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Protocol Level
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Struggling to manage your depression?

Consider participating in the Reliance clinical research study.

Approach your depression differently.

If you've been diagnosed with depression (also known as major depressive disorder), you may qualify to participate in a clinical research study evaluating an investigational drug to treat this condition.

Depression can feel emotionally, mentally, and physically draining while putting a strain on one's quality of life. We need clinical research to find safe and effective depression treatments for everyone who lives with this condition—and your participation may help take us a step closer.

Explore a different method for your depression. Consider joining the Reliance study today.

The Reliance study is enrolling now.

The Reliance study is investigating a medication for people living with depression. Even with treatment, depression symptoms may continue. That is why researchers are exploring how an investigational oral medication may help to manage depression when added to existing antidepressants. If you are currently taking antidepressants but find that they are not fully managing your symptoms, this study may be an option for you.

You may be eligible to participate as a volunteer if you are:

- Are 18-65 years of age
- Have been diagnosed with depression (major depressive disorder)
- Are currently feeling depressed

What is major depressive disorder (MDD)?

Major depressive disorder (MDD) is one of the most common mental health conditions today.

- One in five people experience depression during their lifetime.
- MDD is typically diagnosed when an individual experiences the following symptoms: feelings of sadness, difficulty sleeping, changes in appetite or weight, fatigue, low energy, guilt, or loss of joy in things that typically interest them.
- People living with depression can often experience repeating periods of feeling depressed. On average, up to 50% of those who recover from a first episode of depression have one or more additional episodes in their lifetime.[1]

By joining this research study, your participation may help change the future of how doctors treat MDD.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2169519/

About the Reliance study

The Reliance study is currently testing an investigational drug for people living with depression.

If you have been diagnosed with depression, are currently experiencing symptoms, sometimes referred to as a depressive episode, and are between the ages of 18–65 years, you may be eligible to participate. This investigational drug is administered orally, once daily.

You will receive all study-related care at no cost. Health insurance is not needed.

This study is for people who are currently taking antidepressants but find that they are not fully managing their symptoms. If you are taking an antidepressant and are eligible for this study, you will continue with your current antidepressant in addition to taking the investigational drug.

People who enroll in the study will be randomly assigned (like the flip of a coin) to a study treatment group to take either the investigational drug or a placebo. There is an equal chance (50/50) of being assigned to either group. Neither you nor the study doctor will know whether you are assigned to the investigational or placebo group. Those who qualify and meet all other eligibility criteria will be trained in the use of the investigational drug. Participants may be compensated for time and travel.

How long will the study last?

The Reliance study may last up to ten weeks. This time includes a screening period, a treatment period, and a follow-up period. You can stop your participation in the study at any time.

Why should someone consider participating?

- To help others by expanding what we know about depression and its treatment
- You may gain additional resources for managing your depression

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About clinical research

Clinical research studies seek to advance and improve treatment options for all conditions, including depression.

A clinical research study is designed to answer questions about the safety and effectiveness of potential new drugs. These studies must be performed before a potential new medication or treatment can be approved for use in patients and available on the market.

It is important to test drugs and medical products in the people they are meant to help. Diversity is also important in research because different people may respond differently to treatments.

For each research study, researchers develop eligibility criteria such as age, gender, previous treatment history, and other medical conditions. Not everyone who applies for a research study will be eligible to join. Participants will be selected based on the eligibility criteria. Taking part in a clinical research study can offer several benefits, including:

- Taking an active part in managing your own health
- Having access to breakthrough treatments
- Having access to specialists in the condition being studied
- Helping others by possibly advancing medical research

Frequently asked questions

What is a clinical research study?

Clinical research studies are designed to answer specific questions about the safety or effectiveness of new drugs, vaccines, other therapies, or new ways of using existing medications. Studies are important for medical research advances. Current treatments for diseases and conditions are only available because of study volunteers.

Learn more about clinical studies at:
www.nimh.nih.gov/health/trials/index.shtml

What is an investigational drug?
An investigational drug is a substance that is being tested in clinical research studies and may or may not be approved by the Food and Drug Administration for treatment of this condition.

What is a placebo?

A placebo is a sugar pill that looks like the investigational drug but has no active medication in it. Researchers compare the results of the investigational drug to those of the placebo.

Are research studies safe?

Research studies are conducted by trained medical professionals. An Institutional Review Board (IRB) reviews all research studies. This is a committee made up of doctors, ethicists, members of the general public, and administrators. This group helps to ensure that the rights of research participants are protected. A participant's regular doctor is responsible for their well-being, and they may want to speak with their doctor before agreeing to participate in a study as there are possible risks associated with participation. Whenever someone agrees to enter a study, they are given the name and telephone number of a contact in their study physician's office who will answer their questions as well as a contact for the institutional review board overseeing the study, whom they can contact if they have questions or concerns.

Who can participate in this study?

If someone has been diagnosed with depression, is currently experiencing symptoms (sometimes referred to as a depressive episode), and is between the ages of 18-65 years, they may be eligible to participate. The Reliance study is for people who are currently taking an antidepressant but find that they are not fully managing their symptoms. If they were in this study, they would continue to take their current antidepressant in addition to using the investigational drug.

How long will the study last?

The Reliance clinical research study may last up to ten weeks. This time includes a screening period, a treatment period, and a follow up period. Participants can stop their participation in the study at any time.

How many times will a participant meet with the study doctor and team?

Participants will visit the study team five times during the treatment period.

Do participants have to stop taking their current antidepressant?

No, they will continue to take their current antidepressant while participating in this study.

What will participants be expected to do?

Participants will be expected to take the investigational drug (or placebo) once a day by mouth for 28 days during the treatment period. Lab tests, a physical exam, and other assessments and questionnaires will be conducted at study visits, but not all activities will occur at every visit.

What happens when the study is over?

Participants will enter a 14-day follow-up safety period without the investigational drug. Relmada may conduct an Expanded Access Program where access to the investigational medication is provided when the study is over. Check with the study doctor if this program is available in your area.

What will participation cost?

Participants do not have to pay for participation in a clinical research study. This includes the investigational drug, study supplies, study visits, or any tests that are part of the study. They may receive reimbursement for their time and travel.

Are there risks to participation?

There are possible risks involved with any clinical research study. The study doctor will review the risks with participants, and they will be closely monitored throughout the study. They may experience side effects and be uncomfortable, the investigational drug may not work for them, or it may not be better than their current treatment.

How will a participant's privacy be protected?

Confidentiality is an important part of clinical research studies. Their personal information will be seen only by those authorized to have access.

Why did I disqualify for the study?

Clinical research studies are designed in specific ways, and one or more of the answers that you provided were outside of the guidelines for this study. This does not mean you will not qualify for different research studies.