

A new clinical trial  
for schizophrenia.

**It's not positive. It's not negative.**

**It's cognitive.**

## The cognitive side

### of schizophrenia

While therapies exist to address some symptoms of schizophrenia, there are currently no approved medications for the cognitive impairment associated with this condition. The TALLY clinical trial is researching potential ways to change this.

#### **What is a clinical trial?**

Clinical trials are research studies that explore whether a potential new or known drug is safe and effective for humans. They are designed to help us find:

- Potential new treatments
- Potential new versions of existing treatments
- Potential new uses for existing treatments

**Your safety is the top priority of every clinical trial. In fact, governments have strict rules to protect the safety and privacy of trial volunteers. The known risks and benefits are outlined in a clinical trial's informed consent form (ICF), which you must carefully read and sign before you take part.**

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## The TALLY

### clinical trial

Currently, there are no approved medications for cognitive impairment associated with schizophrenia. We want to understand if an **investigational drug** could be safe and potentially effective in impacting things like attention and memory in people with schizophrenia.

*An investigational drug is simply the potential drug we are studying in the clinical trial. Its safety and effectiveness have not been approved by the FDA.*

#### Who can take part?

We're looking for about 219 people to take part in this clinical trial who, among other things:

- Are aged 18 to 55
- Have been diagnosed with schizophrenia for at least two years
- Are taking a consistent dose of no more than two antipsychotic medications
- Have not been hospitalized due to schizophrenia for at least 12 weeks
- Have a dedicated study partner
  - someone who knows you well, interacts with you (in person or by telephone) at least two times per week and can accompany you to certain visits

## What does taking part involve?

The TALLY clinical trial consists of a two-part screening period, a dosing period, and a final follow-up visit. Your total time in the trial would consist of about 11 clinic visits over about five months.

### Screening period (up to 4 weeks)

You will have a screening visit to see if you qualify



### Screening period (continued) (one week)

You will take a placebo twice daily for one week to see how well you can follow the dosing schedule



### Dosing period (12 weeks)

You will visit a trial clinic about once every two weeks so we can check on your health



### Final follow-up visit (2 weeks after final dose)

You will visit a trial clinic one last time for a final check of your health

We want to test two different doses of this investigational drug against a placebo. During the dosing period, you will randomly (by chance) be assigned to receive either a placebo or the investigational drug. Both the investigational drug and the placebo look the same. Neither you nor your doctor will know which you are taking.

### What is a placebo and why do we use one?

A placebo looks exactly like the investigational drug but does not contain active ingredients. This helps scientists know if any changes in your health are due to the investigational drug and not something else.



## What happens

### at trial visits?

During the clinical trial, you will visit a trial clinic about once every two weeks so we can monitor your health. Assessments will vary between visits but may include:



Physical exams



Activities involving thinking, learning and memory



Vital signs



Questionnaires



Blood samples



Urine samples

## What else

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## should I know?

### **If I join the trial, can I change my mind?**

Taking part in any clinical trial is completely voluntary. If you join the trial but then change your mind you can leave at any time for any reason. This will have no impact on your usual healthcare.

### **Do I have to pay to take part?**

No. All trial-related care is provided to you at no cost – health insurance is not required. Certain additional costs (like transportation and parking) may also be covered.

### **What does taking part mean for me?**

- Your health may be monitored more closely at frequent health checks
- You may provide information that might help grow our knowledge of schizophrenia and CIAS
- There is no guaranteed impact on your disease. Your health may get better, worse or stay the same
- You may experience unwanted side effects, which are outlined in the ICF that you must carefully read and sign before you can take part

**I'm interested  
in taking part.**

**What's next?**

If you are interested in taking part in the TALLY clinical trial or would like more information, please contact the trial team for a no-obligation chat.

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CONTACT INFORMATION