

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

EVALUATING THE EFFECT OF NEIGHBORHOOD ENVIRONMENTS ON CARDIOVASCULAR RISK FACTORS

Sponsored by: the National Heart, Lung, and Blood Institute

Cardiovascular disease (CVD) is a major health problem in the United States. Individuals who live in an environment in which it is difficult to maintain an active lifestyle may be more at risk for developing CVD. Because of an increased interest in healthy living, urban planners and architects are now developing neighborhoods that are designed to encourage physical activity. Parks, walking and bicycle trails, wider sidewalks, and community recreation facilities are examples of amenities that are being included in these neighborhoods. By incorporating these enhancements, the

Stapleton community in Denver, Colorado, has been redeveloped as a more active living environment. The purpose of this study is to determine the effect of the neighborhood environment on the cardiovascular health of residents in 5 racially, ethnically, and socioeconomically diverse neighborhoods in or near the Stapleton community.

In years one and two of this study, 200 households from each of the 5 neighborhoods will be randomly chosen to complete a survey regarding their cardiovascular health, physical activity level, and use and perception of their neighborhood environment

and facilities. Interviews and focus groups with members of the community will also be used to gather information. Additionally, a neighborhood council composed of community members will be formed to study disparities among the five neighborhoods in their use of Stapleton's neighborhood environment, physical activity levels, and cardiovascular risk factors. In year two, study researchers will analyze the collected data and distribute the findings within the communities. They will also begin testing culturally and community-relevant programs aimed at reducing CVD risk factors.

Inclusion criteria: age ≥ 18 years; live in one of the following five neighborhoods in the Greater Stapleton Community: Northeast Park Hill, Greater Park Hill, East Montview, Stapleton, or Original Aurora; speak either English or Spanish.

Study start: September 2006

This study is not yet open for patient recruitment. Contact Debbi S. Main, PhD, University of Colorado at Denver and Health Sciences Center, Aurora, CO 80045; phone: 303-724-1172; debbi.main@uchsc.edu.

TELEMEDICINE-BASED COLLABORATIVE CARE TO REDUCE RURAL DISPARITIES

Sponsored by: the University of Arkansas

An experimental study design and an intent-to-treat analysis will be used to determine the effectiveness and cost-effectiveness of telemedicine-based collaborative care relative to practice-based collaborative care. The research setting will be six community health centers located in medically under-served areas of Arkansas that serve rural,

low-income, and minority populations. Potentially eligible patients will be identified through screening by clinic staff or primary care provider referrals. Patients eligible for the study will be randomized to receive either telemedicine-based or practice-based collaborative care and followed for 18 months to assess processes and outcomes.

On-site clinical staff will screen patients for depression during an 18-month period and refer all patients with clinically significant depression to the study.

Two types of health care professionals will be involved in the practice-based collaborative care model: 1) primary care providers (MD and RNP) and 2) a depression care manager

(LPN or social worker). The on-site care managers will provide care management activities by phone or face-to-face.

Five types of health care professionals will be involved in the telemedicine-based collaborative care model: 1) primary care providers (MD and RNP); 2) a depression nurse care manager (RN); 3) clinical pharmacist

(PharmD); 4) tele-psychologist (PhD); and 5) a tele-psychiatrist (MD). The primary care providers will be located at the community health centers. The off-site depression care team will be located at the clinics of the University of Arkansas for Medical Sciences, Department of Psychiatry. The on-site primary care providers will prescribe medications and schedule all appointments. The off-site nurse

care manager will conduct all care management activities by telephone. The off-site clinical pharmacist will conduct medication histories and provide medication management by telephone. The off-site tele-psychologist will conduct evidence-based psychotherapy (cognitive behavioral therapy) via interactive video. The off-site tele-psychiatrist will conduct interactive-video consultations,

train and supervise the depression care team, and conduct provider education.

Inclusion criteria: age ≥ 18 years, clinically significant depression.

Exclusion criteria: sub-threshold depression, non-English speaking, no telephone access, bereaved, suicidal, currently being treated by a mental health specialist, bipolar disorder, psychotic disorders, drug or alcohol

dependence, cognitively impaired, terminal illness, having a court appointed guardian, or pregnant.

Study start: This study is currently recruiting patients. Contact John Fortney, PhD, University of Arkansas for Medical Science, Little Rock, AR 72205; phone: 501-660-7527; FortneyJohnC@uams.edu.

SURVEY OF PROSTATE CANCER IN Accra, GHANA

Sponsored by: the National Cancer Institute and National Center on Minority Health and Health Disparities

This study, conducted at Korle-Bu Hospital in Accra, Ghana, will help elucidate the roles of lifestyle and genetic factors in prostate cancer risk. There is a strong variation in risk of prostate cancer throughout the world. The rates of the disease among African Americans are some of the world's highest. In the United States, the incidence of prostate cancer is 70% higher in African Americans than in White Americans, and the death rate in African Americans is almost double that of White Americans. The reasons for this excessive risk are unknown, but both genetic and lifestyle factors have been suggested.

Because Africans and African Americans share similar genetic ancestry but have vastly different lifestyles, a better understanding of the rates and risk factor profiles for prostate cancer among Africans

will provide important clues to what causes the disease. This study will try to assess the incidence of prostate cancer in the West African nation of Ghana. The study has two components: 1) the methods of diagnosis at Korle-Bu will be evaluated; and the incidence of prostate cancer over a 5-year period will be estimated and 2) a survey of 1000 men between 50 and 74 years of age will estimate the prevalence of both asymptomatic and undiagnosed symptomatic prostate cancer in the Accra population.

The clinical survey will use data from the cancer logbook and medical records at Korle-Bu Hospital and the Ghanaian National Census to derive an estimate of prostate cancer incidence within Accra. The estimate will be low, since it will be based only on men diagnosed or treated at Korle-Bu and will not include

men with asymptomatic disease, men diagnosed elsewhere, or men without access to medical care. The screening and detection survey will assess the presence of asymptomatic and unrecognized symptomatic prostate cancer using prostate-specific antigen testing and digital rectal examination in a random sample of 1000 men in the general population of Accra. This will provide a high estimate of disease prevalence. The 2 estimates will provide an approximation of the true incidence rate of the disease in Accra. Comparison of these data with similar data from community surveys of African Americans will provide insight into reasons for the excess risk of prostate cancer in African Americans.

The key aim of this study is to assess the burden of prostate cancer in Ghana to evaluate how the impact of prostate

cancer among West Africans compares to that among African Americans, whose reported incidence rates are among the highest in the world. West Africans and African Americans share genetic ancestry but have very different lifestyle and environmental exposures. The study aim will be achieved by deriving lower and upper bounds on the true incidence of prostate cancer in the capital city of Accra.

Inclusion criteria: men age 50–74 years.

Exclusion criteria: history of treatment for prostate cancer (men with untreated prostate cancer will be included).

Study start: June 2002

This study is currently recruiting patients. Contact Ann Hsing, PhD; phone: 301-435-3980; hsinga@exchange.nih.gov.

CLINICAL RESEARCH

IMPROVING DIABETES CARE FOR AFRICAN AMERICANS

Effective solutions are needed to address the parallel persistence of a quality chasm and racial disparities in diabetes care. Many large healthcare systems are adopting components of the Chronic Care Model to achieve substantial gains in diabetes care, though few health systems have successfully incorporated elements specific to minority health. We have previously identified racial disparities in key diabetes outcomes measures within an integrated healthcare delivery system, Harvard Vanguard Medical Associates (HVMA). This project will use a randomized, controlled study design within HVMA to evaluate whether enhancements to the Chronic Care Model can pro-

duce significant improvement in the quality of diabetes care for Black patients. Intervention clinicians will receive bimonthly panel-level disparity report cards, health navigation training, and cultural competency training, while control clinicians will function within the context of the generic Chronic Care Model. The study will occur over a 12-month period and involve 4000 White patients and 2500 Black patients with diabetes receiving care at eight health centers. The primary outcomes will include rates of glucose (hemoglobin A1C [HbA1c] <7.0%), low-density lipoprotein cholesterol (<100 mg/dL), and blood pressure (<130/80 mm Hg) control. We will use patient focus

Sponsored by: Harvard Vanguard Medical Associates, Brigham and Women's Hospital, Harvard University

groups to identify significant barriers to care and guide health navigation training. We will survey clinicians before and after the intervention to assess the effect of the intervention on knowledge and attitudes toward disparities. Patient experiences will be assessed before and after the intervention using a validated instrument to determine whether the intervention can reduce existing racial disparities in patient reports of quality. We will perform a cost-analysis related to the intervention using a health system perspective. In summary, this project will provide health systems with a rigorous analysis of a defined set of tools to improve diabetes care for minority populations.

Inclusion criteria: age ≥ 18 years, diagnosis of diabetes mellitus (based on fasting glucose, HbA1C, and problem list); at least 1 face-to-face visit with HVMA primary care clinician in the last two years.

Exclusion criteria: any patient not categorized as either White or Black based on race identifier in the electronic medical record.

Study start: June 2007

Expected completion: September 2008

This study is not yet open for patient recruitment. Contact Thomas D. Sequist, MD, MPH; phone: 617-525-7509; tsequist@partners.org.