A Multidimensional Integrative Medicine Intervention to Improve Cardiovascular Risk

David Edelman, MD, MHS,[1,2] Eugene Z. Oddone, MD, MHS,[1,2] Richard S. Liebowitz, MD,[1,3] William S. Yancy, Jr, MD, MHS,[1,2] Maren K. Olsen, PhD,[2,4] Amy S. Jeffreys, MStat,[2] Samuel D. Moon, MD, MPH,[3,5] Amy C. Harris, BA,[2] Linda L. Smith, PA,[3] Ruth E. Quillian-Wolever, PhD,[3] Tracy W. Gaudet, MD,[3,6]

[1]Division of General Internal Medicine, Department of Medicine, Duke University Medical Center, Durham, NC, USA; [2]Center for Health Services Research in Primary Care, Durham VA Medical Center, Durham, NC, USA; [3]Center for Integrative Medicine, Duke University Medical Center, Durham, NC, USA; [4]Department of Biostatistics, Duke University Medical Center, Durham, NC, USA; [5]Department of Community and Family Medicine, Duke University Medical Center, Durham, NC, USA; [6]Department of Obstetrics and Gynecology, Duke University Medical Center, Durham, NC, USA.

BACKGROUND: Integrative medicine is an individualized, patient-centered approach to health, combining a whole-person model with evidence-based medicine. Interventions based in integrative medicine theory have not been tested as cardiovascular risk-reduction strategies. Our objective was to determine whether personalized health planning (PHP), an intervention based on the theories and principles underlying integrative medicine, reduces 10-year risk of coronary heart disease (CHD).

METHODS: We conducted a randomized, controlled trial among 154 outpatients age 45 or over, with 1 or more known cardiovascular risk factors. Subjects were enrolled from primary care practices near an academic medical center, and the intervention was delivered at a university Center for Integrative Medicine. Following a health risk assessment, each subject in the intervention arm worked with a health coach and a medical provider to construct a personalized health plan. The plan identified specific health behaviors important for each subject to modify; the choice of behaviors was driven both by cardiovascular risk reduction and the interests of each individual subject. The coach then assisted each subject in implementing her/his health plan. Techniques used in implementation included mindfulness meditation, relaxation training, stress management, motivational techniques, and health education and coaching. Subjects randomized to the comparison group received usual care (UC) without access to the intervention. Our primary outcome measure was 10-year risk of CHD, as measured by a standard Framingham risk score, and assessed at baseline, 5, and 10 months. Differences between arms were assessed by linear mixed effects modeling, with time and study arm as independent variables.

RESULTS: Baseline 10-year risk of CHD was 11.1% for subjects randomized to UC (n=77), and 9.3% for subjects randomized to PHP (n=77). Over 10 months of the intervention, CHD risk decreased to 9.8% for UC subjects and 7.8% for intervention subjects. Based on a linear mixed-effects model, there was a statistically significant difference in the rate of risk improvement between the 2 arms (P=.04). In secondary analyses, subjects in the PHP arm were found to have increased days of exercise per week compared with UC (3.7 vs 2.4, P=.002), and subjects who were overweight on entry into the study had greater weight loss in the PHP arm compared with UC (P=.06).

CONCLUSIONS: A multidimensional intervention based on integrative medicine principles reduced risk of CHD, possibly by increasing exercise and improving weight loss.

KEY WORDS: integrative medicine; randomized-controlled trial; cardiovascular risk reduction.
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Cardiovascular disease prevention is a major goal of almost all health care providers. Traditionally, prevention has been targeted at individual risk factors (e.g., smoking cessation programs, hypertension clinical guidelines).[1] However, patient-centered strategies hold promise in risk reduction. Programs that allow individuals to choose any of a number of their own unhealthy behaviors to reform can provide risk reduction for a broad spectrum of patients, with a wide range of traditional risk factors (e.g., diabetes, hypertension) and risk behaviors (e.g., sedentary lifestyle, smoking).[2,3] These strategies should work by effecting favorable changes in patient behaviors, which would then lead to improved cardiovascular risk by modifying a wide number of risk factors and improving control of several risk conditions.[4–7]

Integrative medicine is based on specific principles, including use of patient-centered, individualized therapeutic approaches and mind-body techniques (e.g., meditation, hypnosis).[8,9] Evidence from randomized, controlled trials supports the use of individualized strategies and mind-body techniques in depression, chronic pain, anxiety, and other diseases in which symptom management is the primary goal of therapy.[10–13] However, randomized, controlled trials of individual techniques utilized in integrative medicine are either lacking[14] or conflicting in their results (e.g., transcendental meditation to treat hypertension).[15–17] No trial has demonstrated reduction in cardiovascular risk because of an overarching integrative medicine approach.

Our primary objective was to test the effect of personalized health planning (PHP), an Integrative Medicine intervention, on cardiovascular risk reduction in a population with heterogeneous cardiovascular risks.

METHODS

We conducted a randomized, controlled trial of our PHP intervention at the Center for Integrative Medicine at Duke University Medical Center (DUMC). The DUMC Institutional Review Board approved all study protocols and all subjects provided written informed consent.

Subjects

We required subjects to be age 45 or over, to have a primary care provider, and to report 1 or more of the following risk factors for cardiovascular disease: diabetes, hypertension, dysli-

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Address correspondence and requests for reprints to Dr. Edelman: HSR&D (152) Durham VA Medical Center, 508 Fulton St., Durham, NC 27705 (e-mail: dedelman@acpub.duke.edu).

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pidemia, smoking, or body mass index (BMI) > 25 kg/m^2. We excluded subjects with active cardiovascular disease, defined as a history of myocardial infarction (MI), congestive heart failure, or cerebrovascular accident (CVA). We also excluded subjects with terminal illness, a history of psychosis, or no access to a telephone. Pregnant women were excluded because of complexity in interpreting longitudinal anthropometric measurements.

Intervention

After obtaining informed consent and gathering baseline data, we randomized participants to either the PHP intervention, or to a comparison group. We balanced treatment arm assignments by using randomization block sizes of 20 subjects. The PHP intervention is summarized in Table 1. The comparison group received a mailed report including their health risk assessment and baseline blood test results. They were then returned to their usual care, with no access to the PHP intervention.

Personalized Health Planning. The PHP intervention was delivered predominantly by a health coach, a Masters-level professional trained in activating techniques to assist patients in setting and achieving health goals.[18–22] A manual standardized the intervention. The intervention proceeded through 2 phases: risk education, and development and execution of a Personalized Health Plan.

Table 1. Outline of the Personalized Health Planning (PHP) Intervention

I. Personal risk education
Visits with integrative medicine provider at baseline and 5 mo
Know your number
II. Personalized health plan
Training on an integrative model of health
Simultaneously consider multiple domains of health behavior
Set personal behavioral goals
Behavioral goal-setting
Prioritize 1 to 3 goals as primary behaviors to change
New behavioral goals added once previous goals are maintained
III. Techniques
Small group sessions
7–11 subjects per group
Mind-body approaches:
Mindfulness meditation
Progressive muscle relaxation
Yoga
Guided visualization
Stress management
Other lifestyle approaches:
Goal setting
Risk prevention
Continuing health self-education
Communication skills
Nutrition
Physical activity
Complementary and alternative approaches
Creating behavior change
Relapse prevention
Individual coaching sessions
20–30 min biweekly phone sessions
Clarifying priorities
Reinforce mind-body and lifestyle skills learned in group
Enhancing motivation
Two individual meetings with a nutritionist

The PHP intervention was standardized by using detailed manuals and formal training for intervention personnel.

Risk Education. We performed a baseline assessment of cardiovascular risk using Know Your Number, a proprietary tool designed to educate patients about their risks for disease and illustrate the possibilities for improving risk. Using the patient's health information (blood pressure, smoking status, frequency of exercise, etc.), Know Your Number provides a graphic display to demonstrate both disease risks that the patient currently has, and what the risk could be if healthier behaviors were adopted or individual diseases (e.g., hypertension) more tightly controlled. Assessment was performed at baseline, 5, and 10 months later. An integrative medicine physician or physician's assistant provided one-on-one feedback to subjects on the baseline and 5-month assessments.

Health Planning. At baseline, each subject was teamed with a coach. Over the first 7 weeks of the intervention, participants learned about the integrative model of health, and explored healthier behavioral changes. After this exploration phase, participants prioritized 1 to 3 goals as primary behaviors to change. The remainder of the intervention was spent changing the specified behaviors chosen during the first 7 weeks through education, skill building, and coaching strategies.

The core of the intervention involved health coaches supporting subjects in the use of specific techniques for maintaining focus on their commitment to healthier behaviors. These techniques included: the following mindfulness meditation; yoga; relaxation training; communication skills, specifically with medical providers and important support people; and exploration of values. Coaches also provided patient education on the topics of nutrition, physical activity, and continuing personal medical education (i.e., how to learn more about specific medical conditions), as well as creating and maintaining behavior change, and the integration of complementary and alternative approaches.

Subjects interacted with the coach during group meetings, and individual telephone sessions. The coach led group meetings. Each group had 7 to 11 participants. Groups had 28 2-hour meetings over the 10 months of the intervention, weekly for the first 4 months, biweekly for months 5 through 9, and then once at the conclusion of the intervention. The groups allowed a context for education, teaching integrative medicine skills (e.g., meditation, relaxation strategies, healthy cooking, strength training), and support among members of the group.

Participants also had 20 to 30 minute phone sessions with their coach every 2 weeks throughout the intervention. The coaches used these calls to reinforce the techniques taught at group meetings. During health planning, phone sessions allowed participants to obtain guidance in clarifying their priorities and setting realistic goals. In later sessions, the individual coaching focused on enhancing motivation to reach and maintain goals, and on support in locating resources. The individual sessions also allowed subjects to add new behavioral goals once previous goals were being maintained. The content of these phone calls was individualized, but in general focused on the subjects' successes with or barriers to achieving the objectives set in their health plan. Subjects wanting further assistance from the coaches were allowed brief contact by telephone or e-mail between scheduled phone calls. Participants also had 2 chances to meet individually with a nutritionist to obtain individualized support and recommendations for improvements in eating behavior.

We measured the intensity of the intervention for each subject by logging both group meeting attendance and completed individual coaching sessions. Subjects also kept a daily log of the number of minutes spent in meditation.

Primary Outcome Measure

The primary outcome measure was the Framingham risk score (FRS), a validated estimate, derived from the Framingham Cohort, of the risk (measured as a proportion) of having nonfatal myocardial infarction or cardiac death over 10 years.[23,24] FRS is often used to measure the efficacy of short-term cardiovascular interventions that have the potential to affect a number of cardiovascular risk factors.[25] We used a version of FRS that required only the input of age, gender, blood pressure, diabetes status, smoking status, and lipid data.[26] A research assistant blinded to treatment arm assignment measured the data required to calculate FRS at baseline, 5, and 10 months; these time points were chosen to measure initial impact and intermediate-term sustainability of the intervention.

Secondary Outcome Measures

The same blinded research assistant measured all secondary outcomes at baseline, 5, and 10 months. Secondary outcomes fell into 2 categories: biological and behavioral.

Biological Outcome Measures. Biological outcome measures included body mass index (calculated as weight in kg/(height in m)^2); waist circumference; blood pressure; and fasting lipid profile. Blood pressure was measured by an electronic cuff on the right arm after resting in the seated position for 5 minutes. Blood pressure was analyzed both as a continuous variable, and as a categorical variable (in or out of control). Blood pressure was defined as in control if a subject without diabetes had both systolic blood pressure (SBP) < 140 mmHg and diastolic blood pressure (DBP) < 90 mmHg. For a subject with diabetes, blood pressure control was defined as SBP < 130 mmHg and DBP < 80 mmHg. Fasting serum lipids were sent to a reference lab for standardized measurement (LabCorp, Durham, NC). Waist circumference was measured twice at each measurement interval, and the 2 results were averaged.

Behavioral Outcome Measures. Behavioral outcome measures included exercise frequency, measured as self-reported days per week of exercising at least 30 minutes; smoking status; and readiness to increase exercise and to lose weight, each measured by a single validated question.[27,28]

Analysis

We used intention-to-treat principles for all comparisons between study arms; all subjects were analyzed as part of the arm to which they were randomized. For our primary analysis, we fit linear mixed effects models with treatment arm, time of measurement, and a treatment arm by time of measurement interaction term as the only independent variables. We log-transformed FRS because of skewed distribution and used log FRS as the dependent variable in the primary analysis. Secondary outcomes were analyzed using linear mixed-effects modeling for continuous variables and generalized estimating equations for dichotomous variables (e.g., proportion of subjects with blood pressure in control); again, treatment arm, time of measurement, and a treatment arm by time of measurement interaction term were the only variables in these models. In our primary analyses, all data from all enrolled patients were used. To assess the impact of differential dropouts on our findings, we also performed the FRS outcome analysis carrying forward the last measured observation for all subjects who dropped out ("last-observation-carried-forward"), as well as using only those subjects who completed the study ("completers").[29] Analyses were performed using the SAS analysis system (Version 9.0, SAS, Cary, NC) and S-PLUS analysis software (Version 6.1, Insightful Corp., Seattle, WA).

RESULTS

Subject Enrollment and Demographics

The flowchart for enrollment and randomization is shown in Figure 1. We randomized 77 subjects to each arm. In the usual care (UC) arm, 66 subjects (86%) were retained through the entire study; desire to receive the intervention was the primary reason for dropout in the UC arm. In the PHP arm, 56 (73%) were retained; time requirement of the intervention was the primary reason for dropout in the PHP arm.

Baseline subject information is summarized in Table 2. Briefly, the population was 80% female; two-thirds were college graduates; over half had family incomes of over $60,000 per year; and three-fourths of the subjects were white. Subjects were at moderate cardiovascular risk, with an average risk of developing coronary disease over the next 10 years (measured by baseline FRS) of approximately 10%.

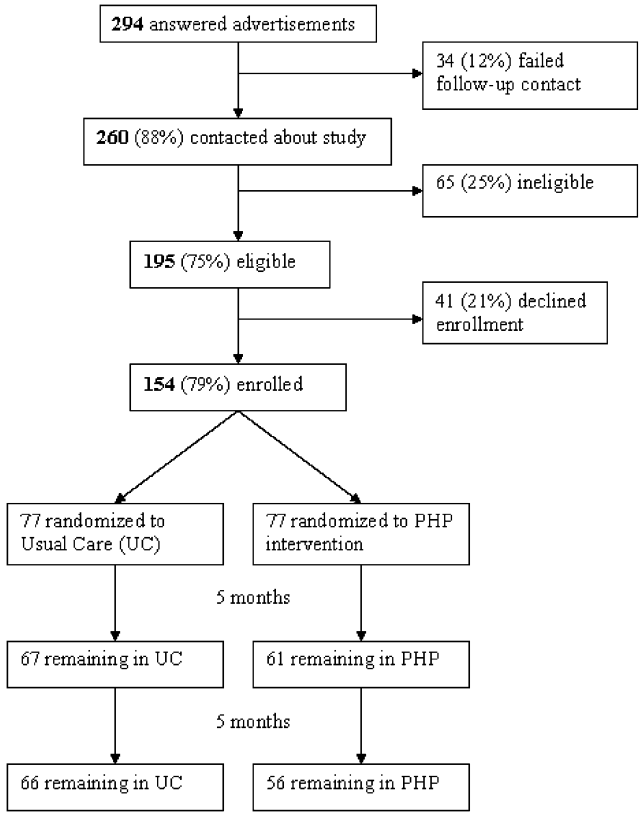

FIGURE 1. Flowchart for subject enrollment.

Table 2. Baseline Subject Characteristics

	UC	PHP	*P*-value
Demographics			
Age—mean (SD)	53.4 (4.8)	52.2 (5.2)	.15
Female gender	79%	82%	.68
Education—completed college	64.9%	70.1%	.49
Marital status—married	57.1%	55.8%	.87
Race			
White	75.3%	77.9%	.26
African American	23.4%	16.9%	
Other	1.3%	5.2%	
Family income			
<$39,999	15.6%	15.6%	.50
$40,000 to $59,999	24.7%	32.5%	
>$60,000	59.7%	50.7%	
Cardiovascular risk factors			
BMI—Mean (SD)	34.1 (7.7)	33.3 (7.8)	.54
LDL cholesterol	137.1 (35.6)	132.4 (35.1)	.41
Hypertension	40.3%	35.1%	.51
Diabetes	15.6%	15.6%	1.00
Smoking	11.7%	9.1%	.60
10-y risk of CHD	11.1%	9.3%	.03

UC, usual care; PHP, personalized health plan; CHD, coronary heart disease; LDL, low density lipid; BMI, body mass index.

Adherence to the Intervention

Intervention subjects attended 61% of group sessions; the median number of sessions attended was 20 (of 28). Subjects completed 63% of scheduled individual phone sessions. The median percentage of calls completed by individual subjects was 74%.

Cardiovascular Risk

Our primary hypothesis was that the PHP intervention would provide greater reduction in 10-year cardiovascular risk as measured by FRS than UC. These results are shown in Figure 2. The Mean FRS improved in both arms, from 11.1% to 9.8% in the UC arm (a 12% relative decline) and from 9.3% to 7.8% in the PHP arm (a 16% relative decline). In a linear mixed-effects model using log-transformed FRS as the outcome, FRS improved more (compared with baseline) for subjects in the PHP arm than in the UC arm at both 5 and 10 months (P=.006 at 5 months and P=.04 at 10 months). These findings were similar in the last-observation-carried-forward analysis (15% relative decline vs 7% relative decline at 10 months, P=.03) and in the completers' analysis (18% relative decline vs 7% relative decline at 10 months, P=.05).

To better understand how the intervention affected cardiovascular risk, we examined separate behavioral changes. Following a model that assumes that the PHP intervention would lead to behavioral changes that, in turn, would lead to improvement in specific cardiovascular risk factors and thus reduce overall cardiovascular risk, we assessed differences in changes between the intervention and UC for 2 categories of precursor to cardiovascular risk: risk behaviors and risk conditions.

Risk Behavior Analyses. We focused our analysis on 2 behaviors: diet and exercise (smoking was not addressed owing to the small number of smokers in the study (n=16)). We first evaluated subjects' readiness to lose weight, and to increase physical activity (Fig. 3). Subjects in both arms showed substantial improvement over baseline. Personalized health plan subjects had greater increases in readiness to increase physical activity than did UC subjects (P=.02) and greater readiness to lose weight (P=.06). Figure 3 shows the differences in exercise and weight between the 2 arms. Subjects in both arms showed increased days of exercise and reduced weight compared with baseline. Days of exercise were significantly increased in the PHP arm compared with the increase in the UC arm (3.7 vs 2.4 days, P=.002), and there was greater weight loss for intervention subjects (BMI reduction 1.2 vs 0.6, P=.11). The weight reduction was approximately 2 pounds greater in the PHP arm.

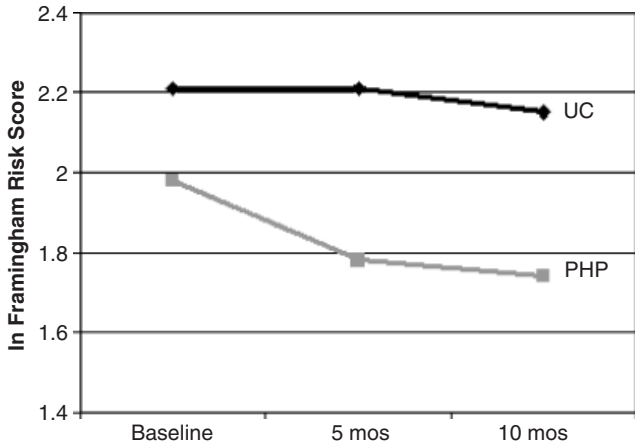

FIGURE 2. Changes in log-transformed Framingham risk score, personalized health planning intervention versus usual care.

Risk Condition Analyses. We next assessed the effects of our intervention on 2 risk conditions prevalent in our population: hypertension and hyperlipidemia (Fig. 4). Over 10 months, we observed an overall (both PHP and UC) 8 mmHg decline in SBP, and a decline of 7 mg/dL in low density lipid (LDL)-cholesterol. The difference in the change in LDL-cholesterol between baseline and 5 months was statistically significant between the 2 arms (P=.02), but the change between baseline and 10 months was not statistically significant (P=.25). Similarly, there was a difference in the improvement in BP control between the 2 arms at 5 months but no such difference at 10 months compared with baseline (P=.06 at 5 months, P=.34 at 10 months).

DISCUSSION

We found that PHP, a multidimensional intervention based on Integrative Medicine principles and using a relationship-centered, mind-body approach in supporting behavior change, improved cardiovascular risk compared with usual care. The magnitude of the relative improvement in FRS at 10 months was modest (16% in the intervention arm vs 12% in the UC arm). This remains statistically significant in part because of small standard deviations in FRS, but also in part owing to failure of randomization. The UC arm would have been expected, in the absence of any intervention effect, to improve more than the intervention arm because of regression to the mean, because they had a much higher mean FRS at baseline. This

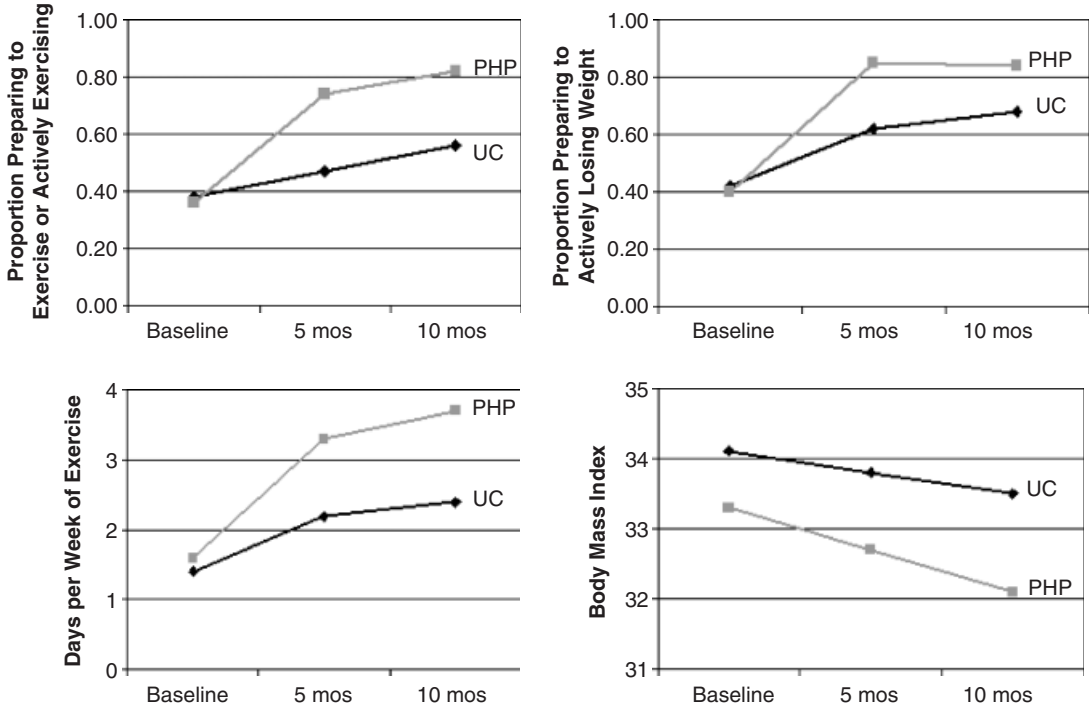

FIGURE 3. Changes in risk behaviors, personalized health planning intervention versus usual care.

greater improvement in an already healthier population supports the statistical (and clinical) significance of our finding.

Secondary analyses to determine a possible mechanism of action for the intervention fit our model in that there was a broad range of modest improvements in risks and conditions. While exercise and weight change are not used in calculating FRS, these behaviors might have translated, indirectly, into improvement in FRS. However, for a number of risk factors, including weight loss, blood pressure control, and LDL-cholesterol, PHP subjects had greater improvement than UC subjects. While the effects were all favorable, suggesting a positive impact on these parameters for the intervention, the differences failed to achieve statistical significance, probably for 3 reasons. First, allowing patients to choose their own focus for the intervention dilutes our ability to measure the effect of the intervention on any single condition. Second, with no cardiovascular risk condition common to our entire population, a relatively smaller number of patients will have to modify a single risk factor, leading to less visible changes in specific risk factors. Third, the unexpected improvement shown by the UC arm led to decrease between arm differences in many risk factors. It is worth noting that the arms had a statistically significant difference in change in FRS despite this improvement by the UC arm. It is also important to note that our measured risk factors are not the only possible mechanisms for improvement in cardiovascular risk; for example, although we did not make medication changes in the intervention, it is possible that we activated patients to take their medication or talk to their doctors about further medication, and that these changes caused part of the improvement.

Our study has a number of limitations. First, our subjects were predominantly female, educated, and had family incomes well above median. It is not clear as to whether the success of our intervention can be translated to a more heterogeneous population. Also, the clinical heterogeneity of our subjects left us without adequate statistical power to measure clinically relevant effects on individual risk factors. The limited time frame of our follow-up does not permit us to draw

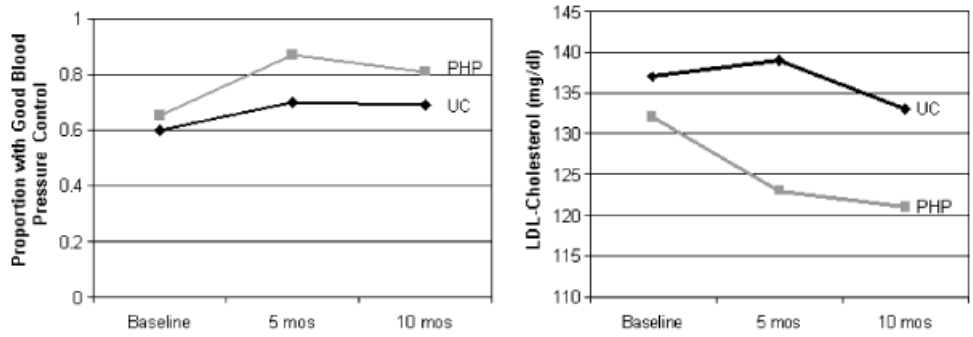

FIGURE 4. Changes in low density lipid-cholesterol and blood pressure control, personalized health planning intervention versus usual care.

inference about the sustainability of this intervention beyond the year in which subjects were studied, and were part of the intervention. Additionally, our intervention is multifaceted; we cannot determine the relative efficacy of components. Regarding our readiness to change data, expectation bias may have led intervention patients to be more likely to assert readiness to change compared with control patients. Finally, the improvements seen in our UC arm suggest that our subjects may have been highly motivated to change their behavior. It is unclear whether our findings generalize to a less engaged population.

Another limitation relates to subject drop-outs. Drop-outs may not have occurred randomly, as many were due to lack of satisfaction with the arm to which they were randomized (both control and intervention). The results from the completer analysis suggest that this issue may not have been critical.

Integrative Medicine incorporates the principles both of whole-person approaches to medicine and evidence-based medicine. This must also include investigation designed to provide evidence of the clinical efficacy of these models. Our study provides the first evidence that these necessarily multidimensional approaches can be efficacious in cardiovascular risk reduction. In order to show the effectiveness of Integrative Medicine and translate its principles into accepted practice, future research in Integrative Medicine should attempt to evaluate specific components of complex and multifaceted interventions for their relative efficacy and cost-effectiveness, and should identify target populations most likely to benefit from these interventions. Nevertheless, our study provides proof of the concept that PHP can reduce, at least in the short term, risk of morbidity from what is conventionally considered a physical disease.

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