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ACTIVATING PERIPHERAL ARTERIAL DISEASE PATIENTS TO REDUCE CHOLESTEROL: A RANDOMIZED TRIAL

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Abstract

Background—Peripheral arterial disease patients are less likely than other high-risk patients to achieve ideal low density lipoprotein cholesterol (LDL-cholesterol) levels. This randomized controlled trial assessed whether a telephone counseling intervention, designed to help peripheral arterial disease patients request more intensive cholesterol lowering therapy from their physician, achieves lower LDL-cholesterol levels than two control conditions.

Methods—355 peripheral arterial disease participants with baseline LDL-cholesterol ≥ 70 mg/dl were enrolled. The primary outcome was change in LDL-cholesterol level at twelve-month follow-up. There were three parallel arms: telephone counseling intervention, attention control condition, and usual care. The intervention consisted of patient-centered counseling, delivered every six weeks, encouraging participants to request increases in cholesterol-lowering therapy from their physician. The attention control condition consisted of telephone calls every six weeks providing information only. The usual care condition participated in baseline and follow-up testing.

Results—At 12-month follow-up, participants in the intervention improved their LDL-cholesterol level, compared to those in attention control (-18.4 mg/dl vs. -6.8 mg/dl, $p=0.010$) but not compared to those in usual care (-18.4 mg/dl vs. -11.1 mg/dl, $p=0.208$). Intervention participants were more likely to start a cholesterol-lowering medication or increase their cholesterol-lowering medication dose than those in the attention control (54% vs. 18%, $p=0.001$) and usual care (54% vs. 31%, $P<0.001$) conditions.

Conclusion—Telephone counseling that helped peripheral arterial disease patients request more intensive cholesterol-lowering therapy from their physician achieved greater LDL-cholesterol declines than an attention control arm that provided health information alone.

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Keywords

Intermittent claudication; secondary prevention; peripheral arterial disease

Men and women with lower extremity peripheral arterial disease have greater cardiovascular morbidity and mortality compared to people without peripheral arterial disease.^{1,2} Although low density lipoprotein (LDL) cholesterol lowering therapy reduces cardiovascular event rates in peripheral arterial disease³, peripheral arterial disease patients are less likely to achieve recommended LDL-cholesterol levels and less likely to take cholesterol-lowering medication than patients with coronary disease.⁴⁻⁷

Observational data suggest that patient requests for treatment and attitudes about the importance of treatment can influence physician behavior regarding prescription of preventive interventions.⁸⁻¹⁰ We conducted a randomized controlled trial to determine whether a telephone counseling intervention that educates patients with peripheral arterial disease about the importance of LDL-cholesterol lowering and activates peripheral arterial disease patients to request more intensive cholesterol lowering medication from their physician can achieve greater reductions in LDL-cholesterol as compared to two control groups. We hypothesized that the intervention would achieve lower LDL-cholesterol levels, compared to those in attention control and usual care conditions, respectively.

METHODS

Design Overview

The institutional review boards of participating medical centers approved the protocol. Participants gave written informed consent. The study was a randomized controlled clinical trial with three parallel conditions: telephone counseling intervention, attention control condition, or usual care. The study was conducted at Northwestern University Feinberg School of Medicine and the University of Massachusetts Medical School (UMASS).

Setting and Participants

At Northwestern, participants were identified from among peripheral arterial disease patients receiving care at Northwestern and other Chicago-area hospitals. Newspaper and radio advertisements, posted signs, community presentations, bulk mailings, and letters mailed to participants with peripheral arterial disease identified in the national Life Line screening program were used for recruitment in Chicago.¹¹ Peripheral arterial disease participants who completed research studies at Northwestern more than three months previously were invited to participate. At UMASS, recruitment consisted of mailed letters to peripheral arterial disease patients, newspaper advertisements, and posted flyers.

Inclusion criteria were presence of peripheral arterial disease and an LDL-cholesterol ≥ 70 mg/dl. An LDL-cholesterol ≥ 70 mg/dl was selected based on recent recommendations for patients at high risk for cardiovascular events.¹² Peripheral arterial disease was defined as one or more of the following: an ankle brachial index (ABI) < 0.95 at baseline, documented lower extremity revascularization, an angiogram demonstrating $\geq 50\%$ obstruction in at least one lower extremity artery, or a certified non-invasive vascular laboratory report documenting peripheral arterial disease.

Exclusion criteria were lack of a physician, life expectancy less than one year, inability to return for follow-up, ongoing participation in other clinical trials, change in prescribed cholesterol-lowering medication within the past three months, and inability to tolerate

cholesterol-lowering medications. Individuals with critical limb ischemia, who were wheel-chair bound, or who had an above or below-knee amputation were excluded.

ABI

A hand-held Doppler probe (Nicolet Vascular Pocket Dop II; Nicolet Biomedical Inc, Golden, CO) was used to obtain systolic pressures in the right and left brachial, dorsalis pedis, and posterior tibial arteries.¹¹ For each leg, the ABI was calculated by dividing the higher of the dorsalis pedis and posterior tibial pressures by the highest brachial pressure.

Patient Characteristics

Medical history, race, and demographics were obtained using patient report.^{11,13}

Randomization

Eligible participants were randomized using block stratified randomization. Block sizes were three, six, and nine.^{14, 15} Randomization was stratified by site (Chicago vs. Worcester). Differences in the proportion of females across the study conditions were observed during the first Data Safety and Monitoring Board meeting after recruitment began. Therefore, randomization was additionally stratified by sex beginning 1/30/2007.

Study Conditions

The intervention consisted of telephone calls, lasting approximately 25 minutes, delivered every six weeks, for a total of eight calls. Patient-centered counseling was delivered by a trained health counselor. First, the counselor educated participants about the importance of LDL-cholesterol lowering. Next the counselor assessed whether the participant was taking cholesterol-lowering medication and (when relevant) whether they were adherent to their medication. If the participant reported taking less than 80% of prescribed cholesterol-lowering medication, the counselor helped the participant increase adherence using patient-centered counseling. If the participant reported no prescribed cholesterol-lowering medication, the counselor encouraged them to request it from their physician. If the participant reported adherence to prescribed cholesterol-lowering medication, the counselor encouraged the participant to request more intensive cholesterol-lowering medication from their physician. Follow-up calls assessed progress toward goals established during the previous call and emphasized increases in cholesterol-lowering therapy or cholesterol-lowering medication adherence until an LDL-cholesterol < 70 mg/dl was achieved. Counselors used information from the six-month follow-up study data and LDL-cholesterol levels measured by participants' physicians to guide recommendations after a change in cholesterol lowering medication. Counselors concluded each call spending five minutes helping the participant adhere to a cholesterol-lowering diet and five minutes helping the participant increase their walking activity.

The attention control condition consisted of eight telephone calls, lasting approximately 25 minutes, delivered every six weeks. These calls provided information about peripheral arterial disease. Topics included peripheral arterial disease risk factors and the diagnosis of peripheral arterial disease. Calls were delivered by people distinct from those delivering the intervention. No attempts were made to change behavior.

Participants randomized to usual care received no scheduled telephone calls.

Outcomes

Outcomes shown in Table 1 were assessed at baseline and at six and 12-month follow-up by examiners blinded to group assignment. The primary outcome was change in LDL-

cholesterol level between baseline and 12 month follow-up. The secondary outcome was the proportion of participants with LDL-cholesterol < 100 mg/dl at twelve-month follow-up. Exploratory outcomes are shown in Table 1.

LDL Cholesterol

Blood specimens were obtained fasting and processed immediately for storage at ≤ -70 degrees Celsius. A detergent solubilized non-LDL lipoproteins. Another detergent solubilized LDL-cholesterol, enabling direct LDL-cholesterol measurement enzymatically.

Split-sample testing was performed in a randomly selected subset of participants. The coefficient of variation percent (CV) for 106 blood sample pairs for within-batch split-sample testing was 3.52. The CV for 56 sample pairs for between-batch split sample testing was 4.50.

Exploratory Outcomes

Patient Activation Measures—The Perceived Efficacy in Patient-Physician Interactions (PEPPI) questionnaire measures patients' self-efficacy regarding their ability to: a) know what questions to ask a physician; b) get a physician to answer all of their questions; c) make the most of their physician visit; d) get a physician to take their chief health concern seriously; and e) get a physician to do something about their chief health concern.¹⁶ Scores range from zero to 50 (50=best).

The 13-item Patient Activation Measure (PAM) assesses: a) the degree to which patients believe it is important for them to influence their health care; b) patient confidence in their ability to influence their healthcare; c) the degree to which patients take action to influence their healthcare; and d) patient confidence that they can continue to affect their healthcare, even under stress.¹⁷ The PAM is scored on a 0–100 scale (100=best).

We developed additional questions to assess participants' inclination to request more intensive cholesterol-lowering medication from their physician.¹¹ A priori, change in the percent of participants who strongly agreed with the statement, "it is my responsibility to bring up my cholesterol treatment with my physician" was selected to measure participants' attitude toward influencing their physician's treatment of their cholesterol.

Health Knowledge—A 27-item questionnaire was developed to measure participants' knowledge regarding the association of peripheral arterial disease with cardiovascular events, the importance of LDL-cholesterol lowering, the ability of patients to influence physician behavior, ideal LDL-cholesterol levels, and characteristics of an LDL-cholesterol lowering diet. Validation of this questionnaire has been described.¹¹

Medication Adherence—To measure adherence to LDL-cholesterol lowering medications, we used an item from the Brief Medication Questionnaire: participant-report of the number of days during the previous week that he/she missed taking cholesterol-lowering medication.¹⁸

Prescribed Medications—Cholesterol-lowering medications and doses were recorded at each visit. An increase in medication intensity was defined as adding a cholesterol lowering medication or increasing the dose of a cholesterol-lowering medication. When participants changed the specific cholesterol-lowering medication they were taking between baseline and follow-up, two investigators (MMM and IO), blinded to all patient characteristics, determined whether the change represented an increased intensity of cholesterol-lowering therapy.^{19–21}

Diet adherence—A 24 hour dietary recall was performed at baseline and 12-month follow-up to measure change in the percent of calories from saturated fat.²²

Power Calculations

Power calculations assumed that 140 people in each condition would complete 12-month follow-up and that a two-sided ANOVA test (F-statistic) with $\alpha=0.05$ would be used to test the null hypothesis of no difference in mean LDL-cholesterol change across the three conditions. The study was designed to have $\geq 85\%$ power to detect differences among means with a standard deviation as small as 4.8. This translated into conditions where at least two groups differed by an 11.1 mg/dl change in LDL-cholesterol between baseline and 12-month follow-up.²³ Power estimates were calculated using PASS 2003²⁴ and assumed a pooled standard deviation of 29.7 mg/dl.

Statistical Analyses

We used chi-square tests and one-way analyses of variance to compare baseline characteristics across the three conditions. Distributional assumptions of the statistical tests were examined graphically and were appropriate. We used ANOVA (F-test) to assess the null hypothesis of no difference in mean LDL-cholesterol change at 12-month follow-up across the three conditions. If results were significant, then two sample, two-sided T-tests were used to compare changes between the intervention and each control condition, without adjusting for multiple comparisons. *A priori*, a p value <0.05 was considered statistically significant. Estimated differences and comparisons were made adjusting for baseline LDL-cholesterol level using linear regression. These procedures were used for assessing changes in other continuous outcomes between baseline and follow-up. Categorical outcomes were compared overall and by paired comparisons using chi-square tests. Adjusted comparisons were made using logistic regression. All analyses were intention-to-treat.

Sensitivity analyses were performed to determine the impact of dropouts. Estimates of the intervention effect on 12-month change in LDL-cholesterol were compared to the primary analyses. We estimated the intervention effect at 12 months based on a linear mixed model using all time points with the patient as a random effect using all available data, using only completers, and adjusting for covariates that differed between completers and dropouts. Missing data were imputed using two methods: 1) return to baseline and 2) multiple imputation using chained equations.^{25–27} The mixed model with multiple imputation resulted in the largest estimated differences, and the imputed return to baseline in the smallest estimated differences. Analyses were performed using Stata 11.0 (StataCorp, College Station, TX).

RESULTS

Of 893 potential participants with a scheduled baseline visit, 193 did not attend their appointment and 150 did not have peripheral arterial disease. Of the remainder, 195 were excluded (Figure 1), leaving 355 participants. Of these, 209 were recruited in Chicago and 146 in Worcester.

Participants randomized to usual care had a higher prevalence of baseline cholesterol lowering medication use (Table 2). Completed call rates were 87.6% and 82.3% in the intervention and attention control conditions, respectively. Telephone call durations were 28.4 ± 4.5 and 21.2 ± 4.1 minutes, respectively.

At twelve-month follow-up, LDL-cholesterol levels were obtained for 85.8%, 92.5%, and 90.2% of participants in the intervention, attention control, and usual care conditions,

respectively. Three participants in each condition died during follow-up. No serious adverse events were attributed to study participation. Participants who dropped out were older ($p=0.041$), had lower education ($p=0.008$), a higher prevalence of lung disease ($p=0.006$), and were more likely to report no alcohol consumption ($p=0.022$) than those completing follow-up.

Primary Outcome

At twelve-month follow-up, mean LDL-cholesterol changes were -18.8 , -6.8 , and -11.1 mg/dl in the intervention, attention control, and usual care conditions, respectively (overall p value $=0.035$), adjusting for baseline LDL-cholesterol (Table 3). The attention control condition had less LDL-cholesterol decline, compared to the intervention ($+10.5$, 95% Confidence Interval (CI) $=+2.5$ to $+18.4$, $p=0.010$). Participants in usual care had less LDL-cholesterol decline compared to the intervention, but this finding was not statistically significant ($+5.1$, 95% CI $=-2.9$ to $+13.1$, $p=0.208$) (Table 3). These differences remained similar even after adjusting for baseline differences in cholesterol-lowering medication use. Sensitivity analyses demonstrated comparable estimates and identical statistical conclusions.

Secondary Outcome

At twelve-month follow-up, changes in proportions of participants with LDL-cholesterol levels <100 mg/dl were $+21.6\%$, $+9.0\%$, and $+9.1\%$ in the intervention, attention control, and usual care conditions, respectively (overall p -value $=0.009$) (Table 3). Compared to the intervention, participants in the attention control condition ($p=0.003$) and usual care ($p=0.018$) were less likely to have an LDL-cholesterol <100 mg/dl (Table 3).

Exploratory Outcomes

Mid-way through the intervention, at six-month follow-up, mean LDL-cholesterol changes were -14.4 , -6.6 , and -8.8 mg/dl in the intervention, attention control, and usual care conditions, respectively (overall p value $=0.193$).

At twelve-month follow-up, participants in the intervention had greater increases in use or dose intensity of cholesterol-lowering medication than participants in the attention control and usual care conditions, respectively ($+54\%$ vs. $+18\%$ vs. $+31\%$, $p<0.001$), adjusting for baseline use of cholesterol-lowering medication (Table 4). Intervention participants were more likely to add a cholesterol-lowering medication or increase their dose, compared to those in the attention control ($p=0.001$) and usual care ($p<0.001$) conditions, respectively. At twelve-month follow-up, relative to the intervention, participants in the attention control and usual care conditions had less improvement in the PAM score ($p=0.016$ and $p=0.007$, respectively), less improvement in the PEPPI score ($p=0.014$ and $p=0.015$, respectively), less improvement in their health knowledge score ($p<0.001$ and $p<0.001$, respectively), and lower increases in the proportion who agreed with the statement, “it is my responsibility to bring up my cholesterol treatment with my physician” ($p=0.001$ and $p=0.009$, respectively) (Table 4).

There were no differences in changes in adherence to cholesterol-lowering medication or percent of calories consumed from saturated fat between the three conditions (Table 4).

DISCUSSION

This randomized controlled trial demonstrates that a telephone counseling intervention, designed to activate patients with peripheral arterial disease to request more intensive LDL-cholesterol lowering medication from their physician, achieved significantly lower LDL-cholesterol levels at twelve-month follow-up, compared to an attention control condition.

Greater LDL-cholesterol lowering in the intervention as compared to the usual care condition did not reach statistical significance. However, the intervention was associated with a significantly greater increase in the proportion of participants with an LDL-cholesterol < 100 mg/dl, greater increases in prescriptions of LDL-cholesterol lowering medication, and greater increases in participant willingness to request LDL-cholesterol lowering medication from their physician, compared to each control condition. Our results suggest that the greater decline in LDL-cholesterol levels in the intervention as compared to the attention control condition resulted from greater increases in cholesterol-lowering medication in the intervention.

There were several challenges to the success of our intervention. First, the intervention required participants to schedule physician appointments, obtain a prescription for cholesterol-lowering therapy, and fill the prescription. Second, previous studies demonstrated that peripheral arterial disease patients and physicians caring for them underappreciate the importance of LDL-cholesterol lowering in peripheral arterial disease.^{28–29} Third, peripheral arterial disease patients often have multiple comorbidities requiring attention during a physician office visit and leaving little opportunity for peripheral arterial disease patients to raise concerns about their cholesterol. Fourth, cholesterol-lowering therapy is not associated with immediate tangible benefits. Nonetheless, the intervention achieved greater increases in use or dose of cholesterol lowering medication, compared to each control condition.

An unexpected outcome was that the intervention was associated with significantly lower LDL-cholesterol levels compared to the attention control condition, but not compared to usual care. The attention control condition received health information, while the intervention combined education with patient-centered counseling to achieve behavior change. Attention control condition participants may have been disinclined to take action about their health, if they perceived reassurance from the telephone callers. Alternatively, the differences observed between LDL-cholesterol lowering in the attention control and usual care conditions may have been due to chance.

This study has limitations. First, medication adherence was measured with patient self-report. Previous studies suggest that patient-reported adherence over-estimates actual adherence.^{30,31} Second, we are unable to determine the extent to which letters participants' physicians in the intervention after each telephone call may have influenced physician behavior. However, prior studies suggest that these letters are unlikely to have substantially influenced physician behavior.^{32–33} Third, our findings may not be generalizable to participants who did not meet study eligibility criteria or who were not interested in study participation.

In conclusion, a telephone counseling intervention that activates peripheral arterial disease patients to request more intensive LDL-cholesterol lowering medication from their physician successfully lowers LDL-cholesterol levels as compared to an attention control condition. Our results suggest that declines in LDL-cholesterol levels in the intervention resulted from greater increases in cholesterol-lowering medication. Further study is needed to determine whether the intervention benefits are sustainable after the intervention ends.

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Figure 1.
STUDY PARTICIPATION AND FOLLOW-UP RATES

Table 1**Outcome Measures for the Reducing Risk Factors in Peripheral Arterial Disease Randomized Controlled Clinical Trial**

Primary Outcome	Change in low density lipoprotein cholesterol (LDL-cholesterol) levels at twelve-month follow-up.
Secondary Outcome	Percent of participants with LDL-cholesterol levels < 100 mg/dl at twelve month follow-up.
Exploratory Outcomes [*]	<ul style="list-style-type: none"> - Change in LDL-cholesterol at six-month follow-up. - Change in intensity of LDL-cholesterol lowering therapy at twelve-month follow-up.¹ - Change in prevalence of LDL-cholesterol lowering medication at twelve-month follow-up. - Change in patient activation regarding their physician interactions at twelve-month follow-up.² - Change in patient knowledge and attitudes regarding the importance of LDL-cholesterol lowering therapy at twelve-month follow-up.³ - Change in adherence to LDL-cholesterol lowering medications at twelve-month follow-up.⁴ - Change in the percent of calories consumed as saturated fat at twelve-month follow-up.⁵

^{*} Change in LDL-cholesterol at six-month follow-up was an outcome to identify whether six-months was sufficient time to achieve an ideal LDL-cholesterol. Other exploratory outcomes were designed to identify potential mediators of the intervention.

¹ Change in intensity of LDL-cholesterol lowering medication was defined as the addition of a new LDL-cholesterol lowering medication or an increase in dose of an LDL-cholesterol lowering medication.

² Measured by the Patient Activation Measure (PAM), Perceived Efficacy in Patient-Physician Interactions (PEPPI), and an additional investigator-developed question (17).

³ Measured by a previously validated investigator questionnaire (17).

⁴ Measured by the Brief Medication Questionnaire (BMQ) question regarding whether participants missed any cholesterol-lowering medication during the previous week.

⁵ Measured by 24-hour dietary recall.

Table 2

Baseline Characteristics of Randomized Participants According to Group Assignment (n=355).

	Attention Control Condition (n=120)	Usual Care Condition (n=122)	Intervention Condition (n=113)	p-value
Age in years	70.24 (10.60)	71.50 (10.00)	69.95 (11.00)	0.484
Gender	59.20%	63.90%	54.90%	0.367
Male	40.80%	36.10%	45.10%	
Race	18.5%	16.4%	9.7%	0.141
African-American	78.2%	83.6%	88.5%	
White				
ABI	0.68 (0.20)	0.70 (0.10)	0.67 (0.20)	0.311
Site	58.30%	58.20%	60.20%	0.943
Northwestern	41.70%	41.80%	39.80%	
UMass				
Education	8.3%	6.6%	12.4%	0.537
Less than high school	22.5%	24.6%	23.0%	
High School	35.0%	39.3%	32.7%	
Some college/technical	19.2%	10.7%	13.3%	
College degree	15.0%	18.9%	18.6%	
More than college				
Status of smoking	58.3%	63.1%	57.5%	0.161
Former smoker	25.8%	18.9%	31.9%	
Current smoker	15.8%	18.0%	10.6%	
Never smoked				
Number of co-morbidities	2.39 (1.4)	2.66 (1.6)	2.57 (1.4)	0.369
Cholesterol (mg/dL)	182.68 (33.90)	180.95 (45.10)	186.97 (39.70)	0.495
Total	51.60 (14.30)	49.12 (12.50)	52.13 (15.50)	0.216
HDL	103.71 (26.30)	101.00 (33.10)	105.71 (32.40)	0.499
LDL	149.67 (87.80)	151.35 (80.60)	155.42 (95.70)	0.798
Triglycerides	75.0%	83.3%	69.6%	0.047
Cholesterol-lowering medication				

* Values are mean (SD) for continuous variables or % for categorical variables. HDL- High density lipoprotein; LDL-Low density lipoprotein.

Table 3

Associations of A Telephone Counseling Intervention on Primary and Secondary LDL Cholesterol Outcomes in Peripheral Arterial Disease Participants

Outcome measures	Group	N	Baseline Value	Twelve month Value	Within Condition Changes (95% Confidence Interval)	Compare to Intervention Condition † (95% Confidence Interval)	Pair-wise P value	P value
Primary Outcome Measure								
LDL-cholesterol (mg/dl)	Usual Care	110	101.0 (33.9)	89.9 (31.0)	-11.1 (-17.0, -5.1)	5.1 (-2.9,13.1)	0.208	
	Attention control	111	103.4 (26.4)	96.6 (33.9)	-6.8 (-13.0, -0.5)	10.5 (2.5, 18.4)	0.010	0.035
	Intervention	97	106.0 (33.3)	87.6 (36.9)	-18.4(-24.8, -12.1)	NA	NA	
Secondary Outcome Measure								
Proportion of participants with LDL-cholesterol < 100 mg/dl (Percent)	Usual Care	110	65 (59.1%)	75 (68.2%)	9.1% (-2.7%, 20.2%)	0.42 ^I (0.20-0.86)	0.018	
	Attention control	111	58 (52.2%)	68 (61.3%)	9.0% (-3.2%, 21.2%)	0.34 ^I (0.17,0.69)	0.003	0.09
	Intervention	97	54 (55.7%)	75 (77.3%)	21.6% (11.5%, 31.8%)	NA	NA	

† Indicates that analyses adjusted for baseline value.

^I Odds ratio.

Table 4

Associations of a Telephone Counseling Intervention with Exploratory Outcome Measures at 12-Month Follow-up in Peripheral Arterial Disease Participants

Exploratory outcomes									
Outcome measures	Group	N	Baseline	12-Month Follow-up Value	Within Group Changes		Between Group Changes Compared to the Intervention Group [†]		P value
					(95% Confidence Interval)	(95% Confidence Interval)	(95% Confidence Interval)	Pair-wise P value	
Percent of participants who increased their cholesterol-lowering medication at 12-month follow-up.	Usual Care	122	N/A	32 (30.5%)	32 (30.5%)	Odds ratio= 0.18 (0.1,0.3)	<0.001		
	Attention Control	120	N/A	18 (17.5%)	18 (17.5%)	Odds ratio= 0.40 (0.2,0.7)	0.001	<0.001	
	Intervention	113	N/A	50 (53.8%)	50 (53.8%)	N/A	N/A	N/A	
Patient Activation Measure (PAM) score	Usual Care	109	60.1 (13.9)	61.2 (15.4)	1.1 (-2.1, 4.2)	-6.1 (-10.6, -1.7)	0.007		
	Attention Control	110	61.0 (18.2)	62.2 (17.5)	1.2 (-2.3, 4.7)	-5.4 (-9.9, -1.0)	0.016	0.014	
	Intervention	93	63.5 (16.8)	68.6 (18.4)	5.1 (0.5, 9.6)	NA			
Perceived Efficacy in Patient-Physician Interactions (PEPPI) score	Usual Care	109	44.6 (8.1)	45.5 (8.6)	0.8 (-0.7, 2.3)	-2.5 (-4.5, -0.5)	0.015		
	Attention Control	110	42.1 (10.2)	44.1 (9.7)	2.0 (0.1, 3.8)	-2.5 (-4.5, -0.5)	0.014	0.021	
	Intervention	93	42.1 (11.5)	46.6 (8.3)	4.5 (2.9, 6.1)	NA			
Health Knowledge Score	Usual Care	109	61.0 (18.8)	66.5 (17.5)	5.5 (3.0, 8.0)	-9.3 (-12.7, -6.0)	<0.001		
	Attention Control	111	56.8 (20.6)	65.7 (17.3)	8.9 (6.2, 11.7)	-7.6 (-10.9, -4.3)	<0.001	<0.001	
	Intervention	93	62.1 (17.2)	76.5 (14.2)	14.4 (11.4, 17.4)	NA			
Percent of participants who agree that, “it is my responsibility to bring up my cholesterol treatment with my physician.”	Usual Care	108	85 (78.7%)	87 (80.6%)	1.9% (-6.8%, 10.5%)	Odds ratio: 0.3 (0.1, 0.7)	0.009		
	Attention Control	105	72 (68.6%)	75 (71.4%)	2.9% (-8.1%, 13.8%)	Odds ratio: 0.2 (0.1, 0.5)	0.001	0.003	
	Intervention	91	66 (72.5%)	83 (91.2%)	18.7% (9.0%, 28.3%)	NA			
Percent who missed a cholesterol-lowering medication during the past week.	Usual Care	92	16 (17.4%)	16 (17.4%)	0.0% (-10.1%, 10.1%)	Odds ratio: 1.1 (0.5, 2.7)	0.796		
	Attention Control	78	9 (11.5%)	9 (11.5%)	0.0% (-10.0%, 10.0%)	Odds ratio: 0.8 (0.3, 2.0)	0.590	0.698	
	Intervention	67	9 (13.4%)	10 (14.9%)	1.5% (-11.3%, 14.3%)	NA			
Percent of calories from saturated fat.	Usual Care	110	12.0 (5.5)	8.7 (6.3)	-3.4 (-4.7, -2.0)	-0.1 (-1.7, 1.5)	0.915		
	Attention Control	110	10.7 (4.4)	8.9 (5.7)	-1.8 (-3.1, -0.6)	0.4 (-1.1, 2.0)	0.591	0.777	

Baseline and twelve-month data shown are means (standard deviations) for all outcomes. Within group changes shown are mean changes (95% confidence intervals) for all outcomes. Between group changes shown are means (95% confidence intervals) for outcomes unless otherwise noted.

[†]Indicates that results control for baseline values.