Reducing Cardiovascular Disease Risk Using Patient Navigators, Denver, Colorado, 2007-2009

Judith C. Shlay, MD, MSPH; Beverly Barber, BSN; Theresa Mickiewicz, MSPH; Moises Maravi, MS; Jodi Drisko, MSPH; Raymond Estacio, MD; Gregory Gutierrez, MD; Christopher Urbina, MD, MPH

Suggested citation for this article: Shlay JC, Barber B, Mickiewicz T, Maravi M, Drisko J, Estacio R, et al. Reducing cardiovascular disease risk using patient navigators, Denver, Colorado, 2007-2009. Prev Chronic Dis 2011;8(6):A143. http://www.cdc.gov/pcd/issues/2011/nov/10_0282.htm. Accessed [date].

Abstract

Introduction
Early identification of cardiovascular disease (CVD) risk is important to reach people in need of treatment. At-risk patients benefit from behavioral counseling in addition to medical therapy. The objective of this study was to determine whether enhanced counseling, using patient navigators trained to counsel patients on CVD risk-reduction strategies and facilitate patient access to community-based lifestyle-change services, reduced CVD risk among at-risk patients in a low-income population.

Methods
We compared clinical characteristics at baseline and 12-month follow-up among 340 intervention and 340 comparison patients from community health centers in Denver, Colorado, between March 2007 and June 2009; all patients had a Framingham risk score (FRS) greater or equal to 10% at baseline. The intervention consisted of patient-centered counseling by bilingual patient navigators. At baseline and at 6-month and 12-month follow-up, we assessed health behaviors of intervention participants. We used an intent-to-treat approach for all analyses and measured significant differences by $\chi^2$ and t tests.

Results
We found significant differences in several clinical outcomes. At follow-up, the mean FRS was lower for the intervention group (mean FRS, 15%) than for the comparison group (mean FRS, 16%); total cholesterol was lower for the intervention group (mean total cholesterol, 183 mg/dL) than for the comparison group (mean total cholesterol, 197 mg/dL). Intervention participants reported significant improvements in some health behaviors at 12-month follow-up, especially nutrition-related behaviors. Behaviors related to tobacco use and cessation attempts did not improve.

Conclusion
Patient navigators may provide some benefit in reducing risk of CVD in a similar population.

Introduction
The Interheart study demonstrated that 90% of the population-attributable risk of a first myocardial infarction is due to modifiable risk factors (1). Many people in the general population have 1 or more risk factors for cardiovascular disease (CVD), and more than 90% of CVD events occur in people with at least 1 risk factor (1,2).

Early identification of CVD risk is important for treating at-risk people. The National Cholesterol Education Program guidelines recommend using the Framingham risk score (FRS) to identify people with an increased 10-year risk for coronary heart disease (CHD) events (3). The evidence for using the FRS consists of large longitudinal studies in which various models assessing multiple variables estimated the risk of CHD events (4). CHD is a
subset of CVD that excludes stroke, peripheral vascular disease, and heart failure.

The appropriate use of a risk score during a provider visit may involve recommendations for preventive lifestyle change in addition to medical therapy (3). However, preventive services are often a low priority in a busy clinical practice because of competing demands, inadequate insurance reimbursement, patient reticence to discuss or follow recommendations, and lack of provider expertise in counseling techniques or knowledge of community-based services (3-7).

Patient navigators have been effective for chronic disease prevention and management activities such as cancer screening and treatment, assessment of primary care services, and cardiovascular health promotion (8-17). The patient-navigator model has been suggested as an approach for facilitating CVD risk-reduction activities in conjunction with other clinical services (18).

The objective of this study was to determine whether enhanced counseling, using patient navigators trained to counsel patients on CVD risk-reduction strategies and facilitate patient access to community-based lifestyle-change services, reduced CVD risk among at-risk patients in a low-income population.

Methods

Study design

We used a quasi-experimental pre–post (baseline and 12-month follow-up) design to compare changes in clinical outcomes among intervention participants with changes among a comparison group drawn from the same patient population. We used a nonexperimental pre–post (baseline and 12-month follow-up) design to assess behavioral changes among the intervention participants only. We used an intent-to-treat approach for all analyses.

We enrolled 486 intervention participants from 3 community health centers in the Denver Health and Hospital Authority (DHHA) from March 2007 through June 2009. We collected data on 480 comparison patients from 3 other DHHA community health centers during the same time. This study was reviewed and approved by the Colorado Multiple Institutional Review Board. All intervention participants verbally consented to participate.

Study setting

DHHA is an urban safety-net health care system that provides services to 25% of Denver residents, including 50% of Denver’s children and a large proportion of the city’s indigent, vulnerable, and racial/ethnic minority populations. Clinical care components of DHHA include a 500-bed hospital, the 9-1-1 medical response system for the city and county of Denver, 8 federally qualified community health centers, 13 school-based clinics, and Denver Public Health.

Patient navigators

The patient navigation model has been successful in facilitating care and improving clinical outcomes among cancer patients (12). We revised several components of the model (eg, staff requirements, training) to tailor it to our CVD risk-reduction intervention. Four navigators participated in the intervention. Navigators are bilingual (English and Spanish) peer counselors, certified in core competencies of community health through a 12-week course offered at a local community college. Intervention staff educated the navigators about intervention objectives and purpose, calculation and use of the FRS, and CVD risk-reduction strategies. We trained navigators to identify a participant’s readiness to change behaviors, based on the transtheoretical model (19) and to use motivational interviewing techniques to guide the participant’s goal-setting process. We provided additional training on human subjects research, privacy practices, smoking cessation, medication adherence, cultural competency, and aggression management. The intervention manager conducted periodic audits on intervention delivery to assess navigator adherence to intervention protocol.

Intervention

The intervention consisted of a 1-hour counseling session, conducted by a patient navigator at a community health center, plus follow-up telephone calls. During the counseling session, navigators assessed the participant’s readiness to change behaviors and encouraged them to set goals. The navigator and participant discussed potential CVD risk-reduction activities, focusing on nutrition, physical activity, and smoking cessation. Navigators encouraged participants to continue or increase current activities (eg, walking), provided a free 3-month pass to local Denver County recreation centers, where participants could engage in exercise programs and bilingual nutrition education.
classes, and referred smokers to the Colorado QuitLine, a free smoking-cessation program. Although all intervention activities were independent of any clinical services, the navigator encouraged follow-up with the primary care provider for ongoing clinical care.

The navigators called participants at 1 to 4 weeks and 6 to 10 weeks after enrollment to assist with and encourage the chosen behavior changes or participation in intervention activities; additional calls were made within 6 months of enrollment. On average, each participant received four 15-minute calls.

Participant eligibility and recruitment

We identified potential intervention participants in a rolling recruitment process through a CVD registry developed for this intervention. We created the registry by collecting the demographic and clinical data needed to calculate an FRS according to methods outlined by Wilson et al (4): age, sex, diabetes diagnosis (based on codes from the International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] [www.cdc.gov/nchs/icd9.htm] [Appendix]), blood pressure, total cholesterol, high-density lipoprotein (HDL) cholesterol, and smoking status (defined as smoking regularly during the previous 12 months). The FRS estimates 10-year risk for CHD outcomes in people who do not have heart disease (4). We created 3 strata of risk: low risk, <10%; moderate risk, 10% to 20%, and high risk, >20%. We calculated body mass index (BMI) by using weight and height measurements in electronic medical charts. We obtained family history of heart disease by self-report. We collected the data from electronic medical record system at the 3 intervention sites. Staff updated the registry monthly, allowing identification of potential participants during the 2-year recruitment period. In addition, we extracted the following demographic information from electronic medical records: income and poverty level, race/ethnicity, marital status, level of education, and language spoken.

Eligibility requirements for participation in the intervention included having an FRS 10% or greater, being aged 30 to 64 years, and having an active status at 1 of the 3 intervention community health centers. We defined active as having been seen at least twice during the previous 18 months; the most recent visit had to be within the previous 6 months. We excluded patients if they were pregnant or lactating; had a history of coronary artery disease, ischemic cardiomyopathy, myocardial infarction, peripheral vascular disease, symptomatic carotid artery disease, or abdominal aortic aneurysm (based on ICD-9-CM codes [Appendix]); or had a comorbid illness with a life expectancy of less than 12 months.

Intervention staff identified 1,425 potentially eligible participants from the registry during the 2-year study period; 506 people had inaccurate contact information, leaving 919 eligible for inclusion. On a monthly basis, staff sent an introductory letter explaining the intervention to approximately 38 patients. Patient navigators followed up by telephone within 2 weeks to assess interest in participation and invite participants to the 1-hour counseling session. A total of 486 patients verbally consented to participate before counseling began.

Not all intervention participants were included in the final analysis. Three participants who experienced a CHD event after enrollment were not eligible. We defined a CHD event as a diagnosis of angina pectoris, myocardial infarction, coronary insufficiency (ie, unstable angina), or CHD death (based on ICD-9-CM codes [Appendix]); we verified outcomes through chart review. Because the cutoff date for analysis was June 30, 2008, we excluded 143 participants who enrolled after this date; 340 participants were thus included in the final analysis.

Comparison group eligibility

We used the same eligibility criteria to select a comparison group of 340 patients from 3 nonintervention community health centers. We matched people in the comparison group to intervention participants by age, race/ethnicity, sex, and the month and year in which we identified the participant for inclusion in the registry; we used this group to evaluate the extent to which the changes in the clinical outcomes among intervention participants may have been related to the intervention. We did not contact or counsel people in the comparison group or assess their health behaviors.

Clinical outcomes

We assessed clinical characteristics at baseline and 12-month follow-up for both intervention and comparison groups. We defined baseline as the date of enrollment for the intervention participants and date of record selection for the comparison group. In addition to the data collected to calculate the FRS at baseline and 12-month follow-up, we extracted the following clinical data from electronic medical charts: blood pressure (systolic and diastolic), heart rate, total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, triglycerides, fasting glucose, diabetes status, age, sex, and the month and year in which we identified the participant for inclusion in the registry; we used this group to evaluate the extent to which the changes in the clinical outcomes among intervention participants may have been related to the intervention. We did not contact or counsel people in the comparison group or assess their health behaviors.
medical records for both groups: weight, height, low-density lipoprotein (LDL) cholesterol, and CHD event.

In addition, we collected information on use of medication for lowering blood pressure or cholesterol levels from DHHA pharmacy databases; we defined baseline pick-up as pick-up at least twice before study enrollment and follow-up pick-up as pick-up at least twice after study enrollment. We calculated medication adherence as a rate: the number of days of medication possession (supply days minus gap days) divided by the number of days of medication exposure (supply days plus gap days).

For certain clinical characteristics, we established dichotomous categories of “at goal” and “not at goal”: FRS (at goal, <10%); blood pressure (at goal, <130/80 mm Hg); total cholesterol (at goal, <160 mg/dL); HDL cholesterol (at goal, ≥60 mg/dL); and LDL cholesterol (at goal, <100 mg/dL).

**Behavioral outcomes**

We developed a questionnaire to guide motivational interviewing and assess behavioral outcomes after reviewing standardized instruments with demonstrated psychometric properties. The final versions included 30 questions designed to assess 13 measures of nutrition, physical activity (20), stages of change for physical activity (21) and weight loss (22), depression symptoms (23), tobacco use and cessation attempts, and use of nutrition classes and recreation centers. We conducted a pilot test on the questionnaire to determine the time needed to complete it and to assess the target population’s comprehension of the questions.

Navigators administered the questionnaire verbally, in English or Spanish, at baseline in person and at 6-month and 12-month follow-up by telephone; completion time averaged 30 minutes. For follow-up, navigators attempted at least 3 telephone calls before considering the participant lost to follow-up. At 12-month follow-up, navigators still attempted to contact participants considered lost to follow-up at 6 months. Among 340 participants eligible for 12-month follow-up, 222 (65%) completed at least 1 follow-up questionnaire at either 6 months or 12 months.

**Statistical analyses**

We generated descriptive statistics on baseline demographic and clinical characteristics for the intervention and comparison groups. We performed bivariate analyses and measured significant differences between the groups by using the χ² test for proportional comparisons and the t test for continuous variables. For clinical outcomes, we compared changes from baseline to 12 months between the 2 groups. To decrease the possibility of selection bias, we used an intent-to-treat approach for all analyses.

For behavioral outcomes, we assessed changes from baseline to follow-up among the intervention participants only. If the 12-month questionnaire was missing, we used either the baseline questionnaire or the 6-month questionnaire, whichever provided the value closest to the 12-month value. A series of questions determined the number of fruits and vegetables consumed per day and amount of physical activity per week; the goal for each corresponds to current recommendations. A series of questions and predefined algorithms defined the stage of change, which we dichotomized as precontemplation/preparation or action/maintenance. We trichotomized the frequency of consuming high-fat or high-calorie foods. We dichotomized other questions as yes or no. We assessed significant differences between baseline and follow-up in behavioral characteristics by using χ² analyses. We used SAS version 9.1.3 software (SAS Institute, Inc, Cary, North Carolina) to conduct all analyses.

**Results**

The participation rate for the intervention was 53% (486/919). Mean age was 56 years (SD, 6 y). Most (66%) participants were Hispanic/ Latino; 34% spoke Spanish only. Most (76%) had incomes of 150% or less than the federal poverty level. At baseline, almost half of participants smoked, almost half self-reported a family history of heart disease, more than half had hypertension or diabetes, most were overweight or obese (mean BMI, 33kg/m²), and the mean FRS was 15.5%. The comparison group was similar to the intervention group, except for income; only 34% of the comparison group had an income of 150% or less of the poverty level (χ² = 209.5, P = .001).

Of the 919 invited to participate, 432 refused participation. Major reasons for refusal included no time (21%), no interest (33%), and failure to keep their appointment with the navigator (33%). Refusers, compared with participants, were significantly more likely to be white non-Hispanic (34% vs 24%), English speakers (79% vs 66%), single (45% vs 35%), and to have a higher baseline total cholesterol level (202 mg/dL vs 192 mg/dL). We found no other demographic or clinical differences.
Clinical outcomes

At follow-up, the mean FRS was significantly lower for the intervention group than the comparison group; 11.8% of the intervention group was at goal for an FRS, compared with 3.5% of the comparison group (Table 1). At follow-up, the intervention group had lower mean total cholesterol than the comparison group; 29% of the intervention group had total cholesterol less than 160 mg/dL compared with 20% in the comparison group. We found no differences in blood pressure, weight, or HDL cholesterol. At follow-up, mean LDL cholesterol was significantly higher in the intervention group than in the comparison group, but we found no differences between groups in the percentage of those with LDL cholesterol less than 100 mg/dL.

The mean baseline rate of cholesterol medication adherence was 70.1% for the intervention group; it increased by 12.0% to 78.5% at follow-up. The baseline rate for the comparison group was 73.9%; it increased by 2.7% to 75.9% at follow-up. The increases in medication adherence between the 2 groups were significantly different. The mean baseline rate (69.1%) of hypertension medication adherence increased by 9.7% for the intervention group; the mean baseline rate (78.8%) for the comparison group increased significantly by 4.2%.

There were 3 CHD events in the intervention group and 4 CHD events in the comparison group between baseline and follow-up.

Behavioral outcomes

We found no differences in baseline demographic, behavioral, or clinical characteristics among participants who completed a behavioral questionnaire and those who did not.

We found significant changes in 10 of 13 behavioral measures from baseline to 12 months (Table 2). Participants reported significant improvements in all 6 nutritional measures. While participants did not report improvement in attaining recommended physical activity levels, a significant proportion reported a change from precontemplation/preparation to action/maintenance for weight and exercise. Significantly more participants also reported attending an exercise class at follow-up than at baseline. Behaviors related to tobacco use and cessation attempts did not improve.

Discussion

This intervention, which used patient navigators to encourage CVD risk-reduction behaviors and connect patients with community-based lifestyle-change services, demonstrated improvements in some clinical and behavioral outcomes for people at risk for CVD. These findings provide evidence for using behavioral approaches to reduce CVD risk in addition to medical therapy.

The most effective approach for CVD prevention is a combination of efforts that works at all levels of influence to create a social and physical environment that is supportive of healthy behaviors. Evidence supports the use of community-based approaches for reducing heart disease risk (24-26). Individually adapted health behavior-change programs improve participation in physical activity, particularly with improved access to locations for physical activity (26). Our intervention linked counseling messages to the participant’s stage of readiness to focus on behaviors the patient was most receptive to modify, an effective approach among primary care patients at risk for heart disease (27). Using this strategy, we demonstrated several behavioral changes and improved medication adherence.

Whereas other successful programs (eg, the Vale study), consisting of a more intensive intervention, achieved better reductions in cholesterol levels and other coronary risk factors (28), our intervention, consisting of an average of 5 counseling sessions, resulted in improvement in some clinical and behavioral outcomes. Patient navigation has been used in improving cancer screening and treatment outcomes and increasing the use of health care services among disenfranchised populations (8,9,11,12). Our intervention, which followed the methodology used in cancer-prevention patient-navigation programs (12), was able to enhance the traditional clinical approaches for reducing CVD risk, suggesting that this model could be used for various chronic disease prevention activities (18).

Our study had limitations. For the clinical analyses, lack of randomization increased the possibility of selection bias and confounding. Matching at-risk comparison group members with intervention participants attenuates this possibility; the demographic and clinical characteristics of the 2 groups were similar, except for income levels. The participation rate of 53% may reflect the population often served by safety-net institutions; this population, composed largely of low-income and racial/ethnic minority patients, may harbor distrust in clinical programs.
Nevertheless, we observed minimal differences between intervention participants and people who refused to participate. Another possible limitation is that only 65% of the eligible participants completed a follow-up behavioral assessment. We used intent-to-treat analyses to avoid selection bias. We found no differences in baseline characteristics between participants who completed a follow-up assessment and those who did not. Because we did not assess behavior changes in the comparison group, we cannot rule out that behavior changes identified in the intervention group were caused by factors other than the patient navigators. Future studies will need to examine health behaviors of both groups to fully assess the effect of using patient navigators. Finally, because follow-up was only for 1 year, the study was not able to assess the long-term effect of the intervention on CHD events.

Using patient navigators to provide individualized counseling, assistance in goal setting, and linkage to community resources, seems to help intervention participants achieve positive behavior change (particularly related to nutritional activities) and improve several clinical outcomes. This intervention potentially offers a simple intervention for enhancing traditional clinical CVD risk-reduction services. Future studies should consider conducting more rigorous evaluations of the effect of patient navigators on changes in health behaviors.

Acknowledgments

Financial support was provided by the Colorado Department of Public Health and Environment’s Cancer, Cardiovascular, and Pulmonary Disease grant program. We thank the patient participants and the Sandos Westside Neighborhood Health Center, La Casa Quigg Newton Family Health Center, and the Webb Center for Primary Care’s Family and Internal Medicine Clinic. We also thank our patient navigators Margarita Hernandez and Isabel Melendez and acknowledge the technical assistance of Jeffrey Berschling, Therese Dam, and Dean McEwen.

Author Information

Corresponding Author: Judith C. Shlay, MD, MSPH, Denver Public Health, 605 Bannock St, Denver, CO 80204. Telephone: 303-602-3700. E-mail: shlay@dhha.org. Dr Shlay is also affiliated with Community Health Services, Denver Health and Hospital Authority, Denver, Colorado, and the Department of Family Medicine, University of Colorado, Aurora, Colorado.

Author Affiliations: Beverly Barber, Theresa Mickiewicz, Moises Maravi, Denver Public Health, Denver, Colorado; Jodi Drisko, Drisko Consulting, Kilauea, Hawaii; Raymond Estacio, Gregory Gutierrez, Christopher Urbina, Denver Health and Hospital Authority, Denver, Colorado, and University of Colorado, Aurora, Colorado.

References

1. Yusuf S, Hawken S, Ounpuu S, Dans T, Avezum A, Lanas F, et al. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study. Lancet 2004;364(9438):937-52.
2. Vasan RS, Sullivan LM, Wilson PW, Sempos CT, Sundstrom J, Kannel WB, et al. Relative importance of borderline and elevated levels of coronary heart disease risk factors. Ann Intern Med 2005;142(6):393-402.
3. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adults Treatment Panel III) final report. Circulation 2002;106(25):3143-421.
4. Wilson PW, D’Agostino RB, Levy D, Belanger AM, Silbershatz H, Kannel WB. Prediction of coronary heart disease using risk factor categories. Circulation 1998;97(18):1837-47.
5. Jackson R, Lawes CM, Bennett DA, Milne RJ, Rodgers A. Treatment with drugs to lower blood pressure and blood cholesterol based on an individual’s absolute cardiovascular risk. Lancet 2005;365(9457):434-41.
6. Lowe LP, Greenland P, Ruth Kj, Dyer AR, Stamler R, Stamler J. Impact of major cardiovascular disease risk factors, particularly in combination, on 22-year mortality in women and men. Arch Intern Med 1998;158(18):2007-14.
7. D’Agostino RB Sr, Grundy S, Sullivan LM, Wilson P. Validation of the Framingham coronary heart disease prediction scores: results of a multiple ethnic groups investigation. JAMA 2001;286(2):180-7.
8. Guadagnolo BA, Boylan A, Sargent M, Koop D, Brunette D, Kanekar S, et al. Patient navigation for American Indians undergoing cancer treatment: utilization and impact on care delivery in a regional healthcare center. Cancer 2011;117(12):2754-61.
9. Phillips CE, Rothstein JD, Beaver K, Sherman BJ, Freund KM, Battaglia TA. Patient navigation to increase mammography screening among inner city women. J Gen Intern Med 2010;26(2):123-9.

10. Griswold KS, Homish GG, Pastore PA, Leonard KE. A randomized trial: are care navigators effective in connecting patients to primary care after psychiatric crisis? Community Ment Health J 2010;46(4):398-402.

11. Percac-Lima S, Grant RW, Green AR, Ashburner JM, Gamba G, Oo S, et al. A culturally tailored navigator program for colorectal cancer screening in a community health center: a randomized, controlled trial. J Gen Intern Med 2009;24(2):211-7.

12. Wells KJ, Battaglia TA, Dudley DJ, Garcia R, Greene A, Calhoun E, et al. Patient navigation: state of the art or is it science. Cancer 2008;113(8):1999-2010.

13. Kim S, Koniak-Griffin D, Flaskerud JH, Guarnero PA. The impact of lay health advisors on cardiovascular health promotion: using a community-based participatory approach. J Cardiovasc Nurs 2004;19(3):192-9.

14. Balcázar H, Alvarado M, Hollen ML, Gonzalez-Cruz Y, Pedregón V. Evaluation of Salud Para Su Corazón (Health for your Heart) National Council of La Raza Promotora outreach program. Prev Chronic Dis 2005;2(3):A09. http://www.cdc.gov/pcd/issues/2005/jul/04_0130.htm.

15. Brownstein JN, Chowdhury FM, Norris SL, Horsley T, Jack L Jr, Zhang X, Satterfield D. Effectiveness of community health workers in the care of people with hypertension. Am J Prev Med 2007;32(5):435-47.

16. Whitley EM, Main DS, McGloin J, Hanratty R. Reaching individuals at risk for cardiovascular disease through community outreach in Colorado. Prev Med 2011;52(1):84-6.

17. Brownstein JN, Bone LR, Dennison CR, Hill MN, Kim MT, Levine DM. Community health workers as interventionists in the prevention and control of heart disease and stroke. Am J Prev Med 2005;29(Suppl 1):128-33.

18. Balcázar HG, de Heer H, Rosenthal L, Aquirre M, Flores L, Puentes FA, et al. A promotores de salud intervention to reduce cardiovascular disease risk in a high-risk Hispanic border population, 2005-2008. Prev Chronic Dis 2010;7(2):1-10:A28. http://www.cdc.gov/pcd/issues/2010/mar/09_0106.htm.

19. Zimmerman GL, Olsen CG, Bosworth MF. A “stages of change” approach to helping patients change behavior. Am Fam Physician 2000;61(5):1409-16.

20. Craig CL, Marshall AL, Sjöström M, Bauman AE, Booth ML, Ainsworth BE, et al. International physical activity questionnaire: 12-country reliability and validity. Med Sci Sports Exerc 2003;35(8):1381-91.

21. Marcus BH, Selby VC, Niaura RS, Rossi JS. Self-efficacy and stages of exercise behavior change. Res Exerc and Sport 1992;16(1):60-6.

22. Weight: stages of change-short form. http://www.uri.edu/research/cprc/Measures/Weight01.htm. Accessed April 12, 2010.

23. Pinto-Meza A, Serrano-Blanco A, Peñarrubia M, Blanco E, Haro JM. Assessing depression in primary care with the PHQ-9: can it be carried out over the telephone? J Gen Intern Med 2005;20(8):738-42.

24. Task Force on Community Preventive Services. Recommendations to increase physical activity in communities. Am J Prev Med 2002;22(4 Suppl):67-72.

25. Increasing physical activity. A report on recommendations of the Task Force on Community Preventive Services. MMWR Recomm Rep 2001;50(RR-18):1-4.

26. Kahn EB, Ramsey LT, Brownson RC, Heath GW, Howze EH, Powell KE, et al. The effectiveness of interventions to increase physical activity. A systematic review. Am J Prev Med 2002;22(4 Suppl):73-107.

27. Steptoe A, Kerry S, Rink E, Hilton S. The impact of behavioral counseling stage of change in fat intake, physical activity, and cigarette smoking in adults at increased risk of coronary heart disease. Am J Public Health 2001;91(2):265-9.

28. Vale MJ, Jelinek MV, Best JD, Santamaria JD. Coaching patients with coronary heart disease to achieve the target cholesterol: a method to bridge the gap between evidence-based medicine and the “real world” — randomized controlled trial. J Clin Epidemiol 2002;55(3):245-52.
Table 1. Clinical Characteristics Among Intervention and Comparison Groups Eligible for 12-Month Follow-Up (Intent-to-Treat Analysis), Study on Use of Patient Navigators to Reduce Risk for Cardiovascular Disease, Denver, Colorado, 2007-2009

| Characteristic                      | Baselinea                          | 12-Month Follow-Upb | P Value | Baselinea                          | 12-Month Follow-Upb | P Value |
|-------------------------------------|------------------------------------|----------------------|---------|------------------------------------|----------------------|---------|
|                                     | Intervention Group (n= 486)        | Comparison Group (n= 480) |         | Intervention Group (n = 340)       | Comparison Group (n = 340) |         |
| Framingham risk score, %e           |                                    |                      |         |                                    |                      |         |
| Mean (SD)                           | 15.5 (6.2)                         | 15.0 (5.9)           | .22e    | 14.8 (6.5)                         | 15.8 (6.0)           | .03e    |
| <10, no. (%)                        | 0                                  | 0                    | NC      | 40 (11.8)                          | 12 (3.5)             | <.001e  |
| 10-20, no. (%)                      | 408 (84)                           | 420 (87)             | .11e    | 255 (75.0)                         | 277 (81.5)           | .04e    |
| >20, no. (%)                        | 78 (16)                            | 60 (13)              | .11e    | 45 (13.2)                          | 51 (15.0)            | .50e    |
| Blood pressure, mm Hg               |                                    |                      |         |                                    |                      |         |
| Mean (SD)                           | 138/81 (18/11)                     | 140/84 (20/10)       | .13/.<.001e | 139/81/18/12                      | 139/83 (19/9)        | .9/.02e |
| <130/80, No. (%)                    | 119 (24.5)                         | 93 (19.4)            | .06e    | 80 (23.5)                          | 66 (19.4)            | .19e    |
| ≥130/80, No. (%)                    | 367 (75.5)                         | 387 (80.6)           |         | 260 (76.5)                         | 274 (80.6)           |         |
| Weight, lb                          |                                    |                      |         |                                    |                      |         |
| Mean (SD)                           | 194 (43)                           | 191 (46)             | .22e    | 195 (44)                           | 191 (7)              | .28e    |
| Total cholesterol, mg/dL            |                                    |                      |         |                                    |                      |         |
| Mean (SD)                           | 192 (40)                           | 197 (48)             | .07d    | 183 (44)                           | 197 (49)             | <.001d  |
| <160, No. (%)                       | 76 (16)                            | 86 (18)              | .34e    | 99 (29)                            | 68 (20)              | <.001e  |
| ≥160, No. (%)                       | 410 (84)                           | 394 (82)             |         | 241 (71)                           | 272 (80)             |         |
| High-density lipoprotein cholesterol, mg/dL |                                    |                      |         |                                    |                      |         |
| Mean (SD)                           | 44 (10)                            | 44 (12)              | .96d    | 44 (10)                            | 44 (12)              | .74d    |
| <60, No. (%)                        | 457 (94)                           | 443 (92)             | .28e    | 316 (93)                           | 312 (92)             | .56e    |
| ≥60, No. (%)                        | 29 (6)                             | 37 (8)               |         | 24 (7)                             | 28 (8)               |         |
| Low-density lipoprotein cholesterol, mg/dL |                                    |                      |         |                                    |                      |         |
| Mean (SD)                           | 114 (37)                           | 112 (39)             | .39d    | 118 (37)                           | 111 (40)             | .02d    |
| <100, No. (%)                       | 181 (38)                           | 185 (40)             | .63e    | 120 (36)                           | 133 (40)             | .21e    |
| ≥100, No. (%)                       | 294 (62)                           | 282 (60)             |         | 218 (64)                           | 198 (60)             |         |

Abbreviation: NC, not calculated; SD, standard deviation.

a Intervention group includes all people enrolled in the intervention; intervention participants received services from a patient navigator, including counseling and referral to community-based lifestyle behavior-change services. Baseline comparison group includes people who met eligibility requirements for enrollment but did not receive the intervention.

b Includes intervention participants and comparison group members eligible for 12-month follow-up. Not eligible for follow-up were 3 intervention participants and 4 comparison group members who had a coronary heart disease event. If no clinical follow-up was completed, we assumed no change occurred and used baseline values.

c The Framingham risk score estimates 10-year risk for coronary heart disease outcomes in people who do not have heart disease (4).

d P value calculated by using pooled t test with equal variances; it compares intervention and comparison groups.

e P value calculated by using χ² test; it compares intervention and comparison groups.
Table 2. Change in Behavioral Characteristics Among Intervention Participants Eligible for 12-Month Follow-Up (Intent-to-Treat Analysis), Study on Use of Patient Navigators to Reduce Risk for Cardiovascular Disease, Denver, Colorado, 2007-2009

| Characteristic                                                                 | Baseline, a No. (%) (n = 343) | 12-Month Follow-Up, b No. (%) (n = 340) | P Value* |
|--------------------------------------------------------------------------------|-------------------------------|----------------------------------------|----------|
| Consume ≥5 servings of fruits and/or vegetables per day                        |                               |                                        |          |
| Yes                                                                            | 7 (2.0)                       | 32 (9.8)                               | <.001    |
| No                                                                             | 336 (98.0)                    | 294 (90.3)                             |          |
| During the past 7 days, number of times drank soda                            |                               |                                        |          |
| None                                                                           | 167 (48.8)                    | 206 (63.4)                             | <.001    |
| ≤Once per day                                                                  | 135 (39.5)                    | 96 (29.5)                              |          |
| ≥Twice per day                                                                 | 40 (11.7)                     | 23 (7.1)                               |          |
| During the past 7 days, number of times pastry eaten                          |                               |                                        |          |
| None                                                                           | 84 (24.5)                     | 147 (45.1)                             | <.001    |
| ≤Once per day                                                                  | 237 (69.1)                    | 166 (50.9)                             |          |
| ≥Twice per day                                                                 | 22 (6.4)                      | 13 (4.0)                               |          |
| During the past 7 days, number of times fried foods eaten                      |                               |                                        |          |
| None                                                                           | 83 (24.3)                     | 133 (40.1)                             | <.001    |
| ≤Once per day                                                                  | 232 (67.8)                    | 183 (56.1)                             |          |
| ≥Twice per day                                                                 | 27 (7.9)                      | 10 (3.1)                               |          |
| During the past 7 days, how often did you read labels?                         |                               |                                        |          |
| Never or rarely                                                                | 212 (61.8)                    | 152 (46.8)                             | <.001    |
| Sometimes or more often                                                        | 131 (38.2)                    | 173 (53.2)                             |          |
| Attended a nutrition class in the last 6 months                                |                               |                                        |          |
| Yes                                                                            | 13 (3.8)                      | 49 (15.0)                              | <.001    |
| No                                                                             | 330 (96.2)                    | 277 (85.0)                             |          |
| Stage of change regarding weight                                               |                               |                                        |          |
| Precontemplation/preparation                                                    | 120 (35.5)                    | 78 (24.5)                              | .002     |
| Action/maintenance                                                             | 218 (64.5)                    | 240 (75.5)                             |          |
| Physical activity levela                                                       |                               |                                        |          |
| At or above recommended level                                                  | 135 (40.5)                    | 129 (38.2)                             | .64      |
| Below recommended level                                                        | 198 (59.5)                    | 209 (61.8)                             |          |

* a At baseline, intervention group includes all people enrolled in the intervention; intervention participants received services from a patient navigator, including counseling and referral to community-based lifestyle behavior-change services. Baseline comparison group includes people who met eligibility requirements for enrollment but did not receive the intervention.

b Includes all intervention participants eligible for the 12-month follow-up interview but excludes 3 who had a coronary heart disease event. If the 12-month questionnaire was missing, we used either the baseline questionnaire or the 6-month questionnaire, whichever provided the value closest to the 12-month value.

* c P-value calculated by using χ² test; it compares baseline with 12-month follow-up.

a Recommended physical activity level defined as 30 minutes of moderate activity or walking 5 or more days per week.

(Continued on next page)
Table 2. (continued) Change in Behavioral Characteristics Among Intervention Participants Eligible for 12-Month Follow-Up (Intent-to-Treat Analysis), Study on Use of Patient Navigators to Reduce Risk for Cardiovascular Disease, Denver, Colorado, 2007-2009

| Characteristic                                           | Baseline,<sup>a</sup> No. (%) | 12-Month Follow-Up,<sup>b</sup> No. (%) | P Value<sup>c</sup> |
|---------------------------------------------------------|-------------------------------|----------------------------------------|---------------------|
| **Stage of change regarding exercise**                   |                               |                                        |                     |
| Precontemplation/preparation                             | 82 (32.0)                     | 47 (19.0)                              | .001               |
| Action/maintenance                                       | 174 (68.0)                    | 201 (81.0)                             |                     |
| **Attended an exercise class in the last 6 months**      |                               |                                        |                     |
| Yes                                                     | 35 (10.2)                     | 94 (29.1)                              | <.001              |
| No                                                      | 307 (89.8)                    | 229 (70.9)                             |                     |
| **Current smoker**                                       |                               |                                        |                     |
| Yes                                                     | 117 (34.2)                    | 97 (30.8)                              | .32                |
| No                                                      | 225 (65.8)                    | 218 (69.2)                             |                     |
| **Among smokers, tried to quit in last 12 months**       |                               |                                        |                     |
| Yes                                                     | 62 (54.9)                     | 47 (49.5)                              | .46                |
| No                                                      | 51 (45.1)                     | 48 (50.5)                              |                     |
| **Over the last 2 weeks, felt depressed for several days or more** |                               |                                        |                     |
| Yes                                                     | 188 (55.0)                    | 109 (33.5)                             | <.001              |
| No                                                      | 154 (45.0)                    | 216 (66.5)                             |                     |

<sup>a</sup> At baseline, intervention group includes all people enrolled in the intervention; intervention participants received services from a patient navigator, including counseling and referral to community-based lifestyle behavior-change services. Baseline comparison group includes people who met eligibility requirements for enrollment but did not receive the intervention.

<sup>b</sup> Includes all intervention participants eligible for the 12-month follow-up interview but excludes 3 who had a coronary heart disease event. If the 12-month questionnaire was missing, we used either the baseline questionnaire or the 6-month questionnaire, whichever provided the value closest to the 12-month value.

<sup>c</sup> P value calculated by using χ^2 test; it compares baseline with 12-month follow-up.

<sup>d</sup> Recommended physical activity level defined as 30 minutes of moderate activity or walking 5 or more days per week.
Appendix. Diagnosis Codes Used to Assess Eligibility for Study on Patient Navigators, Denver, Colorado, 2007-2009

Codes were obtained from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) (www.cdc.gov/nchs/icd9.htm).

| Diagnosis                           | Code                                      |
|-------------------------------------|-------------------------------------------|
| Cardiomyopathy                      | 414.8                                     |
| Coronary artery disease             | 411.0, 411.1, 411.8, 411.81, 411.89, 414.0, 414.00, 414.01, 414.02, 414.03, 414.04, 414.05, 414.06, 414.07, 414.10, 414.11, 414.12, 414.8, 414.9 |
| Myocardial infarction               | 410.0, 410.00, 410.01, 410.02, 410.1, 410.10, 410.11, 410.12, 410.2, 410.20, 410.21, 410.22, 410.3, 410.30, 410.31, 410.32, 410.4, 410.40, 410.41, 410.42, 410.5, 410.50, 410.51, 410.52, 410.6, 410.60, 410.61, 410.62, 410.7, 410.70, 410.71, 410.72, 410.8, 410.80, 410.81, 410.82, 410.9, 410.90, 410.91, 410.92 |
| Peripheral vascular disease         | 440.0, 440.1, 440.2, 440.20, 440.21, 440.22, 440.23, 440.24, 440.29, 440.30, 440.31, 440.32, 440.8, 440.9, 443.21, 443.89, 443.9 |
| Symptomatic carotid artery disease  | 433.1, 433.11, 437.3, 442.81, 900.00, 900.01, 900.02, 900.03, 996.1 |
| Abdominal aortic aneurysm           | 093.0, 441.3, 441.5, 441.9 |
| Diabetes                            | 250, 250.00, 250.01, 250.02, 250.03, 250.10, 250.11, 250.12, 250.13, 250.20, 250.21, 250.22, 250.23, 250.30, 250.31, 250.32, 250.33, 250.40, 250.41, 250.42, 250.43, 250.50, 250.51, 250.52, 250.53, 250.60, 250.61, 250.62, 250.63, 250.70, 250.71, 250.72, 250.73, 250.80, 250.81, 250.82, 250.83, 250.90, 250.91, 250.92, 250.93, 648.00, 648.01, 648.02, 648.03, 648.04 |