

Clinical Trials and Placebo

Grades 9 – 12 Strand A

	A sa sa sa t	
Lesson Plan	Assessment	Observations, peer assess, trials
	Cross-curricular	Medicine
Learning Goals • Learn how to run a double blinded controlled trial.	 Specific Expectations A1.1 formulate scientific questions about observed relationships, ideas, problems, and/or issues, make predictions, and/or formulate hypotheses to focus inquiries or research A1.5 conduct inquiries, controlling some variables, adapting or extending procedures as required, and using standard equipment and materials safely, accurately, and effectively, to collect observations and data A1.6 gather data from laboratory and other sources, and organize and record the data using appropriate formats, including tables, flow charts, graphs, and/or diagrams A1.7 select, organize, and record relevant information on research topics from various sources, including electronic, print, and/or human sources A1.8 analyse and interpret qualitative and/or quantitative data to determine whether the evidence supports or refutes the initial prediction or hypothesis, identifying possible sources of error, bias, or uncertainty A1.9 analyse the information gathered from research findings, and justify their conclusions A1.11 communicate ideas, plans, procedures, results, and conclusions orally, in writing, and/or in electronic presentations, using appropriate language and a variety of formats (e.g., data tables, laboratory reports, presentations, debates, simulations, models) A2.1 identify and describe a variety of careers related to the fields of science under study 	
Materials Clinical Trials Role Instructions Clinical Trials Volunteer Records Clinical Trials Student Write-up Clinical Trials Visuals Safety Notes Always disconnect battery between tests.		

Description

Introduce to students the idea that the scientific method isn't just one single way of doing things. Students will learn how to think critically and do a double blind test.

Introduction

- Introduce to students the idea that the scientific method isn't just one single way of doing things: "Actually there are many different ways of doing the scientific method. Physicists work differently from Biologists, for example, because working with lasers is very different from surveying animals in a stream. (Visuals slide 2) (see link). There isn't one that's better and one that's worse. They are just different. One VERY important way of doing the scientific method that we will study today is the DOUBLE BLINDED CONTROLLED TRIAL. If you've ever taken science based medicine then you've used something that's gone through the double blinded controlled trial."
- 2. Play the following short clip for students to introduce the idea of a double blind controlled trial. http://herebedragonsmovie.com/hd.php Play from 23:50 to 26:58

Action

- Inform students that the class will be performing its own double blind controlled trial. Ask, "Have any of you ever met someone who says that they really prefer tap water to bottled water or prefer bottle to tap water? Tap water is something like 4000 times cheaper so I wonder if those people can really tell the difference?" (note: Coke vs. Pepsi can be substituted for tap/bottled water)
- 2. Pull out two jugs of water, labeled "A" and "B" (one tap water, the other bottled water poured into the jug).
- 3. By volunteers, split the class into three groups. Head researchers (3 people), researchers (5 people), and test volunteers (the remainder). Hand out BLM 1 Role Instructions (See Material/Resources section) and describe each role with the class (Visuals slides 3-5) (See Materials/Resources section).
- 4. Secretly tell the head researchers which jug is which then have them follow the instructions for their role. Providing them a seating chart with names or a class list will help.
 - NOTE: Areas of difficulty where teacher help may be needed.
 - i. Understanding how to assign people to equally sized groups "randomly".
 - ii. Matching numbers with names easily.
 - iii. Mixing up samples.
 - iv. Having a streamlined system for preparing samples.
 - v. Preparing samples so that the researchers and test volunteers can't see what's happening.
 - vi. Tallying results quickly and meaningfully.
- 5. Lead a class discussion about the meaning and nature of the results. Discuss how students felt in their roles.
- 6. During the lesson encourage students to look for an identify 'Sources of Error' any things that are done in the test that might introduce uncertainty but are beyond their ability to control. Examples include:

- The test subjects (people drinking the water) are volunteers and not randomly selected.
- The test subjects are not representative of the population (ex. they are mostly a single grade).
- Test subjects can see one another and might be able to confer.
- Etc.
- 7. Keep a running list on the classroom board or chart paper for all to see and contribute to.

Consolidation/Extension

Independent Consolidation:

Now familiar with the process of a double-blinded controlled trial, students will have to create a plan for running a scientific trial themselves.

- Students will choose a product and complete Clinical Trial Student Write up (see link).
- For students struggling to choose a product, the teacher could recommend Power Balance Bands and show the following video: https://www.youtube.com/watch?v=6gIMxjr3n5U Alternately, these 'applied kinesiology' technique can be used as a demonstration by the teacher as shown by Richard Saunders in the links below: https://www.youtube.com/watch?v=6gIMxjr3n5U https://www.youtube.com/watch?v=2xBVEM2iMns, https://www.youtube.com/watch?v=1gcazD_dMhk. Demonstrating for the class and then explaining how the techniques can be used to deceive, can be an effective method for building critical thinking.

Public Policy Connection:

- In Canada, there is a specific process that drugs follow for approval (Visuals slide 6 see link). So-called 'Natural' and 'Homeopathic' remedies are also assessed by Health Canada and receive Drug Identification Numbers but as a 2015 Marketplace investigation shows, there are severe problems in the testing of these.
- The videos at the following links can act as excellent prompts for further class discussion:
 - 2-Min. Version http://www.cbc.ca/news/health/health-canada-licensing-ofnatural-remedies-a-joke-doctor-says-1.2992414
 - Full Episode http://www.cbc.ca/marketplace/episodes/2014-2015/drugstore-remedies-licence-to-deceive

Tap vs. Bottled Water Comparisons:

Check out these links:

http://www.triplepundit.com/2015/06/infographic-please-stop-drinking-bottled-water/ http://www.cbc.ca/news/health/bottle-vs-tap-7-things-to-know-about-drinking-water-1.2774182 http://www.dailyinfographic.com/bottled-water-facts

http://www.tataandhoward.com/2015/05/5-reasons-to-choose-tap-over-bottled-water-infographic/