

EXPERIMENTAL DESIGN AND ETHICS

- Randomization
- Completely Randomized Design
- Block Design
- Full Factorial Design
- Blinding
- Ethical Principles



EXPERIMENT

- **Experiment:** a method of data collection where:
 - Experimenters decide on the explanatory variables (or **factors**) and response variable they wish to study the relationship between
 - Subjects are:
 - Recruited to participate
 - Randomly divided into groups
 - Assigned a **treatment** (a value of the explanatory variable) they will experience during the study
 - A period of time passes while the study is taking place
 - Results are collected from each subject and analyzed by the experimenter

TERMINOLOGY

- **Factor:** an explanatory variable in an experiment
 - Usually a categorical variable with at least two categories
- **Treatment:** the specific category of a factor that a subject has been assigned in an experiment
 - Subjects are (usually) only given one treatment from each factor
- **Control group:** a group of subjects in an experiment that receives no treatment
 - Used as a baseline to compare against other groups to see how well the actual treatment worked
- **Placebo:** an ineffective treatment given to a control to prevent them from knowing that they are not receiving a real treatment

DIFFERENCE BETWEEN EXPERIMENT AND OBSERVATIONAL STUDY

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- Both observational studies and experiments study the relationship between an explanatory variable and a response.
- **Question:** What is the primary difference between the two types?
- **Answer:** _____ – the process of assigning a _____ to a _____
 - In an observational study, subjects have _____ to live their lives as they choose with _____
 - In an experiment, subjects are assigned a treatment by the _____
- **Question:** Why randomize in an experiment?
- **Answer:** Helps to remove the _____ and make the groups being compared as _____ as possible

EXAMPLE: OBSERVATIONAL STUDY VS. EXPERIMENT

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- **Scenario:** A high school teacher makes a practice test available to his 50 students before the final exam. Students can choose to take the practice test. After the final exam, the teacher studies the relationship between final exam score and whether the student took the practice test.
- **Question:** Is there randomization in this study?
- **Answer:** _____
 - Each subject _____ if they were going to _____
- **Question:** What method of data collection is being used?
- **Answer:** _____

EXAMPLE: OBSERVATIONAL STUDY VS. EXPERIMENT

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- **Question:** If the students who took the practice test scored higher, why can we not say the practice exam caused higher scores?
- **Answer:** _____ is a confounding variable
 - Those who are _____ to do well are _____ to study using the practice exam and also likely had _____ going into the exam
 - Groups are _____ with respect to _____ level

Group	Number of Students	Grade Going Into Final	Final Exam Grade
Practice Test	40	85	80
No Practice Test	10	65	55

EXAMPLE: OBSERVATIONAL STUDY VS. EXPERIMENT

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- **Scenario:** A high school teacher chooses 25 of his 50 students to receive a practice test prior to a final exam but makes the other 25 students rely on their own methods to prepare. After the final exam, the teacher studies the relationship between final exam score and whether the student was given a practice test.
- **Question:** Is there randomization in this study?
- **Answer:** _____
 - _____ the class into _____ to decide who got a practice test
- **Question:** What method of data collection is being used?
- **Answer:** _____

EXAMPLE: OBSERVATIONAL STUDY VS. EXPERIMENT

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- **Question:** If the students who took the practice test scored higher, why is it likely that the practice exam caused higher scores?
- **Answer:** Two groups were probably _____ (e.g. motivation, pre-exam grades, sex, etc.) because of the _____
 - Motivation level is no longer _____ the experiment because we have motivated and unmotivated students in _____

Group	Number of Students	Grade Going Into Final	Final Exam Grade
Practice Test	25	75	85
No Practice Test	25	75	70

COMMON EXPERIMENTAL DESIGNS

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- **Completely randomized design:** every subject is randomly assigned a treatment without regards for any other characteristic
- **Randomized block design:** subjects are first divided into groups based on a variable that cannot be randomized (called a **block**) and are then assigned a treatment within each block
 - **Example:** Sex is a block because it is an explanatory variable that cannot be randomized, but where experimenters believe a difference may exist
- **Factorial design:** an experiment with more than one factor where combinations of the treatments for the factors are created
 - A **full factorial** design that contains treatments for all possible combinations of factors at all levels

EXAMPLE: COMPLETELY RANDOMIZED DESIGN

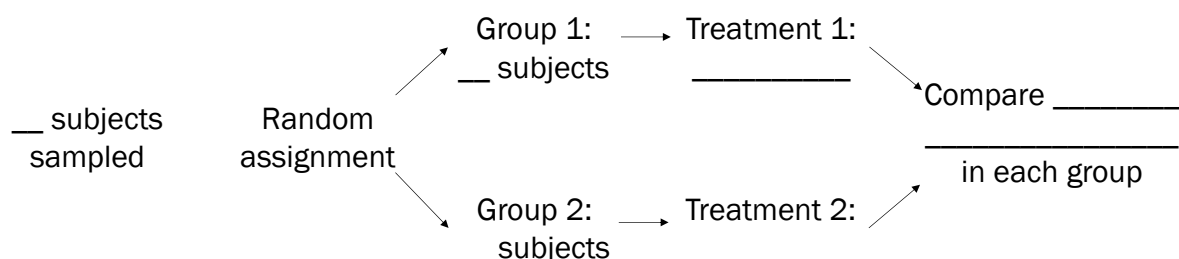
10

- **Scenario:** A dentist recruits 40 of her patients to test a new toothpaste with more fluoride. Each subject is asked to use either this new toothpaste or an identical looking toothpaste without the fluoride for 6 months. Upon returning for their next appointment, the dentist counts the number of cavities each patient has.
- **Question:** Why is a completely randomized design appropriate?
- **Answer:** _____ factor with _____ blocking
 - **Factor:** _____ (Either had _____)
 - **Block:** _____ among subjects
 - **Goal:** Use _____ to explain _____

EXAMPLE: COMPLETELY RANDOMIZED DESIGN

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- **Scenario:** A dentist recruits 40 of her patients to test a new toothpaste with more fluoride. Each subject is asked to use either this new toothpaste or an identical looking toothpaste without the fluoride for 6 months. Upon returning for their next appointment, the dentist counts the number of cavities each patient has.
- **Task:** Outline the design of this experiment.
- **Answer:**



EXAMPLE: BLOCK DESIGN

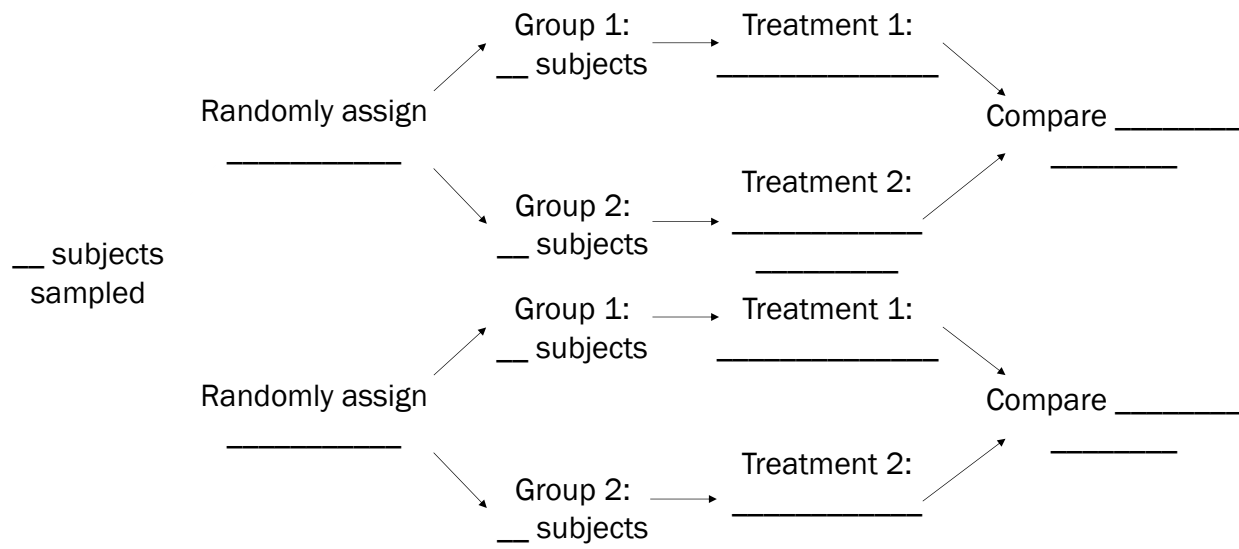
12

- **Scenario:** In 2008, 16 patients with Alzheimer's (6 male and 10 female) were recruited to participate in a study where half received tri-weekly 75-minute physical activity sessions for 12 weeks and the other half received routine medical care. Each subject's gait and balance was measured on a scale from 0 to 28 using the Tinetti scale at the beginning of the study and again at the end.
- **Question:** Why is this a block design?
- **Answer:** _____ factor and _____ block
 - **Factor:** _____ (Either _____ in daily routine)
 - **Block:** _____ - Males and females have _____ so physical activity may impact their _____
 - **Goal:** Use _____ to explain improvement in _____

EXAMPLE: BLOCK DESIGN

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- **Task:** Outline the design of this experiment.



EXAMPLE: FULL FACTORIAL DESIGN

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- **Scenario:** A recent study recruited 42 subjects and gave each a tincture containing both THC and CBD. The possible THC levels were 0 mg, 7.5 mg, and 12.5 mg while the possible CBD levels were 0 mg and 20 mg. Two hours after ingestion, each subject had a 10-minute conversation with the experimenter, where the number of 5-second pauses was counted.

- **Question:** Why is this a full factorial design?

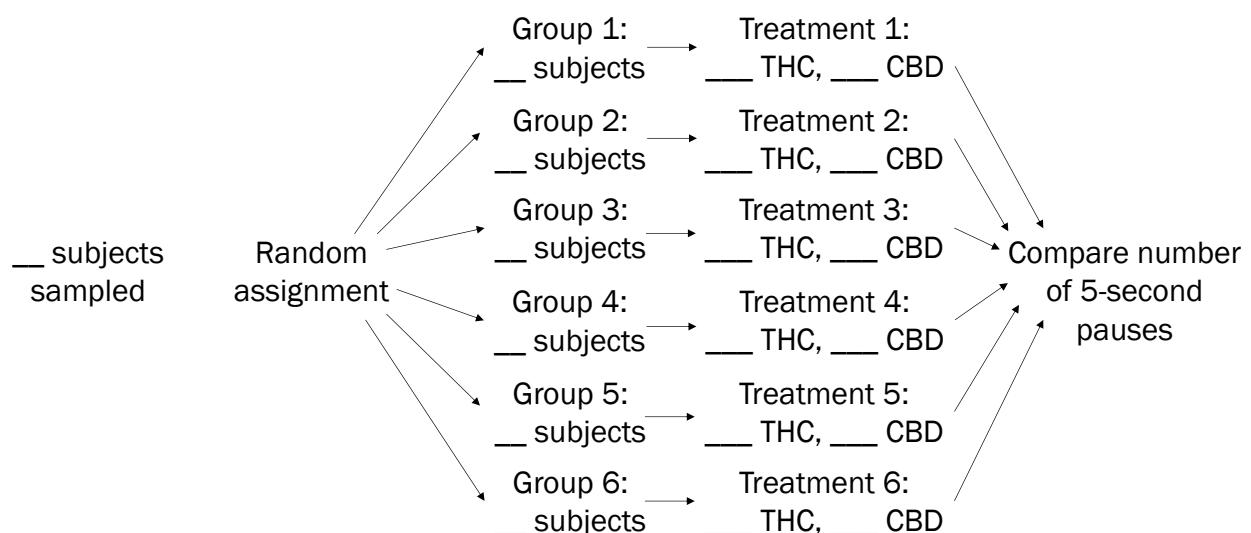
- **Answer:** ___ factors with ___ blocking

- **Factors:** ___ dosage (_____ mg) and ___ dosage (_____ mg)
- **Block:** _____ among subjects
- **Goal:** Use _____ dosages to explain _____ in conversation

EXAMPLE: FULL FACTORIAL DESIGN

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- **Task:** Outline the design of this experiment.



EXAMPLE: CONTROL GROUPS

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- **Question:** What was the control group in each experiment?
- **Answer:**
 - **Toothpaste:** Group with _____
 - **Tinetti Scores:** Groups receiving _____
 - **THC/CBD:** Group receiving ____ mg THC and ____ mg CBD
- **Question:** Does an experiment always require a control group?
- **Answer:** _____
 - **Example:** If the other group of Alzheimer's patients received _____ instead of physical, then a control group would _____.
 - Comparison would have been between _____ stimulation

BLINDING

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- **Blinding:** the process of hiding the treatment a subject is receiving from either the subjects or experimenters
 - **Single-blind experiment:** an experiment where either the subjects or experimenters are blinded, but not both
 - **Double-blind experiment:** an experiment where both the subjects and experimenters are blinded
- Blinding is often done to avoid:
 - **Placebo effect:** subjects respond to the idea of taking a treatment rather than the actual treatment
 - **Experimenter effect:** an attempt to influence the response of a subject due to knowledge of the treatment being given

EXAMPLE: BLINDING

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- **Scenario:** A dentist recruits 40 of her patients to test a new toothpaste with more fluoride. Each subject is asked to use either this new toothpaste or an identical looking toothpaste without the fluoride for 6 months. Upon returning for their next appointment, the dentist counts the number of cavities each patient has.
- **Question:** What type of blinding should be used?
- **Answer:** _____
 - **Subjects:** Should _____ to avoid _____
 - **Experimenter:** _____ necessary – will count the _____ on the follow-up visit regardless

EXAMPLE: BLINDING

- **Scenario:** In 2008, 16 patients with Alzheimer's (6 male and 10 female) were recruited to participate in a study where half received tri-weekly 75-minute physical activity sessions for 12 weeks and the other half received routine medical care. Each subject's gait and balance was measured on a scale from 0 to 28 using the Tinetti scale at the beginning of the study and again at the end.
- **Question:** What type of blinding should be used?
- **Answer:** _____
 - **Subjects:** _____
 - **Experimenter:** Could be _____ to avoid _____ scores

EXAMPLE: BLINDING

- **Scenario:** A recent study recruited 42 subjects and gave each a tincture containing both THC and CBD. The possible THC levels were 0 mg, 7.5 mg, and 12.5 mg while the possible CBD levels were 0 mg and 20 mg. Two hours after ingestion, each subject had a 10-minute conversation with the experimenter, where the number of 5-second pauses was counted.
- **Question:** What type of blinding should be used?
- **Answer:** _____
 - **Subjects:** Want to avoid subjects _____ the conversation
 - **Experimenter:** _____ blinded so the _____ with each subject is _____

ETHICS IN EXPERIMENTS

- **Before the study begins:**
 - Researchers must get study approved by an **institutional review board**
 - Ensures all subjects are protected and that any potential harm is minimized
 - Prevents researchers from selecting disadvantaged groups (racially, economically, mentally, etc.) for the purposes of being exploited for a risky treatment
 - All recruited subjects must give **informed consent**, agreeing to participate and acknowledging any potential risks they may encounter.
- **During and after the study:**
 - The data must be kept **confidential** and **anonymous** so that only the researchers can match respondents with individuals.
 - Subjects have **autonomy** (right to choose what they participate in) and the right to **withdraw** at any time
 - Subjects must be **debriefed** (discuss the study with the researchers and have access to treatment to counter any negative effects)

EXAMPLE: TUSKEGEE STUDY (1932-1972)

- **Scenario:** [Link](#) to Tuskegee study YouTube video
 - 600 poor, illiterate African-American males were monitored for 40 years, about 400 of whom had contracted syphilis.
 - Subjects were given free medical exams but were not told their diagnosis.
 - Goal was to understand how syphilis affected the subjects.
 - Despite penicillin being available in the 1950s, subjects were denied this treatment. The government stopped the study in November 1972.
- **Question:** What was ethically wrong with this study?
- **Answer:**
 - Doctors were not acting in subjects' _____
 - Subjects were not made aware of _____ – no _____
 - Subjects were exploited based on _____ without the intent to _____ their lives

EXAMPLE: MILGRAM EXPERIMENT (1961)

- **Scenario:** [Link](#) to Milgram experiment YouTube video
 - Volunteer attached to wires and asked a series of questions
 - Subject was told the goal of the experiment was to improve memory through electric shock punishment.
 - Subject was told by experimenter to increase the voltage and press a button that shocked the person if the volunteer answered incorrectly
 - In reality, the button did nothing, and the actual goal was to gauge the subject's conscience about harming another individual
- **Question:** What was ethically wrong with this experiment?
- **Answer:**
 - Subjects were _____ – told the person _____ was being studied when they were actually the ones _____
 - Ordinary people are more likely to follow orders given by an _____

EXAMPLE: FACEBOOK EXPERIMENT (2012)

- **Scenario:** [Link](#) to Facebook experiment YouTube video
 - Facebook manipulated news feeds of 690,000 randomly selected users for one week to change how many positive and negative posts they saw
 - Goal was to determine if users' emotions changed during the study by comparing the content they saw and the posts they wrote
 - Facebook published a journal article without notifying any users that they had been studied
- **Question:** What was ethically wrong with this experiment?
- **Answer:**
 - None of the subjects provided _____
 - Subjects did not have the opportunity to _____, be _____, or get _____ if they suffered _____ (e.g. depression)