



Virtual Learning

Medical Interventions

Clinical Trials

May 1, 2020



Medical Interventions

Lesson: May 1, 2020

Objective/Learning Target:

Recognize that clinical trials are regulated by strict guidelines that ensure data collected is valid and human subjects are treated ethically. (3.4.3)



Let's Get Started:

1. Watch [this video](#) on the basics of clinical trials. What are the 4 phases?
2. Find a clinical trial that is currently ongoing for COVID-19 by viewing the [Clinical Trials database](#). What do you notice?



Let's Get Started: **Answers**

1. Watch [this video](#) on the basics of clinical trials. What are the 4 phases?
 - a. Phase 1 - determines safety/right dosage
 - b. Phase 2 - additional safety/efficacy
 - c. Phase 3 - confirm effectiveness, monitor side effects
 - d. Phase 4 - after drug enters market
2. Find a clinical trial that is currently ongoing for COVID-19 by viewing the [Clinical Trials database](#). What do you notice?
 - a. There are over 600 trials in various stages, many lasting a long time, etc.



Lesson Activity

Read through [this presentation](#) and identify each of the following different types of Clinical trials:

1. Randomized, double-blind trials
2. Open trials
3. Factorial trials
4. Crossover trials
5. Orphan drug trials



Lesson Activity - **Answers**

1. Controlled, Randomized, double-blind trials
 - a. One group receives the treatment and another group does not, control group and treatment group are chosen at random and Neither subjects nor scientists know who is assigned to which group until after the data are collected
2. Open trials
 - a. Set-up where researchers and subjects know what treatment is being given
3. Factorial trials
 - a. Used to test medicines in combination (First group tests therapy A, Second group tests therapy B, Third group tests therapy A and therapy B combined, Fourth group, the control group, tests neither therapy A nor therapy B)
4. Crossover trials
 - a. Used to test 2 treatments and set-up where each participant gets both treatments being tested
5. Orphan drug trials
 - a. Used to test drugs designed to treat rare diseases and tested on small number of participants who are very sick



Practice

Indicate which clinical trial would best fit with the description below.

1. A new surgical procedure is being developed for amputations.
2. A researcher want to learn the effects of replacing butter with margarine on the lipoprotein profile of subjects with hypercholesterolaemia.
3. Considered the “gold standard” of clinical trials by preventing unconscious bias.
4. A study is set up where different groups receive two doses of Marvistatin and/or Omega-3 Supplement in patients with heart failure.
5. Haem arginate is used to treat acute intermittent porphyria, a rare metabolic disorder.



Practice - **Answers**

Indicate which clinical trial would best fit with the description below.

1. Open Trial
2. Crossover Trial
3. Controlled, Randomized, double-blind trials
4. Factorial Trial
5. Orphan Drug Trial



Additional Practice/Resources

1. Check your understanding by reviewing with [these flashcards](#).
2. Now that you know about clinical trials, why do you think it is going to take so long to develop a vaccine for COVID-19? Read more about it [here](#).
3. View another example of why clinical trials are so important for determining, safe, effective treatments for COVID-19 by viewing this [article](#).