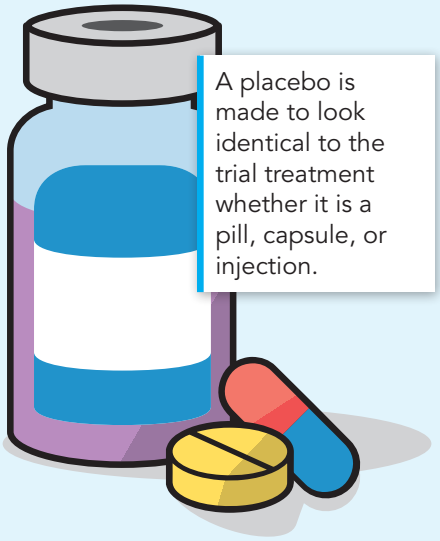
What is a Placebo?

And why are placebos used in clinical trials?

What is a placebo?

A **placebo** (pla-SEE-bow) looks like a **trial treatment** but does not have the actual trial treatment in it. A trial treatment is a new drug, vaccine, or other treatment that researchers are studying.

A placebo does not contain the active ingredients that the trial treatment contains. It could be salt water, a sugar pill or a tablet that contains all the same ingredients as the trial treatment except for the active ingredient.



A placebo is made to look identical to the trial treatment whether it is a pill, capsule, or injection.

Researchers may also use a **sham treatment**, which is like a placebo for a surgery or procedure. A sham treatment looks and feels identical to the trial surgery or procedure, but the trial doctor doesn't actually complete the steps that they think could provide benefit.

Why are placebos used in clinical trials?

Researchers use a placebo to help make sure any of the effects they see are actually caused by the trial treatment.

The **placebo effect** describes effects someone might experience after receiving a trial treatment or a placebo because they believed it would have an effect. The effects they experience could be positive or negative.

For example, a person who received a treatment might feel better because they thought the treatment would help them get better. Or, they might feel worse because they thought the treatment would cause side effects.

Using a placebo during a clinical trial helps researchers learn if the effects participants experience after receiving the trial treatment might be caused by the placebo effect. The researchers do this by comparing the results of participants who received the trial treatment to the results of those who received the placebo.

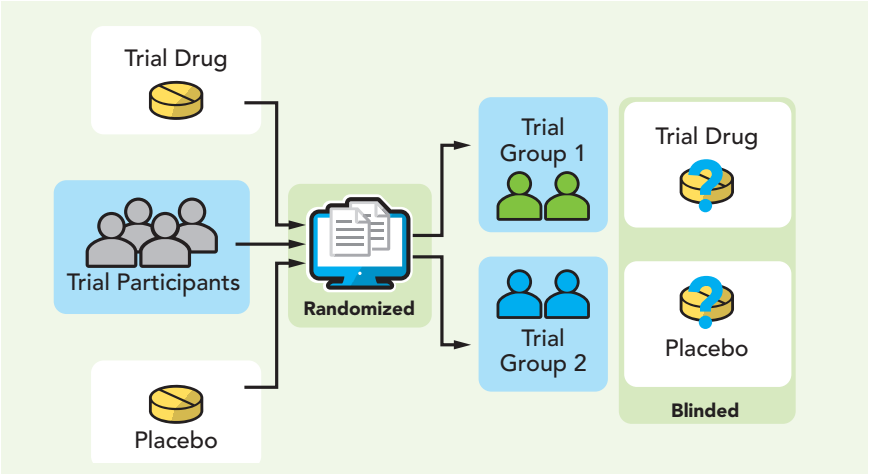
If the results for the trial treatment and the placebo are similar, this might mean that the effects the researchers see in the participants who received the trial treatment could have been caused by the placebo effect.

Government agencies may require a placebo to be used in a clinical trial to help show that a trial treatment is safe and effective.

How are placebos used in clinical trials?

Clinical trials with placebos are often **randomized**. This means that a computer program is used to randomly assign a trial treatment to each participant.

Randomized trials can also be **blinded**. This means that the participants are not told if they are being given the trial treatment or the placebo. Sometimes, the trial doctors and staff may also not know what trial treatment the participants are receiving until the end of the trial.



Will I receive a placebo?

Not all trials use a placebo. If there is a chance you may receive a placebo and you do not want it, you do not have to join that trial.

Before agreeing to be in a clinical trial, you are told if you **might** receive a placebo. You do not get to choose if you receive the trial treatment or the placebo.

If you have a condition that needs treatment, you will likely be given the standard medical treatment in addition to the placebo. All clinical trial plans are reviewed and approved by Institutional Review Boards (IRBs). An IRB will not approve a clinical trial plan that says participants will only receive a placebo if they also need a standard medical treatment.

Whether or not you receive a placebo, your health is monitored during a clinical trial. If there is a change in your medical condition while you are in the trial, the trial staff will tell you and discuss the situation with you. They may recommend that you leave the clinical trial, or they may recommend that you receive a different treatment.

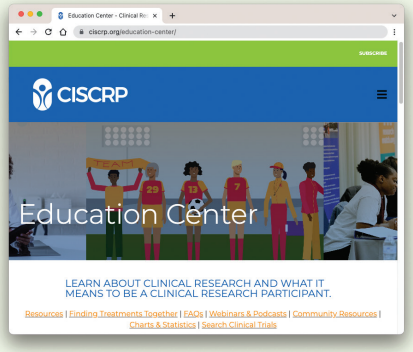
Will I be told if I received a placebo?

At the end of a trial, you may be told if you received a placebo or not. Typically, you will only find out what treatment you are receiving during the trial if it is for a medical emergency.

Remember: The choice to be in a clinical trial is yours. At any time, if you have questions or concerns about your clinical trial, you can speak with the trial staff. Also, you can stop being in a trial at any time and for any reason. The trial staff will help you do this safely.

General resources

- **ClinicalTrials.gov**–A public service that compiles clinical trial listings
  clinicaltrials.gov 1-800-411-1222
- **Search Clinical Trials**–A service from CISCRP that helps you find clinical trials
  www.searchclinicaltrials.org 1-877-MED-HERO
- **CISCRP Education Center**
  Visit www.CISCRP.org/education-center for more information, including disease and condition-specific resources.



CISCRP REVIEW PANEL

A panel of patients, professionals, and members of the public reviewed this educational brochure.

CISCRP

CISCRP is an independent non-profit organization dedicated to engaging the public and patients as partners in the clinical research process.

CISCRP does not recruit patients for clinical trials and does not conduct clinical research. CISCRP is also known as the Center for Information and Study on Clinical Research Participation.

Visit www.CISCRP.org or call toll free 1-877-633-4376

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