

**National Institute of Mental Health
of the National Institutes of Health (NIH)**

Patient Recruitment - Pediatric Disorders

Bipolar Disorder (Pediatric) Research Study

"1. A Study of Brain Function and Symptoms in Children who have Bipolar Disorder, or a Parent or Sibling with Bipolar Disorder"

This research protocol seeks to learn more about bipolar disorder in children and adolescents ages 6-17. Researchers will describe the moods and behaviors of children with bipolar disorder and use specialized testing and brain imaging to learn about specific brain changes associated with the disorder. This protocol studies children who have been diagnosed with bipolar disorder, and those who have a sibling or parent with bipolar disorder and are thus considered "at risk" for developing the disorder.

Disease and Treatment Information

Detailed Protocol Description

jumpstartA) Descriptive/Longitudinal Study:

1 initial outpatient visit, then visits over time. Testing and brain imaging occurs at yearly visits, which can continue to age 25. Yearly phone contact occurs in between visits. (details below)

jumpstartB) Treatment: Optional 4-5 month study with hospitalization to withdraw current medications followed by inpatient, outpatient, and/or day treatment. (details below)

jumpstartC) Family Study: Phone Interview, initial outpatient visit, and yearly outpatient visits over time. This part of the protocol studies children who have a sibling or parent with bipolar disorder and are thus considered "at risk" for developing the disorder. (details below)

jumpstartD) Sleep Study: 5-8 week inpatient stay (details below)

After a preliminary phone interview, participants may be invited to NIMH for an on-site interview. Children must be in treatment with a psychiatrist or provider, and/or medically healthy and not currently hospitalized, psychotic or suicidal. If eligibility criteria are met, participants may choose to enroll in the descriptive study, receive treatment, or do both. Study procedures include interviews, research testing, and brain imaging scans.

The studies are conducted at the NIH Clinical Center in Bethesda, Maryland and enroll participants from across the USA. All clinical evaluations, research procedures, inpatient hospitalization and outpatient visits are free of cost. Travel expenses and lodging are paid by NIMH. Both parent and child must agree to the child's participation in research. Children and parents are compensated for participation.

To find out about study criteria and qualifications, or for more information, please call (301 496-8381) or email us at bipolarkids@mail.nih.gov

jumpfinishA) Descriptive/Longitudinal Study: When children have bipolar disorder, do their brains work in ways that are different than those of other children? How do the symptoms of bipolar disorder change as children grow up?

This research study will describe the moods, behaviors and brain development of bipolar disorder in children over time. Participants, ages 6-17, may be invited to enroll after an initial outpatient visit. If found to be eligible based on their past mood and behaviors, they are invited to participate in follow-up. Face-to-face evaluations and study procedures occur at yearly study visits, which can continue to age 25. Yearly phone contact occurs in between visits.

Study procedures at these one to two day visits may include obtaining information about mood and behavior, research tasks, and Magnetic Resonance Imaging (MRI). Tasks includes questionnaires, interviews, and direct observation; tests of mood, memory, and thinking using paper-and-pencil and computer tests; behavioral research tasks; and Magnetic Resonance Imaging (MRI) and functional MRI (fMRI) scans. Children continue in treatment with a provider or psychiatrist in their community. This part of the study does not involve treatment medications.

jumpfinishB) Treatment

Some children may be eligible to receive treatment at the NIH. During a portion of their stay for treatment, when they are off all medication, the study is designed to learn about mood, behavior and brain changes by asking children to perform MRI and computer tasks.

Some patients, ages 7-17, may be eligible to participate in this study over the course of a four to five months inpatient stay. This time may include outpatient visits and/or day treatment. To be eligible for this part of the study, children must be eligible for the longitudinal study and also be unstable/doing poorly on their current medications. The child must currently be in treatment with a psychiatrist in their community to participate. When clinically indicated, children may receive treatment that begins with gradually tapering off all medications. During a 2-week medication-free period children are invited to perform research and computer tasks, and have brain imaging scans, like those in the descriptive study.

Children also attend school and have recreation therapy while staying at NIH. After the medication-free period of observation, participants receive standard treatment medications and are supported to transition back to their local provider.

jumpfinishC) Family Study

Although most children with a parent or sibling with bipolar disorder do not themselves develop bipolar disorder, they are at increased risk to do so compared to children who do not have a relative with the illness. The purpose of this study is to compare symptoms and brain function in children "at risk" vs. children who are not at risk, with the ultimate goal of being able to predict who will develop the illness and how to prevent it.

In this study, children, ages 6-17 who have a parent or a sibling with

bipolar disorder may participate in non-treatment research. Children may or may not have been diagnosed with a psychiatric disorder. Those taking medications for Attention Deficit Hyperactivity Disorder may be eligible for participation. This part of the study does not involve treatment. Families who are interested in enrolling complete preliminary telephone interviews. Eligibility is based on the past mood, behaviors, and diagnoses of their parent or sibling with bipolar disorder. Those who meet eligibility criteria are invited to come to NIMH for an initial outpatient visit. Children receive a clinical assessment and testing. If found to be eligible, these children will be invited to participate in follow-up over time and perform study procedures like those described in for the Descriptive Study (above).

jumpfinishD) Sleep Study

This research study seeks to learn about brain function, and the effects of sleep changes on mood in children diagnosed with bipolar disorder when they are off medication. Some patients, ages 7-17, may be eligible to participate in this inpatient sleep study that typically lasts 5- to 8-weeks. The child must currently be in treatment with a psychiatrist in their community to participate. Treatment includes gradually tapering children off all medications. During a 2-week medication-free period children undergo periods of extended and reduced sleep, and are invited to perform research and computer tasks and have brain imaging scans like those in the descriptive study (above).