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Quantitative Research

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Randomized Control Design (RCT)

- Is the gold standard of all studies
- Is prospective

- Two or more groups assigned by randomization
- Take baseline measure on all groups

- Give different treatments
- Measure outcome
Schemata

- Group 1: O1  X1  O2
- Group 2: O1  X2  O2
- Where O= Observation
- Where X= Treatment
Types of Clinical Trials (1)

- **Treatment trials** test experimental treatments, behavioral therapies, new combinations of drugs, or new approaches to surgery or radiation therapy.

- **Prevention trials** look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning:
  - These approaches may include medicines, vitamins, vaccines, minerals, or lifestyle changes.
Types of Clinical Trials (2)

- **Diagnostic trials** are conducted to find better tests or procedures for diagnosing a particular disease or condition.

- **Screening trials** test the best way to detect certain diseases or health conditions.

- **Quality of life trials** (also called supportive care trials) explore ways to improve comfort and the quality of life for individuals with a chronic illness.
• Decide inclusion and exclusion criterion
  - Example of inclusion criterion: “All newly diagnosed head and neck cancer patients with squamous cell carcinoma that smoke”
  - Example of exclusion criterion: “Those who are terminally ill, mentally or cognitively unstable, pregnant, etc.”

• Exclusion criterion control for errors
Randomization (1)

- Assigned to groups by method similar to “flipping a coin”
- If randomization works, groups will be the same/comparable
- The larger the sample, the greater the likelihood of equal groups

- Results should show that the demographic characteristics between groups are similar
- If groups are similar, do not need to control for extraneous variables
Randomization (2)

- Some times cannot randomize people (e.g., cross-contamination or “system” interventions)
- Can randomize hospitals, or units instead
  - For example, testing clinical reminder systems
- Once randomized, always randomized
- Subjects are treated as part of that group, even if they die, are lost to follow up, or withdraw
Fidelity Checks

- Did the investigator make sure the intervention was delivered as it was supposed to be delivered?

- Becomes more of an issue when having multiple sites with multiple providers of the intervention

- Important to provide training and booster sessions and making spot checks
Blinding

- Un-blinded: Everyone knows treatment
- Single Blinded: Researcher or patient does not know treatment
- Double Blinded: Neither researcher or patient knows treatment

Why blinding?
- Many people believe they feel better if they are given something
- This is the placebo effect
Double Blind Example

- **Patient:**
  - Patient agrees that he will be randomized to one of 4 smoking cessation treatments
  - None of these 4 smoking cessation treatments are known to be better than the other

- **Provider:**
  - Providers do not know that patients are assigned to groups
  - Hire different people to run each group and do not tell them about the study
Intervention/Treatment

- Treatment versus placebo
- Treatment versus standard of care

- Treatments should be made to be as same as possible
  - For example, new drug versus sugar pill
### Four Arm Study Example: Factorial Design

<table>
<thead>
<tr>
<th>Cessation counseling and meds</th>
<th>Cessation counseling only</th>
</tr>
</thead>
<tbody>
<tr>
<td>40% quit rate</td>
<td>10% quit rate</td>
</tr>
<tr>
<td>Cessation meds only</td>
<td>Placebo group</td>
</tr>
<tr>
<td>35% quit rate</td>
<td>Nothing or</td>
</tr>
<tr>
<td></td>
<td>Blank patch + Attention Control</td>
</tr>
<tr>
<td></td>
<td>6% quit rate</td>
</tr>
</tbody>
</table>
Outcome Variable

- The outcome variable should be the same as pretreatment measure
- For example,
  - Pretreatment: Smoked within the last 24 hours
  - Post treatment: Smoked within the last 24 hours at the 7th day and the 30th days

- Could have short-term and long term outcomes
  - Short-term: Quit rate
  - Medium-term: 1-year quality of life
  - Long-term: Survival rate
Randomized Cross-Over Design

- 2 groups, each get a different treatment
- Washout period

- Give each group the other treatment
  - O1 X1 O2  washout  O3 X2 O4
  - O1 X2 O2  washout  O3 X1 O4

- Advantage
  - Can not only compare between groups, but also within groups
  - Subjects serve as their own controls
  - Controls for extraneous variables

- Not a common design
Phases of Clinical Trials (1)

- **Phase I trials** (a pilot study): Researchers test an experimental drug or treatment in a small group of people (5-60 subjects) for the first time to
  - Evaluate its safety
  - Determine a safe dosage range
  - Identify side effects

- **Phase II trials** (a larger pilot study): The experimental study drug or treatment is given to a larger group of people (100 subjects) to see if it is effective and to further evaluate its safety
Phases of Clinical Trials (2)

- **Phase III trials** (RCT): The experimental study drug or treatment is given to large groups of people (200-3,000 subjects) to
  - Confirm its effectiveness
  - Monitor side effects
  - Compare it to commonly used treatments
  - Collect information that will allow the experimental drug or treatment to be used safely

- **Phase IV trials** (implementation research):
  - Post marketing studies
  - Delineate additional information, including: the drug's risks, benefits, and optimal use
Non-Randomized Comparison Group

- Next best thing to RCT
- Used when we cannot randomize our subjects
  - For example, due to cross-contamination, or facility- or community-level interventions
- Make sure groups are as similar as possible
Non-Randomized Cross-Over Design

- Same as the previously described randomized cross-over design
- But groups are not randomized

- O₁ X₁ O₂  washout  O₃ X₂ O₄
- O₁ X₂ O₂  washout  O₃ X₁ O₄
Case Control Study

- Quick and dirty, but able to obtain lots of information
- Used in epidemiology to look at exposures
- Retrospective or prospective
- Has a comparison group

- Sometimes, does not control for extraneous variables
- Sometimes, controls for by matching
- Sometimes, nested in a larger study (e.g., nested case control)
## Non-Matched Case Control Example

<table>
<thead>
<tr>
<th></th>
<th>Worked in Coal Mine N=20</th>
<th>Did not work in Coal Mine N=20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black Lung-Yes</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Black Lung-No</td>
<td>10</td>
<td>20</td>
</tr>
</tbody>
</table>

Quantitative Research
Matched Case Control Examples

- **Example 1:** Want to look at the beta carotene blood levels of the head-neck cancer patients, smokers compared to non-smokers
  - Match on age, gender, race, BMI, fruit and vegetable intake, cancer site, cancer stage
  - Please also see next slide

- **Example 2:** Want to look at the effect of Doulas on birth outcomes for pregnant adolescents
  - Match on age, race, BMI, provider type, gestational age, pregnancy complications
Matched Case Control Example 1

<table>
<thead>
<tr>
<th></th>
<th>Smoked N=30</th>
<th>Not Smoke N=30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta carotene High</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>Beta carotene Low</td>
<td>50%</td>
<td>50%</td>
</tr>
</tbody>
</table>
Historical Controls (1)

- Not the best design
- Better than no comparison group

- Look at a group before an intervention was implemented compared to after an intervention was implemented
- Comparison not at same time
Historical Control (2)

- **Example 1:**
  - Initiation of skin to skin contact following delivery on temperature, breast feeding rates and blood sugar
  - Looks at those outcome prior to the intervention and then after this intervention was initiated

- **Example 2:**
  - Infections rates in the OR before and after a new protocol implemented
  - Compare old rates to new rates
  - O1  O2  O3  O4  X  O5  O6  O7
    - Where O=Observation of infection rate
    - Where X= New operating room procedures
One Group Pre-post Design

- $O_1 \times O_2$
- Used a lot in nursing
- Not a good design because there is no comparison group
- Biggest drawback is it cannot control for historical effect
Cross-Sectional Design

- Takes a measure of a population at a certain point in time (e.g., a survey research)
- Descriptive
- Are easy, fast, and inexpensive
- Can determine prevalence of disease
- Can look at associations between variables
- Cannot determine cause and effect
Cohort Study

- Tim series, longitudinal, repeated measures
- Repeated cross-sectional measures over time
- O₁ O₂ O₃

- Could have a repeated measures design with a comparison group
- Can determine changes in population
- Can determine cause and effect
- Are expensive and take a long time
- Example: Nurses Health Study
Nested Design

- Cohort Study nested within a repeated measures design
- Example: Followed up 600 head-neck cancer patients over time
- Did case-control study (n=60) to see if beta carotene blood levels were different between smokers and nonsmokers
Definitions

- **Causality**
  - Correlation between 2 factors
  - Cause must precede effect
  - Cause is always present when effect occurs

- **Multi-causality** (e.g., smoking, diet, and genes all may cause heart disease)

- **Probability**

- **Bias**—slant from truth

- Reduce bias by blinding or randomization
Summary of Quantitative Designs

- **Experimental**
  - RCT
  - Cross-over RCT
- **Quasi-experimental**
  - Nonrandomized comparison group
  - Nonrandomized cross-over
  - Case control (matched or non-matched)
  - Historical control
  - One group pre-post design
  - Cross-sectional (slice in time)
  - Cohort (repeated measure)
  - Nested (one study nested in another)
Hawthorne Effect

- Example:
  - Implemented an intervention to see if it could increase the workers’ productivity in a factory
  - Watched workers to see if the intervention worked and it did
  - Then, watched workers, who did not have the intervention, and found that their productivity rose too

- Hawthorne effect: Attention alone produces results

- That is why we try to use an equal attention control design
Validity-Truth or Accuracy of Claim

- **Validity**: Are you measuring what you say you are measuring?

- **Reliability**: Does the measure give the same result each time it measures the same thing?
Internal and External Validity and Methods of Control

INTERNAL/EXTERNAL VALIDITY AND THE METHODS OF CONTROL

- **Internal Validity**: Are the findings due to the independent variable?
- **External Validity**: Can I generalize the results to another group?

- **Selection Bias**
  - Mortality
  - Maturation
  - Instrumentation
  - Testing
  - History

- **Effects of Selection**
- **Effects of Testing**
- **Reactivity**

- **Methods of Control**:
  - Randomization
  - Homogenous Samples
  - Consistency in Data Collection
  - Manipulation of the independent Variable
More About Validity

- Note that the question under the term “internal validity” on the diagram (the previous slide)
- This is the first question for us to consider before we “consume” research and use a study for clinical practice
- How do we know that what the researcher found is really the result of what she did?
Internal Validity (1)

- If internal validity is not strong, it means that something other than the variable we studied may have made the difference.

- As a reader of research, you should always be looking for explanations for the findings, other than the one the researcher is giving you.
Internal Validity (2)

- How will we know that if we find differences in the groups that they are most likely due to the rest period?
  - Selection bias: Low risk due to random assignment, but still there due to small sample size
  - Mortality: Moderate threat, not because clients might die but because they might drop out or not do what is necessary and have to be dropped
  - Maturation: Low threat, no known maturation in this area
  - Instrumentation: Low to moderate threat since different people will be documenting over the period and recording may be inconsistent
  - Testing: Low threat, all patients will have data recorded
  - History: Low threat, should affect both groups equally.
Note the question under “external validity” on your diagram (Slide #34)

Assessing the threats to external validity helps us to consider how well this study could relate to other groups, not just the one studied

External versus internal validity:
- Internal validity deals with the inside of the study
- External validity deals with outside the study
- External validity is about the ability to generalize a study’s findings to another group
External Validity (2)

• How well can we apply the results of this study to clients over 60 yrs in other nursing homes?
  ○ Effects of selection: High since only 1 nursing home will be used, nursing homes could differ easily in factors that might affect the results
  ○ Effects of Testing: Moderate threat the limitation of 1 site again means that we can’t be too sure any findings aren’t due to other factors
  ○ Reactivity: Low to moderate threat, clients & staff in this nursing home may react differently than clients/staff in other nursing homes
Methods of Control

- **Methods used**
  - Random Assignment
  - Manipulation of the independent variable: e.g., one group gets the rest period the other doesn’t
  - Data consistency: An operational definition that is easily understood is given for “rest periods”

- **A few other things that could be done depending on resources available**
  - Random sampling from a state wide or national ranking
  - Homogenous grouping with same size nursing homes or limiting types of clients
  - Consistency in data collection with training of staff and developing a set form/procedure for data collection
Randomization

Two kinds of randomization:

- **Random sampling**
  - Every person in a population must have an equal chance of getting into the sample

- **Random assignment**
  - Each person in a sample must have an equal chance of getting into the experimental and control group
  - That is, they are randomly placed in one of the groups
Randomization (2)

- Researcher must actually go through some randomization process
  - For example, number each potential subject, and then pull numbers from a box or use a random table to determine assignment to a group

- Randomization is a very strong and positive control method
- Randomization can always strengthen a study
Homogenous Sampling

- Trying to make your sample as much alike is helpful in studies
  - because it can minimize the possibility extraneous variables have affected the results
- However, it also has limitations
  - Because it makes generalization more difficult since the study population is smaller and applies to fewer people
  - It can also make it more difficult to get enough people in the study
- So, homogenous sampling increases internal validity, but decreases external
Consistency in Data Collection

- The researcher needs to make the process the same for everyone in the sample

- In reality, this can be difficult, because many studies use a number of individuals to collect data and it is easy to have variances
The Five Elements of Design

- **Setting:**
  - Example: A 110 bed long term care facility in the Midwest, the study will be done from February to April 2009

- **Population:**
  - Example: All the clients over 60 years of age who are in nursing homes

- **Subjects:**
  - Example: 60 clients who are willing to participate in a nursing home where the researcher works. Half will be randomly assigned to an experimental group who will take the rest period, half will be assigned to a control group

- **Instrument used to collect data:**
  - Example: Data collection sheet developed for this study includes demographic data, activity in the afternoon and fall data from medical records
Example:

- The RN assigned to the units will establish a protocol to insure that clients in the experimental group get a 1 hour rest period each afternoon between the hours of 1 and 3 pm.
- The operational definition of a rest period is: A one-hour period where the client remains in bed with no verbal or other mentally stimulating activities.
  - Clients in the comparison group will be encouraged to spend time in the TV area or in the therapy rooms.
  - They will not be allowed to return to bed, but may return to their own room.
• No study is 100% valid
• Most studies have some aspect of various threats present
• The more control, the less this occurs
• But controlling the threats must be balanced with the resources and realities of the research environment as well as with the skill of the researcher