

Randomized Controlled Trials

Medical research answers many questions about health, illness, and treatment options. Evaluating new medicines and other treatments may involve research using **randomized controlled trials**. In such trials the participants who receive the treatment under study are assigned at **random** (by chance, like the flip of a coin). This is necessary to ensure that the outcomes are determined only by the treatment under study and not by other factors that could otherwise influence treatment assignment. Other participants who, by the randomization process, serve as **controls** receive a standard treatment or **placebo treatment** (a pill or procedure that does not include active ingredients). The June 21, 2006, issue of *JAMA* includes an article about clinical trials. This Patient Page is based on one previously published in the November 2, 2005, issue of *JAMA*.

CLINICAL TRIALS

Clinical trials are designed to answer a specific question about a treatment, usually the safety and **efficacy** (how well it works under optimal conditions) of the treatment. Volunteers who meet specific criteria, including having the condition being studied, receive an explanation and, if they choose, join the trial. This **informed consent** process should include explaining the random treatment assignment as well as the risks and possible benefits of the trial and often includes a written form to document those issues and the volunteer's consent. In a **double-blind** trial, neither the clinicians caring for the patients nor the participating volunteers know who has been assigned to the active treatment until the trial is concluded (unless a medical problem requires that the information be released before that). In a **single-blind** trial, the investigators know the treatment assignments but the participants do not. Blinding procedures protect against the influence of **bias** (prejudice) for or against the treatment being studied.

RESEARCH ETHICS

Before any persons can be enrolled in a clinical trial, the study must receive approval by an ethics committee (called an **institutional review board** in the United States). This is a panel of individuals, including doctors and community members, who discuss all of the proposed research studies at a specific institution (university, medical center, or hospital). The ethics committee reviews the purpose of the study and its design, the risks and possible benefits to the participants, and the adequacy of the informed consent process.

PARTICIPATING IN A CLINICAL TRIAL

- Sometimes participating in clinical trials may allow patients to receive experimental treatments, especially when they have a disease that has not responded to other therapies.
- All participants in clinical trials are volunteers who can withdraw from a trial if they choose.
- Participants should have the option to review the purpose and design of the study and understand whether control participants will receive standard therapy or placebo.
- Participants should have all their questions answered before agreeing to participate in a clinical trial.
- If you are thinking of joining a clinical trial, discuss participation with your doctor to be sure it fits with your ongoing care.

Sources: National Cancer Institute, National Institutes of Health, Centers for Disease Control and Prevention

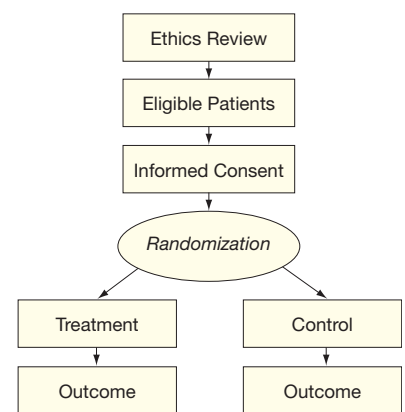
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To find this and previous JAMA Patient Pages, go to the Patient Page link on JAMA's Web site at www.jama.com. A Patient Page on cancer clinical trials was published in the June 4, 2004, issue; and one on supporting medical research was published in the September 21, 2005, issue.

