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Review Article

An Overview of Research Study Designs: Methodological Principles and Applications

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Abstract

Research study designs are the structural foundation of any empirical investigation, and the careful selection of an appropriate design is vital for producing credible and reproducible evidence. The choice of design greatly affects the internal and external validity and the overall strength of the conclusions drawn from a study. This paper comprehensively updates and simplifies the principles, classification, and applications of the major research study designs, providing evidence to assist researchers in selecting a design that matches their research question and resources. The differences between the principal observational designs—cross-sectional, cohort, case-control, case reports and series, and ecological studies—and the principal experimental designs—randomized controlled trials, quasi-experimental, pre-experimental, and crossover designs—are fully explained. Observational designs document exposures and outcomes as they naturally occur, while experimental designs involve the deliberate assignment of an intervention by the investigator. The quantification of associations is addressed through the relative risk, the odds ratio, incidence and prevalence measures, and the number needed to treat, together with their appropriate interpretation. The paper contributes both theoretical guidance and practical tools for selecting suitable designs and positioning evidence within the hierarchy of evidence. In sum, it sets a standard for best practice in research methodology that drives validity, reproducibility, and empirical rigour across diverse studies.

Keywords Research Study Designs · Observational Studies · Experimental Studies · Cohort Studies · Case-Control Studies · Randomized Controlled Trials · Hierarchy of Evidence · Relative Risk · Odds Ratio · Causal Inference · Research Methodology

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1. Introduction

The empirical study will be accurate and meaningful only when an appropriate research design is carefully selected. The study design is the framework, or the set of methods and procedures used to collect and analyse data, and it is core to research, since the validity and generalizability of findings depend on it (Ranganathan and Aggarwal, 2018). The success of any study would depend upon the appropriateness of its design.

The rationale for study designs is the capability of these frameworks to organize the collection of evidence in a way that allows the research question to be answered with the least possible error. This is very important and necessary in the health and social sciences, where the relationship between an exposure and an outcome must often be inferred from data collected under real-world constraints (Aggarwal and Ranganathan, 2019a). A properly chosen design would capture and enhance the internal and external validity of the findings.

Research designs are generally divided into two broad families: observational and experimental (Ranganathan and Aggarwal, 2019; Aggarwal and Ranganathan, 2019b). Observational designs, including cross-sectional, cohort, and case-control studies, document exposures and outcomes without any intervention by the investigator, who merely records events as they occur. Experimental designs, by contrast, involve the deliberate assignment of an intervention by the investigator, with the randomized controlled trial regarded as the reference standard. An observational study can suggest associations, but a well-conducted experimental study is generally required to establish causation (Grimes and Schulz, 2002a).

The selection of an appropriate study design is intrinsically identified with a few specific research goals, the nature of the exposure and outcome under study, and some methodological and ethical limitations of the study. Proper selection of the design bears great relevance to the validity and reproducibility of the study outcomes. This calls for wide-ranging acquaintance with the different designs and their consequences on the part of the researcher who intends to be methodologically correct.

The article tried to discuss various approaches to research study designs, and to determine the most appropriate measures of association so that the researcher may choose the best fit for a particular research situation. This paper will attempt to give a close look at the strengths and limitations of the different designs in promoting best practices of research and enhancing empirical rigour.

2. The research design selection process

The design selection process is one of the most important parts of the research methodology, through which the accuracy and validity of findings from a study are guaranteed (Grimes and Schulz, 2002b). This process starts with the clear formulation of the research question, which could be any well-defined query relating to an exposure, an outcome, or their association. Defining clearly and properly what constitutes the research question is highly important to make sure that the chosen design can actually answer it. The research question means a statement that should reflect the population, the exposure or intervention, the comparison, the outcome, and every other feature which could be relevant for the design.

Having defined the research question, the next process is the determination of the nature of the inquiry. In view of research goals and resources and a need for causal inference, researchers have to decide whether the study is descriptive or analytical, and whether it is observational or experimental. The justification for preference, if the objective is to estimate the effect of an intervention, normally favours an experimental design, whereas an observational design is generally adopted when intervention is impractical, unethical, or when the exposure cannot be manipulated.

Once the broad category is effected, the specific design has to be selected by the researcher, and this is taken as vital for the credibility of the results. In selecting the design, several factors may be important: the prevalence of the outcome, the latency between exposure and outcome, the availability of existing data, and the resources at hand. This can be achieved with the help of methodological frameworks or algorithms in order not to adopt a design that is either underpowered or unsuited to the research question.

Feasibility and ethical appraisal refer to the stage where the practical and moral constraints will decide whether the chosen design can be implemented as planned. This could be done through assessment of cost, time, sample availability, and ethical approval in the case of interventional studies. In simpler studies, it could be related to ensuring access to records or clarifying the eligibility criteria relevant to the study at hand.

Finally, the researcher must plan the data collection and analysis appropriate to the design, taking into consideration that no conclusion can be made if the design is not considered. In other words, it is to have in mind how much bias and confounding the design can contain, or where the limitation is and whether the results can be generalized. A formal design plan will enable the researcher to enhance the

validity and reproducibility of the results and, therefore the accuracy and meaningfulness of his conclusions. Steps of the process are presented in Fig. 1.

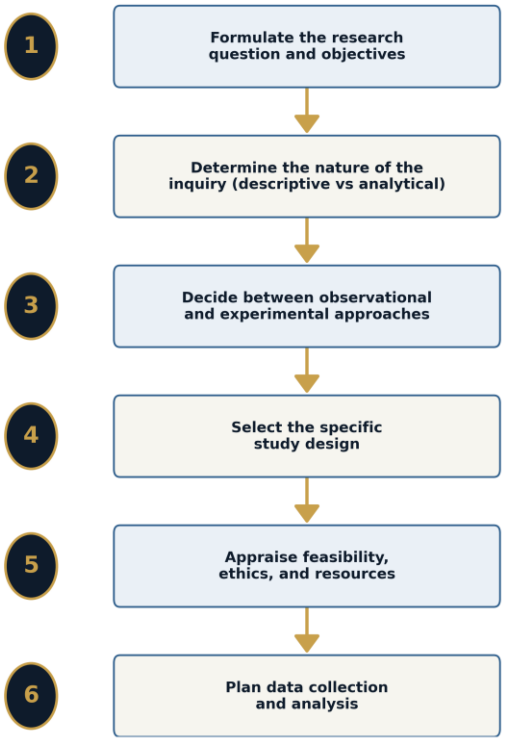

Figure 1. Steps in selecting a research study design.

3. Types of research study designs

Differentiating between the two, observational and experimental designs are mainly two different but complementary families adopted in research for the generation of evidence (Schulz and Grimes, 2002). Each has its own forms and procedures. Observational designs allow the investigator to study exposures and outcomes as they occur naturally, without any manipulation. The absence of intervention in this approach makes the findings reflect real-world conditions, though it leaves them more vulnerable to confounding. Observational designs provide the researcher with the opportunity to study associations where experimentation is impractical or unethical. Examples of designs falling under this category include cross-sectional, cohort, and case-control studies. While observational designs are versatile, they tend to be limited in establishing causation, since uncontrolled factors may distort the observed associations.

On the contrary, experimental designs involve the deliberate assignment of an exposure or intervention by the investigator, who controls who receives it. This is mainly used when the researcher seeks to establish a causal relationship between an intervention and an outcome. Some of the experimental designs include randomized controlled trials, quasi-experimental, and crossover designs, in which the allocation of the intervention by the investigator is depended on. This latter family, while more demanding and resource-intensive, has the strength of minimizing confounding and providing the strongest evidence of cause and effect.

Where the research situation calls for a high degree of certainty about causation, an experimental design is preferred. Only in situations where experimentation is impractical, unethical, or premature can one resort chiefly to observational designs when feasibility or ethics turn out to be more important than the strength of causal inference. Both families have a place in research, but the choice of one or the other depends upon research objectives, resources, and needs regarding causal inference. Fig. 2 and Table 1 summarize the types of observational and experimental designs in detail, together with a number of advantages and disadvantages associated with each. This should be helpful in enabling the researcher to choose the most appropriate design for their studies.

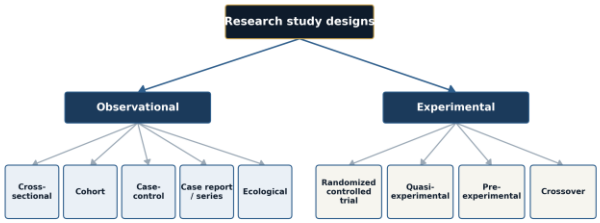

Figure 2. Types of research study designs.

Table 1. Pros and cons of observational and experimental study designs.

Design	Pros	Cons
Cross-sectional study	1. Quick and inexpensive to conduct. 2. Good for estimating prevalence. 3. Can study several exposures at once.	1. Cannot establish temporal sequence. 2. Unsuitable for rare conditions.
Cohort study	1. Establishes the exposure–outcome sequence. 2. Yields incidence and relative risk. 3. Can examine multiple outcomes.	1. Costly and time-consuming. 2. Vulnerable to loss to follow-up.
Case-control study	1. Efficient for rare outcomes. 2. Quick and relatively inexpensive. 3. Can study multiple exposures.	1. Prone to recall and selection bias. 2. Cannot calculate incidence directly.
Case report / series	1. Useful for novel or rare conditions. 2. Quick to produce and hypothesis-generating. 3. Rich clinical detail.	1. No comparison group. 2. Cannot test associations or causation.
Ecological study	1. Uses readily available population data. 2. Useful for generating hypotheses. 3. Inexpensive and rapid.	1. Subject to the ecological fallacy. 2. Cannot link exposure and outcome individually.
Randomized controlled trial	1. Strongest design for causal inference. 2. Randomization minimizes confounding. 3. Allows blinding to reduce bias.	1. Expensive and ethically constrained. 2. May lack external validity.
Quasi-experimental design	1. Useful when randomization is not feasible. 2. Can evaluate real-world interventions. 3. More practical than a full trial.	1. Greater risk of confounding. 2. Weaker causal inference than an RCT.
Pre-experimental design	1. Simple and inexpensive to run. 2. Useful for preliminary or pilot work. 3. Quick to implement.	1. No control group or randomization. 2. Very weak evidence of effect.
Crossover trial	1. Each participant serves as own control. 2. Requires fewer participants. 3. Controls between-subject variability.	1. Risk of carryover effects. 2. Unsuitable for conditions that change or resolve.

3.1. Observational study designs

3.1.1. Cross-sectional studies

Cross-sectional studies, although conceptually basic, are an effective method of measuring the exposure and the outcome in a population at a single point in time. Following the selection of participants based on inclusion and exclusion criteria, the investigator records the presence of the exposure and the outcome simultaneously. This design is highly valued because it is quick and inexpensive and provides estimates of prevalence, although it might be very limited in practice, especially when the temporal sequence between exposure and outcome cannot be established, so that cause and effect cannot be distinguished.

3.1.2. Cohort studies

In cohort studies, groups of participants are classified according to their exposure status and then followed forward in time to determine the incidence of the outcome. The investigator compares the rate of new cases between exposed and unexposed groups, commonly expressing the result as a relative risk. This increases the strength of the evidence, given that the exposure is measured before the outcome, thereby making this design more suitable for studying incidence, prognosis, and multiple outcomes. However, it is costly and time-consuming, and may be inefficient for rare outcomes.

3.1.3. Case-control studies

Case-control studies are a method of identifying associations by starting from the outcome and working backwards to the exposure. Participants with the outcome (cases) are compared with participants without it (controls) for their prior exposure, and the result is expressed as an odds

ratio. It will be very useful in the study of rare outcomes and conditions with a long latency, since it avoids prolonged follow-up. Though efficient, case-control studies might be reduced in validity by recall bias and by difficulty in selecting an appropriate control group.

3.1.4. Case reports and case series

In case reports and case series, the investigator describes the clinical features, course, or outcome of a single patient or a small group of patients. It is efficient for documenting novel, rare, or unexpected conditions and for generating hypotheses that can later be tested with stronger designs. Case reports and series may be valuable for early signals, however, because they lack a comparison group, they cannot be used to test associations or to establish causation.

3.1.5. Ecological studies

In ecological studies, the unit of analysis is a population or group rather than the individual, and exposure and outcome are compared at the aggregate level, for instance across regions or time periods. The use of routinely collected population data is useful in generating hypotheses quickly and inexpensively about possible determinants of disease. While this may save resources, the inference can be distorted by the ecological fallacy, since associations observed at the group level may not hold at the individual level.

3.2. Experimental study designs

3.2.1. Randomized controlled trials

Of the various experimental designs, the randomized controlled trial concerns the assignment of participants to an intervention or a control group by a random process (Akobeng, 2005). This is normally regarded as the reference standard for evaluating effectiveness, since randomization balances known and unknown confounders between the groups and blinding reduces bias. However, in most instances, this design introduces practical and ethical constraints, since it is costly, time-consuming, and cannot be used where withholding an intervention would be harmful.

3.2.2. Quasi-experimental designs

In quasi-experimental designs, an intervention is evaluated without random allocation, for example by comparing groups formed by setting, time, or policy. This is normally used when randomization is impractical or unethical, yet the investigator still wishes to assess the effect of an intervention. Though the method can evaluate real-world interventions, it carries a higher risk of confounding and therefore provides weaker evidence of causation than a randomized trial.

3.2.3. Pre-experimental designs

Pre-experimental designs, such as the one-group before-and-after study, assess an intervention without a control group or randomization. They are simple, quick, and inexpensive, and are often used for preliminary or pilot work before a more rigorous study is undertaken. However, the absence of a comparison group means that observed changes cannot be confidently attributed to the intervention, so these designs provide very weak evidence of effect.

3.2.4. Crossover trials

In crossover trials, each participant receives the competing interventions in succession, so that the participant serves as their own control. It is efficient for reducing between-subject variability and for requiring fewer participants than a parallel-group trial. Crossover trials may be challenging, however, because carryover effects between treatment periods must be controlled, and the design is unsuitable for conditions that are progressive or that resolve during the study.

4. Measures of association and the hierarchy of evidence

The quantification of associations is vital in research for trustworthy and interpretable results (Mann, 2003; Concato et al., 2000). In expressing the relationship between an exposure and an outcome, applying the correct measure ensures that the strength of the association can be compared across studies and positioned within the hierarchy of evidence (Thiese, 2014).

4.1. Relative risk

Among all measures used in research, perhaps the most common for cohort designs is the relative risk (Grimes and Schulz, 2002b). A commonly used formula is:

$$RR = [\, a / (a + b) \,] / [\, c / (c + d) \,]$$

Where:

- RR = relative risk (risk ratio),
- a = exposed participants with the outcome, b = exposed without the outcome,
- c = unexposed participants with the outcome, d = unexposed without the outcome.

This measure is applied when a researcher is interested in the ratio of the risk of an outcome in an exposed group to that in an unexposed group, such as in a cohort study. A relative risk greater than 1 indicates an increased risk, whereas a value below 1 indicates a protective effect.

4.2. Odds ratio

The measure for the strength of association in case-control studies, where the risk cannot be calculated directly, is given by the odds ratio:

$$OR = (\, a \times d \,) / (\, b \times c \,)$$

Where:

- OR = odds ratio,

- *a*, *b*, *c*, *d* = cell counts of exposure and outcome in a 2 × 2 table.

This is an important measure when one is working with case-control studies. The further the odds ratio departs from 1, the stronger the association between the exposure and the outcome; a value of 1 indicates no association.

4.3. Incidence rate

The incidence rate is normally used when the occurrence of new cases over time has to be quantified in a cohort or longitudinal design (Grimes and Schulz, 2002b). The general formula for the calculation:

IR = (number of new cases) / (total person-time at risk)

Where:

- IR = incidence rate,
- number of new cases = new events arising during the observation period,
- total person-time at risk = the sum of the time each participant is at risk.

The incidence rate is widely applied when a cohort or longitudinal design is used, in which the researcher follows participants over time.

When the incidence in two groups is compared, the measure has to be extended by the incidence rate ratio. This is done in the following manner:

IRR = IRexposed / IRunexposed

Where:

- IRR = incidence rate ratio,
- IRexposed, IRunexposed = incidence rates in the exposed and unexposed groups.

This will summarize the relative speed at which new cases arise in the exposed compared with the unexposed group.

4.4. Prevalence

Prevalence is used when the burden of an existing condition is measured at a single point in time, typically in a cross-sectional design. The proportion can be determined as follows:

P = (number of existing cases) / (total population at a given time)

Where:

- P = prevalence,
- number of existing cases = all individuals with the condition at the time of measurement,
- total population = all individuals examined at that time.

This would ensure that the burden of a condition is expressed as a proportion of the population. Prevalence is useful in a situation where a cross-sectional design is the primary source of data.

4.5. Number needed to treat

The number needed to treat is one of the common methods used to express the clinical impact of an intervention in a trial (Aggarwal and Ranganathan, 2019b). This measure is derived from the absolute risk reduction between the experimental and control groups. For using this method, the event rates in the two groups are first determined.

The formula for the number needed to treat is:

NNT = 1 / ARR, where ARR = CER − EER

Where:

- NNT = number needed to treat,
- ARR = absolute risk reduction,
- CER = control event rate, EER = experimental event rate.

4.6. The role of the hierarchy of evidence

One common means of easing the interpretive burden in appraising study designs is through the use of the hierarchy of evidence (Burns et al., 2011). This hierarchy generally provides a ranking of designs according to their susceptibility to bias, from systematic reviews and randomized controlled trials at the top to case reports and expert opinion at the base. Such a hierarchy provides quick reference points for researchers and readers who may want to judge the strength of evidence for a certain question without necessarily relying on a single study (Tables 2 and 3).

Table 2. Hierarchy of evidence by research study design.

Level	Study design / source	Description
I	Systematic review / meta-analysis of RCTs	Highest quality; synthesises multiple trials
II	Individual randomized controlled trial	Strong causal inference with low bias
III	Controlled trial without randomization / quasi-experimental	Moderate causal inference
IV	Cohort study	Good for incidence and prognosis; prone to confounding
V	Case-control study	Efficient for rare outcomes; prone to recall and selection bias
VI	Cross-sectional study / descriptive survey	Estimates prevalence; no causal inference
VII	Case report, case series, or expert opinion	Hypothesis-generating; lowest level of evidence

Adapted from Burns et al. (2011) and Concato et al. (2000).

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Table 3. Common measures of association and their interpretation by study design.

Measure	Typical design	Interpretation
Relative risk (RR)	Cohort study / RCT	RR = 1 no effect; > 1 increased risk; < 1 protective
Odds ratio (OR)	Case-control study	OR = 1 no association; > 1 positive; < 1 negative
Incidence rate	Cohort study	New cases per unit of person-time at risk
Incidence rate ratio (IRR)	Cohort study	Ratio of incidence between exposed and unexposed
Prevalence	Cross-sectional study	Proportion with the condition at a point in time
Hazard ratio (HR)	Cohort / RCT (survival)	Relative hazard of an event over follow-up
Absolute risk reduction (ARR)	Randomized controlled trial	Difference in event rates between groups
Number needed to treat (NNT)	Randomized controlled trial	Patients treated to prevent one event; lower is better
95% confidence interval	All analytical designs	Precision of the estimate; excludes the null if significant

Sources: Grimes and Schulz (2002); Mann (2003); Akobeng (2005).

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4.7. Factors affecting the choice of study design

The choice of a study design is determined by a number of factors. First, there is the research question and its objectives; whether the aim is to describe, to find associations, or to establish causation will largely dictate the design. Second, the nature of the exposure and outcome significantly influences the design; rare outcomes favour case-control designs, whereas rare exposures favour cohort designs. Other important considerations include the time and resources available – longitudinal designs are more demanding than cross-sectional ones. The ethical acceptability of the study might also affect the design; interventions that could cause harm cannot be tested experimentally. It is equally important to look at the prevalence of the condition and the need for causal inference, since these shape both feasibility and the strength of the conclusions. Any research setting – clinical, community, or laboratory – will further stipulate the design requirements. Lastly, the risk of bias and confounding must be weighed, since an inappropriate design may produce results that are confidently misleading. The said factors, if considered with due deliberation, will lead a researcher to a design that is both feasible and valid. The factors affecting the choice of study design are illustrated in Fig. 3.

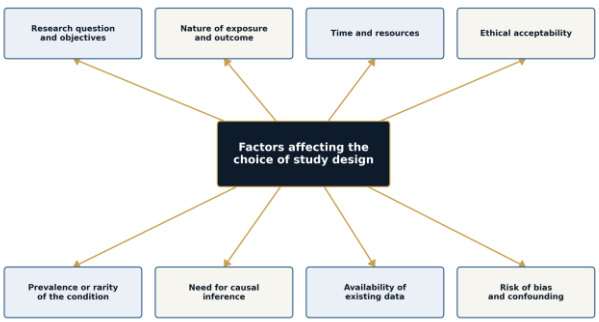

Figure 3. Factors affecting the choice of study design.

5. Conclusion

The precision of methodology in research depends on the careful selection of an appropriate study design. Observational designs, for example cross-sectional, cohort, and case-control studies, are thus fundamental in those studies that aim to describe distributions or to detect associations under real-world conditions. By contrast, experimental designs, through randomized and quasi-experimental approaches, provide the strongest evidence for causal relationships between interventions and outcomes. Accurate quantification of associations is a very important step in any research project. This factor has a great bearing on the statistical power and the precision of conclusions that may be drawn from any study. Designs that are poorly matched to the research question cannot yield conclusive results, whereas designs that appear rigorous but are biased may produce confident yet misleading conclusions. Measures such as the relative risk, the odds ratio, incidence and prevalence, and the number needed to treat, together with the hierarchy of evidence, remain some of the key tools that help researchers ensure their designs facilitate strong findings. In that respect, the methodological guidelines include ways a researcher can contribute to the advance of scientific knowledge by setting up works that other researchers will refer to as foundational for many years to

come. This guide hopefully sets a benchmark with regard to research methodology and thus serves as a reference point for scholars committed to the production of work of the highest empirical and theoretical standards, with an ultimate aim of globally increasing the impact and citation potential of the research.

Statements and Declarations

Ethics Approval

Ethical approval was not required, as the study conducted did not involve any ethical concerns or issues.

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Data Availability

No data were used in the research described in this article.

CRediT Authorship Contribution Statement

Rebar Yahya Abdullah: Conceptualization, Data curation, Supervision, Writing – original draft, Writing – review and editing.

Declaration of Competing Interest

The author declares that he has no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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