

Should I Participate in Lewy Body Dementia Clinical Research?

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Despite being the second most common form of progressive dementia, there is still much we do not know about Lewy body dementia (LBD), nor do we have effective treatments for this condition. Through the Lewy Body Dementia Association (LBDA) Research Centers of Excellence program, we hope to propel LBD clinical research forward in great strides, to learn all we can about LBD and develop new, effective treatments. To do so, clinicians and researchers must work closely together with people living with LBD, as well as their loved ones — clinical research is truly a partnership between us all!

What is clinical research?

Clinical research refers to research studies designed to learn new information about human health and diseases. In a nutshell, it is research that involves people. This is different from basic science research, or "preclinical" research, which is done in laboratories. Clinical research helps move discoveries made in laboratories out into the real world.

A clinical trial is a type of clinical research study designed to test a new treatment, procedure or medical device for a medical condition in people. This requires people to volunteer to take part in the research study; sometimes studies are looking for healthy people to volunteer, and other times they need people with a particular medical condition, such as LBD. There are several different stages of clinical trials, meaning that it often takes many years to determine if a treatment works and should be approved for use for a medical condition.

How are clinical trials developed?

Usually, many years of preclinical research has indicated that a new treatment might be promising for treatment of a medical condition. This preclinical work is often done using laboratory animals, such as mice. The next step is translation of this work to people in the real world.

Researchers must develop very specific plans for their studies, called protocols, which outline how they plan to answer their research question and what will be required of research participants in the study. Each protocol must be approved by a research ethics committee, called an institutional review board, to ensure that human participants are being kept safe. After receiving approval, researchers can start recruiting volunteers for their study.

What are the stages of clinical trials?

Clinical trials are designed to test new treatments for medical conditions. Specific questions must be answered through these trials before any treatment can be approved by the Food and Drug

Administration (FDA): Does the new treatment work at all? Does it work better than other available treatments? What is the best dose of the treatment? Are there any side effects?

To answer these questions, clinical research must move through rigorous, defined stages as it develops to ensure that scientists can be confident about their results and that people who are participating are kept safe.

Phase I studies test new treatments in humans for the first time, primarily to make sure they are safe and to determine the best doses of new medications. Phase I studies are performed with small groups of healthy participants.

Phase II studies expand to a larger group of people who have a medical condition to start to explore whether the treatment works well and to assess side effects in the disorder of interest.

Phase III studies are done in large groups of people with a medical condition to more clearly determine if the treatment works well, if it has any side effects, and how it compares to other existing treatments.

Phase IV studies are done after the treatment has been approved by the FDA to learn more about the treatment and its effects once it is in use.

If I participate in a clinical trial, will I definitely get the new treatment?

The quick answer is no, not necessarily. This will often depend on the stage of the clinical trial and the study design. In most Phase II and all Phase III studies, participants will be assigned to different treatment groups. This is called randomization. Researchers use computer programs to randomly assign participants so that they do not know who is getting which treatments. The participants also do not know which treatment group to which they are assigned; this is called a double-blind study.

Depending on the study design, the treatment groups may involve different doses of the same drug, different drugs or a placebo. A placebo is a treatment that seems to be "real" to everyone involved in the study, but isn't — it could be a sugar pill, a saline injection or sham surgery. Researchers compare the responses in people receiving the active treatment with those receiving the placebo to prove that the active treatment is effective, or "better than placebo."

It is important to note that some individuals in any clinical trial do appear to experience a positive effect when receiving a placebo — this is known as the placebo effect. Any new treatment must be shown to be superior to placebo before that treatment is considered for potential approval by the FDA.

While many people volunteer for clinical trials because they hope to get a new treatment for their condition, there is no guarantee that they will receive it. Performing clinical trials in this way is necessary to ensure new treatments actually work.

Why should I volunteer for a clinical trial?

Participating in a research study is a very personal decision, which should be made with full information and support from your family and loved ones, your doctor, and the research team. You should never feel pressured to participate — it is **always** completely voluntary. You can also change your mind at any time and withdraw from a study, even if you initially agreed to participate.

You should fully understand why the study is being done, what the researchers are hoping to learn, and the possible risks and benefits of participation before signing up to participate. Risks of participation include possibly experiencing side effects or complications of an experimental treatment. Benefits of participating in a clinical trial include potentially having access to an experimental treatment that is not yet available to the public, but also helping others by contributing to medical knowledge about a condition and treatments for it.

Clinical research simply cannot be done without the generous contributions of people living with medical conditions, including Lewy body dementia.

For more information about participating in clinical research, review these resources:

- [The Lewy Body Dementia Association](#)
- [Countway Library Guide to Participating in Health Research](#)