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A randomized controlled trial to evaluate the effectiveness of CouPLES: A spouse-assisted lifestyle change intervention to improve low-density lipoprotein cholesterol ☆

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ABSTRACT

Objective. This randomized controlled trial evaluated the effectiveness of a telephone-delivered, spouse-assisted lifestyle intervention to reduce patient LDL-C.

Method. From 2007 to 2010, 255 outpatients with LDL-C > 76 mg/dL and their spouses from the Durham Veterans Affairs Medical Center were randomized to intervention or usual care. The intervention comprised nine monthly goal-setting telephone calls to patients and support planning calls to spouses. Outcomes were assessed at 11 months.

Results. Patients were 95% male and 65% White. LDL-C did not differ between groups (mean difference = 2.3 mg/dL, 95% CI = −3.6, 8.3, p = 0.44), nor did the odds of meeting goal LDL-C (OR = 0.95, 95% CI = 0.6, 1.7; p = 0.87). Intakes of calories (p = 0.03), total fat (p = 0.02), and saturated fat (p = 0.02) were lower for the intervention group. Cholesterol and fiber intake did not differ between groups (p = 0.11 and 0.26, respectively). The estimated rate of moderate intensity physical activity per week was 20% higher in the intervention group (IRR = 1.2, 95% CI = 1.0, 1.5, p = 0.06). Most participants did not experience a change in cholesterol medication usage during the study period in the intervention (71.7%) and usual care (78.9%) groups.

Conclusion. This intervention might be an adjunct to usual primary care to improve adherence to lifestyle behaviors.

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Background

Coronary heart disease (CHD) is the leading cause of death in the United States (Roger et al., 2012). The short-term risk of a major coronary event can be reduced by lowering the low-density lipoprotein cholesterol (LDL-C), the primary target of cholesterol-lowering therapy in the Adult Treatment Panel (ATP) III guidelines (Anon., 2001).

Despite the proven success and cost effectiveness of lifestyle changes and cholesterol-lowering medications (McKenney, 1998; Szucs, 1998), patient adherence is suboptimal (Jackevicius et al., 2002; King et al., 2009). Effective, low-cost behavioral interventions are needed to increase patient adherence, thereby improving LDL-C levels.

Patient adherence may be increased by increasing self-efficacy and social support (Bandura, 1986, 1997; Cohen, 2004). Self-efficacy is promoted through goal achievement (Bandura, 1997). Spouse-assisted interventions can promote greater adherence than patient-only intervention if spouses are taught strategies for providing support that is perceived positively by patients (Baucom et al., 1998; Martire et al., 2010).

These principles provided the foundation for an intervention, Couples Partnering for Lipid Enhancing Strategies (CouPLES), to increase patient treatment adherence to the cholesterol-lowering regimen. In this paper, we report on the primary and secondary outcomes from a randomized, controlled trial to evaluate the effectiveness of the CouPLES intervention.

Methods

Setting and design

The study was approved by ethics committees and conducted at the Durham Veterans Affairs Medical Center (VAMC). In this two-group, randomized, controlled trial (Fig. 1), couples in both groups received educational handouts

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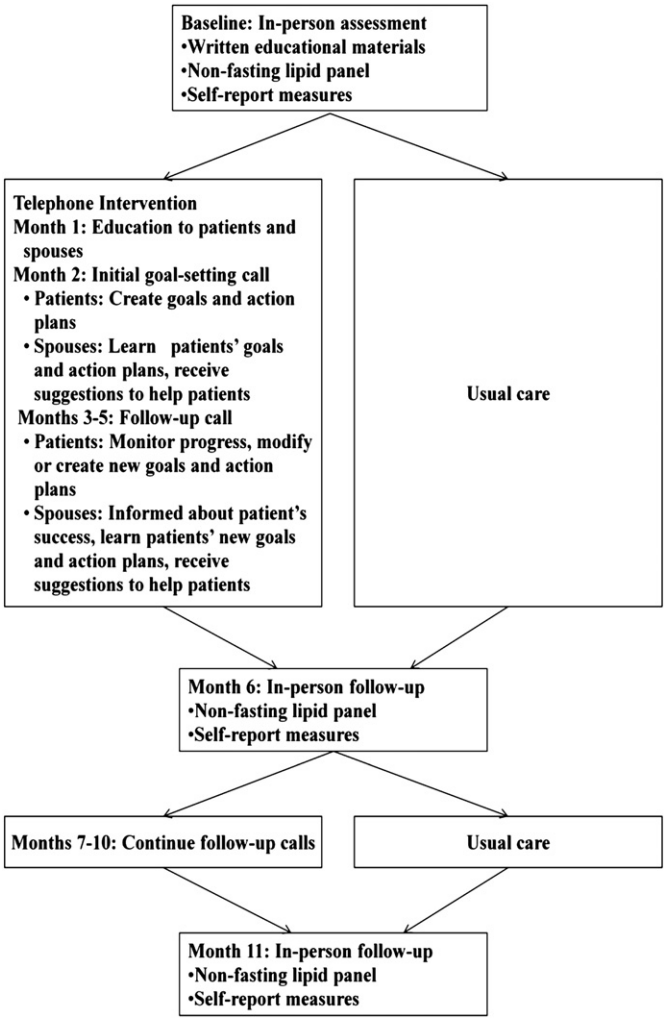

Fig. 1. Study design.
Adapted from Voils et al. (2011).

containing guideline-concordant recommendations (2001) and providing spousal support; provided baseline measurements; and then were randomized to usual care or the intervention.

Patient recruitment and enrollment

Eligibility was determined in a 3-step process (see Voils et al., 2009, 2011 for more details). In Step 1, electronic medical records were used to identify patients who were married, one or more LDL-C≥100 mg/dL, and one or more primary care visits in the previous 12 months. Patient exclusion criteria included no record of a telephone number; active diagnosis of psychosis or dementia; no specified primary care provider at the VA; and enrolled in VA long-term care.

In Step 2, patients with an upcoming clinical appointment received a recruitment letter followed by a screening telephone call. Patient exclusion criteria included no longer married; unwilling to have blood drawn for a lipid panel; enrolled in a study focusing on lifestyle changes; and hospitalization for a stroke, myocardial infarction, coronary artery revascularization in the previous 3 months. Patient and spouse exclusion criteria included inconsistent access to telephone; impaired cognition (Callahan et al., 2002) or hearing; health problem that precluded participation; and resident of nursing home or receiving long-term care.

In Step 3, couples passing the telephone screening were scheduled for baseline assessments, where written informed consent was obtained and patient LDL-C was measured to determine final eligibility. Initially, patients were eligible if their baseline LDL-C was above the ATP III guideline-recommended goal (see Table 1). Because inadequate numbers of patients had high LDL-C values

Table 1
Risk categories and LDL-C goal.
Previously published in Voils et al. (2009).

Risk category	LDL-C goal
High: CHD and risk equivalents[a]	<100 mg/dL
Medium: No CHD, ≥2 risk factors[b]	<130 mg/dL
Low: No CHD, 0–1 risk factor	<160 mg/dL

Note. LDL-C: low-density lipoprotein cholesterol. CHD: coronary heart disease.
[a] Risk equivalents: diabetes, clinical forms of atherosclerotic disease, and multiple risk factors that confer a 10-year risk for CHD >20% according to the Framingham risk score.
[b] Risk factors: hypertension (blood pressure≥140/90 mm Hg or on antihypertensive medication), cigarette smoking, high-density lipoprotein cholesterol<40 mg/dL, age (men≥45 years, women≥55 years), and family history of premature coronary heart disease (present in male first degree relative<55 years or female first degree relative<65 years).

based on this criterion to fulfill recruitment goals, we modified it to LDL-C>76 mg/dL, a value 2 SD above the alternative ATP III LDL-C goal of <70 mg/dL for high-risk patients (Grundy et al., 2004). Patients and spouses initially received $10 each for each outcome visit; later, compensation was increased to $20 to address increases in transportation expenses (Voils et al., 2011).

Randomization

Couples were randomized to the intervention or usual care group at a ratio of 1:1 using stratified, blocked randomization with block sizes of 2. Randomization was stratified by patient race (White vs. non-White) and CHD risk (an a priori decision based on pilot data was to have two strata: high risk vs. moderate and low risk combined; see Table 1). After baseline lab results were obtained, the project coordinator invoked software to determine group assignment based on the randomization sequence generated by the project statistician. The nurse then called patients to inform them of their assignment and, for those assigned to the intervention group, to schedule the first intervention telephone call. This method allowed the outcome assessors to remain blinded to randomization assignment.

CouPLES intervention

Intervention telephone calls were delivered first to patients and then to spouses. In month 1, patients and spouses received information about hypercholesterolemia and an overview of self-management principles. Spouses also received an orientation on strategies to support patient goal achievement (e.g., focusing on patients' goals instead of what spouses think patients should do).

In months 2–5 and 7–10, patient calls focused on goal-setting and problem-solving. Because self-efficacy is enhanced when people set graduated, achievable goals (Bandura, 1997), we allowed patients to choose a behavior on which to focus and to set their own goals and action plans according to what they felt confident they could accomplish.

At the beginning of each call, participants selected one of four topics: diet, physical activity, patient–physician communication, or medication adherence. Via open-ended questioning, patients generated reasons for changing their behaviors and made measurable behavioral goals. They rated their confidence to achieve each goal on a scale from 1 (*not at all confident*) to 10 (*very confident*). Whenever ratings <7 were provided, patients revised their goals to increase the likelihood of achieving them (Bodenheimer et al., 2002). For each goal, patients generated one or more action plans. The nurse recorded goals and action plans in the intervention software, and patients were asked to record them on a provided paper. Starting in month 3, all patient calls began with a review of the previous month's progress, with responses recorded in the software. If patients achieved their goals, the nurse reinforced them and guided creation of new goals and action plans for the next month. If patients did not achieve their goals, the nurse helped patients generate a more achievable goal for the next month.

Spouse calls occurred within one week of patient calls and began with a review of patients' success meeting the previous month's goals. Spouses were informed of patients' goals and action plans for the upcoming month and were asked to record them. Then spouses were asked to generate a specific behavior plan that they would follow to support patient goal achievement (e.g., provide verbal reinforcement, change cooking habits),

supplemented by recommendations from the interventionist when necessary. For diet or physical activity goals, spouses were asked if they planned to make the same changes that the patient planned to make; recommended support behaviors were then tailored to whether spouses intended to make the same changes.

The intervention was delivered by a research nurse using a custom software package that helped maximize intervention fidelity. Prior to enrolling couples into the trial, the research nurse underwent 12 h of training with a social psychologist (CIV) and a clinical psychologist (SK), which included reading and discussing material on motivational interviewing, role-playing, and practicing using the software.

Usual care

Usual care consisted of clinical management of lipid disorders by providers augmented by local and national health system efforts at improving lipid management. The ATP III guidelines (Anon., 2001) and their supplements were used to develop local and national clinical reminders and performance measures that were integrated into the electronic medical record. Guideline adherence was emphasized in 11 electronic mail messages encouraging improved provider performance via the use of appropriate medications, which resulted in greater average simvastatin doses and a greater proportion of high-risk patients at LDL-C goal compared to baseline (Goldberg et al., 2007). In addition, two referral clinics were available to practitioners: a subspecialty lipid disorders clinic for difficult to manage cases and a subspecialty risk factor management clinic that enrolled high-risk patients whose LDL-C was above the goal. These clinics provided lifestyle behavior counseling, medication management, and follow-up.

Outcomes and measurements

All couples attended in-person outcome assessment visits conducted by blinded study personnel at 6 and 11 months, with 11 months as the primary endpoint. At baseline, data were collected on demographics and information necessary for calculating Framingham risk scores. At every visit, all primary and secondary outcomes were obtained from patients except the Brief Food Frequency Questionnaire (FFQ), which was completed at home and returned by mail.

Primary outcome

The primary outcome was patient LDL-C. The blood sample was analyzed directly with an LXi from Beckman Coulter, with the coefficient of variation ranging from 3.3% at 106 mg/dL to 4.1% at 149 mg/dL.

Secondary outcomes

Goal LDL-C was a dichotomous outcome (met the ATP III guideline LDL-C goal or not; Table 1) and was not affected by the updated LDL-C inclusion criterion. Self-reported physical activity was assessed with the Community for Healthy Activities Model Program for Seniors (CHAMPS) questionnaire (Stewart et al., 2001), which assesses frequency (times per week) and duration (hours per week) over the past 4 weeks. We focused on moderate intensity physical activity (e.g., heavy housework, walking briskly) as it is important for health maintenance (US Department of Health Human Services, 2008).

Self-reported dietary intake was assessed with the Brief FFQ, (Block, 2000) which assesses the frequency of eating per week over the previous 6 months. We focused on total fat, saturated fat, dietary cholesterol, and fiber because they are targeted in the ATP III guidelines (2001). We also examined total caloric intake because ATP III guidelines suggest weight loss if needed.

Patients who self-reported taking a cholesterol medication indicated how often they missed the medication in the past 30 days. Pharmacy and medical records were reviewed by the nurse to enumerate cholesterol medication history from VA records for each participant over the course of the study; participants were then categorized into one of the following: 1) initiated medication, 2) increased dose, 3) no change, 4) discontinued medication, and 5) decreased dose.

For health care services utilization, we collected data on primary care visits, emergency/urgent care visits, hospitalizations, and medication utilization from the VA Decision Support System's national data extract.

Sample size and statistical power

The primary hypothesis was that the intervention would result in a 7% greater reduction in LDL-C at 11 months as compared to usual care; this was based on the ATP III guidelines for a clinically meaningful difference (2001). A sample size of 250 couples (125 in each group) provided 80% power to detect a between-group difference of this magnitude. We assumed a 20% dropout rate by the end of the study, an α of 0.05, a correlation between time points for LDL-C of 0.50, and a baseline mean LDL-C of 132.3 (SD = 27.3).

Analysis

All analyses were conducted with patients analyzed in the group to which they were randomized using SAS software (SAS Institute, Inc., Cary, NC). For the analysis of continuous LDL-C and FFQ dietary outcomes, we fit linear mixed models (LMM) (Verbeke and Molenbergh, 2000). LMMs were fit to log-transformed FFQ dietary outcomes; however, the percentage of calories from total fat and saturated fat was not log-transformed. For the dichotomous secondary outcome of goal LDL-C, we used generalized estimating equation (GEE) models (Diggle et al., 2002) with a logit link function to account for repeated measures within participants. Empirical standard errors were used for inference. For the frequency and duration of physical activity outcomes, we fit a generalized LMM using a negative-binomial distribution with a log link function because the distribution of these variables followed a Poisson-type process (Diggle et al., 2002). The primary predictors in all of these models included a common intercept and indicator variables for the 6- and 11-month time points and treatment group by time interaction. All available data were used; no observations were deleted due to missing follow-up data (Little and Rubin, 2002).

For the repeated measures, we used an unstructured covariance matrix. Final models included our stratification variables race and CHD risk. Our primary inference was on the treatment by 11-month follow-up time point indicator variable, as this was the estimated difference between the intervention and usual care groups at the primary endpoint.

Because few patients were on cholesterol medications at all three time points, descriptive statistics characterized these variables. To determine whether the intervention was more resource intensive than usual care, we examined differences in patients' median medical resource use in the 11 months after initiating the intervention using Chi-square, t- and Wilcoxon tests (Diggle et al., 2002).

A micro-costing approach was used to estimate intervention cost (Smith and Barnett, 2003). Intervention cost was the labor cost of the nurse conducting the telephone-based care. Labor inputs consisted of time for training and conducting the calls. The collected time data were multiplied by the nurse's hourly rate for wage and fringe benefits to derive total labor cost. The total labor cost was divided by the number of patients in the intervention group to derive average labor cost per patient. We also included a per-patient cost for the education materials in deriving intervention cost. Intervention development cost was treated as a study-related, one-time sunk cost because it will not need to be replicated if the intervention is implemented in clinical practice.

Results

Participants

Recruitment letters were mailed to 2379 patients meeting the medical record eligibility criteria (Fig. 2). Of 2060 patients for whom screening telephone calls were attempted, 362 patients and their spouses were scheduled for baseline interviews. Of those, 329 attended and provided written informed consent; 74 were ineligible to due low patient LDL-C (below the goal at the beginning of the study, later <76 mg/dL). Thus, 255 couples were randomized (128 to usual care, 127 to the intervention). There were 203 patients at the 6 month follow-up and 212 (106 intervention; 106 usual care) for the 11 month follow-up; the 83% follow-up rate at 11 months was the same in both arms. Patients' baseline characteristics are presented in Table 2.

LDL-C

After adjusting for stratification variables, there was no significant difference in the mean LDL-C between intervention and usual care groups at 11 months (mean difference = 2.3 mg/dL, 95% CI = −3.6, 8.3; p = 0.44) (Table 3). Similarly, there was no difference in the

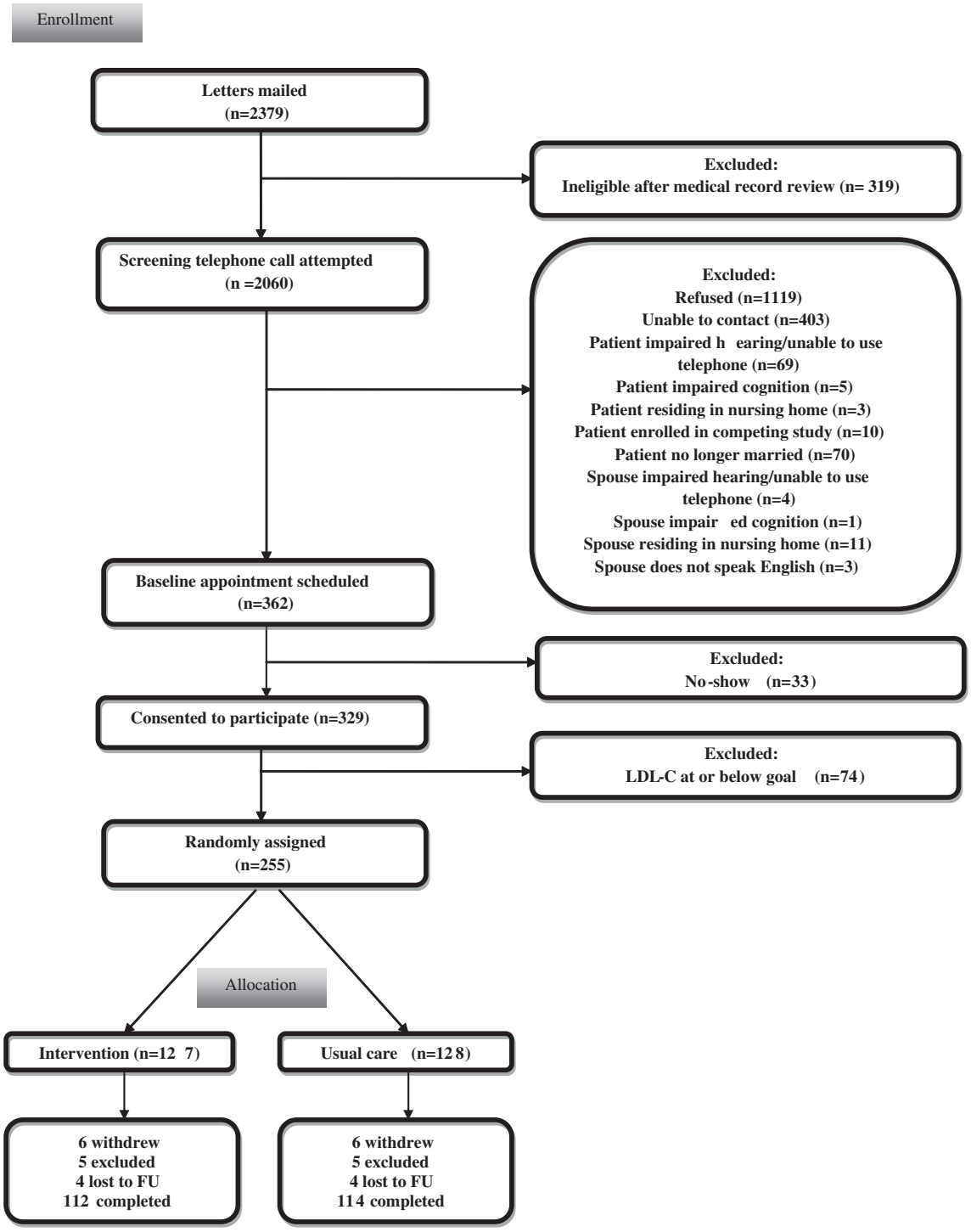

Fig. 2. CONSORT flow diagram.
Previously published in Voils et al. (2011).

odds of meeting goal LDL-C between groups at 11 months (Odds Ratio = 0.95, 95% CI = 0.6, 1.7; p = 0.87).

Self-reported dietary intake and physical activity

For the dietary outcomes, 31 patients (12 intervention; 19 usual care) had no FFQ data at any time point. The sample of patients with FFQ data for at least one time point (n = 224) did not differ by patient characteristics or baseline LDL-C values from the study sample (n = 255) (results are available from the first author). Unadjusted raw means of FFQ outcomes at each time point are shown in Table 4. Caloric intake per day was lower in the intervention group as compared to the usual care group at 11 months (p = 0.03). Total and saturated fat intake and percentage of calories from total fat were also lower in the intervention group ($p < 0.04$). Percentage of calories from saturated fat, total dietary cholesterol, and fiber intake did not differ between groups (p = 0.09, p = 0.11 and p = 0.26, respectively).

Table 2
Baseline characteristics of enrolled patients.[a]

Demographic variable	All patients (N = 255)	Intervention (N = 127)	Usual care (N = 128)
Age, M(SD)	61.3 (12.3)	61.7 (12.3)	61.0 (12.2)
White (%)	64.9	66.1	63.8
Male (%)	94.9	92.1	97.7
High school graduate or less (%)	23.9	25.8	22.0
Full-time employment (%)	41.4	37.1	45.7
High risk group (%)	17.3	19.7	14.8
LDL-C, mg/dL, M(SD)	126.3 (26.3)	130.0 (27.2)	122.7 (24.9)
Met goal LDL-C (%)	44.0	37.5	50.4
Weekly frequency of moderate intensity physical activity, Median (IQR)	8 (4, 14)	7 (3.5, 12)	9 (5, 15)
Weekly duration of moderate intensity physical activity (hours), Median (IQR)	6 (2.8, 12.5)	5.4 (2.3, 11.1)	7.3 (3.8, 14.0)
Taking cholesterol medication (%)[b]	46.3	48.8	43.8
Missed at least one dose of cholesterol medication in previous 30 days (%)[c]	50.4	50.0	50.9

Note. Participants were outpatients from the Durham Veterans Affairs Medical Center during 2007–2010. M = mean; SD = standard deviation; LDL-C = low-density lipoprotein cholesterol; IQR = interquartile range.

[a] 4 patients were missing data on race, education, and employment (3 intervention; 1 usual care UC)). 12 patients are missing a baseline LDL-C measurement (7 intervention, 5 UC). 8 patients are missing baseline data on the frequency and duration of moderate intensity physical activity (3 intervention, 5 UC). 2 patients who reported taking cholesterol medication are missing baseline data on the whether or not they missed a dose of their cholesterol medication in the last 30 days (2 UC). Participants with missing data are excluded from percentage calculations.

[b] According to electronic medical record abstraction.

[c] Of the patients who self-reported taking cholesterol medication.

The estimated rate of frequency and duration of physical activity was 20% higher (Incidence Rate Ratio (IRR) = 1.2, 95%CI = 1.0, 1.5; p = 0.06) and 10% higher (IRR = 1.1, 95%CI = 0.9, 1.4; p = 0.37), respectively, for the intervention than the usual care group at 11 months (Table 5).

Cholesterol medication usage

Based on VA electronic medical records, 47% (n = 119) of patients were on cholesterol-lowering medication at baseline. Most patients had no evidence of change in cholesterol medication usage: 78.9% (n = 101) in usual care and 71.7% (n = 91) in the intervention group. Of these patients, in both groups, 50% had no cholesterol medication use over the study period, whereas the other 50% had no cholesterol medication prescription changes during the course of the study.

Table 3
Model estimates for low-density lipoprotein cholesterol (LDL-C) by group and time point.[a]

Outcome and time point	Intervention	Usual care	Intervention vs. usual care	p-Value
Primary outcome				
Estimated mean LDL-C (mg/dL)			Mean difference (95% CI)	
Baseline	126.2	126.2		
Midpoint	124.1	125.3		
Final	121.3	119.0	2.3 (−3.6, 8.3)	0.44
Secondary outcome				
% of patients with LDL-C at goal[b]			Odds ratio (95% CI)	
Baseline	42%	42%		
Midpoint	56%	45%		
Final	55%	57%	0.95 (0.6, 1.7)	0.87

Note. Participants were outpatients from the Durham Veterans Affairs Medical Center during 2007–2010.

[a] Due to changes in laboratory tests available early in the study, several patients had calculated LDL-C instead of direct LDL-C at baseline; calculated LDL-Cs were excluded from our analysis. Patients missing LDL-C and LDL-C goal: baseline — 12 patients (7 intervention, 5 usual care (UC)), midpoint — 52 patients (24 intervention, 28 UC), and final — 43 patients (21 intervention, 22 UC).

[b] For high-risk patients, goal is LDL-C <100 mg/dL; for moderate-risk, goal is LDL-C <130 mg/dL; and for low-risk, goal is LDL-C <160 mg/dL.

Health care utilization

There was a median number of 2 primary care encounters over 11 months in both groups (p = 0.08). There was no difference in the proportion of emergency department or urgent clinic visits over 11 months between groups (18% vs. 20%; p = 0.66).

Intervention dose and cost

The intervention nurse conducted approximately 1800 intervention calls to patients and spouses. Of the 127 patients and spouses randomized to the intervention group, 117 received at least 2 calls during the study period (including the educational call); 92 patients (72%) and 88 spouses (69%) received at least 8 calls. For those who participated, the mean (SD) number of calls was 7.9 (1.9) per patient and 7.7 (2.1) per spouse. The mean (SD) duration of calls was 13.6 (6.3) minutes for patients and 8.8 (4.6) minutes for spouses. Ten patients randomized to the intervention did not participate in any of the intervention telephone calls.

Patients selected the diet and physical activity topics for 364 (51%) and 245 (49%) of calls, respectively. Spouses agreed to make the same changes as patients in 96.7% of calls in which the patient sets dietary change goals and 65.4% of calls in which the patient sets exercise goals. The patient–physician communication topic was only selected for 2 calls, and the medication management topic was never selected. Ninety-seven percent (n = 113) of patients who participated in the intervention had at least one call on diet; 81% (n = 95) had at least one call on physical activity. Over the course of the study, patients in the intervention group set 594 goals and met 79% (n = 470) of these goals; 86% of goals set for diet were met and 71% of goals set for physical activity were met. Only 2 goals for talking with your doctor were set; both were met.

The intervention cost consisted of 12 h for training and 386.5 h for making intervention calls. Based on salary and fringe benefits of a registered nurse at the Durham VAMC conducting the calls, the cost per couple who completed the intervention was $148.16.

Discussion

We conducted a randomized controlled trial to evaluate the effectiveness of a spouse-assisted lifestyle change intervention to improve LDL-C relative to usual care delivered in real-world practice. Over 11 months, both groups experienced a clinically meaningful reduction

Table 4
Mean (SD) dietary energy and nutrient intake by group and time point.[a]

Macronutrient	Intervention	Usual care	p
Energy, kcal/d			
Baseline	1596 (827)	1475 (735)	
6-month	1243 (670)	1245 (588)	
11-month	1175 (579)	1254 (575)	0.03[b]
Total fat, g/d			
Baseline	68.8 (42.7)	64.9 (38.1)	
6-month	49.6 (30.1)	53.1 (28.4)	
11-month	46.5 (25.6)	54.2 (31.1)	0.02[b]
Total fat, %			
Baseline	38.2 (7.8)	38.4 (7.5)	
6-month	35.3 (7.0)	38.5 (8.9)	
11-month	35.4 (7.3)	38.2 (9.1)	0.04[c]
Saturated fat, g/d			
Baseline	22.5 (14.8)	21.3 (12.6)	
6-month	15.8 (10.3)	17.2 (9.6)	
11-month	15.1 (8.9)	17.4 (9.8)	0.02[b]
Saturated fat, %			
Baseline	12.3 (2.9)	12.6 (2.7)	
6-month	11.1 (2.9)	12.5 (3.3)	
11-month	11.4 (2.8)	12.3 (2.9)	0.09[c]
Cholesterol, mg/d			
Baseline	210.5 (145.5)	211.0 (140.6)	
6-month	161.6 (111.1)	182.1 (119.4)	
11-month	152.1 (97.4)	175.5 (117.1)	0.11[b]
Fiber, g/d			
Baseline	14.8 (6.8)	13.9 (6.7)	
6-month	13.4 (6.7)	12.5 (7.7)	
11-month	13.2 (6.3)	11.9 (5.7)	0.26[b]

Note. Participants were outpatients from the Durham Veterans Affairs Medical Center during 2007–2010.

[a] Unadjusted raw data with no imputations for missing data. Sample sizes (number missing) for baseline, 6-month, and 11-month are n = 97 (30), n = 81 (46), and n = 88 (39), respectively, for the intervention group and n = 90 (38), n = 74 (54), and n = 80 (48), respectively, for the usual care group. Brief Food Frequency Questionnaire (FFQ) data were missing for all time points for n = 31 (12 intervention group; 19 usual care group — included in the above summary of individual time point sample size and missing) because the FFQ was completed at home and returned by mail.

[b] p-Value for test of difference between intervention and usual care at 11 months from linear mixed models of log-transformed FFQ nutrient outcomes.

[c] p-Value for test of difference between intervention and usual care at 11 months from linear mixed models of FFQ percentage of calories from nutrient outcome.

in LDL-C levels (5–7%). The intervention group improved in self-reported caloric, total fat, and saturated fat intake and tended toward a greater improvement in frequency of moderate intensity physical activity. These findings are noteworthy given the relatively low cost and dose of the intervention.

Table 5
Model estimates of self-reported physical activity by group and time point.[a]

Measurement and study time point	Intervention	Usual care	Incidence rate ratio (95% CI)	p-Value
Frequency of moderate intensity physical activity per week				
Baseline	8.3	8.3		
Midpoint	10.5	8.9		
Final	10.1	8.4	1.2 (1.0, 1.5)	0.06
Duration of moderate intensity physical activity (hours) per week				
Baseline	6.9	6.9		
Midpoint	7.5	6.7		
Final	7.3	6.6	1.1 (0.9, 1.4)	0.37

Note. Participants were outpatients from the Durham Veterans Affairs Medical Center during 2007–2010. CI = confidence interval.

[a] Patients missing frequency and duration of moderate intensity physical activity: baseline = 8 patients (3 intervention, 5 usual care (UC)), midpoint = 65 patients (31 intervention, 34 UC), and final = 57 patients (27 intervention, 30 UC).

That usual care patients experienced the same magnitude of LDL-C reduction as intervention patients was unexpected. Regression to the mean is unlikely with randomization and repeated measurements (Barnett et al., 2005). Possible explanations include the co-occurrence of facility-level quality improvement interventions and revised ATP III guidelines suggesting more aggressive treatment among high-risk patients prior to study start up (Grundy et al., 2004). Together, these efforts may have resulted in an overall secular trend toward more aggressive cholesterol management among providers at our facility. We cannot rule out the explanation that enrolling a study and receiving educational materials are sufficient for reducing LDL-C, although the fact that we found between-group differences in health behaviors is inconsistent with this explanation.

Our findings can inform intervention refinement. For example, we allowed patients to choose their own goals and action plans rather than prescribing changes. Patients appear to desire assistance and support for lifestyle changes. Notably, no intervention patient chose the medication adherence module, despite the fact that more than 40% of patients were on cholesterol medications, and half of those reported missing at least one dose in the previous month. Thus, future interventions may require attention to medication adherence. In addition, small, incremental behavioral changes may be insufficient or require more than 11 months to yield optimal LDL-C levels. Research is needed to develop and test behavior change strategies that simultaneously build self-efficacy and yield clinical benefit.

Our study has several limitations. First, self-reported behaviors are subject to bias, including overestimates of adherence. Second, FFQ data were frequently missing, although 88% of enrolled patients had at least one FFQ. Future studies may consider telephone assessment to yield more complete data. Third, the generalizability of the results is limited by the high refusal rate and being conducted among relatively healthy older men who received care from a single VA Medical Center. Finally, we could not determine whether improvements in dietary intake were due to the patient portion of the intervention, the spousal portion, or both. This would require a different study design.

Our study also has several strengths. The intervention was designed to be low-cost, scalable, and easily disseminated in a primary care setting. A single research nurse delivered the intervention to a relatively large panel of patients and their spouses and achieved high call completion rates. The customized software application ensured standardization while allowing input of data such as patient goals and action plans, spouse action plans, patient self-efficacy ratings, and whether goals were achieved. This application should facilitate interventionist training and dissemination into a health care system. Finally, the significant proportion of African Americans in our sample increases the external validity of our findings.

In summary, the dietary changes experienced by intervention patients, if sustained, could yield important health benefits. As health care systems such as the VA continue outreach efforts to patients for whom frequent travel for healthcare is prohibitive, telemedicine interventions may be an important adjunct to usual care.

Conflict of interest
No author declares any conflict of interest.

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