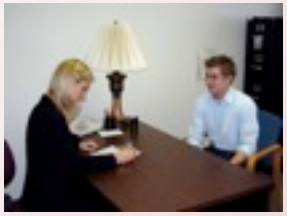
Why are clinical studies important?

Clinical studies provide information to improve understanding about a mental disorder and to develop better treatments. In clinical treatment studies, volunteers are treated with either FDA-approved medication or investigational drugs and the results are carefully monitored by study personnel. Other studies help scientists learn more about how the brain works or about the causes of the condition.



What are the benefits and risks of participating in a clinical trial?

Clinical studies help eligible participants to:

- ☑ Help others by contributing to research
- ☑ Play an active role in their own health care
- ☑ Obtain expert medical care
- ☑ Obtain treatment at no cost

There are risks to clinical studies. Although side effects can vary from person to person, there may be unpleasant, serious, or even life-threatening side effects. The study treatment may not be effective and may require more of the participant's time and attention than standard care treatment, including trips to the study site or more detailed assessment. All studies are completely voluntary, and prospective subjects are fully informed about the study before they are asked to enroll.

All subjects are able to drop out of a study at any time, without affecting their ability to resume standard care treatment.

Schizophrenia Trials at the U of M

The Schizophrenia Program has been conducting studies of medication treatment for several years and participated in the landmark CATIE and CAFÉ studies comparing antipsychotics in schizophrenia and first episode psychosis. The CATIE network continues as the NIMH Schizophrenia Trial Network (STN) of which we are a participant.

Schizophrenia Information

Schizophrenia is a serious brain disorder affecting more than 2 million Americans. The disease can be extremely disabling, affecting the ability to think clearly, to distinguish reality from fantasy, to manage emotions, make decisions, and relate to others. While the causes of schizophrenia remain unknown, its symptoms can be treated.

Symptoms of Schizophrenia:

- A loss of contact with reality (psychosis)
- Hallucinations (false perceptions)
- Delusions (false beliefs)
- Abnormal thinking
- Restricted range of emotions
- Diminished motivation
- Disturbed work and social functioning

Medications for schizophrenia—called antipsychotics—change the balance of chemicals in the brain and are effective in treating schizophrenia, especially in controlling delusions and hallucinations. However, they are also associated with side effects that may discourage a patient from taking them regularly. Also, they have little effect on the negative and cognitive symptoms of schizophrenia.

Research is needed to know how to use these medications more effectively and to develop new treatments to lessen the burden of schizophrenia on patients and their families.

How to Contact Us

To find out more information about research at the University of Minnesota, or to learn more about schizophrenia or other psychotic disorders, call

612-627-4840

or email

schizophrenia@umn.edu

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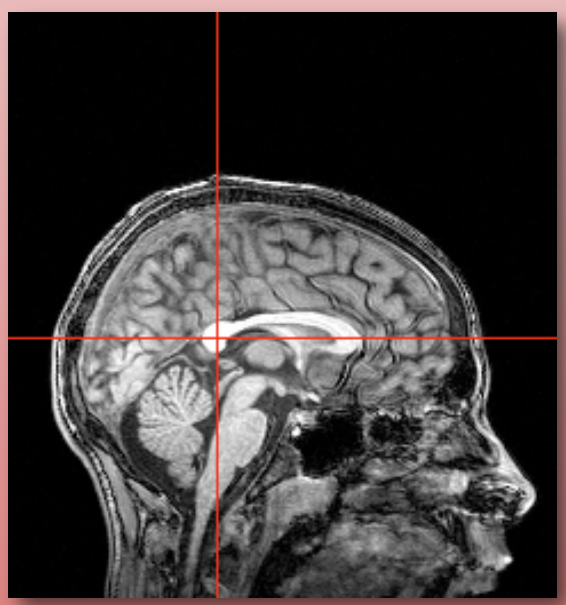
University of Minnesota

Schizophrenia Research

Assessment

Treatment

Imaging Studies



Current Studies as of January 2007

Solvay 12 month study

Patients with a diagnosis of schizophrenia are needed for a study of an investigational drug. Subjects will be hospitalized for the first 11 days, then followed as an outpatient for up to a year. Hospital and clinic costs, study drug, and lab tests at no cost to participants.

Research on Schizophrenia-related Disorders

"Switch or Stay" Studies

These studies are sponsored by the NIMH Schizophrenia Trial Network (STN) to determine the benefit of changing medication. Adults diagnosed with with schizophrenia or schizoaffective disorder will continue treatment with their regular providers and come to the U of MN research office seven times in the year-long study.

Two groups of patients are sought:

Two Drugs or One?

Patients who are currently taking **two antipsychotic medications** and who have some continuing side effects or symptoms and would consider stopping one of their medications.

Decanoate or Consta?

Patients who are currently receiving Haldol or Prolixin **long-acting injections** and who have some continuing side effects or symptoms and would consider changing to Risperdal Consta injections.

Metabolic study

Patients who are overweight with high cholesterol but not diabetes, currently taking Zyprexa, Risperdal or Seroquel are needed for a STN sponsored trial called Comparison of Antipsychotics for Metabolic Problems (CAMP). The study will compare the effect of an individualized nutrition/exercise program with a switch of medication to Abilify over a 6 month period. Subjects must be 18-65 with a diagnosis of schizophrenia or schizoaffective disorder. Antipsychotic medication, psychiatric care, metabolic testing, and the behavioral program all at no cost to participants.

Long-Term Maintenance Study

Patients with schizophrenia currently taking medication who are **mildly ill** and age 18 or over, will be treated with an investigational drug for 6 months, then if continue to be clinically stable, enter a placebo-controlled phase for another 6 months. Subjects must have a caregiver who can participate with them in the study.

Brain Imaging Study

Volunteers between the ages of 18 and 60 with schizophrenia or related illness are needed for a **brain imaging** study using Magnetic Resonance Imaging (MRI). This is not a medication trial. A stipend is offered. For more information, please call (612) 627-4825. Flexible appointments are available.

Schizophrenia Medication Study

Adults ages 18-65 needed to participate in a 14 week **medication treatment** study. All participants will receive either Risperdal® or Zyprexa® (no placebo). Participants may be either inpatient or outpatient. Participants will receive a stipend for their participation and transportation is available.

Negative Symptom Study

Seeking participants for a study to evaluate an investigational drug with an emphasis on treating **negative symptoms** of schizophrenia. These can include lack of emotion, lack of interest in life, difficulty speaking, slow movements, social withdrawal, low motivation, and a feeling of being "out-of-touch." The study lasts 6 months with a possible 6 month extension.

All study drugs and medical evaluations will be covered at no cost and participants will be reimbursed for their travel and time expenses.

Medication Add-On Study

Persons 18 and over with a diagnosis of schizophrenia or schizoaffective disorder in good general physical health are sought to volunteer for a 16 week study. Patients must be currently taking either Risperdal or Seroquel and the study involves **randomization to add-on** either Abilify or placebo to their current medication. Study medications are provided at no cost. You may also be reimbursed for time and travel related to this study.

Research Registry

If you do not qualify or are not interested in participating in current studies, but might be interested in some other project in the future, you may sign up for the **ARC research registry**. We will keep basic contact information and get in touch with you when a new study starts to see if you are interested and whether you may be appropriate to participate in it.

Schizophrenia Program

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