How many times will I meet with my study doctor and team?

For this study you will visit your study team five times during the treatment period.

Do I have to stop taking my current antidepressant?

No, you will continue to take your current antidepressant while participating in the study.

What will I be expected to do?

You will be expected to take the investigational medication (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?

You will be followed for a 14-day period to monitor safety. 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?

You do not have to pay for participation in a clinical research study. This includes the investigational medication, study supplies, study visits, and tests that are part of the study. You may receive reimbursement for your time and travel.

Will I benefit from volunteering?

You may receive more frequent health check-ups as part of your participation. You will help others by contributing to what we know about Major Depressive Disorder (MDD), and you may gain additional resources for managing your depression.

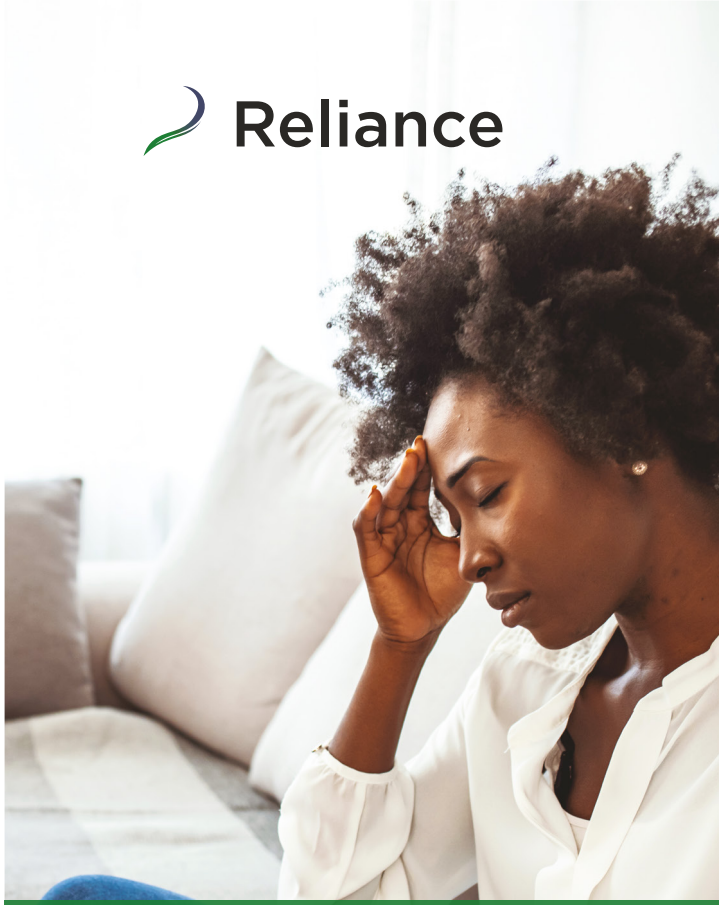
Are there any risks if I participate?

There are possible risks involved. Your study doctor will review the risks with you, and you will be closely monitored throughout the study. You may experience side effects and be uncomfortable, the investigational drug may not work for you, or it may not be better than your current treatment.

How will my privacy be protected?

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

Reliance



Struggling to manage your depression?

The Reliance clinical research study is currently testing an investigational medication for people living with depression, or Major Depressive Disorder (MDD)

Even with treatment, depression may continue to be challenging. That is why researchers are exploring how an investigational medication, when added to an existing antidepressant, may help manage MDD. If you are currently taking an antidepressant but find it is not fully managing your symptoms, participating in the Reliance Clinical Research Study may be an option for you.

What is a clinical research study?

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

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

Who can participate in this study?

If you have been diagnosed with Major Depressive Disorder (MDD), are currently experiencing depression (sometimes referred to as a depressive episode), and are between the ages of 18-65 years, you may be eligible to participate in this study.

The Reliance study is for people who are currently taking an antidepressant but find it is not fully managing their symptoms. If you were to participate in this study, you would continue to take your current antidepressant.

The Reliance study has two groups: one that receives the investigational medication and one group that will receive a placebo (a sugar pill that has no medicine in it).

An investigational medication 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. A placebo looks like the investigational medication but has no active drug in it. Researchers compare the results of the investigational medication to those of the placebo.

If you are eligible for this study, you will be randomly assigned (like the flip of a coin) to a study treatment group to take either the investigational medication 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 medication or placebo group.

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.

Thank you

We appreciate your interest in the Reliance study

You can learn more about the Reliance study by contacting:

Brooklyn Montgomery
(845) 235-9237
clinicaltrials@relmada.com
Relmadastudies.com

Reliance