2002 – NHLBI Conference

CLINICAL EFFECTIVENESS AND REPRODUCIBILITY OF A CORPORATE CARDIOVASCULAR DISEASE (CVD) RISK REDUCTION PROGRAM

Susan Pickel BSN MHM, Richard Salmon DDS MBA, Kosta Arabatzis MS, Leah Adams PharmD, Scott Kallish MA, Ivan Levinrad RPT, Brenda Mitchell PhD, Barry Franklin PhD, Neil Gordon MD, North Broward Hospital District, Fort Lauderdale, FL, and INTERxVENT Coordinating Center, Savannah, GA

Rapidly escalating healthcare costs are causing employers to focus unprecedented attention on chronic disease prevention. In this study, we evaluated the clinical effectiveness and reproducibility of a comprehensive CVD risk reduction program (INTERxVENT) administered to employees at companies in three different U.S. cities (designated A, B, and C). Employees (n=1,483) were evaluated at baseline and after approximately 12 weeks. The program was administered in each city by non-physician healthcare professionals guided by a computerized participant management system. For participants with abnormal baseline risk factors, clinically relevant improvements were observed for multiple variables as follows ($p \leq 0.05$ unless otherwise indicated): systolic/diastolic blood pressure, City A = -17/-10 mmHg, City B = -20/-12 mmHg, City C = -13/-13 mmHg; total cholesterol, City A = -30 mg/dl, City B = -44 mg/dl, City C = -34 mg/dl; LDL cholesterol, City A = -16 mg/dl, City B = -29 mg/dl, City C = -21 mg/dl; HDL cholesterol, City A = 5 mg/dl, City B = 4 mg/dl (p=NS); City C = 0.4 mg/dl (p=NS); triglycerides, City A = -73 mg/dl, City B = -30 mg/dl (p=NS), City C = -53 mg/dl; weight, City A = -3 lbs, City B = -9 lbs, City C = -5 lbs; and fasting glucose, City A = -32 mg/dl, City B = -35 mg/dl, City C = -36 mg/dl. These data demonstrate that a comprehensive CVD risk reduction program can elicit clinically relevant and reproducible improvements in the risk factor status of employees with abnormal baseline values.

2002 – NHLBI Conference

BENEFIT OF A WORKSITE-BASED CARDIOVASCULAR RISK REDUCTION PROGRAM ON EMPLOYEE HEALTHCARE CLAIMS

Brenda Mitchell PhD, Chip Faircloth MBA MHA, Sheldon Warman MD, Susan Pickel BSN MHM, Richard Salmon DDS MBA, Barry Franklin PhD, Neil Gordon MD, North Broward Hospital District, Fort Lauderdale, FL, and INTERxVENT Coordinating Center, Savannah, GA

It is estimated that cardiovascular diseases and stroke will cost the United States $298.2 billion in 2001. Clearly, there is an urgent need to reduce avoidable death, disability, and financial expenditure by increasing access to clinically effective cardiovascular risk reduction interventions. In this study, we investigated the effect of a worksite-based cardiovascular risk reduction program (INTERxVENT) on employee healthcare claims. INTERxVENT was implemented at the company under investigation in January 2000. Healthcare claims data of 3,062 employees who were employed by the company on February 1, 1999 and who were still employed by the company on July 31, 2000 were analyzed. Of these employees, 636 (21%) participated in INTERxVENT between February 1, 2000 and July 31, 2000. A comparison was made of the average healthcare claims per employee for February 1, 1999 through July 31, 1999 versus February 1, 2000 through July 31, 2000 for the 636 employees who participated and the 2,426 employees who did not participate in INTERxVENT. When comparing the 1999 to the 2000 data, the average 6-month healthcare claims per employee increased by 10.3% ($1,072.91 versus $1,183.54) for the non-INTERxVENT participants and decreased by 14.3% ($997.65 versus $855.18) for the INTERxVENT participants. These findings have important ramifications for United States employers in terms of the curtailment of rapidly escalating healthcare expenditures.

2002 - ACSM Annual Meeting

CLINICAL EFFECTIVENESS OF A COMMUNITY-BASED CARDIOVASCULAR RISK REDUCTION PROGRAM IN PARTICIPANTS WITH AND WITHOUT ARTHRITIS

L.I. Levinrad, R.D. Salmon, C.D. English, G. C. Faircloth, B.S. Mitchell, W.E. Saxon, K.S. Reid, B.A. Franklin, FACSM, and N.F. Gordon, FACSM. INTERxVENT Coordinating Center, Savannah, GA

In the United States, arthritis is the leading cause of disability. By the year 2020, an estimated 60 million Americans will be affected by arthritis. Individuals with arthritis may engage in lower levels of physical activity and be at heightened risk for atherosclerotic cardiovascular disease (CVD). This study is the first, to our knowledge, to compare the clinical effectiveness of a community-based lifestyle management and CVD risk reduction program in participants with and without arthritis. Lifestyle management interventions included exercise training, correct nutrition, weight management, stress management, and smoking cessation. Participants were referred to their personal physicians for consideration of medication changes in accordance with national clinical guidelines. Subjects (n=1,830) were evaluated at baseline and after approximately 1 year of participation in the program. Participants with self-reported arthritis (n=357) were older (55.2 years versus 46.8 years) and more likely to have CVD and/or diabetes (31 percent versus 15.5 percent) as compared to participants without arthritis (n=1,473). For participants with abnormal baseline CVD risk factors (based on national clinical guidelines), clinically relevant improvements were observed for multiple variables in both groups as follows ($p \leq 0.05$): systolic/diastolic BP (arthritis, -16/-13 mmHg; no arthritis, -17/-10 mmHg); total cholesterol (arthritis, -35 mg/dl; no arthritis, -28 mg/dl); LDL cholesterol (arthritis, -23 mg/dl; no arthritis, -14 mg/dl); HDL cholesterol (arthritis, 3 mg/dl; no arthritis, 6 mg/dl); triglycerides (arthritis, -48 mg/dl; no arthritis, -60 mg/dl); fasting glucose (arthritis, -43 mg/dl; no arthritis, -21 mg/dl), and weight (arthritis, -4.4 lbs; no arthritis, -3.3 lbs). With the exception of LDL cholesterol (greater reduction in participants with arthritis) and HDL cholesterol (greater increase in participants without arthritis), no statistically significant differences were observed for participants with arthritis as compared to participants without arthritis. These data demonstrate the similar clinical effectiveness of a community-based lifestyle management and CVD risk reduction program in participants with and without arthritis.

2002 - ACSM Annual Meeting

CLINICAL EFFECTIVENESS AND REPRODUCIBILITY OF A CORPORATE LIFESTYLE MANAGEMENT AND CARDIOVASCULAR DISEASE RISK REDUCTION PROGRAM

K. Arabatzis, R.D. Salmon, S. Pickel,L.C. Adams, I.S. Kallish, B.S. Mitchell, C.D. English, B.A. Franklin, FACSM, N.F. Gordon, FACSM.

INTERxVENT Coordinating Center, Savannah, GA.

Rapidly escalating healthcare costs are causing employers to focus unprecedented attention on cost-effective interventions aimed at chronic disease prevention. In this study, we evaluated the clinical effectiveness and reproducibility of a comprehensive lifestyle management and cardiovascular disease (CVD) risk reduction program administered to employees at companies in three different U.S. cities (designated A, B, and C). Employees (n=1,274) were evaluated at baseline and after approximately 1 year. The program was administered in each city by non-physician healthcare professionals guided by a computerized participant management system. Lifestyle management interventions were based on several behavior change models, primarily, social learning theory, the stages of change model, and single concept learning theory. Participants were referred to their personal physicians for consideration of medication changes in accordance with national clinical guidelines. For participants with abnormal baseline CVD risk factors (as determined using national clinical guidelines), clinically relevant improvements were observed for multiple variables as follows ($p \leq 0.05$ unless otherwise indicated): systolic/diastolic blood pressure, City A = -17/-10 mmHg, City B = -15/-11 mmHg, City C = -18/-13 mmHg; total cholesterol, City A = -25 mg/dl, City B = -35 mg/dl, City C = -26 mg/dl; LDL cholesterol, City A = -13 mg/dl, City B = -23 mg/dl, City C = -11 mg/dl; HDL cholesterol, City A = 5 mg/dl, City B = 5 mg/dl, City C = 4 mg/dl (p=NS); triglycerides, City A = -61 mg/dl, City B = -24 mg/dl (p=NS), City C = -57 mg/dl; weight, City A = -3 lbs, City B = -8 lbs, City C = -6 lbs; and fasting glucose, City A = -17 mg/dl, City B = -31 mg/dl (p=NS), City C = -36 mg/dl. These data demonstrate that a comprehensive lifestyle management and CVD risk reduction program, administered by non-physician healthcare professionals guided by a computerized participant management system, can elicit clinically relevant and reproducible improvements in the risk factor status of employees with abnormal baseline values.

2002 - ACSM Annual Meeting

CLINICAL EFFECTIVENESS OF A COMPREHENSIVE CARDIOVASCULAR RISK REDUCTION PROGRAM: ON-SITE VERSUS TELEPHONE/INTERNET DELIVERY

C.E. Watson, R.D. Salmon, K. Arabatzis, C.D. English, B.S. Mitchell, G.C. Faircloth, L.I. Levinrad, W.E. Saxon, K.S. Reid, B.A. Franklin, FACSM, N.F. Gordon, FACSM. INTERxVENT Coordinating Center, Savannah, GA

Geographic accessibility and convenience are important predictors of participation in and compliance with behavior modification programs. In this study, we compared the clinical effectiveness of a comprehensive lifestyle management and cardiovascular disease (CVD) risk reduction program when administered by non-physician health care professionals on-site to employees at a company (on-site delivery; n=50) versus from a call center using the telephone and the Internet (remote delivery; n=50). Lifestyle management interventions were based on several behavior change models, primarily, social learning theory, the stages of change model, and single concept learning theory. Participants were referred to their personal physicians for consideration of medication changes in accordance with national clinical guidelines. Participants were evaluated at baseline and after approximately 12 weeks of program participation. For participants with abnormal baseline CVD risk factors (based on national clinical guidelines), improvements were observed for multiple variables in both groups of participants as follows (*$p \leq 0.05$): systolic/diastolic blood pressure (on-site, -16*/-10* mmHg; remote, -13*/-10* mmHg); total cholesterol (on-site, -51* mg/dl; remote, -53* mg/dl); LDL cholesterol (on-site, -36* mg/dl; remote, -66* mg/dl); HDL cholesterol (on-site, 4 mg/dl; remote, 3 mg/dl); triglycerides (on-site, -73* mg/dl; remote, -114* mg/dl); fasting glucose (on-site, -33* mg/dl; remote, -40 mg/dl), and weight (on-site, -7.9* lbs; remote, -14.2* lbs). With the exception of LDL cholesterol and weight (which decreased to a greater degree with remote as compared with on-site delivery), no other statistically significant differences were observed for on-site as compared with remote delivery. These data demonstrate the similar clinical effectiveness of a comprehensive lifestyle management and CVD risk reduction program when administered remotely from a call center using the telephone and the Internet as compared with on-site delivery. These data have important implications for increasing convenience and accessibility to clinically effective CVD risk reduction interventions.

2002 - ACSM Annual Meeting

CLINICAL EFFECTIVENESS OF A PHASE 2 CARDIAC REHABILITATION PROGRAM IN PARTICIPANTS WITH AND WITHOUT ARTHRITIS

S.S. Haapaniemi, B.A. Franklin, FACSM, L.S. Sperling, D.T. Badenhop, FACSM, R.D.Salmon, C.D. English, N.F. Gordon, FACSM. William Beaumont Hospital, Royal Oak, MI and INTERxVENT Coordinating Center, Savannah, GA

Arthritis is one of the most common chronic conditions and the leading cause of disability in the United States. Accordingly, it may serve to negatively influence exercise trainability and associated clinical outcomes. In this multicenter study, we investigated the prevalence of arthritis in patients entering phase 2 exercise-based cardiac rehabilitation programs, and the clinical effectiveness of these programs in improving abnormal risk factor values in patients with and without self-reported arthritis. Of 1,217 patients who enrolled in the phase 2 cardiac rehabilitation program at 11 centers in the United States, 493 (40.5 percent) noted that they had experienced arthritis as a co-morbid condition and 329 (27.0 percent) indicated ongoing residual sequelae. On exit from the phase 2 cardiac rehabilitation program (mean duration = 72 days), improvements in multiple cardiovascular disease risk factors were observed for participants with and without arthritis who had abnormal baseline risk factor values (based on national clinical guidelines), as follows (*$p<0.05$): systolic/diastolic blood pressure (arthritis, -19*/-21* mmHg; no arthritis, -20*/-15* mmHg); total cholesterol (arthritis, -40* mg/dl; no arthritis, -41* mg/dl); LDL cholesterol (arthritis, -56* mg/dl; no arthritis, -39* mg/dl); HDL cholesterol (arthritis, 2 mg/dl; no arthritis, 4 mg/dl); triglycerides (arthritis, -92* mg/dl; no arthritis, -61 mg/dl); fasting glucose (arthritis, -42* mg/dl; no arthritis, -60* mg/dl), and weight (arthritis, -2.9* lbs; no arthritis, -2.9* lbs). With the exception of diastolic blood pressure (which decreased to a greater degree in patients with arthritis), no statistically significant differences were observed for participants with arthritis as compared to participants without arthritis. These data demonstrate: 1. a high prevalence of self-reported arthritis among participants entering phase 2 cardiac rehabilitation programs; and 2. a similar clinical effectiveness of phase 2 cardiac rehabilitation in terms of risk factor modification in participants with and without arthritis.

2002 – AACVPR Annual Meeting

CLINICAL EFFECTIVENESS OF A COMMUNITY-BASED CARDIOVASCULAR RISK REDUCTION PROGRAM IN PARTICIPANTS WITH VERSUS WITHOUT PREDIABETES

Tom Savona, MA; Richard Salmon, DDS; Carla English, MHS; Laurence Sperling, MD; Susan Pickel, BSN,MHM; Richard Leighton, MD; Barry Franklin, PhD; Neil Gordon, MD
Heart Advocates and INTER$_x$VENT Coordinating Center
Newburgh, NY and Savannah, GA

Prediabetes, known previously as impaired glucose tolerance or impaired fasting glucose, is associated with a heightened risk for atherosclerotic cardiovascular disease (CVD). This study is the first, to our knowledge, to compare the clinical effectiveness of a community-based comprehensive lifestyle management and CVD risk reduction program in participants with (Group A, n=175) and without (Group B, n=2,872) prediabetes. Subjects were evaluated at baseline and after approximately 12 weeks of program participation. Lifestyle interventions included exercise, correct nutrition, weight management, stress management, and smoking cessation. Participants were referred to their personal physicians for consideration of medication changes in accordance with national guidelines. Fasting blood glucose decreased by 7 mg/dl ($p \leq 0.05$) in Group A and remained essentially unaltered in Group B ($p \leq 0.05$ for Group A versus Group B). For participants with abnormal baseline CVD risk factors (based on national guidelines), clinically relevant improvements were observed for multiple variables in both groups, as follows ($p \leq 0.05$): total cholesterol (Group A, -26 mg/dl; Group B, -31 mg/dl); LDL cholesterol (Group A, -21 mg/dl; Group B, -18 mg/dl); HDL cholesterol (Group A, 2 mg/dl; Group B, 3 mg/dl); triglycerides (Group A, -43 mg/dl; Group B, -39 mg/dl); systolic/diastolic BP (Group A, -17/-11 mmHg; Group B, -17/-10 mmHg) and weight (Group A, -4.9 lbs; Group B, -2.8 lbs). With the exception of weight (greater decrease in Group A) and HDL cholesterol (greater increase in Group B), no statistically significant differences were observed for Group A compared with Group B. In participants without coronary heart disease, the calculated Framingham 10-year coronary heart disease risk score decreased ($p \leq 0.05$) by 19.4% in Group A and by 23.4% in Group B. These data demonstrate the similar clinical effectiveness of a lifestyle management and cardiovascular risk reduction program in participants with and without prediabetes.

2002 – AACVPR Annual Meeting

CLINICAL EFFECTIVENESS OF A COMMUNITY-BASED CARDIOVASCULAR RISK REDUCTION PROGRAM IN PARTICIPANTS WITH VERSUS WITHOUT DIABETES

Susan Pickel, BSN, MHM; Sheldon Warman, MD; Brenda Mitchell, PhD; Ivan Levinrad, RPT; Richard Leighton, MD; Carla English, MHS; Richard Salmon, DDS; Barry Franklin, PhD; Neil Gordon, MD
North Broward Hospital District and INTER$_x$VENT Coordinating Center, Fort Lauderdale, FL and Savannah GA

Diabetes is a major contributor to cardiovascular disease (CVD) morbidity and mortality. Previous studies have documented the clinical effectiveness of the INTER$_x$VENT Lifestyle Management and Cardiovascular Risk Reduction Program (INTER$_x$VENT) in healthy persons and persons with CVD. In this study, we compared the effect of approximately 1 year of participation in INTER$_x$VENT on multiple CVD risk factors in 2,316 consecutive participants with (n=258) and without (n=2,058) diabetes. Lifestyle management interventions included exercise training, correct nutrition, weight management, stress management, and smoking cessation. Participants were referred to their personal physicians for consideration of medication changes in accordance with national clinical guidelines. Fasting blood glucose decreased by 15 mg/dl ($p \leq 0.05$) in participants with diabetes and remained essentially unaltered in participants without diabetes ($p \leq 0.05$ for participants with versus without diabetes). For participants with abnormal baseline values for other CVD risk factors, improvements ($p \leq 0.05$) were observed for participants with and without diabetes, as follows: total cholesterol (diabetes, -33 mg/dl; no diabetes, -29 mg/dl); LDL cholesterol (diabetes, -11 mg/dl; no diabetes, -17 mg/dl); HDL cholesterol (diabetes, 5 mg/dl; no diabetes, 4 mg/dl); triglycerides (diabetes, -35 mg/dl; no diabetes, -35 mg/dl); systolic/diastolic BP (diabetes, -14/-11 mmHg; no diabetes, -18/-10 mmHg) and weight (diabetes, -3.0 lbs; no diabetes, -2.5 lbs). With the exception of systolic BP (which decreased to a greater degree in participants without versus with diabetes, $p \leq 0.05$), no other statistically significant differences were observed for participants with diabetes compared to participants without diabetes. In participants without coronary heart disease, the calculated Framingham 10-year coronary heart disease risk score decreased by 15.3% ($p \leq 0.05$) in participants with diabetes and by 23.7% ($p \leq 0.05$) in participants without diabetes (p=NS for participants with versus without diabetes). These data serve to document the similar clinical effectiveness of INTER$_x$VENT in persons with and without diabetes.

2002 – AACVPR Annual Meeting

EFFECT OF EDUCATIONAL STATUS ON CLINICAL OUTCOMES IN PARTICIPANTS IN A CONTEMPORARY PHASE 2 CARDIAC REHABILITATION PROGRAM

Michele Doughty, MD; Laurence Sperling, MD; Kathy Lee Bishop Lindsay, MS, PT; Richard Salmon, DDS; Brenda Mitchell, PhD; Barry Franklin, PhD; Neil Gordon, MD.
Emory University and INTER$_x$VENT Coordinating Center, Atlanta, GA

Patient education, counseling, and behavioral interventions are important elements of cardiac rehabilitation. INTER$_x$VENT^{CR} is designed to help facilitate these elements during phase 2 cardiac rehabilitation and includes the use of written and audio materials together with brief one-on-one counseling. In this multicenter study, we investigated the clinical effectiveness of phase 2 cardiac rehabilitation programs that utilize INTER$_x$VENT^{CR} in participants with (Group A, n=539) and without (Group B, n=264) 1 or more years of college education. Cardiovascular disease (CVD) risk factors were evaluated at baseline and after an average of approximately 90 days of participation in the phase 2 cardiac rehabilitation program at 12 centers in the United States. On exit from the phase 2 cardiac rehabilitation program, clinically relevant improvements ($p \leq 0.05$, unless otherwise indicated) in multiple CVD risk factors were observed for participants in both groups who had

abnormal baseline risk factor values (based on national clinical guidelines), as follows: total cholesterol (Group A, -40 mg/dl; Group B, -42 mg/dl); LDL cholesterol (Group A, -25 mg/dl; Group B, -32 mg/dl); HDL cholesterol (Group A, 4 mg/dl; Group B, 4 mg/dl); triglycerides (Group A, -85 mg/dl; Group B, -16 mg/dl, p=NS); fasting glucose (Group A, -52 mg/dl, p=NS; Group B, -32 mg/dl); systolic/diastolic BP (Group A, -23/-20 mmHg; Group B, -17/-16 mmHg) and weight (Group A, -2 lbs; Group B, -2 lbs). With the exception of serum triglycerides and systolic BP (which decreased to a greater degree in Group A versus Group B, $p \leq 0.05$), no other statistically significant differences were observed for Group A as compared with Group B. These data demonstrate that patients with and patients without 1 or more years of previous college education derive clinically relevant improvements in multiple CVD risk factors during participation in a phase 2 cardiac rehabilitation program that utilizes INTERxVENTCR.

2002 – AACVPR Annual Meeting

CLINICAL EFFECTIVENESS OF A COMMUNITY-BASED CARDIOVASCULAR RISK REDUCTION PROGRAM IN PARTICIPANTS WITH VERSUS WITHOUT THE METABOLIC SYNDROME

Laurence Sperling, MD; Scott Kallish, MA; John Thiel, MA; Richard Leighton, MD; Ivan Levinrad, RPT; Richard Salmon, DDS; Barry Franklin, PhD, Neil Gordon, MD
Emory Heart Center and INTERxVENT Coordinating Center, Atlanta, GA

The metabolic syndrome, a constellation of lipid and nonlipid risk factors linked to insulin resistance, is now recognized as a target of cardiovascular disease (CVD) risk reduction therapy. This study is the first, to our knowledge, to compare the clinical effectiveness of a community-based comprehensive lifestyle management and CVD risk reduction program in participants with (Group A, n=515) and without (Group B, n=1,291) the metabolic syndrome. Subjects were evaluated at baseline and after approximately 1 year of participation in the program. Lifestyle interventions included exercise, correct nutrition, weight management, stress management, and smoking cessation. Participants were referred to their personal physicians for consideration of medication changes in accordance with national guidelines. For participants with abnormal baseline CVD risk factors (based on national guidelines), clinically relevant improvements were observed for multiple variables in both groups, as follows ($p \leq 0.05$, unless otherwise indicated): total cholesterol (Group A, -24 mg/dl; Group B, -30 mg/dl); LDL cholesterol (Group A, -15 mg/dl; Group B, -17 mg/dl); HDL cholesterol (Group A, 4 mg/dl; Group B, 4 mg/dl); triglycerides (Group A, -38 mg/dl; Group B, -29 mg/dl); fasting glucose (Group A, -10 mg/dl; Group B, -9 mg/dl, p=NS); systolic/diastolic BP (Group A, -16/-10 mmHg; Group B, -19/-12 mmHg) and weight (Group A, -4.7 lbs; Group B, -1.2 lbs). With the exception of weight (greater decrease in Group A) and blood pressure (greater decrease in Group B), no other statistically significant ($p \leq 0.05$) differences were observed for Group A compared with Group B. In participants without coronary heart disease, the calculated Framingham 10-year coronary heart disease risk score decreased ($p \leq 0.05$) by 22.3% in Group A and by 22.5% in Group B. These data demonstrate the similar clinical effectiveness of a comprehensive lifestyle management and cardiovascular risk reduction program in participants with and without the metabolic syndrome.

2002 – AACVPR Annual Meeting

CLINICAL EFFECTIVENESS OF A COMMUNITY-BASED CARDIOVASCULAR RISK REDUCTION PROGRAM IN AFRICAN AMERICANS VERSUS CAUCASIANS

Carlye Barat, MS; Carla English, MHS; Susan Pickel, BSN, MHM; Sheldon Warman, MD; Richard Salmon, DDS; Linda Hall, PhD; Barry Franklin, PhD; Neil Gordon, MD
North Broward Hospital District and INTERxVENT Coordinating Center, Fort Lauderdale, FL and Savannah, GA

Since the mid-1980s, coronary heart disease (CHD) mortality rates have declined more slowly in African Americans than in Caucasians in the United States. In this study, we compared the clinical effectiveness of a community-based lifestyle management and cardiovascular risk reduction program (INTERxVENT) in African American (n=701) and Caucasian (n=1,461) participants. Subjects were evaluated at baseline and after approximately 1 year of participation in the INTERxVENT program. Lifestyle management interventions included exercise training, correct nutrition, weight management, stress management, and smoking cessation. Participants were referred to their personal physicians for consideration of medication changes in accordance with national clinical guidelines. For participants with abnormal baseline CVD risk factors (based on national clinical guidelines), clinically relevant improvements ($p \leq 0.05$) were observed for multiple variables in African Americans and Caucasians, as follows: total cholesterol (African Americans, -20 mg/dl; Caucasians, -32 mg/dl); LDL cholesterol (African Americans, -11 mg/dl; Caucasians, -19 mg/dl); HDL cholesterol (African Americans, 6 mg/dl; Caucasians, 4 mg/dl); triglycerides (African Americans, -52 mg/dl; Caucasians, -31 mg/dl); fasting glucose (African Americans, -32 mg/dl; Caucasians, -26 mg/dl); systolic/diastolic BP (African Americans, -17/-10 mmHg; Caucasians, -17/-11 mmHg) and weight (African Americans, -1.6 lbs; Caucasians, -5.1 lbs). Total cholesterol, LDL cholesterol, and weight decreased to a greater degree ($p \leq 0.05$) in Caucasians as compared with African Americans. Moreover, in participants without CHD, the calculated Framingham 10-year CHD risk score decreased to a greater degree ($p \leq 0.05$) in Caucasians (22.9% decrease, $p \leq 0.05$) as compared with African Americans (14.2% decrease, $p \leq 0.05$). These data indicate that while African Americans and Caucasians both benefit substantially from INTERxVENT, the magnitude of benefit may be greater for Caucasian participants.

2002 – AACVPR Annual Meeting

CLINICAL EFFECTIVENESS OF A PHASE 2 CARDIAC REHABILITATION PROGRAM IN PATIENTS WITH VERSUS WITHOUT DIABETES

Susan Haapaniemi, MS; Barry Franklin, PhD; Dalynn Badenhop, PhD; Laurence Sperling, MD; Richard Salmon, DDS; Neil Gordon, MD
William Beaumont Hospital and INTERxVENT Coordinating Center, Royal Oak, MI and Savannah GA

Diabetes is one of the most common co-morbid chronic conditions in cardiac rehabilitation program participants. However, scarce data are

available on the clinical effectiveness of a contemporary phase 2 cardiac rehabilitation program in participants with diabetes compared to participants without diabetes. In this multicenter study, we compared the effect of a phase 2 cardiac rehabilitation program on multiple cardiovascular disease (CVD) risk factors in patients with (n=241) and without (n=575) diabetes. Risk factors were evaluated at baseline and after an average of approximately 90 days of participation in a phase 2 cardiac rehabilitation program at 12 centers in the United States. Fasting blood glucose decreased by 34 mg/dl ($p \leq 0.05$) in participants with diabetes and remained essentially unaltered in participants without diabetes ($p \leq 0.05$ for participants with versus without diabetes). On exit from the phase 2 cardiac rehabilitation program, improvements in multiple other CVD risk factors were observed for participants with and without diabetes who had abnormal baseline risk factor values (based on national clinical guidelines), as follows ($p \leq 0.05$ unless otherwise indicated): total cholesterol (diabetes, -47 mg/dl; no diabetes, -40 mg/dl); LDL cholesterol (diabetes, -32 mg/dl; no diabetes, -29 mg/dl); HDL cholesterol (diabetes, 3 mg/dl; no diabetes, 5 mg/dl); triglycerides (diabetes, -61 mg/dl; no diabetes, -33 mg/dl, p=NS); systolic/diastolic BP (diabetes, -19/-16 mmHg; no diabetes, -21/-18 mmHg) and weight (diabetes, -1.7 lbs; no diabetes, -2.1 lbs). No statistically significant differences were observed when comparing the changes in participants with and without diabetes. These data indicate that patients with diabetes derive similar benefits in terms of CVD risk factor modification from participation in a contemporary phase 2 cardiac rehabilitation program as compared to patients without diabetes.

2002 – AACVPR Annual Meeting

CLINICAL EFFECTIVENESS OF A PHASE 2 CARDIAC REHABILITATION PROGRAM IN PATIENTS WITH VERSUS WITHOUT A SELF-REPORTED HISTORY OF DEPRESSION

Barry Franklin, PhD; Susan Haapaniemi, MS; Richard Salmon, DDS; Brenda Mitchell, PhD; Neil Gordon, MD
William Beaumont Hospital and INTERxVENT Coordinating Center
Royal Oak, MI and Savannah, GA

Recent studies suggest that depressed patients with cardiovascular disease (CVD) are less likely to take prescribed medications and adhere to recommended behavior and lifestyle changes intended to reduce the risk of recurrent cardiac events. In this multicenter study, we compared the effect of a contemporary phase 2 cardiac rehabilitation program on multiple CVD risk factors in patients with (n=165) and without (n=760) self-reported current or previous problems with depression. Risk factors were evaluated at baseline and after an average of approximately 90 days of participation in a phase 2 cardiac rehabilitation program at 12 centers in the United States. Of the patients with a self-reported history of depression, 73 (44%) indicated that they were experiencing problems with depression at baseline. On exit from the phase 2 cardiac rehabilitation program, improvements ($p \leq 0.05$) in multiple CVD risk factors were observed for participants with and without a self-reported history of depression who had abnormal baseline risk factor values (based on national clinical guidelines), as follows: total cholesterol (depression, -35 mg/dl; no depression, -45 mg/dl); LDL cholesterol (depression, -27 mg/dl; no depression, -33 mg/dl); HDL cholesterol (depression, 3 mg/dl; no depression, 6 mg/dl); triglycerides (depression, -62 mg/dl; no depression, -36 mg/dl); fasting glucose (depression, -33 mg/dl; no depression, -33 mg/dl); systolic/diastolic BP (depression, -17/-15 mmHg; no depression, -21/-18 mmHg) and weight (depression, -2.5 lbs; no depression, -1.9 lbs). No statistically significant differences were observed when comparing the changes in participants with and without a self-reported history of depression. Although additional research is needed to fully clarify the influence of depression on clinical outcomes, these data suggest that participants with a self-reported history of depression and abnormal CVD risk factors derive similar improvements in CVD risk factors during participation in a contemporary phase 2 cardiac rehabilitation program as compared with participants without a self-reported history of depression.

2002 – AACVPR Annual Meeting

EFFECT OF PERCEIVED HEALTH STATUS ON CLINICAL OUTCOMES IN PARTICIPANTS IN A CONTEMPORARY PHASE 2 CARDIAC REHABILITATION PROGRAM

Jana Webb, BS; Linda Hall, PhD; Richard Salmon, DDS; Carla English, MHS; Barry Franklin, PhD; Neil Gordon, MD
Forrest General Hospital and INTERxVENT Coordinating Center
Hattiesburg, MS and Savannah, GA

The effect of perceived health status on cardiac rehabilitation clinical outcomes has yet to be fully elucidated. To clarify the situation further, in this multicenter study we compared the effect of a contemporary phase 2 cardiac rehabilitation program on multiple CVD risk factors in patients who rated their health as fair or poor on program entry (Group A; n=251) and those who rated their health as good, very good, or excellent (Group B; n=549) at program entry. Risk factors were evaluated at baseline and after an average of approximately 90 days of participation in a phase 2 cardiac rehabilitation program at 12 centers in the United States. On exit from the phase 2 cardiac rehabilitation program, improvements in multiple CVD risk factors were observed for participants in both groups who had abnormal baseline risk factor values (based on national clinical guidelines), as follows ($p \leq 0.05$ unless otherwise indicated): total cholesterol (Group A, -47 mg/dl; Group B, -39 mg/dl); LDL cholesterol (Group A, -26 mg/dl; Group B, -31 mg/dl); HDL cholesterol (Group A, 4 mg/dl; Group B, 4 mg/dl); triglycerides (Group A, -63 mg/dl; Group B, -27 mg/dl, p=NS); fasting glucose (Group A, -45 mg/dl; Group B, -28 mg/dl); systolic/diastolic BP (Group A, -24/-19 mmHg; Group B, -18/-16 mmHg) and weight (Group A, -2.4 lbs; Group B, -1.8 lbs). With the exception of systolic BP (which decreased to a greater degree in Group A versus Group B, $p \leq 0.05$), no other statistically significant differences were observed for Group A as compared with Group B. These data indicate that patients who rate their health as fair or poor on entry into a phase 2 cardiac rehabilitation program derive similar improvements in multiple CVD risk factors as compared with patients with a more favorable perceived health status.

2002 – AACVPR Annual

A COMPREHENSIVE CARDIOVASCULAR DISEASE RISK REDUCTION PROGRAM THAT INCLUDES A LOW FAT/HIGH COMPLEX CARBOHYDRATE DIET IS BENEFICIAL IN INDIVIDUALS WITH HYPERTRIGLYCERIDEMIA

Meeting

Neil Gordon, MD; Richard Salmon, DDS; Carla English, MHS; William Saxon, ASRT; Richard Leighton, MD; William Dafoe, MD; Barry Franklin, PhD; St. Joseph's/Candler Health System, Savannah, GA and INTER$_x$VENT Coordinating Center, Savannah, GA

The clinical effectiveness of a low fat/high complex carbohydrate diet in individuals with hypertriglyceridemia is controversial. In this study, we investigated the clinical effectiveness of a comprehensive cardiovascular disease (CVD) risk reduction program that includes a low fat (approximately 20% of daily calories)/high complex carbohydrate (approximately 50-60% of daily calories) diet in 2,424 individuals with (n=429) and without (n=1,995) hypertriglyceridemia (that is, baseline fasting serum triglycerides > 199 mg/dl). Testing was conducted at baseline and after approximately 12 weeks of intervention. Fasting serum triglycerides decreased by 66 mg/dl ($p \leq 0.05$) in individuals with baseline hypertriglyceridemia (baseline value = 291 mg/dl) and increased by 3 mg/dl (p= NS) in individuals without baseline hypertriglyceridemia (baseline value = 118 mg/dl). For individuals with abnormal baseline values for other CVD risk factors, significant ($p \leq 0.05$) improvements were observed in both groups as follows: total cholesterol (hypertriglyceridemia, -45 mg/dl; no hypertriglyceridemia, -28 mg/dl), LDL cholesterol (hypertriglyceridemia, -28 mg/dl; no hypertriglyceridemia, -19 mg/dl), HDL cholesterol (hypertriglyceridemia, 3 mg/dl; no hypertriglyceridemia, 3 mg/dl), fasting glucose (hypertriglyceridemia, -42 mg/dl; no hypertriglyceridemia, -22 mg/dl), systolic/diastolic blood pressure (hypertriglyceridemia, -15/-10 mmHg; no hypertriglyceridemia, -16/-10 mmHg), and weight (hypertriglyceridemia, -5 lbs; no hypertriglyceridemia, -4 lbs). These data demonstrate that when a low fat/high complex carbohydrate diet is administered as part of a comprehensive CVD risk reduction program, individuals with and without baseline hypertriglyceridemia derive substantial improvements in multiple risk factors.

2002 – AACVPR Annual Meeting

EFFECT OF A PHASE 2 CARDIAC REHABILITATION PROGRAM ON SERUM LIPIDS AND LIPOPROTEINS IN PATIENTS WITH VERSUS WITHOUT KNOWN PERIPHERAL ARTERIAL DISEASE

Tim Maynard, MSS; Laurence Sperling, MD; Barry Franklin, PhD; Linda Hall, PhD; Richard Salmon, DDS; Neil Gordon, MD
Providence Hospital and INTER$_x$VENT Coordinating Center, Mobile AL and Savannah, GA

The cornerstone of treatment for peripheral arterial disease (PAD) is intensive cardiovascular disease (CVD) risk factor modification. In this multicenter study, we compared the effect of a contemporary phase 2 cardiac rehabilitation program on fasting serum lipids and lipoproteins in patients with (n=45) and without (n=326) a documented history of PAD. Serum lipids and lipoproteins were evaluated at baseline and after an average of approximately 90 days of participation in a contemporary phase 2 cardiac rehabilitation program at 12 centers in the United States. On exit from the phase 2 cardiac rehabilitation program, clinically relevant improvements in fasting serum lipids and lipoproteins were observed for participants with and without PAD who had abnormal baseline risk factor values (based on national clinical guidelines), as follows ($p \leq 0.05$): total cholesterol (PAD, -24 mg/dl; No PAD, -44 mg/dl); LDL cholesterol (PAD, -16 mg/dl; No PAD, -32 mg/dl); HDL cholesterol (PAD, 7 mg/dl; No PAD, 5 mg/dl); and triglycerides (PAD, -44 mg/dl; No PAD, -43 mg/dl). Reductions in total cholesterol and LDL cholesterol were greater ($p \leq 0.05$) in participants without PAD as compared to participants with PAD. Although additional research is warranted, these observations suggest that while patients with and without PAD substantially improve their lipid profiles during participation in a phase 2 cardiac rehabilitation program, the magnitude of improvement may be greater for participants without PAD.

2001 – Journal of Stroke & Cerebro Vascular Disease

CARDIOVASCULAR DISEASE (CVD) RISK FACTOR STATUS OF AFRICAN AMERICAN VERSUS CAUCASIAN PATIENTS REFERRED TO A STROKE SECONDARY PREVENTION PROGRAM

F. Lafranchise, W. Widener, B. Franklin, R. Salmon, C. English, R. Leighton, and N. Gordon (Savannah, GA and Royal Oak, MI).

Background: Suboptimal CVD risk factor management contributes to the more than 700,000 strokes that occur annually in the U.S. Recently, we have demonstrated the clinical effectiveness of a physician supervised, nurse case managed stroke secondary prevention program. In this study, we compared the CVD risk factor status of African American versus Caucasian patients referred by physicians to a stroke secondary prevention program. **Methods**: Multiple CVD risk factors were evaluated in 307 consecutive African American (n=77) and Caucasian (n=230) patients who previously suffered a stroke or TIA or had carotid artery disease. **Results**: Although African Americans were younger than Caucasians (63 versus 68 years, $p < 0.05$), African Americans had higher ($p<0.05$) BMI (difference=3kg/m^2), fasting LDL cholesterol (difference=19 mg/dL), Lp(a) (difference=40 mg/dL), fasting glucose (difference=16 mg/dL), and homocysteine (difference=3.9 umol/L) levels, and were more likely to smoke cigarettes (15.6 versus 13.9%) and be sedentary (74 versus 68.3%). Statistically significant differences were not observed for HDL cholesterol, triglycerides, and blood pressure.
Conclusions: Multiple CVD risk factors are less well controlled in African American than in Caucasian patients referred to a stroke secondary prevention program.

2001, June – Stroke (journal)

NEED FOR AND CLINICAL EFFECTIVENESS OF A NEUROLOGIST SUPERVISED, NURSE CASE MANAGED STROKE RISK REDUCTION PROGRAM

E. Frank Lafranchise, Wallette G. Widener, Neurological Institute of Savannah, Savannah, GA; Barry A. Franklin, William Beaumont Hospital, Royal Oak, MI; Richard D. Salmon, Richard F. Leighton, Carla D. English, Neil F. Gordon, St. Joseph's/Candler Health System, Savannah, GA

Patients who have suffered a previous stroke or TIA and those with carotid artery disease are at an accentuated risk for a first or recurrent stroke. In this study, we: 1. investigated the prevalence of potentially modifiable cardiovascular disease (CVD) risk factors in 247 consecutive patients at a private practice neurology clinic who had previously suffered a stroke or TIA and/or had documented carotid artery

disease, and 2. evaluated the clinical effectiveness of 12 weeks (n=125) and 1 year (n=36) of participation by these patients in an neurologist supervised, nurse case managed stroke risk reduction program. At baseline, potentially modifiable CVD risk factors included physical inactivity (68% of patients), elevated systolic BP (54% of patients), elevated LDL cholesterol (46% of patients), obesity (36% of patients), elevated diastolic BP (32% of patients), and cigarette smoking (15% of patients). On completion of 12 weeks and 1 year of program participation, clinically relevant and statistically significant ($p \leq 0.05$) improvements were observed for these and other select CVD risk factors in patients with abnormal baseline values. These data demonstrate that potentially modifiable CVD risk factors are often suboptimally controlled in patients at high risk for stroke. They further document the clinical effectiveness of a neurologist supervised, nurse case managed stroke risk reduction program.

2001 – CDC Prevention Conference

IMPLEMENTATION OF AN INNOVATIVE COMMUNITY-BASED HEART DISEASE AND STROKE RISK REDUCTION PROGRAM (INTER$_x$VENT)

N. Gordon (presenter), R. Salmon, C. Faircloth, I. Levinrad, B. Mitchell, W. Saxon, K. Reid, and S. Salmon, INTER$_x$VENT^{USA}, Inc., Savannah, GA.

We have developed, tested, and successfully implemented an affordable, evidence-based, comprehensive cardiovascular disease (CVD) risk reduction program for use in primary and secondary prevention settings. The program, INTER$_x$VENT, can be administered in a standardized, but individualized, way to large numbers of people with or at risk for atherosclerotic CVD and stroke in a variety of medical and non-medical environments. Program delivery sites have been established in seven states in the U.S. and currently include: (a) hospitals; (b) physician practices; (c) cardiac rehabilitation programs; (d) shopping malls; and (e) health clubs. The program is also delivered from a call center using telephone, the Internet, and mail. Program staff are guided by a computerized participant management and tracking system. Lifestyle interventions are based on several behavior change models, primarily, social learning theory, the stages of change model, and single concept learning theory. At most sites, the program is administered entirely by non-physician health care professionals. Outcome data, including data from randomized clinical trials, have confirmed the cost-effectiveness and reproducibility of this approach. Practical experiences support the feasibility of increasing access to affordable CVD risk reduction services throughout a community via the widespread implementation of INTER$_x$VENT programs.

2001 – AACVPR Annual Meeting

NEED FOR CONTINUED CARDIOVASCULAR DISEASE (CVD) RISK REDUCTION INTERVENTION AFTER COMPLETION OF A CONTEMPORARY PHASE 2 CARDIAC REHABILITATION PROGRAM

Kim Bonzheim MS, Claire Watson MS, Barry Franklin PhD, Laurence Sperling MD, Dalynn Badenhop PhD, Andres Digenio MD PhD, Carla English MHS MHSA, Richard Salmon DDS MBA, Neil Gordon MD, INTERxVENT Coordinating Center, Savannah, GA

Cardiac rehabilitation involves the provision of comprehensive CVD risk reduction services. Recently, the American Heart Association (AHA) and American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) published recommendations on expected outcomes in each of the core components of cardiac rehabilitation programs. In this multicenter study, we investigated the percentage of patients not at the AHA/AACVPR goal level for select CVD risk factors: 1. on entry to and exit from a contemporary phase 2 cardiac rehabilitation program (average duration = 6-12 weeks) at five centers in the United States (number of patients = 275), and 2. on exit from and 9 months after exit from the program at one center (number of patients = 40). The percentage of patients *not* at goal on program entry and exit included: cigarette smoking, entry = 5.1%, exit = 4.4%; systolic blood pressure, entry = 42.5%, exit = 36.7%; diastolic blood pressure, entry = 16.7%, exit = 8.4%; LDL cholesterol, entry = 52.2%, exit = 33.6%; and body mass index, entry = 78.9%, exit = 77.1%. The percentage of patients not at goal was greater 9 months after program exit versus on program exit for all of these CVD risk factors. These data indicate that while CVD risk factor status improves substantially during participation in a phase 2 cardiac rehabilitation program, risk factors frequently are not at the goal level on program exit. Moreover, CVD risk factor status remains unchanged, or may worsen, over time when patients receive usual medical care after participation in a phase 2 cardiac rehabilitation program.

2001 – AACVPR Annual Meeting

CLINICAL EFFECTIVENESS AND REPRODUCIBILITY OF A CORPORATE CARDIOVASCULAR DISEASE (CVD) RISK REDUCTION PROGRAM

Richard Salmon DDS MBA, Kosta Arabatzis MS, Susan Pickel BSN MHM, Leah Adams PharmD, Scott Kallish MA, Ivan Levinrad RPT, Brenda Mitchell PhD, Barry Franklin PhD, Neil Gordon MD, INTERxVENT Coordinating Center, Savannah, GA

Rapidly escalating healthcare costs are causing companies to focus unprecedented attention on chronic disease prevention. In this study, we evaluated the clinical effectiveness and reproducibility of a comprehensive CVD risk reduction program (INTER$_x$VENT) administered to employees at companies in three different U.S. cities (designated A, B, and C). Employees (n=1,483) were evaluated at baseline and after approximately 12 weeks. The program was administered in each city by non-physician healthcare professionals guided by a computerized participant management system. For participants with abnormal baseline risk factors, clinically relevant improvements were observed for multiple variables as follows ($p \leq 0.05$ unless otherwise indicated): systolic/diastolic blood pressure, City A = -17/-10 mmHg, City B = -20/-12 mmHg, City C = -13/-13 mmHg; total cholesterol, City A = -30 mg/dl, City B = -44 mg/dl, City C = -34 mg/dl; LDL cholesterol, City A = -16 mg/dl, City B = -29 mg/dl, City C = -21 mg/dl; HDL cholesterol, City A = 5 mg/dl, City B = 4 mg/dl (p=NS); City C = 0.4 mg/dl (p=NS); triglycerides, City A = -73 mg/dl, City B = -30 mg/dl (p=NS), City C = -53 mg/dl; weight, City A = -3 lbs, City B = -9 lbs, City C = -5 lbs; and fasting glucose, City A = -32 mg/dl, City B = -35 mg/dl, City C = -36 mg/dl. These data demonstrate that a comprehensive CVD risk reduction program can elicit clinically relevant and reproducible improvements in the risk factor status of employees with abnormal baseline values.

2001 – AACVPR Annual Meeting

BENEFIT OF A WORKSITE-BASED CARDIOVASCULAR RISK REDUCTION PROGRAM ON EMPLOYEE HEALTHCARE CLAIMS

Chip Faircloth MBA MHA, Sheldon Warman MD, Susan Pickel BSN MHM, Richard Salmon DDS MBA, Brenda Mitchell PhD, Barry Franklin PhD, Neil Gordon MD, INTERxVENT Coordinating Center, Savannah, GA

It is estimated that cardiovascular diseases and stroke will cost the United States $298.2 billion in 2001. Clearly, there is an urgent need to reduce avoidable death, disability, and financial expenditure by increasing access to clinically effective cardiovascular risk reduction interventions. In this study, we investigated the effect of a worksite-based cardiovascular risk reduction program (INTERxVENT) on employee healthcare claims. INTERxVENT was implemented at the company under investigation in January 2000. Healthcare claims data of 3,062 employees who were employed by the company on February 1, 1999 and who were still employed by the company on July 31, 2000 were analyzed. Of these employees, 636 (21%) participated in INTERxVENT between February 1, 2000 and July 31, 2000. A comparison was made of the average healthcare claims per employee for February 1, 1999 through July 31, 1999 versus February 1, 2000 through July 31, 2000 for the 636 employees who participated and the 2,426 employees who did not participate in INTERxVENT. When comparing the 1999 to the 2000 data, the average 6-month healthcare claims per employee increased by 10.3% ($1,072.91 versus $1,183.54) for the non-INTERxVENT participants and decreased by 14.3% ($997.65 versus $855.18) for the INTERxVENT participants. These findings have important ramifications for United States companies in terms of the curtailment of rapidly escalating healthcare expenditures.

2001 – AACVPR Annual Meeting

CLINICAL EFFECTIVENESS OF A NEUROLOGIST SUPERVISED, NURSE CASE MANAGED STROKE RISK REDUCTION PROGRAM IN AFRICAN AMERICAN VERSUS CAUCASIAN PATIENTS

Wallette Widener MSN RN, Frank Lafranchise MD, Barry Franklin PhD, Richard Leighton MD, Carla English MHS MHSA, Richard Salmon DDS MBA, Neil Gordon MD, Neurological Institute of Savannah, Savannah, GA and INTERxVENT USA, Savannah, GA

Despite recent advances in cardiovascular medicine, suboptimal cardiovascular disease risk factor management continues to contribute to the more than 700,000 strokes that occur annually in the United States. In this study, we compared the clinical effectiveness of 12 weeks of participation in a neurologist supervised, nurse case managed stroke risk reduction program in African American (n=32) versus Caucasian (n=121) patients who had previously suffered a stroke or TIA and/or had documented carotid artery disease. For patients with abnormal baseline cardiovascular disease risk factors, improvements ($p \leq 0.05$ unless otherwise indicated) were observed in African American and Caucasian patients for multiple variables, including systolic blood pressure (African Americans, -12 mmHg; Caucasians, -12 mmHg), diastolic blood pressure (African Americans, -7 mmHg, p= NS; Caucasians, -6 mmHg), total cholesterol (African Americans, -54 mg/dl; Caucasians, -57 mg/dl), LDL cholesterol (African Americans, -28 mg/dl; Caucasians, -28 mg/dl), HDL cholesterol (African Americans, 8 mg/dl, p=NS; Caucasians, 4 mg/dl), triglycerides (African Americans, -67 mg/dl, p=NS; Caucasians, -54 mg/dl) and body weight (African Americans, -4.3 lbs; Caucasians, -5.0 lbs). No statistically significant differences were observed for African American versus Caucasian patients. These data document the similar clinical effectiveness of a neurologist supervised, nurse case managed stroke risk reduction program in African American versus Caucasian patients at high risk for a first or recurrent stroke.

2001 – AACVPR Annual Meeting

COMPARISON OF A 12-WEEK PHASE 2 CARDIAC REHABILITATION PROGRAM AND A PHYSICIAN SUPERVISED, NURSE CASE MANAGED CARDIOVASCULAR DISEASE (CVD) RISK REDUCTION PROGRAM

Neil Gordon MD, Carla English MHS MHSA, Richard Leighton MD, Melanie Willoughby RN, Barry Franklin PhD, Richard Salmon DDS MBA, St. Joseph's/Candler Health System, Savannah, GA and INTERxVENT USA, Savannah, GA

Previous studies have documented the clinical effectiveness of phase 2 cardiac rehabilitation programs and physician supervised, nurse case managed CVD risk reduction programs. This study is the first, to our knowledge, to compare these two approaches in a randomized clinical trial. Lower risk patients with coronary artery disease were randomly assigned after baseline testing to 12 weeks of participation in the cardiac rehabilitation program (Group A, n=52) or the physician supervised, nurse case managed program (Group B, n=54). For patients with abnormal baseline CVD risk factors, statistically significant ($p \leq 0.05$) improvements were observed in both groups for multiple variables, including systolic/diastolic blood pressure (Group A, -8.4/-7.6 mmHg; Group B, -6.9/-5.8 mmHg), LDL cholesterol (Group A, -21.5 mg/dl; Group B, -22.7 mg/dl), and body weight (Group A, -2.1 lbs; Group B, -2.6 lbs). No statistically significant differences between Groups A and B were observed for these variables. In contrast, measured maximal oxygen uptake increased to a greater degree ($p \leq 0.05$) in Group A (1.9 ml/kg/min, $p \leq 0.05$) versus Group B (0.8 ml/kg/min, $p \leq 0.05$) patients with a baseline value $\leq$ 24.5 ml/kg/min. These data indicate that 12 weeks of participation in a phase 2 cardiac rehabilitation program results in similar improvements in multiple CVD risk factors and greater increases in maximal oxygen uptake as compared with a physician supervised, nurse case managed CVD risk reduction program.

2001 – AACVPR Annual Meeting

A LOW FAT/HIGH COMPLEX CARBOHYDRATE DIET IS EQUALLY BENEFICIAL IN INDIVIDUALS WITH AND WITHOUT DIABETES WHEN ADMINISTERED AS PART OF A COMPREHENSIVE CARDIOVASCULAR DISEASE (CVD) RISK REDUCTION PROGRAM

Neil Gordon MD, Richard Salmon DDS MBA, Carla English MHS MHSA, Ivan Levinrad RPT, Richard Leighton MD, Barry Franklin PhD, St. Joseph's/Candler Health System, Savannah, GA and INTERxVENT USA, Savannah GA

The clinical effectiveness of a low fat/high complex carbohydrate diet in individuals with insulin resistance is controversial. In this study, we compared the clinical effectiveness of a low fat (approximately 20% of daily calories)/high complex carbohydrate (approximately 50-60% of

daily calories) diet administered as part of a comprehensive CVD risk reduction program in 2,050 individuals with (n=238) and without (n=1,812) diabetes. Testing was conducted at baseline and after approximately 12 weeks of intervention. Fasting blood glucose decreased by 26 mg/dl ($p \leq 0.05$) in diabetics with a baseline value $\geq$ 126 mg/dl. For individuals with abnormal baseline values for other CVD risk factors, significant ($p \leq 0.05$) improvements were observed in both groups as follows: total cholesterol (diabetes, -43 mg/dl; no diabetes, -36 mg/dl), LDL cholesterol (diabetes, -23 mg/dl; no diabetes, -21 mg/dl), HDL cholesterol (diabetes, 2 mg/dl; no diabetes, 4 mg/dl), triglycerides (diabetes, -76 mg/dl; no diabetes, -69 mg/dl), systolic/diastolic blood pressure (diabetes, -15/-12 mmHg; no diabetes, -16/-10 mmHg), and weight (diabetes, -5 lbs; no diabetes, -4 lbs). The calculated Framingham 10-year coronary heart disease risk score decreased by 16.7% and 15.1% in individuals with and without diabetes, respectively. No statistically significant differences were observed between the two groups. These data demonstrate that, when a low fat/high complex carbohydrate diet is administered as part of a comprehensive CVD risk reduction program, individuals with and without diabetes derive similar improvements in multiple risk factors.

2001 – AACVPR Annual Meeting

AN INNOVATIVE CONTINUING EDUCATION PROGRAM FOR NURSES THAT ADDRESSES PERSONAL IMPROVEMENT AND PROFESSIONAL DEVELOPMENT

Susan Pickel BSN MHM, Sheldon Warman MD, Brenda Mitchell PhD, Terry Ray RN MN, Neil Gordon MD, North Broward Hospital District, Fort Lauderdale, FL and INTERxVENT USA, Savannah, GA

The State of Florida Board of Nurses requires 24 contact hours of approved continuing education every two years. To meet this requirement and provide a health benefit for its nursing staff, the North Broward Hospital District (NBHD) offered an innovative continuing education program that was tied to an employee health benefit program. Beginning in February 2000, the NBHD implemented a comprehensive lifestyle management and cardiovascular risk reduction program as a benefit for all its employees. The evidence-based program, called INTERxVENT, included an initial assessment, short- and long-term goals for improvement, personal action plan to achieve personal goals, referrals to personal physicians if needed, and follow-up evaluations. Employees met for approximately 20 individualized sessions over a 12-month period. Sessions focused on specific educational topics that addressed cognitive and behavioral processes related to exercise, nutrition and weight management, stress management, smoking cessation, and prevention and health promotion. For nurses, participation in the INTERxVENT program could be justified as a continuing education activity. In addition to improving their personal health and lifestyle, nurses could learn principles of behavior change that would be useful when working with their patients. From the patient's perspective, there is an expectation for nurses to be healthy role models. Participation in a continuing education activity that was convenient (onsite, no travel time or expense) and free of charge was an added benefit for the nurses. Approximately 100 of the nurses participated in the INTERxVENT program during Year One. The program will continue to be available to nurses who have not participated previously. This innovative program that combines personal improvement and professional development could serve as a model for numerous other health care providers in Florida and in other states.

2001 – AACVPR Annual Meeting

EFFECTS OF PHASE 2 CARDIAC REHABILITATION PARTICIPATION ON PATIENTS WITH ABNORMAL BASELINE RISK FACTORS: IMPLICATIONS FOR EVALUATING PROGRAM EFFECTIVENESS

Barry Franklin, Kim Bonzheim, JoAnne Warren, Sue Haapaniemi, Nancy Byl, Leilani Ware, Staci Barnhart, and Neil Gordon. William Beaumont Hospital, Royal Oak, MI

Phase 2 cardiac rehabilitation programs are associated with improvements in exercise tolerance, coronary risk factors, and psychosocial well-being. Nevertheless, previous reports have generally evaluated the global effectiveness of these programs (i.e., on all subjects, collectively), which may serve to camouflage or attenuate the impact of these interventions on specific patient subsets. METHODS: In this study, we investigated the effectiveness of a contemporary cardiovascular risk reduction program (INTERxVENT), using a computerized database on 117 patients ($\underline{x}$ age = 66.5 yrs; 68% men; 96% Caucasian) who completed pre- and post Phase 2 evaluations. Exercise training involved three 45-60 minute sessions per week at 40/50 to 70% $\underline{V}O2$ max for 6-8 weeks. RESULTS: The effectiveness of the exercise training program was substantiated by significant ($p \leq 0.05$) reductions in heart rate (-8 beats/min), systolic blood pressure (-11 mmHg), and rating of perceived exertion (-2, 6-20 scale) at a standard submaximal workload. Initial and follow-up ratings of overall health were improved: excellent (2.6 to 4.3%); and, very good (20.7 to 35.7%). Average changes ($p \leq 0.05$ unless otherwise indicated) for all participants and those with abnormal baseline risk factors were: systolic blood pressure (-4 mmHg; -16 mmHg); diastolic blood pressure (-5 mmHg, -18 mmHg); total cholesterol (-19 mg/dL, -75 mg/dL); LDL-cholesterol (-17 mg/dL, -61 mg/dL); HDL-cholesterol (-1 mg/dL [NS], + 11 mg/dL); and, triglycerides (-5 mg/dL [NS], -82 mg/dL), respectively. CONCLUSION: The present findings suggest that a dose-response relationship characterizes the change in coronary risk factors subsequent to a Phase 2 cardiac rehabilitation program. Patients with the worst coronary risk factor profiles at baseline, demonstrated the greatest improvements.

2000, May – AHA Conference

CLINICAL EFFECTIVENESS OF THREE MODELS FOR COMPREHENSIVE CARDIOVASCULAR RISK REDUCTION IN LOWER RISK PATIENTS WITH CORONARY ARTERY DISEASE

Neil F. Gordon, Center for Heart Disease Prevention, St. Joseph's/Candler Health System, Savannah, GA

Current evidence provides a strong rationale for the long-term aggressive control of multiple coronary artery disease (CAD) risk factors as an essential strategy to reduce morbidity, mortality, and the ongoing cost of medical care in CAD patients. Despite the documented benefits of traditional cardiac rehabilitation programs, factors such as cost and accessibility currently contribute to relatively low participation rates. In this study, we are comparing the clinical effectiveness of two less-costly and potentially more accessible approaches to comprehensive

cardiovascular disease risk reduction with that of a traditional phase 2 cardiac rehabilitation program. Lower risk CAD patients were randomly assigned to one of three groups as follows: Group 1 = 12 weeks of participation in a traditional phase 2 cardiac rehabilitation program; Group 2 = one year of participation in a physician-supervised, nurse-case managed program; and Group 3 = one year of participation in a community-based program administered by non-physician health care professionals. Preliminary analyses have been performed using the data of 112 patients. These analyses show significant improvements in a variety of CAD risk factors and functional capacity, including systolic blood pressure, diastolic blood pressure, LDL cholesterol, weight and maximal oxygen uptake, in all three groups after approximately 12 weeks of program participation. No statistically significant differences among the three groups were observed for these variables. These preliminary data confirm the benefits of traditional cardiac rehabilitation programs in lower risk CAD patients. They further serve to demonstrate the feasibility and similar clinical effectiveness (relative to traditional cardiac rehabilitation) of two less-costly and potentially more accessible approaches to comprehensive cardiovascular disease risk reduction. These data have significant ramifications for cost-containment in cardiovascular medicine. Additional definitive analyses will be performed using the data of all patients on completion of one year of study participation.

2000, October – Circulation – Stroke

FEASIBILITY AND CLINICAL EFFECTIVENESS OF A NEUROLOGIST SUPERVISED, NURSE CASE MANAGED STROKE RISK REDUCTION PROGRAM

Neil F. Gordon, Carla D. English, Ash Contractor, Richard F. Leighton, Richard D. Salmon, St. Joseph's/Candler Health System, Savannah, GA.; E. Frank Lafranchise, Wallette G. Widener, Neurological Institute of Savannah, Savannah, GA; Barry A. Franklin, William Beaumont Hospital, Royal Oak, MI.

Despite the recognition of modifiable risk factors for a first or recurrent stroke, suboptimal CVD risk factor control continues to contribute to more than 700,000 strokes in the U.S. each year. In this study, we evaluated the clinical effectiveness of a neurologist supervised, nurse case managed stroke risk reduction program at a private practice neurology clinic in 98 consecutive patients who had previously suffered a stroke or TIA and/or had documented carotid artery disease. Using data from 32 of the patients who were matched on the basis of age and sex with 32 participants in a 12-week traditional phase 2 cardiac rehabilitation (CR) program, we also compared the clinical effectiveness of the stroke risk reduction program with that of a CR program. On completion of 12 weeks of participation in the stroke risk reduction program (n=98), significant ($p \leq 0.05$) improvements were observed for select CVD risk factors in patients with abnormal baseline values, including systolic BP (-8 mmHg), diastolic BP (-4 mmHg), LDL cholesterol (-17mg/dl), HDL cholesterol (5 mg/dl), triglycerides (-31mg/dl), and weight (-3.9 pounds). No significant differences were observed when comparing changes in CVD risk factors in the participants in the stroke risk reduction program (n=32) versus the CR program (n=32). These data are the first to document the feasibility and clinical effectiveness of a neurologist supervised, nurse case managed stroke risk reduction program in patients at high risk for a first or recurrent stroke.

Legend:

AACVPR	= American Association of Cardiovascular and Pulmonary Rehabilitation
ACSM	= American College of Sports Medicine
AHA	= American Heart Association
CDC	= Center for Disease Control and Prevention
NHLBI	= National Heart, Lung and Blood Institute

KEY SCIENTIFIC MANUSCRIPTS

1. Gordon NF, Scott CB, Levine BD. Comparison of single versus multiple lifestyle interventions: Are the antihypertensive effects of exercise training and diet-induced weight loss additive? *Am J Cardiol* 1997;79:763-767.

2. Gordon NF, Haskell WA. Comprehensive cardiovascular disease risk reduction in a cardiac rehabilitation setting. *Am J Cardiol* 1997;80(8B):69H-73H.

3. Gordon NF. Comprehensive cardiovascular disease risk reduction in the clinical setting. *Coronary Artery Disease* 1998; 9:731-735.

4. Gordon NF, Salmon RD, Mitchell BS, Faircloth GC, Levinrad LI, Salmon S, Saxon WE, Reid KS. Innovative approaches to comprehensive cardiovascular disease risk reduction in clinical and community-based settings. *Current Atherosclerosis Reports* 2001; 3:498-506.

5. Franklin BA, Bonzheim K, Warren J, Haapaniemi S, Byl N, Gordon N. Effects of a contemporary, exercise-based rehabilitation and cardiovascular risk reduction program on coronary patients with abnormal baseline risk factors. *CHEST* 2002; 122:338-343.

6. Gordon NF, English CD, Contractor AS, Salmon RD, Leighton RF, Franklin BA, Haskell WL. Effectiveness of 3 models for comprehensive cardiovascular disease risk reduction. *Am J Cardiol* 2002;89:1263-1268.