

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 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.

THE INFLUENCE OF BREAST CANCER RISK AND RISK PERCEPTION ON LIFESTYLE BEHAVIORS AMONG WOMEN WITH A FAMILY HISTORY: A MIXED-METHOD APPROACH

Lifestyle behaviors among women with a family history of breast cancer are likely to be influenced by a number of factors, including both objective risk factors and subjective risk, or perceived risk. The aims of this mixed-method study are twofold and will be explored through both quantitative (ie, secondary survey data) and qualitative data (ie, personal in-depth interviews) derived from the Sister Study, a large epidemiologic study being conducted through NIEHS, which is addressing risk factors for

breast cancer in sisters of women who have had breast cancer. The quantitative aims include an exploration of lifestyle behaviors and behavioral differences between White and African American women, as well as an exploration of the relationships between lifestyle behaviors and additional factors that may be contributors to perceived risk.

The primary outcome measures for the quantitative component of the study are dietary fat intake, fruit and vegetable consumption, alcohol use, and

Sponsored by: the National Institute of Environmental Health Sciences (NIEHS)

physical activity, which will all be measured categorically. Qualitative data will be analyzed through content analysis, which will involve the identification of common themes or ideas expressed in response to questions from a semistructured interview guide developed specifically to address the aims of the study.

Inclusion criteria: data from the first 20,000 women enrolled in the Sister Study will be used for the quantitative analysis. Participants for the qualitative study will include women living in North Carolina who reside

within a 3.5-hour driving distance from the researcher.

Exclusion criteria: women who were adopted, history of cancer (except non-melanoma skin cancer), ethnic groups classified as "other."

Study start: October 2006

This study is currently recruiting patients. Contact Dale Sandler, PhD, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709; phone: 919-541-4668; sandler@niehs.nih.gov.

EXERCISE AND ACTIVITY GUIDANCE IN OLDER ADULTS WITH DIABETES

The purpose of this project is to better understand how exercise and education will help mobility and health in older adults with diabetes. The investigators are trying to learn what type of exercises and classes are needed to help older adults stay active.

Interested persons are screened for eligibility and undergo a directed medical history and examination, echocardi-

ogram (if not done within one year), and maximal treadmill test with oxygen kinetics. Participants are randomly assigned to classes on flexibility and toning exercises with health education or functional circuit training plus home activities plus tailored physical activity guidance. Classes will meet three times a week for 10 weeks for an hour. Fitness level will be measured at the

Sponsored by: the University of Michigan and the Department of Veterans Affairs

beginning of the exercise training, at 10 weeks, and again at 20 weeks (10 weeks of follow-up).

Inclusion criteria: history of type 2 diabetes on medication, age ≥ 60 , ability to attend local class three times per week for 10 weeks.

Exclusion criteria: ejection fraction $< 40\%$, symptomatic obstructive valvular disease (pri-

marily aortic stenosis), atrial fibrillation with poor rate control (particularly during exercise) or high-grade atrioventricular block, substantial dementia (Folstein Mini Mental State Examination < 24 out of 30), blood tests suggesting severe renal or hepatic disease, alcohol intake > 3 oz/day, hemiplegia or lower limb amputation, participating in regular exercise two or more

hours per week, significant orthopedic or musculoskeletal condition that limits weight bearing,

acute medical conditions such as acute flare-up of joint condition or infection

Study start: August 2005

This study is currently recruiting patients. Contact Caro-

line S. Blaum, MD, University of Michigan, Ann Arbor, MI 48105; phone: 866-444-3302.

HEALTH RELATED QOL, DEPRESSION AND LIFESTYLE CHANGES IN INSULIN RESISTANT ADOLESCENTS

Sponsored by: the Children’s Mercy Hospital Kansas City

This matched historical control study is designed to examine outcomes on insulin-resistant adolescents who were treated in the Insulin Resistance Syndrome Clinic at Children’s Mercy Hospital in the past year. New patients will be screened at baseline, 4 months, and 12 months

to evaluate improvement in the body mass index Z-score, hemoglobin A1C, lipid profile, or waist circumference when depression or altered health-related quality of life are identified and treated in this population

Study start: June 2007

Inclusion criteria: age 11–17 years, seen in the Insulin Resistance Syndrome Clinic for the first time.

Exclusion criteria: co-morbid syndrome (eg, Downs, Turner’s, Prader Willi), diagnosis of type 2 diabetes, taking metformin before the initial visit, taking medication

for or diagnosis of a psychiatric condition before the initial visit, developmentally delayed.

This study is currently recruiting patients. Contact Adrienne Platt, MS, CPNP, Children’s Mercy Hospital, Kansas City, MO 64108; phone: 813-234-6756; aplatte@cmh.edu.

BETTER ADHERENCE TO THERAPEUTIC LIFESTYLE CHANGE EFFORTS TRIAL (BATTLE)

Sponsored by: Walter Reed Army Medical Center

The purpose of this research study is to determine whether different types of cardiovascular risk factor information influence the practice of healthy lifestyle behaviors, such as diet and exercise.

Study start: May 2007

Expected completion: December 2008

Inclusion criteria: age ≥18, military healthcare beneficiary, willing to modify current diet and exercise habits, two or more cardiovascular disease risk factors (hypertension, hyperlipidemia,

family history, tobacco use, body mass index ≥25 kg/m²), metabolic syndrome.

Exclusion criteria: clinical cardiovascular disease or conditions that limit safe participation, no significant preclinical atherosclerosis.

This study is not yet open for patient recruitment. Contact Elaine M. Walizer, MSN, RN, Walter Reed Army Medical Center, Washington DC 20307; phone: 202-782-1555; elaine.walizer@na.amedd.army.mil.