

# INTERVENT:

## RESEARCH PUBLISHED AND / OR PRESENTED AT NATIONAL / INTERNATIONAL SCIENTIFIC MEETINGS: 1997 - 2020

### LEGEND

AACVPR	= American Association of Cardiovascular and Pulmonary Rehabilitation
ACC	= American College of Cardiology
ACSM	= American College of Sports Medicine
AHA	= American Heart Association
CACR	= Canadian Association of Cardiac Rehabilitation
CDC	= Centers for Disease Control and Prevention
DMAA/CCA	= Disease Management Association of America/Care Continuum Alliance/Population Health Alliance
FIMS	= International Federation of Sports Medicine
NHLBI	= National Heart, Lung and Blood Institute
2 <sup>nd</sup> Int Conf	= Second International Conference on Women, Heart Disease and Stroke

### KEY SCIENTIFIC MANUSCRIPTS / BOOKS

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**ABSTRACTS**

**1998 - AACVPR Annual Meeting**

**INDEPENDENT AND COMBINED EFFECTS OF THE EXERCISE AND NUTRITION COMPONENTS OF A COMMUNITY-BASED PRIMARY PREVENTION PROGRAM (INTERVENT<sup>USA</sup>).**

Neil F. Gordon, L. Ivan Levinrad, Richard D. Salmon, Brenda S. Mitchell, and Lori A. Alexander. Center for Heart Disease Prevention, St. Joseph's/Candler Health System and INTERVENT<sup>USA</sup>, Inc., Savannah, GA.

1.

INTERVENT<sup>USA</sup> is a community-based, lifestyle management and cardiovascular disease (CVD) risk reduction program. We investigated the independent and combined effects of 12 weeks of intervention with the exercise and nutrition components of INTERVENT<sup>USA</sup> on select CVD risk factors. At two study sites, namely, Dallas, TX (TX; n=48) and Savannah, GA (GA; n=67), subjects were randomly assigned after baseline testing to 1 of 3 interventions for 12 weeks: exercise training only, dietary modification only, or exercise training plus dietary modification. Results were as follows (\*p<0.05; --- = variable not analyzed; BP=blood pressure; chol=cholesterol):

	<u>Exercise Only</u>		<u>Diet Only</u>		<u>Exercise + Diet</u>	
	TX	GA	TX	GA	TX	GA
Weight loss (lbs)	-2.2	-1.7	-13*	-12*	-16*	-14*
Reduction in systolic BP (mmHg)	-10*	-9*	-11*	-12*	-13*	-9*
Reduction in diastolic BP (mmHg)	-6*	-5*	-8*	-6*	-8*	-7*
Increase in VO <sub>2</sub> max (%)	11*	---	8*	---	17*	---
Reduction in dietary fat (%)	-10	---	-73*	---	-68*	---
Reduction in serum chol (mg/dl)	---	-13*	---	-24*	---	-23*

These data document the beneficial effect of the exercise and nutrition components of INTERVENT<sup>USA</sup> on select CVD risk factors. They further demonstrate that in contrast to weight loss, the effects of exercise training and dietary modification on blood pressure and serum total cholesterol are not additive.

**1999 - ACSM Annual Meeting**

**EFFECT OF SEQUENCE OF LIFESTYLE INTERVENTION ON SELECT CARDIOVASCULAR DISEASE (CVD) RISK FACTORS**

A. S. Contractor, L. A. Alexander, FACSM, E.A. Blaschko, L. I. Levinrad, B. S. Mitchell, R. D. Salmon, and N. F. Gordon, FACSM. Center for Heart Disease Prevention and INTERVENT USA, Savannah, GA. (Sponsor: N. F. Gordon, FACSM)

2.

Previous studies have compared the effects of exercise training (E), dietary modification (D), and the combination of both interventions (E + D) on CVD risk factors. In this study, we investigated the effect of the sequence of lifestyle intervention on weight, blood pressure, serum cholesterol and treadmill performance in 42 male and female volunteers (age=51 ± 11 years). After baseline testing, subjects were randomized to one of three intervention groups for the 48-week study period. Group 1 = E only during weeks 1 to 12, followed by E + D during weeks 13 to 48; Group 2 = D only during weeks 1 to 12, followed by E+D during weeks 13 to 48; and Group 3 = E+D during weeks 1 to 48. Testing was repeated after 12 and 48 weeks of intervention. At 12 weeks, subjects in Groups 2 and 3 experienced a greater weight loss (p<0.05) than those in Group 1. However, after 48 weeks of intervention statistically significant (p<0.05) improvements in all experimental variables were observed in all three study groups and differences between the three study groups were not statistically significant for any experimental variable. These data indicate that it may not always be necessary to implement multiple lifestyle interventions simultaneously since comparable long-term improvements in select CVD risk factors can be achieved if the interventions are implemented in sequence. The data further demonstrate that the precise sequence of lifestyle intervention does not significantly impact the long-term effect on select CVD risk factors.

**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, Walette G. Widener, Neurological Institute of Savannah, Savannah, GA; Barry A. Franklin, William Beaumont Hospital, Royal Oak, MI.

3.

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 ≤ 0.05) improvements were observed for select CVD risk factors in patients with abnormal baseline values, including

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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.

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

4.

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.

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**STAGE OF READINESS TO CHANGE MULTIPLE BEHAVIORS AT ENTRY TO A PHASE 2 CARDIAC REHABILITATION PROGRAMS**

N. Gordon, FACSM, B. Franklin, FACSM, L. Sperling, D. Badenhop, FACSM, A. Digenio, B. Mitchell, R. Salmon. INTERVENT<sup>CR</sup> Coordinating Center, Savannah, GA e-mail: [ngordon@interventusa.com](mailto:ngordon@interventusa.com)

5.

The definition of cardiac rehabilitation has been expanded to include the modification of multiple cardiovascular disease risk factors using comprehensive behavioral interventions. To help facilitate this, readiness for change theory has received wide acceptance and use by health care practitioners. However, no comprehensive data are currently available on the readiness of patients to make multiple lifestyle changes at entry into a Phase 2 cardiac rehabilitation program. In this multi-center study, we assessed readiness to change multiple lifestyle behaviors in 470 patients at entry into Phase 2 cardiac rehabilitation programs at five centers in the United States. For program participants not already in the action or maintenance stage of readiness to change and for whom the specific behavior change was relevant, the percentage of participants determined to be in the precontemplation, contemplation, and preparation stages are shown in the table.

Behavior	% of All Participants	Precontemplation (%)	Contemplation (%)	Preparation (%)
Exercise	99.4	1.1	16.5	82.4
Nutrition	97.2	2.6	84.7	12.7
Stress management	92.6	3.2	28.0	68.8
Smoking cessation	7.7	13.9	38.9	47.2

These data indicate that at program entry the majority of participants in phase 2 cardiac rehabilitation programs are in the contemplation or preparation stage of readiness for multiple lifestyle behaviors. These data may be relevant to cardiac rehabilitation programs when designing and developing behavior modification programs that incorporate readiness for change theory.

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ACSM  
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**RISK FACTOR STATUS ON ENTRY INTO CONTEMPORARY PHASE 2 CARDIAC REHABILITATION PROGRAMS**

D. Badenhop, FACSM, B. Franklin, FACSM, L. Sperling, A. Digenio, R. Salmon, N. Gordon, FACSM. INTERVENT<sup>CR</sup> Coordinating Center, Savannah, GA e-mail: [Dbadenhop@mco.edu](mailto:Dbadenhop@mco.edu)

6.

According to the American Heart Association (AHA), cardiac rehabilitation programs should provide comprehensive cardiovascular disease (CVD) risk reduction services in addition to exercise training. In recognition of this, the AHA and American Association for Cardiovascular and Pulmonary Rehabilitation (AACVPR) recently published recommendations on expected outcomes in each of the core components of

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cardiac rehabilitation programs. However, no comprehensive data are currently available on the percentage of participants already at versus not at the AHA/AACVPR goal level on entry into a phase 2 cardiac rehabilitation program. In this multi-center study, we documented the percentage of participants at goal versus not at goal for select CVD risk factors at entry into a Phase 2 cardiac rehabilitation program. Subjects were 470 patients enrolled in Phase 2 cardiac rehabilitation programs at five centers in the United States. Results are shown in the table.

<u>Risk Factor</u>	<u>Goal</u>	<u>% At Goal</u>	<u>% Not At Goal</u>
Cigarette smoking	Smoking cessation	92.3	7.7
Systolic BP	< 130 mm Hg	51.6	48.4
Diastolic BP	< 85 mmHg	80.1	19.9
LDL cholesterol	< 100 mg/dl	49.3	50.7
HDL cholesterol	> 35 mg/dl	76.9	23.1
Triglycerides	< 200 mg/dl	79.1	20.9
BMI	< 25 kg/m <sup>2</sup>	22.4	77.6
All of above	All of above	4.7	95.3

These data indicate that multiple CVD risk factors are often inadequately controlled in patients entering into contemporary phase 2 cardiac rehabilitation programs. These data may be relevant to cardiac rehabilitation programs when prioritizing, designing, and developing comprehensive CVD risk reduction interventions in accordance with the recent recommendations of the AHA/AACVPR.

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

7.

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 (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% V̇O<sub>2</sub> max for 6-8 weeks. RESULTS: The effectiveness of the exercise training program was substantiated by significant (p ≤ 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 ≤ 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.

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

8.

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

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providers in Florida and in other states.

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#### **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

9.

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.

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#### **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

10.

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.

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

Walette 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

11.

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.

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

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RESEARCH PUBLISHED AND / OR PRESENTED AT NATIONAL / INTERNATIONAL SCIENTIFIC MEETINGS: 1997 - 2020

AACVPR Annual Meeting	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
12.	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 (INTER <sub>x</sub> VENT) on employee healthcare claims. INTER <sub>x</sub> VENT 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 INTER <sub>x</sub> VENT 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 INTER <sub>x</sub> VENT. 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-INTER <sub>x</sub> VENT participants and decreased by 14.3% (\$997.65 versus \$855.18) for the INTER <sub>x</sub> VENT participants. These findings have important ramifications for United States companies in terms of the curtailment of rapidly escalating healthcare expenditures.
2001 – AACVPR Annual Meeting	<b>USING DISCREPANCY ANALYSIS TO ASSESS AND IMPROVE PARTICIPANT SATISFACTION IN A COMPREHENSIVE CARDIOVASCULAR RISK REDUCTION PROGRAM</b>
13.	<p>Brenda Mitchell PhD, Sheldon Warman MD, Susan Pickel BSN MHM, Terry Ray RN MN, Richard Salmon DDS MBA, Neil Gordon MD, North Broward Hospital District, Fort Lauderdale, FL, and INTERxVENT USA, Savannah, GA</p> <p>Health care is a service business. Discrepancy analysis is a useful methodology for evaluating participant (or customer) satisfaction and setting priorities for improvement because it gives weight to the most important needs. Most participant surveys address only “satisfaction.” Knowing how “important” an aspect of service is to the participant provides additional information upon which to base decisions and actions for improving participant service and expending limited resources. In this study, we used discrepancy analysis to assess participants’ satisfaction with a comprehensive lifestyle management and cardiovascular risk reduction program (INTER<sub>x</sub>VENT) offered at a worksite. Our participant satisfaction survey was developed to measure five domains critical to service businesses: reliability, assurance, empathy, responsiveness, and tangibles. Three statements addressed each domain. Participants were asked to respond on two variables, “importance” and “satisfaction,” for each statement using five-point Likert-type scales. INTER<sub>x</sub>VENT participants (n=204) completed the survey as part of their 12-week follow-up evaluation. The results were extremely positive. The ranges of means were 4.74 to 4.29 and 4.75 to 4.40 on “importance” and “satisfaction,” respectively. The highest Adjusted Needs Index (ANI) was .50. ANIs can range from 20 to -20. Negative ANIs mean “satisfaction” exceeds “importance.” Negative ANIs were computed for 10 of the 15 statements. “Assurance” (confidentiality, safety, competence of the health professional) was the domain of participant service that was most important to INTER<sub>x</sub>VENT participants. “Tangibles” (facility, educational materials, health professional as a role model) was the domain of participant service with which participants were most satisfied. This study documents the high level of satisfaction with a worksite-based cardiovascular risk reduction program. The data further demonstrate how discrepancy analysis can be used to help identify priorities for program improvement.</p>
2001 – AACVPR Annual Meeting	<b>NEED FOR CONTINUED CARDIOVASCULAR DISEASE (CVD) RISK REDUCTION INTERVENTION AFTER COMPLETION OF A CONTEMPORARY PHASE 2 CARDIAC REHABILITATION PROGRAM</b>
14.	<p>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</p> <p>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 <i>not</i> 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.</p>
2001 – CDC Prevention	<b>IMPLEMENTATION OF AN INNOVATIVE COMMUNITY-BASED HEART DISEASE AND STROKE RISK REDUCTION PROGRAM (INTER<sub>x</sub>VENT)</b>

## INTERVENT:

### RESEARCH PUBLISHED AND / OR PRESENTED AT NATIONAL / INTERNATIONAL SCIENTIFIC MEETINGS: 1997 - 2020

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| <p>Conference</p> <p>15.</p>  | <p>N. Gordon (presenter), R. Salmon, C. Faircloth, I. Levinrad, B. Mitchell, W. Saxon, K. Reid, and S. Salmon, INTER<sub>x</sub>VENT<sup>USA</sup>, Inc., Savannah, GA.</p> <p>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<sub>x</sub>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<sub>x</sub>VENT programs.</p>   |
| <p>2001, June –<br/>Stroke<br/>(journal)</p> <p>16.</p>                                       | <p><b>NEED FOR AND CLINICAL EFFECTIVENESS OF A NEUROLOGIST SUPERVISED, NURSE CASE MANAGED STROKE RISK REDUCTION PROGRAM</b></p> <p>E. Frank Lafranchise, Walette 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</p> <p>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 a 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 (<math>p \leq 0.05</math>) 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.</p> |
| <p>2001 –<br/>Journal of<br/>Stroke &amp;<br/>Cerebro<br/>Vascular<br/>Disease</p> <p>17.</p> | <p><b>CARDIOVASCULAR DISEASE (CVD) RISK FACTOR STATUS OF AFRICAN AMERICAN VERSUS CAUCASIAN PATIENTS REFERRED TO A STROKE SECONDARY PREVENTION PROGRAM</b></p> <p>F. Lafranchise, W. Widener, B. Franklin, R. Salmon, C. English, R. Leighton, and N. Gordon (Savannah, GA and Royal Oak, MI).</p> <p><b>Background:</b> 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. <b>Methods:</b> 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. <b>Results:</b> Although African Americans were younger than Caucasians (63 versus 68 years, <math>p &lt; 0.05</math>), African Americans had higher (<math>p &lt; 0.05</math>) BMI (difference=3kg/m<sup>2</sup>), 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. <b>Conclusions:</b> Multiple CVD risk factors are less well controlled in African American than in Caucasian patients referred to a stroke secondary prevention program.</p>  |



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**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<sub>x</sub>VENT Coordinating Center, Mobile AL and Savannah, GA

18.

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.

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

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<sub>x</sub>VENT Coordinating Center, Savannah, GA

19.

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.

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**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 INTER<sub>x</sub>VENT Coordinating Center  
Hattiesburg, MS and Savannah, GA

20.

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.

**INTERVENT:****RESEARCH PUBLISHED AND / OR PRESENTED AT NATIONAL / INTERNATIONAL SCIENTIFIC MEETINGS: 1997 - 2020**2002 –  
AACVPR  
Annual  
Meeting**CLINICAL EFFECTIVENESS OF A PHASE 2 CARDIAC REHABILITATION PROGRAM IN PATIENTS WITH VERSUS WITHOUT A SELF-REPORTED HISTORY OF DEPRESSION**

21.

Barry Franklin, PhD; Susan Haapaniemi, MS; Richard Salmon, DDS; Brenda Mitchell, PhD; Neil Gordon, MD  
William Beaumont Hospital and INTER<sub>x</sub>VENT 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  
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Meeting**CLINICAL EFFECTIVENESS OF A PHASE 2 CARDIAC REHABILITATION PROGRAM IN PATIENTS WITH VERSUS WITHOUT DIABETES**

22.

Susan Haapaniemi, MS; Barry Franklin, PhD; Dalynn Badenhop, PhD; Laurence Sperling, MD; Richard Salmon, DDS; Neil Gordon, MD  
William Beaumont Hospital and INTER<sub>x</sub>VENT 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.

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

23.

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 INTER<sub>x</sub>VENT 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 (INTER<sub>x</sub>VENT) 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 INTER<sub>x</sub>VENT 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 INTER<sub>x</sub>VENT, the magnitude of benefit may be greater for Caucasian participants.

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#### 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

24. Emory Heart Center and INTER<sub>x</sub>VENT 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.

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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.

25. Emory University and INTER<sub>x</sub>VENT Coordinating Center, Atlanta, GA

Patient education, counseling, and behavioral interventions are important elements of cardiac rehabilitation. INTER<sub>x</sub>VENT<sup>CR</sup> 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<sub>x</sub>VENT<sup>CR</sup> 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 INTER<sub>x</sub>VENT<sup>CR</sup>.

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

INTERVENT:

RESEARCH PUBLISHED AND / OR PRESENTED AT NATIONAL / INTERNATIONAL SCIENTIFIC MEETINGS: 1997 - 2020

Meeting	<p>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                  26. North Broward Hospital District and INTER<sub>x</sub>VENT Coordinating Center, Fort Lauderdale, FL and Savannah GA</p>
	<p>Diabetes is a major contributor to cardiovascular disease (CVD) morbidity and mortality. Previous studies have documented the clinical effectiveness of the INTER<sub>x</sub>VENT Lifestyle Management and Cardiovascular Risk Reduction Program (INTER<sub>x</sub>VENT) in healthy persons and persons with CVD. In this study, we compared the effect of approximately 1 year of participation in INTER<sub>x</sub>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 ≤0.05) in participants with diabetes and remained essentially unaltered in participants without diabetes (p ≤0.05 for participants with versus without diabetes). For participants with abnormal baseline values for other CVD risk factors, improvements (p ≤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 ≤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 ≤0.05) in participants with diabetes and by 23.7% (p ≤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<sub>x</sub>VENT in persons with and without diabetes.</p>
2002 – AACVPR Annual Meeting	<p><b>CLINICAL EFFECTIVENESS OF A COMMUNITY-BASED CARDIOVASCULAR RISK REDUCTION PROGRAM IN PARTICIPANTS WITH VERSUS WITHOUT PREDIABETES</b></p>
27.	<p>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<sub>x</sub>VENT Coordinating Center                  Newburgh, NY and Savannah, GA</p>
	<p>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 ≤0.05) in Group A and remained essentially unaltered in Group B (p ≤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 ≤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 ≤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.</p>
2002 – ACSM Annual Meeting	<p><b>CLINICAL EFFECTIVENESS OF A PHASE 2 CARDIAC REHABILITATION PROGRAM IN PARTICIPANTS WITH AND WITHOUT ARTHRITIS</b></p>
28.	<p>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 INTER<sub>x</sub>VENT Coordinating Center, Savannah, GA</p>
	<p>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&lt;0.05): systolic/diastolic blood pressure</p>

(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 –  
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

29.

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 < 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 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.

30.

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 ≤ 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 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

INTERVENT:

RESEARCH PUBLISHED AND / OR PRESENTED AT NATIONAL / INTERNATIONAL SCIENTIFIC MEETINGS: 1997 - 2020

31. 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 –  
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

32.

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 –  
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

33.

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.

2003 –  
CACR  
Annual  
Meeting

**OUTCOMES OF A CASE-MANAGED HOME PROGRAM IN A CARDIAC REHABILITATION SETTING**

Sandra Black, Andrea Stellmach, Louise Morrin, University of Ottawa Heart Institute, Ottawa, ON

34.

**Background:** A limited number of eligible patients attend formal on-site cardiac rehabilitation (CR) programs due to geographic and system barriers. **Methods:** A case managed home program (CMHP) consisting of a personalized education program for risk reduction supported by a computerized patient management system was established to provide CR services to patients previously not referred. The 1-year, 24-

contact, program was delivered in person or via telephone. Cardiac risk factor assessment was performed at intake, 3 mo and 12 mo time points. Paired t-tests were used to compare means between baseline and 3 mo and between baseline and 12 mo. CMHP outcomes were also compared to a cohort of on-site CR patients, being followed at the same time points. **Results:** 235 patients (mean age 59.7 yrs; 81.3% male) enrolled in the CMHP from Sept 2001 to Jan 2003. This represents a 26% increase in CR participants for this period. 63% traveled 45 minutes or more to the centre. 72% of patient contacts were done by phone. Significant improvements in most cardiac risk factors were found in those patients who were not at target at baseline (see table). Peak functional capacity increased by 13% at 3 mo and 22% at 12 mo. Significant, and clinically relevant, improvements in quality of life (SF-36) and Hospital Anxiety and Depression Scale (HADS) scores were evident at 3 months and retained at program completion. Patient satisfaction with CMHP was rated very high as assessed by a client-centred satisfaction survey. Comparison with the on-site cohort showed equitable changes in risk factors, functional capacity, psychosocial variables and client satisfaction.

Variable	3-mo	p-value	12-mo	p-value
T-Chol mmol/L	-2.0	0.001	-3.2	0.129
LDL-C mmol/L	-0.9	0.001	-0.4	0.012
HDL-C mmol/L	0.1	0.001	0.2	0.001
Tg mmol/L	-0.4	0.014	-0.7	0.007
BMI	-0.4	0.001	-0.6	0.026

**Conclusions:** Patients in CMHP achieved significant improvement in cardiac risk factors, quality of life, anxiety and depression scores and similar outcomes as those attending the on-site program. This program format allowed increased access to CR services for those who were unable to attend the on-site program and suggests a viable alternative in the presence of geographic and scheduling barriers.

2003 –  
AACVPR  
Annual  
Meeting

35.

**GETTING TO GOAL: IS LIFESTYLE INTERVENTION WORTH THE EFFORT IN PATIENTS WITH HYPERTENSION?**

Allan Lewis, MS; Barry Franklin, PhD; Linda Hall, PhD; Laurence Sperling, MD; Chip Faircloth, MBA; Ivan Levinrad, RPT; Richard Salmon, DDS; Neil Gordon, MD; Memorial Health Care System (Chattanooga); St. Joseph's/Candler Health System and INTERVENT Coordinating Center

**Rationale:** Hypertension is a leading cause of potentially avoidable morbidity, mortality and healthcare-related expenditures. National clinical guidelines emphasize lifestyle management as a standard of care in hypertensive patients. Because of the widespread availability of powerful antihypertensive medications, however, the value of lifestyle intervention per se in contemporary medical practice is often questioned by clinicians and health insurers. **Objectives:** In this study, we investigated the effect of a comprehensive lifestyle management program on systolic and diastolic blood pressure (BP) control in adults with a systolic BP  $\geq 140$  mmHg and/or diastolic BP  $\geq 90$  mmHg at program entry and who took no antihypertensive medications at baseline and follow-up. **Methodology:** Lifestyle management included exercise training, nutrition counseling, smoking cessation, and stress management. Lifestyle interventions were based on several behavior change models, including: social learning theory; the stages of change model; and, single concept learning theory. Participants were evaluated at baseline and after approximately 3 months of program participation. **Results:** In patients with a systolic BP  $\geq 140$  mmHg at baseline (n=335), systolic BP decreased from 149 +/- 10 mmHg to 133 +/- 15 mmHg ( $p \leq 0.05$ ). Of these patients, 212 (or 63%) were at the goal value (i.e.,  $< 130$  mmHg for patients with diabetes and/or atherosclerosis;  $< 140$  mmHg for other patients) at follow up. In patients with a diastolic BP  $\geq 90$  mmHg at baseline (n=346), diastolic BP decreased from 95 +/- 5 mmHg to 85 +/- 9 mmHg ( $p \leq 0.05$ ). Of these patients, 224 (or 65%) were at the goal value (i.e.,  $< 80$  mmHg for patients with diabetes;  $< 85$  mmHg for patients with atherosclerosis;  $< 90$  mmHg for other patients) at follow up. **Conclusion:** These data serve to emphasize the effectiveness of lifestyle management in the contemporary treatment of patients with hypertension and have associated cost-containment implications.

2003 –  
AACVPR  
Annual  
Meeting

36.

**GETTING TO GOAL: IS LIFESTYLE INTERVENTION WORTH THE EFFORT IN PATIENTS WITH AN ELEVATED FASTING BLOOD GLUCOSE LEVEL?**

Jana Webb, BS; Linda Hall, PhD; Barry Franklin, PhD; Laurence Sperling, MD; Allan Lewis, MS; Chip Faircloth, MBA; Ivan Levinrad, RPT; Richard Salmon, DDS; Neil Gordon, MD; Forrest General Hospital; St. Joseph's/Candler Health System and INTERVENT Coordinating Center

**Rationale:** Elevated fasting blood glucose constitutes a major risk factor for premature morbidity and mortality, and is a leading condition associated with potentially avoidable healthcare-related expenditures. National clinical guidelines promulgate therapeutic lifestyle changes as a standard of care in the management of patients with fasting blood glucose levels  $\geq 110$  mg/dl. Because of the widespread availability of powerful hypoglycemic medications, however, the value of lifestyle intervention per se in contemporary medical practice is often questioned by clinicians and health insurers. **Objectives:** In this study, we investigated the clinical effectiveness of a comprehensive lifestyle management program in 249 adults with a fasting blood glucose level  $\geq 110$  mg/dl at program entry and who took no hypoglycemic medications at baseline and follow-up. **Methodology:** Lifestyle management interventions included exercise training and nutrition counseling, and were based on several behavior change models, including: social learning theory; the stages of change model; and, single

concept learning theory. Participants were evaluated at baseline and after approximately 3 months of program participation. **Results:** The lifestyle management program resulted in significant ( $p \leq 0.05$ ) mean reductions in body weight (-5.9 lbs), body mass index (-0.9 kg/m<sup>2</sup>) and waist circumference (-0.8 inches). Fasting blood glucose decreased from 144 +/- 43 mg/dl at baseline to 129 +/- 43 mg/dl at follow up ( $p \leq 0.05$ ). At follow up, 101 (or 41%) of participants had achieved a fasting blood glucose goal of <110 mg/dl. Moreover, whereas 141 participants had a fasting blood glucose >125 mg/dl at baseline, only 92 participants had a value >125 mg/dl at follow up (representing a 35% reduction in the prevalence of values compatible with a diagnosis of diabetes mellitus). **Conclusion:** These data highlight the effectiveness of therapeutic lifestyle changes in the contemporary management of patients with elevated fasting blood glucose levels and have relevant cost-containment implications.

2003 –  
AACVPR  
Annual  
Meeting

37.

#### EFFECT OF EDUCATIONAL STATUS ON CLINICAL OUTCOMES IN PARTICIPANTS IN A COMPREHENSIVE LIFESTYLE MANAGEMENT AND CARDIOVASCULAR RISK REDUCTION PROGRAM

Susan Haapaniemi, MS; Barry Franklin, PhD; Brenda Mitchell, PhD; Ivan Levinrad, RPT; William Saxon, ASRT; Kevin Reid, MA; Chip Faircloth, MBA; Richard Salmon, DDS; Neil Gordon, MD; William Beaumont Hospital; St. Joseph's/Candler Health System and INTERVENT Coordinating Center

**Rationale:** Patient education, counseling, and behavioral interventions are core components of a comprehensive cardiovascular disease (CVD) risk reduction program. The INTERVENT Lifestyle Management and Cardiovascular Risk Reduction Program (INTERVENT) is designed to help facilitate these components in persons with or without known CVD and includes the use of written materials, audio materials, and brief one-on-one counseling. **Objectives:** In this study, we investigated the clinical effectiveness of 1 year of participation in INTERVENT in participants with (Group A; n=1968; age=49 +/-11 years) and without (Group B; n=640; age=51 +/-11 years) 1 or more years of college education. **Methodology:** Lifestyle interventions included exercise training, nutrition counseling, weight management, stress management, and smoking cessation guidance. Participants were referred to their personal physicians for consideration of medication changes in accordance with national clinical guidelines. **Results:** For participants with abnormal baseline CVD risk factors (based on national guidelines), clinically relevant improvements ( $p \leq 0.05$ ) were observed for multiple variables, as follows: systolic/diastolic blood pressure (Group A, -18/-11 mmHg; Group B, -14/-9 mmHg); LDL cholesterol (Group A, -16 mg/dl; Group B, -14 mg/dl); HDL cholesterol (Group A, 5 mg/dl; Group B, 4 mg/dl); triglycerides (Group A, -32 mg/dl; Group B, -37 mg/dl); fasting glucose (Group A, -30 mg/dl; Group B, -26 mg/dl) and weight (Group A, -4.1 lbs; Group B, -3.4 lbs). With the exception of blood pressure (greater decrease in Group A), no statistically significant differences were observed for Group A versus Group B. In participants with a calculated Framingham 10-year coronary heart disease risk score  $\geq 20\%$  at baseline, the risk score decreased significantly ( $p \leq 0.05$ ) in Group A (-28.1%) and Group B (-22.6%). **Conclusion:** These data demonstrate that participants with and participants without 1 or more years of college education derive clinically relevant improvements in multiple CVD risk factors during 1 year of participation in INTERVENT.

2003 –  
AACVPR  
Annual  
Meeting

38.

#### CLINICAL EFFECTIVENESS OF A COMPREHENSIVE CARDIOVASCULAR RISK REDUCTION PROGRAM IN PRE-MENOPAUSAL VERSUS POST-MENOPAUSAL WOMEN

Linda Hall, PhD; Barry Franklin, PhD; Daniel Biggerstaff, III, MD; Susan Pickel, BSN, MHM; Laurence Sperling, MD; John Thiel, MA; Scott Kallish, MA; Brenda Mitchell, PhD; Richard Salmon, DDS; Neil Gordon, MD; Forrest General Hospital; St. Joseph's/Candler Health System and INTERVENT Coordinating Center

**Rationale:** The proportion of women living past the age of menopause has tripled during the past century. Cardiovascular disease (CVD) remains the leading cause of death in post-menopausal American women, irrespective of whether or not they take hormone replacement therapy (HRT). **Objectives:** In this study, we compared the effectiveness of a comprehensive lifestyle management and CVD risk reduction program in pre-menopausal women (Group A; n=922; age=42 +/-7 years), post-menopausal women not on HRT (Group B; n=317; age=56 +/-9 years), and post-menopausal women on HRT (Group C; n=319; age=56 +/-7 years). **Methodology:** Subjects were evaluated at baseline and after 1 year. Lifestyle interventions included exercise, nutrition counseling, stress management, and smoking cessation. Participants were referred to their personal physicians for consideration of medication changes in accordance with national guidelines. **Results:** For participants with abnormal baseline CVD risk factors (based on national guidelines), clinically relevant improvements ( $p \leq 0.05$ ) were observed for multiple variables, including: systolic/diastolic blood pressure (Group A, -21/-10 mmHg; Group B, -20/-13 mmHg; Group C, -17/-12 mmHg); LDL cholesterol (Group A, -12 mg/dl; Group B, -17 mg/dl; Group C, -15 mg/dl); HDL cholesterol (Group A, 4 mg/dl; Group B, 7 mg/dl; Group C, 4 mg/dl); triglycerides (Group A, -29 mg/dl; Group B, -40 mg/dl; Group C, -36 mg/dl); and weight (Group A, -2.8 lbs; Group B, -5.8 lbs; Group C, -4.1 lbs). With the exception of diastolic blood pressure and weight (greater decreases in Group B versus Group A), no significant differences were observed among the 3 groups. In participants with a calculated Framingham 10-year coronary heart disease risk score  $\geq 10\%$  at baseline, the score decreased significantly ( $p \leq 0.05$ ) in Groups A (-23.1%), B (-26.2%), and C (-16.9%). **Conclusion:** These data demonstrate the similar effectiveness of a comprehensive CVD risk reduction program in pre-menopausal and post-menopausal women, irrespective of HRT status.

2003 –  
AACVPR  
Annual

#### CLINICAL EFFECTIVENESS OF A COMPREHENSIVE CARDIOVASCULAR RISK REDUCTION PROGRAM IN FEMALE VERSUS MALE PARTICIPANTS



INTERVENT:

RESEARCH PUBLISHED AND / OR PRESENTED AT NATIONAL / INTERNATIONAL SCIENTIFIC MEETINGS: 1997 - 2020

<p>Meeting 39.</p>	<p>Barry Franklin, PhD; Linda Hall, PhD; Daniel Biggerstaff, III, MD; Laurence Sperling, MD; Susan Pickel, BSN, MHM; Scott Kallish, MA; John Thiel, MA; Brenda Mitchell, PhD; Richard Salmon, DDS; Neil Gordon, MD; William Beaumont Hospital; St. Joseph's/Candler Health System and INTERVENT Coordinating Center</p> <p><b>Rationale:</b> Atherosclerotic cardiovascular disease (CVD) is a significant cause of morbidity and the single leading cause of death among American women. Although atherosclerosis is largely preventable, there are alarming trends in the prevalence and management of CVD risk factors in women. <b>Objectives:</b> In this study, we compared the clinical effectiveness of a comprehensive lifestyle management and CVD risk reduction program in female (n=1764; age=49 +/- 11 years) and male (n=831; age=52 +/-11 years) participants. <b>Methodology:</b> Subjects were evaluated at baseline and after approximately 1 year of program participation. Lifestyle interventions included exercise training, nutrition counseling, 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. <b>Results:</b> For participants with abnormal baseline CVD risk factors (based on national clinical guidelines), clinically relevant improvements (<math>p \leq 0.05</math>) were observed for multiple variables in female and male participants, as follows: systolic/diastolic blood pressure (females, -20/-11 mmHg; males, -13/-9 mmHg); total cholesterol (females, -26 mg/dl; males, -37 mg/dl); LDL cholesterol (females, -15 mg/dl; males, -19 mg/dl); HDL cholesterol (females, 5 mg/dl; males, 4 mg/dl); triglycerides (females, -35 mg/dl; males, -32 mg/dl); fasting glucose (females, -29 mg/dl; males, -27 mg/dl) and weight (females, -3.7 lbs; males, -4.7 lbs). With the exception of blood pressure (greater decrease in females) and total cholesterol (greater decrease in males), no statistically significant differences were observed for female versus male participants. In participants with a calculated Framingham 10-year coronary heart disease risk score <math>\geq 10\%</math> at baseline, the risk score decreased to a similar degree in female (-23.1%, <math>p \leq 0.05</math>) and male (-19.4%, <math>p \leq 0.05</math>) participants. <b>Conclusion:</b> These data demonstrate the similar clinical effectiveness of a comprehensive lifestyle management and CVD risk reduction program in female versus male participants and refute the notion of a gender difference in responsiveness.</p>
<p>2003 – AACVPR Annual Meeting 40.</p>	<p><b>EFFECT OF A TELEPHONE/INTERNET DELIVERED COMPREHENSIVE CARDIOVASCULAR RISK REDUCTION PROGRAM ON SELF-REPORTED HEALTH STATUS IN PARTICIPANTS FROM RURAL COMMUNITIES</b></p> <p>Richard Salmon, DDS; Margaret Ann Selman, MBA; Carla English, MHS; Allyson Rose, MS; Julie Blakely, BS; Kim Allen, RD; Robert Skiljan, MS; Barry Franklin, PhD; Neil Gordon, MD; INTERVENT Coordinating Center, South Georgia Access Network, and St. Joseph's/Candler Health System</p> <p><b>Rationale:</b> People living in rural communities have less access to preventive healthcare services than those in urban communities. <b>Objectives:</b> In this study, we investigated the effect on self-reported health status of a comprehensive lifestyle management and cardiovascular disease (CVD) risk reduction program when administered via the telephone and Internet to 98 adults (age=54 +/-13 years) from 5 rural counties in Georgia by nonphysician healthcare professionals. This cohort was compared with 556 adults (age=50 +/-11 years) from an urban county in Georgia who were participants in the same CVD risk reduction program delivered onsite at a freestanding facility. <b>Methodology:</b> Lifestyle management interventions were based on several behavior change models, including: 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. Self-reported health status was assessed at baseline and after approximately 3 months of program participation using the SF-36. <b>Results:</b> At baseline, SF-36 transformed scores were significantly higher (<math>p \leq 0.05</math>) for all 8 domains in the urban participants (U) versus the rural participants (R). At follow-up, mean improvements in SF-36 transformed scores were observed as follows (<math>*p \leq 0.05</math>): physical functioning (R,13*; U, 3*); role-physical (R,15*; U,1); bodily pain (R,8*; U,4*); general health (R,16*; U,7*); vitality (R,13*; U,4*); social functioning (R,14*; U,3*); role-emotional (R,7; U,0); and mental health (R,13*; U,4*). Improvements were greater (<math>p \leq 0.05</math>) in the rural versus urban participants. <b>Conclusion:</b> These data demonstrate the beneficial effect on multiple indices of self-reported functional status and well-being of a telephone/Internet delivered comprehensive CVD risk reduction program in participants from rural communities.</p>
<p>2003 – AACVPR Annual Meeting 41.</p>	<p><b>CLINICAL EFFECTIVENESS OF A TELEPHONE/INTERNET DELIVERED COMPREHENSIVE CARDIOVASCULAR RISK REDUCTION PROGRAM IN PARTICIPANTS FROM RURAL COMMUNITIES</b></p> <p>Tom Savona, MA; Carla English, MHS; Margaret Ann Selman, MBA; Kim Allen, RD; Julie Blakely, BS; Allyson Rose, MS; Robert Skiljan, MS; Richard Salmon, DDS; Barry Franklin, PhD; Neil Gordon, MD; INTERVENT Coordinating Center, South Georgia Access Network, and St. Joseph's/Candler Health System</p> <p><b>Rationale:</b> Geographic accessibility is an important predictor of participation in cardiovascular disease (CVD) risk reduction programs. <b>Objectives:</b> In this study, we investigated the clinical effectiveness of a comprehensive lifestyle management and CVD risk reduction program when administered via the telephone and Internet to 98 adults (age=54 +/-13 years) from 5 rural counties in Georgia by nonphysician healthcare professionals. This cohort was compared with 556 adults (age=50 +/-11 years) from an urban county who were participants in the same program delivered onsite at a freestanding facility. <b>Methodology:</b> Lifestyle interventions were based on several behavior change models, including: social learning theory; the stages of change model; and, single concept learning. 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 3 months of participation. <b>Results:</b> For participants with abnormal baseline CVD risk</p>

factors (based on national clinical guidelines), improvements were observed for multiple variables, as follows ( $p \leq 0.05$ ; R=rural participants; U=urban participants): systolic/diastolic blood pressure (R, -9/-15 mmHg; U, -18/-10 mmHg); total cholesterol (R, -21 mg/dl; U, -17 mg/dl); LDL cholesterol (R, -25 mg/dl; U, -15 mg/dl); HDL cholesterol (R, 6 mg/dl; U, 2 mg/dl); triglycerides (R, -58 mg/dl; U, -61 mg/dl); and weight (R, -7.1 lbs; U, -4.5 lbs). With the exception of systolic blood pressure (greater decrease for U versus R) and weight (greater decrease for R versus U), no statistically significant differences were observed for rural versus urban participants. Of the 9 rural participants who smoked cigarettes, 5 (56%) quit smoking; of the 63 urban participants who smoked cigarettes, 14 (22%) quit smoking. **Conclusion:** These data demonstrate the clinical effectiveness of a telephone/Internet delivered CVD risk reduction program in participants from rural communities and have implications for bridging the treatment gap in cardiovascular medicine.

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#### CLINICAL EFFECTIVENESS OF A CONTEMPORARY CARDIAC REHABILITATION PROGRAM IN OBESE AND NON-OVERWEIGHT PATIENTS

B.A. Franklin, FACSM, S.S.Haapaniemi, A. deJong, K.A. Bonzheim, R.D. Salmon, N.F. Gordon, FACSM. William Beaumont Hospital, Royal Oak, MI and INTERVENT Coordinating Center, Savannah, GA

42.

Despite unprecedented public attention, the obesity epidemic continues virtually unabated with no sign of reversal in the U.S. **PURPOSE:** In this multicenter study, we investigated the effect of a contemporary phase 2 cardiac rehabilitation program on multiple cardiovascular disease (CVD) risk factors in obese patients (Group A,  $n=552$ , BMI  $\geq 30$  kg/m<sup>2</sup>) and patients who were not overweight (Group B,  $n=347$ , BMI  $< 25$  kg/m<sup>2</sup>). **METHODS:** Outcome measures were evaluated at baseline and after approximately 12 weeks of participation in a phase 2 cardiac rehabilitation program at 12 centers in the U.S. **RESULTS:** Body weight (-3.1 lbs.,  $p<0.05$ ) and BMI (-0.5 kg/m<sup>2</sup>,  $p<0.05$ ) decreased in Group A patients and increased slightly in Group B patients (weight: 1.2 lbs.,  $p<0.05$ ; BMI: 0.2 kg/m<sup>2</sup>,  $p<0.05$ ) on program exit. Improvements in multiple CVD risk factors were observed on program exit for patients in both groups who had abnormal baseline risk factor values (based on national guidelines), as follows ( $p<0.05$ ): systolic/diastolic blood pressure (Group A, -20/18 mmHg; Group B, -20/18 mmHg); LDL cholesterol (Group A, -26 mg/dl; Group B, -33 mg/dl); HDL cholesterol (Group A, 3 mg/dl; Group B, 4 mg/dl); triglycerides (Group A, -71 mg/dl; Group B, -19 mg/dl); and fasting glucose (Group A, -26 mg/dl; Group B, -17 mg/dl). Improvements in weight, BMI, and triglycerides were significantly greater ( $p<0.05$ ) in Group A as compared with Group B participants. **CONCLUSION:** Although additional research is warranted, these observations suggest that while obese and non-overweight patients improve multiple CVD risk factors during participation in a phase 2 cardiac rehabilitation program, obese patients may derive greater improvements in certain risk factors.

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#### EFFECTIVENESS OF A CONTEMPORARY CARDIAC REHABILITATION PROGRAM IN PATIENTS WITH A HISTORY OF HEART FAILURE

A. Fowler, B. A. Franklin, FACSM, R. D. Salmon, N. F. Gordon, FACSM. William Beaumont Hospital, Royal Oak, MI and INTERVENT Coordinating Center, Savannah, GA

43.

Moderate intensity exercise increases functional capacity in patients with congestive heart failure (CHF). However, few data are available regarding the effect of such programs on traditional cardiovascular disease (CVD) risk factors in this patient subset. **PURPOSE:** In this multicenter study, we investigated the effect of a contemporary phase 2 cardiac rehabilitation program on multiple CVD risk factors in patients with (Group A,  $n=161$ ) and without (Group B,  $n=1367$ ) a history of CHF. **METHODS:** Outcome measures were evaluated at baseline and after approximately 12 weeks of participation in a phase 2 cardiac rehabilitation program at 12 centers in the U.S. **RESULTS:** On program exit, improvements ( $p<0.05$ ), unless otherwise indicated) in multiple CVD risk factors were noted for patients in both groups who had abnormal baseline risk factor values (based on national guidelines), as follows: systolic/diastolic blood pressure (Group A, -19/13 mmHg; Group B, -20/18 mmHg); LDL cholesterol (Group A, -36 mg/dl; Group B, -46 mg/dl); HDL cholesterol (Group A, 1 mg/dl,  $p=NS$ ; Group B, 5 mg/dl); triglycerides (Group A, -15 mg/dl,  $p=NS$ ; Group B, -47 mg/dl); fasting glucose (Group A, -44 mg/dl; Group B, -19 mg/dl); and weight (Group A, -3 lbs; Group B, -3 lbs). The increase in HDL cholesterol and decrease in diastolic blood pressure were significantly greater ( $p<0.05$ ) in Group B as compared with Group A participants. **CONCLUSION:** Although additional research is warranted, these observations suggest that while patients with and without a history of CHF substantially improve multiple CVD risk factors during participation in a phase 2 cardiac rehabilitation program, the magnitude of improvement may be less for certain risk factors in patients with a history of CHF.

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#### CLINICAL EFFECTIVENESS OF A CONTEMPORARY CARDIAC REHABILITATION PROGRAM IN PATIENTS WITH THE METABOLIC SYNDROME

S. S. Haapaniemi, A. deJong, K.A. Bonzheim, B. A. Franklin, FACSM, R. D. Salmon, N. F. Gordon, FACSM. William Beaumont Hospital, Royal Oak, MI and INTERVENT Coordinating Center, Savannah, GA

44.

The metabolic syndrome, a constellation of lipid and nonlipid risk factors linked to insulin resistance, is now recognized as a specific target of cardiovascular disease (CVD) risk reduction therapy. **PURPOSE:** In this multicenter study, we investigated the effect of a contemporary phase 2 cardiac rehabilitation program on multiple CVD risk factors in patients with (Group A,  $n=136$ ) and without (Group B,  $n=231$ ) the metabolic syndrome. Diagnosis of the metabolic syndrome was made when 3 or more of the risk determinants outlined in ATP III were

identified. **METHODS:** Outcome measures were evaluated at baseline and after approximately 12 weeks of participation in a phase 2 cardiac rehabilitation program at 12 centers in the U.S. **RESULTS:** On program exit, improvements ( $p < 0.05$ ) in multiple CVD risk factors were observed for patients in both groups who had abnormal baseline risk factor values (based on national clinical guidelines), as follows: systolic/diastolic blood pressure (Group A, -19/19 mmHg; Group B, -16/25 mmHg); LDL cholesterol (Group A, -25 mg/dl; Group B, -32 mg/dl); HDL cholesterol (Group A, 2 mg/dl; Group B, 6 mg/dl); triglycerides (Group A, -56 mg/dl; Group B, -50 mg/dl); fasting glucose (Group A, -11 mg/dl; Group B, -14 mg/dl); and weight (Group A, -4 lbs; Group B, -3 lbs). No statistically significant differences were observed for Group A compared with Group B. **CONCLUSION:** These data are the first, to our knowledge, to demonstrate that patients with the metabolic syndrome derive similar improvements in multiple CVD risk factors as patients without the metabolic syndrome after participating in a contemporary phase 2 cardiac rehabilitation program.

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#### EFFECT OF CARDIAC REHABILITATION ON SELF-REPORTED HEALTH STATUS IN MARRIED VERSUS UNMARRIED PARTICIPANTS

45.

Emily E. McGuckin, Barry A. Franklin, FACSM, Patricia M. Allard-Gould, Brenda S. Mitchell, Richard D. Salmon, L. Ivan Levinrad, G. Chipstead Faircloth, Neil F. Gordon, FACSM. William Beaumont Hospital, Royal Oak, MI, St. Joseph's/Candler Health System and INTERVENT Coordinating Center, Savannah, GA

**PURPOSE:** Recent research suggests that marital status may be an important predictor of recovery after an acute cardiac event. In this multicenter study, we investigated the effect of a contemporary phase 2 cardiac rehabilitation program on self-reported health status in 1,291 married ( $n=1,197$ ; age =  $65 \pm 11$  years) and unmarried ( $n=94$ ; age =  $64 \pm 14$  years) patients. **METHODS:** Self-reported health status was assessed at baseline and after approximately 12 weeks of participation in a phase 2 cardiac rehabilitation program using the SF-36.

**RESULTS:** At baseline, SF-36 transformed scores were significantly ( $p < 0.05$ ) lower in the unmarried versus married patients for 5 of the 8 domains (i.e., physical functioning, role-physical, general health, vitality, and mental health). On program exit, improvements ( $p < 0.05$  for within group change from baseline, unless otherwise indicated) in SF-36 transformed scores were observed, as follows: physical functioning (Married, 11; Unmarried, 13); role-physical (Married, 32; Unmarried, 33); bodily pain (Married, 16; Unmarried 5,  $p=NS$ ); general health (Married, 3; Unmarried, 2,  $p=NS$ ); vitality (Married, 9; Unmarried, 12); social functioning (Married, 15; Unmarried, 15); role-emotional (Married, 12; Unmarried, 6,  $p=NS$ ); and mental health (Married, 5; Unmarried, 6). With the exception of bodily pain (greater improvement in married patients), no statistically significant differences were observed for the magnitude of improvement from baseline in married versus unmarried patients. **CONCLUSION:** These data demonstrate that: 1. unmarried patients have poorer self-reported health status on entry into a phase 2 cardiac rehabilitation program as compared to married patients; and 2. both married and unmarried patients derive improvements in multiple indices of self reported functional status and well-being with participation in a contemporary phase 2 cardiac rehabilitation program.

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#### CLINICAL EFFECTIVENESS OF A PHASE 2 CARDIAC REHABILITATION PROGRAM IN MARRIED VERSUS UNMARRIED PARTICIPANTS

46.

Kirk D. Henrickson, Barry A. Franklin, FACSM, Patricia M. Allard-Gould, Brenda S. Mitchell, Richard D. Salmon, L. Ivan Levinrad, G. Chipstead Faircloth, Neil F. Gordon, FACSM. William Beaumont Hospital, Royal Oak, MI, St. Joseph's/Candler Health System and INTERVENT Coordinating Center, Savannah, GA

**PURPOSE:** Social support is an important determinant of cardiac mortality. In this multicenter study, we investigated the effect of a contemporary phase 2 cardiac rehabilitation program on multiple cardiovascular disease (CVD) risk factors in 1,291 married ( $n=1,197$ ; age =  $65 \pm 11$  years) and unmarried ( $n=94$ ; age =  $64 \pm 14$  years) patients. **METHODS:** Outcome measures were evaluated at baseline and after approximately 12 weeks of participation in a phase 2 cardiac rehabilitation program. **RESULTS:** On program exit, improvements ( $p < 0.05$ , unless otherwise indicated) in multiple CVD risk factors were noted for patients in both groups who had abnormal baseline risk factor values (based on national clinical guidelines), as follows: systolic/diastolic blood pressure (Married, -20/-17 mmHg; Unmarried, -24/-14 mmHg); LDL cholesterol (Married, -51 mg/dl; Unmarried, -69 mg/dl); HDL cholesterol (Married, 3 mg/dl; Unmarried, 3 mg/dl); triglycerides (Married, -28 mg/dl; Unmarried, -43 mg/dl); fasting glucose (Married, -23 mg/dl; Unmarried, -6 mg/dl,  $p=NS$ ); and weight (Married, -3.7 lbs; Unmarried, -2.4 lbs). No statistically significant differences were observed for married versus unmarried patients. **CONCLUSION:** Although social support is a strong predictor of recovery after an acute cardiac event, these data demonstrate that unmarried patients derive similar improvements in multiple CVD risk factors as married patients during participation in a contemporary phase 2 cardiac rehabilitation program.

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#### EFFECT OF A PHASE 2 CARDIAC REHABILITATION PROGRAM ON SELF-REPORTED HEALTH STATUS IN PATIENTS WITH VERSUS WITHOUT A SELF-REPORTED HISTORY OF DEPRESSION

47.

Thomas Draper, MBA; Melvyn Rubenfire, MD; Barry Franklin, PhD; Richard Salmon, DDS; Neil Gordon, MD; University of Michigan, Ann Arbor, MI; INTERVENT Coordinating Center, Savannah, GA; and St. Joseph's/Candler Health System, Savannah, GA.

**Rationale:** Recent research suggests that depressed patients with cardiovascular disease are less likely to take prescribed medications and adhere to recommended lifestyle changes intended to reduce the risk of recurrent cardiac events. **Objectives:** In this multicenter study, we investigated the effect of a contemporary phase 2 cardiac rehabilitation (CR) program on self-reported health status in 2,981 patients with

(n=538) and without (n=2,457) a self-reported history of significant problems with depression. Of the patients with a history of depression, 248 (46%) indicated that they were experiencing problems with depression at baseline. **Methodology:** Self-reported health status was assessed at baseline and after 12 weeks of participation in a CR program using the SF-36. **Results:** At baseline, SF-36 transformed scores were lower ( $p < 0.05$ ) in patients with versus without a history of depression for all 8 domains. On program exit, improvements ( $p < 0.05$  for within group change from baseline) in SF-36 transformed scores were observed, as follows: physical functioning (With depression, 12; Without depression, 13); role-physical (With depression, 32; Without depression, 35); bodily pain (With depression, 15; Without depression, 18); general health (With depression, 5; Without depression, 3); vitality (With depression, 15; Without depression, 9); social functioning (With depression, 18; Without depression, 18); role-emotional (With depression, 22; Without depression, 11); and mental health (With depression, 8; Without depression, 5). Statistically significant ( $p < 0.05$ ) differences were observed for the magnitude of improvement from baseline in patients with versus without a history of depression for bodily pain (greater improvement in patients without depression) and for general health, vitality, role-emotional, and mental health (greater improvements in patients with depression). **Conclusion:** Although additional research is warranted, these data suggest that: 1. patients with a history of depression have poorer self-reported health status on entry into a CR program; and 2. patients with and without a history of depression derive improvements in multiple indices of self-reported functional status and well-being with participation in a CR program.

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#### EFFECT OF A PHASE 2 CARDIAC REHABILITATION PROGRAM ON SELF-REPORTED HEALTH STATUS IN PATIENTS WITH VERSUS WITHOUT A HISTORY OF HEART FAILURE

Adam deJong, MA; Barry Franklin, PhD; Richard Salmon, DDS; Martin Berk, MD; Neil Gordon, MD; William Beaumont Hospital, Royal Oak, MI; INTERVENT Coordinating Center, Savannah, GA; and St. Joseph's/Candler Health System, Savannah, GA.

48.

**Rationale:** Previously, we demonstrated that while patients with and without congestive heart failure (CHF) improve multiple cardiovascular disease risk factors during participation in a contemporary phase 2 cardiac rehabilitation (CR) program, the magnitude of improvement may be less in patients with CHF. **Objectives:** In this multicenter study, we investigated the effect of a CR program on self-reported health status in 2,995 patients with (n=306) and without (n=2,689) a history of CHF. **Methodology:** Self-reported health status was assessed at baseline and after an average of approximately 12 weeks of participation in a CR program using the SF-36. **Results:** At baseline, SF-36 transformed scores were lower ( $p < 0.05$ ) in the patients with a history of CHF, versus those without, for 6 of the 8 domains (i.e. physical functioning, role physical, bodily pain, general health, vitality, and social functioning). On program exit, statistically significant improvements ( $p < 0.05$  for within group change from baseline) in SF-36 transformed scores were observed, as follows: physical functioning (With CHF, 15; Without CHF, 12); role-physical (With CHF, 32; Without CHF, 35); bodily pain (With CHF, 15; Without CHF, 17); general health (With CHF, 5; Without CHF, 4); vitality (With CHF, 14; Without CHF, 10); social functioning (With CHF, 18; Without CHF, 18); role-emotional (With CHF, 14; Without CHF, 13); and mental health (With CHF, 7; Without CHF, 5). Additionally, a statistically ( $p < 0.05$ ) greater magnitude of improvement was observed from baseline in patients with a history of CHF for physical functioning, vitality, and mental health as compared to those without CHF history. **Conclusion:** Although additional research is warranted, these data suggest that: 1. patients with a history of CHF tend to have poorer self-reported health status on entry into a CR program; and 2. patients with and without a history of CHF derive substantial improvements in multiple indices of self-reported functional status and well-being with participation in a CR program.

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#### EFFECT OF A PHASE 2 CARDIAC REHABILITATION PROGRAM ON SELF-REPORTED HEALTH STATUS IN OBESE VERSUS NON-OVERWEIGHT PATIENTS

Allan Lewis, MS; Richard Salmon, DDS; Barry Franklin, PhD; Neil Gordon, MD; Memorial Health Care System, Chattanooga, TN; INTERVENT Coordinating Center, Savannah, GA; and St. Joseph's/Candler Health System, Savannah, GA.

49.

**Rationale:** Previously, we demonstrated that while obese and non-overweight patients improve multiple cardiovascular disease risk factors during participation in a phase 2 cardiac rehabilitation program, obese patients may derive greater improvements in certain risk factors. **Objectives:** In this multicenter study, we investigated the effect of a contemporary phase 2 cardiac rehabilitation program on self-reported health status in obese patients (Group A; n=1,088; BMI =30 kg/m<sup>2</sup> or higher) and patients who were not overweight (Group B; n=648; BMI <25 kg/m<sup>2</sup>). **Methodology:** Self-reported health status was assessed at baseline and after an average of approximately 12 weeks of participation in a phase 2 cardiac rehabilitation program using the SF-36. **Results:** On program exit, statistically significant improvements ( $p < 0.05$  for within group change from baseline) in SF-36 transformed scores were observed, as follows: physical functioning (Group A, 13; Group B, 15); role-physical (Group A, 32; Group B, 37); bodily pain (Group A, 16; Group B, 19); general health (Group A, 4; Group B, 3); vitality (Group A, 12; Group B, 10); social functioning (Group A, 16; Group B, 20); role-emotional (Group A, 13; Group B, 13); and mental health (Group A, 5; Group B, 5). Statistically significant ( $p < 0.05$ ) differences were observed for the magnitude of improvement from baseline in obese versus non-overweight patients for physical functioning, role physical, bodily pain, and social functioning (greater improvements in non-overweight patients), and for general health and vitality (greater improvements in obese patients). **Conclusion:** Although additional research is needed to fully clarify the influence of obesity on self-reported health status, these data suggest that obese patients and non-overweight patients derive substantial improvements in multiple indices of self-reported functional status and well-being with participation in a contemporary phase 2 cardiac rehabilitation program.

## INTERVENT:

### RESEARCH PUBLISHED AND / OR PRESENTED AT NATIONAL / INTERNATIONAL SCIENTIFIC MEETINGS: 1997 - 2020

- 2004 – AACVPR Annual Meeting**  
50. **EFFECTIVENESS OF A TOBACCO CESSATION INTERVENTION, ADMINISTERED AS A COMPONENT OF A COMPREHENSIVE CARDIOVASCULAR RISK REDUCTION PROGRAM, IN PARTICIPANTS IN DIFFERENT STAGES OF READINESS TO QUIT SMOKING**
- Russell G. O'Neal, Laurence S. Sperling, Emory University, Atlanta, GA; Barry A. Franklin, William Beaumont Hospital, Royal Oak, MI; Richard D. Salmon, George C. Faircloth, Brenda S. Mitchell, Ivan Levinrad, Neil F. Gordon, St. Joseph's/Candler Health System and INTERVENT Coordinating Center, Savannah, GA.
- OBJECTIVE:** Cigarette smokers who participate in multi-factor cardiovascular risk reduction programs (i.e. comprehensive cardiovascular risk reduction programs) may be in different stages of readiness to quit smoking at program entry. In this study, we evaluated the effectiveness of a tobacco cessation intervention, administered as one component of a comprehensive cardiovascular risk reduction program, in participants in the precontemplation, contemplation, or preparation stage of readiness to quit smoking. **METHODS:** Participants in a community-based comprehensive cardiovascular risk reduction program (the INTERVENT program) who were current cigarette smokers at program entry (n=205) were followed for approximately 1 year. Stage of readiness to quit smoking, based on the model of Prochaska and Diclemente, was assessed at baseline and 18.5% (n=38), 47.3% (n=97), and 34.2% (n=70) of participants were determined to be in the precontemplation, contemplation, and preparation stage, respectively. Smoking cessation interventions were based primarily on guidelines from the Agency for Healthcare Quality and Research and differed based on stage of readiness to change. **RESULTS:** After approximately 1 year of follow-up, 24.9% of participants (n=51) reported that they had quit smoking cigarettes. Of participants who smoked >10 cigarettes/day at baseline (n=100), 38% reported smoking ≤10 cigarettes/day at follow-up. Cigarette smoking cessation rates were 23.7%, 19.7%, and 32.9% for participants in the precontemplation, contemplation, and preparation stage at baseline, respectively. Of participants who smoked >10 cigarettes/day at baseline, 29.4%, 39.2%, and 40.6% of those in the precontemplation, contemplation, and preparation stage at baseline, respectively, reported smoking ≤10 cigarettes/day at follow up. **CONCLUSION:** These data are the first, to our knowledge, to demonstrate that appropriately designed tobacco cessation interventions, administered as a component of a comprehensive cardiovascular risk reduction program, can be effective in helping cigarette smokers discontinue tobacco use, irrespective of their stage of readiness to quit at program entry.
- 2004 – ACC Annual Meeting**  
51. **GETTING RISK FACTORS TO GOAL: LIFESTYLE INTERVENTION IS WORTH THE EFFORT IN PATIENTS WITH HYPERTENSION, HYPERLIPIDEMIA, AND/OR HYPERGLYCEMIA**
- Neil F. Gordon, Richard D. Salmon, William E. Saxon, Kevin S. Reid, George C. Faircloth, Ivan Levinrad, Brenda S. Mitchell, Richard F. Leighton, St. Joseph's/Candler Health System and INTERVENT Coordinating Center, Savannah, GA; Laurence S. Sperling, Emory University, Atlanta, GA; William L. Haskell, Stanford University, CA; Barry A. Franklin, William Beaumont Hospital, Royal Oak, MI
- Background:** Hypertension, hyperlipidemia, and hyperglycemia are leading causes of potentially avoidable morbidity, mortality, and healthcare expenditures. National clinical guidelines promulgate therapeutic lifestyle changes (TLC) as a standard of care in the management of these cardiovascular disease risk factors. Because of the widespread availability of pharmacotherapeutic agents, however, the value of TLC per se in contemporary medical practice is often discounted by clinicians and health insurers. The aim of this study was to evaluate the precise role of TLC in helping patients achieve goal risk factor levels. **Methods:** We studied the effect of TLC on the control of: blood pressure (BP) in unmedicated patients with a baseline systolic BP ≥ 140 mmHg (n=335) and/or diastolic BP ≥ 90 mmHg (n=346); LDL cholesterol in unmedicated patients with a baseline value ≥ 100 mg/dl (n = 1,553); and fasting blood glucose in unmedicated patients with a baseline value ≥ 110 mg/dl (n=249). TLC included exercise training and nutrition counseling. Interventions were based on several well established behavior change models. Patients remained unmedicated throughout the study and were evaluated at baseline and after 3 months of TLC. **Results:** Systolic BP decreased from 149 ± 10 to 133 ± 15 mmHg (p<0.05) and 63% of patients achieved goal (i.e., <130 mmHg for patients with diabetes and/or atherosclerosis; <140 mmHg for others). Diastolic BP decreased from 95 ± 5 to 85 ± 9 mmHg (p<0.05) and 65% of patients achieved goal (i.e., <80 mmHg for patients with diabetes; <85 mmHg for patients with atherosclerosis; <90 mmHg for others). LDL cholesterol decreased from 143 ± 28 to 134 ± 30 mg/dl (p<0.05) and 27% of patients achieved goal (using ATP III criteria). Fasting glucose decreased from 144 ± 43 to 129 ± 43 mg/dl and 41% of patients achieved goal (i.e. <110 mg/dl); of patients with a baseline value compatible with diabetes (i.e., >125 mg/dl; n=141), 35% achieved a value <125 mg/dl. **Conclusion:** These data show that many patients with classic cardiovascular disease risk factors can achieve goal without medications within 3 months of initiating TLC and refute the notion that intensive lifestyle intervention is not worth the effort.
- 2005 – ACC Annual Meeting**  
52. **MULTICENTER STUDY OF THE CLINICAL EFFECTIVENESS OF A CONTEMPORARY CARDIAC REHABILITATION PROGRAM IN ELDERLY VERSUS YOUNGER PATIENTS**
- Neil F. Gordon, Richard D. Salmon, Ivan Levinrad, George C. Faircloth, Richard F. Leighton, Martin R. Berk, Linda K. Hall, Laurence S. Sperling, William A. Dafoe, Melvyn Rubenfire, Diane Vogel, C. Noel Bairey Merz, William L. Haskell, Barry A. Franklin, St. Joseph's/Candler Health System, Savannah, GA, INTERVENT Coordinating Center, Savannah, GA
- Background:** The aging of the American population and improving survival of patients with cardiovascular disease (CVD) has created a large population of elderly patients (≥65 years of age) eligible for cardiac rehabilitation. However, no comprehensive data are currently

available on the effect of a contemporary phase 2 cardiac rehabilitation program on multiple CVD risk factors in elderly versus younger patients. **Methods:** In this multicenter study, we investigated the effect of a contemporary phase 2 cardiac rehabilitation program on multiple CVD risk factors in 5,418 consecutive patients  $\geq 65$  years of age (Group A;  $n=2,526$ ;  $\text{age}=74\pm 6$  years) and  $< 65$  years of age (Group B;  $n=2,892$ ;  $\text{age}=52\pm 10$  years). Outcome measures were evaluated at baseline and after approximately 12 weeks of participation in a phase 2 cardiac rehabilitation program at 30 centers in the U.S. **Results:** On program exit, improvements ( $p \leq 0.05$ ) in multiple CVD risk factors were observed for both elderly and younger patients who had abnormal baseline risk factor values (based on national clinical guidelines), as follows: systolic blood pressure (Group A, -19 mmHg; Group B, -22 mmHg;  $p \leq 0.05$  for Group A versus Group B); diastolic blood pressure (Group A, -17 mmHg; Group B, -14 mmHg;  $p \leq 0.05$  for Group A versus Group B); LDL cholesterol (Group A, -28 mg/dl; Group B, -18 mg/dl;  $p \leq 0.05$  for Group A versus Group B); HDL cholesterol (Group A, 4 mg/dl; Group B, 4 mg/dl;  $p=NS$  for Group A versus Group B); triglycerides (Group A, -41 mg/dl; Group B, -43 mg/dl;  $p=NS$  for Group A versus Group B); fasting glucose (Group A, -14 mg/dl; Group B, -17 mg/dl;  $p=NS$  for Group A versus Group B); and weight (Group A, -4 lbs; Group B, -4 lbs;  $p=NS$  for Group A versus Group B). **Conclusion:** To our knowledge, these are the first multicenter clinical trial data to demonstrate that elderly patients derive similar improvements in multiple CVD risk factors as compared to younger patients during participation in a contemporary phase 2 cardiac rehabilitation program. Increased efforts should be devoted to providing these important services to elderly patients.

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#### CLINICAL EFFECTIVENESS OF THERAPEUTIC LIFESTYLE CHANGES IN AFRICAN AMERICANS VERSUS CAUCASIANS

Neil F. Gordon, Richard D. Salmon, Kevin S. Reid, William E. Saxon, George C. Faircloth, Ivan Levinrad, Brenda S. Mitchell, Richard F. Leighton, Anil Verma, Martin R. Berk, Laurence S. Sperling, William L. Haskell, Barry A. Franklin, St. Joseph's/Candler Health System, Savannah, GA, INTERVENT Coordinating Center, Savannah, GA

53.

**Background:** Despite impressive medical advances during the past century, striking differences remain in cardiovascular disease (CVD) mortality rates by race/ethnicity. Although national guidelines promulgate therapeutic lifestyle changes (TLC) as a cornerstone in CVD risk reduction, scarce data are available on the effectiveness of TLC in minority subpopulations in the U.S. **Methods:** In this study, we compared the effectiveness of TLC in 1,967 consecutive, unmedicated, African American (Group A;  $n=412$ ;  $\text{age}=44\pm 9$  years) and Caucasian (Group B;  $n=1,555$ ;  $\text{age}=47\pm 11$  years) patients with an elevated blood pressure (BP), LDL cholesterol, and/or fasting plasma glucose level. Patients were evaluated at baseline and after ~12 weeks of participation in a community-based lifestyle management program. TLC included exercise training, nutrition, weight management, stress management, and smoking cessation interventions. All patients remained unmedicated throughout the study. **Results:** Among patients with abnormal baseline risk factors (based on national guidelines), improvements were observed for multiple variables, as follows ( $p \leq 0.05$ , unless otherwise noted): systolic BP (Group A, -9 mmHg; Group B, -10 mmHg;  $p=NS$  for Group A versus B); diastolic BP (Group A, -6 mmHg; Group B, -7 mmHg;  $p \leq 0.05$  for Group A versus B); total cholesterol (Group A, -20 mg/dl; Group B, -27 mg/dl;  $p=NS$  for Group A versus B); LDL cholesterol (Group A, -10 mg/dl; Group B, -15 mg/dl;  $p=NS$  for Group A versus B); HDL cholesterol (Group A, 5 mg/dl; Group B, 3 mg/dl;  $p=NS$  for Group A versus B); triglycerides (Group A, -10 mg/dl,  $p=NS$ ; Group B, -55 mg/dl;  $p \leq 0.05$  for Group A versus B); fasting glucose (Group A, -3 mg/dl,  $p=NS$ ; Group B, -11 mg/dl;  $p=NS$  for Group A versus B); and weight (Group A, -3 lbs; Group B, -7 lbs;  $p \leq 0.05$  for Group A versus B). In patients with a Framingham 10-year coronary heart disease risk score  $\geq 10\%$  at baseline, the score decreased significantly ( $p \leq 0.05$ ) in Group A (-13%) and Group B (-19.4%);  $p=NS$  for Group A versus B. **Conclusions:** These data indicate that while both African Americans and Caucasians benefit substantially from TLC, the magnitude of benefit may be greater for Caucasians for certain CVD risk factors.

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#### CLINICAL EFFECTIVENESS OF THERAPEUTIC LIFESTYLE CHANGES IN PRE-MENOPAUSAL VERSUS POST-MENOPAUSAL WOMEN

Neil F. Gordon, Richard D. Salmon, Terri L. Gordon, Daniel Biggerstaff, William E. Saxon, Kevin S. Reid, George C. Faircloth, Ivan Levinrad, Brenda S. Mitchell, Richard F. Leighton, Anil Verma, St. Joseph's/Candler Health System and INTERVENT Coordinating Center, Savannah, GA; Laurence S. Sperling, Emory University, Atlanta, GA; Linda Hall, PhD, Forrest General Hospital; William L. Haskell, Stanford University, CA; Barry A. Franklin, William Beaumont Hospital, Royal Oak, MI

54.

**Background:** The proportion of women living past the age of menopause has tripled during the past century. Although recent national clinical guidelines promulgate therapeutic lifestyle changes (TLC) as a cornerstone in cardiovascular disease (CVD) risk reduction in all women, no studies have evaluated the effect of menopausal status on responses to TLC. **Methods:** In this study, we compared the clinical effectiveness of TLC in 1,601 consecutive pre-menopausal (Group A;  $n=1,014$ ;  $\text{age}=41\pm 8$  years) and post-menopausal (Group B;  $n=587$ ;  $\text{age}=55\pm 8$  years) women with an elevated blood pressure, LDL cholesterol, and/or fasting plasma glucose level who were not taking medication for hypertension, hyperlipidemia, or diabetes. Subjects were evaluated at baseline and after approximately 12 weeks of participation in a community-based lifestyle management program. TLC included exercise training, correct nutrition, weight management, stress management, and smoking cessation interventions. All women remained off antihypertensive, antilipemic, and antidiabetic medications throughout the study. **Results:** For subjects with abnormal baseline CVD risk factors (based on national guidelines), clinically relevant improvements ( $p \leq 0.05$ ) were observed for multiple variables, including: systolic/diastolic blood pressure (Group A, -11/-7 mmHg; Group B, -9/-8 mmHg); LDL cholesterol (Group A, -12 mg/dl; Group B, -11 mg/dl); HDL cholesterol (Group A, 3 mg/dl; Group B, 7 mg/dl); triglycerides (Group A, -41 mg/dl; Group B, -59 mg/dl); fasting glucose (Group A, -12 mg/dl; Group B, -6 mg/dl); and weight (Group A, -5 lbs; Group B, -6

lbs). With the exception of diastolic blood pressure (greater decrease in Group B), no significant differences were observed between the 2 groups. In women without coronary heart disease, the calculated Framingham 10-year coronary heart disease risk score decreased significantly ( $p \leq 0.05$ ) and by a similar magnitude in both groups. **Conclusions:** These data are the first, to our knowledge, to demonstrate the similar clinical effectiveness of TLC in pre-menopausal and post-menopausal women.

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#### CLINICAL EFFECTIVENESS OF THERAPEUTIC LIFESTYLE CHANGES IN PATIENTS WITH LOW-DENSITY LIPOPROTEIN SUBCLASS PATTERN B VERSUS A

55.

Kirk D. Hendrickson, Barry A. Franklin, FACS, Adam T. deJong, Richard D. Salmon, Ivan Levinrad, George C. Faircloth, Anil Verma, Richard F. Leighton, William C. Cromwell, Neil F. Gordon, FACS. *William Beaumont Hospital, Royal Oak, MI. INTERVENT Coordinating Center, Savannah, GA. Liposcience, Inc., Raleigh, NC. St. Joseph's/Candler Health System, Savannah, GA.*

**PURPOSE:** Recent research suggests that persons with a predominance of small LDL particles (LDL pattern B) may respond differently to short-term therapeutic lifestyle changes (TLC) as compared to persons with a predominance of large LDL particles (LDL pattern A). However, scarce long-term data are available to substantiate or refute this possibility. In this study, we compared the effect of 1 year of TLC on plasma lipids and lipoproteins in participants with LDL pattern B ( $n=11$ ; LDL size  $<20.6$  nm) versus LDL pattern A ( $n=50$ ; LDL size  $>20.5$  nm), as determined using NMR spectroscopy. **METHODS:** TLC included counseling on a low fat (20% of daily calories)/high complex carbohydrate (60% of daily calories) diet and exercise training. Counseling was provided by healthcare professionals via telephone and the Internet. Participants were evaluated at baseline and after 1 year using standardized procedures. No changes in antilipemic medications occurred between evaluations. **RESULTS:** Body weight decreased to a similar degree in participants with LDL pattern B (-5.4 lbs,  $p < 0.05$ ) versus LDL pattern A (-5.2 lbs,  $p < 0.05$ ). In contrast, participants with LDL pattern B tended to derive more favorable changes in total cholesterol (-15 mg/dl,  $p < 0.05$  versus -3 mg/dl,  $p = NS$ ;  $p < 0.05$  for pattern B versus A participants), LDL cholesterol (-11 mg/dl,  $p < 0.05$  versus -6 mg/dl,  $p < 0.05$ ;  $p = NS$  for pattern B versus A participants), LDL particle number (-291 nmol/L,  $p < 0.05$  versus -91 nmol/L,  $p < 0.05$ ;  $p < 0.05$  for pattern B versus A participants), LDL particle size (0.5 nm,  $p < 0.05$  versus 0.1 nm,  $p = NS$ ;  $p < 0.05$  for pattern B versus A participants), HDL cholesterol (6 mg/dl,  $p < 0.05$  versus 3 mg/dl,  $p < 0.05$ ;  $p = NS$  for pattern B versus A participants); large HDL cholesterol (4 mg/dl,  $p < 0.05$  versus 4 mg/dl,  $p < 0.05$ ;  $p = NS$  for pattern B versus A participants), triglycerides (-91 mg/dl,  $p < 0.05$  versus -3 mg/dl,  $p = NS$ ;  $p < 0.05$  for pattern B versus A participants), and large VLDL cholesterol (-58 mg/dl,  $p = NS$  versus 6 mg/dl,  $p = NS$ ;  $p < 0.05$  for pattern B versus A participants). **CONCLUSIONS:** Although additional research is warranted, these data support the notion that individuals with LDL pattern B may be more responsive to a long-term program of TLC that includes a low fat/high complex carbohydrate diet and exercise training as compared to individuals with LDL pattern A.

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#### MULTICENTER STUDY OF EFFECT OF CARDIAC REHABILITATION ON SELF-REPORTED HEALTH STATUS: ELDERLY VERSUS YOUNGER PATIENTS

56.

Adam deJong, Barry A. Franklin, FACS, Richard D. Salmon, Ivan Levinrad, George C. Faircloth, Brenda S. Wright, Kevin S. Reid, William E. Saxon, Neil F. Gordon, FACS. *William Beaumont Hospital, Royal Oak, MI. INTERVENT Coordinating Center, Savannah, GA. St. Joseph's/Candler Health System, Savannah, GA.*

**PURPOSE:** Improved survival of patients with cardiovascular disease (CVD) and the aging of America have created a large population of elderly patients ( $\geq 65$  years of age) eligible for cardiac rehabilitation. No comprehensive data are currently available on the effect of a contemporary phase 2 cardiac rehabilitation program on multiple indices of self-reported health status in elderly versus younger patients. In this multicenter study, we investigated the effect of a contemporary phase 2 cardiac rehabilitation program on self-reported health status in 5,418 consecutive patients  $\geq 65$  years of age (Group A;  $n=2,526$ ; age =  $74 \pm 6$  years) and  $< 65$  years of age (Group B;  $n=2,892$ ; age =  $52 \pm 10$  years). **METHODS:** Self-reported health status was assessed at baseline and after an average of approximately 12 weeks of participation in a phase 2 cardiac rehabilitation program at 30 centers in the U.S. using the SF-36. **RESULTS:** On program exit, statistically significant improvements ( $p < 0.05$  for within group change from baseline) in SF-36 transformed scores were observed in both groups, as follows: physical functioning (Group A, 14; Group B, 11); role-physical (Group A, 36; Group B, 24); bodily pain (Group A, 17; Group B, 13); general health (Group A, 3; Group B, 5); vitality (Group A, 11; Group B, 9); social functioning (Group A, 19; Group B, 13); role-emotional (Group A, 14; Group B, 9); and mental health (Group A, 5; Group B, 6). Statistically significant ( $p < 0.05$ ) differences were observed for the magnitude of improvement from baseline in Group A versus Group B patients for physical functioning, role physical, bodily pain, vitality, social functioning, and role emotional (greater improvements in elderly patients), and for general health (greater improvement in younger patients). **CONCLUSIONS:** These data indicate that both elderly and younger patients derive substantial improvements in multiple indices of self-reported functional status and well-being with participation in a contemporary phase 2 cardiac rehabilitation program. The data further suggest that, with the exception of general health and, possibly, mental health, the magnitude of improvement may be greater in elderly patients.

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#### CLINICAL EFFECTIVENESS OF A COMPREHENSIVE LIFESTYLE MANAGEMENT AND CARDIOVASCULAR RISK REDUCTION PROGRAM IN CANCER SURVIVORS

Neil F. Gordon, FACS, Richard D. Salmon, Ivan Levinrad, George C. Faircloth, Brenda S. Wright, Kevin S. Reid, William E. Saxon, Richard

INTERVENT:

RESEARCH PUBLISHED AND / OR PRESENTED AT NATIONAL / INTERNATIONAL SCIENTIFIC MEETINGS: 1997 - 2020

57. F. Leighton, Adam T. deJong, Barry A. Franklin, FACSM. *St. Joseph's/Candler Health System, Savannah, GA; INTERVENT Coordinating Center, Savannah, GA; William Beaumont Hospital, Royal Oak, MI.*

**PURPOSE:** Recent research indicates that cancer survivors have poorer long-term health outcomes than do similar individuals without cancer across multiple burden of illness measures. This study is the first, to our knowledge, to evaluate the clinical effectiveness of a community-based comprehensive lifestyle management and cardiovascular disease (CVD) risk reduction program in cancer survivors and to make a comparison to individuals without a personal history of cancer. **METHODS:** Subjects were 3,761 consecutive men and women with (Group A; n=254) and without (Group B; n=3,507) a personal history of cancer. Subjects were evaluated at baseline and after approximately 1 year of participation in a community-based lifestyle management and CVD risk reduction program. Lifestyle management included exercise training, nutrition, weight management, stress management, and smoking cessation interventions. Participants were referred to their personal physicians for consideration of medication changes in accordance with national clinical guidelines. **RESULTS:** Among subjects with abnormal baseline CVD risk factors (based on national guidelines), clinically relevant improvements ( $p \leq 0.05$ ) were observed in both groups for multiple variables, including: systolic/diastolic blood pressure (Group A, -14/-9 mmHg; Group B, -17/-12 mmHg); LDL cholesterol (Group A, -21 mg/dl; Group B, -17 mg/dl); HDL cholesterol (Group A, 6 mg/dl; Group B, 4 mg/dl); triglycerides (Group A, -33 mg/dl; Group B, -34 mg/dl); fasting glucose (Group A, -12 mg/dl; Group B, -26 mg/dl); and weight (Group A, -7 lbs; Group B, -6 lbs). With the exception of diastolic blood pressure (greater reduction in Group B versus Group A,  $p \leq 0.05$ ), no statistically significant differences were observed for Group A versus B. Among cigarette smokers, 30.4 % ( $p \leq 0.05$ ) of Group A and 21.7 % ( $p \leq 0.05$ ) of Group B subjects quit smoking;  $p=NS$  for Group A versus B. In subjects with a calculated Framingham 10-year coronary heart disease risk score  $\geq 10\%$  at baseline, the score decreased significantly ( $p \leq 0.05$ ) in Group A (-20.5 %) and in Group B (-21.7 %);  $p=NS$  for Group A versus B. **CONCLUSIONS:** These data demonstrate that cancer survivors derive substantial improvements in multiple CVD risk factors during participation in a comprehensive lifestyle management and CVD risk reduction program.

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**MULTI-CENTER STUDY OF RISK FACTOR STATUS ON ENTRY INTO CARDIAC REHABILITATION: ELDERLY VERSUS YOUNGER PATIENTS**

58.

Amy L. Fowler, Barry A. Franklin, FACSM, Adam T. deJong, Richard D. Salmon, Ivan Levinrad, George C. Faircloth, Brenda S. Wright, Kevin S. Reid, William E. Saxon, Neil F. Gordon, FACSM. *William Beaumont Hospital, Royal Oak, MI; INTERVENT Coordinating Center, Savannah, GA; St. Joseph's/Candler Health System, Savannah, GA.*

**PURPOSE:** According to the American Heart Association, cardiac rehabilitation programs should provide comprehensive cardiovascular disease (CVD) risk reduction interventions aimed at the control of multiple risk factors. Published guidelines are available on goals for each CVD risk factor. However, no comprehensive data are available on the percentage of participants who are not already at recommended goal risk factor levels on entry into a contemporary phase 2 cardiac rehabilitation program. In this multi-center study, we compared the percentage of participants not at goal for select CVD risk factors in elderly ( $\geq 65$  years) versus younger ( $< 65$  years) patients at entry into a phase 2 cardiac rehabilitation program. **METHODS:** Subjects were 12,083 consecutive elderly (Group A; n=5,103; age=74 $\pm$ 6 years; males=66%) and younger (Group B; n=6,980; age=51 $\pm$ 10 years; males=52%) patients enrolled in phase 2 cardiac rehabilitation programs at 30 centers in the United States. CVD risk factors were evaluated on program entry using standardized procedures. **RESULTS:** Results are shown in the table.

CVD Risk Factor	Goal (Based on National Clinical Guidelines)	% Not At Goal.		P (Group A versus Group B)
		Group A	Group B	
Cigarette smoking	Smoking cessation	3.3	9.2	<0.001
Systolic BP	<120 mm Hg	67.0	54.7	<0.001
Diastolic BP	<80 mm Hg	25.3	37.6	<0.001
LDL cholesterol	<100 mg/dl	40.9	57.3	<0.001
HDL cholesterol	>39 mg/dl	38.0	33.8	<0.001
Triglycerides	<150 mg/dl	40.5	38.2	<0.05
Body Mass Index	<25 kg/m <sup>2</sup>	72.5	80.7	<0.001
Fasting glucose	<100 mg/dl	60.8	38.8	<0.001
Sedentary lifestyle	>149 min/wk	81.1	79.8	NS

**CONCLUSION:** These data indicate that multiple CVD risk factors are often inadequately controlled at entry into a contemporary phase 2 cardiac rehabilitation program, especially body mass index and a sedentary lifestyle. Our findings further indicate that differences exist between elderly and younger patients for multiple CVD risk factors. These data may be relevant to cardiac rehabilitation programs when prioritizing, designing, and developing comprehensive CVD risk reduction interventions for elderly and younger participants.

2005 – AACVPR Annual Meeting

**EFFECT OF GENDER ON CLINICAL RESPONSIVENESS TO THERAPEUTIC LIFESTYLE CHANGES**

Marlene Sigler, RN, MS; Richard D. Salmon, DDS; Terri L. Gordon; George C. Faircloth, MHA; Brenda S. Wright, PhD; Richard F. Leighton, MD; Barry A. Franklin, PhD; and Neil Gordon, MD. *New Hanover Regional Medical Center, Wilmington, NC, St. Joseph's/Candler Health System, Savannah, GA, and INTERVENT Coordinating Center, Savannah, GA*



59.

**Rationale:** Emerging data have displayed important gender-based differences in the response to cardiovascular disease (CVD) therapies. Although national clinical guidelines promulgate therapeutic lifestyle changes (TLC) as a cornerstone in CVD risk reduction in both men and women, scarce comprehensive data are available on the effect of gender on responses to TLC. **Objectives:** In this study, we compared the clinical effectiveness of TLC in 2,144 consecutive men (n=543; age=47+/-10 years) and women (n=1,601; age=46+/-10 years) with an elevated blood pressure, LDL cholesterol, and/or fasting plasma glucose level who were not taking medication for hypertension, hyperlipidemia, or diabetes. **Methodology:** Subjects were evaluated at baseline and after approximately 12 weeks of participation in a community-based lifestyle management program. TLC included exercise training, nutrition, weight management, stress management, and smoking cessation interventions. All subjects remained off antihypertensive, antilipemic, and antidiabetic medications throughout the study. **Results:** Among subjects with abnormal baseline CVD risk factors (based on national guidelines), clinically relevant improvements ( $p \leq 0.05$ ) were observed for multiple variables, including: systolic/diastolic blood pressure (Men, -7/-6 mmHg; Women, -10/-7 mmHg;  $p \leq 0.05$  for Men versus Women); LDL cholesterol (Men, -18 mg/dl; Women, -11 mg/dl;  $p \leq 0.05$  for Men versus Women); HDL cholesterol (Men, 2 mg/dl; Women, 4 mg/dl;  $p=NS$  for Men versus Women); triglycerides (Men, -55 mg/dl; Women, -49 mg/dl;  $p=NS$  for Men versus Women); fasting glucose (Men, -10 mg/dl; Women, -9 mg/dl;  $p=NS$  for Men versus Women); and weight (Men, -7 lbs; Women, -5 lbs;  $p \leq 0.05$  for Men versus Women). In subjects with a calculated Framingham 10-year coronary heart disease risk score  $\geq 10\%$  at baseline, the score decreased significantly ( $p \leq 0.05$ ) in men (-18.8%) and women (-18.9%);  $p=NS$  for Men versus Women. **Conclusions:** These data demonstrate the similar clinical effectiveness of TLC in men and women with an elevated blood pressure, LDL cholesterol, and/or fasting plasma glucose level.

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#### MULTI-CENTER STUDY OF RISK FACTOR STATUS ON ENTRY INTO CARDIAC REHABILITATION: MALE VERSUS FEMALE PATIENTS

Adam T. deJong, MA; Barry A. Franklin, PhD; Richard D. Salmon, DDS; Kevin S. Reid, MA; William E. Saxon, ASRT; George C. Faircloth, MHA; Brenda S. Wright, PhD; Richard F. Leighton, MD; and Neil Gordon, MD. William Beaumont Hospital, Royal Oak, MI, St. Joseph's/Candler Health System, Savannah, GA, and INTERVENT Coordinating Center, Savannah, GA.

60.

**Rationale:** Contemporary cardiac rehabilitation (CR) programs provide comprehensive cardiovascular disease (CVD) risk reduction interventions aimed at the control of multiple risk factors. Guidelines are available on goals for each risk factor. However, no comprehensive gender-specific data are available on the percentage of participants who are not already at recommended goal risk factor levels on entry into a contemporary phase 2 CR program. **Objectives:** In this multi-center study, we compared the percentage of participants not at goal for select risk factors in male versus female patients at entry into a phase 2 CR program. **Methodology:** Subjects were 11,148 consecutive male (Group A; n=7,725; age=65+/-11 years) and female (Group B; n=3,423; age=66+/-12 years) patients who enrolled in a phase 2 CR program at 30 centers in the United States after May 16, 2001 (i.e., the publication date of the National Cholesterol Education Program Adult Treatment Panel III Guidelines). Risk factors were evaluated using standardized procedures. **Results:** Results are shown in the table.

<u>CVD Risk Factor</u>	<u>Goal (Based on National Clinical Guidelines)</u>	<u>% Not At Goal, Group A</u>	<u>% Not At Goal, Group B</u>	<u>P (Group A versus Group B)</u>
Cigarette smoking	Smoking cessation	6.7	6.3	NS
Systolic BP	<120 mm Hg	57.8	64.3	<0.001
Diastolic BP	<80 mm Hg	29.4	26.0	<0.001
LDL cholesterol	<100 mg/dl	41.0	47.4	<0.001
HDL cholesterol	>39 mg/dl	52.7	22.9	<0.001
Triglycerides	<150 mg/dl	40.7	47.2	<0.001
Body Mass Index	<25 kg/m <sup>2</sup>	80.2	72.9	<0.001
Fasting glucose	<100 mg/dl	62.2	56.3	<0.001
Sedentary lifestyle	>149 min/wk	78.2	88.1	<0.001

**Conclusion:** These data indicate that multiple risk factors are often inadequately controlled at entry into a contemporary phase 2 CR program. Our findings further indicate that gender-specific differences exist for multiple risk factors. These data are relevant to CR programs when prioritizing, designing, and developing comprehensive risk reduction interventions.

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#### MULTI-CENTER STUDY OF RISK FACTOR STATUS ON COMPLETION OF A CONTEMPORARY PHASE 2 CARDIAC REHABILITATION PROGRAM: MALE VERSUS FEMALE PATIENTS

Diane Vogel, RN, BS; Barry A. Franklin, PhD; Richard D. Salmon, DDS; Kevin S. Reid, MA; William E. Saxon, ASRT; George C. Faircloth; Brenda S. Wright, PhD; Richard F. Leighton, MD; and Neil Gordon, MD. Bryan LGH Medical Center, Lincoln, NE, St. Joseph's/Candler Health System, Savannah, GA, and INTERVENT Coordinating Center, Savannah, GA

61.

**Rationale:** No comprehensive gender-specific data are available on the percentage of participants who are still not at recommended cardiovascular disease (CVD) risk factor goal levels on completion of a contemporary phase 2 cardiac rehabilitation (CR) program and, therefore, in need of additional intervention. **Objectives:** In this multi-center study, we compared the percentage of participants not at goal

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for select risk factors in male versus female patients on exit from a phase 2 CR program. **Methodology:** Subjects were 4,873 consecutive male (Group A; n=3,511; age=66+/-11 years) and female (Group B; n=1,362; age=68+/-11 years) patients who enrolled in a phase 2 CR program at 30 centers in the United States after May 16, 2001 (i.e., the publication date of the National Cholesterol Education Program Adult Treatment Panel III Guidelines) and subsequently completed an exit evaluation on program completion. Risk factors were evaluated using standardized procedures. **Results:** Results are shown in the table.

CVD Risk Factor	Goal (Based on National	% Not At Goal,	% Not At Goal,	P (Group A versus Group B)
	Clinical Guidelines)	Group A	Group B	
Cigarette smoking	Smoking cessation	4.1	3.6	NS
Systolic BP	<120 mm Hg	54.2	55.0	NS
Diastolic BP	<80 mm Hg	22.6	17.9	<0.001
LDL cholesterol	<100 mg/dl	26.6	37.5	<0.001
HDL cholesterol	>39 mg/dl	46.6	18.1	<0.001
Triglycerides	<150 mg/dl	33.0	42.2	<0.001
Body Mass Index	<25 kg/m <sup>2</sup>	79.3	69.2	<0.001
Fasting glucose	<100 mg/dl	59.3	49.5	<0.02
Sedentary lifestyle	>149 min/wk	48.8	53.7	<0.01

**Conclusion:** These data indicate that multiple CVD risk factors are often inadequately controlled on exit from a contemporary phase 2 CR program. Our findings further indicate that gender-specific differences exist for multiple risk factors. These data emphasize the urgent need for ongoing risk reduction interventions in post-phase 2 CR program participants.

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**HEALTH RISK APPRAISAL ONLY VS. TARGETED DISEASE MANAGEMENT FOR WORKSITE CARDIOVASCULAR RISK REDUCTION**

David J. Maron, Barbara L. Forbes, Jay R. Groves, Vanderbilt University Medical Center, Nashville, TN; Mary S. Dietrich, Vanderbilt University, Nashville, TN; Patrick Sells, Belmont University, Nashville, TN; Andres G. DiGenio, Pfizer Inc., Groton, CT

62.

**Objective:** To evaluate the effectiveness of health risk appraisal (HRA) only compared with health risk appraisal followed by targeted disease management (DM) among employees at increased risk for cardiovascular disease. **Methods:** We randomized 133 high-risk employees to HRA and DM conditions. Subjects randomized to DM received individualized counseling for nutrition, exercise, smoking cessation, and weight control. This intervention was delivered using a commercial, evidence-based cardiovascular disease risk reduction program. When indicated by national guidelines, medications for control of hypertension and high cholesterol were recommended to DM subjects and their physicians. The primary endpoint of the study was the mean change, compared with baseline, of the Framingham Risk Score at one year of follow-up in each group. **Results:** The difference noted between groups in baseline Framingham Risk Scores was not statistically significant (p=0.279). The DM group had a significant decrease in the mean Framingham Risk Score (-1.33, decrease of 22.6%), while the HRA group had a non-significant rise in the mean Framingham Risk Score from baseline to one year (+0.20, increase of 4.3%). The difference between DM and HRA groups in the mean changes in risk scores from baseline was statistically significant (p=0.017). **Conclusions:** Among employees with increased cardiovascular risk, a targeted DM program is more effective.

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**MULTI-CENTER STUDY OF THE PREVALENCE OF THE METABOLIC SYNDROME AND ITS COMPONENT RISK FACTORS ON ENTRY INTO A PHASE 2 CARDIAC REHABILITATION PROGRAM**

Thomas Draper, MBA; Melvyn Rubenfire, MD; Richard Salmon, DDS; Kevin Reid, MA; William Saxon, ASRT; George Faircloth, MHA; Brenda Wright, PhD; Richard Leighton, MD; Barry Franklin, PhD; and Neil Gordon, MD. University of Michigan, Ann Arbor, MI, St. Joseph's/Candler Health System, Savannah, GA, and INTERVENT Coordinating Center, Savannah, GA.

63.

**Rationale:** The metabolic syndrome (MS) is a constellation of interrelated coronary heart disease (CHD) risk factors of metabolic origin (MS risk factors) that influence first and subsequent cardiovascular event rates. No comprehensive, multi-center data are available on the prevalence of MS and its component MS risk factors on entry into a contemporary phase 2 cardiac rehabilitation (CR) program.

**Objectives:** In this multi-center study, we determined the prevalence of MS and its component MS risk factors on entry into a contemporary phase 2 CR program.

**Methodology:** Subjects were 15,714 consecutive male (69.6%) and female (30.4%) patients (age = 66±12 years) who enrolled in a phase 2 CR program in 37 sites in North America. MS and its 5 individual component MS risk factors were defined in accordance with the National Cholesterol Education Program Adult Treatment Panel III Guidelines, with the exception that a fasting glucose ≥100 mg/dl (rather than ≥ 110 mg/dl) was used. Electronic medical records were analyzed to categorize MS status as follows: MS present (i.e., presence of ≥3 MS risk factors), MS absent (i.e., definite absence of ≥3 MS risk factors), or MS indeterminate (i.e., incomplete data). In patients with MS and data on all 5 individual component MS risk factors, data were further analyzed to determine the number and percentage of patients with 3, 4, or 5 MS risk factors and the prevalence of each of the individual MS risk factors.

**Results:** MS status could be determined in 7,590 (48.3 %) of patients. In these patients, MS was present in 3,512 (46.3 %) and absent in 4,078 (53.7 %) patients. Results for patients (n = 2,105) with MS and data on all 5 MS risk factors are shown in the table.

MS Risk Factors	Number of Patients	%	Rank
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3 MS Risk Factors	1,104	52.4 %	
4 MS Risk Factors	764	36.3 %	
5 MS Risk Factors	237	11.3 %	
waist	1,598	75.9 %	3
triglyceride	1,410	67.0 %	4
HDL	1,649	78.3 %	2
BP	1,162	55.2 %	5
glucose	1,734	82.4 %	1

**Conclusion:** These data indicate that MS and multiple MS risk factors are commonly present at entry into a contemporary phase 2 CR program. The findings characterize the magnitude of lifestyle related risk factors. These data are relevant to CR programs when prioritizing, designing, and developing comprehensive risk reduction interventions with an emphasis on specific nutrition and exercise recommendations.

2006 – AACVPR Annual Meeting

**PREVALENCE OF THE METABOLIC SYNDROME AND ITS COMPONENT RISK FACTORS ON ENTRY INTO A COMPREHENSIVE LIFESTYLE MANAGEMENT/CARDIOVASCULAR RISK REDUCTION PROGRAM**

Neil Gordon, MD; Thomas Draper, MBA; Melvyn Rubenfire, MD; Richard Salmon, DDS; Kevin Reid, MA; William Saxon, ASRT; George Faircloth, MHA; Brenda Wright, PhD; Richard Leighton, MD; and Barry Franklin, PhD. St. Joseph's/Candler Health System and INTERVENT Coordinating Center, Savannah, GA.

64.

**Rationale:** The metabolic syndrome (MS) is a constellation of interrelated risk factors of metabolic origin (MS risk factors) that are strongly influenced by lifestyle.

**Objectives:** In this study, we determined the prevalence of MS and its component MS risk factors on entry into a national comprehensive lifestyle management/cardiovascular disease (CVD) risk reduction program (the INTERVENT program) specifically designed to function outside of a formal/traditional cardiac rehabilitation program setting.

**Methodology:** Subjects were 20,304 consecutive adult (age = 49 ± 12 years) males (26.5%) and females (73.5%) who completed an initial evaluation as part of the INTERVENT program. MS risk factors were evaluated using standardized procedures and entered into an electronic medical record. MS and its 5 individual component MS risk factors were defined in accordance with the National Cholesterol Education Program Adult Treatment Panel III Guidelines, with the exception that a fasting glucose ≥100 mg/dl (rather than ≥ 110 mg/dl) was used. Electronic medical records were analyzed to categorize MS status as follows: MS present (i.e., presence of ≥3 MS risk factors), MS absent (i.e., definite absence of ≥3 MS risk factors), or MS indeterminate (i.e., not possible to definitively identify or exclude MS due to incomplete data). In individuals with MS and data on all 5 individual MS risk factors, data were further analyzed to determine the number and percentage of individuals with 3, 4, or 5 MS risk factors and the prevalence of each of the individual MS risk factors.

**Results:** Of the study subjects, 89.4 % did not have a diagnosis of known CVD. MS status could be determined in 17,169 (84.6 %) individuals. In these subjects, MS was present in 5,398 (31.4 %) and absent in 11,771 (68.6 %) individuals. Results for individuals (n = 4,641) with MS and data on all 5 MS risk factors are shown in the table.

MS Risk Factors	Number of Individuals	%	Rank
3 MS Risk Factors	2,574	55.5 %	
4 MS Risk Factors	1,540	33.2 %	
5 MS Risk Factors	527	11.4 %	
Positive waist	4,054	87.4 %	1
Positive triglyceride	3,004	64.7 %	4
Positive HDL	3,176	68.4 %	3
Positive BP	3,395	73.2 %	2
Positive glucose	2,888	62.2 %	5

**Conclusion:** These data indicate that MS and multiple MS risk factors are very commonly present at entry into a comprehensive lifestyle management/CVD risk reduction program. Our findings are particularly relevant when designing and prioritizing components of programs to foster comprehensive lifestyle management and CVD risk reduction outside of a formal cardiac rehabilitation setting.

2006 – AACVPR Annual Meeting

**CLINICAL EFFECTIVENESS OF THERAPEUTIC LIFESTYLE CHANGES IN PATIENTS WITH PREHYPERTENSION**

Venkata V. Bavikati, MBBS; Laurence S. Sperling, MD; Richard D. Salmon, DDS; George C. Faircloth, MHA; Richard F. Leighton, MD; Barry A. Franklin, PhD; and Neil F. Gordon, MD. Emory University School of Medicine, Atlanta, GA, St. Joseph's/Candler Health System, Savannah, GA, and INTERVENT Coordinating Center, Savannah, GA

65.

**Rationale:** Prehypertension is a precursor of hypertension and an established predictor of excessive cardiovascular risk. Although national clinical guidelines promulgate therapeutic lifestyle changes (TLC) as a cornerstone in the management of prehypertension, recent research has focused on the use of pharmacotherapy due to the perceived ineffectiveness of TLC in daily clinical practice.

**Objectives:** In this study of 2,478 ethnically diverse (African Americans, n = 448; Caucasians, n = 1,881) men (n = 666) and women (n =

1,812) with prehypertension who were not taking antihypertensive medication (age = 48±10 years), we evaluated the clinical effectiveness of TLC in helping patients normalize their blood pressure (BP) without using drug therapy.

**Methodology:** Subjects were evaluated at baseline and after an average of approximately 6 months of participation in a community-based lifestyle management program (the INTERVENT program). At baseline, all subjects met the criteria for the diagnosis of prehypertension as defined by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7), namely, a systolic BP of 120-139 mmHg and a diastolic BP ≤ 89 mmHg or a diastolic BP of 80-89 mmHg and a systolic BP ≤ 139 mmHg. Subjects did not have known atherosclerotic cardiovascular disease, diabetes, or chronic kidney disease at baseline. TLC included exercise training, nutrition, weight management, stress management, and smoking cessation interventions. All subjects remained off antihypertensive medications throughout the study.

**Results:** Baseline systolic BP (125±8 mmHg) decreased by 6±12 mmHg ( $p \leq 0.001$ ) and baseline diastolic BP (79±3 mmHg) decreased by 3±3 mmHg ( $p \leq 0.001$ ) with TLC. In subjects with a baseline systolic BP of 120-139 mmHg ( $n=2,082$ ), systolic BP decreased by 7±12 mmHg ( $p \leq 0.001$ ) with TLC. In subjects with a baseline diastolic BP of 80-89 mmHg ( $n=1,504$ ), diastolic BP decreased by 6±3 mmHg ( $p \leq 0.001$ ) with TLC. Based on JNC 7 criteria, 952 (39%) subjects normalized their BP (i.e., achievement of both a systolic BP <120 mmHg and a diastolic BP <80 mmHg) with TLC ( $p \leq 0.001$ ).

**Conclusions:** The present study adds to previous research by reporting on the effectiveness (i.e., extent to which TLC works in actual practice) rather than on the efficacy (i.e., determining whether TLC can work when administered in a clinical trial) of TLC in patients with prehypertension. Although further research is warranted, these data clearly show that many patients with prehypertension can normalize their BP with TLC. The data have important clinical and cost-containment implications for physicians and their patients.

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66.

#### SELF REPORTED DEPRESSION IS ASSOCIATED WITH DECREASED BUT CONSIDERABLE BENEFIT FROM PHASE 2 CARDIAC REHABILITATION

Melvyn Rubenfire, Thomas Draper, Katherine Smith, University of Michigan Health System, Ann Arbor, MI; Richard Salmon, Kevin Reid, William Saxon, George Faircloth, Brenda Wright, Richard Leighton, Barry Franklin, Neil Gordon, St. Joseph's/Candler Health System and INTERVENT Coordinating Center, Savannah, GA

**Background:** Depressed patients with cardiovascular disease (CVD) are less likely to take prescribed medications and adhere to appropriate lifestyle changes. **Objective:** We sought to determine how depression impacts the benefit of a contemporary Phase 2 cardiac rehabilitation program (CRehab). **Methods:** 14,007 participants in 37 centers in North America were stratified by self reported current or previous depression to compare the effect of CRehab on classic CVD risk factors. Risk factors were evaluated at baseline and after an average of 12 weeks of participation. **Results:** Depression was present in 2,767 patients (19.75%) (mean age 64.2±11.5 years) and 11,240 had no depression (age 66.5±11.6 years). Those with depression at baseline were less likely to complete the exit evaluation (depression, 41.7% completion; no depression, 47.9% completion;  $P < .05$ ). On exit from CRehab, improvements (each  $P < .05$ ) in classic CVD risk factors were observed for participants with and without a self-reported history of depression who had abnormal baseline values based on national guidelines. Although highly relevant and significant, the magnitude of benefit in those with depression was less for reduction in total and LDL cholesterol, triglycerides, and diastolic BP. Patients with depression were more often current cigarette smokers at program entry (depression, 10.6%; no depression, 5.7%;  $P < .05$ ); however, both groups of patients were equally successful in quitting (depression, 17.8% of smokers quit; no depression, 19.3% of smokers quit;  $p = NS$ ). **Conclusions:** Patients with self-reported current and previous depression may derive less, but still gain considerable benefit from contemporary Phase 2 CRehab. The effect of depression on long term compliance with the principles of CRehab needs to be determined.

	<i>Change in Value from Baseline</i>		<i>P Value between groups</i>
	<i>History of Depression</i>	<i>No Depression</i>	
Total Cholesterol	-36 mg/dl	-47 mg/dl	$P < .05$
LDL Cholesterol	-26 mg/dl	-32 mg/dl	$P < .05$
HDL Cholesterol	4 mg/dl	4 mg/dl	NS
Triglycerides	-37 mg/dl	-49mg/dl	$P < .05$
Fasting Glucose	-18 mg/dl	-15mg/dl	NS
Systolic BP	-10 mmHg	-10 mmHg	NS
Diastolic BP	-10 mmHg	-11 mmHg	$P < .05$
Weight	-3.7 lbs	-3.9 lbs	NS
Quitting Smoking	17.8%	19.3%	NS

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67.

#### THE DEFINITION FOR RISK FACTORS HAS A SIGNIFICANT IMPACT ON THE PREVALENCE OF THE METABOLIC SYNDROME

Thomas A Draper, Melvyn Rubenfire, University of Michigan Health System, Ann Arbor, MI; Richard Salmon, Kevin Reid, William Saxon, George Faircloth, Brenda Wright, Richard Leighton, Barry Franklin, Neil Gordon, St. Joseph's/Candler Health System and INTERVENT Coordinating Center, Savannah, GA

**Background:** The metabolic syndrome (MS) is a constellation of interrelated cardiovascular disease (CVD) risk factors of metabolic origin. The AHA and NHLBI jointly recently revised the criteria to diagnose MS with changes in criteria for reduced HDL-C, hypertension, elevated glucose, and elevated triglycerides. **Objective:** To determine the impact the revision of the criteria had on the prevalence of MS. **Methods:**

The prevalence of MS was assessed in 19,097 individuals who had data for all 5 MS risk factors using both the AHA/NHLBI revised and non-revised criteria. Subjects were 4,411 consecutive adult (age = 66±11 years) males (70.8%) and females who enrolled in a phase 2 cardiac rehabilitation program (Group A; CVD = 94.8%) and 14,686 consecutive adult (age = 48.9±12 years) males (25.9%) and females who enrolled in a national comprehensive lifestyle management/CVD risk reduction program (Group B; CVD = 10.1%). For the non-revised prevalence determinations for MS and its 5 individual components, MS risk factors were defined in accordance with the original ATP III Guidelines, with the exception of a fasting glucose ≥100 mg/dl (rather than ≥ 110 mg/dl). The revised prevalence determinations included each parameter and medication use. **Results:** The prevalence of MS in cardiac rehabilitation patients increased by about 25% using the revised criteria but remained at about 1/3<sup>rd</sup> of participants in the lifestyle/CVD risk reduction program. **Conclusion:** 1) Whether the AHA/NHLBI ATP III revised or non-revised criteria are used, MS is commonly present at entry into lifestyle management/CVD risk reduction programs (especially a phase 2 cardiac rehabilitation program); 2) the implication of the AHA/NHLBI's recent revisions depends on the precise population under evaluation; 3) the findings are particularly relevant to expectations from and comparing results of programs, and when developing comprehensive risk reduction interventions with an emphasis on nutrition and exercise.

Group	Prevalence of MS - Revised		
	Prevalence of MS - Non-revised Criteria	Criteria	% Relative Increase in Prevalence
Group A	48.7% (n = 2,105)	59.6 % (n = 2,628)	24.8% (p<0.001)
Group B	31.6% (n = 4,641)	34.1% (n = 5,004)	7.8% (p<0.001)

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#### EFFECT OF GENDER AND ETHNICITY ON EFFECTIVENESS OF THERAPEUTIC LIFESTYLE CHANGES IN PATIENTS WITH PREHYPERTENSION

Venkata V. Bavikati, MBBS, MPH; Laurence S. Sperling, MD; Richard D. Salmon, DDS; George C. Faircloth, MHA; Terri L. Gordon; Barry A. Franklin, PhD; and Neil F. Gordon, MD. Emory University School of Medicine, Atlanta, GA and INTERVENT Coordinating Center, Savannah, GA

68.

**Rationale:** Although national clinical guidelines promulgate therapeutic lifestyle changes (TLC) as a cornerstone in the management of prehypertension, recent research has focused on the use of pharmacotherapy due to the perceived ineffectiveness of TLC.

**Background:** In this study of 2,478 ethnically diverse (African Americans, n = 448; Caucasians, n = 1,881) men (n = 666) and women (n = 1,812) with prehypertension who were not taking antihypertensive medications (age = 48±10 years), we evaluated the clinical effectiveness of TLC in normalizing their blood pressure (BP) without using drug therapy.

**Methodology:** Subjects were evaluated at baseline and after an average of 6 months of participation in a community-based program of TLC. At baseline, all subjects met the criteria for prehypertension as defined by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7). Subjects did not have known atherosclerotic heart disease, diabetes, or chronic kidney disease. TLC included exercise training, nutrition, weight management, and smoking cessation interventions.

**Results:** Baseline BP (125±8/79±3 mmHg) decreased by 6±12/3±3 mmHg (p ≤0.001) with TLC. In subjects with a baseline systolic BP of 120-139 mmHg (n=2,082), systolic BP decreased by 7±12 mmHg (p ≤0.001) with TLC. In subjects with a baseline diastolic BP of 80-89 mmHg (n=1,504), diastolic BP decreased by 6±3 mmHg (p ≤0.001) with TLC. Based on JNC 7 criteria, 952 (39%) subjects normalized their BP with TLC (p ≤0.001). The magnitude of reduction in BP was similar in African Americans (7±12/5±3 mmHg) and Caucasians (7±12/6±3 mmHg). In contrast, the magnitude of reduction in BP was greater (p ≤0.001) in women (8±12/6±3 mmHg) versus men (6±11/5±3 mmHg).

**Conclusions:** The present study adds to previous research by reporting on the effectiveness (rather than the efficacy) of TLC in an ethnically diverse group of men and women with prehypertension. Although further research is warranted, these data show that while many patients with prehypertension can normalize their BP, there are gender-related differences in BP responsiveness to TLC.

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#### EVALUATION OF A NOVEL HEART RATE MONITOR: COMPARISON WITH TELEMTRY ELECTROCARDIOGRAPHY

Richard Salmon, DDS; William Saxon, Jr, ASRT; Tiana Speight, BS; Ami Drimmer, PhD, Julie Blakely, BS; Megan Zamora, BS; Chip Faircloth, MHA; and Neil Gordon, MD. St. Joseph's/Candler Health System, Savannah, GA and INTERVENT Coordinating Center, Savannah, GA

69.

**Rationale:** Heart rate is widely used as an index of intensity when prescribing exercise training for healthy individuals and, especially, cardiac patients. Accurate measurement is critical when using target heart rates to prescribe exercise intensity. Many commercially available heart rate monitors are limited by the need to wear a strap-like device around the chest.

**Objectives:** In this study of 10 participants in a phase 2 cardiac rehabilitation program and 10 non-cardiac rehabilitation participants, we evaluated the accuracy of a heart rate monitor (HRM) that uses blue LED technology to monitor heart rate with a finger- rather than a chest-sensor device.

**Methodology:** Subjects were 20 male and female volunteers (age = 54±18 years; males = 11; females = 9). Subjects exercised for 20 minutes on a treadmill, at a speed and gradient that were individually regulated to achieve a perceived exertion rating of between 11 and 15 (Borg 6-20 scale), while wearing the HRM watch (Seiko-Epson Corporation, Japan) on their wrist and sensor device on their index finger. Heart rates were continually monitored during exercise using the HRM and telemetry electrocardiography (Scott Care, United States). Comparisons were made of heart rates recorded using the HRM and telemetry electrocardiography at 5, 10, 15, and 20 minutes of treadmill

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exercise.

**Results:** Perceived exertion ratings were 11±1, 12±1, 13±3, and 13±1 at 5, 10, 15, and 20 minutes of treadmill exercise, respectively. Heart rates were as follows:

Time (mins)	Telemetry	HRM	P	r
5	116 ± 14	116 ± 15	NS	0.990
10	126 ± 21	129 ± 21	NS	0.996
15	134 ± 22	132 ± 22	NS	0.989
20	136 ± 25	134 ± 24	NS	0.997

**Conclusions:** The present study documents the high degree of accuracy during treadmill exercise of a novel HRM that does not require the use of a chest device.

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**EFFECT OF GENDER ON EFFECTIVENESS OF THERAPEUTIC LIFESTYLE CHANGES IN MEN AND WOMEN WITH PREDIABETES**

Richard D. Salmon, DDS, MBA; Neil F. Gordon, MD, PhD, MPH; William E. Saxon Jr., ASRT, Nationwide Better Health

70.

**Rationale:** Prediabetes affects an estimated 54 million Americans. Prediabetes is a precursor of diabetes and a predictor of excessive risk for cardiovascular disease. Recent research has documented gender-related differences in the responsiveness of multiple cardiovascular disease risk factors to lifestyle and pharmacologic interventions. In this study of 967 men (n = 399; age = 56.9±11.5 years) and women (n = 568; age = 55.4±11.4 years) with prediabetes, we evaluated the effect of gender on the effectiveness of therapeutic lifestyle changes (TLC) in normalizing fasting plasma glucose without using drug therapy.

**Methodology:** At baseline, all participants met the American Diabetes Association's criteria for prediabetes (i.e., fasting plasma glucose = 100 to 125 mg/dl). Participants were evaluated at baseline and after an average of ~ 4 months of TLC. TLC included exercise training, nutrition, weight management, and smoking cessation interventions.

**Results:** In male participants, baseline fasting plasma glucose (108±6 mg/dl) decreased by 5±13 mg/dl (p ≤0.001) with TLC. Similarly, baseline fasting plasma glucose (107±6 mg/dl) decreased by 5±13 mg/dl (p ≤0.001) with TLC in female participants. Based on American Diabetes Association criteria, 172 (43.1%) men and 250 (44.0%) women normalized their fasting plasma glucose (i.e., fasting plasma glucose below 100 mg/dl) with TLC. Thus, both the magnitude of reduction in fasting plasma glucose and the percentage of participants who normalized their fasting plasma glucose with TLC did not differ significantly for male versus female participants.

**Conclusions:** The present study adds to previous research by reporting on the effectiveness (rather than the efficacy) of TLC in men and women with prediabetes. The data show that many individuals with prediabetes can normalize their fasting plasma glucose with TLC and, in contrast to certain other cardiovascular disease risk factors, there do not appear to be gender-related differences in responsiveness to TLC.

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**GENDER ALTERS THE RESPONSIVENESS OF MULTIPLE CARDIOVASCULAR DISEASE RISK FACTORS TO A LIFESTYLE MANAGEMENT AND RISK REDUCTION PROGRAM IN PARTICIPANTS WITH PREHYPERTENSION**

Richard D. Salmon, DDS, MBA; Neil F. Gordon, MD, PhD, MPH; Kevin S. Reid, MA, Nationwide Better Health

71.

**Rationale:** Prehypertension is associated with the presence of other cardiovascular disease (CVD) risk factors and with excess morbidity and mortality. In this study, we evaluated the effect of gender on the responsiveness of multiple CVD risk factors to a lifestyle management/risk reduction program in individuals with prehypertension. **Methodology:** Subjects were 666 men and 1,812 women with prehypertension who were not taking antihypertensive medications and did not have known CVD, diabetes, or chronic kidney disease. Subjects were evaluated at baseline and after ~ 6 months of participation in a lifestyle management/risk reduction program. Lifestyle intervention included exercise training, nutrition, weight management, and smoking cessation interventions. Although participants did not receive antihypertensive medication, they were referred to their physicians for consideration of medication changes for the modification of other risk factors in accordance with national guidelines.

**Results:** For participants with abnormal baseline risk factors, clinically relevant improvements were observed for multiple variables in men and women, as follows

(p <0.05): systolic/diastolic blood pressure (Males, -6/-5 mmHg; Females, -8/-6 mmHg); LDL cholesterol (Males, -21 mg/dl; Females, -13 mg/dl); HDL cholesterol (Males, 2 mg/dl; Females, 3 mg/dl); triglycerides (Males, -73 mg/dl; Females, -36 mg/dl); and weight (Males, -7.1 lbs; Females, -5.1 lbs). Whereas blood pressure was reduced to a greater degree (p ≤0.05) in females, LDL cholesterol, triglycerides, and weight were reduced to a greater degree (p ≤0.05) in males. In participants with a baseline 10-year Framingham coronary heart disease risk score ≥10%, the score decreased (p ≤0.05) by 15.5% in males and 19.3% in females (p=NS for males versus females).

**Conclusions:** This study is the first, to our knowledge, to show that while both males and females with prehypertension derive favorable improvements in multiple CVD risk factors by participating in a lifestyle management/risk reduction program, there are gender-related differences in therapeutic responsiveness.

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**EFFECT OF A CONTEMPORARY CARDIAC REHABILITATION PROGRAM ON SELF-REPORTED HEALTH STATUS: MYOCARDIAL INFARCTION VERSUS BYPASS SURGERY PATIENTS**

INTERVENT:

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<p>Meeting 72.</p>	<p>Adam deJong, Susan Haapaniemi, Barry A. Franklin, FACS, Johnny E. Case, Allan Lewis, Richard D. Salmon, Neil F. Gordon, FACS, William Beaumont Hospital, Royal Oak, MI; Memorial Health Care System, Chattanooga, TN; and Nationwide Better Health, Savannah, GA</p> <p>Substantial changes occurred in the core components of cardiac rehabilitation (CR) during the 1990s and first decade of the new millennium. These changes have raised concerns about the relevance of findings from earlier studies on the effect of early outpatient CR (Phase 2 CR) on various outcome measures, including self-reported health status.</p> <p><b>Purpose:</b> In this multicenter study, we investigated the effect of a contemporary phase 2 CR program on self-reported health status in 4,791 post-myocardial infarction patients (Group A, n=2,154) versus post-coronary artery bypass graft surgery patients (Group B, n=2,637).</p> <p><b>Methods:</b> Self-reported health status was assessed using the SF-36 at baseline and after approximately 12 weeks of participation in a contemporary phase 2 CR program.</p> <p><b>Results:</b> On program exit, improvements (<math>p &lt; 0.05</math> for within group change from baseline) in SF-36 transformed scores were observed, as follows: physical functioning (Group A, 13; Group B, 19); role-physical (Group A, 35; Group B, 41); bodily pain (Group A, 13; Group B 22); general health (Group A, 4; Group B, 3); vitality (Group A, 10; Group B, 12); social functioning (Group A, 17; Group B, 23); role-emotional (Group A, 12; Group B, 16); and mental health (Group A, 6; Group B, 6). With the exception of general health (slightly greater improvement in Group A versus Group B patients) and mental health (no difference between groups), the magnitude of improvement from baseline was significantly greater (<math>p &lt; 0.05</math>) for Group B versus Group A patients.</p> <p><b>Conclusion:</b> These data serve to document the magnitude of improvement in self-reported health status in post-myocardial infarction and post-coronary artery bypass graft surgery patients in response to participation in a contemporary phase 2 CR program. The data demonstrate that both groups of patients experience significant improvements in multiple indices of self-reported health status and that the magnitude of improvement differs for certain indices in post-myocardial infarction versus post-coronary artery bypass graft surgery patients.</p>
<p>2008- AACVPR Annual Meeting 73.</p>	<p><b>EFFECT OF A LIFESTYLE HEALTH COACHING PROGRAM ON MULTIPLE CARDIOVASCULAR DISEASE RISK FACTORS IN PARTICIPANTS WITH CLASSES I, II, AND III OBESITY</b></p> <p>Neil F. Gordon, MD, PhD, Richard D. Salmon, DDS, MBA, David A. Alter, MD, PhD, Barry A. Franklin, PhD. Nationwide Better Health, Columbus, OH; University of Toronto, Canada; and William Beaumont Hospital, Royal Oak, MI.</p> <p><b>Introduction:</b> Scarce comprehensive data are available on the effect of lifestyle health coaching on multiple cardiovascular disease (CVD) risk factors in individuals with Classes I, II and III obesity.</p> <p><b>Purpose:</b> In this study, we evaluated the effect of lifestyle health coaching on multiple CVD risk factors in 3,613 obese individuals with Class I (i.e., body mass index [BMI]=30-34.9 kg/m<sup>2</sup>; n=1,933), Class II (i.e., BMI=35-39.9 kg/m<sup>2</sup>; n= 820), or Class III (i.e., BMI &gt;39.9 kg/m<sup>2</sup>; n= 860) obesity.</p> <p><b>Design:</b> Outcome measures were assessed at baseline and after approximately 1 year of participation in a lifestyle health coaching program.</p> <p><b>Methods:</b> Lifestyle health coaching included exercise training, nutrition, weight management, stress management and smoking cessation interventions. Coaching was provided primarily via the telephone. Statistical analyses were performed using paired and unpaired t-tests. Statistical significance was established at <math>p &lt; 0.05</math>.</p> <p><b>Results:</b> Weight (Class I, -4.8 lbs; Class II, -6.6 lbs; Class III, -11.4 lbs) and BMI (Class I, -0.8 kg/m<sup>2</sup>; Class II, -1.1 kg/m<sup>2</sup>; Class III, -1.9 kg/m<sup>2</sup>) decreased significantly in participants in all 3 classes (<math>p &lt; 0.05</math> for Class III versus II, Class III versus I, and Class II versus I). For participants with abnormal baseline risk factors (based on national guidelines), significant improvements were observed for multiple additional variables, as follows: blood pressure (Class I, -8/7 mmHg; Class II, -9/7 mmHg; Class III, -8/7 mmHg); LDL cholesterol (Class I, -22 mg/dl; Class II, -19 mg/dl; Class III, -18 mg/dl); HDL cholesterol (Class I, 5 mg/dl; Class II, 4 mg/dl; Class III, 3 mg/dl); triglycerides (Class I, -39 mg/dl; Class II, -39 mg/dl; Class III, -41 mg/dl); and fasting glucose (Class I, -7 mg/dl; Class II, -4 mg/dl; Class III, -14 mg/dl). In participants with a baseline Framingham 10-year coronary heart disease risk score <math>\geq 10\%</math>, the score decreased significantly in participants in all 3 classes (Class I, -22.6%; Class II, -20.4%; Class III, -22.7%; <math>p = NS</math> for the differences between classes).</p> <p><b>Conclusions:</b> These data serve to document the magnitude of improvement in multiple CVD risk factors in individuals with Classes I, II and III obesity in response to participation in 1 year of lifestyle health coaching. The data demonstrate that while weight loss is greatest for participants with Class III obesity, the magnitude of improvement in the Framingham 10-year coronary heart disease risk score is similar for all 3 classes of obese participants.</p>
<p>2008- DMAA Annual Meeting 74.</p>	<p><b>EFFECT OF LIFESTYLE HEALTH COACHING ON SELF-REPORTED HEALTH STATUS IN PARTICIPANTS WITH CLASSES I, II, AND III OBESITY</b></p> <p>Neil F. Gordon, MD, PhD, MPH, Richard D. Salmon, DDS, MBA, and William E. Saxon Jr., ASRT. Nationwide Better Health, Columbus, OH.</p> <p><b>Rationale:</b> Despite unprecedented public attention, the obesity epidemic continues virtually unabated in the U.S. In this study, we evaluated the effect of 1 year of lifestyle health coaching (LHC) on self-reported health status in participants with classes I, II, and III obesity.</p> <p><b>Methodology:</b> Subjects were 3,613 adults with classes I (BMI=30-34.9 kg/m<sup>2</sup>; n=1,933), II (BMI=35-39.9 kg/m<sup>2</sup>; n= 820), or III (BMI &gt;39.9 kg/m<sup>2</sup>; n= 860) obesity. Self-reported health status was assessed using the SF-36 at baseline and after approximately 1 year of participation</p>

in a LHC program. LHC included exercise training, nutrition, weight management, stress management and smoking cessation interventions. **Results:** At baseline, SF-36 transformed scores tended to be highest for participants with class I obesity and lowest for participants with class III obesity ( $p < 0.05$  for all SF-36 domains for class I versus III obesity). After 1 year of LHC, statistically significant improvements ( $p < 0.05$  for within group change from baseline) in SF-36 transformed scores were observed, as follows: physical functioning (Class I, 4.9; Class II, 6.5; Class III, 9.7); role-physical (Class I, 6.4; Class II, 7.9; Class III, 10.4); bodily pain (Class I, 2.4; Class II, 4.0; Class III, 7.4); general health (Class I, 6.5; Class II, 8.7; Class III, 10.0); vitality (Class I, 6.2; Class II, 9.3; Class III, 11.5); social functioning (Class I, 4.1; Class II, 4.1; Class III, 5.4); role-emotional (Class I, 4.0; Class II, 6.3; Class III, 5.4); and mental health (Class I, 5.4; Class II, 5.4; Class III, 5.0).

**Conclusions:** These data are the first, to our knowledge, to demonstrate that while all sub-groups of obese participants experience significant improvements in multiple indices of self-reported health status in response to 1 year of LHC, the magnitude of improvement tends to be greatest for participants with class III obesity.

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#### EFFECT OF GENDER ON RESPONSIVENESS OF MULTIPLE CARDIOVASCULAR DISEASE RISK FACTORS TO LIFESTYLE HEALTH COACHING IN ADULTS WITH PREDIABETES

Neil F. Gordon, FACSM, Richard D. Salmon, Terri L. Gordon, David A. Alter, Barry A. Franklin, FACSM. William Beaumont Hospital, Royal Oak, MI, INTERVENT Canada, Toronto, Canada, and Nationwide Better Health, Columbus, OH.

75.

Prediabetes affects ~22.6% of men and ~33.5% of women in the U.S. Scarce data are available on the effect of gender on the responsiveness of cardiovascular disease (CVD) risk factors to lifestyle health coaching (LHC) in adults with prediabetes.

**Purpose:** In this study of 967 men ( $n = 399$ ; age = 57 years) and women ( $n = 568$ ; age = 55 years) with prediabetes, we evaluated the effect of gender on the responsiveness of multiple CVD risk factors to LHC.

**Methods:** At baseline, all participants met the American Diabetes Association's (ADA) criteria for prediabetes. Participants were evaluated at baseline and after an average of ~4 months of LHC. LHC included individualized coaching on exercise, nutrition, weight management, and smoking cessation.

**Results:** In men, baseline fasting glucose (108 mg/dl) decreased by 5 mg/dl ( $p < 0.05$ ) with LHC. Similarly, baseline fasting glucose (107 mg/dl) decreased by 5 mg/dl ( $p < 0.05$ ) with LHC in women. Based on ADA criteria, 172 (43.1%) men and 250 (44.0%) women normalized their fasting glucose (i.e., fasting glucose below 100 mg/dl). For participants with abnormal baseline risk factors, significant ( $p < 0.05$ ) improvements were observed for multiple additional variables, as follows: blood pressure (Men, -9/7 mmHg; Women, -9/7 mmHg); LDL cholesterol (Men, -25 mg/dl; Women, -15 mg/dl;  $p < 0.05$  for Men versus Women); HDL cholesterol (Men, 2 mg/dl; Women, 3 mg/dl); triglycerides (Men, -56 mg/dl; Women, -35 mg/dl;  $p < 0.05$  for Men versus Women); and weight (Men, -8 lbs; Women, -7 lbs). Of the participants who smoked cigarettes at baseline, 19.6% of men and 0% of women quit smoking. In participants with a baseline Framingham 10-year coronary heart disease risk score  $> 10\%$ , the score decreased significantly ( $p < 0.05$ ) in men and women (Men, -22.8%; Women, -18.1%;  $p < 0.05$  for Men versus Women). Thus, while the magnitude of reduction in fasting glucose was similar in men and women, men derived a slightly greater benefit in terms of overall CVD risk reduction.

**Conclusions:** The present study adds to previous research by reporting on the effectiveness (rather than the efficacy) of LHC in adults with prediabetes. The data show that many adults with prediabetes can normalize their fasting glucose with LHC but suggest that there may be gender-related differences in the therapeutic responsiveness of certain risk factors.

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#### EFFECT OF LIFESTYLE HEALTH COACHING ON MULTIPLE CARDIOVASCULAR DISEASE RISK FACTORS IN OVERWEIGHT AND OBESE PARTICIPANTS

Barry A. Franklin, FACSM, Richard D. Salmon, Terri L. Gordon, David A. Alter, Neil F. Gordon, FACSM. William Beaumont Hospital, Royal Oak, MI, INTERVENT Canada, Toronto, Canada, and Nationwide Better Health, Columbus, OH.

76.

Lifestyle health coaching (LHC) has gained increased popularity as a strategy to facilitate behavior change. Scarce comprehensive data are available on the effect of LHC on multiple cardiovascular disease (CVD) risk factors in overweight and obese adults.

**Purpose:** In this study, we evaluated the effect of LHC on multiple CVD risk factors in 7,281 adults, of whom 3,784 were obese (Group I, baseline body mass index [BMI]  $> 30$  kg/m<sup>2</sup>), 2,134 were overweight (Group II, baseline BMI = 25-29.9 kg/m<sup>2</sup>) and 1,363 were not overweight (Group III, baseline BMI  $< 25$  kg/m<sup>2</sup>).

**Methods:** Outcome measures were assessed at baseline and after approximately 1 year of LHC. LHC included individualized coaching on exercise, nutrition, weight management, stress management and smoking cessation.

**Results:** Weight (Group I, -6.9 lbs; Group II, -2.3 lbs; Group III, 0.1 lbs) and BMI (Group I, -1.1 kg/m<sup>2</sup>; Group II, -0.4 kg/m<sup>2</sup>; Group III, 0 kg/m<sup>2</sup>) decreased significantly ( $p < 0.05$ ) in the overweight and obese participants ( $p < 0.05$  for Group I versus Groups II and III;  $p < 0.05$  for Group II versus Group III). For participants with abnormal baseline risk factors, significant improvements ( $p < 0.05$ ) were observed for multiple additional variables in all 3 groups, as follows: blood pressure (Group I, -8/7 mmHg; Group II, -8/7 mmHg; Group III, -11/8 mmHg); LDL cholesterol (Group I, -19 mg/dl; Group II, -21 mg/dl; Group III, -21 mg/dl); HDL cholesterol (Group I, 4 mg/dl; Group II, 4 mg/dl; Group III, 6 mg/dl); triglycerides (Group I, -39 mg/dl; Group II, -46 mg/dl; Group III, -58 mg/dl); and fasting glucose (Group I, -9 mg/dl; Group II, -6 mg/dl; Group III, -14 mg/dl). In participants with a baseline Framingham 10-year coronary heart disease risk score  $> 10\%$ , the score decreased



significantly ( $p < 0.05$ ) in participants in all 3 groups (Group I, -20.8%; Group II, -21.3%; Group III, -17.2%;  $p = \text{NS}$  for the differences among groups).

**Conclusions:** These data serve to document the magnitude of improvement in multiple CVD risk factors in overweight and obese individuals in response to participation in 1 year of LHC. The data demonstrate that while weight loss is greatest for obese participants, the magnitude of improvement in the Framingham 10-year coronary heart disease risk score is similar for all participants.

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#### EFFECT OF LIFESTYLE HEALTH COACHING ON MULTIPLE CARDIOVASCULAR DISEASE RISK FACTORS: COMPARISON WITH CARDIAC REHABILITATION

Neil F. Gordon, FACSM, Richard D. Salmon- David A. Alter, George C. Faircloth, Brenda S. Wright, Jeff Harner, Calvin C. Wilhide, III, Melissa G. Bresnick, Barry A. Franklin, FACSM. Nationwide Better Health, Savannah, GA. INTERVENT Canada, Toronto, ON, Canada. William Beaumont Hospital, Royal Oak, MI.

77.

During the past decade, lifestyle health coaching (LHC) has gained increased popularity as a strategy to facilitate behavior change. Few data are available on the effect of LHC on multiple cardiovascular disease (CVD) risk factors.

**Purpose:** In this multi-center study, we evaluated the effect of LHC on multiple CVD risk factors in 9,134 consecutive adults and compared the effect of a phase 2 cardiac rehabilitation (CR) program in 11,875 consecutive patients.

**Methods:** Outcome measures were assessed at baseline and after approximately 12 weeks of LHC and CR. LHC included individualized coaching, predominantly via the telephone and Internet, on exercise training, nutrition, weight management, stress management and tobacco cessation interventions. CR was conducted at multiple centers in the United States.

**Results:** At baseline, CR patients were significantly ( $p < 0.05$ ) older ( $69 \pm 11$  years vs.  $51 \pm 12$  years), and had a higher prevalence of atherosclerotic CVD (95.3% vs. 10.6%) and diabetes (23.7% vs. 9.1%) than those participating in LHC. For participants with abnormal baseline risk factors, statistically significant improvements ( $p < 0.05$ ) were observed for multiple variables, as follows: blood pressure (LHC, -9/7 mmHg; CR, -10/10 mmHg;  $p < 0.05$  for CR versus LHC); LDL cholesterol (LHC, -22 mg/dl; CR, -50 mg/dl;  $p < 0.05$  for CR versus LHC); HDL cholesterol (LHC, 3 mg/dl; CR, 5 mg/dl;  $p < 0.05$  for CR versus LHC); triglycerides (LHC, -46 mg/dl; CR, -52 mg/dl;  $p = \text{NS}$  for CR versus LHC); fasting glucose (LHC, -13 mg/dl; CR, -15 mg/dl;  $p = \text{NS}$  for CR versus LHC); and body weight (LHC, -5.8 lbs; CR, -2.5 lbs;  $p < 0.05$  for LHC versus CR). In participants in the LHC program with a baseline Framingham 10-year coronary heart disease risk score  $\geq 10\%$ , the score decreased by 20.5% (relative risk reduction,  $p < 0.05$ ).

**Conclusions:** These data serve to document the magnitude of improvement in multiple CVD risk factors in response to participation in approximately 12 weeks of LHC. The data demonstrate that LHC results in clinically relevant improvements in multiple CVD risk factors and that the precise magnitude of improvement may be similar to, less than or greater than that observed with CR depending on the specific risk factor in question.

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#### EFFECT OF LIFESTYLE HEALTH COACHING ON THE PREVALENCE OF METABOLIC SYNDROME AND ITS COMPONENT RISK FACTORS

Barry A. Franklin, FACSM, Richard D. Salmon, David A. Alter, George C. Faircloth, Brenda S. Wright, Jeff Harner, Calvin C. Wilhide, III, Melissa G. Bresnick, Neil F. Gordon, FACSM. William Beaumont Hospital, Royal Oak, MI. Nationwide Better Health, Savannah, GA. INTERVENT Canada, Toronto, ON, Canada.

78.

Metabolic syndrome (MS) is a constellation of interrelated coronary heart disease and type 2 diabetes risk factors of metabolic origin (MS risk factors) that are associated with increased cardiovascular event rates. Although MS risk factors are strongly influenced by lifestyle, few data are available on the effect of lifestyle health coaching (LHC) on MS risk factors.

**Purpose:** In this study, we determined the prevalence of MS and its component MS risk factors on entry into and after ~ 1 year of participation in LHC.

**Methods:** Subjects were 7,929 consecutive adults (mean age =  $52 \pm 12$  years) who completed both a baseline evaluation on entry into a LHC program and a follow-up evaluation after ~1 year of participation in the LHC program. LHC included individualized coaching, predominantly via the telephone and Internet, on exercise training, nutrition counseling, weight management, stress management and tobacco cessation. MS and its 5 individual component MS risk factors were defined in accordance with the National Cholesterol Education Program Adult Treatment Panel III Guidelines; however, a fasting glucose  $\geq 100$  mg/dl (rather than  $\geq 110$  mg/dl) was used. In individuals with MS at baseline and data on all 5 individual MS risk factors both at baseline and follow-up ( $n = 1,887$ ), results were analyzed to determine the number of individuals with  $\geq 3$ , 3, 4, or 5 MS risk factors and the number of individuals with each of the individual MS risk factors.

**Results:** Results were as follows:

MS Risk Factors	Baseline (n)	Follow-up (n)	Change
$\geq 3$ MS Risk Factors	1887	1304	-30.9%
3 MS Risk Factors	1034	805	-22.1%
4 MS Risk Factors	655	392	
5 MS Risk Factors	198	107	
Positive waist circumference	1656	1101	
Positive blood pressure	1353	821	

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Positive HDL cholesterol	1315	920	-30.0%
Positive fasting triglycerides	1202	819	-31.9%
Positive fasting glucose	1186	857	-27.7%

**Conclusions:** LHC was associated with a 30.9% reduction in the prevalence of MS and had a favorable impact on all 5 MS risk factors.

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**EFFECT OF CARDIAC REHABILITATION ON CORONARY HEART DISEASE RISK FACTORS IN PATIENTS TAKING ANTIDEPRESSANTS**

79.

Anwer Habib, Richard Salmon, Kathy Lee Bishop, Laurence Sperling, Andrea Pinzon, Melvyn Rubenfire, Kevin Reid, George Faircloth, Brenda Wright, Ami Drimmer, Barry Franklin, David Alter, and Neil Gordon. Emory University School of Medicine, Atlanta, GA; University of Michigan Health System, Ann Arbor, MI; William Beaumont Hospital, Royal Oak, MI; INTERVENT Canada, Toronto, Canada; and Nationwide Better Health, Savannah, GA.

**Introduction:** Depression is commonly present in patients with coronary heart disease (CHD) and is independently associated with increased cardiovascular morbidity and mortality. CHD patients treated with antidepressants have been reported to be at a reduced risk for death or recurrent myocardial infarction as compared with depressed patients not taking antidepressants. **Purpose:** In this multi-center study, we sought to determine whether a history of depression and current use of antidepressants impacts the benefit of cardiac rehabilitation on multiple CHD risk factors. **Design:** 26,957 patients were stratified at baseline by self-reported past or current depression and current use of antidepressants to compare the effect of exercise-based cardiac rehabilitation on CHD risk factors. **Methods:** CHD risk factors were assessed at baseline and following 12 weeks of program participation. Statistical analyses were performed using paired t-tests, unpaired t-tests, and chi-square tests, where appropriate. **Results:** Self-reported past or current depression was present in 5,172 patients (19.2%). Patients with depression (Group A; n = 2,147) who were taking antidepressants at baseline were less likely to complete the exit evaluation as compared to patients without depression (Group B; n = 20,237) who were not taking antidepressants at baseline (Group A, 43.5% completion versus Group B, 49.4% completion; p<0.05 for Group A versus B). Among patients with abnormal baseline CHD risk factors (based on national guidelines), significant improvements (p <0.05) were observed for multiple variables, as follows (p=NS for Group A versus B for all variables): blood pressure (Group A, -10/10 mmHg; Group B, -10/10 mmHg); LDL cholesterol (Group A, -31 mg/dl; Group B, -33 mg/dl); HDL cholesterol (Group A, 5 mg/dl; Group B, 5 mg/dl); triglycerides (Group A, -51 mg/dl; Group B, -52 mg/dl); fasting glucose (Group A, -13 mg/dl; Group B, -13 mg/dl); and weight (Group A, -3.7 lbs; Group B, -4.0 lbs). Patients in Group A were more likely to smoke cigarettes at baseline and less likely to quit smoking during cardiac rehabilitation (Group A, 9.3% quit smoking versus Group B, 17.6% quit smoking; p<0.05 for Group A versus B). **Conclusions:** Patients with self-reported depression who take antidepressants on cardiac rehabilitation program entry are less likely to complete the exit evaluation and less likely to quit smoking cigarettes as compared to their counterparts without depression who are not taking antidepressants. However, both groups of patients derive similar benefit in terms of improvements in blood pressure, serum lipids and lipoproteins, fasting glucose and body weight.

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**EFFECT OF CARDIAC REHABILITATION ON SELF-REPORTED HEALTH STATUS IN PATIENTS TAKING ANTIDEPRESSANTS**

80.

Kathy Lee Bishop, Richard Salmon, Anwer Habib, Laurence Sperling, Andrea Pinzon, Melvyn Rubenfire, Kevin Reid, George Faircloth, Brenda Wright, Ami Drimmer, Barry Franklin, David Alter and Neil Gordon. Emory University School of Medicine, Atlanta, GA; University of Michigan Health System, Ann Arbor, MI; William Beaumont Hospital, Royal Oak, MI; INTERVENT Canada, Toronto, Canada; and Nationwide Better Health, Savannah, GA.

**Introduction:** Depression is commonly present in patients with coronary heart disease and is associated with higher healthcare utilization and greatly reduced quality of life. **Purpose:** In this multi-center study, we sought to determine whether a history of depression and current use of antidepressants impacts the benefit of exercise-based cardiac rehabilitation on self-reported health status. **Design:** 26,957 patients were stratified at baseline by self-reported past or current depression and current use of antidepressants to compare the effect of cardiac rehabilitation on self-reported health status. **Methods:** Self-reported health status was assessed at baseline and after 12 weeks of program participation using the SF-36. Statistical analyses were performed using paired t-tests, unpaired t-tests, and chi-square tests, where appropriate. **Results:** Self-reported past or current depression was present in 5,172 patients (19.2%). Patients with depression (Group A; n = 2,147) who were taking antidepressants at baseline were less likely to complete the exit evaluation as compared to patients without depression (Group B; n = 20,237) who were not taking antidepressants at baseline (Group A, 43.5% completion versus Group B, 49.4% completion, p<0.05). At baseline, SF-36 transformed scores were lower (p <0.05) in patients in Group A versus B for all 8 SF-36 domains. On program exit, improvements (p <0.05 for within group change from baseline) in SF-36 transformed scores were observed, as follows: physical functioning (Group A, 14; Group B, 16); role-physical (Group A, 34; Group B, 36); bodily pain (Group A, 16; Group B, 17); general health (Group A, 5; Group B, 3); vitality (Group A, 17; Group B, 10); social functioning (Group A, 19; Group B, 19); role-emotional (Group A, 17; Group B, 12); and mental health (Group A, 9; Group B, 6). Statistically significant (p<0.05) differences were observed for the magnitude of improvement from baseline in patients in Group A versus B for physical functioning (greater improvement in patients in Group B) and for general health, vitality, role-emotional, and mental health (greater improvements in Group A). **Conclusions:** Patients with self-reported depression who take antidepressants have poorer self-reported health status on entry into a cardiac rehabilitation program and are less likely to complete the exit evaluation when compared to patients without depression who are not taking antidepressants. However, both groups of

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patients derive significant benefit in terms of improvements in multiple indices of self-reported health status.

#### COMPLIANCE WITH LIFESTYLE HEALTH COACHING SESSIONS PREDICTS REDUCTION IN MODIFIABLE RISK FACTORS

Melissa G. Bresnick, David A. Alter, Kyahn Kamali, Richard D. Salmon, Calvin C. Wilhide, Jeff Harner, Barry A. Franklin, Neil F. Gordon.

**Objective:** To explore the relationship between compliance with a telephonic lifestyle health coaching program and the reduction in health risks. **Methods:** Risk factor data were derived from a baseline health risk assessment and participants were reassessed after approximately 12 weeks of participation in a telephonic lifestyle health coaching program. Changes in risk between baseline and follow-up were linked to the frequency of completed telephonic sessions with a health coach. Hierarchical linear regression was used to model the association between completed coaching sessions and change in the number of health risks. **Results:** 3,539 participants completed the baseline and follow-up assessments. The total number of initially defined health risks at baseline decreased by 31% with 12 weeks of lifestyle health coaching program participation. Compliance with lifestyle health coaching sessions predicted a significant dose-response reduction in the number of health risks ( $\beta=-0.048$ ,  $p<0.001$ , 95% CI[-0.076, -0.020]). **Conclusions:** Dose-response analysis demonstrates the importance of participant engagement and retention in telephonic lifestyle health coaching programs for reducing health risks.

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#### EVIDENCE-BASED LIFESTYLE HEALTH COACHING: PROGRAM DESIGN, IMPLEMENTATION, DETERMINANTS OF SUCCESS, AND OUTCOMES

Neil F. Gordon.

Despite impressive recent technologic advances in the field of medicine, potentially preventable non-communicable chronic diseases remain the leading cause of death, disability and avoidable health care costs in the US and other industrialized countries. Because many chronic diseases are lifestyle related, unprecedented attention is being focused on lifestyle health coaching (LHC). We have spent over 15 years developing, testing and implementing evidence-based LHC programs. The programs were originally modeled after protocols utilized as part of several landmark studies and are now being provided to employees from numerous US- and foreign-based employers. In this presentation, the evolution of the LHC program design and core features is discussed together with key factors identified as determinants of success. Outcomes data are presented from several studies, including randomized clinical trials, documenting the benefits of LHC in various populations in terms of improvements in lifestyle practices, self-reported health status, clinical status and return on investment.

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#### PARTICIPANT SATISFACTION WITH A LIFESTYLE MANAGEMENT PROGRAM IN THE SAMMPRIS CLINICAL TRIAL

Tanya N Turan; Michele F Caskey; Stephanie Helwig; Megan R Steiner; Brenda S Wright; Jean Montgomery; Bethany Lane; Michael J Lynn; Colin P Derdeyn; David Fiorella; Scott Janis; Marc I Chimowitz; SAMMPRIS Investigators.

**Background:** SAMMPRIS was the first secondary prevention stroke trial to provide a lifestyle modification program to all clinical trial participants. We sought to determine if SAMMPRIS participants would have a high level of satisfaction with the compulsory lifestyle program. **Methods:** Patients enrolled in SAMMPRIS who were actively participating in the lifestyle modification program for > 12 weeks were mailed anonymous surveys. The survey was conducted by the company that administered the lifestyle program and the data was provided to the authors. The survey measured 6 constructs: consistency of program delivery, quality of materials, confidentiality, coach-participant relationship, individualization, and time efficiency, with 2 statements addressing each construct. Participants were asked to respond to 2 variables, "importance" and "satisfaction", for each statement using five-point Likert-type scales (5 = high; 1 = low). An adjusted needs index (ANI) was computed for each statement: [(mean importance - mean satisfaction) x (mean importance)]. Participants were also asked to respond ("strongly agree" or "strongly disagree") to 2 statements related to their overall evaluation of the program and if they would recommend the program to others. **Results:** Surveys were completed by 199/327 (61%) participants. For the 6 constructs, mean scores for "importance" ranged from 4.36 - 4.73 and mean scores for "satisfaction" ranged from 4.38 - 4.69. The coach-participant relationship rated highest for both "importance" and "satisfaction". ANIs for 8 of 12 statements were either 0 or negative values, indicating that expectations were met or exceeded. Individualization of the program had the highest ANI at 0.45. Statements regarding overall evaluation received high ratings (means 4.65, 4.66). **Conclusion:** SAMMPRIS clinical trial participants had a high level of satisfaction with the study's lifestyle management program. These data, coupled with final data from SAMMPRIS showing that compliance with the program resulted in improved control of risk factors, would strongly support the use of lifestyle programs in future stroke prevention clinical trials and in clinical practice.

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#### MULTI-CENTER STUDY OF RISK FACTOR STATUS ON COMPLETION OF A CONTEMPORARY PHASE 2 CARDIAC REHABILITATION PROGRAM: TEMPORAL TRENDS

Neil Gordon, Richard Salmon, Kevin Reid, Brenda Wright, George Faircloth, Kim Allen, John Thiel, Tom Savona, Julie Blakely, Terri Gordon.

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84.

**Introduction:** No comprehensive data are available on temporal trends in the percentage of participants who are not at recommended cardiovascular disease risk factor goal levels on completion of a contemporary phase 2 cardiac rehabilitation (CR) program and, therefore, in need of additional intervention. **Purpose:** The purpose of this study was to determine whether improvements have occurred in recent years in the control of multiple risk factors in patients exiting CR. **Design:** In this multi-center study, we compared the percentage of participants not at goal for select risk factors on exit from CR during 2000-2004 versus 2005-2009. **Methods:** Subjects were 12,984 consecutive patients who enrolled in a phase 2 CR program at 35 centers in the US between 2000 and 2009 and subsequently completed an exit evaluation on program completion (2000-2004: n=5,468; age=64+/-11 years; 2005-2009: n=7,516; age=65+/-11 years). Statistical significance of differences between groups was analyzed using chi-square tests and statistical significance was established at  $p < 0.05$ . **Results:** Percentages of patients with risk factors not at goal levels on CR completion were as follows (p values are for 2000-2004 versus 2005-2009): 1. Cigarette smoking (goal = no smoking): 2000-2004, 4.1% not at goal; 2005-2009, 4.7% not at goal; p=NS; 2. Systolic BP (goal <120 mm Hg): 2000-2004, 54.5% not at goal; 2005-2009, 50.9% not at goal;  $p < 0.001$ ; 3. Diastolic BP (goal <80 mm Hg): 2000-2004, 21.4% not at goal; 2005-2009, 17.3% not at goal;  $p < 0.001$ ; 4. LDL cholesterol (goal <100 mg/dl): 2000-2004, 29.7% not at goal; 2005-2009, 20.5% not at goal;  $p < 0.001$ ; 5. HDL cholesterol (goal >39 mg/dl): 2000-2004, 38.6% not at goal; 2005-2009, 43.5% not at goal;  $p < 0.001$ ; 6. Triglycerides (goal <150 mg/dl): 2000-2004, 35.3% not at goal; 2005-2009, 28.2% not at goal;  $p < 0.001$ ; 7. Body mass index (goal <25 kg/m<sup>2</sup>): 2000-2004, 76.9% not at goal; 2005-2009, 79.0% not at goal;  $p < 0.01$ ; 8. Fasting glucose (goal <100 mg/dl): 2000-2004, 57.5% not at goal; 2005-2009, 54.8% not at goal; p=NS; and 9. Sedentary lifestyle (goal >149 min/wk): 2000-2004, 51.1% not at goal; 2005-2009, 37.4% not at goal;  $p < 0.001$ . **Conclusions:** These data indicate that while the control of many risk factors has improved significantly over time, the control of some risk factors (namely, HDL cholesterol and body mass index) has worsened. The data further demonstrate that multiple risk factors are often inadequately controlled on exit from contemporary phase 2 CR programs and serve to emphasize the need for ongoing intervention.

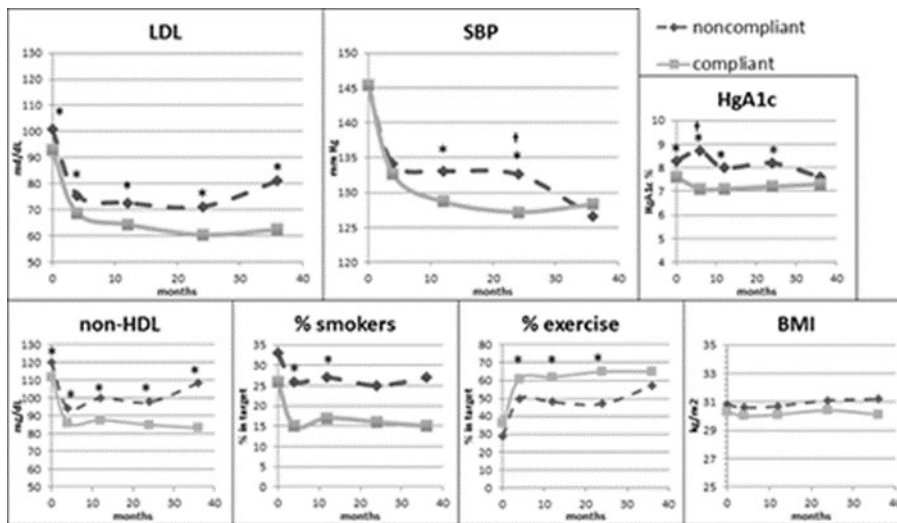
2014 –  
International  
Stroke  
Conference

**RELATIONSHIP BETWEEN COMPLIANCE WITH THE LIFESTYLE MODIFICATION PROGRAM AND RISK FACTOR CONTROL IN THE STENTING AND AGGRESSIVE MEDICAL MANAGEMENT FOR PREVENTING RECURRENT STROKE IN INTRACRANIAL STENOSIS (SAMMPRIS) TRIAL**

Turan TN, Nizam A, Lynn MJ, Montgomery J, Derdeyn CP, Fiorella D, Lane BF, Janis S, Chimowitz MI.

85.

**Background and Purpose:** SAMMPRIS was the first vascular disease prevention trial to provide a commercially available lifestyle modification program to subjects to enhance risk factor control. We sought to determine the relationship between compliance with the lifestyle modification program and risk factor control in SAMMPRIS. **Methods:** SAMMPRIS aggressive medical management included a telephonic lifestyle modification program provided free of charge to all subjects (n=451) during their participation in the study. Subjects with < 3 expected lifestyle coaching calls were excluded from these analyses. Subjects with  $\geq 78.5\%$  of calls (median % of completed/expected calls) were considered Compliant (n=201). Subjects with < 78.5% and those who refused to participate were considered Noncompliant (n=200). Mean risk factor values or % in-target for each risk factor were compared between Compliant vs. Noncompliant subjects, using t-tests and chi-square tests. Risk factor changes from baseline to follow-up were compared between the groups to account for baseline differences between the groups. **Results:** As shown in the figure, Compliant subjects had better risk factor control throughout follow-up for LDL, SBP, HgA1c, non-HDL, non-smoking, and exercise than Noncompliant subjects, but there was no difference for BMI. Compliant subjects also had better control of LDL, non-HDL, and HgA1c at baseline. Both groups had some improvement in risk factors throughout the study (except for BMI), but after adjusting for baseline differences between the groups, Compliant subjects had a greater change from baseline than Noncompliant subjects for SBP at 24 months and HgA1c at 6 months. **Conclusions:** SAMMPRIS subjects who were compliant with the lifestyle modification program had better risk factor control during the study for almost all risk factors.



\*  $P < 0.05$  for difference between compliant vs. noncompliant

+  $p < 0.05$  for difference in change from baseline between compliant vs. noncompliant

INTERVENT:

RESEARCH PUBLISHED AND / OR PRESENTED AT NATIONAL / INTERNATIONAL SCIENTIFIC MEETINGS: 1997 - 2020

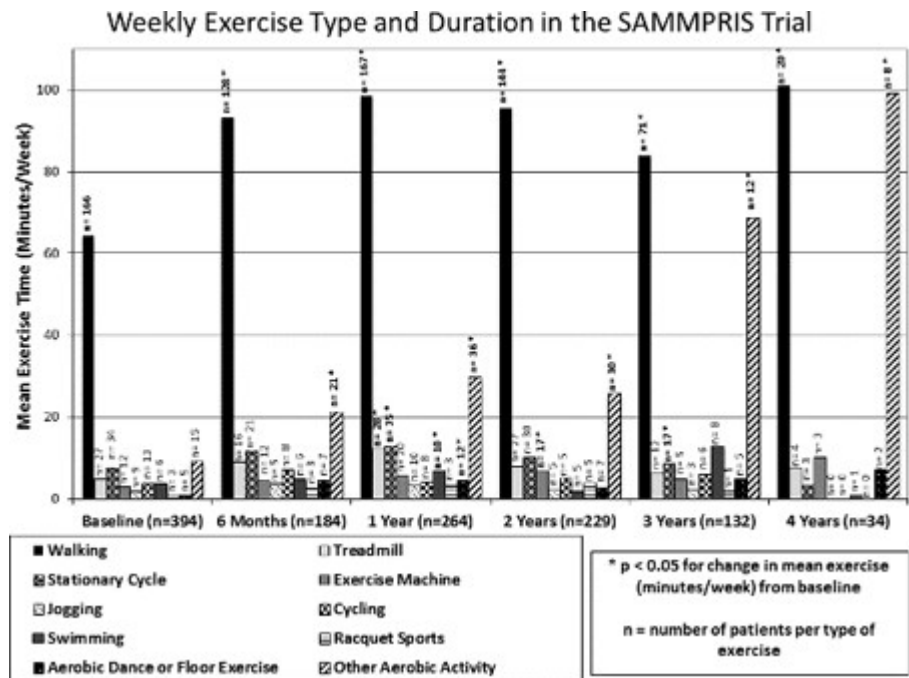
2015 -  
International  
Stroke  
Conference

86.

TYPE AND DURATION OF EXERCISE IN THE SAMMPRIS TRIAL

Hannah J, Turan TN; Nizam A, Lynn MJ, Derdeyn CP, Fiorella D, Janis LS, Lane BF, Montgomery J, Chimowitz MI, for the SAMMPRIS Investigators.

**Background:** Previous analyses of SAMMPRIS trial data showed that good risk factor control resulted in a significant reduction in the risk of vascular events (stroke, MI, and vascular death), with exercise as the most important predictor of good outcome. We sought to determine the type and duration of exercise that SAMMPRIS patients reported during the trial. **Methods:** In SAMMPRIS, 451 patients with recent TIA or stroke attributed to 70-99% intracranial stenosis were randomized to aggressive medical management (AMM) alone or percutaneous transluminal angioplasty and stenting plus AMM at 50 USA sites. AMM included a telephonic lifestyle modification program, INTERVENT, that was provided free of charge to all subjects during their participation in the study. We analyzed self-reported data collected by INTERVENT on the patients' type and duration of exercise from baseline (n=394) to 4 years (n=34). We calculated the mean duration for each exercise type at each time period and then compared the change in exercise duration from baseline using paired t-tests and Wilcoxon signed rank tests. **Results:** Data from subjects who completed the INTERVENT questionnaires were included in these analyses. As shown in the Figure, walking was the most common form of exercise at all time points, as measured by both the duration of exercise and the number of patients performing the exercise. The mean duration of walking and other aerobic activities increased significantly from baseline to all other time points. **Conclusions:** The type of self-reported exercise performed by SAMMPRIS patients included mostly walking or other aerobic activity and increased significantly during follow-up. Given that exercise was protective against recurrent vascular events, future secondary prevention stroke trials should encourage and monitor exercise participation and neurologists should encourage physical activity in clinical practice.



2015 -  
AACVPR  
Annual  
Meeting

87.

PARTICIPANT SATISFACTION WITH AN EVIDENCE-BASED TELEPHONE LIFESTYLE HEALTH COACHING PROGRAM

Neil Gordon, Brenda Wright, Richard Salmon, George Faircloth, Tom Savona, Terri Gordon.

**Introduction:** Improving the patient experience of care, including quality and satisfaction, is one of the three dimensions of the Institute for Healthcare Improvement's Triple Aim. Although the American Heart Association has recommended that cardiac rehabilitation/secondary prevention programs be reengineered to include telephone lifestyle health coaching (TLHC), scarce data are available on participant satisfaction with TLHC. **Purpose:** The purpose of this study was to assess participants' satisfaction with a TLHC program using discrepancy analysis. **Design:** Subjects completed an anonymous participant satisfaction survey after at least 12 weeks of participation in an evidence-based TLHC program that has previously been proven effective in modifying cardiovascular disease multiple risk factors. **Methods:** Subjects were 829 participants in a TLHC program provided as a component of a worksite health promotion initiative. The participant satisfaction survey was available online, via telephone and via the mail. The survey included up to 12 statements, addressing the consistency of program delivery, quality of program materials, confidentiality, coach-participant relationship, individualization and time efficiency. Participants were asked to respond to two variables, "importance" and "satisfaction," for each statement using five-point Likert-type scales (5 = high; 1 = low). An adjusted needs index (ANI) was computed for each statement, as follows: ANI = [(mean importance - mean satisfaction) x (mean importance)]; ANIs can range from -4 to 20 and negative ANIs mean "satisfaction" exceeds "importance". Participants were also asked to respond (5 = "strongly agree" or 1 = "strongly disagree") to two statements related to their overall satisfaction with the TLHC program and if they would recommend the TLHC program to others. **Results:** The results were extremely positive. For the 12 statements, mean scores for "importance" ranged from 4.55 to 4.78 and mean scores for "satisfaction" ranged from 4.54 to 4.76. Statements related to coach

competency/knowledge, confidentiality/privacy and staff courtesy/helpfulness were rated highest for both "importance" and "satisfaction." ANIs ranged from -0.37 to 0.42, which are very low values, indicating that expectations were generally met or exceeded. Statements regarding overall satisfaction with the TLHC program (mean = 4.62) and recommending the TLHC program to others (mean = 4.66) received high ratings. **Conclusions:** This study shows that appropriately designed and executed TLHC programs can result in high levels of participant satisfaction. The data further demonstrate how discrepancy analysis can be used to evaluate participant satisfaction and help identify priorities for program improvement as part of patient-centered care initiatives.

2016 -  
ACC Annual  
Meeting

#### STATINS DO NOT ATTENUATE IMPROVEMENTS IN FASTING PLASMA GLUCOSE AND MULTIPLE CORONARY HEART DISEASE RISK FACTORS DURING EXERCISE-BASED CARDIAC REHABILITATION

Schultz W, Gordon N, Salmon R, Eapen D, Sperling L.

88.

**Background:** Previous studies have linked statins to elevated plasma glucose levels and raised concerns that statins may attenuate favorable effects of therapeutic lifestyle changes on plasma glucose control. **Methods:** In this multi-center study, we evaluated the effect of a 12-week exercise-based phase 2 cardiac rehabilitation (CR) program on fasting plasma glucose and multiple coronary heart disease (CHD) risk factors in 7,292 patients. Patients completed assessments on entry into and exit from CR at 35 US-based centers and were categorized into 2 cohorts, namely, those taking statins (Cohort A; n=4,795; mean age=71.7 years) and those not taking statins or any other anti-lipidemic agents (Cohort B; n=2,497; mean age=72.0 years). Statistical analyses were performed using paired t-tests, unpaired t-tests, and chi-square tests. **Results:** Fasting plasma glucose decreased from 115.0±35.4 to 108.6±30.1 mg/dl (5.6% decrease, p <0.001) in Cohort A and from 117.0±43.6 to 108.3±29.1 mg/dl (7.4% decrease, p <0.001) in Cohort B (p=0.357 versus Cohort A). Significant (p <0.05) improvements were also observed for other CHD risk factors in both cohorts, including: total cholesterol (Cohort A, -13.7 mg/dl; Cohort B, -4.0 mg/dl; p<0.001 for Cohort A versus B); LDL cholesterol (Cohort A, -13.4 mg/dl; Cohort B, -3.3 mg/dl; p<0.001 for Cohort A versus B); HDL cholesterol (Cohort A, 2.1 mg/dl; Cohort B, 1.3 mg/dl; p=0.123 for Cohort A versus B); triglycerides (Cohort A, -14.2 mg/dl; Cohort B, -10.5 mg/dl; p=0.381 for Cohort A versus B); systolic BP (Cohort A, -2.5 mmHg; Cohort B, -2.9 mmHg; p=0.386 for Cohort A versus B); diastolic BP (Cohort A, -1.8 mmHg; Cohort B, -1.5 mmHg; p<0.001 for Cohort A versus B); weight (Cohort A, -1.6 lbs; Cohort B, -1.5 lbs; p=0.688 for Cohort A versus B); aerobic physical activity (Cohort A, 125 min/week; Cohort B 128 min/week; p=0.477 for Cohort A versus B); and cigarette smoking (Cohort A, 11.2% quit rate; Cohort B, 15.5% quit rate; p=0.261 for Cohort A versus B). **Conclusion:** These data are the first to demonstrate that statins do not significantly attenuate improvements in fasting plasma glucose levels or other CHD risk factors during exercise-based CR.

2016 -  
FIMS Annual  
Meeting

#### GENDER DIFFERENCES IN IMPROVEMENTS IN ATHEROSCLEROTIC CARDIOVASCULAR DISEASE RISK FACTORS DURING EXERCISE-BASED CARDIAC REHABILITATION: IMPACT OF STATIN THERAPY

Constantinou D, Gradidge P, Salmon R, Schultz W, Sperling L, Franklin B, Gordon N.

89.

**Introduction:** Studies have raised concerns that statins may attenuate favorable effects of lifestyle intervention on cardiovascular risk factors. **Hypothesis:** We hypothesized that gender differences may exist in the responsiveness of risk factors to exercise-based phase 2 cardiac rehabilitation (CR) in statin-treated patients. **Methods:** We compared the effect of a 12-week CR program on multiple risk factors in 5,734 male (age=64±11 yrs) and 2,148 female (age=67±11 yrs) statin-treated patients (Cohort A, n=7,882). Where significant gender differences were noted, similar comparisons were made between 1,516 male (age=66±12 yrs) and 813 female (age=64±13 yrs) CR participants not taking statins (Cohort B, n=2,329). Patients completed assessments on entry and exit from CR at 35 U.S.-based centers. Statistical analyses were performed using paired and unpaired t-tests. **Results:** For Cohort A, significant (p<0.05) improvements were observed for all risk factors in men and women, including: LDL cholesterol (males, -13.0 mg/dl; females, -10.8 mg/dl; males vs. females, p=0.114); HDL cholesterol (males, 1.8 mg/dl; females, 1.6 mg/dl; males vs. females, p=0.640); triglycerides (males, -17.0 mg/dl; females, -9.1 mg/dl; males vs. females, p=0.041); BP (males, -1.8/-1.6 mmHg; females, -4.6/-2.7 mmHg; males vs. females, p<0.001); BMI (males, -0.2 kg/m<sup>2</sup>; females, -0.2 kg/m<sup>2</sup>; males vs. females, p=1.000); fasting glucose (males, -6.3 mg/dl; females, -4.6 mg/dl; males vs. females, p=0.472); and weekly duration of aerobic activity (males, 122 min; females 123 min; males vs. females, p=0.832). With the exception of BP (greater decrease in females) and triglycerides (greater decrease in males), no significant gender differences were observed. In participants not taking statins (Cohort B), similar gender differences were noted for BP but not triglycerides. **Conclusions:** Our findings suggest that: 1) male and female statin-treated patients derive significant improvements in multiple risk factors during CR; and, 2) in statin-treated CR participants, with the possible exception of triglycerides, there are either no gender differences in the magnitude of improvement or, in the case of BP, gender differences that are similar to those in patients not taking statins.

2017 -  
ACC Annual  
Meeting  
(Accepted for  
Presentation)

#### EVALUATION OF THE CARDIOSMART POPULATION HEALTH MANAGEMENT INITIATIVE: CHANGES IN HEALTH RISKS AND PARTICIPANT SATISFACTION

Gordon NF, Salmon RD, Wright BS, Faircloth GC, Gordon TL, Hargrett M, Berk MR, Franklin BA, Gulati M.

90.

**Background:** Rapidly escalating healthcare costs have led to increasing attention on population health management (PHM). CardioSmart (CS) is a patient education and empowerment initiative of the American College of Cardiology that includes worksite wellness (CS@Work) and telehealth (CS OnCall) PHM components. In this study, we evaluated the clinical effectiveness of CS@Work/CS OnCall and participant satisfaction with CS OnCall in an employee population. **Methods:** A cohort of 19,022 adult (mean age = 42 years) male (n = 7,784) and female (n = 11,238) employees were evaluated at baseline and after a mean follow-up of 3.1 years. CS@Work included access to: the CardioSmart.org patient education website; a health

risk assessment; prevention-related challenges/activities; online lifestyle management programs; and the CS OnCall telehealth coaching program. Outcome variables included changes in 13 health risks that are predictive of future healthcare costs and the 10-year coronary heart disease (CHD) risk score. Participants in CS OnCall ( $n = 2,370$ ) were also asked to respond (5 = most favorable; 1 = least favorable rating) to statements related to their overall satisfaction with the program and whether they would likely recommend it to others. **Results:** The total number of health risks decreased by 4.9% and the magnitude of decrease was greater in those who participated in CS OnCall compared with those who did not (Decrease = 10.5% versus 3.6%;  $p = 0.001$ ). For employees with a baseline CHD risk  $\geq 10\%$ , the score decreased by 2.9% (relative risk reduction) and the decrease was greater in those who participated in CS OnCall compared with those who did not (Relative risk reduction = 13.7% versus 1.4%;  $p < 0.001$ ). For participants in CS OnCall, statements regarding overall satisfaction with the program (mean = 4.62) and recommending it to others (mean = 4.66) received very high ratings. **Conclusions:** These unique data demonstrate that: 1) the CS@Work and, especially, CS OnCall PHM programs elicit significant improvements in multiple risk factors and reduce overall CHD risk; and 2) CS OnCall is associated with very high participant satisfaction ratings. Collectively, these findings have important implications for PHM.

2020 -  
American  
Diabetes  
Association  
Annual  
Meeting

**COMPARATIVE EFFECTIVENESS OF LIFESTYLE INTERVENTION ON FASTING PLASMA GLUCOSE IN NORMAL WEIGHT VS. OVERWEIGHT/OBESE ADULTS WITH PREDIABETES.**

Salmon MK, Wright BS, Kridl TL, Faircloth GC, Salmon RD, Gordon NF.

91.

Almost 1 in 5 U.S. adults with prediabetes have a normal BMI. It is hypothesized that such individuals develop diabetes through different pathophysiological mechanisms and that methods of prevention may differ in the absence of overweight/obesity. Normal BMI is an exclusion criterion for many diabetes prevention programs and scarce data are available on the effectiveness of lifestyle intervention in normal weight adults with prediabetes. In this study, we compared the effect of technology-enabled lifestyle health coaching (LHC) on fasting plasma glucose (FPG) in normal weight (BMI 18.5-24.9 kg/m<sup>2</sup>;  $n = 188$ ), overweight (BMI 25.0-29.9 kg/m<sup>2</sup>;  $n = 495$ ) and obese (BMI  $\geq 30.0$  kg/m<sup>2</sup>;  $n = 1,214$ ) adults with prediabetes. Subjects were 1,897 consecutive adults with prediabetes (FPG = 100-125 mg/dl and not taking antidiabetic medication) who completed a baseline and follow-up evaluation as part of an LHC program (mean follow-up = 145 days). LHC included 1-on-1 behaviorally-oriented coaching, predominantly via the telephone and Internet, on exercise, nutrition and weight management. BMI decreased significantly ( $p < 0.001$ ) in the overweight ( $-0.6 \pm 1.1$  kg/m<sup>2</sup>) and obese ( $-1.3 \pm 1.8$  kg/m<sup>2</sup>) participants but was unchanged ( $0.0 \pm 1.5$  kg/m<sup>2</sup>) in the normal weight participants. In contrast, weekly aerobic exercise increased (normal weight =  $77 \pm 167$  min/week increase; overweight =  $98 \pm 191$  min/week increase; and obese =  $95 \pm 146$  min/week increase) and FPG decreased (normal weight =  $-9 \pm 9$  mg/dl decrease; overweight =  $-7 \pm 9$  mg/dl decrease; and obese =  $-6 \pm 10$  mg/dl decrease) significantly ( $p < 0.001$ ) in all 3 groups ( $p < 0.05$  for magnitude of decrease in FPG in normal weight versus obese participants). FPG was reduced to  $< 100$  mg/dl in 62.4%, 51.7% and 43.6% of the normal weight, overweight and obese participants, respectively. These data suggest that LHC is at least as effective in managing FPG in normal weight adults with prediabetes versus those who are overweight/obese.