

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.

HEALTH EDUCATION COUNSELING WITH OR WITHOUT BUPROPION IN HELPING AFRICAN AMERICANS STOP SMOKING

Sponsored by: the University of Kansas and the National Cancer Institute

A stop-smoking plan that includes health education counseling and bupropion may help African American smokers stop smoking. We do not know whether health education counseling is more effective with or without bupropion in helping African Americans stop smoking. This clinical trial is studying health education counseling

and bupropion to see how well they work compared with a placebo and health education counseling in helping African Americans smokers stop smoking.

Inclusion criteria: African American who has smoked ≤ 10 cigarettes per day for ≥ 25 years and has smoked for ≥ 25 days in the past month, no other

forms of tobacco in the past 30 days and must be interested in stopping smoking.

Exclusion criteria: pregnant or nursing, alcohol or substance abuse in the past year, history of seizures or head trauma, history of bulimia or anorexia nervosa, myocardial infarction in the past 30 days, use of opiates or cocaine, diabetes that

requires oral hypoglycemics or insulin.

Study start: December 2007
Study end: April 2009

This study is currently recruiting patients. Contact Lisa S. Cox, PhD, University of Kansas Medical Center, Kansas City, Kansas; 913-588-4709.

EFFECTIVENESS OF BEHAVIORAL TREATMENTS FOR OBESITY AND MAJOR DEPRESSION IN WOMEN

Sponsored by: the National Institute of Mental Health

Obesity is one of the most alarming health problems in the United States, and 31% of the population is considered obese. The incidence of depression is high in people who are overweight, but we do not know whether depression causes obesity or vice versa; the association may stem from the stigma of obesity or from the appetite and weight gain caused by depressive symptoms. This study compares the effectiveness of two weight loss programs, one supplemented with health education and the other supplemented with behavioral counseling, in treating

women who are depressed and overweight.

Participants in this two-year study will be divided into one of two treatment groups: one group will address weight loss and depression via nutrition, exercise, and health education, and the other group will address weight loss and depression via nutrition, exercise, and behavioral counseling. Participants receiving health education will learn about women's health topics and receive tips on staying healthy and preventing disease. Participants receiving behavioral counseling will learn about de-

pression and links between activity and mood. They will also be asked to keep a diary of moods and activities. Participants in both treatment groups will undergo the same schedule of study visits and assessments.

Inclusion criteria: women aged 21–65 years, major depressive disorder, score of 12–24 on Hamilton Depression Rating Scale, body mass index 30–40 kg/m².

Exclusion criteria: current smoker; diagnosis of bipolar disorder, psychotic disorder, bulimia, or posttraumatic stress disorder; type 1 or 2 diabetes;

plan to have bariatric surgery during the study; inability to walk unaided or unable to walk one-fourth mile without stopping.

Study start: July 2007
Study end: April 2012

This study is currently recruiting patients. Contact Jessica Oleski, MA, University of Massachusetts Medical School, Worcester, Massachusetts; 508-856-1579; jessica.oleski@umassmed.edu.

PREVENTING EXCESSIVE WEIGHT GAIN IN ADOLESCENT GIRLS AT HIGH RISK FOR ADULT OBESITY

The most prevalent disordered eating pattern described in overweight youth is loss of control (LOC) eating, during which youth experience an inability to control the amount of food they are consuming. LOC eating appears to be associated cross-sectionally with greater adiposity in children and adolescents and appears to predispose youth to gain weight or body fat above that expected from normal growth, thus likely contributing to obesity in susceptible children. Interpersonal psychotherapy (IPT), a form of psychotherapy that has been adapted for the

treatment of eating disorders, has demonstrated efficacy in reducing binge eating episodes and inducing modest weight loss (or at least weight stabilization) among adults diagnosed with binge eating disorder. We adapted group IPT for the targeted prevention of excessive weight gain among adolescent girls. Our pilot data support the feasibility and acceptability of a 12-week group IPT trial among adolescent girls at high risk for obesity who report LOC eating, and preliminary findings suggest that IPT can prevent excessive weight gain. We now propose an ade-

Sponsored by: the Eunice Kennedy Shriver National Institute of Child Health and Human Development

quately powered clinical trial to evaluate the efficacy of IPT compared with a standard-of-care health education for stabilizing weight and body fat gain trajectories in 110 adolescent girls at high risk for adult obesity who report LOC eating.

Inclusion criteria: girls aged 12–17 years, body mass index between 75th and 97th percentile, English speaking, good general health, normal laboratory test values.

Exclusion criteria: major illnesses, obesity-related medical complication, regular use of prescription medications, in-

volvement in psychotherapy or a structured weight loss program, pregnancy or recent pregnancy.

Study start: May 2008

This study is currently recruiting patients. Contact the Patient Recruitment and Public Liaison Office, National Institutes of Health Clinical Center, 9000 Rockville Pike; 800-411-1222; prpl@mail.cc.nih.gov.

RELAXATION AND VISUALIZATION THERAPY FOR BREAST CANCER PATIENTS

The purpose of this study is to find out if it is possible to study relaxation and visualization therapy (RVT) with women who have breast cancer. We will also look at what effects, positive and negative, RVT has when used with radiation therapy. We are interested in how RVT may relate to energy, quality of life, stress, and the immune system. In this study, participants will be led through an RVT exercise, providing an interactive process. In addition,

women will perform solitary RVT exercises at home on weekends. Participants for this study will be drawn from the principal investigator's regular patient base. To be sure that we are testing the effects of RVT alone, we will use three groups. The three groups will be RVT, education, and a control. The RVT group will receive RVT with radiation, and the education group will receive breast cancer-related health education with radia-

Sponsored by: the National College of Natural Medicine, Oregon Health and Science University

tion. The third group will receive no treatment beyond radiation. The entire study will last for ≈ 12 weeks. No experimental drug or device will be used during the study.

Inclusion criteria: women aged 45–60 years, diagnosis of breast cancer and referral to radiotherapy at Oregon Health and Science University.

Exclusion criteria: receiving chemotherapy, use of tobacco, history of hypertension, recreational drug use, drink more than

5 alcoholic beverages per week, taking antiinflammatory medications, infection or compromised immune system.

Study start: June 2008

Study end: June 2009

This study is not yet open for participant recruitment. Contact Kimberly Brown, Oregon Health and Science University, Portland, Oregon; 503-552-1747; kbrown@ncnm.edu.