

Control Treatments

- Often, we want to *compare* a situation involving a specific treatment to the status quo situation.
- A baseline (“business as usual”) measurement is called a **control treatment**, and the experimental units to whom it is applied is called the **control group**.

Experiments In YOUR World



Maggots? Don't Say "Eww" So Fast!

So... would you rather have an open wound on your foot intentionally infested with maggots, or have your lower leg amputated?

That may sound like a ridiculous question, but for many diabetes patients, it's not. Diabetics often develop foot sores that are stubbornly resistant to healing. Many become infected, leading to more than 70,000 amputations of toes, feet, or lower legs in the U.S. each year.

A promising solution to this serious health risk: yes, maggots. When applied to the wounds, the maggots (green bottle fly larvae) can remove decaying flesh tissue and stimulate growth of healthy cells.

A 2002 experiment run by Dr. Ronald Sherman of the University of California-Irvine helped establish the effectiveness of maggot therapy. The subjects, 18 patients with 20 non-healing wounds, were randomly assigned to 3 groups. The first group was treated with the standard therapy, the second with maggots, and the third with a combination of the two. During treatment all wounds were covered with identical bandages and patients were blindfolded whenever the dressings were changed.



After 4 weeks the maggot-treated wounds were completely free of dead tissue and had regrown healthy tissue over more than half of the previously infected area. For the group that received the conventional treatment, even after 5 weeks dead tissue still covered a third of the wound area and healthy growth was limited to 15% coverage. All the differences were statistically significant.

As a result of this and other studies, in 2004 the FDA classified maggots as "live medical devices". Now the U.S. has over 1000 maggot therapists. Applications are expanding to include burns, bed sores, surgical wounds, skin cancer, and even MRSA, a dangerous bacterial infection largely resistant to antibiotics. There could be maggots in your future.

Sources: *Diabetes Care* (Journal of the American Diabetes Association), *health.howstuffworks.com*, *ScienceNOW*

1 Your World Discussion Questions

1. Why is this research an experiment, rather than a sample survey or an observational study? *The researcher applied a treatment.*
2. Who were the subjects? How does that effect the conclusions that can be made? *18 patients with non-healing wounds; limits who the results*
3. The article says the subjects were divided into three groups. What's that called, and why did the researchers do it? *Random assignment, to spread out variation that are not can be applied to.*
4. What were the treatments? What was the response variable? *maggots ~~vs~~ / Regular Trtm / Both controlable. amt of dead tissue and healthy*
5. What was the control treatment in this experiment? Why was it important? *Regular treatment - to have a baseline to compare regrowth*
6. What conclusion was reached, and how is it limited? *The maggot-treated wounds improves significantly more than the other two groups. Results limited to diabetic patients*

Blinding

- When we know what treatment was assigned, it's difficult not to let that knowledge influence our assessment of the response, even when we try to be careful.
- In order to avoid the bias that might result from knowing what treatment was assigned, we use **blinding**.
- Blinding is important. People are so good at picking up subtle cues about treatments that it's important to keep anyone who could affect the outcome or the measurement of the response from knowing which subjects have been assigned to which treatments.

Blinding (cont.)

- There are two main classes of individuals who can affect the outcome of the experiment:
 - those who could influence the results (subjects, treatment administrators, technicians)
 - those who evaluate the results (judges, treating physicians, etc.)
- When all individuals in either one of these classes are blinded, an experiment is said to be **single-blind**.
- When everyone in *both* classes is blinded, the experiment is called **double-blind**.

Placebos

- Often simply applying *any* treatment can induce an improvement.
- To separate out the effects of the treatment of interest, we can use a control treatment that mimics the treatment itself.
- A “fake” treatment that looks just like the treatment being tested is called a placebo.
 - Placebos are the best way to blind subjects from knowing whether they are receiving the treatment or not.

Placebos (cont.)

- The **placebo effect** occurs when taking the sham treatment results in a change in the response variable.
 - This highlights both the importance of effective blinding and the importance of comparing treatments with a control.
- Placebo controls are so effective that you should use them as an essential tool for blinding whenever possible.

The Best Experiments...

- are usually:
 - Randomized (random assignment of treatments)
 - Comparative (treatment vs. other)
 - double-blind
 - placebo-controlled

Homework:

Pg. 261 # 13, 14, 17, 19

Put answers on the chart on worksheet pg. 10-13

Example: #12

12. Over a 4-month period, among 30 people with bipolar disorder, patients who were given a high dose (10 g/day) of omega-3 fats from fish oil improved more than those given a placebo. (Archives of General Psychiatry 56 [1999]: 407)

Name _____ Statistics Chapter 10: "What's the design?" Organizer
Use this page with exercises 12-23 in the textbook

OBSERVATIONAL STUDIES				
Exercise	Retrospective or prospective	Subjects who; how selected	Parameter of interest	Conclusion Nature and scope

EXPERIMENTS						
Exercise	Factor and levels	# treatments	Response variable	Design Completely randomized, blocked, matched	Blinding None Single Double	Conclusion Nature and scope
12	omega-3 fish oil placebo	2	"Improvement" four symptom	Not stated (assured randomized)	Single (double?)	fish oil caused improvement in bipolar patients

12-23. What's the design? Read each brief report of statistical research, and identify

a) whether it was an observational study or an experiment.

If it was an observational study, identify (if possible)

b) whether it was retrospective or prospective.

c) the subjects studied and how they were selected.

d) the parameter of interest.

e) the nature and scope of the conclusion the study can reach.

If it was an experiment, identify (if possible)

b) the subjects studied.

c) the factor in the experiment and the levels.

d) the number of treatments.

e) the response variable measured.

f) the design (completely randomized, blocked, or matched).

g) whether it was blind (or double-blind).

h) the nature and scope of the conclusion the experiment can reach.

13. Among a group of disabled women aged 65 and older who were tracked for several years, those who had a vitamin B₁₂ deficiency were twice as likely to suffer severe depression as those who did not. (*American Journal of Psychiatry* 157 [2000]: 715)
14. In a test of roughly 200 men and women, those with moderately high blood pressure (averaging 164/89 mm Hg) did worse on tests of memory and reaction time than those with normal blood pressure. (*Hypertension* 36 [2000]: 1079)
17. Scientists at a major pharmaceutical firm investigated the effectiveness of an herbal compound to treat the common cold. They exposed each subject to a cold virus, then gave him or her either the herbal compound or a sugar solution known to have no effect on colds. Several days later they assessed the patient's condition, using a cold severity scale ranging from 0 to 5. They found no evidence of benefits associated with the compound.
19. Some people who race greyhounds give the dogs large doses of vitamin C in the belief that the dogs will run faster. Investigators at the University of Florida tried three different diets in random order on each of five racing greyhounds. They were surprised to find that when the dogs ate high amounts of vitamin C they ran more slowly. (*Science News*, July 20, 2002)