Looking to REKINDLE Your Ability to Cope With a Life-Changing Medical Illness?

For those experiencing mental health struggles due to cancer or other medical illness, The REKINDLE Study for Adjustment Disorder may be an option.

Living with cancer or other serious medical condition changes everything — including your mental health. Those experiencing negative mental health changes after becoming ill may be dealing with what is known as Adjustment Disorder.

Adjustment Disorder is more than just sadness — it can deeply affect how you feel and cope. If you are struggling with feelings of:

- ***Sadness***
- ***Hopelessness***
- ***Worry***
- ***Or other symptoms of Depression with or without Anxiety***

Our study involving a single dose of an investigational drug may be an option for you.

The Toll of Adjustment Disorder on Mental Health

With adjustment disorder, profound feelings of fear, anger, and loss are very common. The emotional toll of being in the middle of uncertainty and grappling with loss of control can be just as heavy as the physical symptoms.

It is important to remember to prioritize your mental health in these situations because these feelings can sometimes become truly overwhelming. When these feelings affect your ability to cope, this is called adjustment disorder.

Recognizing Symptoms of Adjustment Disorder

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

- ✓ Persistent sadness, crying, or emotional numbness
- ✓ Overwhelming worry or fear
- ✓ Loss of interest in daily activities
- ✓ Withdrawing from friends, family, or work
- ✓ Trouble sleeping or concentrating
- ✓ Feeling hopeless about the future

If you recognize these mental health symptoms in yourself or someone you care about, please consider whether participating in The REKINDLE Study might be right for you.

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What Will Happen If I Participate in The REKINDLE Study?

Participation in The REKINDLE Study is voluntary. Interested potential study participants will be screened at a Study Center where they will be assessed to ensure they can participate safely. During the Screening process, Study Participants will also meet and get to know their Session Monitors, professionals trained to guide and stay with them during their investigational dosing experience.

Participants will receive a single subcutaneous injection of the study medication 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 a high dose or low dose of the study drug. After dosing, Study Participants will be followed for six additional weeks to evaluate their symptoms and check on their safety.

How Long Will The REKINDLE Study Last?

Screening Period – Up to 28 days

Dosing Visit – 1 Day

Post-Dose Follow-up Period – 6 Weeks

Including the Screening Period, the Dosing Visit, and the Post-Dose Follow-up Period, participation in this study will last up to ten weeks.

What Type of Medication Is Being Evaluated?

The study drug is an investigational medication that is structurally similar to psilocybin (a drug with psychoactive properties) that may help ease psychiatric symptoms of adjustment disorder.

Participation Requirements

The REKINDLE Study is testing an investigational single-dose, short-acting psychedelic medication. Our goal is to see if it can help people with symptoms of depression with or without anxiety linked to adjustment disorder due to a serious medical illness.

To be eligible to participate, the participant must be:

- Between 18 and 80 years old
- Diagnosed with cancer (stages 1-4), or other serious conditions such as Amyotrophic Lateral Sclerosis (ALS), Multiple Sclerosis (MS), Parkinson's disease (PD), or idiopathic pulmonary fibrosis (IPF)
- Experiencing symptoms of depression with or without anxiety and feeling overwhelmed for at least four weeks

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 the:

- 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

Adjustment disorder can be common during a serious illness, causing intense feelings of sadness, anxiety, hopelessness, or difficulty coping with daily life. Unfortunately, there are currently no FDA-approved medications specifically for adjustment disorder related to serious illness.

Previous research with the psychedelic substance psilocybin has shown that it may rapidly improve anxiety and depressive symptoms, improve feelings of hopelessness and overall quality of life, and provide durable mental health relief to people with cancer.

Research studies like this one help us explore potential new treatments for emotional distress linked to major medical conditions. 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 adjustment disorder.

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:

Esmeralda Terrazas
Senior, Clinical Research Lead CaTS
520-626-8000
esmeralda97h@arizona.edu

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