LESSON 2: THE RESULTS

Activity 2A: Clinical Trials & Study Designs

BACKGROUND

When you go to the doctor, he or she uses various instruments to check your heart rate, oxygen levels, and blood pressure. Sometimes the doctor may prescribe a medicine based on your condition. There are thousands of different medications which can be prescribed by a physician. Before it can be prescribed, it must first be proven safe for the population to take. Scientists and doctors perform *clinical trials* before any type of medication is approved for public consumption.

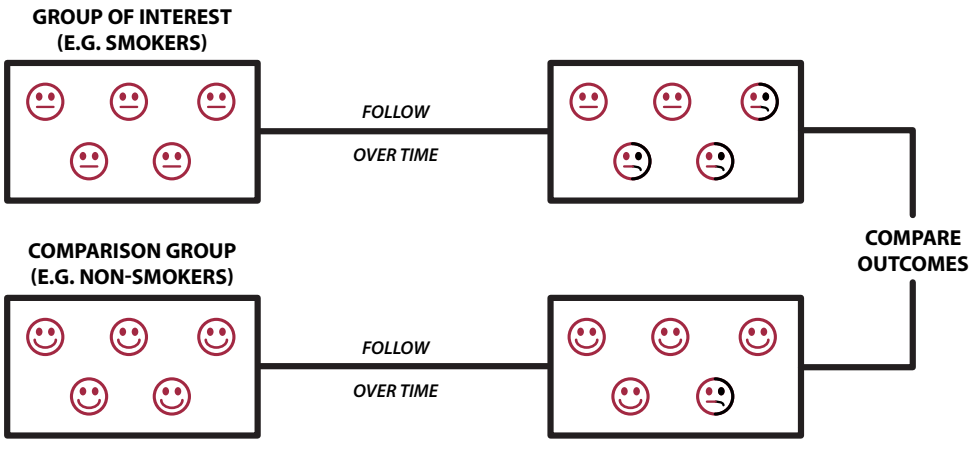
What is a clinical trial?

The overall purpose of clinical trials is to determine if medications are safe for people. Years before a particular medication is approved as a prescription, scientists test and re-test drugs through clinical trials to determine how effective the medication is and what side-effects it may cause.

Not everyone can participate in a clinical trial. Before joining a clinical trial, the participant must qualify for the study. Some research studies seek participants with illnesses or conditions being studied, while other clinical trials need healthy participants. Anyone who chooses to participate in a clinical trial must be informed of known side effects, good or bad, that they may experience as a result of participating in the trial. Clinical trials are federally regulated and must follow strict ethical guidelines and protocols. The guidelines and testing protocols must be explained to each potential participant. Next, each potential participant must sign a consent that acknowledges they understand the risks and the requirements of the clinical trial. Once the clinical trial begins every participant has the right to withdraw at any time.

Different study designs

Cohort Study: There are several types of studies scientists can perform. The first is known as a ***cohort study***. A cohort is a group of people that share a common characteristic or condition. This study design is a type of *observational study*. A cohort of people is monitored for a certain amount of time. The observations, also known as outcomes or results, are then compared to those of another cohort of people who may or may not have that particular characteristic or condition.



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The diagram on the previous page shows an example of a cohort study. As you can see, there are two cohorts of people that are followed over a period of time. These two groups are smokers vs. non-smokers. The outcomes of both groups are compared after the study is over.

Randomized Clinical Trial: The second type of clinical trial is called a randomized clinical trial or RCT. In an RCT, participants are randomly placed into one of two groups. When participants are "randomized", participants are randomly assigned to different groups. An RCT is most frequently used in clinical trials. Randomized clinical trials are typically used to test how well various medications work or to gather information about possible side effects of the drug being studied. One group is given the active version of the drug (contains the *real* medication) that is being tested while the other group is given an inactive version of the drug (*does not contain* the real medication). The inactive version is known as a ***placebo***. The subjects from both groups are monitored and their information is gathered in exactly the same way.

Meta-Analysis: The third type of clinical trial is known as an analysis study. A meta-analysis is not a typical "trial" where participants are physically involved. It is a statistical method that compares many similar studies to see if any patterns emerge. A meta-analysis study combines the findings from different studies and analyzes the results. Before beginning any type of study, most scientists know that several trials have previously attempted to answer similar questions. Therefore, they look for completed studies that are similar to the one they want to do and compare those results. Sometimes an individual trial may fail to show a significant difference between two different treatments. But when the results of these individual trials are combined, a statistical significance may be found that shows one medication or treatment may in fact be better than another.

Writing a Hypothesis

Generally, before a hypothesis is written, someone makes an observation, which is followed by a question. A hypothesis is then formed based on the question. A hypothesis is a *testable* statement that states what you ***think*** might happen or ***why*** you think something happened.

Example – Worms and Rain

Observation: When it rains, worms come out of the ground.

Question: Why do worms come out of the ground?

Hypothesis 1: When it rains, worms come out of the ground because the rain makes them wet and they do not like to get wet.

Hypothesis 2: When it rains, worms come out of the ground because the rain reduces the amount of air in the soil.

Which hypothesis is actually testable, 1 or 2? If you are not sure, identifying the independent variable and dependent variable in each hypothesis may help. Use the IV C DV chart explained in Activity 1B.

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Hypothesis 1: Worms come out of the ground because the rain makes them wet and worms do not like to get wet.

IV	Constants	DV
Rain	Ground/Soil Worms	Worms do not like to get wet

How would you test the hypothesis? Can you ask a worm how it feels about getting wet?

Hypothesis 2: Worms come out of the ground because the rain reduces the amount of air in the soil.

IV	Constants	DV
Rain	Ground/Soil Worms	Amount of air in the soil

Can you test this hypothesis? Of course! There are several ways to test this. You can demonstrate that water, which is denser than air, displaces the air in spaces in the soil, or you can use an instrument that actually measures the amount of oxygen in dry and wet soil samples.

Remember that a hypothesis can only have one IV and one DV. The question may be too general, with lots of possibilities for independent variables. Your hypothesis will need to focus in on only one independent variable.

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REFERENCES

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