Is Anxiety Making Everyday Life Harder Than It Should Be?

*Learn whether **The RECLAIM Study** may be an option for you.*

This research study is evaluating a single dose of an investigational psychedelic medication vs. placebo to see if it may help reduce symptoms of generalized anxiety disorder (GAD).

If you live with generalized anxiety disorder, you know anxiety isn't limited to stressful moments. Ongoing worry can affect how you feel, think, and manage daily life.

You may relate to symptoms such as:

- Uncontrollable worry and anxiety about everyday things
- Feeling irritable or "on edge" frequently
- Having difficulty concentrating
- Restlessness, trouble relaxing, and/or sleeping difficulties

A research study evaluating a single dose of an investigational psychedelic medication compared to placebo may be an option for you.

Please continue reading to learn more about The RECLAIM Study and what participation involves.

The Toll of Generalized Anxiety Disorder (GAD) on Mental Health

GAD often involves persistent feelings of anxiety or dread that interfere with daily life. People with GAD feel extremely worried or nervous more frequently or more intensely, even when the worry is out of proportion to the situation. For people with GAD, these symptoms can last for months or years. It is important to remember that with the right treatment and support, people with GAD can manage their anxiety and improve their quality of life.

Recognizing Symptoms of Generalized Anxiety Disorder

GAD can look different for everyone, but common signs may include:

- ✓ Excessive worry about everyday things
- ✓ Trouble controlling worries and nervousness
- ✓ Feeling irritable or easily frustrated
- ✓ Difficulty concentrating, or feeling that your mind "goes blank"
- ✓ Overthinking plans and solutions to all possible worst-case outcomes
- ✓ Indecisiveness and fear of making the wrong decision
- ✓ Feeling situations or events are threatening, even when they aren't

GAD can also cause physical symptoms including:

- ✓ Fatigue
- ✓ Trouble falling asleep or staying asleep
- ✓ Muscle tension or aches
- ✓ Trembling or feeling twitchy
- ✓ Sweating or being easily startled
- ✓ Nausea or other gastrointestinal symptoms

If you recognize these symptoms in yourself, please consider whether participating in The RECLAIM Study might be right for you.

What Will Happen If I Participate in The RECLAIM Study?

Participation in The RECLAIM Study is voluntary. Interested potential study participants will be screened at a Study Center where they will be assessed to ensure they meet all eligibility criteria and can participate safely.

Eligible participants will receive a single injection under the skin at the Study Center and will be monitored in a comfortable environment. Study Participants will have a 50/50 chance (like the flip of a coin) of being assigned to either the study drug or placebo, a substance that looks like the study drug but has no active ingredients. After the treatment session, Study Participants will be followed for 12 additional weeks with follow-up visits over the phone and in person to help monitor safety and well-being.

How Long Will The RECLAIM Study Last?

Including the Screening Period, the Treatment Session, and the Post-Treatment Follow-up Period, participation in this study will last up to 15 weeks.

Screening Period	Treatment Session	Post-Treatment Follow-up Period						
(up to 21 or 28 days)	Day 0	Day 1 (Remote)	Day 7 (Remote)	Day 7	Day 14 (Remote)	Day 28	Day 56	Day 84
Visit 1 Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10

What Type of Study Drug Is Being Evaluated?

The study is evaluating the safety and effects of an investigational study drug in adults with generalized anxiety disorder (GAD). The study drug is structurally similar to psilocybin (a drug with psychoactive properties) that may help ease psychiatric symptoms of GAD.

Participation Requirements

The RECLAIM Study is testing an investigational single-dose, short-acting psychedelic medication. Our goal is to learn if and how well it may help people with symptoms of generalized anxiety disorder.

To be eligible to participate, the participant must:

- ► Be between 18 and 74 years old
- ► Be currently experiencing symptoms of generalized anxiety disorder (GAD)
- ► Have an adult (e.g., family member or trusted friend) to escort them home from the treatment session
- ► Not be pregnant or planning to become pregnant

This is not a complete list of study eligibility requirements. The staff at the Study Center will explain the complete list of requirements.

Is There a Charge to Participate?

There is no charge to participate. Study Participants do not pay for:

- ► Assigned study drug
- ► Clinic visits
- ► Study-related procedures, tests, or exams

Study Participants may be reimbursed for study-related expenses. Please ask the study staff for details.

Why This Research Matters

Doctors have several prescription treatment options for generalized anxiety disorder (GAD). Antidepressants are often used as the first treatment for the symptoms of GAD. However, in some people, these treatments may not provide enough relief from excessive worry and other GAD symptoms.

This is why there is a need for new treatment options for GAD. Since so many people's symptoms may not respond to these currently available treatments, there is still a need for other therapies that are safe and effective.

Before new medications can be approved for public use, they must be tested in research studies like this one. Research studies help us explore potential new treatments for people living with GAD. Your participation could help shape the future of care.

Risks and Benefits

All medical treatments and procedures come with potential risks. As a result, participants in this study may experience some discomfort or side effects from the investigational treatment, study procedures, or tests. Before making a decision about participation, the study staff will provide a detailed explanation of these risks to ensure potential participants are fully informed. Throughout the study, participant safety will be closely monitored by the research team.

While there is no guarantee of direct personal benefit, the information gained from this study could help create better treatments for people with GAD.

Next Steps

If you are interested in learning more, please contact us using the information below. If you contact us, you are not obligated to participate in this study. Participation is entirely voluntary.

For more information about this research study, please contact:

CONTACT UNM STUDY TEAM TO LEARN MORE AND FIND OUT IF YOU ARE ELIGIBLE:

Text or leave message at:
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Reclaim@salud.unm.edu

HRRC #26-080

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