal Impact Factor Calculation

$$\text{2019 Journal Impact Factor} = \frac{122}{34} = 3.588$$

How is Journal Impact Factor Calculated?

$$JIF = \frac{\text{Citations in 2019 to items published in 2017 (78) + 2018 (44)}}{\text{Number of citable items in 2017 (17) + 2018 (17)}} = \frac{122}{34}$$

What are the steps of research process?

Research Process

(2) Literature review

Journal metrics

Usage

- 255K annual downloads/views

Citations metrics

- 8.302 (2019) Impact Factor
- Q1 (2019) Impact Factor Best Quartile
- 10.404 (2019) 5 year IF
- 13.3 (2019) CiteScore
- 2.591 (2019) SNIP
- 2.074 (2019) SJR

Speed/acceptance

- 13 days avg. from submission to first decision
- 47 days avg. from submission to first post-review decision
- 18 days avg. from acceptance to online publication
- 27% acceptance rate

What are the steps of research process?

Research Process

(2) Literature review

What are the steps of research process?

Research Process

Development of working hypothesis

After an extensive literature survey, the researcher should state in clear terms the working hypothesis.

For a researcher hypothesis is a formal question that he intends to resolve.

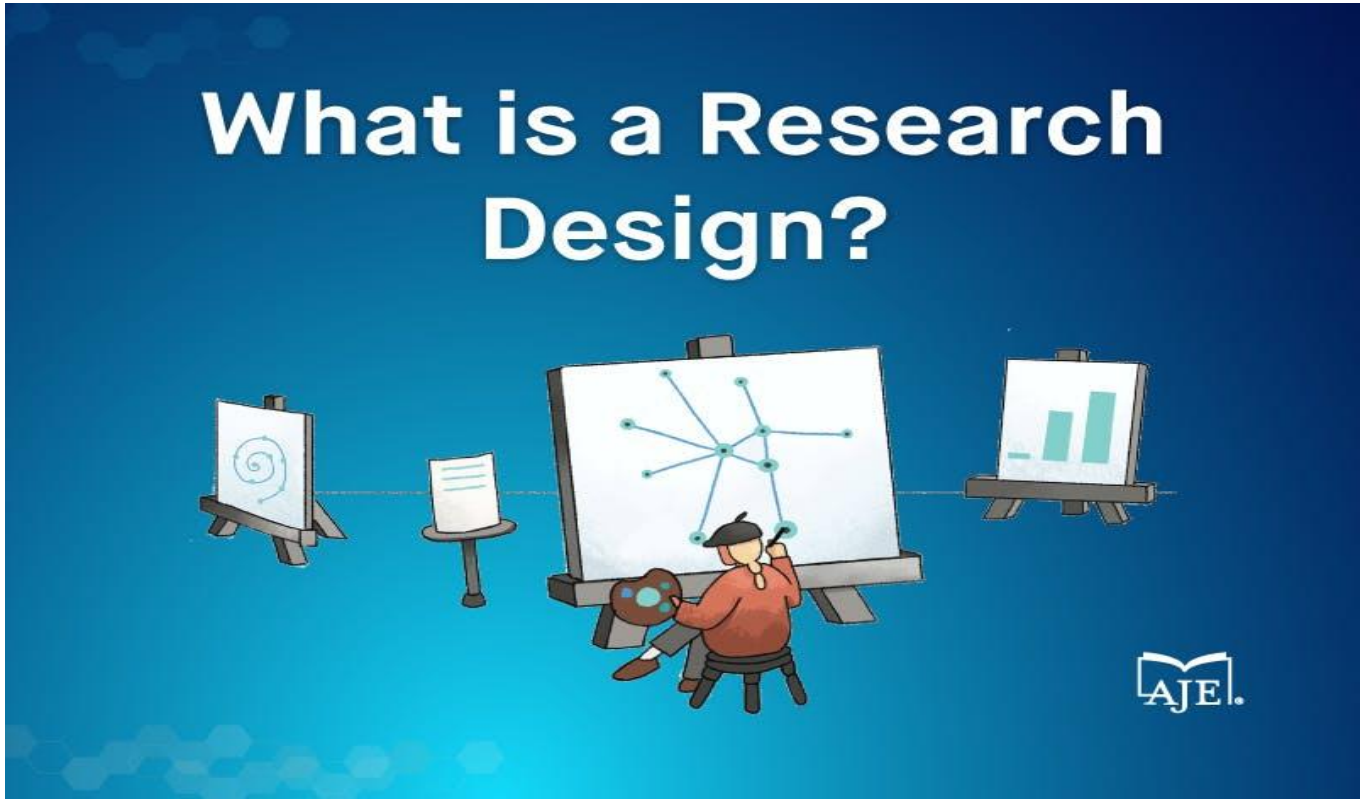
A hypothesis is a **proposed explanation for an observable phenomenon which is capable of being tested by scientific methods.**

For example, consider a statement: "The drug A is equally efficacious as drug B." This is a hypothesis capable of being objectively verified and tested.

What are the steps of research process?

Research Process

Preparation of research design



The research problem having been formulated in clear-cut terms, the researcher will be required to prepare a research design, i.e., he will have to state the conceptual structure within which the **research would be conducted.**

What are the steps of research process?

Research Process

Preparation of research design

A research design **is the arrangement of conditions for the collection and analysis of data in a manner that aims to combine relevance to the research purpose with economy in procedure.**

An outline of what the researcher will do, from writing the hypothesis and its operational implications to the final analysis of data.

It constitutes ***the blueprint for the collection, measurement and analysis of data.***

What are the steps of research process?

Research Process

Preparation of research design

- The function of research design is to **provide for the collection of relevant evidence with minimal expenditure of effort, time and money.**
- But how all these can be achieved depends **mainly on the research purpose.**

What are the characteristics of good Research?

Characteristics of good research

What are the characteristics of good Research?

Objectivity

The design should permit the use of **objective measuring instruments and scoring, ensuring agreement between independent observers.**

Reliability

Refers to **consistency** throughout a series of measurements.

A respondent should give the same response to an item if asked repeatedly.

Validity

The measuring instrument should measure what it is expected to measure. An intelligence test should measure intelligence, not something else.

Generalizability

The design should allow **findings from the sample to be generalized to the larger population** from which the sample was drawn.

What are the steps of research process?

Research Process

Collecting data

The Data Collection is a process by which the ***researcher collects the information*** from all the relevant sources to find answers to the research problem, test the hypothesis and evaluate the outcome.

There are several ways of collecting the appropriate data which **differ considerably** in terms of ***money costs, time and other resources*** at the disposal of the researcher.

What are the steps of research process?

Research Process

Collecting data

- Primary data can be collected either through an ***experiment or through a survey.***
- If the researcher ***conducts an experiment***, he observes some quantitative measurements, or the data, with the help of which he examines the truth contained in his hypothesis.
- **But in the case of a survey, data can be collected by any one or more of the following ways:**

What are the steps of research process?

Research Process

Execution of the project

- Execution of the project is a **crucial step** in the research process.
- If the execution of the project proceeds on correct lines, the data to be collected would be **adequate and dependable**.
- The researcher should see that the project is executed in a ***systematic manner and in time***.

What are the steps of research process?

Research Process

Statistical Analysis

- After the data have been collected, the researcher turns to the task of analysing them.
- The analysis of data requires some **closely related operations such as the establishment of categories, the application of these categories to raw data through coding, tabulation and then drawing statistical inferences**.

What are the steps of research process?

Research Process

Statistical Analysis

Microsoft Excel

GraphPad Prism

SPSS

SPSS

SPSS Statistics is a statistical software suite developed by IBM for data management, advanced analytics, multivariate analysis, business intelligence, and criminal investigation. Long produced by SPSS Inc., it was acquired by IBM in 2009. Wikipedia

Minitab

Minitab is a statistics package developed at the Pennsylvania State University by researchers Barbara F. Ryan, Thomas A. Ryan, Jr., and Brian L. Joiner in conjunction with Triola Statistics Company in 1972. Wikipedia

What are the steps of research process?

Research Process

Hypothesis Testing

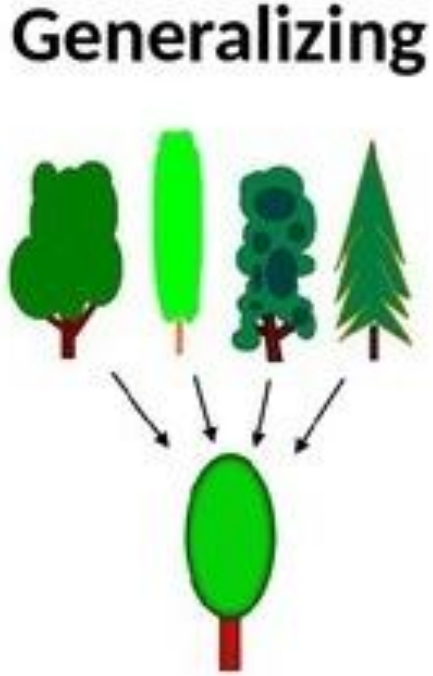
- After analyzing the data as stated above, the researcher is in a position to **test the hypotheses**, if any, he had formulated earlier.
- **Do the facts support the hypotheses, or do they happen to be contrary?**
- The hypotheses may be tested through the use of one or more of such tests, depending upon the nature and object of the research inquiry.
- Hypothesis-testing will result in ***either accepting the hypothesis or rejecting it.***

What are the steps of research process?

Research Process

Generalizations and interpretation

- If a hypothesis is tested and upheld several times, the ***researcher can arrive at generalization, i.e., to build a theory.***
- As a matter of fact, the real value of research lies in ***its ability to arrive at certain generalizations***.
- If the researcher had **no hypothesis** to start with, he might seek to explain his findings based on some theory. **It is known as interpretation.**



What are the steps of research process?

Research Process

Generalizations and interpretation

- Interpretation in research refers to the ***process of making sense of data and findings.***
- It involves ***analyzing the results of a study to derive meaningful conclusions, insights, and implications.***

Interpretation is a critical step in the research process, as it ***transforms raw data into actionable knowledge*** and helps ***communicate the significance of the research to a broader audience***.

What are the steps of research process?

Research Process

Generalizations and interpretation

Here are key aspects of interpretation in research:

- Placing findings within the broader context of existing literature and theories.
- Understanding how results relate to previous studies and contribute to the field.
- Examining statistical results, patterns, and trends to draw conclusions.
- Identifying significant findings and their implications.
- Drawing Conclusions:

Highlighting the significance of the findings in relation to the research questions.

- Implications:

Discussing the practical applications of the findings.

- Limitations:

Acknowledging the limitations of the study and how they may affect interpretation.
Discussing potential biases or confounding factors that could influence results.

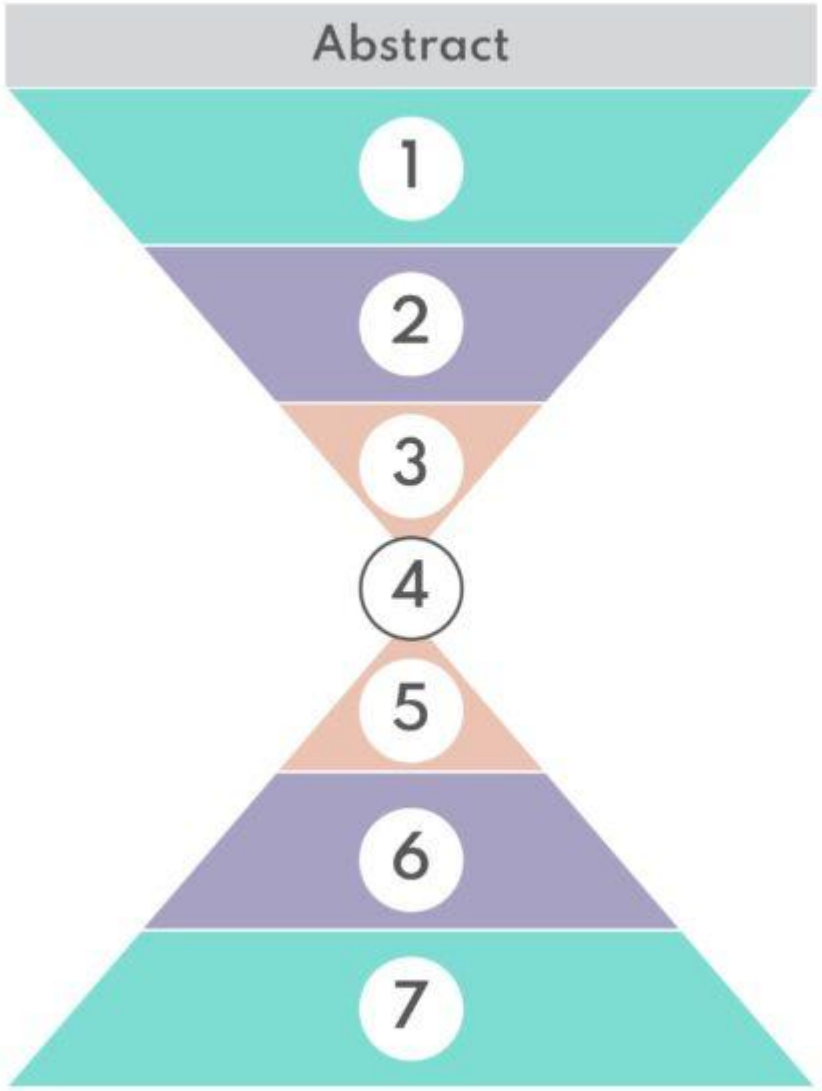
- Recommendations for Future Research:

Suggesting areas for further investigation based on the findings.

What are the steps of research process?

Research Process

Preparation of report



1. INTRODUCTION
What is known?
(Our understanding of the world)

2. What is unknown?
(What is the gap in knowledge?)

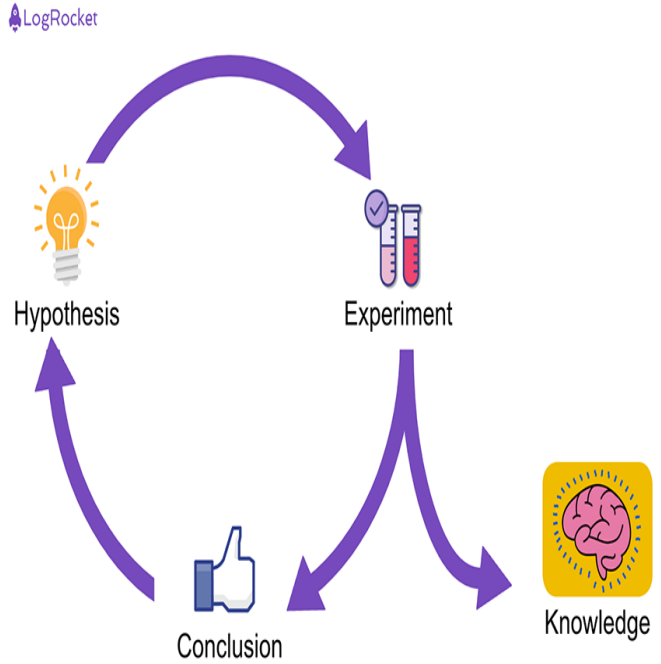
3. How and why should the gap be filled?
(The rationale/purpose/hypothesis)

4. METHODS
What was done?

5. RESULTS
What were the results?

6. DISCUSSION
How do the results fill the gap?

7. CONCLUSION
What does this mean going forward?



What are the steps of research process?

Research Process

Preparation of report

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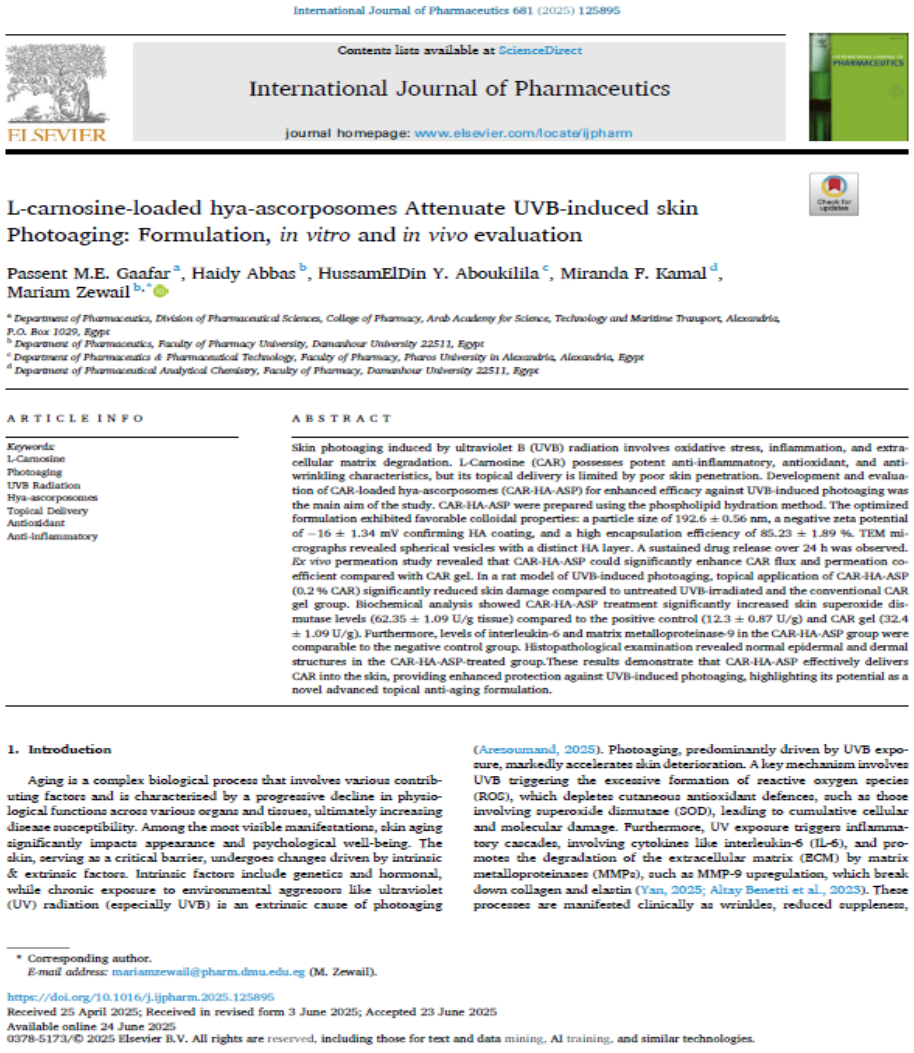
Examples of research paper



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L-carnosine-loaded hya-ascorposomes Attenuate UVB-induced skin Photoaging: Formulation, *in vitro* and *in vivo* evaluation

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ABSTRACT

Skin photoaging induced by ultraviolet B (UVB) radiation involves oxidative stress, inflammation, and extracellular matrix degradation. L-Carnosine (CAR) possesses potent anti-inflammatory, antioxidant, and anti-wrinkling characteristics, but its topical delivery is limited by poor skin penetration. Development and evaluation of CAR-loaded hya-ascorposomes (CAR-HA-ASP) for enhanced efficacy against UVB-induced photoaging was the main aim of the study. CAR-HA-ASP were prepared using the phospholipid hydration method. The optimized formulation exhibited favorable colloidal properties: a particle size of 192.6 ± 0.56 nm, a negative zeta potential of −16 ± 1.34 mV confirming HA coating, and a high encapsulation efficiency of 85.23 ± 1.89 %. TEM micrographs revealed spherical vesicles with a distinct HA layer. A sustained drug release over 24 h was observed. *Ex vivo* permeation study revealed that CAR-HA-ASP could significantly enhance CAR flux and permeation coefficient compared with CAR gel. In a rat model of UVB-induced photoaging, topical application of CAR-HA-ASP (0.2 % CAR) significantly reduced skin damage compared to untreated UVB-irradiated and the conventional CAR gel group. Biochemical analysis showed CAR-HA-ASP treatment significantly increased skin superoxide dismutase levels (62.35 ± 1.09 U/g tissue) compared to the positive control (12.3 ± 0.87 U/g) and CAR gel (32.4 ± 1.09 U/g). Furthermore, levels of interleukin-6 and matrix metalloproteinase-9 in the CAR-HA-ASP group were comparable to the negative control group. Histopathological examination revealed normal epidermal and dermal structures in the CAR-HA-ASP-treated group.These results demonstrate that CAR-HA-ASP effectively delivers CAR into the skin, providing enhanced protection against UVB-induced photoaging, highlighting its potential as a novel advanced topical anti-aging formulation.

1. Introduction

Aging is a complex biological process that involves various contributing factors and is characterized by a progressive decline in physiological functions across various organs and tissues, ultimately increasing disease susceptibility. Among the most visible manifestations, skin aging significantly impacts appearance and psychological well-being. The skin, serving as a critical barrier, undergoes changes driven by intrinsic & extrinsic factors. Intrinsic factors include genetics and hormonal, while chronic exposure to environmental aggressors like ultraviolet (UV) radiation (especially UVB) is an extrinsic cause of photoaging (Arezoumand, 2025). Photoaging, predominantly driven by UVB exposure, markedly accelerates skin deterioration. A key mechanism involves UVB triggering the excessive formation of reactive oxygen species (ROS), which depletes cutaneous antioxidant defences, such as those involving superoxide dismutase (SOD), leading to cumulative cellular and molecular damage. Furthermore, UV exposure triggers inflammatory cascades, involving cytokines like interleukin-6 (IL-6), and promotes the degradation of the extracellular matrix (ECM) by matrix metalloproteinases (MMPs), such as MMP-9 upregulation, which break down collagen and elastin (Yan, 2025; Altay Benetti et al., 2023). These processes are manifested clinically as wrinkles, reduced suppleness,

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Conclusion

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If you think research is expensive, try disease!

MARY LASKER