

STUDIES:

CARDIOVASULAR:

Title: Coronary Risk Factor Screening and Behavior Change in Women

Funding Source: Centers for Disease Control and Prevention

Funding Period: 10/98 – 10/99

Study Design: Randomized Prospective Study

Purpose: The purpose of this study was to compare the effect of conventional cardiac risk factor screening, with and without CT imaging (a form of x-ray) of the coronary arteries, on behavior change related to cardiac risk in post-menopausal women.

Eligibility: Postmenopausal women between the ages of 55 and 75 years of age.

Further Study Details: Fifty six (56) healthy post-menopausal women were given a standard health risk assessment to gauge current medication use and physical activity levels along with blood pressure measures and cholesterol levels. The women were then assigned to one of two groups: conventional cardiac risk factor screening and counseling or conventional screening and counseling plus CT imaging of the coronary arteries (CT scan). Once the risk assessments were completed, all participants received one tailored counseling session based focusing on nutrition, supplement use, physical activity, weight management, smoking cessation, and appropriate use of hormone replacement therapy and medications for heart disease risk reduction. In addition to the counseling session, those in the CT group had a CT scan and were shown the x-ray imaging of their coronary arteries. Follow-up assessments were conducted at 6 and 12 months.

Findings: Results from this pilot study suggest that a targeted risk-screening program can promote behavior change in postmenopausal women. However, the addition of a CT scan did not have added benefit to this population.

Publications/Presentations:

02/01 - American College of Preventive Medicine Annual Meeting – Miami, FL.: Coronary Risk Detection and Behavior Change in Post-Menopausal Women Poster Presentation

02/02 – ACPM Annual Meeting: Coronary Risk Factor Screening and Behavior Change in Women Poster Presentation

For additional information, please contact: Jennifer Ballard (jennifer.ballard@yalegriffinprc.org)

Title: At-home Exercise Regimen for Outcome Benefit in Congestive Heart Failure (AEROBIC)

Funding Source: American Teachers of Preventive Medicine (ATPM)/Centers for Disease Control and Prevention (CDC)

Funding Period: 10/00 –4/04

Study Design: Randomized, controlled, prospective study

Purpose: The goal of this study is to determine whether the addition of a home-based exercise program to a chronic disease management program provides an effective and safe means of improving the health and functional status of patients with congestive heart failure (CHF).

Eligibility: Adult men and women with an established diagnosis of CHF.

Further Study Details: Twenty (20) adult men and women enrolled in this study were assigned to one of two groups: a chronic disease management program or chronic disease management plus exercise. Those in the exercise group are provided with a treadmill for use in their home and receive supervised

exercise instruction by a cardiac rehabilitation exercise specialist. The program lasts for one year; in addition to routine monthly telephone calls, participants undergo assessments at 3, 6 and 12 months.

Findings: The study is expected to be completed in early 2004 at which time results will be available.

Publications/Presentations:

For additional information, please contact: Hilary Alonzo, MPH (hilary.alonzo@yalegriffinprc.org)

Title: Assessment of Total Cholesterol / HDL Ratio as a Stable Lab Value for Hospitalized

Patients: Changes in Lipid Levels (CLIPS)

Funding Source: The Griffin Hospital Medical Education Library Fund.

Funding Period: 10/99 – 10/01

Study Design: Prospective trial

Purpose: The purpose of this study was to assess whether the total cholesterol/HDL ratio remains stable during and after hospitalization as compared to total cholesterol and the remainder of the lipid profile.

Eligibility: Male and female patients, between the ages of 30 – 85 years, admitted to Griffin Hospital. Must not be currently taking lipid-lowering medication.

Further Study Details: Early treatment of hyperlipidemia (high cholesterol) has been shown to provide benefit; however, total cholesterol is known to vary with acute illness, delaying treatment decisions around the time of hospitalization. A total of 61 patients admitted to Griffin Hospital, an acute care community hospital, with various admitting diagnosis participated in this study to assess changes in lipid profile values. Participants had lipid profiles done at admission, on day 3 of hospitalization (or upon discharge whichever occurred first) and again 4 weeks after discharge.

Findings: In patients hospitalized with various diagnoses, lipid profile values varied significantly during and after the hospital stay, while the ratio of total cholesterol to HDL remained stable. This ratio may serve as a reliable predictor in the early diagnosis and treatment of abnormal cholesterol levels in hospitalized patients.

Publications/Presentations:

For additional information, please contact: Beth Patton Comerford, MS
(beth.comerford@yalegriffinprc.org)

Title: Connecticut WISEWOMAN project

Funding Source: Connecticut Department of Public Health (DPH)

Funding Period: 10/00-9/01

Purpose: The Yale-Griffin Prevention Research Center assisted the Connecticut Department of Public Health in the development of an assessment and counseling tool for the Well-Integrated Screening of Women Across the Nation (WISEWOMAN) program.

Further Details: This tool is used to counsel women enrolled in the WISEWOMAN program on reducing risk factors for cardiovascular disease, with a particular focus on promoting physical activity and healthy dietary practices.

For additional information, please contact: Ming Chin-Yeh, PhD, MS (myeh@hunter.cuny.edu)

COMMUNITY:

Title: Healthy People 2010 Microgrant Initiative

Funding Source: US Department of Health and Human Services, Office of Disease Prevention and Health Promotion (ODPHP)

Funding Period: 10/01 – 12/03

Purpose: The goals of this project include: establishing a demonstration project to assess the utility of distributing small grants for promoting *Healthy People 2010* objectives; evaluating the effect of the micro-finance mechanism applied on prevailing measures of community mobilization and capacity building; and development of documentation to support efforts for national replication.

Eligibility: Nonprofit organizations (i.e. community organizations and groups, schools, faith-based organizations, civic groups) serving or residing in the lower Naugatuck Valley (Ansonia, Beacon Falls, Derby, Oxford, Seymour, Shelton), Bridgeport, New Haven and Hartford, CT.

Further Study Details: The Yale-Griffin Prevention Research Center (PRC) was one of two organizations across the country selected to develop and pilot a national microgrant initiative. In May 2002, the PRC awarded a total of 103 microgrants (in the amount of \$2010) through a competitive application/selection process to community-based organizations/agencies throughout Connecticut to support health promotion and disease prevention activities that address the national goals of Healthy People 2010. This funding was made available with the goal of developing a national model for engaging local organizations to improve the health of their communities. Technical assistance was provided to all grantees during the year-long funding period; an end-of year colloquium was held in March 2003 to encourage networking and information sharing among community agencies. The microgrant project implementation phase ran from May 2002 through July 2003, after which time program evaluation activities will commence.

Findings: This project is expected to be completed by December 2003 at which time findings will be available.

Publications/Presentations:

American Public Health Association, Philadelphia, PA, 11/02: Show me the money! Small grants for HP 2010 should we bother?

Secretary's Healthier US Prevention Summit, Baltimore, MD, 04/03: Resources: Communities Contributing to a Healthier US

For additional information, please contact: Margot Zaharek, MS
(margot.zaharek@yalegriffinprc.org)

ENDOTHELIAL FUNCTION:

A research priority at the Yale-Griffin Prevention Research Center is cardiovascular health. We have a vascular lab where we conduct studies of **endothelial function** – a measure of blood vessel behavior. Blood flow and blood vessel reactivity are indicators of heart health. When blood vessels dilate (expand) or constrict (shrink) properly, endothelial function is considered to be normal. If they constrict when they should dilate, endothelial function is abnormal. Impaired (or abnormal) endothelial function is associated with an increased risk of heart disease. We measure endothelial functioning with the use of ultrasound imaging of the brachial artery in the arm (called Brachial Artery Reactivity Scan or BARS) – a simple and painless procedure which provides a picture of the blood vessels.

Title: Endothelial Function in Response to Sustained Consumption of Soy Protein and Lecithin by Healthy Post-menopausal Women

Funding Source: Eridania Beghin-Say America

Funding Period: 7/01-9/03

Study Design: Randomized, double-blind, placebo controlled crossover trial.

Purpose: The purpose of this study was to determine the effects of certain components of soy (soy isoflavone protein and soy lecithin) on endothelial function in healthy post-menopausal women. If soy, which contains natural phytoestrogens, can be shown to provide the cardiovascular benefit similar to that found in conventional estrogen replacement pharmaceuticals, it may provide an alternative for post-menopausal women who favor “natural” therapies.

Eligibility: Healthy post-menopausal women not taking HRT, vasoactive medications or cholinesterase inhibitors.

Further Study Details: Twenty-two women participated in this study. Participants drank four different combinations of the study beverage (soy isoflavone protein and soy lecithin; soy isoflavone and placebo lecithin; placebo protein and soy lecithin, and placebo protein and placebo lecithin), each twice a day for a 4-week period of time. Brachial Artery Reactivity Scan (BARS) and cholesterol testing was done after completion of each 4-week treatment assignment.

Findings: Soy isoflavone protein and soy lecithin were found to significantly improve the lipid profile (cholesterol); although a positive influence on endothelial function could not be confirmed. This may however be due to the small number of participants in the study.

Publications/Presentations:

09/03 - American Oil Chemists Society (AOCS): Endothelial Function in Response to Sustained Consumption of Soy Protein and Lecithin By Healthy Postmenopausal Women Poster Presentation

For additional information, please contact: Marian Evans, MD (marian.evans@yalegriffinprc.org)

Title: Effects of Egg Ingestion on Endothelial Function in Hyperlipidemic Adults: A Randomized, Controlled, Crossover Trial

Funding Source: Egg Nutrition Center of the USDA

Funding Period: 12/03 – 1/05

Study Design: Single-blind crossover study

Purpose: To assess the effects of daily egg consumption on endothelial function among adults with untreated hyperlipidemia (high cholesterol).

Eligibility:** Adult men and women with high cholesterol (total cholesterol of ≥ 240 mg/dl and/or LDL cholesterol of ≥ 160 mg/dl, and/or a total cholesterol to HDL ratio of ≥ 5.7) not currently taking lipid lowering medication.

Further Study Details: A total of 40 adults will be recruited to participate in this study. The study will involve an acute phase where participants will undergo endothelial function (BARS) and cholesterol testing following two separate study breakfasts (eggs, and a high-fat sausage patty with cheese). Participants will then be assigned to two treatments breakfasts, in random order, each for a period of 6 weeks: 1) 2 eggs daily and 2) one serving of Egg Beaters. The Egg Beaters will be used as a comparison since it is similar to eggs in most ways with the exception of the amount of dietary cholesterol. At the end of each six-week treatment period, participants will undergo endothelial function (BARS) and cholesterol testing.

Findings: This study is expected to be completed in January 2005 at which time results will be available.

Publications/Presentations:

For additional information, please contact: Marian Evans, MD (marian.evans@yalegriffinprc.org)

Title: Randomized, Crossover Study of Endothelial Function Responses to Acute and Sustained Egg Consumption in Healthy Subjects

Funding Source: Egg Nutrition Center of the USDA

Funding Period: 5/00-6/01

Study Design: Single-blind crossover study

Purpose: The purpose of this study was to determine the effects of daily egg consumption on endothelial function (or heart health).

Eligibility: Healthy adults (over the age of 35 for men; post-menopausal and not currently using hormone replacement therapy for females) with no known coronary artery or other vascular disease and no daily prescription medication use.

Further Study Details: A total of 49 adults participated in this study. Participants were assigned to two treatments breakfasts, in random order, each for a period of 6 weeks: 1) 2 eggs daily and 2) one serving of oatmeal daily. The oatmeal breakfast was used as a comparison since oatmeal has been shown to have a beneficial effect on endothelial function. At the end of each six-week treatment period, participants underwent endothelial function testing (BARS) and cholesterol testing.

Findings: At the end of six weeks, cholesterol levels were significantly lower among those who ate oatmeal, while cholesterol levels stayed fairly constant for those who ate eggs. With regard to endothelial function, there was no meaningful difference between the oat and egg treatment, indicating that eating eggs in moderation does not adversely affect endothelial function. These findings are consistent with the view that dietary cholesterol (as found in eggs) may be less detrimental to cardiovascular health than previously thought.

Publications/Presentations:

Katz DL, Nawaz H, Evans MA, Njike VY, Comerford BP, Hoxley ML. Short-term egg consumption does not adversely affect endothelial function in healthy adults. [abstract] JADA 2002;102 (Supplement):A-12.

American Dietetic Association, 10/02; Philadelphia, PA: Short-Term Egg Consumption Does Not Adversely Affect Endothelial Function in Healthy Adults

For additional information, please contact: Marian Evans, MD (marian.evans@yalegriffinprc.org)

Title: Phytoestrogen & Raloxifene Effects on Endothelial Reactivity (PREFER): Double-blind, placebo controlled, randomized crossover trial of raloxifene versus soy phytoestrogens on endothelial reactivity in healthy postmenopausal women.

Funding Source: Eli Lilly & Co., Inc.

Funding Period: 2/01-3/02

Study Design: Randomized, double-blind, placebo controlled crossover trial.

Purpose: Many women take natural products and/or pharmaceuticals for the treatment of menopause-related conditions. The purpose of this study was to compare the effects of raloxifene (a commonly prescribed medication for the prevention of osteoporosis) and soy phytoestrogens on endothelial function in healthy post-menopausal women. Participants were also surveyed regarding their preference for natural vs. synthetic therapy both before and after the study.

Eligibility: Healthy, post-menopausal woman not currently taking hormone replacement therapy.

Further Study Details: A total of 25 women who participated in this study were assigned to three different treatments: raloxifene (60mg), soy phytoestrogen (55mg), and placebo in random order each for six weeks. Following each treatment assignment, participants underwent BARS and lipid profile testing.

Findings: Neither of the active treatments (raloxifene or soy phytoestrogens) was found to enhance endothelial function (i.e. provide a protective effect on vascular functioning) in this pilot study. With regard to cholesterol findings, all three treatments (including placebo) were found to significantly lower total cholesterol and LDL from baseline. Further study is required to determine if particular

subgroups of postmenopausal women would experience cardiovascular benefit from the use of synthetic or natural forms of estrogen.

Publications/Presentations:

For additional information, please contact: Marian Evans, MD (marian.evans@yalegriffinprc.org)

Title: Randomized, Double-blind, Placebo Controlled Trial of Raloxifene on Endothelial Reactivity in Healthy Post-menopausal Women.

Funding Source: Eli Lilly & Co., Inc.

Funding Period: 4/99-5/00

Study Design: Randomized, double-blind, placebo controlled crossover trial.

Purpose: The purpose of this study was to assess the effects of raloxifene (a synthetic estrogen receptor modulator) on blood vessel performance in healthy post-menopausal women. Raloxifene is commonly prescribed for osteoporosis prevention in post-menopausal women; however, cardioprotective effects have not been studied to date.

Eligibility: Healthy, post-menopausal woman not currently taking hormone replacement therapy.

Further Study Details: Twenty (20) women enrolled in this study were assigned to 2 treatments – raloxifene (60mg) or placebo daily for six weeks. Following each treatment assignment, participants underwent BARS and laser Doppler velocimetry (LDV) testing.

Findings: Treatment with raloxifene was shown to improved blood vessel reactivity as compared to placebo, thus suggesting that raloxifene may have a cardioprotective effect in this population. Additionally, raloxifene was not associated with any more side effects than placebo.

Publications/Presentations:

Sarrel PM, Nawaz H, Chan W, Fuchs M, Katz DL. Raloxifene and endothelial function in healthy postmenopausal women. *Am J Obstet Gynecol* 2003;188(2):304-9.

American Heart Association, 11/00; New Orleans, LA: Raloxifene Improves Brachial Artery and Microcirculatory Flow-Mediated Dilation in Healthy Postmenopausal Women.

For additional information, please contact: Beth Patton Comerford (beth.comerford@yalegriffinprc.org)

Title: Oats, Antioxidants, and Endothelial Function in Insulin Resistant Adults.

Funding Source: The Quaker Oats Company

Funding Period: 10/99-7/01

Study Design: Randomized, double-blind, placebo controlled crossover trial.

Purpose: The purpose of this study was to determine the effects of oats and antioxidant vitamins on endothelial function in adults with features of insulin resistance. While metabolic benefits of soluble fiber-rich grains in insulin resistance (which can lead to diabetes) are well known, effects on endothelial function (heart health) have not been reported.

Eligibility: Adult men (35-75 years old) and women (postmenopausal – 75 years old) with features of insulin resistance (overweight, hypertriglyceridemia).

Further Study Details: The thirty participants in this study were assigned, in random order, to 4 different treatments: oats plus vitamin E and C, oats plus placebo vitamin E & C, vitamin E & C only, and placebo vitamin E & C. Treatment assignments were taken daily for a period of 6 weeks. Endothelial function (BARS) testing was done at the beginning of the study (after a one-time intake of each treatment), and again following each 6-week assignment.

Findings: Results from this study indicate that oats improve endothelial dysfunction in adults with features of insulin resistance, with particularly strong effects in women. Immediate beneficial effects were found on endothelial function from eating a single bowl of oatmeal, with greater benefit seen from eating oats daily for 6 weeks. These findings are consistent with previous study of oat ingestion in healthy adults (see below). The antioxidant vitamins, E and C, did not provide any benefit, and actually seemed to have a negative effect in these women.

Publications/Presentations:

Katz DL, Evans MA, Chan W, Nawaz H, Comerford, BP, Hoxley ML, Sarrel PM. Oats, antioxidants and endothelial function in adults with clinical features of insulin resistance. *Diabetes* 2002;51(Supplement 2):A401 (abstr).

American Diabetes Association, 06/02; San Francisco, CA: Oats, Antioxidants and Endothelial Function in Adults with Clinical Features of Insulin Resistance.

For additional information, please contact: Marian Evans, MD (marian.evans@yalegriffinprc.org)

Title: Acute Nutrient Effects on Endothelial Function: A Randomized, Single-blind Crossover Trial in Healthy Adults.

Funding Source: The Quaker Oats Company

Funding Period: 7/98-6/99

Study Design: Randomized, single-blind crossover trial.

Purpose: To determine the effects of acute and month-long whole grain oat and wheat cereal ingestion on endothelial function in healthy adults following a high fat meal.

Further Study Details: Fifty adults (25 men and 25 women) participated in this study. At the beginning of the study, participants underwent endothelial function (BARS) testing before and after ingesting 3 different treatment assignments - whole grain oatmeal plus high fat milkshake, wheat cereal plus high fat milkshake, and vitamin E and high fat milkshake. Participants were then assigned, in random order, to 4-week intake of oat and wheat cereals. Endothelial function (BARS) testing was done at the completion of each 4-week treatment assignment.

Eligibility: Healthy men (35-75 years old) and women (postmenopausal – 75 years old).

Findings: The findings from this study confirm that acute fat ingestion induces endothelial dysfunction in healthy adults. Both vitamin E and oatmeal in the doses tested preserve normal endothelial function when ingested concurrently with a high fat meal. In the month-long supplementation, oats and wheat had comparable effects on endothelial function. These results suggest that nutrient distribution and meal composition may have significant implications for cardiovascular health.

Publications/Presentations:

Katz DL, Nawaz, H, Boukhalil J, Chan W, Ahmadi R, Giannamore V, and Sarrel P. Effects of Oat and Wheat Cereals on Endothelial Responses. *Prev Med*, 2001; 33(6); 476-484.

For additional information, please contact: Marian Evans, MD (marian.evans@yalegriffinprc.org)

COMPLEMENTARY AND ALTERNATIVE MEDICINE:

Title: IVMT for Fibromyalgia Syndrome: A Pilot Study

Funding Source: National Institutes of Health/NCCAM

Funding Period: 12/03-1/05

Study Design: Randomized, double-blind, placebo controlled pilot study.

Purpose: To assess the effectiveness and safety of the use of intravenous micronutrient therapy (IVMT) for the treatment of fibromyalgia.

Eligibility:** Adult men and women previously diagnosed with fibromyalgia.

Further Study Details: Approximately 40 adults with a diagnosis of fibromyalgia will be enrolled in this pilot study. Half of the group will be assigned to the active treatment (Intravenous Micronutrient Therapy, or IVMT) while the other half will receive placebo. Participants will receive the treatment once a week for eight consecutive weeks. The primary outcomes of interest in this study are pain, functional status, and quality of life.

Findings: This study is expected to be completed by January 2005 at which time results will be available.

Publications/Presentations:

For additional information, please contact: Alyse Sabina, MPH (alyse.sabina@yalegriffinprc.org)

Title: Complementary/Alternative Medicine (CAM) Outcomes Research Project (CORP)

Funding Source: Centers for Disease Control and Prevention

Funding Period: 10/00 – 12/03

Study Design: Literature Review

Purpose: The purpose of the CAM Outcomes Research Project (CORP) is to identify best research methods for the evaluation of complementary and alternative medicine (CAM).

Further Study Details: The CORP activities are guided by a 13-member Expert Panel of nationally recognized CAM authorities and a subcommittee of CAM practitioners representing the following disciplines: acupuncture/Chinese medicine, chiropractic, energy therapy, massage therapy, mind-body therapy, naturopathy/homeopathy, and traditional osteopathy. The scope of the CORP project incorporates a comprehensive systematic review of the published CAM literature and creation of an “evidence matrix”, as well as the development and implementation of four pilot studies in areas where evidence is needed, as identified by the first phase of the project (the literature review). Criteria were developed to guide the planning of pilot studies so that evidence would be generated where most useful. Pilots were deemed most useful if they addressed the any of the following: gaps in the evidence base; high priority condition/treatment pairs; a methodologic challenge; and/or providing preliminary evidence of treatment effect. The pilot studies are listed below.

Findings: This study is expected to be completed by February 2004 at which time results will be available.

Publications/Presentations:

Katz DL, Williams A, Girard C, Goodman J, Comerford B, Behrman A, Bracken M. Evidence Mapping: Introduction of Methods with Application to Complementary and Alternative Medicine Research, *Alternative Therapies In Health and Medicine*, 2003 July/August, 9 (4): 22-30.

Katz DL, Sabina A, Girard C, Adelson A, Liberti L, Williams A Teaching Evidence-Based Integrative Medicine: Description of A Model Program. *Evidence Based Integrative Medicine*. In press: 9/03.

American Public Health Association Conference, Boston, MA, 11/00: Developing an Integrative Medicine Research Agenda

Society for Gynecologic Oncology, Nashville, TN, 03/01: Complementary Medicine and Gynecologic Oncology

19th National Conference on Health Education and Health Promotion, Atlanta, Georgia, 04/01:
Developing an Integrative Medicine Research Agenda - Round Table Discussion

Society of Public Health Education 2003 Midyear Scientific Conference, 06/03, Las Cruces, NM:
The Integrative Medicine Center at Griffin Hospital: Holistic Partnerships for Health Poster
Presentation

For additional information, please contact: Anna-leila Williams, PA-C, MPH
(annaleila.williams@yalegriffinprc.org)

CORP Pilot Studies:

Title: Homeopathic Treatment for Attention Deficit-Hyperactivity Disorder

Funding Period: 2/03 – 8/03

Study Design: Randomized, placebo-controlled, double-blinded pilot study

Purpose: The purpose of this study is to determine the safety and efficacy (effectiveness) of homeopathy for the treatment of Attention Deficit-Hyperactivity Disorder (ADHD) in children ages 6-12 years.

Eligibility: Children between the ages of 6 –12 years with a diagnosis of ADHD.

Further Study Details: The study is being conducted by Dr. Jennifer Jacobs at The Evergreen Center for Homeopathic Medicine in Edmonds, WA. Attention deficit-hyperactivity disorder is a prevalent condition affecting an estimated 4-12% of school aged-children. The standard conventional treatments are effective at minimizing symptoms, however, these medications have some potential for addiction and abuse, and have the potential to produce notable side effects. It is believed that homeopathic medicine may offer the potential to be an effective adjuvant and perhaps alternative to conventional treatment.

Forty eight children participated in this study and were assigned to one of two groups - individualized homeopathic remedy or placebo. All children received a standard homeopathic evaluation prior to beginning their treatment assignment. Outcomes of interest included attention and behavior as well as use/dose of conventional medications. The intervention lasted 18 weeks and children were evaluated at baseline (before treatment), 6, 12, and 18 weeks.

Findings: Data analysis is currently underway; results are expected to be available in early 2004.

Publications/Presentations:

For additional information, please contact: Anna-leila Williams, PA-C, MPH
(anna-leila.williams@yalegriffinprc.org)

Title: A Retrospective Cohort Study of Modified Citrus Pectin for the Prevention of Metastases in Prostate Cancer

Funding Period: 1/03-10/03

Study Design: Retrospective cohort study

Purpose: To assess the impact, by medical record review, of modified citrus pectin (MCP) use on the prevention of metastasis in men with prostate cancer.

Eligibility: Prostate cancer patients treated at Southwestern Regional Medical Center, Midwestern Regional Medical Center, and Cancer Treatment Centers of America/Seattle.

Further Study Details: This study involves a chart review of prostate cancer patients. Of particular interest is stage of prostate cancer, metastasis, types of therapy undergone, use of nutraceuticals and

For additional information, please contact: Meghan O'Connell, MPH
(meghan.oconnell@yalegriffinprc.org)

Title: Obesity Prevention Program - State of CT Department of Public Health

Funding Source: State of CT Department of Public Health

Funding Period: 11/02 – 9/03

Purpose: The PRC was contracted by the State of CT Department of Public Health to assist with their Obesity Prevention Program, a three-year initiative funded by the CDC. In addition to serving on numerous advisory and planning committees, the PRC was asked to develop a community assessment profile instrument which would be pilot tested in 2 local communities.

Further Study Details: The CT Community Health Asset Profiler (CHAP) was designed to assist communities in the identification and assessment of its resources, both environmental and policy-related, as they relate to the prevention of obesity, with a specific focus on the areas of nutrition and physical activity. The CHAP is not intended to measure/assess utilization of resources within a community, nor to conduct obesity surveillance; rather, the tool is designed to provide a comprehensive and objective picture/reporting of resources, assets and liabilities within a defined area that might impact utilization and obesity prevalence. The tool is intended to inform decisions of resource allocation and policy development.

Publications/Presentations:

For additional information, please contact: Beth Patton Comerford
(beth.comerford@yalegriffinprc.org)

Title: Technical Skills for Weight Management

Funding Source: Centers for Disease Control and Prevention

Funding Period: 10/98-10/00

Study Design: Randomized controlled trial

Purpose: To compare conventional dietary counseling to a novel, group-based skill-building program on long-term weight management (loss and maintenance) in women.

Eligibility: Overweight/obese adult women.

Further Study Details: A total of 80 women participated in this weight loss study; half were assigned to the conventional dietary counseling group, while the other half were assigned to the skill-building group. The skill-building program included educational lectures, a supermarket shopping tour conducted by a registered dietitian, dining at 2 restaurants which included instruction on healthful menu selections, and a home visit conducted by the dietitian who evaluated the participant's pantry selections and supervised a meal preparation. The study lasted for one year; participants were evaluated at 6, 12, and 24 months.

Findings: Although both groups demonstrated weight loss, participants receiving the conventional (individualized) office-based counseling lost more weight than did those in the skill-building group, and compared to their baseline values, both groups were able to maintain some weight loss one year following the intervention. Dietary analysis did reflect a significant decrease in the percent of fat consumed in the diet of those in the skill-building group, and showed a difference (increase) in physical activity patterns. The effects of the skill-based intervention on dietary intake behavior and physical activity patterns are encouraging, and warrant further study.

Publications/Presentations:

Katz DL, Chan W, Gonzalez M, Larson D, Nawaz H, Abdulrahman M, Yeh MC. Technical skills for weight loss: preliminary data from a randomized trial. *Prev Med.* 2002;34:608-15

Nawaz H, Chan W, Abdulrahman M, Larson D, Katz DL, Self-Reported Weight And Height: Implications For Obesity Research. *American Journal of Preventive Medicine*. 2001; 20(4): 294-298.

Yeh MC, Rodriguez E, Nawaz H, Gonzalez M, Nakamoto D, Katz DL. Technical Skills for Weight Loss: Two-year follow-up results of a randomized trial. *International Journal of Obesity*. In press: 7/03

For additional information, please contact: Jennifer Ballard
(jennifer.ballard@yalegriffinprc.org)

PHYSICAL ACTIVITY:

Title: Physician Counseling and Patient Risk Factors for Chronic Disease: Training Resident Physicians to Promote Physical Activity: A Randomized Trial

Funding Source: American Heart Association

Funding Period: 7/01 - 12/03

Study Design: Randomized controlled trial

Purpose: The goals of this study are 1) to evaluate the impact of a novel and relatively simple training program in behavioral counseling techniques (the Pressure System Model) on physicians' counseling behavior, and 2) to demonstrate that patients seen by physicians with specialized training in counseling techniques show greater increases in physical activity as compared to patients seen by physicians who have not received this training.

Eligibility: First year medical residents based at 7 Connecticut hospitals/clinics within the Yale-affiliated Internal Medicine Residency system and those patients assigned to them.

Further Study Details: Seven hospitals in the Yale-affiliated residency program participated in this study. The hospitals were randomly assigned to either participate in the Pressure System Model (PSM) training program or not. The first year medical residents working at those hospitals assigned to PSM training were given a series of four training sessions, after which time they were instructed to use the Pressure System Model with their patients. Outcomes of interest include physician counseling, physician and patient perception, and patient physical activity and were assessed by the use of both physician and patient questionnaires.

Findings: This study is expected to be completed in January 2004 at which time results will be available.

Publications/Presentations:

Katz DL. Behavior Modification in Primary Care: The Pressure System Model. *Preventive Medicine*. 2001;32: 66-72.

For additional information, please contact: Karen Schultz, MPH (karen.schultz@yalegriffinprc.org)

SMOKING CESSATION:

Title: Worksite Smoking Cessation Program: Creating Healthy and Nicotine-free Griffin Employees (CHANGE)

Funding Source: Centers for Disease Control and Prevention and Griffin Hospital

Funding Period: 2/02-2/03

Study Design: Intervention Study

Purpose: To create a worksite smoking cessation program utilizing the impediment profile approach developed and tested in prior studies conducted by the PRC.

Eligibility: Employees of Griffin Hospital, Derby, CT

Further Study Details: This program was based on a successful smoking cessation pilot study (TISC; see below) developed by the PRC in 1999. As in the TISC study, participants completed the impediment profile questionnaire, were provided with their individual results, and were offered as many as seven different “interventions” or programs to assist in their attempt to quit smoking. The CHANGE program used a personalized approach for its participants – tailoring the treatment to each person based on their needs. All therapies were offered at the worksite, during regular work hours, at no cost to employees and included medications and nicotine replacement, group counseling, dietary counseling, acupuncture, stress management and others.

Findings: At the end of the one-year program, 45% participants were smoke free; and, those who were still smoking reported having cut down considerably on the number of cigarettes smoked daily. The success of the CHANGE program has led to plans for offering the program as a permanent benefit to hospital employees and family members, as well as expanding it to other area employers.

Publications/Presentations:

For additional information, please contact: Meghan O’Connell, MPH
(meghan.oconnell@yalegriffinprc.org)

Title: Adolescent Smoking Cessation Program: Amity High School

Funding Source: Centers for Disease Control and Prevention; Connecticut Southwest Area Educational Council; CT Orange Drug and Alcohol Action Council

Funding Period: 2000-2001 school year

Study Design: Intervention Study

Purpose: This adolescent smoking cessation program was developed in collaboration with the Amity Regional Senior High School to address the worsening problem of regular tobacco use by high school students. The program was evaluated to determine feasibility and impact of a smoking cessation program tailored specifically to the needs of high school students.

Eligibility: High school students enrolled at Amity Regional Senior High School (Woodbridge, CT) with a desire to quit smoking.

Further Study Details: Feedback from focus groups conducted with students was used to develop a tailored smoking cessation program. Some of the therapies offered included: stress management, educational sessions lead by a physician, weekly group meetings and a smoking cessation program for parents; students also had the option of taking a medication (bupropion) to reduce cravings to smoke. Parental counseling was offered to help parents understand how household smoke affects their child’s ability to quit and to increase awareness of ways they could support their teenager’s efforts to quit. A total of 22 students participated in the first program.

Findings: At the end of the 8-week program, 27% of the participants reported being smoke-free, while the average number of cigarettes smoked per day among students who were not able to quit decreased from 22 (per day) prior to the program to 9. Because of the initial program’s successes and the effective partnership with the Yale-Griffin PRC, Amity Regional Senior High School completed a second program in 2001 and has initiated a third in 2003.

Publications/Presentations:

O’Connell ML, Freeman M, Jennings G, Chan W, Greci LS, Manta I, Katz DL. Smoking Cessation for High School Students: Process Evaluation of a Tailored Program – Amity. *Behavior Modification*. In press: 4/02

American College of Preventive Medicine Annual Meeting, San Antonio, TX, 02/02:

Adolescent Smoking Cessation Study and Tailored Intervention for Smoking Cessation Study (Poster)

National Conference on Tobacco, San Francisco, CA, 11/02: Amity: Adolescent Smoking Cessation (Poster)

11/02 - American Public Health Association, Philadelphia, PA, 11/02: Amity: Adolescent Smoking Cessation (Poster)

For additional information, please contact: Meghan O'Connell, MPH
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Title: Impediment Profiling for Smoking Cessation: Evaluation Using a Retrospective Cohort Design

Funding Source: Centers for Disease Control and Prevention

Period:

Study Design: Prospective pilot study with a retrospective match cohort control.

Purpose: The purpose of this study was to compare the results from our previous smoking cessation study (Tailored Interventions for Smoking Cessation (TISC): see below) against a similar group of adults who did not participate in the original study, but were also motivated to quit smoking.

Eligibility: Adult men and women smoking with a history of smoking for at least one year and an average of 15 or more cigarettes per day.

Further Study Details: Eighty-six (86) adults completed the impediment profile questionnaire used in the TISC study and responded to questions regarding smoking status. Carbon monoxide (CO) readings were also taken to compare to self reported information. These findings were then compared to the results of the TISC study to determine whether there was a difference in smoking status between adults, motivated to quit smoking, who participated in the TISC study and those who did not.

Findings: This study showed that the TISC program was more effective at helping women quit smoking as compared to quitting without assistance, however this difference was not evidenced in men.

Publications/Presentations:

For additional information, please contact: Meghan O'Connell, MPH
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Title: Tailored Interventions for Smoking Cessation (TISC)

Funding Source: Centers for Disease Control and Prevention

Funding Period: 10/98 – 10/00

Study Design: Intervention

Purpose: The TISC study was developed to test the effectiveness of a smoking cessation program based on "impediment profiling" which identifies an individual's own barriers to quit smoking and provides tailored interventions accordingly.

Eligibility: Adult men and women smoking with a history of smoking for at least one year and an average of 15 or more cigarettes per day.

Further Study Details: There are at least seven barriers that people face when trying to quit smoking, some face more than others. Among these things that make smoking cessation more difficult are nicotine dependence, addiction to other chemical substances, depression, anxiety, stress, concern about weight gain, and having family and friends who smoke. During the initial phase of this project, a questionnaire was developed to identify an individual's personal barriers. This questionnaire was then

used with the 20 participants enrolled in this study. Participants completed the questionnaire, after which time their results were shared with them individually and they were assigned to as many of the seven “interventions” or programs as their results indicated would be helpful to them in their quit attempt. The study lasted for a total of 12 months and included a follow-up after 12 and 24 months.

Findings: 42% of participants were smoke free at the end of the year-long program; and 26% remained smoke-free after 2 years. This is a much higher success rate than traditional smoking cessation programs that normally produce a 25% quit rate at program completion (typically 2-4 months.) The results from this pilot study indicate that impediment profiling as a basis for tailored smoking cessation is associated with a higher than average quit rate and appears quite promising.

Publications/Presentations:

Katz DL, Boukhalil J, Lucan S, Shah D, Chan W, Yeh M.C., Impediment Profiling for Smoking Cessation: Preliminary Experience. *Behavior Modification*. 2003; 27(4):524-537.

O’Connell M, Lucan SC, Yeh MC, Rodriguez E, Shah D, Chan W, Katz DL. Impediment Profiling for Smoking Cessation: Results of a Pilot Study, *American Journal of Health Promotion*, 2003 May/June, 17(5): 300-3.

American Teachers of Preventive Medicine, Albuquerque, NM, 03/03: Impediment Profiling for Smoking Cessation: From Protocol to Practice?

For additional information, please contact: Meghan O’Connell, MPH
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VIOLENCE PREVENTION:

Title: Reaching Emotions through Arts-based Creative Teaching (REACT)

Funding Source: Centers for Disease Control and Prevention

Period: 1/03 – 5/03

Study Design: Prospective intervention study

Purpose: To evaluate the effectiveness of a novel teaching approach which merges methods of conflict resolution skill-building with a unique application of creative writing and expression, permitting the incorporation of violence prevention into existing language arts curricula.

Eligibility: 5th grade students at the Mead Elementary School, Ansonia, CT.

Further Study Details: Aggression and hostility are of underlying risk factors of youth violence, compounded by low self-esteem, feelings of alienation and widespread media violence. Given the current climate of vigilance and media messages pertaining to terrorism, these risk factors may well be heightened. In the wake of September 11th, 2001 the Yale-Griffin Prevention Research Center and the Mead Elementary School assisted, through the implementation of Project REACT, 5th grade students to explore and express their emotions through poetry and music. This pilot intervention is intended to test the effects of poetry/movement/music skill-building activities on conflict resolution skills, self-expression, and anger management.

Findings: Data analysis is currently underway; results are expected to be available by December 2003.

Publications/Presentations:

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