Important terms to know

Institutional Review Boards (IRBs):
A committee that ensures that a clinical trial is ethical and that the rights of study participants are protected. All clinical trials in the U.S. must be approved by an IRB before they can begin. IRBs initially approve and periodically review clinical trials in order to protect participants' rights.

Placebo Effect:
A physical or emotional change, occurring after an inactive drug or treatment is taken that is not the result of any special property of that inactive drug or treatment.

Blind:
A clinical trial is called "double blind" when both volunteers and researchers do not know which groups volunteers are assigned to in a study. A trial is "single blind" when only the volunteers are unaware of the group they are assigned to in the study.

Control Group:
In many clinical trials, one group of volunteers will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo.

Randomization:
A method based on chance by which study participants are assigned to a treatment group. Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms.

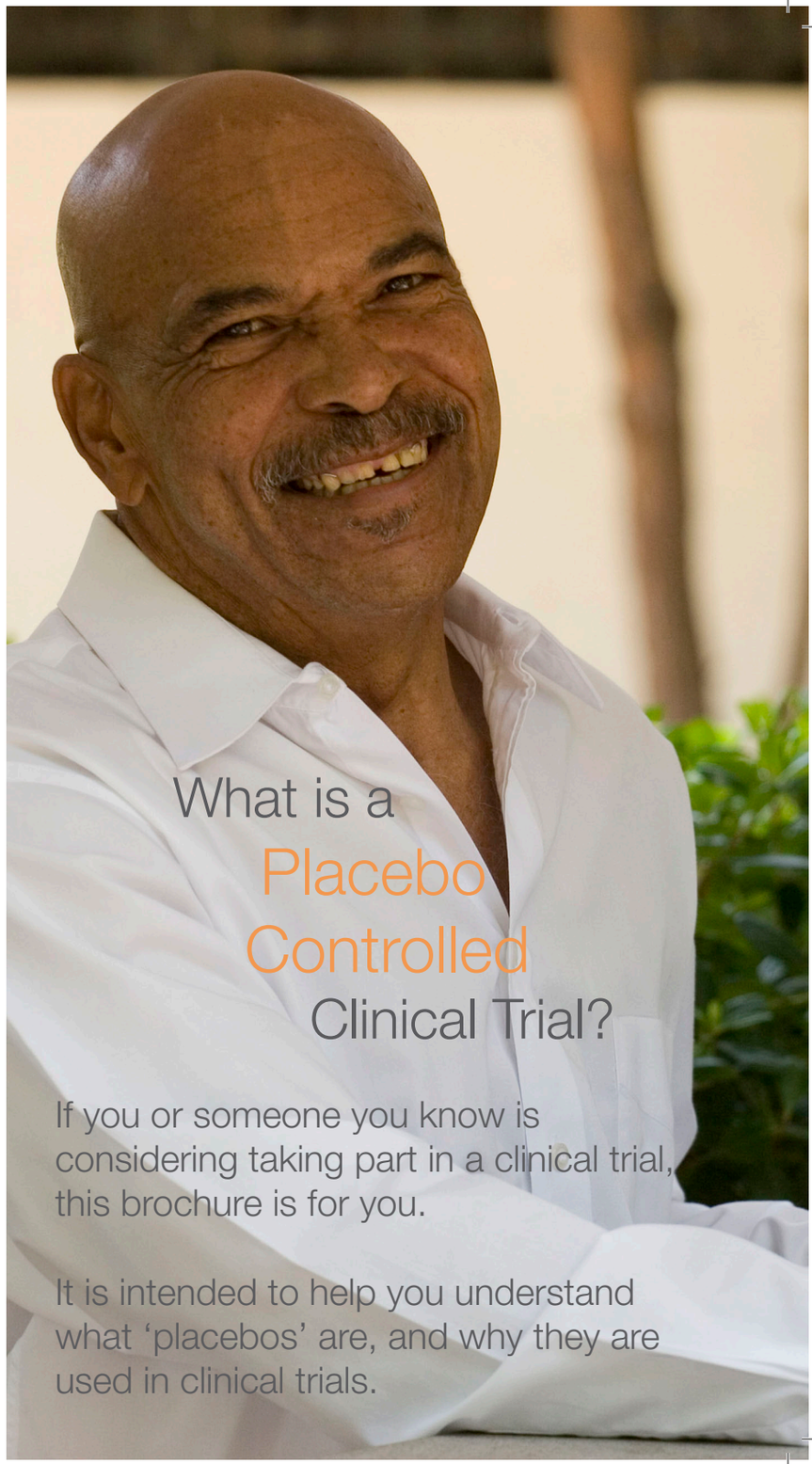
Data Safety Monitoring Boards (DSMBs):
An independent committee that reviews data while a clinical trial is in progress to ensure that volunteers are not exposed to undue risk. A DSMB may recommend that a clinical trial be halted if there are safety concerns or if the trial objectives have been met.

Adverse Event:
An unwanted reaction caused by the administration of a drug or treatment. Adverse events may include headache, nausea, skin irritation, or other physical problems.

Bias:
When an evaluation or judgment cannot be impartial or objective.

The Center for Information and Study on Clinical Research Participation (CISCRP)

is an independent nonprofit organization founded for the purpose of educating and informing the public and patients in order to foster greater understanding and awareness of the clinical trial process. For additional information, please visit our web site at www.ciscrp.org or contact us at 1-877-MEDHERO (1-877-633-4376).



What is a Placebo Controlled Clinical Trial?

If you or someone you know is considering taking part in a clinical trial, this brochure is for you.

It is intended to help you understand what 'placebos' are, and why they are used in clinical trials.

What is a placebo?

A placebo is an inactive treatment, sometimes called a ‘sugar pill. ‘In fact, a placebo may be in a pill or tablet form. It may be an injection or a medical device. Whatever the form, placebos often look like the real medical treatment that is being studied except they do not contain the active medication.

Before they are started, all clinical research programs, including those that involve placebos, are reviewed and approved by an ethical review board.

Why are placebos used?

Using placebos in clinical research helps scientists more clearly understand whether a new medical treatment is safer and more effective than no treatment at all. This is not always easy because some patients get better in a clinical trial even when they don’t receive any active medical treatment during the study. This is called the ‘Placebo Effect.’

Because of this ‘Effect’, researchers have for many years observed that volunteers who receive a placebo often improve for psychological reasons. Some volunteers feel better in a clinical trial because they are receiving a lot of care and attention. Also, some volunteers report having a reaction to the medication that they’re receiving during a clinical trial – yet only a placebo was given. This is another psychological effect.

In order to best determine whether a new medical treatment is safe and effective, researchers need to subtract the impact of the Placebo Effect. By doing so, researchers are able to gather meaningful and useful scientific information about the safety profile of a new therapy and its effectiveness in treating a specific medical condition.

How are placebos used in clinical trials?

Placebos have been used in clinical trials for a long time and they have played an important role in the development of many medical treatments. Placebos are used in a variety of ways:

- Sometimes, one group of volunteers receives a placebo and a comparison group receives the study medication. This is called a Placebo-Controlled, Randomized, Double-Blind clinical trial.
- Some studies involve having a group of volunteers take a placebo, while other volunteers take the new medical treatment or one that is already available at the pharmacy. This is called an Active-Controlled, Randomized, Double Blind clinical trial.
- In some cases, volunteers receive both the study medication and a placebo at different times during a clinical trial. This is called a Cross-Over Study.

Placebos are not used in clinical trials where patients have life threatening illnesses and a proven treatment already exists. Even for diseases where treatments are available, there are some instances where the use of a placebo might be required. The Food and Drug Administration, for example, may require that a placebo be used in order to prove that a medical treatment is safe and effective.

Placebos are also not used in research studies where volunteers will be harmed if they do not receive a real medical treatment for their condition.

Whenever a placebo is used, study volunteers will be informed before they agree to take part in the study. And all volunteers –whether they receive a new medical treatment or a placebo – are monitored carefully by the clinical research study staff. If there is a change in your medical condition while you are participating in the study, the physician will inform you immediately and discuss the situation with you.

It’s important to remember that volunteers who receive a placebo get the same attention, monitoring, care and follow-up as volunteers who receive an active treatment.

Will I receive a placebo?

Volunteers are usually not told what treatment they are being given until a clinical trial is over. So you will not know if you are receiving the study drug or placebo during the trial. Using this approach, there is less chance that bias will be introduced from study participants knowing which treatment they have received.

In most cases, the research investigator and study staff themselves do not know which volunteers are receiving the study drug or the placebo. This also helps reduce possible biases that could affect the results of the research.

The safety and effectiveness of a new medical treatment is best determined when the investigator, study staff and volunteers are ‘blinded’ to the treatment assignments. So it’s very important to take a placebo even though it contains no active medication.

You will be monitored very closely during the clinical trial. If there is a change in your medical condition while you are participating in the study, the research staff will inform you immediately and discuss the situation with you. They may recommend that you drop out of the trial or they may recommend that you receive an active medical treatment. However, for many trials conducted among critically-ill patients for whom there is no effective treatment, volunteers are usually not switched from one group to another.

You will be notified if any new information comes available during the course of a clinical trial that might change your decision to participate in the clinical trial.

Whichever group you are in, you can expect to receive excellent medical care during a clinical trial. And remember, the choice to be in the trial is yours. If at any time you have concerns about your clinical trial, you can speak with the research investigator, study staff, or a patient advocate.