

Placebo Control

COMMON QUESTIONS

- Why are placebos used in clinical trials?
- Do participants have to stop current treatment(s) to participate in clinical trials?

BACKGROUND INFORMATION

Participating in a research study can raise hope, which in turn can improve participants' outcomes, at least for a period of time. To determine if a drug works, researchers must know its true effect separate from the possible effect of participation alone. In order to determine if a new treatment works, it must be compared to another "treatment" or measure. In drug therapy research for Alzheimer's and virtually every other disease or medical condition, that "treatment" is a placebo: an inactive substance that has no benefits, but also no risks, for the participant.

Giving some participants a placebo and others the investigational drug is the best way to learn the true effect of the drug. Placebos are typically identical to the active drug in as many ways as possible, such as color, shape, size and taste, so those involved in the study will not know whether they receive the drug or placebo.

In a clinical study for an experimental drug, results from the group receiving a placebo are compared with those from the group receiving the active drug. Any effect in the group receiving the active drug that does not occur in the group receiving the placebo is the true effect of the drug. Placebo-controlled studies enable scientists to know if a new treatment is beneficial beyond the potential benefit that a person may experience by participating in a study.

Some studies use existing treatments, known as the "standard of care," instead of or in addition to a placebo. In the United States, the majority of clinical trials for Alzheimer's are placebo-controlled and allow participants to continue taking the current Food and Drug Administration-approved medications for the disease, regardless of whether participants are assigned to the placebo group or the intervention group.

ASSOCIATION POSITION

The Association believes placebo-controlled studies provide valuable information to determine the effectiveness of new treatments for Alzheimer's disease. The Association recognizes that some clinical trial designs may require that the use of currently approved medications for Alzheimer's be limited in order to determine the effectiveness of investigational therapies.

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