Nursing Research Series

Essentials of Science:
Methods, Appraisal and Utilization

Southern California Nursing Research

©Kaiser Permanente Southern California Nursing Research
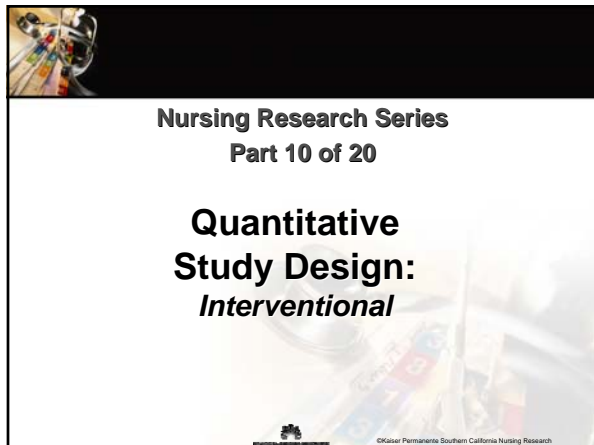

Nursing Research Series
Part 10 of 20

Quantitative Study Design:
Interventional

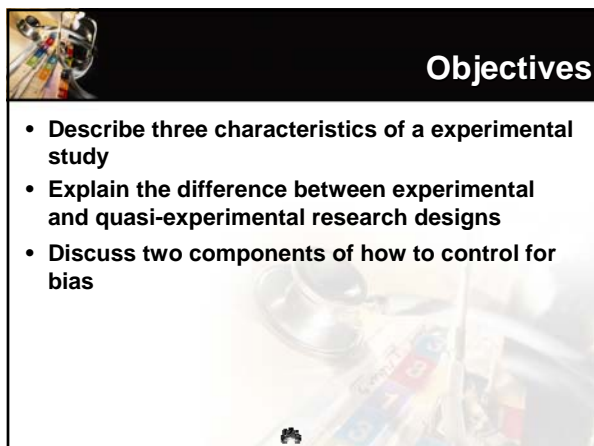©Kaiser Permanente Southern California Nursing Research

---

Objectives

- Describe three characteristics of a experimental study
- Explain the difference between experimental and quasi-experimental research designs
- Discuss two components of how to control for bias

Research Design Blueprint

- Action plan for conducting research study
  - Techniques and procedures
  - Reduces researcher bias
  - Controls for extraneous variables
  - Controls for other sources of variances

- Produces credible, high quality research findings
  - Clear and detailed
    - Understand study aim & purpose
    - How research was conducted
    - Evaluate the research process
    - Reproduce research study

Research Design

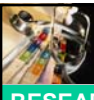| APPROACH	TYPES	DESIGN
QUALITATIVE (discovers)	PHENOMENOLOGICAL GROUNDED THEORY ETHNOGRAPHIC HISTORICAL PHILOSOPHICAL	See Module 8
QUALITATIVE or QUANTITATIVE (describes)	CORRELATIONAL DESCRIPTIVE	Nonexperimental (Observational)
QUANTITATIVE (explains; cause & effect)	EXPERIMENTAL QUASIEXPERIMENTAL	Experimental

Terminology

RESEARCH APPROACH	SOCIAL SCIENCE TERM	MEDICAL RESEARCH TERM
QUANTITATIVE	EXPERIMENTAL	Randomized Control Trial; Randomized Clinical Trial (RCT)
	QUASIEXPERIMENTAL	Controlled Trial; Controlled Trial without randomization
	NONEXPERIMENTAL: DESCRIPTIVE CORRELATIONAL RETROSPECTIVE PROSPECTIVE	Observational Studies Case-Series Case-Control Cross-Sectional Cohort Prevalence Incidence

Quasi- Experimental Research vs. Experimental Research

Quasi-Experimental Research:
- Examines the causal relationships or determines the effect of one variable on another
- Involve implementing a treatment and examining the effects of this treatment using select methods of measurement
- Lack a certain level of control over:
  - the manipulation of the treatment
  - the setting
  - the subject selection

Quasi- Experimental Research vs. Experimental Research

Experimental Research:
- An objective, systematic, highly controlled investigation for the purpose of predicting and controlling phenomena in nursing practice
- Causality between the independent and dependent variables is examined under highly controlled conditions
- Considered the most powerful quantitative method due to the rigorous control.

Quasi-Experimental Research Design

Quasi-experimental study designs vary widely
- Pretest and Posttest
  - The researcher has a group of subjects who receive the experimental treatment (intervention) and the comparison group who receive no treatment

Quasi-Experimental Research Design

Posttest-only:
- **Used in situations where a pretest is not possible**
- **Example of pain during a painful procedure**

Experimental Research Design

- **Three main components are:**
  - **Controlled manipulation of at least one treatment variable (the independent variable)**
  - **Exposure of some of the subjects to the treatment (experimental group), and no exposure of the remaining subjects (control group)**
  - **Random assignment of subjects to either the control group or the experimental group**

Experimental Research Design

•**Pretest and Posttest with Multiple groups**
- **One control group could receive no treatment, and another control group could receive a placebo treatment.**
- **Each of the multiple experimental groups could receive a variation of the treatment such as:**
  - **Different frequency**
  - **Intensity**
  - **Duration of nursing care measures**

To Consider

- **Control**
- **Variance in experimental design**
- **Bias**

Control in Quantitative Research

Control involves the imposing of rules by the researcher\to decrease the possibility of error, which in turn increases the probability that the findings are an accurate reflection of reality

Type of Research	Researcher Control	Research Setting
Descriptive	Uncontrolled	Natural or partially controlled
Correlational	Uncontrolled or partially controlled	Natural or partially controlled
Quasi-Experimental	Partially controlled	Partially controlled
Experimental	Highly controlled	Laboratory or research unit

Variance in Experimental Designs

- **Systematic Variance: Variance due to the effect of the Independent Variable on the Dependent Variable.**
- **Extraneous Variance: Nuisance Variance; Controlled by Randomization**
- **Error Variance: Variability due to random fluctuations; Controlled by Standardization of Experimental Condition and Reliability of Instruments**

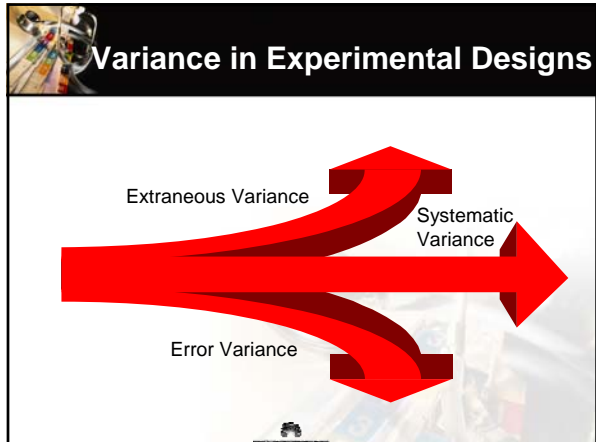### Variance in Experimental Designs

Extraneous Variance

Systematic Variance

Error Variance

Bias

Bias is defined as *a slant or deviation from the true or expected*

- **Any component of a study that deviates or causes a deviation from the true measurement of the study variables contributes to distorted findings**
- **An important focus in critiquing a study is to identify possible sources of bias**

Bias

Factors related to research that can be biased:
- **Attitudes or motivation of the researcher**
- **Environment**
- **Selection of the individual subjects**
- **Composition of the sample**
- **The groups formed**
- **The measurement tools**
- **The data collection process**
- **The data**
- **Statistics**

Nursing Research Series
Essentials of Science: Methods, Appraisal and Utilization

Controlling for Bias

A method of controlling bias is to increase the amount of control in the design:

- – The greater the researchers control over the study situation, the more credible the study findings.

- **Blinding:** The experiment group and control group are not aware of which received which the intervention.
  - – In medicine, a placebo effect is a form of bias
- **Randomizing the sample:** In randomized controlled trials, the research participants are assigned by chance, rather than by choice, to either the experimental group or the control group

---

Randomized Clinical Trials

RESEARCH APPROACH	SOCIAL SCIENCE TERM	MEDICAL RESEARCH TERM
QUANTITATIVE	EXPERIMENTAL	Randomized Control Trial; Randomized Clinical Trial (RCT)
	QUASIEXPERIMENTAL	Controlled Trial; Controlled Trial without randomization

A randomized clinical (RCT) is not often seen in nursing

Randomized Clinical Trials

An RCT uses large numbers of subjects to test the effects of a treatment and compare the results with those of a control group that has not received the treatment (or that has not received a traditional treatment)

Subjects are drawn from a reference population using clearly defined criteria and are randomly assigned to treatment or control groups.

Validity of Randomized Trials

- The validity of a randomized control trial depends greatly on the process of randomization.
- Randomization insures that both measurable and unmeasurable factors will balance out on average.
- If a factor other than the treatment itself could possibly influence an outcome measure in your study, then randomization insures that patients with this factor are equally likely to receive either the treatment or the placebo.
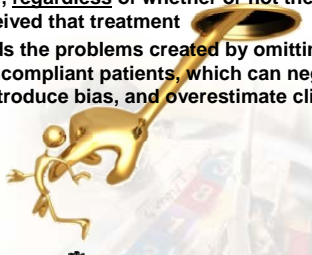- This prevents many types of bias that can occur in a non-randomized trial.

Intention-To-Treat Analysis (ITT)

- A method of analysis for randomized trials in which all patients randomly assigned to one of the treatments are analyzed together, underlinedregardless of whether or not they completed or received that treatment
- ITT analysis avoids the problems created by omitting dropouts and noncompliant patients, which can negate randomization, introduce bias, and overestimate clinical effectiveness

Number Needed to Treat (NNT) / Number Needed to Harm (NNH)

- The NNT is the number of patients who need to be treated in order to prevent one additional bad outcome (i.e. the number of patients that need to be treated for one to benefit compared with a control in a clinical trial)
  - These are sometimes used for specific purposed- such in vaccinations

Number Needed to Treat (NNT) / Number Needed to Harm (NNH)

- **The NNH indicates how many patients need to be exposed to a risk factor over a period to cause harm in one patient that would not otherwise have been harmed**
  - **The NNH is an important measure in evidence based medicine and in deciding whether it is prudent to proceed with a particular treatment which may expose the patient to harms while providing therapeutic benefits.**

Summary/ Conclusion

- **Defined the term "Design"**
- **Identified the Defining Characteristics of**
  - **Experimental and Quasi-Experimental Design**
- **Discussed Control**
- **Discussed Variance**
- **Discussed Bias**
- **Randomized Clinical/Control Trials**
- **Touched on the terms of NNT/NNH**

References to Consider

- Burns, N. & Grove, S.K (2007). *Understanding Nursing Research, building an Evidence-Based Practice 4th Edition.* St. Louis, Missouri: Saunders.
- Campbell, D. T., and Stanley, J. C.(1966) *Experimental and Quasi-experimental Designs for Research.* Chicago: Rand McNally.
- Harris, M. & Taylor, G. (2008). *Medical Statistics Made Easy, 2nd Edition.* Oxfordshire: Scion Publishing
- Polit, D. F., & Beck, C. T. (2008). *Nursing Research: Generating and assessing evidence for nursing practice* (8th ed.). Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins.
- Sidani, S. & Braden, C.J. (1998). Evaluating nursing interventions: A theory-driven approach. Thousand Oaks: Sage Publications.

Nursing Research Series
Essentials of Science: Methods, Appraisal and Utilization

References to Consider

For more information please contact:
Nursing.Research@kp.org
http://nursingpathways.kp.org/scal/research/index.html

Southern California Nursing Research

©Kaiser Permanente Southern California Nursing Research

_____

_____

_____

_____

_____

_____

_____