Clinical Trials

Study participation can be a gateway to better therapies for yourself and others.

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Everything we know about HIV prevention and treatment comes from research involving people at risk for or living with the virus. Joining a clinical trial can be a good way to access new therapies and contribute to science, but it's important to weigh the risks and benefits.

Clinical trials are a key part of the multistep process for testing new prevention, treatment or cure approaches.

- Preclinical: Most experimental therapies first undergo testing in a laboratory, followed by animal studies. But promising activity in a lab or in animals does not mean a drug will work in people.
- Phase I: Early safety trials usually include 10 to 100 participants, often starting with healthy volunteers. They look for common side effects and collect information about pharmacokinetics, or how a drug is processed in the body.
- Phase II: Mid-level trials typically include a few hundred participants. They assess whether a new therapy appears safe in a larger group and gather preliminary information about efficacy.
- Phase III: The largest and longest trials, typically involving hundreds or thousands of participants, test how well a therapy works compared with other options. Less common side effects may show up only after a drug is used by many people over a longer period.
- Phase IV: After a drug has been approved, post-marketing studies are done to see how well the therapy works in the real world.

Randomized controlled trials are the gold standard for testing new drugs.

A controlled trial means participants are randomly assigned to get the experimental therapy or a comparison intervention—for example, the current standard of care or a placebo. Randomization means any participant has an equal chance of ending up in any study arm, which ensures that the groups are otherwise similar.

Trials for new prevention methods follow a similar pathway, but the safety bar is higher because they will be used by healthy people. Other types of trials assess behavioral interventions, such as exercise or smoking cessation.

HIV cure trials are more complex and can involve greater risk. To determine whether a cure strategy leads to long-term remission, participants may be asked to temporarily stop antiretroviral therapy, which could lead to disease progression and HIV transmission.

A good study design is essential for ensuring that clinical trials provide reliable information. It is important that trials enroll the full range of people who will use a new therapy, including women, transgender people and participants from diverse racial and ethnic groups.

Your HIV care team, advocates and support groups can be good sources of information about available clinical trials. The National Institutes of Health's ClinicalTrials.gov website lists open studies for all conditions.

When considering a trial, learn all you can about the therapy being tested and what other options are available. Find out the frequency of study visits and whether the trial reimburses expenses. Don't be afraid to ask questions! Before agreeing to join, you must sign an informed consent document, but this is not a contract—you have the right to withdraw at any time for any reason.

Benefits of trial participation can include early access to promising new therapies, care delivered by leading experts and altruism—knowing you are contributing to science and helping others. Drawbacks can include time-consuming study visits, the need to forgo other therapies and the risk of side effects. And in a randomized trial, you might not get the experimental treatment.

Remember, trials of new antiretroviral drugs, HIV prevention methods and cure strategies can't offer guarantees. Researchers don't yet know how effective experimental therapies will be, and they can't rule out unforeseen adverse events. Despite this uncertainty, clinical trials can be a gateway to better prevention and treatment for yourself and other people living with HIV.

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