



LIFESTYLE MANAGEMENT AND CARDIOVASCULAR RISK REDUCTION PROGRAMS

INTER_xVENT: RESEARCH SUMMARY AND ABSTRACTS (MARCH 2005)

The INTER_xVENT Lifestyle Management and Chronic Disease Risk Reduction Programs are based on models shown to be effective in randomized clinical trials. Moreover, because the data on all participants in the INTER_xVENT programs are computerized, the company has been able to utilize its proprietary outcomes analysis software to document the clinical effectiveness of its products and services. Over 50 published scientific manuscripts and abstracts have resulted from INTER_xVENT's work with its clients. Additionally, the company has conducted randomized clinical trials to further validate the clinical effectiveness of the INTER_xVENT programs in a variety of patient populations. Data on the effect of INTER_xVENT on specific important health risk factors have been published in journals including the *American Journal of Cardiology*, *Chest*, *Journal of the American College of Cardiology*, *Circulation*, *Coronary Artery Disease*, *Medicine and Science in Sports and Exercise*, *Current Atherosclerosis Reports* and the *Journal of Cardiopulmonary Rehabilitation*. Results have been presented at annual scientific meetings, including those of the American Heart Association, American College of Cardiology, American Association of Cardiovascular and Pulmonary Rehabilitation, American College of Sports Medicine, and the American Neurology Association.

Collectively, these studies have culminated in an evidence-based product that has been enthusiastically embraced and used by mainstream medical leaders. Current INTER_xVENT licensees include: Emory University (Atlanta, GA); St. Joseph's/Candler Health System (Savannah, GA); the University of Michigan (Ann Arbor, MI); the Medical College of Ohio (Toledo, OH); William Beaumont Hospital (Detroit, MI); the University of Ottawa Heart Institute (Ottawa, Ontario, Canada); Cedars-Sinai Health System (Los Angeles, CA); New Hanover Regional Health System (Wilmington, NC); Providence Health System (a unit of Ascension Healthcare, Mobile, AL); Heart Advocates, LLC (Hudson Valley, New York area); Texas Health System for five of its hospitals – Presbyterian Hospital of Dallas, Harris Methodist Hospital-Fort Worth, Presbyterian Hospital of Plano, Harris Methodist HEB Hospital, and Arlington Memorial Hospital (Dallas-Fort Worth, TX); Memorial Health System (Chattanooga, TN); Tallahassee Heart and Vascular Institute of Tallahassee Memorial HealthCare

(Tallahassee, FL); Forrest General Hospital (Hattiesburg, MS); The Summit at Kalispell Regional Medical Center (Kalispell, MT); St. Claire's Medical Center (Morehead, KY); PREVENT Consulting Services (Columbia, MO); Bryan LGH Medical Center (Lincoln, NE); Swedish Heart Institute (Seattle, WA); Olympic Medical Center (Port Angeles, WA); Capital Health and University of Alberta (Edmonton, Canada); and Virgin Active (South Africa and Namibia).

INTER_xVENT's research efforts are guided by Neil F. Gordon, MD, PhD, MPH (President and CEO, INTER_xVENT^{USA}, Inc.; Medical Director, Center for Heart Disease Prevention, St. Joseph's/Candler Health System, Savannah, GA; and Clinical Professor, Emory University School of Medicine, Atlanta, GA) in consultation with a prestigious Scientific Advisory Committee that has included these leading academicians / clinicians / scientists: R. Wayne Alexander, MD, PhD (R. Bruce Logue Professor and Chairman of Medicine, Emory University School of Medicine, Atlanta, GA); Barry A. Franklin, PhD (Director, Cardiac Rehabilitation and Exercise Laboratories, William Beaumont Hospital, Royal Oak, MI); William L. Haskell, PhD (Chairman, INTER_xVENT Scientific Advisory Committee and Professor of Medicine, Stanford University School of Medicine, Stanford Center for Research in Disease Prevention, Palo Alto, CA); Harold W. Kohl, III, PhD (Lead Epidemiologist and Epidemiology Team Leader-Physical Activity and Health Branch of the Division of Nutrition and Physical Activity, Centers for Disease Control and Prevention [CDC] Atlanta, GA); Penny M. Kris-Etherton, PhD, RD (Distinguished Professor of Nutrition, The Pennsylvania State University, University Park, PA); Bess H. Marcus, PhD (Director, Physical Activity Research Center, Professor of Psychiatry and Human Behavior, Brown Medical School and The Miriam Hospital, Providence, RI); David J. Maron, MD (Associate Professor of Medicine, Vanderbilt University Medical Center, Nashville, TN and Medical Director, Cardiovascular Services of America); and Kenneth R. Pelletier, PhD (President, American Health Association, and Clinical Professor of Medicine, Stanford University, University of Maryland School of Medicine and University of Arizona School of Medicine, residing in Walnut Creek, CA).

Key INTER_xVENT-related recent scientific abstracts and manuscripts are listed in the attached document. Briefly, these studies show that INTER_xVENT:

- a. Results in impressive improvements in multiple cardiovascular disease (CVD) risk factors (including blood pressure, total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, fasting glucose, body weight and body mass index, cardiorespiratory fitness and tobacco use) in diverse populations. These populations include African Americans and Caucasians (abstracts 23 and 54) and healthy persons as well as persons with a variety of chronic medical conditions (in particular, see abstract 31 - participants with arthritis; abstract 27 - participants with prediabetes; abstract 26 - participants with diabetes; abstract 24 - participants with the metabolic syndrome; abstract 19 - participants with hypertriglyceridemia; abstract 16 - participants with stroke/TIA/carotid artery disease; abstract 58 - cancer survivors).
- b. Is clinically effective in males and females, including premenopausal women, post-menopausal women taking hormone replacement therapy, and post-menopausal women not taking hormone replacement therapy (abstracts 38, 39, 53 and 55).
- c. Is clinically effective in educated and less-well-educated participants (abstract 37).
- d. Elicits clinically relevant and reproducible improvements in multiple CVD risk factors when administered by licensee institutions in multiple geographic locations (in particular, see abstracts 30 and 33).
- e. Is at least as effective when administered remotely from a call center using the telephone and the Internet as compared with onsite, face-to-face, program delivery (abstract 29).
- f. Is clinically effective when administered via telephone and the Internet to adults living in rural communities (abstracts 40 and 41).
- g. Results in high participant satisfaction rates (abstracts 13 and 34).
- h. Results in improvements in multiple indices of self-reported functional status and well-being (measured using the SF-36 - abstract 40).
- i. Can be of immense benefit in helping to control hypertension, hyperlipidemia and elevated blood glucose levels/diabetes in many individuals through lifestyle intervention alone - that is, INTER_xVENT can help reduce the need for drug therapy and thereby be of potential benefit from a cost-containment perspective (abstracts 35, 36 and 51 and manuscripts 1 and 7).
- j. Can be used to help overweight and obese individuals manage their weight while at the same time optimizing multiple CVD risk factors (abstracts 1 and 2 and manuscripts 1 and 3; also see abstracts 9, 19, 23, 24, 26, 27, 29-31, 33-39, 41 and 51 and manuscripts 6 and 7).
- k. Is effective in helping cigarette smokers discontinue tobacco use, irrespective of their stage of readiness to quit at program entry (abstract 50).
- l. Is at least as effective as a formal phase 2 cardiac rehabilitation program and a physician-supervised/ nurse case managed program in patients with coronary artery disease, despite its substantially lower cost and greater accessibility (see manuscript 6; also see abstract 34).
- m. Results in a reduction in healthcare claims in employee participants (abstract 32). The same data have now also been analyzed for two years of INTER_xVENT participation and show even a greater reduction in average health care claims per employee for INTER_xVENT participants as compared to nonparticipants, as follows: Claims per non-participating employee increased in each of the two years (compared to the baseline year) by a total of 66% (or \$708); Claims per participating employee decreased in each of the two years (compared to the baseline year) by a total of 36% (or \$559); This represents a two-year total difference in claims cost of \$1,267 per participant, representing a return of \$2.30 for each \$1.00 spent (or Return on Investment of 130%) based upon retail pricing in the United States).
- n. Can be used to help phase 2 cardiac rehabilitation programs provide comprehensive cardiovascular disease risk reduction services (abstracts 7, 14, 18, 20-22, 25, 28, 42-44, 45-49 and 52 and manuscript 5).

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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
- NHLBI = National Heart, Lung and Blood Institute
- 2nd Int Conf = Second International Conference on Women, Heart Disease and Stroke

KEY SCIENTIFIC MANUSCRIPTS

1. Gordon NF, Scott CB, Levine BD. Comparison of single versus multiple lifestyle interventions: Are the antihypertensive effects of exercise training and diet-induced weight loss additive? *Am J Cardiol* 1997;79:763-767.
2. Gordon NF, Haskell WA. Comprehensive cardiovascular disease risk reduction in a cardiac rehabilitation setting. *Am J Cardiol* 1997;80(8B):69H-73H.
3. Gordon NF. Comprehensive cardiovascular disease risk reduction in the clinical setting. *Coronary Artery Disease* 1998; 9:731-735.
4. Gordon NF, Salmon RD, Mitchell BS, Faircloth GC, Levinrad LI, Salmon S, Saxon WE, Reid KS. Innovative approaches to comprehensive cardiovascular disease risk reduction in clinical and community-based settings. *Current Atherosclerosis Reports* 2001; 3:498-506. <http://www.interventusa.com/research/article1.pdf>
5. Franklin BA, Bonzheim K, Warren J, Haapaniemi S, Byl N, Gordon N. Effects of a contemporary, exercise-based rehabilitation and cardiovascular risk reduction program on coronary patients with abnormal baseline risk factors. *CHEST* 2002; 122:338-343.
6. Gordon NF, English CD, Contractor AS, Salmon RD, Leighton RF, Franklin BA, Haskell WL. Effectiveness of three models for comprehensive cardiovascular disease risk reduction. *Am J Cardiol* 2002; 89:1263-1268. <http://www.interventusa.com/research/ajc062002.pdf>
7. Gordon NF, Salmon RD, Franklin BA, Sperling LS, Hall L, Leighton RF, Haskell WL. Clinical effectiveness of therapeutic lifestyle changes in patients with hypertension, hyperlipidemia, and/or hyperglycemia. *Am J Cardiol* 2004; 94:1558-1561. <http://www.interventusa.com/research/AJC12162004.pdf>

ABSTRACTS

1998 -
AACVPR
Annual
Meeting

INDEPENDENT AND COMBINED EFFECTS OF THE EXERCISE AND NUTRITION COMPONENTS OF A COMMUNITY-BASED PRIMARY PREVENTION PROGRAM (INTER_xVENT^{USA}).

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 INTER_xVENT^{USA}, Inc., Savannah, GA.

1. INTER_xVENT^{USA} 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 INTER_xVENT^{USA} 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):

	Exercise Only		Diet Only		Exercise + Diet	
	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 ₂ 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 INTER_xVENT^{USA} 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 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.
- 2001 - ACSM Annual Meeting**
- 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^{CR} Coordinating Center, Savannah, GA e-mail: 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.

<u>Behavior</u>	<u>% of All Participants</u>	<u>Precontemplation (%)</u>	<u>Contemplation (%)</u>	<u>Preparation (%)</u>
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.

2001 -
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RISK FACTOR STATUS ON ENTRY INTO CONTEMPORARY PHASE 2 CARDIAC REHABILITATION PROGRAMS

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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 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 ²	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.

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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 (INTER_xVENT), using a computerized database on 117 patients (\bar{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% $\dot{V}O_2$ max for 6-8 weeks. RESULTS: The effectiveness of the exercise training program was substantiated by significant ($p \leq 0.05$) reductions in heart rate (-8 beats/min), systolic blood pressure (-11 mmHg), and rating of perceived exertion (-2, 6-20 scale) at a standard submaximal workload. Initial and follow-up ratings of overall health were improved: excellent (2.6 to 4.3%); and, very good (20.7 to 35.7%). Average changes ($p \leq 0.05$ unless otherwise indicated) for all participants and those with abnormal baseline risk factors were: systolic blood pressure (-4 mmHg; -16 mmHg); diastolic blood pressure (-5 mmHg, -18 mmHg);

total cholesterol (-19 mg/dL, -75 mg/dL); LDL-cholesterol (-17 mg/dL, -61 mg/dL); HDL-cholesterol (-1 mg/dL [NS], + 11 mg/dL); and, triglycerides (-5 mg/dL [NS], -82 mg/dL), respectively. **CONCLUSION:** The present findings suggest that a dose-response relationship characterizes the change in coronary risk factors subsequent to a Phase 2 cardiac rehabilitation program. Patients with the worst coronary risk factor profiles at baseline, demonstrated the greatest improvements.

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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 providers in Florida and in other states.

2001 –
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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 ≥ 126 mg/dl. For individuals with abnormal baseline values for other CVD risk factors, significant ($p \leq 0.05$) improvements were observed in both groups as follows: total cholesterol (diabetes, -43 mg/dl; no diabetes, -36 mg/dl), LDL cholesterol (diabetes, -23 mg/dl; no diabetes, -21 mg/dl), HDL cholesterol (diabetes, 2 mg/dl; no diabetes, 4 mg/dl), triglycerides (diabetes, -76 mg/dl; no diabetes, -69 mg/dl), systolic/diastolic blood pressure (diabetes, -15/-12 mmHg; no diabetes, -16/-10 mmHg), and weight (diabetes, -5 lbs; no diabetes, -4 lbs). The calculated Framingham 10-year coronary heart disease risk score decreased by 16.7% and 15.1% in individuals with and without diabetes, respectively. No statistically significant differences were observed between the two groups. These data demonstrate that, when a low fat/high complex carbohydrate diet is administered as part of a comprehensive CVD risk reduction program, individuals with and without diabetes derive similar improvements in multiple risk factors.

2001 –
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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 ≤ 24.5 ml/kg/min. These data indicate that 12 weeks of participation in a phase 2 cardiac rehabilitation program results in similar improvements in multiple CVD risk factors and greater increases in maximal oxygen uptake as compared with a physician supervised, nurse case managed CVD risk reduction program.

2001 –
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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 INTER_xVENT 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.

2001 –
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BENEFIT OF A WORKSITE-BASED CARDIOVASCULAR RISK REDUCTION PROGRAM ON EMPLOYEE HEALTHCARE CLAIMS

Chip Faircloth MBA MHA, Sheldon Warman MD, Susan Pickel BSN MHM, Richard Salmon DDS MBA, Brenda Mitchell PhD, Barry Franklin PhD, Neil Gordon MD, INTER_xVENT 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_xVENT) on employee healthcare claims. INTER_xVENT 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_xVENT 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_xVENT. 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_xVENT participants and decreased by 14.3% (\$997.65 versus \$855.18) for the INTER_xVENT participants. These findings have important ramifications for United States companies in terms of the curtailment of rapidly escalating healthcare expenditures.

2001 –
AACVPR
Annual
Meeting

USING DISCREPANCY ANALYSIS TO ASSESS AND IMPROVE PARTICIPANT SATISFACTION IN A COMPREHENSIVE CARDIOVASCULAR RISK REDUCTION PROGRAM

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13. 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_xVENT) 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_xVENT 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_xVENT 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.

2001 –
AACVPR
Annual
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NEED FOR CONTINUED CARDIOVASCULAR DISEASE (CVD) RISK REDUCTION INTERVENTION AFTER COMPLETION OF A CONTEMPORARY PHASE 2 CARDIAC REHABILITATION PROGRAM

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

2001 – CDC
Prevention
Conference

IMPLEMENTATION OF AN INNOVATIVE COMMUNITY-BASED HEART DISEASE AND STROKE RISK REDUCTION PROGRAM (INTERxVENT)

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15. 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, INTERxVENT, 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 INTERxVENT programs.

2001, June –
Stroke
(journal)

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

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16. 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 ($p \leq 0.05$) improvements were observed for these and other select CVD risk factors in patients with abnormal baseline values. These data demonstrate that potentially modifiable CVD risk factors are often suboptimally controlled in patients at high risk for stroke. They further document the clinical effectiveness of a neurologist supervised, nurse case managed stroke risk reduction program.

2001 –
Journal of
Stroke &
Cerebro
Vascular
Disease

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

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

17. **Background:** Suboptimal CVD risk factor management contributes to the more than 700,000 strokes that occur annually in the U.S. Recently, we have demonstrated the clinical effectiveness of a physician supervised, nurse case managed stroke secondary prevention program. In this study, we compared the CVD risk factor status of African American versus Caucasian patients referred by physicians to a stroke secondary prevention program. **Methods:** Multiple CVD risk factors were evaluated in 307 consecutive African American (n=77) and Caucasian (n=230) patients who previously suffered a stroke or TIA or had carotid artery disease. **Results:** Although African Americans were younger than Caucasians (63 versus 68 years, $p < 0.05$), African Americans had higher ($p < 0.05$) BMI (difference=3kg/m²), fasting LDL

cholesterol (difference=19 mg/dL), Lp(a) (difference=40 mg/dL), fasting glucose (difference=16 mg/dL), and homocysteine (difference=3.9 umol/L) levels, and were more likely to smoke cigarettes (15.6 versus 13.9%) and be sedentary (74 versus 68.3%). Statistically significant differences were not observed for HDL cholesterol, triglycerides, and blood pressure. **Conclusions:** Multiple CVD risk factors are less well controlled in African American than in Caucasian patients referred to a stroke secondary prevention program.

2002 –
AACVPR
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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

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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.

2002 –
AACVPR
Annual
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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_xVENT 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.

2002 –
AACVPR
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EFFECT OF PERCEIVED HEALTH STATUS ON CLINICAL OUTCOMES IN PARTICIPANTS IN A CONTEMPORARY PHASE 2 CARDIAC REHABILITATION PROGRAM

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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.

2002 –
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CLINICAL EFFECTIVENESS OF A PHASE 2 CARDIAC REHABILITATION PROGRAM IN PATIENTS WITH VERSUS WITHOUT A SELF-REPORTED HISTORY OF DEPRESSION

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21. 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 –
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CLINICAL EFFECTIVENESS OF A PHASE 2 CARDIAC REHABILITATION PROGRAM IN PATIENTS WITH VERSUS WITHOUT DIABETES

Susan Haapaniemi, MS; Barry Franklin, PhD; Dalynn Badenhop, PhD; Laurence Sperling, MD; Richard Salmon, DDS; Neil Gordon, MD
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22. 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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CLINICAL EFFECTIVENESS OF A COMMUNITY-BASED CARDIOVASCULAR RISK REDUCTION PROGRAM IN AFRICAN AMERICANS VERSUS CAUCASIANS

Carlye Barat, MS; Carla English, MHS; Susan Pickel, BSN, MHM; Sheldon Warman, MD; Richard Salmon, DDS; Linda Hall, PhD; Barry Franklin, PhD; Neil Gordon, MD
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23. 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_xVENT) 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_xVENT 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_xVENT, 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
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24. 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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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.
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25. Patient education, counseling, and behavioral interventions are important elements of cardiac rehabilitation. INTER_xVENT^{CR} is designed to help facilitate these elements during phase 2 cardiac rehabilitation and includes the use of written and audio materials together with brief one-on-one counseling. In this multicenter study, we investigated the clinical effectiveness of phase 2 cardiac rehabilitation programs that utilize INTER_xVENT^{CR} in participants with (Group A, n=539) and without (Group B, n=264) 1 or more years of college education. Cardiovascular disease (CVD) risk factors were evaluated at baseline and after an average of approximately 90 days of participation in the phase 2 cardiac rehabilitation program at 12 centers in the United States. On exit from the phase 2 cardiac rehabilitation program, clinically relevant improvements ($p \leq 0.05$, unless otherwise indicated) in multiple CVD risk factors were observed for participants in both groups who had abnormal baseline risk factor values (based on national clinical guidelines), as follows: total cholesterol (Group A, -40 mg/dl; Group B, -42 mg/dl); LDL cholesterol (Group A, -25 mg/dl; Group B, -32 mg/dl); HDL cholesterol (Group A, 4 mg/dl; Group B, 4 mg/dl); triglycerides (Group A, -85 mg/dl; Group B, -16 mg/dl, $p=NS$); fasting glucose (Group A, -52 mg/dl, $p=NS$; Group B, -32 mg/dl); systolic/diastolic BP (Group A, -23/-20 mmHg; Group B, -17/-16 mmHg) and weight (Group A, -2 lbs; Group B, -2 lbs). With the exception of serum triglycerides and systolic BP (which decreased to a greater degree in Group A versus Group B, $p \leq 0.05$), no other statistically significant differences were observed for Group A as compared with Group B. These data demonstrate that patients with and patients without 1 or more years of previous college education derive clinically relevant improvements in multiple CVD risk factors during participation in a phase 2 cardiac rehabilitation program that utilizes INTER_xVENT^{CR}.

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

Susan Pickel, BSN, MHM; Sheldon Warman, MD; Brenda Mitchell, PhD; Ivan Levinrad, RPT; Richard Leighton, MD; Carla English, MHS; Richard Salmon, DDS; Barry Franklin, PhD; Neil Gordon, MD
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26. Diabetes is a major contributor to cardiovascular disease (CVD) morbidity and mortality. Previous studies have documented the clinical

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

2002 –
AACVPR
Annual
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CLINICAL EFFECTIVENESS OF A COMMUNITY-BASED CARDIOVASCULAR RISK REDUCTION PROGRAM IN PARTICIPANTS WITH VERSUS WITHOUT PREDIABETES

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

2002 –
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CLINICAL EFFECTIVENESS OF A PHASE 2 CARDIAC REHABILITATION PROGRAM IN PARTICIPANTS WITH AND WITHOUT ARTHRITIS

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

2002 –

CLINICAL EFFECTIVENESS OF A COMPREHENSIVE CARDIOVASCULAR RISK REDUCTION PROGRAM: ON-SITE VERSUS

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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. INTER_xVENT 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 –
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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. INTER_xVENT 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 –
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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. INTER_xVENT Coordinating Center, Savannah, GA

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 ≤ 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 –
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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 –
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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 –
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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 –
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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

35.

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 ≥ 140 mmHg and/or diastolic BP ≥ 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 ≥ 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 ≥ 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.

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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

36.

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 ≥ 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 ≥ 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/m²) 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.

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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

37. **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.

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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

38. **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.

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

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

39. **Rationale:** 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. **Objectives:** 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. **Methodology:** 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. **Results:** 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 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 $\geq 10\%$ at baseline, the risk score decreased to a similar degree in female (-23.1%,

$p \leq 0.05$) and male (-19.4%, $p \leq 0.05$) participants. **Conclusion:** 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.

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EFFECT OF A TELEPHONE/INTERNET DELIVERED COMPREHENSIVE CARDIOVASCULAR RISK REDUCTION PROGRAM ON SELF-REPORTED HEALTH STATUS IN PARTICIPANTS FROM RURAL COMMUNITIES

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

40.

Rationale: People living in rural communities have less access to preventive healthcare services than those in urban communities. **Objectives:** 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. **Methodology:** 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. **Results:** At baseline, SF-36 transformed scores were significantly higher ($p \leq 0.05$) 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 ($*p \leq 0.05$): 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 ($p \leq 0.05$) in the rural versus urban participants. **Conclusion:** 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.

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CLINICAL EFFECTIVENESS OF A TELEPHONE/INTERNET DELIVERED COMPREHENSIVE CARDIOVASCULAR RISK REDUCTION PROGRAM IN PARTICIPANTS FROM RURAL COMMUNITIES

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41.

Rationale: Geographic accessibility is an important predictor of participation in cardiovascular disease (CVD) risk reduction programs. **Objectives:** 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. **Methodology:** 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. **Results:** For participants with abnormal baseline CVD risk 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

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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 30 kg/m²) and patients who were not overweight (Group B, n=347, BMI <25 kg/m²). **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/m², $p < 0.05$) decreased in Group A patients and increased slightly in Group B patients (weight: 1.2 lbs., $p < 0.05$; BMI: 0.2 kg/m², $p < 0.05$) 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

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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

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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

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45. **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 ± 11 years) and unmarried ($n=94$; age = 64 ± 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

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

46. **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 ± 11 years) and unmarried (n=94; age = 64 ± 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

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47. **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

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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

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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/m² or higher) and patients who were not overweight (Group B; $n=648$; BMI < 25 kg/m²). **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.

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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

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50.

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.

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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

51. **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 \geq 140 mmHg (n=335) and/or diastolic BP \geq 90 mmHg (n=346); LDL cholesterol in unmedicated patients with a baseline value \geq 100 mg/dl (n = 1,553); and fasting blood glucose in unmedicated patients with a baseline value \geq 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.

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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

52. **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 ≥ 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). 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.

2005 –
In Review

EFFECT OF GENDER ON CLINICAL RESPONSIVENESS TO THERAPEUTIC LIFESTYLE CHANGES

Neil F. Gordon, Richard D. Salmon, Terri L. Gordon, E. Daniel Biggerstaff, George C. Faircloth, Ivan Levinrad, Brenda S. Mitchell, Richard F. Leighton, Anil Verma, Martin R. Berk, Laurence S. Sperling, Linda K. Hall, C. Noel Bairey Merz, Nanette K. Wenger, William L. Haskell, Barry A. Franklin, St. Joseph's/Candler Health System, Savannah, GA, INTERVENT Coordinating Center, Savannah, GA

53. **Background:** 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. **Methods:** In this study, we compared the clinical effectiveness of TLC in 2,144 consecutive men (n=543; age=47 \pm 10 years) and women (n=1,601; age=46 \pm 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. 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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CLINICAL EFFECTIVENESS OF THERAPEUTIC LIFESTYLE CHANGES IN AFRICAN AMERICANS VERSUS CAUCASIANS

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54.

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; age=44+/-9 years) and Caucasian (Group B; n=1,555; age=47+/-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 ≤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≤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≤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≤0.05 for Group A versus B). In patients with a Framingham 10-year coronary heart disease risk score ≥10% at baseline, the score decreased significantly (p ≤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

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55.

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; age=41+/-8 years) and post-menopausal (Group B; n=587; age=55+/-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 ≤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≤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.

2005 –
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CLINICAL EFFECTIVENESS OF THERAPEUTIC LIFESTYLE CHANGES IN PATIENTS WITH LOW-DENSITY LIPOPROTEIN SUBCLASS PATTERN B VERSUS A

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56.

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, $p = \text{NS}$; $p < 0.05$ for pattern B versus A participants), LDL cholesterol (-11 mg/dl, $p < 0.05$ versus -6 mg/dl, $p < 0.05$; $p = \text{NS}$ 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, $p = \text{NS}$; $p < 0.05$ for pattern B versus A participants), HDL cholesterol (6 mg/dl, $p < 0.05$ versus 3 mg/dl, $p < 0.05$; $p = \text{NS}$ for pattern B versus A participants); large HDL cholesterol (4 mg/dl, $p < 0.05$ versus 4 mg/dl, $p < 0.05$; $p = \text{NS}$ for pattern B versus A participants), triglycerides (-91 mg/dl, $p < 0.05$ versus -3 mg/dl, $p = \text{NS}$; $p < 0.05$ for pattern B versus A participants), and large VLDL cholesterol (-58 mg/dl, $p = \text{NS}$ versus 6 mg/dl, $p = \text{NS}$; $p < 0.05$ 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

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57.

PURPOSE: Improved survival of patients with cardiovascular disease (CVD) and the aging of America have created a large population of elderly patients (≥ 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 ≥ 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). **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

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58.

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; $p = \text{NS}$ 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 %); $p = \text{NS}$ 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

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59.

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 (≥ 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.

<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	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 ²	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.