

Clinical Trials: Information and Options for People with Mood Disorders



NATIONAL



We've been there.
We can help.

National Depressive and Manic-Depressive Association

National DMDA, its advisors and consultants, do not endorse or recommend the use of any specific treatments or medications, or participation in any specific clinical trial. For advice about specific treatments, medications or clinical trials, individuals should consult their physicians and/or mental health professionals.



What are clinical trials?

Clinical trials are research studies involving people, which may be conducted by universities, hospitals, non-profit community agencies or for-profit testing companies. Some trials evaluate the effects of new or existing

medications. Others study new forms of psychotherapy or other treatment methods. Each follows a structured plan developed before the trial begins.

What happens during a clinical trial?

In some clinical trials, participants are given some type of treatment, such as medication and/or psychotherapy. In others, some participants are given a treatment while others are given a placebo, or “sugar pill.” Sometimes participants are given more than one type of treatment over the course of the trial. Researchers continuously evaluate the condition of each participant. The participants may be asked if their symptoms are improving or if they are experiencing any side effects. Laboratory tests, such as blood tests, may be included.

Common clinical trial terms

Control: The treatment which has a predictable outcome. Research subjects in the control group may receive a standard, commonly used treatment or a placebo (“sugar pill”).

Crossover: A study in which participants are randomly assigned one of two or more treatment options for a specified time period. When that time period ends, the participants “cross over” to one of the remaining treatments for another specified time period.

Double-blind: A study in which neither the participants nor the investigators who work with them knows which treatment or placebo is being given to which participant.

Informed consent: The required signed, written acknowledgement from a participant in a clinical trial (or his or her legal representative), which states that he or she understands what is going to happen in the trial and the risks involved.

Institutional Review Board (IRB): A group of people (including scientific experts as well as non-scientists) that oversees the design of a clinical study and periodically reviews clinical research to ensure there are no ethical violations. A clinical trial must be approved by the IRB before it begins.

Placebo: A pill or treatment designed to have no effect on the person who takes it, also called a “sugar pill.”

Placebo effect: Situation in which an individual feels an improvement in his or her condition after taking an inactive substance or “sugar pill.”

Protocol: Procedures which must be followed. To protect the trial’s scientific accuracy, straying from protocol is seldom allowed.

Randomized: A study in which participants are assigned by chance (not by the investigators’ choice) to their particular groups.

Single-blind: A study in which the investigators know which treatments each participant is receiving, but participants do not.



Why participate in a clinical trial?

Without clinical trials, many of the treatments that help people manage their illnesses would not be available today. For example, in most cases, medications cannot be prescribed until the Food and Drug Administration

(FDA) approves them. In order to be approved by the FDA, medications must first demonstrate safety and effectiveness in clinical trials. Clinical trials have evolved a great deal in recent years, and more attention than ever is being paid to the well-being of research volunteers.

Taking part in a clinical trial may give you the opportunity to try a new medication or treatment before it is widely available, or to receive the attention of multiple specialists. The medication being tested may lack the side effects of the medication you are currently taking. In the majority of studies, patients are not charged for medications, visits or tests.

Your decision to participate in a clinical trial is voluntary, and should be based on your personal needs, interests, beliefs and expectations. *It is important that you understand your rights as a research volunteer and the risks involved before making your decision.*

What are the drawbacks of clinical trials?

Every clinical trial involves a trade-off. Nothing is without risks, including illness itself. A study may not benefit you personally at the time of the clinical trial. You may have to stop taking your current medications, even if they are working. It is very important that you understand potential risks of participation before agreeing to take part in a trial. Consult your physician when deciding whether or not the trade-off involved is reasonable for you.

It is important to remember that the goal of a clinical trial is to learn more about your illness and its treatments. In addition, keep in mind, your participation in a trial does not guarantee you will be given a new treatment. You may be given an older medication or even a placebo—an inactive substance that resembles a real medication in appearance.

Agree in advance with your doctor, family members or trusted friends what will be done (and by whom) if your symptoms worsen or become severe during the course of the trial. Write down what you would like done, what medications you are taking, your health care providers' names and phone numbers, and your insurance information, for use in an emergency.

Many people think that participating in a clinical trial means they will get better treatment for their illness. While this may be true, please keep in mind that the trial is being conducted for research purposes. Taking part in a trial does not guarantee individual benefits to the participant in the form of newer or safer treatment. The contribution made by a clinical trial is to science first and to the patient second.

Do I have to meet certain participation requirements?

Yes. Admission into a clinical trial is based on a rigid set of criteria. These criteria vary with each trial and may include:

- You must be diagnosed with the illness that is treated by the treatment being studied.
- Sometimes admission criteria will specify a particular subtype of an illness (e.g., chronic depression, bipolar I or II) or certain symptoms (e.g., rapid cycling).
- Other co-existing mental or physical disorders usually must be absent.
- Some trials do not permit the use of medications other than those given as part of the study.
- Excessive alcohol intake or “street drug” use may disqualify an applicant from participation.
- Participants may be required to have never taken the medication being studied.

Is hospitalization necessary during a clinical trial?

Clinical trials that test mood disorder treatments are usually conducted on an outpatient basis, unless the clinical trial is specifically designed to include hospitalized patients.

What is involved with “Informed Consent”?

You will be asked to sign an informed consent form after you discuss the clinical trial with study personnel. Informed consent forms describe the plan of the trial, including an explanation of all treatment possibilities and any required testing procedures. The potential benefits and risks of the treatments being studied will be listed, as well as any hazards or discomforts associated with the study procedures. Carefully read the entire form and ask questions if there is anything you do not understand. Take the consent form home; do not sign it without considering it overnight. You may want to discuss the trial with your family or health care provider.

What information do I need to know before participating?

Before agreeing to participate in a trial, make sure you have the following information. This information may be found in the study materials or the informed consent form, so be sure you have read them carefully.

Facts about the trial

- The treatment the clinical trial is studying
- The goals of the trial
- How long the trial will last
- Who is paying for the trial (for example, a pharmaceutical company, a hospital or a non-profit foundation)
- Where the research will take place
- How to contact the study coordinators
- What will happen during the trial and what study/treatment methods will be used

What is required of you

- How often you will need to travel to the testing site and how far the site is from your home
- How long each appointment will be
- Whether transportation costs will be reimbursed
- Whether you will be charged for the study
- Whether you will be paid for your participation
- Whether child care will be available

Facts about the treatment

- Your chance of receiving the new treatment being studied, an existing treatment or a placebo
- Whether you will be able to try or continue the new treatment being studied after the trial is complete

Treatment issues

- Whether you will have to discontinue your present medication(s)/treatment(s)
- Whether the experimental medication will cause your current medications to be less effective, or whether there will be any possible health risks when you take the experimental medication along with your current medication
- Whether you will be able to raise or lower the dosages of the medication you receive
- What is known about the benefits, risks, possible discomforts or side effects of the medication/treatment being studied (you may want to ask for written material)
- What side effects you should expect when taking (or stopping) a medication, and how to handle any severe side effects you experience
- Whether you will be able to continue seeing your own doctor
- Whether you will receive follow-up care after the trial is complete, and for how long

Illness issues

- How it will be handled if your symptoms worsen, and how and when study personnel will be notified if you become ill
- Whether you will be allowed to take a mood stabilizer during the trial

Disclosure issues

- How your confidentiality and privacy will be protected during and after the trial
- How any negative findings will be handled and how you will be informed
- How to drop out if necessary and who to contact
- What you can do or how you will be compensated if you suffer injury during the trial



How can I find out about clinical trials that may benefit me?

First, ask your health care professional about clinical trials that might be appropriate for you. Research organizations and universities conduct

clinical trials in most major metropolitan areas. Visit National DMDA's web site, www.ndmda.org, for a listing of clinical trials. (National DMDA does not necessarily endorse the clinical trials on its list.) Ads for clinical trials also may appear in newspapers and magazines, and on billboards, the radio and television. Trials may be paid for by a variety of organizations; find out who is sponsoring the trial before you participate.

For another source, contact the Office of Public Inquiries at the National Institute of Mental Health (NIMH), (301) 443-4513/fax (301) 443-4279, or visit NIMH's web site, www.nimh.nih.gov, and click on the Clinical Trials link. You may also send e-mail to nimhinfo@nih.gov, or write: NIMH Public Inquiries, 6001 Executive Boulevard, Rm. 8184, MSC 9663, Bethesda, MD 20892-9663.

An additional source which may list trials near you is www.centerwatch.com.

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Please send this form with payment to: National DMDA
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Questions? Call (800) 826-3632 or (312) 642-0049.

Credit card payments (Visa, MasterCard or Discover) may be faxed to (312) 642-7243.

Secure online donations can also be made at www.ndmda.org.

A fee will be applied on all returned checks and resubmitted credit card charges.

National DMDA is a not-for-profit organization. Your contributions may be tax deductible. For more information, please consult your tax advisor. **Thank you for your gift!**

NATIONAL



**We've been there.
We can help.**

THE MISSION of the National Depressive and Manic-Depressive Association (National DMDA) is to educate patients, families, professionals and the public concerning the nature of depressive and manic-depressive illnesses as *treatable* medical diseases; to foster self-help for patients and families; to eliminate discrimination and stigma; to improve access to care; and to advocate for research toward the elimination of these illnesses.

National DMDA: Your Resource for Education and Support

The National Depressive and Manic-Depressive Association is the nation's largest patient-directed, illness-specific organization. Incorporated in 1986 and headquartered in Chicago, Illinois, National DMDA has a worldwide grassroots network of more than 800 support groups. It is guided by a 65-member Scientific Advisory Board composed of the leading researchers and clinicians in the field of mood disorders.

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