

# CLINICAL RESEARCH: FOCUS ON MENTAL HEALTH

---

Current clinical research related to the health of ethnic minority populations is essential to eliminate health disparities.

Readers of *Ethnicity & Disease* may be interested in the progress and results of the following clinical trials. These trials de-

scribe only some of the exciting research performed in ethnic minority health; other current trials may be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

The information below was accurate at press time; the study researchers should be contacted for more information.

---

## BRAIN CHANGES IN CHILDREN AND ADOLESCENTS WITH BEHAVIORAL PROBLEMS

Sponsored by: National Institute of Mental Health

The goal of this protocol is to investigate the neurocognitive underpinnings of the emotional dysfunction linked to childhood behavioral disturbance, in particular psychopathic tendencies but also attention deficit/hyperactive disorder (ADHD). The functional hypotheses are that: 1) psychopathic tendencies, but not ADHD, are associated with dysfunction in the formation and operational

use of stimulus-punishment and, to a lesser extent, stimulus-reward association information; and 2) that ADHD, but not psychopathic tendencies, is associated with impairment in executive systems related to the representation and execution of task demands.

Participants may be invited to participate in a genetics study and a study of fatty acids in the blood.

Inclusion criteria: age 8–17 years, score >30 on the APSD/PCL-VY or diagnosis of ADHD according to DSM-IV criteria.

Exclusion criteria: IQ <80, use of any medication that may have psychotropic effects, contraindication to discontinuing medication for 48 hours, psychiatric disorder (other than those in inclusion criteria), neurologic disorder (including seizures), im-

planted metallic objects (metal plates, some dental braces, pacemakers, etc), claustrophobia.

Study start: February 17, 2005

This study is recruiting patients. Contact Patient Recruiting and Public Liaison Office, National Institute of Mental Health, 9000 Rockville Pike, Bethesda, MD 20892; 800-411-1222; [prpl@mail.cc.nih.gov](mailto:prpl@mail.cc.nih.gov)

---

## PSYCHIATRIC PROBLEMS IN CHILDREN AND ADOLESCENTS INFECTED WITH HIV AT BIRTH

Sponsored by: National Institute of Allergy and Infectious Diseases, National Institute of Mental Health, National Institute of Child Health and Human Development

Research has shown that HIV is able to penetrate the blood-brain barrier and may significantly affect the central nervous system (CNS). Although the effects of HIV on the CNS are not fully understood, growing evidence suggests that the effects are psychosocial in nature; HIV-infected children experience higher rates of psychiatric symptoms and hospitalizations than their uninfected counterparts. Confounding the HIV-CNS relationship is evidence that suggests that the CNS effects of HIV may also be related to antiretro-

viral treatment. This study will examine the rates and severity of psychiatric symptoms in both HIV-infected and uninfected children and adolescents. In addition, this study will determine the relationship between duration of antiretroviral treatment and psychiatric symptoms.

No treatment will be given as part of this study. The study will last for 96 weeks and be divided into two parts. In part 1, HIV-infected and uninfected participants and their caregivers will complete a series of measures and questionnaires

regarding mental health, pain, and adherence to treatment. In part 2, all participants and their caregivers will complete a subset of the original measures at weeks 48 and 96. This follow-up part of the study will assess any long-term changes in psychiatric symptoms. In addition, a subset of HIV-infected and uninfected participants and their caregivers will take part in psychiatric interviews at specified study sites. A portion of these interviews will be audiotaped.

Inclusion criteria: age 6–17 years, living with same

parent or primary caregiver  $\geq 12$  months before screening, willingness and ability to provide informed consent, HIV infection acquired vertically (study group) or no HIV infection (control group).

Exclusion criteria: IQ  $\leq 69$ .

This study is recruiting patients. Contact Denise M. Ferraro, RN, State University of New York at Stony Brook, Stony Brook, New York, 11794-8111; 631-444-8225; [denise.ferraro@sunysb.edu](mailto:denise.ferraro@sunysb.edu)

---

## HORMONAL CAUSES OF MENSTRUAL-RELATED MOOD DISORDERS

Sponsored by: National Institute of Mental Health

This study will explore possible hormonal causes of menstrual-related mood disorders (MRMD) by stopping the menstrual cycle with leuprolide and then giving in sequence progesterone and estrogen. The study will first evaluate leuprolide's effectiveness in treating MRMD and will then examine the effects of giving estrogen and progesterone on mood and behavior. In addition, positron emission tomography (PET) and magnetic resonance imaging (MRI) will be used to study serotonin receptors and transporters.

Menstruating women between 18 and 45 years of age who are in good health, not

pregnant, and not taking medications may be eligible for this study. Women with MRMD must have had at least moderately severe MRMD or behavioral disturbances for at least 6 months within 2 years of entering the study. Healthy controls must have no history of MRMD or behavioral disturbances. Candidates undergo physical and neurologic examinations, chest x-ray, electrocardiogram, and blood and urine tests. Results of a recent Pap smear (no longer than 12 months before beginning the study) must be available.

Inclusion criteria: all patients who participate in this protocol

will have already participated in protocol no. 81-M-0126 and will have a prospectively confirmed and predictable relationship between their mood disorder and the premenstrual phase of the menstrual cycle, ie, a 30% change in severity of symptom self-rating scales, relative to the range of the scale employed, during the seven days before menstruation compared with the seven days after menstruation in two out of three months of study.

Exclusion criteria: history of endometriosis; diagnosis of ill-defined, obscure pelvic lesions, particularly undiagnosed ovarian enlargement; hepatic disease as manifested by abnormal liver

function test; history of mammary carcinoma; history of pulmonary embolism or phlebotrombosis; undiagnosed vaginal bleeding; porphyria; diabetes mellitus; history of malignant melanoma; cholecystitis or pancreatitis; cardiovascular or renal disease; pregnancy; axis I psychiatric disorder.

Study start: December 22, 2004

This study is recruiting patients. Contact Patient Recruitment and Public Liaison Office, National Institute of Mental Health, 9000 Rockville Pike, Bethesda, MD 20892; 800-411-1222; prpl@mail.cc.nih.gov

---

## ETHNIC VARIATIONS IN ANTIDEPRESSANT RESPONSE

Sponsored by: National Institute of Mental Health

Depressed patients vary substantially in their responses to antidepressants. Genetic factors may account for a large part of these differences in response. This study will include both African Americans and Caucasians to examine the role of genetic factors in treatment response.

Participants receive citalopram for 8 weeks and a placebo for 1 week. Visits occur once a week for 11 weeks. A variety of interviews, scales, tests, and

questionnaires are used to assess participants.

Inclusion criteria: age 18–70 years, DSM-IV major depression, African-American or Caucasian ethnicity (both parents and three grandparents),

Exclusion criteria: schizophrenia, schizophreniform disorder, schizoaffective disorder, schizotypal disorder, psychotic depression, or bipolar disorder; current drug abuse or history of drug abuse within the past 6 months;

unstable medical or neurologic conditions that interfere with the treatment of depression; allergy to citalopram; failure to respond to adequate citalopram drug trial (40 mg for at least 6 weeks); seizure disorder; pregnancy; psychotropic medications, including antidepressants and neuroleptics; suicidal ideation or other safety issues; fluoxetine or monoamine oxidase inhibitors in the last 2 months; ongoing cognitive behavioral therapy or

intensive psychotherapy (general talk therapy is acceptable).

Study start: June 2002

Expected study end: December 2006

This study is currently recruiting patients: Sarah Rowe, Cedars-Sinai Medical Center, Department of Psychiatry, Clinical Trials Unit, Los Angeles, CA 90048; 310-423-6515; xrowes@cshs.org