Experimental Design

The Point

Experiments are designed to gather data and make decisions. For many experiments, there is a novel (new) intervention that researchers wish to examine to determine the effect it has on a dependent variable.

The Setup

Participants (people, animals, buildings, companies… there are lots of different types of participants) are divided into a variety of Experimental Groups and Control Groups.

An **Experimental Group** consists of participants who receive a novel (new) intervention. There can be more than one experimental group (for example, two groups of people receive different doses of a medication).

A **Control Group** consists of participants who receive **no** intervention, an **existing** intervention, or a **placebo** intervention.

In general, participants are randomly assigned to these groups to help avoid bias.

For **small studies** in particular, it's critical that the groups are similar with respect to key factors. For example, suppose a study is examining the efficacy (effectiveness) of a new exercise regime. If 30% of all study participants are vegetarian and 70% are not, the groups should likely each reflect that stratification. In this case, participants who are vegetarian are distributed randomly and evenly throughout the groups, as are the non-vegetarian participants.

> **The Placebo Effect** occurs when the act of intervening has a perceived or actual effect on participant condition. For example, taking a pill makes you feel better, even if the pill has no medicinal ingredients. The participant has an expectation that there will be an effect, and so they perceive and effect.

Blinding and Double-Blinding

When the participants are not aware of which intervention (if any) they are receiving, they are **blinded**. The same is true for researchers.

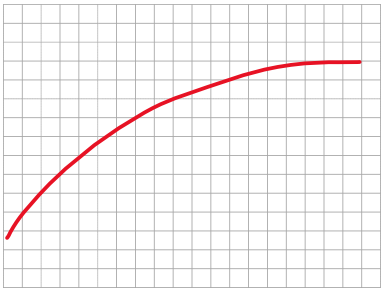
If the participants *and* the researchers are blinded, the study is called a **double-blind** study. This is the preferred type of research. It helps to reduce bias, allow for the placebo effect, and generally improve the validity of the results.

The "Gold Standard" for studies is a **randomized, placebo-controlled, double-blind study.** Unfortunately, not all research is (or can be) this rigorous.

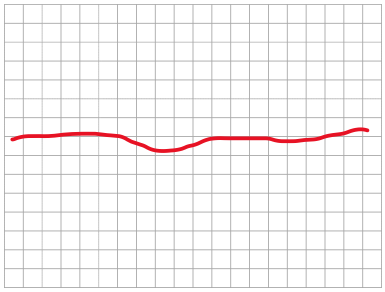
The Dose-Response Curve

For effective interventions, we look for a positive correlation between the intervention and the outcome. Without a dose-response curve, the intervention is often not causing an effect.

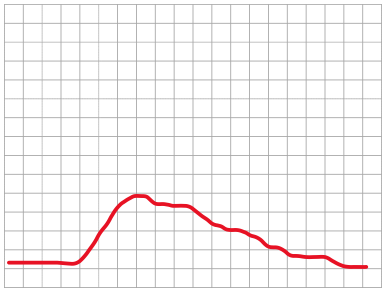
Examples: medication dosage, the weight lifted in an exercise routine, duration of a therapy



Typical "positive" dose-response



Typical "negative" dose-response



"Positive" over a small interval

Experimental Design Example

Suppose researchers have developed a new medication to treat a known, benign skin rash. There are two existing treatments (here called A and B). The novel treatment (called C) is being tested in three different doses: 5%, 12%, and 20% preparations. Each of these medications is applied as a cream to the affected area.

The research team divides the 600 participants into 6 groups of 10 people:

- Control Treatment A
- Control Treatment B
- Experimental Treatment C (5%)
- Experimental Treatment C (12%)
- Experimental Treatment C (20%)
- Placebo Treatment

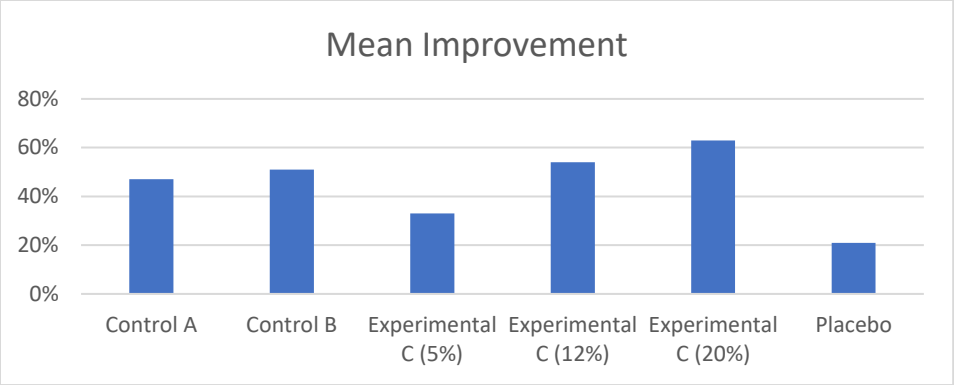
The Placebo group receives a cream which has no medicinal ingredients.

The dependent variable that will be measured is a percentage improvement in the rash after 3 days. From prior research, both treatments A and B will typically result in a 50% improvement in symptoms after 3 days. For each group, the mean and standard deviation improvement will be reported.

Note that a maximum improvement of 100% is possible (the rash is gone). Since it is possible this will occur before 3 days have elapsed, each participant will be monitored daily.

Results

Group	number of participants	number of participants who completed	mean improvement	standard deviation of improvement
Control A	60	58	47%	12%
Control B	60	59	51%	10%
Experimental C (5%)	60	57	33%	8%
Experimental C (12%)	60	55	54%	9%
Experimental C (20%)	60	51	63%	8%
Placebo	60	52	21%	7%



Interpretation

We see a nice dose-response curve for the experimental group, and the placebo group showed less improvement than any of the intervention groups.

This means that the novel medication appears to have an effect, improving the outcome for patients. Increasing the dose (5% to 12% to 20%) shows increased effect. Further, the standard deviation was lower for the Experimental groups compared with the Control groups A and B, which means the novel medication may act more consistently than the standard medications.

However, there is a point of concern. The number of participants who did not finish the study increased with the dosage of medication C. The highest dosage group (20%) attrition rate was similar to the placebo group. Presumably the use of the medication caused a negative side effect or simply did not work quickly enough for the participants. More information is required to make a complete interpretation.