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Can attention control conditions have detrimental effects in behavioral medicine randomized trials?

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Abstract

Objective—Attention control conditions are used to balance nonspecific attention in randomized trials of behavioral interventions. Very little guidance is available in the literature about which behavioral interventions and outcomes merit an attention control. The primary aim of the present paper is to demonstrate a scenario in which use of attention control in a behavioral randomized trial was unnecessary and possibly detrimental.

Methods—Exploratory analyses were performed in a randomized controlled trial that tested whether a patient-centered telephone counseling (PC) intervention reduced low-density lipoprotein cholesterol (LDL-C) levels in 355 participants with peripheral arterial disease (PAD), compared to attention control (AC) and usual care (UC) conditions. The PC intervention was designed to activate participants to ask their physician for lipid-lowering medication and/or increase dose intensity, increase medication adherence, and reduce fat intake. The AC condition involved attention-matched phone-delivered health education, and the UC condition consisted of an educational pamphlet.

Results—At 12-month follow-up, mean LDL-C changes were −11.1, and −6.8 mg/dl in the UC and AC conditions, respectively (p=.17). The proportion of participants who increased use or dose intensity of medication was significantly lower in AC than UC, 17.5% versus 30.5% (p=0.03). No significant difference between AC and UC were observed on other outcomes.

Conclusions—The AC had significantly worse medication outcomes and there was no indication of a therapeutic effect on other endpoints. Implications for use of attention control in behavioral randomized trials are discussed.

Keywords

Attention control; control groups; placebo; behavioral interventions; randomized controlled trials

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Attention control is often used in randomized trials for behavioral interventions to control for the nonspecific effects of the intervention in a similar way that pill placebo is used to control for expectancy effects in a drug trial. Attention control conditions balance attention, treatment contact, social support, and nonspecific therapist effects across conditions so that a clearer test of the hypothesized active component of the psychological intervention can be made (1). Although originating in trials of psychological interventions with psychological endpoints (2), attention controls have become commonplace in behavioral medicine trials that target psychological, behavioral, and biological endpoints.

Freedland and colleagues (3) state that attention control groups require two main ingredients: clinical attention and an intervention that induces the expectation of therapeutic benefit. The latter is likely the source of variability because creating a credible intervention that induces the expectation of benefit will depend on the outcome for which benefit is expected to occur. For example, a credible intervention for pain relief may be very different than one for blood pressure control. Types of attention control conditions employed in behavioral medicine trials include stretching exercises (e.g., (4)), magnet therapy (e.g., (5)), touch therapy (e.g., (6)), information relevant to population but not the health condition (7) and health education (e.g., (8–10)). Expectancy effects can also be in the negative direction, and in this case are referred to as nocebo effects (11). A common example of a nocebo effect is when participants randomized to placebo conditions report the negative side effects of the active drug as a result of being made aware of the possibility of such side effects. Nocebo effects can also involve medication discontinuation or poor adherence, given fear of side effects or increased perception of side effects(12). Given the complexity involved in designing an attention control condition, more guidance is needed regarding appropriate methodology to avoid inadvertently producing negative expectancies and nocebo effects.

The challenge of designing an attention control condition is the lack of data on whether attention actually produces a positive expectancy effect or an effect on the targeted outcome. Nonspecific attention is known to influence depression (13), pain (14), and anxiety(15), but we know less about the impact of nonspecific attention (relative to no attention) on behavioral and biological endpoints such as dietary intake, medication adherence, and lipids. Also it is not clear to what extent expectancy effects lead to behavior change. For example, if participants believe that an intervention will reduce their cholesterol, will that lead them to make dietary changes even when no dietary instruction is provided? Behavioral medicine trials target a vast array of endpoints including psychological, behavioral, and biological outcomes. To the extent that attention does not influence certain endpoints or even worse, creates negative expectancy effects, attention control conditions in trials with those endpoints would be unnecessary and in the latter case unethical. The identification of circumstances in which attention control is unnecessary could reduce trial costs, which is essential given the high cost of clinical trials in a shrinking research economy.

The primary aim of this paper is to demonstrate a scenario in which an attention control condition produced a negative effect relative to a usual care condition on biological and behavioral endpoints, and to describe the potential implications of this finding on the design of future trials. Exploratory data analysis are reported from a randomized clinical trial that tested the efficacy of a patient-centered counseling intervention designed to activate patients with peripheral artery disease (PAD) to seek lipid-lowering treatment from their physician and improve their lipid medication adherence and diet, with the primary outcome measure of change in LDL-C. Participants were randomized to a 12-month patient-centered counseling intervention, an attention control condition (AC) that balanced contact and nonspecific attention via health education, or usual care (UC). By including both AC and UC care conditions, the trial provides a unique opportunity to compare attention control to usual care on biological and behavioral endpoints. The primary endpoint was the low-density

lipoprotein cholesterol (LDL-C) level at 12-month follow-up. The secondary outcome was the proportion of participants in each group with LDL-C levels < 100 mg/dl at 12-month follow-up. Behavioral endpoints included the percent of participants in each group who started or increased their cholesterol-lowering medication, saturated fat intake, and lipid medication adherence.

Methods

The institutional review boards of participating medical centers approved the protocol and all participants provided informed consent. Data were collected between 2/1/06 and 9/30/09. Participants with PAD were randomized into one of three conditions: telephone-delivered patient-centered counseling (PC) intervention, attention control (AC) condition (telephone-delivered health education), or usual care (UC). A detailed description of the design and methodology of this trial have been published elsewhere (16) as have the primary results which showed that the PC intervention reduced LDL-C significantly more than the AC condition but not as compared to the UC condition (17).

Study Conditions

Patient-Centered Counseling—The intervention consisted of 8 telephone calls, lasting approximately 25 minutes, delivered every six weeks over the course of a year. Patient-centered counseling was delivered by a trained health counselor. During the first call, the counselor educated participants about the importance of lowering LDL-C to the management of PAD. 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 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.

Attention Control—We included an attention control condition to control for the possible effect of attention and health knowledge on medication seeking by patients. Patients might be more likely to ask their physician for additional treatment merely as a function of learning more about their condition or spending time with a health educator discussing it. In this case, trained health counselors would not be necessary. The AC condition consisted of eight telephone calls, lasting approximately 25 minutes, delivered every six weeks for one year. These calls provided information about PAD. Topics included peripheral arterial disease risk factors, symptoms, leg ulcers, diagnosis of PAD, available treatments, exercise and PAD, and C-reactive protein. Topics were selected to inform the patient about PAD but designed specifically not to provide advice. If participants asked for advice, they were referred to their physician and reminded that the purpose of this condition was to educate them about their PAD, but not provide advice on how to care for it. Calls were delivered by a different set of health counselors than the PC condition who had no training in patient-centered counseling and no clinical or medical background.

Usual Care—Participants randomized to usual care received no scheduled telephone calls but were mailed an educational pamphlet about PAD at baseline.

Measures

Participant characteristics by randomized condition are shown in Table 1. Outcomes shown in Tables 2 and 3 were assessed at baseline and 12-month follow-up by examiners blinded to condition assignment. The primary outcome was change in LDL-C level between baseline and 12 month follow-up, also evaluated as the proportion of participants with LDL-C < 100 mg/dl at twelve-month follow-up. Secondary outcomes include percent of participants in each group who started or increased their cholesterol-lowering medication, saturated fat intake, and lipid medication adherence.

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. Both mean LDL-C and percent reaching the study target (LDL-C < 100) were calculated and compared between groups.

Medication Changes—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.

Medication Adherence—To measure adherence to LDL-C 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).

Saturated Fat Intake—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 (19).

Patient Activation—The 13-item Patient Activation Measure (PAM) assesses the degree to which patients believe it is important for them to influence their health care, patient confidence in their ability to influence their healthcare, the degree to which patients take action to influence their healthcare; and patient confidence that they can continue to affect their healthcare(20). The PAM is scored on a 0–100 scale (100=best).

Self-Efficacy—The Perceived Efficacy in Patient-Physician Interactions (PEPPI) questionnaire measures patients' self-efficacy regarding their ability to know what questions to ask a physician, get answers to all their questions, get a physician to take their health concerns seriously and treat it appropriately (21). Scores range from zero to 50 (50=best).

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 (16).

Statistical Analyses

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 AC and the UC 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 percent calories from saturated fat between baseline and follow-up. Categorical outcomes were compared overall and by paired comparisons using chi-square tests. Comparisons were made using logistic regression adjusting for baseline values. Statistical comparison of call rates and duration of calls was carried out using generalized estimating equation regression in order to account for multiple calls per participant. All analyses were intention-to-treat.

Sensitivity analyses for the primary outcome 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. A 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).

The study was designed to have 85% power for variation in the mean change in LDL as low as 4.9 mg/dL (e.g. mean change of 0, −6 and −12 in the three groups) with 140/group. The resulting samples averaged 117/group which resulted in 80% power under the same conditions.

Results

Completed call rate was significantly higher in the intervention group with 87.6% completed vs. the attention control group with 82.3% completed (p=0.03). Telephone call duration was significantly higher in the intervention group with 28.4 ± 4.5 minutes versus the attention control group with 21.1 ± 4.1 minutes (p<0.01).

LDL-C—At 12-month follow-up, mean LDL-C changes from baseline were −18.8, −11.1, and −6.8 mg/dl in the intervention, UC, and AC conditions, respectively (overall p value=0.04, adjusting for baseline LDL-C levels). UC and AC were not significantly different on LDL-C change (p=.0.17). At 12-month follow-up, the change in proportion of participants meeting the LDL-C study goal (LDL-C < 100) in the intervention, UC, and AC conditions was 21.6%, 9.1%, and 9.0%, respectively (overall p value = .009). UC and AC were not significantly different (p=.53).

Medication Changes—At 12-month follow-up, the changes in proportion of participants increasing use or dose intensity of cholesterol-lowering medication from baseline in the intervention group, UC, and AC conditions were 53.8% vs. 30.5% vs. 17.5%, respectively (p<0.01). UC participants were significantly more likely to increase use or dose compared to AC participants (p=.03).

Medication Adherence—At 12-month follow-up, the changes from baseline in proportion of participants who missed a dose of medication in the past week in the intervention, UC, and AC conditions were 1.5%, 0%, and 0%, respectively (p = .69). Rates

of missed doses were fairly low at baseline, thus very little change was observed in any group.

Saturated Fat—At 12-month follow-up, the changes in mean percent of calories from saturated fat from baseline for the intervention, UC, and AC conditions were −3.4%, −2.6%, and −1.8%, respectively (p=.77).

Patient Activation, Self-Efficacy, and Health Knowledge—At 12-month follow-up, the changes in patient activation scores from baseline in the intervention, UC, and AC conditions were 5.1, 1.1, and 1.2, respectively (p=.60). The changes in self-efficacy scores were 4.5, 0.8, and 2.0, respectively (p=.09), and the changes in health knowledge scores were 14.4, 5.5, and 8.9, respectively, (p=.26).

Discussion

The findings revealed that the AC did not result in significant improvement over UC on any endpoint. Participants in the AC condition were significantly less likely to have increased use or dose intensity of cholesterol-lowering medication compared to those in the UC condition. The AC and UC groups were not different in terms of change in patient activation, self-efficacy in patient-physician interactions, or health knowledge, which rules these out as explanations for the medication change findings. The AC condition did not appear to produce a positive change in any outcome. Based on data presented here, controlling for attention does not appear to be necessary for this type of counseling intervention with this range of endpoints.

One possible explanation for the adverse results in the AC condition compared to usual care in the present study may be that the AC condition undermined the care that patients received outside of the study. Receiving health information in the absence of advice or behavioral recommendations may reinforce complacency or inadvertently send the message that no further action is needed. Participants may have perceived the absence of behavioral or care advice as reassurance regarding their current situation, especially if they were ambivalent about taking medication. Even though AC participants were repeatedly advised that as part of the AC condition, they would not receive any medical treatment, some participants regularly asked counselors for medical advice. Perhaps health education as an attention control is confusing to some participants. An alternative explanation for our findings is that participants assigned to the UC condition may have been more proactive regarding their cholesterol-lowering therapy since they were aware that they were not receiving any intervention (neither counseling nor health education). Randomized trials tend to attract patients who are motivated and interested in their health. Assigning these individuals to usual care may have “activated” them to seek cholesterol-lowering medication on their own. In contrast, motivated individuals in the AC condition might have accepted the health education as sufficient intervention. This possibility is supported by a trial that randomized 179 elderly veterans to a high intensity physical activity telephone counseling intervention, a health education telephone counseling attention control, or usual care control condition. (22). Findings for the primary outcome of self-reported physical activity revealed a significant omnibus F test between the 3 groups. Intervention participants increased their weekly physical activity by five hours, while UC participants increased their physical activity by 4 hours and AC participants increased their physical activity by 0.3 hours per week. However, the pairwise comparisons of intervention condition versus control conditions and attention control versus usual care conditions had p-values of .07 and .08, respectively. For the secondary outcome of caloric expenditure, the UC condition increased their expenditure significantly more than the AC condition and there was no difference

between the intervention condition and UC. In this case, UC may have been roused to action knowing they were not going to receive any assistance.

Another possibility is that the content of the health education condition regarding symptoms and complications of PAD may have lead people who did not experience certain symptoms or complications to perceive their disease as less severe which consequently reduced their motivation to seek treatment. On the other hand, content regarding symptoms and complications could have generated fear and avoidance beliefs which have been shown to be associated with worse adherence, functioning, and outcomes among people suffering from chronic conditions (23). Because side effects of lipid-lowering medication were not discussed in the health education content or consent form, findings would not be classified as a "nocebo effect" which is when patients assigned to a placebo condition report negative side effects and possibly reduced adherence as a function of being informed of medication side effects (24).

The findings are consistent with two other trials, in which the greatest improvement in outcomes was observed in the intervention condition and the least improvement was observed in the attention control condition (25, 26). However, neither study included a statistical comparison of usual care with attention control. In one study, a telephone-based self-management condition resulted in greater pain reduction compared to a telephone-delivered health education attention control condition at 12-month follow-up but not compared to usual care in 515 adults with osteoarthritis (25). Pain ratings in the AC group declined less over time than in UC, and only the AC condition was significantly different from the intervention. The attention control condition in that study included health information about unrelated medical conditions, while usual care involved no contact. One possibility for smaller improvements in pain in attention control versus usual care is that usual care participants may have been more motivated to explore other treatment options given they may have been more likely to realize that they were in the "control" group. A second trial randomized 199 adults with diabetes to a blood glucose monitoring counseling intervention, attention control, or usual care (26). The attention control condition received a blood glucose meter and a 30-minute educational session on blood glucose monitoring, while the intervention condition received a blood glucose meter and an educational booklet which was reviewed in a 30-minute session with a diabetes educator. While no pairwise comparison of conditions on the primary outcome of hemoglobin A1c were significant, the secondary outcome of the participant's ability to define "hemoglobin A1c" significantly differed between groups. Participants in the attention control condition were the least able to correctly define hemoglobin A1c, with accuracy rates of 88% (intervention), 75% (usual care), and 63% (attention control) (26). In addition, participants in the attention control condition had a higher prevalence of reporting unfavorable emotional reactions to blood glucose monitoring results (65%), compared to the intervention condition (38%), and usual care condition (57%). Only the omnibus tests were reported, so it is unknown which pairs were significantly different. One can only speculate as to why the attention control fared worse than usual care on outcomes relating to a competency and emotional reactions, however further exploration into the content of the educational session may lead to clues.

Further research is needed to determine the appropriate circumstances for use of attention control versus usual care conditions. Mohr et al (27) provided the following guidelines for use of attention control conditions. Investigators should 1) clearly identify the factors controlled for, 2) ensure equipoise, 3) balance interventionist skill and enthusiasm across conditions, 4) assess interventionist outcome expectations, and 5) include adequate sample size given that attention may influence outcomes, more than usual care or wait list control conditions. We would add that investigators should only employ attention control when previous data have demonstrated an effect of attention on the outcome variable of interest or

an important mediator of that outcome variable. In circumstances where there is no known effect of attention on the outcome, attention control conditions may not only inflate the difference between control and intervention conditions, but also possibly cause harm with no benefit and be an unnecessary expense. Additional research is needed to better define when attention control should be used and the impact of attention control conditions on various outcomes.

As this example illustrates, investigators should not assume that attention control conditions will achieve a positive effect on behavioral and/or biological endpoints. A meta-analysis of placebo pill effects in osteoarthritis randomized trials found consistent evidence for placebo effects on subjective outcomes (e.g., pain) but very little evidence on objective outcomes (e.g., muscle strength) (28). In addition to pain, placebo effects have been observed for depression (27, 29), and the mechanisms may include social support, regression to the mean, the Hawthorne effect, and expectancy effects (27, 30). To the extent that such psychological outcomes affect behavior change, they could be affected by attention. For example, if attention control improves symptoms of depression, this association may also improve other outcomes, such as medication adherence. However, in populations with a low prevalence of depression, attention control may have little impact.

Results should be viewed in consideration of the following limitations. The comparison of the AC and UC conditions was not planned a priori and the study was not powered to detect effects in this pair of conditions. Only one outcome (i.e., medication changes) was statistically significant in terms of a disadvantage to the AC condition. Findings on LDL-C were not significant, although mean differences were in the direction of the medication change variable which might be expected because improved medication regimens could certainly lead to improved LDL-C. Additionally, expectancy effects and social desirability were not measured which means no conclusions can be drawn about whether the AC actually produced effects on these hypothesized mechanisms of attention control. Finally, the mean call time turned out to be lower in the AC condition (21.1 minutes) compared to the intervention condition (28.4 minutes), even though the call time goal was 20 minutes for both conditions. The discrepancy in mean call time between conditions would not seem to further our understanding of why the AC condition fared worse than UC, who received no calls.

Attention does not appear to always have a positive effect on outcomes. In some cases, attention control may be unnecessary and possibly even detrimental. In the design of trials, attention control conditions should be considered only when empirical evidence suggests that nonspecific attention has a positive impact on the outcome variables of interest. Given the variability in content in attention control conditions across trials, content also should be selected based on evidence. Further research is needed to aid investigators in determining the appropriate methodological circumstances to utilize attention control conditions.

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List of abbreviations

PC	patient centered counseling condition
AC	attention control condition
UC	usual care condition

LDL-C	low density lipoprotein cholesterol
PAD	peripheral arterial disease
PAM	patient activation measure
PEPPI	Perceived Efficacy in Patient-Physician Interactions
ANOVA	analysis of variance

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Table 1

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

*Values are mean (SD) for continuous variables or % for categorical variables.

Table 2

Associations of A Telephone Counseling Intervention on Primary 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 Attention Control† (95% Confidence Interval)	Pair-wise P value	P value
Primary Outcome Measure								
LDL-C (mg/dl)	Usual Care	110	101.0 (33.9)	89.9 (31.0)	−11.1 (−17.0, −5.1)	−5.38 (−13.07 to 2.32)	0.170	
	Attention control	111	103.4 (26.4)	96.6 (33.9)	−6.8 (−13.0, −0.5)	NA	NA	0.035
	Intervention	97	106.0(33.3)	87.6 (36.9)	−18.4(−24.8, −12.1)	−10.40 (−18.44 to −2.55)	0.010	
Secondary Outcome Measure								
Proportion of participants with LDL-C < 100 mg/dl (Percent)	Usual Care	110	65 (59.1%)	75 (68.2%)	9.1% (−2.7%, 20.2%)	1.22 1 (0.66, 2.24)	0.530	
	Attention Control	111	58 (52.2%)	68 (61.3%)	9.0% (−3.2%, 21.2%)	NA	NA	0.009
	Intervention	97	54 (55.7%)	75 (77.3%)	21.6% (11.5%, 31.8%)	2.90 1 (1.44, 5.83)	0.003	

†Indicates that analyses adjusted for baseline value.

1Odds ratio.

Table 3

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

Exploratoryoutcomes								
Outcome measures	**Group**	**N**	**Baseline**	**12-Month Follow-Up Value**	**Within Group Changes (95% Confidence Interval)**	**Between Group Changes Compared to the Attention ControlGroup† (95% Confidence Interval)**	**Pair-wise P value**	**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%)	2.07[1] (1.07, 3.99)	0.03	
	Attention Control	120	N/A	18 (17.5%)	18 (17.5%)	N/A	N/A	<0.001
	Intervention	113	N/A	50 (53.8%)	50 (53.8%)	5.49[1] (2.86, 10.54)	<0.001	
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%)	1.48[1] (0.60, 3.64)	0.398	
	Attention Control	78	9 (11.5%)	9 (11.5%)	0.0% (−10.0%,10.0%)	NA	NA	0.698
	Intervention	67	9 (13.4%)	10 (14.9%)	1.5% (−11.3%,14.3%)	1.31[1] (0.49, 3.53)	0.590	
Percent of calories from saturated fat.	Usual Care	110	12.0 (5.5)	8.7 (6.3)	−3.4 (−4.7, −2.0)	−0.52 (−2.04, 1.01)	0.506	
	Attention Control	110	10.7 (4.4)	8.9 (5.7)	−1.8 (−3.1, −0.6)	NA	NA	0.777
	Intervention	95	11.2 (4.3)	8.5 (5.4)	−2.6 (−3.9, −1.4)	−0.43 (−2.00, 1.14)	0.591	
Patient Activation Scale	Usual Care	109	60.1 (13.9)	61.2 (15.4)	1.1 (−2.1, 4.2)	−.96 (−4.62, 2.70)	.60	
	Attention Control	110	61.0 (18.2)	62.2 (17.5)	1.2 (−2.3, 4.7)	NA	NA	0.014
	Intervention	93	63.5 (16.8)	68.6 (18.4)	5.1 (0.5, 9.6)	4.44 (.62, 8.26)	.02	
Perceived Efficacy in Patient-Physician Interactions (PEPPI)	Usual Care	109	44.6 (8.1)	45.5 (8.6)	0.8 (−0.7, 2.3)	1.92 (−.31, 4.15)	.09	
	Attention Control	110	42.1 (10.2)	44.1 (9.7)	2.0 (0.1, 3.8)	NA	NA	0.021
	Intervention	93	42.1 (11.5)	46.6 (8.3)	4.5 (2.9, 6.1)	1.25 (−1.07, 3.58)	.29	
Health Knowledge Score	Usual Care	109	61.0 (18.8)	66.5 (17.5)	5.5 (3.0, 8.0)	2.46 (−1.87, 6.81)	.26	
	Attention Control	111	56.8 (20.6)	65.7 (17.3)	8.9 (6.2, 11.7)	NA	NA	<0.001
	Intervention	93	62.1 (17.2)	76.5 (14.2)	14.4 (11.4, 17.4)	8.03 (3.50, 12.56)	.001	

† Indicates that analyses adjusted for baseline value.

[1] Odds ratio.