

New Hopes for Managing Depression

by BRENDA VANTA

Clinical Studies for Depression

Many people who suffer from depression consider becoming involved in a research study. First, you must understand the different types of research studies available to people who decide to volunteer.

Clinical studies are broadly classified as clinical trials and observational studies. If you know the difference, you'll be more informed and more capable of making a decision.

Clinical trials

Clinical trials, also known as interventional studies, are created to provide specific interventions to the participants of the study. These interventions follow a rigorous protocol created by the research team and may include drugs, medical devices, procedures like MRI or lifestyle adjustments (diet change, fitness plans, etc.). Clinical trials may also be designed to compare a new therapy with the current standard or to a dummy pill. The purpose of these studies is to find if new methods of intervention are helpful and safe.

For example, a new drug for depression may be given to participants who suffer from depression to determine whether or not it works, it's safe and how effective it is when compared with an older anti-depressant. Clinical trials designed for drug development run over several years, and are described in phases (i.e. Phases I, II, III trials). It takes roughly seven years for a potentially beneficial drug to undergo clinical testing. Many drugs don't complete all three phases of the trials, and even if they do, the FDA does not approve them because they fail to meet certain standards. Phase IV is sometimes conducted for drugs that have already been approved and are available on the market, to better understand how that drug works or to be compared with other meds.

In case you are not eligible to participate in a clinical trial, you still may have access to new, experimental drugs outside of a clinical trial through the 'Expanded Access Program'.

Observational Studies

As the name implies, an observational study will evaluate the outcomes in a group of subjects according to a protocol or research plan. If it is designed for individuals with depression, participants may receive interventions as part of the medical care, but they will not receive interventions as part of the study (as it happens in clinical trials).

For example, the participants will continue to follow treatment for depression as usual, but the researchers will observe and monitor your symptoms to learn how diet, fitness routine or other lifestyle factors influence your symptoms of depression.

Many people who consider participating first time in a study will choose an observational study because they can learn about lifestyle changes that prove to be beneficial, while not having to risk taking a new drug that has not

been approved by the FDA.
For more information about what you should know before getting involved in a study visit: What Participants Need to Know About Clinical Trials