

# CLINICAL RESEARCH

---

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 describe 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.

---

## HYPERTENSION CONTROL AND THERAPY ADHERENCE

Sponsored by: National Heart, Lung, and Blood Institute

To improve patients' adherence with prescribed antihypertensive medication, blood pressure control, and doctor-patient communication and to decrease racial disparities in each, the investigators will conduct a three-armed, randomized, controlled trial in the general internal medicine clinics of a large urban teaching hospital serving many poor African American and White patients. They will implement proven intervention strategies by teaching clinicians to use patient-centered counseling, enhancing skills that are known to help patients change

health-related behaviors and to enhance clinicians' cultural competency and thereby further improve clinician-patient communication. In one set of clinicians, they will implement only the patient-centered counseling program; in a second set they will implement the patient-centered counseling education program, augmenting it with an established method for cultural competency training; and a third set (control group) will provide usual care. To assess outcomes, investigators will first assess the preintervention patient adherence to prescribed medications

through patient self-report and the use of electronic pill top monitoring, clinicians' provision of advice and counseling about antihypertensive medications and use of cultural competency skills, and the proportion of patients with controlled blood pressure. Subsequent to the interventions, they will reassess each of these outcomes.

Inclusion criteria: age  $\geq 21$  years, diagnosis of hypertension, taking antihypertensive medications.

Exclusion criteria: musculoskeletal problems that prevent

opening of electronic pill tops, cognitive status limitations, including psychiatric disorders such as schizophrenia, and active alcohol or substance abuse problems.

Study start: February 2004

Expected study end: January 2008

This study is recruiting patients. Contact Nancy Kressin, Boston University School of Public Health, Bedford, MA 01730; 781-687-2949; [nkressin@bu.edu](mailto:nkressin@bu.edu).

---

## EXPLORING FOLK HEALTH PRACTICES IN LATINOS WITH CHRONIC MEDICAL CONDITIONS

Sponsored by: Weill Medical College of Cornell University

Sociocultural aspects of using ethnomedical health practices in a community-based Latino population will be described with both qualitative and quantitative survey methods. This study will rely heavily on its descriptive section, which will use in-depth, open-ended questions in a semi-structured personal interview format following qualitative research principles. It will also use closed-ended questions in a short

survey format to begin to explore some variables that may be associated with using traditional healing practices. These variables include level of acculturation, degree of family social support, degree of adherence to standard medical regimens, perceived health status, presence of depressive symptoms, and severity of co-morbidities. These variables will be examined with common, validated scales.

Inclusion criteria: age  $\geq 18$  years; Mexican, Puerto-Rican, Cuban, Dominican, Central American, South American, or other Hispanic ethnicity; self-identification of at least one chronic condition, including diabetes, hypertension, asthma, heart disease or stroke or musculoskeletal disease; report of using complementary or alternative therapies, including ethnomedical healing practices or practitioners.

Exclusion criteria: refusal to participate.

Study start: September 2005

Expected study end: June 2006

Contact Monique Toussaint, The New York Presbyterian Hospital-Weill Medical Center, New York, NY 10021; [mot2005@med.cornell.edu](mailto:mot2005@med.cornell.edu)

## EFFECTIVENESS OF CULTURALLY BASED CONGRUENT CARE IN TREATING HISPANICS WITH MAJOR DEPRESSIVE DISORDER

Sponsored by: National Institute of Mental Health

Major depressive disorder (MDD) is a type of depression that is characterized by a combination of symptoms that can interfere with the ability to work, study, sleep, eat, and enjoy activities that were once pleasurable. Studies have shown that individuals of Hispanic descent underutilize specialized mental health care services (SMHS), despite their need for them. In addition, Hispanic individuals have been associated with lower rates of retention in specialized mental health treatment. In particular, dropout rates from medication therapy for the treatment of MDD within SMHS are two to three times higher in Hispanics than in non-Hispanic Whites. This study will develop and evaluate the effectiveness of a culturally based program that aims to facilitate entry, retention, and successful treatment in SMHS for Hispanics with MDD.

This open-label study will consist of four phases. Participants will be recommended for inclusion in the study upon receiving a diagnosis of MDD based on a standard health questionnaire completed in their primary care physician's office.

Phase 1 of the study will entail an initial evaluation of the culturally congruent program of care for Hispanics with MDD (CCP-MDD).

Participants will be placed in one of two focus groups, each composed of 8 to 10 people. One group will include individuals referred by their primary care physician. The other group will include family members of Hispanics with MDD. Discussions will focus on participants' understandings of depression-like illness, their treatment expectations for these conditions, and their perceived barriers to SMHS utilization. Information gathered in the focus groups will be used to develop a second version of CCP-MDD.

Phase 2 of the study will evaluate the revised version of CCP-MDD and will include additional treatments with antidepressant medication, weekly interpersonal psychotherapy, or a combination of the two. Following treatment, participants will take part in a focus group, which will involve participant feedback. Based on the information obtained in the focus groups and from clinical obser-

vations, a third version of CCP-MDD will be developed.

In phase 3, participants will receive the third version of CCP-MDD along with antidepressant medication, weekly interpersonal psychotherapy, or a combination of the two. Focus groups will be held following treatment in order to obtain information about individuals' satisfaction or dissatisfaction with their care. Based on these findings, as well as clinical observations, a fourth and final version of CCP-MDD will be developed in phase 4. All treatments will last a total of 18 weeks. A follow-up session will be held at week 30 to assess depressive symptoms.

Inclusion criteria: age 18–80 years, self-identification as Hispanic, Spanish speaking, positive for MDD.

Exclusion criteria: co-morbid medical or psychiatric conditions that may prevent focus group participation, active suicidal or homicidal ideation that may pose a danger to oneself or others.

Treatment phase exclusion criteria: history of schizophrenia, bipolar disorder, schizoaffective

disorder, depression with psychotic symptoms, or organic brain syndromes; clinically unstable medical disease, including glaucoma; blood pressure >150/90 mm Hg; pregnant or breastfeeding; current or past history of seizure disorder (except febrile seizure in childhood); alcohol or substance abuse or dependence (except nicotine) within the six months before screening; use of monoamine oxidase inhibitors or fluoxetine within four weeks before screening or use of other selective serotonin reuptake inhibitors, antidepressants, neuroleptics, mood stabilizers, buspirone, benzodiazepines, or other psychotropic drugs, except zolpidem for insomnia within two weeks before screening; receiving formal psychotherapy from a mental health provider, whether or not the focus of the therapy is MDD.

Study start: November 2005

This study is recruiting patients. Contact Jose Medina, New York State Psychiatric Institute–Hispanic Treatment Program, New York, NY 10032; 212-543-6514; medinaj@nyspi.cpmc.columbia.edu.

## A TEAM MODEL OF HYPERTENSION CARE IN AFRICAN AMERICANS

Sponsored by: University of Wisconsin

This study will evaluate the cost-effectiveness of an organizational-level intervention in a randomized controlled trial involving 900 treated hypertensive

African American patients in the Milwaukee and Chicago areas. The study will involve 36 community pharmacies (18 intervention, 18 control) owned

by a pharmacy corporation that operates >2,000 pharmacies nationwide. The intervention will include 1) redefinition of pharmacist and pharmacy technician

roles, 2) implementation of a pharmacy-based "refill clinic" and tools for enhanced monitoring and collaboration with patients and physicians, and

## CLINICAL RESEARCH

3) special training/certification of pharmacy personnel in blood pressure measurement, collaborative skills, and cultural competency.

Inclusion criteria: age  $\geq 18$  years, African American ethnicity, obtain all prescribed drugs at the study pharmacy.

Exclusion criteria: history of organ transplant, kidney dialysis, terminal illness.

Study start: September 2005

Contact Bonnie L Svarstad, PhD, University of Wisconsin, Madison, WI 53792; 608-265-2128; blsvarstad@pharmacy.wisc.edu.

---

## PROMOTING ACTIVITY AND CHANGES IN EATING (PACE)

Sponsored by: National Heart, Lung, and Blood Institute

Reducing the prevalence of obesity in the population is one of the *Healthy People 2010* goals, and increased vigilance is required in all age groups in preventing and reversing overweight and obesity. On an individual level, behavioral factors that influence body weight include eating choices leading to excess calorie intake and physical activity patterns leading to diminished calorie expenditure. A balance between the two over time leads to increased weight. On a population basis, the prevalence of overweight is associated with a myriad of influences, including social, behavioral, cultural, and environmental factors as well as genetic and physiologic factors. For

most overweight individuals, restoring a balance between energy intake and expenditure is difficult, and therefore emphasis is increasing on preventing obesity on a population level. The long-term goal of this research is to prevent further increase in rates of obesity in the population.

In the adult population of working age, most of the day is spent in the worksite, suggesting that interventions at the worksite level may offer the opportunity for success in this age group. We propose to develop and test a comprehensive intervention with simple messages that will integrate changes in dietary intake with changes in energy expenditure, while simultaneously modifying structural

and environmental factors to promote social support and opportunities for behavioral change.

We will recruit and randomize 48 worksites to a two-year intervention in which we will build a physical activity intervention combining increased daily physical activity and regular, structured exercise; build a dietary intervention that will promote lower calorie intake; and increase worksite access to both healthy foods and physical activity. Our primary aim is to evaluate the effectiveness of the intervention in reducing or maintaining body mass index in a randomized controlled trial of worksites. We will compare changes in body mass index in

intervention versus control worksites by using two cross-sectional surveys at baseline and follow-up. Additional assessments with biomarkers and fitness measures will be performed in a subset of employees.

Inclusion criteria: age 18–80 years, employed at a participating worksite.

Study start: September 2004

Expected study end: June 2008

This study is recruiting patients. Contact Shirley Beresford, Fred Hutchinson Cancer Research Center, Seattle, WA 98109-1024; 206-667-4793.