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## Integrated medical care management and behavioral risk factor reduction for multicondition patients: behavioral outcomes of the TEAMcare trial

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### Abstract

**Purpose**—The purpose of the study was to compare behavioral outcomes (physical activity, sedentary behavior, smoking cessation, diet) between the intervention and usual care conditions from the TEAMcare trial.

**Methods**—TEAMcare was a randomized trial among 214 adults with depression and poorly controlled diabetes and/or coronary heart disease that promoted health behavior change and pharmacotherapy to improve health. Behavioral outcomes were measured with the International Physical Activity Questionnaire (physical activity, sitting time) and the Summary of Diabetes Self-Care Activities Measure (smoking, diet, exercise). Poisson regression models among completers ( $N=185$ ) were conducted adjusting for age, education, smoking status and depression.

**Results**—Intervention participants had more days/week following a healthy eating plan [relative rate=1.2, 95% confidence interval (CI)=1.1–1.4] and more days of participation in 30 min of physical activity (relative rate=1.2, 95% CI=1.1–2.0) compared to usual care. Intervention participants were more likely to meet physical activity guidelines (7.5% increase) compared to usual care (12% decrease;  $P=.053$ ).

**Conclusion**—Diet and activity generally improved for those receiving the intervention, while there were no differences in some aspects of diet (fruit and vegetable and high-fat food intake), smoking status and sitting time between conditions in the TEAMcare trial.

### Keywords

Physical activity; Diet; Diabetes; Depression; Cardiovascular disease

## 1. Introduction

Twenty percent of American adults have two or more chronic conditions [1,2]. A common group of illnesses that tend to co-occur is diabetes, coronary heart disease (CHD) and

depression. People with diabetes or CHD have twice the odds of having comorbid depression compared to primary care populations [3]. Having multiple chronic conditions greatly increases health care expenditures. Costs are nearly three times higher for those with three or more chronic conditions compared to those with one. Average per capita spending is \$1900 for persons with one chronic condition compared to \$5600 for those with three or more [2].

Common behavioral risk factors among those with diabetes, CHD and depression include physical inactivity, sedentary behavior, smoking and poor diet [4,5]. Physical activity has been shown to significantly reduce hemoglobin A1c (HbA1c) levels among people with type 2 diabetes [4,6]. Increased physical activity is associated with improvements in depression [7,8], as well as decreased risk of cardiovascular disease mortality [9]. Healthy diet, particularly low glycemic index foods, has also been associated with improvements in glycemic control [4]. Due to the projected increase in the numbers of people who have diabetes and multimorbidities associated with an aging and more obese population, interventions that integrate medical and behavioral management of chronic disease to address cardiovascular disease risk factors and promote quality of life are needed [2].

Despite the need of primary care clinicians, there has been surprisingly little research testing interventions that integrate medical and pharmacologic care management and behavioral risk factor reduction, particularly among complex patients with multiple chronic conditions. Management of patients with comorbid depression and chronic physical diseases is complex and multifaceted. Enhancing chronic illness self-management is an important goal for such patients [10]. Effective self-management should be patient-centered to maximize adherence to multiple complex behavior change targets (e.g., medications that can have side effects, routine monitoring of blood pressure and glucose levels, engaging in regular physical activity, smoking cessation, weight control and following a healthy diet plan) [11].

We sought to determine whether health behaviors relevant to chronic disease behavioral self-management were improved in a randomized trial of a multifaceted intervention for patients with comorbid depression and poorly controlled diabetes or CHD. TEAMcare was a 12-month collaborative care intervention for people with depression and one or more measures of poorly controlled diabetes and/or CHD with the goal of improving depression and medical outcomes. This team-based and integrated intervention focused on managing depression and improving control of blood glucose levels, blood pressure and lipids via enhanced medical management of chronic disease and supporting patients in achieving personal self-care goals involving exercise, diet, weight loss, smoking cessation and behavioral activation. Self-care targets were individualized and included goals for self-monitoring of blood pressure and blood glucose levels, as well as changing health behaviors (exercise, diet).

Given the widely understood difficulty in changing multiple behaviors (e.g., medication adherence and physical activity) simultaneously, primary emphasis was placed on pharmacologic management of blood pressure, glycemic control, lipids and depression. However, progress toward behavioral self-care goals was viewed as essential as the nurse care managers also focused on activating and empowering patients in chronic disease self-

management. At 12-month follow-up, intervention participants had larger improvements than usual care participants in glycated hemoglobin, low-density lipoprotein (LDL) cholesterol, systolic blood pressure and depression [12]. Only preliminary, limited analyses of behavioral risk factors could be included in the main outcomes paper. There were no statistically significant intervention differences in adhering to 2 or more days per week of following a general healthy eating plan, specific healthy eating plan, physical activity (general) or specific exercise plans at 12 months [12]. However, all measures showed trends in favor of the intervention relative to the usual care group, with the strongest trends for participants adhering to 2 or more days of a general exercise plan (54% intervention compared to 44% usual care) and adhering to a specific exercise plan (29% intervention compared to 21% usual care). The purpose of this secondary analysis of the TEAMcare intervention was to expand beyond the initial brief analyses by using additional items measuring diet quality (servings of fruit and vegetables, servings of high-fat foods) and physical activity [International Physical Activity Questionnaire (IPAQ)]. We conducted analyses using continuous outcomes for the primary analysis and dichotomous outcomes for a secondary analysis to improve understanding of how behavioral risk patterns overall changed during the course of the intervention. We also sought to explore behavior changes for other relevant health behaviors and risks including sedentary behavior, tobacco use and obesity.

## 2. Methods

### 2.1. Participants

The TEAMcare trial recruited participants from May 2007 through October 2009. Participants were recruited from 14 primary care clinics that are part of Group Health Cooperative in Washington State. Potential participants were identified from electronic medical records using the *International Classification of Diseases, Ninth Revision*, codes for diagnoses of diabetes, CHD or both. Patients had to have one or more measures of poorly controlled disease within the past 12 months including LDL cholesterol >130 mg/dl, glycated hemoglobin >8.5%, as well as blood pressure >140/90 mmHg on two separate visits within 12 months. Inclusion criteria were ambulatory, English-speaking and planning to continue enrollment at Group Health for 12 months. Exclusion criteria included terminal illness, residing in long-term care, severe hearing loss, planning on having bariatric surgery in the next 3 months, pregnancy or breast-feeding, ongoing psychiatric care, serious mental health disorder (i.e., bipolar or schizophrenia, use of antipsychotic or mood stabilizers) or observed mental confusion which could suggest dementia. Eligible patients completed a Patient Health Questionnaire (PHQ)-2 to screen for likelihood of major depression by mail or telephone. Those with scores >3 also completed a PHQ-9 by telephone interview (scores range from 0 to 27, with higher scores indicating greater severity of depressive symptoms). Those who scored 3 or more on the PHQ-2 and 10 or higher on the PHQ-9 were eligible. A recent systematic review found that a cutoff of 10 or higher on the PHQ-9 was shown to have high sensitivity (80%) and specificity (92%) for a diagnosis of major depression among adults [13,14].

## 2.2. Study procedures

Study measurements were obtained by trained research assistants blinded to intervention condition at baseline, 6 months and 12 months. After baseline measurements, patients were randomized to receive enhanced usual care or the intervention program using a permuted block design and randomly selected blocks of 4, 6 and 8 patients. After the baseline measurements, a study nurse contacted patients who were randomized to the intervention condition to begin treatment.

**2.2.1. Intervention**—The 12-month intervention was conducted by registered nurses with experience in diabetes education in collaboration with primary care physicians. The intervention aimed to improve depression, glycemic control, blood pressure and cholesterol using pharmacotherapy and self-care support. Patients worked with nurses to establish self-care goals during primary care visits occurring every 2–3 weeks. The nurses monitored patient progress with self-care activities as well as other targets (e.g., depression, medication). Nurses were supervised weekly by a primary care physician and psychiatrist who made targeted recommendations regarding medications to improve disease control that were communicated to the patient's primary care physician by the nurse. The nurses used behavioral activation and motivational interviewing strategies to help patients problem-solve and set self-care goals for exercise, diet changes and/or smoking cessation. Patients who chose to focus on increasing exercise were given a free pedometer and encouraged to log their daily steps and to set goals to increase steps per day. Further details on the intervention are published elsewhere [12].

**2.2.2. Enhanced usual care**—Patients received usual diabetes, depression and CHD care through their primary care physician including referral to mental health care services. Enhancements to usual care included the following: (1) participants were encouraged to discuss care for depression, diabetes and/or CHD with their primary care physician, and (2) providers were notified about patients' depression and poor control of medical disease and received laboratory test results at baseline, 6 months and 12 months.

## 2.3. Measures

**2.3.1. Health behaviors**—The IPAQ short form assessed physical activity and sitting time [15]. Items on the IPAQ assess the time spent engaging in vigorous, moderate and walking physical activities for more than 10 min at a time in the last 7 days. Responses were scored according to the IPAQ scoring protocol (available at: <http://www.ipaq.ki.se/scoring.htm>). The protocol involves multiplying minutes spent in vigorous, moderate and walking activities by the number of days per week participants reported engaging in them. We scored activities according to their metabolic equivalent (MET) values (moderate=4.0, walking=3.3, vigorous=8.0) and calculated total METs per week. Participants were then classified based on their responses to items and their total MET values as engaging in low, medium or high levels of physical activity. Medium activity was defined as spending 3 or more days per week in vigorous-intensity activity for at least 20 min per day, 5 or more days of moderate-intensity activity or walking activity of at least 30 min per day, or any combination of walking, moderate or vigorous activity that accumulated at least 600 MET min/ week. High activity was classified as vigorous activity on at least 3 days per week that

achieves a minimum of 1500 MET min/week or a combination of any type of activity that achieves at least 3000 MET min/week. People were classified as achieving low levels of physical activity if they did not meet the moderate or vigorous criteria. We made two other physical activity variables that were explored in analyses. We classified those in the medium or high category as meeting physical activity guidelines. And because a large number of participants reported no physical activity on the IPAQ, we separately classified people as reporting no physical activity or reporting any physical activity. Sitting time was also measured by one of the IPAQ items that assesses total self-reported minutes spent sitting on a usual week day.

As reported in a previous publication, participants also answered items from the Summary of Diabetes Self-Care Activities Measure (SDSCA) [16]. Physical activity was assessed by asking how many of the last 7 days they engaged in 30 min of uninterrupted physical activity and how many days they participated in specific exercise sessions (such as swimming, walking, biking; other than activities around the house or as part of work). Dietary variables were assessed with three items from the SDSCA including how many days in the last 7 days they followed a healthy eating plan, ate five or more servings of fruit and vegetables, and ate high-fat foods such as red meat or whole-fat dairy products. We also classified people as having the following risk factors from the SDSCA: reporting a healthy eating plan less than 5 days per week, eating five or more servings of fruit and vegetables on less than 5 days per week, and eating high-fat foods 3 or more days per week. We considered people smokers if they affirmatively responded to an item from the SDSCA asking “Have you smoked a cigarette — even one puff — during the past 7 days?”

**2.3.2. Demographic and health variables**—Participants self-reported their age, race/ethnicity, education, employment and marital status. Body mass index (BMI) was calculated from height and weight measured at baseline and 12 months. Waist circumference in centimeters was also measured at baseline and 12 months. Depressive symptoms were measured with the PHQ-9.

## 2.4. Analysis plan

Analyses were conducted among participants that completed the 12-month follow-up. Descriptive statistics such as means and standard deviations for continuously scored variables and percent and frequencies for categorically and binary scored variables were provided for comparison of intervention and usual care participants. Multivariable Poisson regression with robust standard errors adjusting for age, education, smoking and depression was used to examine the relationship of the intervention with each health behavior outcome from the IPAQ (meeting physical activity guidelines, IPAQ report of any physical activity, sedentary time) and SDSCA (days following a healthy eating plan, days eating five or more servings of fruit and vegetables, days eating high-fat foods, days participating in 30 min of physical activity and days participating in specific exercise sessions). We also examined the percent of intervention and control group participants who did not meet the physical activity guideline (IPAQ), reported unhealthy eating habits, smoked and had a BMI in the obese range (BMI >30) using baseline value adjusted Poisson regression models. Finally, we counted and compared the number of risk factors participants in the intervention and usual

care group had at baseline and 1 year using Poisson regression models. Statistical analysis was performed using Stata 12.0.

### 3. Results

A total of 214 participants were enrolled in the study, with 185 (93 intervention and 92 usual care participants) completing the 12-month follow-up. At baseline, those who completed the study were on average 57 years of age. Intervention and usual care group completers did not differ on any baseline variables (Table 1). Participants reported 772 min per week of physical activity on average, with just under half of the sample falling into the low category of physical activity level. A CONSORT diagram was previously published for the trial [12].

#### 3.1. Multivariable regression findings

We found that, over 12 months of intervention, participants in the intervention group were 24% more likely to report following a healthy eating plan. Intervention participants reported an increase of 1.6 days/week for following a healthy eating plan, while usual care participants had an increase of .5 day per week. Participants in the intervention group were also 16% more likely to report participation in 30 min of physical activity. Intervention participants reported participating in 30 min of physical activity 0.8 days per week more at 12 months compared to an increase of .2 days per week for the usual care group after adjustment for age, education, smoking and depression. In addition, there was a trend for more intervention participants to meet physical activity guidelines, with a net increase of 7.5% compared to a 12% decrease in meeting physical activity guidelines in the usual care group (Table 2). However, the number of people reporting no physical activity did not appreciably change in the intervention group compared to the usual care group.

Both groups had decreases in self-reported minutes spent sitting per day (intervention decrease=53.2 min; usual care decrease= 16.1 min), with no significant between-group differences. Both groups also showed improvements in the number of days they eat five or more fruit and vegetables (intervention increase=.9 day; usual care increase=.3 day). Similarly, both groups reported fewer days per week they eat high-fat foods (intervention decrease=.7 day; usual care decrease=.4 day), with no significant between-group difference.

#### 3.2. Health behavior risks

Over the 1-year period, intervention participants were more likely to meet physical activity guidelines (trend for significance), engage in a healthy eating plan 5 or more days per week and report 5 or more days per week of engaging in 30 min of physical activity than usual care participants (Table 3). Contrary to favorable trends for other behavioral risk factors, intervention participants were more likely to smoke at follow-up than control participants. There were no significant differences for fruit and vegetable intake, eating high-fat foods, participating in specific exercise sessions or obesity.

### 4. Discussion

Overall, we found that an integrated medical and depression care management program with a focus on enhancing self-care activities had generally favorable effects on health behaviors

including physical activity and healthy diet. By analyzing continuous outcomes rather than the binary derivation used in the original outcomes publication, we demonstrated significant effects of the intervention on improving exercise and adherence to healthy diet compared to usual care. We did not, however, observe meaningful weight changes or reduced sedentary time. Although smoking rates were relatively low in both groups at baseline, there was an unexpected observation of slightly increased smoking rates among intervention patients, while there was a slight decrease in smoking among controls. Some health behaviors increased for the intervention group (physical activity, following a healthy eating plan). However, physical activity may have only improved among people that did some physical activity at baseline because we found no change in the number of people reporting no physical activity. The findings suggest that it may be possible to integrate personalized behavioral risk factor reduction with care management that emphasizes medical management of chronic disease. The tailoring of self-management goals to individual patients' readiness and preferences may help counter risks of overwhelming patients. At the same time, improvements were modest, and some risk factors did not change at all (e.g., smoking, weight, and fruit and vegetable and dietary fat components of diet).

A prospective study of people with stable showed that those with depressive symptoms had 31% higher rates of cardiovascular events, but the increased rate was largely explained by physical inactivity [17]. Patients with comorbid depression and diabetes compared to those with diabetes alone have also been found to be significantly more likely to be obese, be inactive and smoke [18]. One recent randomized trial showed that both exercise and sertraline were effective in reducing depressive symptoms in people with CHD [7]. Another recent trial showed that cognitive behavioral therapy plus exercise was effective in decreasing depressive symptoms and blood pressure in patients with comorbid depression and diabetes [19]. These results underscore the importance of behavioral risk factors in the health of people with depression and comorbid health conditions. Yet, most previous studies examining integrated medical care for patients with depression and comorbidities such as diabetes have focused on improving medication adherence and have not emphasized health behaviors [20]. The TEAMcare intervention and results suggest that individualized support for health behavior change, in the context of improved medical management of chronic disease, may be beneficial and suggest that there is room for further health behavior change to occur.

Previous publications on the outcomes of TEAMcare have shown that the primary outcomes of the trial including depressive symptom scores and indicators of diabetes/CHD risk (e.g., HbA1c, blood pressure and LDL cholesterol levels) were significantly improved with frequent and vigilant pharmacotherapy adjustments [21]. Our new analysis shows that these improvements in disease control measures occurred without changes in BMI or smoking cessation, while there were some improvements in activity level and diet. The behavioral goals developed by TEAMcare participants were up to each individual, with greater emphasis on medication adherence and intensification than on health behavior change. Thus, the modest improvements in physical activity and diet achieved in this trial are promising, as initial progress towards a healthier lifestyle may provide a foundation for subsequent change.

Previous studies have not examined sitting time among patients with depression, diabetes and/or CHD comorbidities. Participants in our study self-reported a high amount of sitting time — on average 8 h/day. There is growing evidence that time spent sitting promotes adverse health impacts including weight gain, glucose tolerance, depression, low physical function and mortality independent of physical activity level [22–36]. In the current study, explicit goals were not made around reducing sitting time, and we found no effects on sitting time. Given the need to focus on achievable behavioral goals with complex chronic disease patients, future research might examine the feasibility of reducing sitting time among patients with comorbid conditions.

## 5. Study limitations

We used completer analyses, but we had high rates of follow-up at 12 months (86%) and did not find baseline differences on any variable examined between intervention and usual care groups. Self-reports of physical activity and dietary behaviors may have limited validity. Problems with patient self-reports on the IPAQ include reporting physical activity lasting less than 10 min, reporting the same activities more than once, confusion over what types of activities to include and including the total time of activities where really only a portion was at high enough intensity [37]. For these reasons, use of objective activity monitoring devices in future studies would be beneficial. Our use of two measures of self-reported physical activity (IPAQ and SDSCA) with results that converge supports our findings. In addition, we were only able to include summary measures of diet and did not conduct comprehensive food frequency assessments. Finally, our *P* values did not account for multiple comparisons; our findings detected by model *P* values less than .05 should be interpreted with care. However, with the exception of smoking, all of the physical activity and dietary measured changes favored the intervention group compared to usual care participants even if the results did not reach significance. Our study was not powered on these measures, so it is not surprising that only some reached significance.

## 6. Conclusions

The TEAMcare intervention for depressed patients with comorbid chronic conditions integrated pharmacologic care management and health behavior change. Promising behavioral risk factor results included increased rates of meeting physical activity guidelines and improved diet. Future research should include objective assessment of physical activity and sedentary behavior. Also, efforts to continue improvement in behavioral risks, such as smoking cessation and weight management, are warranted in this complex patient population with depression, diabetes and/or cardiovascular disease. These results suggest that integration of enhanced pharmacologic and behavioral management of complex chronic disease may be possible with individualized and realistic behavioral goals.

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**Table 1**

Demographic characteristics of the sample (completers only)

	<u>Total sample</u>	<u>Intervention (N=93)<sup>a</sup></u>	<u>Usual care (N=92)<sup>a</sup></u>
	<u>Mean (S.D.) or %</u>	<u>Mean (S.D.) or %</u>	<u>Mean or %</u>
Age	56.7 (11.3)	57.0 (10.7)	56.5 (11.9)
Female sex	54.1%	50.5%	57.6%
Race			
American Indian or Alaska Native	8.1%	8.6%	7.6%
Black or African-American	6.0%	9.7%	2.2%
White	78.9%	74.2%	83.7%
Native Hawaiian, Pacific Islander, Asian or other	7%	7.7%	6.5%
Non-Hispanic ethnicity	96.8%	97.9%	95.7%
Employment			
Part-time or full-time	56.5%	53.3%	59.8%
Retired or homemaker	33.2%	36.0%	29.4%
Unemployed or disabled	10.3%	9.8%	10.9%
Some college or higher education	57.8%	61.3%	54.3%
Married or living as married			
Married, living as married	58.4%	60.2%	56.5%
PHQ-9	14.2 (3.4)	14.4 (3.6)	14.0 (3.1)
Diabetes	84.9%	88.2%	81.5%
Coronary heart disease	27.0%	22.6%	31.5%
BMI	36.8 (8.4)	37.0 (7.7)	36.7 (8.8)
Waist circumference (cm)	118.3 (17.9)	119.4 (17.4)	117.3 (18.4)
Currently smoke	18.9%	19.4%	18.5%
IPAQ measures			
Total physical activity METs/wk	2132.52 (3356.3)	2518.7 (3955.5)	1742.2 (2579.2)
Meeting PA guidelines			
1: Low	43.2%	46.2%	40.2%
2: Medium	31.4%	25.4%	38.0%
3: High	25.4%	29.0%	21.7%
Total sitting time	480.0 (272.7)	475.1 (289.6)	485.0 (255.7)
Diabetes questionnaire (SDSCA)			
Healthy eating plan (days/week)	2.9 (2.3)	2.8 (2.3)	3.0 (2.3)
Days per week 5+ fruit and vegetables)	2.7 (2.7)	2.4 (2.6)	3.0 (2.7)
Days ate high-fat foods	3.6 (2.4)	3.9 (2.3)	3.4 (2.4)
Days participated in 30 min of PA	1.7 (2.3)	1.8 (2.4)	1.6 (2.1)
Days participated in exercise	1.0 (2.0)	1.4 (2.4)	.70 (1.5)

<sup>a</sup>N for sitting time was 92 intervention and 90 for control groups.

Table 2

Between-group differences in behavioral risk factors

	Intervention (N=93)			Usual care (N=93)			Poisson regression models <sup>a</sup>		
	Unadjusted mean or %	Change (12 months-BL)	Unadjusted mean or %	Change (12 months-BL)	Adjusted 12-month difference or relative rate	95% CI	P value	LL	UL
<b>IPAQ measures</b>									
Reports no PA (vs. any PA)	BL 16.0%	-0.9%	12.0%	5.4%	0.89	0.48	1.64	0.7	
	12 mo 15.1%		17.4%						
Meeting PA guidelines med or high (vs. low)	BL 53.8%	7.5%	59.8%	-12.0%	1.29	1.00	1.66	.053	
	12 mo 61.3%		47.8%						
Minutes of sitting time per day	BL 485.1	-53.2	486.4	-16.1	0.90	.78	1.04	.17	
	12 mo 431.9		470.3						
<b>SDSCA measures</b>									
Days per week with a healthy eating plan	BL 2.8	1.6	3.0	0.5	1.24	1.06	1.44	0.005	
	12 mo 4.4		3.5						
Days per week 5+ fruit and vegetables	BL 2.4	0.9	3.0	0.3	1.04	0.85	1.30	0.672	
	12 mo 3.3		3.3						
Days per week eat high-fat foods	BL 3.9	-0.7	3.4	-0.4	0.98	0.82	1.20	0.909	
	12 mo 3.2		3.0						
Days per week participated in 30 min of PA	BL 1.8	0.8	1.6	0.2	1.16	1.07	1.97	0.018	
	12 mo 2.6		1.8						
Days per week participated in exercise	BL 1.4	0.0	0.7	0.2	1.19	0.69	2.01	0.527	
	12 mo 1.4		0.9						

BL, baseline; LL, lower limit; UL, upper limit.

<sup>a</sup> Adjusted for age, education, smoking and depression.

**Table 3**

Presence of behavioral risk factors at baseline and 1 year

	Intervention		Control		P value <sup>a</sup>
	Baseline	1 year	Baseline	1 year	
<i>Behavioral risk factors</i>					
Does not meet PA guideline (IPAQ; risk 1)	46.2%	38.7%	40.2%	52.2%	0.053
Follow healthy eating plan < 5 days/week	77.4%	46.2%	68.5%	62.0%	0.027
Eat 5 servings of fruit and vegetables less than 5 days/week (risk 2)	73.1%	62.4%	62.6%	63.0%	0.694
Eat high-fat foods 3 or more days/week (risk 3)	67.7%	60.2%	54.3%	58.7%	0.636
Participate in less than 5 days/week of PA for 30 min (SDSCA)	83.9%	68.8%	88.0%	84.8%	0.016
Participate in specific exercise sessions less than 5 days/week (SDSCA)	87.0%	84.9%	95.7%	93.5%	0.303
Smoker (risk 4)	19.4%	22.6%	18.5%	14.1%	0.01
Obese (BMI >30; risk 5)	79.6%	80.2%	77.2%	78.5%	0.661
<i>Total number of risk factors</i>					
0	1.9%	2.4%	2.8%	2.5%	0.086
1	8.5%	14.1%	17.6%	12.7%	
2	19.8%	28.2%	27.8%	25.3%	
3	39.6%	32.9%	26.9%	34.2%	
4	27.4%	20.0%	22.2%	25.3%	
5	2.8%	2.4%	2.8%	0.0%	

<sup>a</sup> Baseline adjusted 1-year P value.