

**ORIGINAL RESEARCH**

# Outcomes of Biomarker Feedback on Physical Activity, Eating Habits, and Emotional Health: From the Americans in Motion-Healthy Intervention (AIM-HI) Study

Nia S. Mitchell, MD, MPH, Brian K. Manning, MPH, Elizabeth W. Staton, MSTC, Caroline D. Emsermann, MS, L. Miriam Dickinson, PhD, and Wilson D. Pace, MD

**Purpose:** The purpose of this article was to test whether physical activity, healthy eating, and emotional well-being would improve if patients received feedback about biomarkers that have been shown to be responsive to changes in weight and fitness.

**Methods:** Patients were randomized to limited feedback (weight, body mass index [BMI], and blood pressure at 4 and 10 months) or enhanced feedback (weight, BMI, blood pressure, homeostatic insulin resistance, and nuclear magnetic resonance lipoprotein profiles at 2, 4, 7, and 10 months). Repeated measures mixed effects multivariate regression models were used to determine whether BMI, fitness, diet, and quality of life changed over time.

**Results:** Major parameters were similar in both groups at baseline. BMI, measures of fitness, healthy eating, quality of life, and health state improved in both patient groups, but there was no difference between patient groups at 4 or 10 months. Systolic blood pressure improved in the enhanced feedback group, and there was a difference between the enhanced and limited feedback groups at 10 months (95% confidence interval,  $-6.011$  to  $-0.5113$ ).

**Conclusions:** Providing patients with enhanced feedback did not dramatically change outcomes. However, across groups, many patients maintained or lost weight, suggesting the need for more study of nondiet interventions. (J Am Board Fam Med 2014;27:61–69.)

**Keywords:** Diet, Exercise, Obesity, Practice-based Research

Obesity and related chronic conditions (eg, diabetes, hypertension) remain major health concerns in the United States. One third of adults and approximately 17% of children and adolescents are obese.<sup>1</sup> Lifestyle choices contribute to the preven-

tion and management of chronic conditions and overall health.<sup>2,3</sup> There is a shortage of effective tools, approaches, and resources to support healthy lifestyle choices. Regular feedback and monitoring have shown promise in helping to support ongoing behavioral change and management.<sup>4,5</sup>

Primary care practices are well positioned to deliver effective brief interventions to support healthy lifestyle choices.<sup>6</sup> The American Academy of Family Physicians developed a public health initiative, Americans in Motion-Healthy Interventions (AIM-HI), to promote healthy lifestyle choices related to nutrition, physical activity, and emotional well-being. The ongoing initiative was

This article was externally peer reviewed.

Submitted 21 December 2012; revised 12 July 2013; accepted 22 July 2013.

From the Department of Medicine, Division of General Internal Medicine, Colorado Health Outcome Program, and Anschutz Health and Wellness Center (NSM), and the Department of Family Medicine (EWS, CDE, LMD, WDP), University of Colorado Anschutz Medical Campus, Aurora; and the American Academy of Family Physicians National Research Network, Leawood, KS (BKM, EWS, LMD, WDP).

**Funding:** This research was funded by the Pepsico Foundation, a not-for-profit corporation independent of, although funded by, Pepsico, Inc. After reviewing and approving the grant application, the Pepsico Foundation had no authority over conduct of the project and has not reviewed the content of this manuscript.

**Conflict of interest:** none declared.

**Corresponding author:** Nia S. Mitchell, MD, MPH, Mail Stop F433, 13199 E. Montview Blvd., Suite 300, Room 361, Aurora, CO 80045 (E-mail: Nia.Mitchell@ucdenver.edu).

designed to support family physician offices and increase attention to healthy lifestyle choices to prevent and treat chronic illnesses.<sup>7</sup>

The AIM-HI program was developed around the 5 As (Ask, Advise, Assess, Assist, and Arrange) and the Transtheoretical Model of behavior change (stages of change); it is designed to support incremental behavior changes in individuals.<sup>8,9</sup> Clinicians engage in conversations about healthy lifestyles with patients using principles of motivational interviewing. They help patients select lifestyle behaviors to address and develop personalized goals and feasible plans. AIM-HI tools include a fitness inventory, fitness prescription, a fitness promotion poster, a food and activity journal, and a practice manual.<sup>7,10</sup> Practices are encouraged to integrate these tools into routine clinical care.

In the larger study, AIM-HI was implemented in 2 steps: First, physicians and staff examined their lifestyles and attempted to make changes in their own lifestyles using the program tools to enhance their familiarity with the tools, create an office environment that encourages healthy lifestyles, and demonstrate the lifestyle changes to patients. Second, clinicians and staff were encouraged to use the AIM-HI tools and approach with patients.

Other types of feedback have improved ongoing adherence to behavioral change programs. For instance, individuals who weigh themselves regularly have improved weight control,<sup>11</sup> and individuals who track their blood pressure exhibit better blood pressure control.<sup>12</sup> Feedback is a common theme in many weight loss programs that conduct regular weigh-ins.<sup>13</sup> In this project we increased the frequency of follow-up during which patients received feedback and added feedback about 2 new physiologic measures in an effort to improve lifestyle change outcomes.

The AIM-HI program was well received by a number of family practices.<sup>14</sup> However, there has not been a thorough assessment of the program's impact on participants' health behavior and related outcomes. This article examines patient-level outcomes related to weight, physical activity, eating habits, and emotional health. Patient-level outcomes (blood pressure, body mass index [BMI], fasting glucose and insulin levels, nuclear magnetic resonance lipoprotein profiles, fitness, dietary intake, physical activity, and emotional well-being) by practice randomization are reported elsewhere.<sup>10</sup> Study patients were randomly assigned to

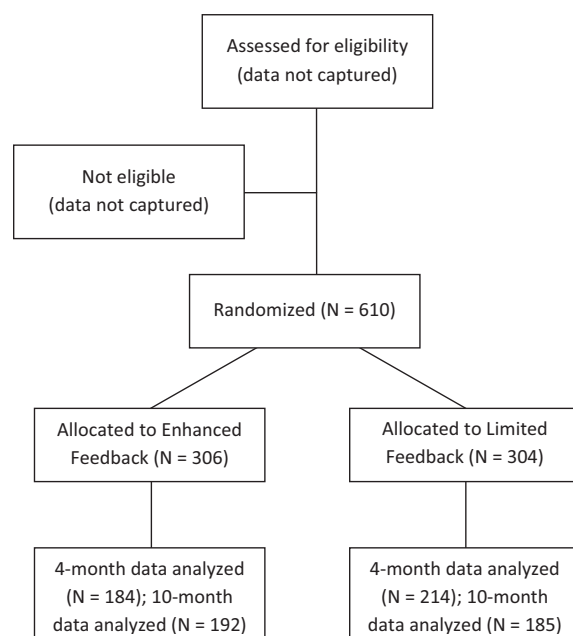
1 of 2 groups: (1) limited feedback, which was intended to mimic the frequency of feedback received in standard of care, or (2) enhanced feedback. Patients in the enhanced feedback group received feedback more often than those in the limited feedback group, and they also received information about their calculated insulin resistance and lipoprotein lipid profiles. We hypothesized that patients in the enhanced feedback group would show greater improvement in selected health outcomes than those in the limited feedback group.

## Methods

### Study Design

This study was part of a randomized, practice-based trial of family medicine practices that implemented AIM-HI. Patients were randomized to receive either enhanced or limited feedback. Patient allocation was not concealed from patients or clinicians (see Figure 1). All research participants were required to sign an informed consent. This study was approved by the American Academy of Family Physicians institutional review board and local institutional review boards of participating sites.

**Figure 1. Assignment of patients to treatment groups for the Americans in Motion Healthy Intervention (AIM-HI) clinical trial.**



### **Setting and Participants**

Twenty-four family physician practices were recruited from members of 3 practice-based research networks, including the American Academy of Family Physicians National Research Network, LA Net, and Southeast Clinicians Research Network. Details of practice recruitment have been described elsewhere.<sup>10,15</sup> In brief, we solicited members of the American Academy of Family Physicians by E-mails to members and publications. From among interested practices, 24 practices from 16 different states were randomized to include stratification with respect to size (small was defined as  $\leq 3$  clinicians and large as  $\geq 4$  clinicians) and percentage of minority patients, with at least 35% minority as the dividing point.

The AIM-HI intervention is intended for all patients in a practice and was implemented as a practice-wide quality improvement effort. To evaluate the effectiveness of the intervention, a sample of patients ( $n \leq 40$ ) from each practice was enrolled in this study. Up to 40 patients per practice were enrolled if they agreed to participate and met the eligibility criteria ( $>17$  years old, a BMI  $\geq 30$ , able to participate in moderate physical activity, life expectancy  $>1$  year, and able to read English or Spanish). Exclusion criteria included a diagnosis of coronary heart disease, HIV/AIDS, or hepatitis C. Pregnant women and those planning to become pregnant in the next 12 months were also excluded. Patients diagnosed with type 2 diabetes or hyperlipidemia before the index visit initially were not eligible for the study; however, because of slow enrollment, this criterion was relaxed approximately 3 months after the initiation of patient enrollment as long as the condition and treatment regimen had been stable for at least 6 months.

### **Data Collection and Feedback**

All study patients attended study-specific visits with local study coordinators, typically nurses or medical assistants, who were trained in the study protocol. Clinical measures included height (at baseline only); weight; BMI; 3-minute step test with heart rate measured immediately and converted to a 7-point physical activity scale based on age, sex, and heart rate<sup>16</sup>; 2 indicators of cardiovascular risk: the homeostatic assay–insulin resistance (HOMA-IR) (LipoScience, Inc., Raleigh, NC); and nuclear magnetic resonance lipoprotein profiles (NMRLPs)

(LipoScience, Inc.). HOMA-IR is an estimate of insulin resistance, and the NMRLP measures multiple components of cholesterol transport within the blood. The HOMA-IR and NMRLP may change more quickly than classic biomarkers such as weight, blood pressure, and total cholesterol or low-density lipoprotein cholesterol with improvements in physical activity and diet.<sup>17–19</sup> These tests have not been widely introduced into clinical practice in primary care but were tested here to study whether changes in them led to increased lifestyle changes by patients.

The PrimeScreen questionnaire was used to measure food intake, specifically macronutrients such as fruits, vegetables, and dairy.<sup>20</sup> The Treatment Self-Regulation Questionnaire (TSRQ) was used to measure the motivation behind participants' health behaviors.<sup>21</sup> Subscales of the TSRQ include perceived competence scales for maintenance and capability. The visual analog scale from the EuroQuol EQ-5 Days was used as a subjective measure of overall health state.<sup>22</sup> The Mental Component Summary of the 12-item Short Form (SF12) was used to measure emotional quality of life.<sup>23</sup>

Patients were randomized to 1 of 2 groups at the baseline visit: (1) limited feedback (control) or (2) enhanced feedback (intervention). Patients who received limited feedback were seen at 3 points: baseline, 4 months, and 10 months. Individuals in the enhanced feedback group were seen at baseline and 2, 4, 7, and 10 months. Patients and clinicians were free to schedule office visits that were specifically focused on healthy lifestyles and behavioral change, but the study did not pay for those visits. The intervals for the limited feedback group were chosen to replicate the time intervals for follow-up visits in usual practice settings.

All patients and clinicians received feedback reports about the patient's completed health survey, height, weight, BMI, and blood pressure at each visit. Individuals in the enhanced feedback group and their clinicians were also given results of the HOMA-IR and/or NMRLP. Patient feedback reports included explanations of outcome measures, their meanings, and healthy ranges.

### **Statistical Methods**

#### *Baseline Characteristics*

The demographics of the limited and enhanced feedback groups were compared using analysis of

variance (ANOVA) for continuous descriptors with normal distributions; the Kruskal-Wallis nonparametric test was used for continuous descriptors that were not normally distributed. Categorical descriptors were compared using the  $\chi^2$  test. All 610 patients were included in this analysis.

#### *Changes in Weight and Physical Activity*

For patients who completed both the baseline and 10-month surveys, the percentage of weight loss/gain as well as fitness loss/gain were calculated. Weight loss/gain was categorized as weight loss or gain of 0 to <5% and  $\geq 5\%$ ; physical activity change was categorized as a <2-point increase and a  $\geq 2$ -point increase. The  $\chi^2$  test was used to compare the percentage of patients in the enhanced versus limited feedback groups by weight loss/gain categories. A total of 374 patients were included in this analysis.

#### *Multivariate Repeated Measures Mixed Effects Models*

Repeated measures mixed effects multivariate regression models were used to determine whether outcomes changed over the course of the study period. Models were adjusted for repeated measures within patients and clustering of patients within practices, with patient and practice included as random effects. Independent variables (fixed effects) included patient group (limited, enhanced), patient demographic characteristics (age, comorbidities, education, gender, income, marital status, and race and ethnicity), time (baseline, 4 months, 10 months), and a time by patient group interaction. The interaction term measured differential change over the study period by patient group. In addition, one degree of freedom hypotheses were made *a priori* to measure average change by patient group from baseline to 4 months, baseline to 10 months, and average change between patient groups at 4 and 10 months. All 610 patients were included in this analysis. Before the analysis, data missing for each outcome as it relates to baseline measures and observed data were analyzed using Kendall's  $\tau$  correlation coefficient and explored graphically by plotting the averages of each outcome by patients' last completed assessment. In addition, associations were determined between overall patient attrition and each of the outcomes and covariates.  $\chi^2$  Tests were run for categorical characteristics and 1-way ANOVA models were performed for continuous variables. Since evalua-

tion of the missing data as it relates to each outcome is primarily monotonic, an ordinal variable was created to measure drop out: 1 (baseline only), 2 (last assessment at 4 months), and 3 (last assessment at 10 months).

There were 3 surveys throughout the study: baseline, 4 months, and 10 months. Of the 610 patients completing the baseline survey, 75 (12.3%) completed a second survey as their last assessment and 377 (61.8%) completed the third survey as their last assessment. Therefore, 158 (25.9%) completed only a baseline survey, indicating a 25% dropout rate from baseline. Since the data are missing at random all models are adjusted for covariates associated with the missingness (patients' age) and used maximum likelihood estimation, using all available data. All analyses were performed using SAS software version 9.2 (SAS, Inc., Cary, NC).

## **Results**

### ***Baseline Characteristics***

The baseline characteristics of the patient feedback groups are shown in Tables 1 and 2. Demographics are shown in Table 1; the continuous descriptors that were compared with ANOVA and nonparametric tests are shown in Table 2. Both groups had similar distributions of all major parameters that were assessed, including sex, racial background, ethnicity, income, number of people in the household, marital status, baseline blood pressure, insulin resistance (as measured by the HOMA-IR and the Quantitative Insulin Sensitivity Check Index), and lipoprotein profiles (as measured by NMRLP). Baseline physical activity categories (as measured by the International Physical Activity Questionnaire), overall self-reported health levels (as measured by the full SF12), and motivation to engage in healthy eating behaviors and physical activity (as measured by the TSRQ) were also similar between groups (data not shown).

### ***Outcome Variables***

The results for the repeated measures mixed effects multivariate regression models for differences in the outcome variables between baseline data and 4- and 10-month data in the limited and enhanced feedback groups are shown in Table 3. Average change from baseline to 4 and 10 months between the 2 patient intervention groups are shown in Table 4. Differential changes between patient

**Table 1. Demographics: Limited versus Enhanced Feedback Patient Group—Baseline Survey**

Variables	Limited Feedback (n = 304)	Enhanced Feedback (n = 306)	P value
Sex			
Female	227 (74.7)	239 (78.1)	.3181
Male	77 (25.3)	67 (21.9)	
Racial background			
White	174 (57.2)	177 (57.8)	.7117
African American	50 (16.4)	53 (17.3)	
Other	58 (19.1)	49 (16.0)	
Missing	22 (7.2)	27 (8.8)	
Ethnicity			
Non-Hispanic/Latino	249 (81.9)	263 (85.9)	.1743
Hispanic/Latino	55 (18.1)	43 (14.1)	
Education			
Less than high school	13 (4.3)	14 (4.6)	.7647
High school grad/GED	82 (27.0)	77 (25.2)	
Some college/graduate school	187 (61.5)	186 (60.8)	
Missing	22 (7.2)	29 (9.5)	
Income (\$)			
<20,000	66 (21.7)	59 (19.3)	.5084
20,001–50,000	104 (34.2)	98 (32.0)	
51,001–75,000	41 (13.5)	46 (15.0)	
>75,000	64 (21.1)	61 (19.9)	
Missing	29 (9.5)	42 (13.7)	
Marital status			
Single	53 (17.4)	64 (20.9)	.6562
Married	180 (59.2)	168 (54.9)	
Separated/divorced/widowed	55 (18.1)	59 (19.3)	
Missing	16 (5.3)	15 (4.9)	

Data are n (%).

groups from baseline are shown in terms of the enhanced patient group by survey (4 months, 10 months). Thus, a statistically significant positive change in the outcome indicates that change among patients receiving the enhanced treatment increased at the specified time point (4 months, 10 months) from baseline compared with patients receiving the limited treatment, whereas a statistically significant negative change in the outcome indicates that change among patients receiving the enhanced intervention decreased at the specified time point (4 months, 10 months) compared with patients receiving the limited treatment.

#### Body Mass Index

In general, the multivariate analysis showed that there was a decrease in BMI over time for all

patients ( $P = .048$ ). Average BMI among patients who received limited feedback decreased from 37.7 kg/m<sup>2</sup> at baseline to 37.4 kg/m<sup>2</sup> at 4 months ( $P = .014$ ), whereas the average baseline BMI for patients who received enhanced feedback trended down over the 10-month follow-up period. However, the overall change from baseline did not reach statistical significance (BMI at baseline, 36.9 kg/m<sup>2</sup>; at 4 and 10 months, 36.7 and 36.6 kg/m<sup>2</sup>, respectively;  $P = .115$  and 0.054).

#### Systolic Blood Pressure

Systolic blood pressure decreased differentially over time by patient group. In general, systolic blood pressure declined more rapidly among patients in the enhanced feedback group at 10 months (average change between groups at 4 months, 0.40; at 10 months,  $-3.26$ ; time by group interaction,  $P = .025$ ). Average systolic blood pressure for patients in the limited feedback group showed no change from baseline to 4 or 10 months (128.8–128.9 and 129.6 mmHg, respectively;  $P = .985$  and 0.450, respectively). On the other hand, the average systolic blood pressure for patients in the enhanced feedback group was unchanged at 4 months but improved significantly at the 10-month follow-up visit when compared with baseline (128.0 vs 128.5 mmHg at 4 months,  $P = .621$ ; 125.5 mmHg at 10 months,  $P = .011$ ).

#### Physical Activity

Multivariate results also indicated that physical activity generally increased over time among all patients (time,  $P = .022$ ). Physical activity, as measured by the 3-minute step test, increased on average from baseline at 4 months (3.9 vs 4.2;  $P = .010$ ) and 10 months (3.9 vs 4.2;  $P = .048$ ), but there was no difference between the 4 and 10 month values in the limited feedback group, whereas physical activity in the enhanced feedback group did not differ significantly from baseline at either time point.

#### PrimeScreen

Multivariate analyses determined that PrimeScreen scores also increased among all patients ( $P < .001$ ). Average PrimeScreen scores improved significantly from baseline to 4 and 10 months among patients in both groups.

**Table 2. Baseline Survey Data (Continuous Descriptors) for Outcome Variables for Limited and Enhanced Feedback Groups\***

Variables	Limited Feedback (n = 304)		Enhanced Feedback (n = 306)		P value
	Mean	SD	Mean	SD	
Imputed age	44.73	12.69	43.02	11.92	.0874
Systolic blood pressure	127.3	16.26	125.9	15.46	.2882
PrimeScreen–AimHi	−0.049	0.384	−0.065	0.385	.6017
Overall health variable: self-report	0.017	0.674	−0.012	0.700	.6356
	Median	IQR	Median	IQR	
BMI	35.55	33.0–41.0	35.00	32.0–40.0	.1968
Fitness	4.000	2.0–6.0	4.000	2.0–6.0	.3369
SF-12 mental score	−0.030	−0.9–0.5	−0.268	−1.1–0.5	.2089

\*Means and standard deviations (SDs) reported for data with normal distribution. Medians (25th to 75th percentiles) reported for data with nonnormal distribution.

BMI, body mass index; IQR, interquartile range; SF-12, 12-item Short Form.

*SF12 Mental Component Summary*

Quality of life, as measured by the SF12 Mental Component Summary, improved over time among

all patients ( $P = .005$ ; data not shown). Average scores were improved at 4 months compared with baseline in both the limited and enhanced feedback

**Table 3. One Degree of Freedom Contrast Estimates of the Repeated Mixed Effects Multivariate Regression Model**

Outcome	Limited Feedback Patient Group							
	Baseline (n = 304)		4 Months (n = 214)			10 Months (n = 185)		
	Estimate	SE	Estimate	SE	Change from Base P	Estimate	SE	Change from Base P
BMI*	37.7	0.72	37.4	0.72	.014	37.6	0.72	.242
Systolic blood pressure <sup>†</sup>	128.8	1.75	128.9	1.81	.985	129.6	1.84	.450
Fitness*	3.9	0.27	4.2	0.28	.010	4.2	0.28	.048
PrimeScreen*	0.0	0.04	0.1	0.04	.000	0.1	0.04	<b>.000</b>
SF-12 mental score*	0.0	0.12	0.2	0.12	.001	0.1	0.12	.304
HealthState*	65.7	2.54	65.3	2.67	.827	69.5	2.73	<b>.041</b>
	Enhanced Feedback Patient Group							
	Baseline (n = 306)		4 Months (n = 184)			10 Months (n = 192)		
	Estimate	SE	Estimate	SE	Change from Base P	Estimate	SE	Change from Base P
BMI*	36.9	0.72	36.7	0.72	<b>0.115</b>	36.6	0.72	<b>0.054</b>
Systolic blood pressure <sup>†</sup>	128.0	1.77	128.5	1.85	0.621	125.5	1.85	<b>0.011</b>
Fitness*	3.9	0.28	4.0	0.28	0.245	3.9	0.28	0.771
PrimeScreen*	0.0	0.04	0.1	0.04	<b>0.000</b>	0.2	0.04	<b>0.000</b>
SF-12 mental score*	−0.2	0.12	0.0	0.12	<b>0.027</b>	0.0	0.12	<b>0.031</b>
HealthState*	66.7	2.56	67.9	2.74	0.497	70.7	2.74	<b>0.023</b>

The models were adjusted for repeated measures, clustering of patients within practices, age, comorbidities, education, sex, income, marital status, race, and ethnicity.

\*Multivariate model:  $P < .05$ , time.

<sup>†</sup>Multivariate model:  $P < .05$ , time by patient group interaction.

BMI, body mass index; SE, standard error; SF-12, 12-item Short Form.

**Table 4. One Degree of Freedom Contrast Estimates of the Repeated Mixed Effects Multivariate Regression Model: Mean Difference in Change from Baseline by Patient Intervention Group**

Outcome	Change Between Groups at 4 Months†		Change Between Groups at 10 Months†		P Value
	Mean	95% Confidence Interval	Mean	95% Confidence Interval	
BMI	0.095	-0.220 to 0.410	-0.085	-0.406 to 0.237	.583
Systolic blood pressure*	0.478	-2.224 to 3.180	-3.262	-6.011 to -0.513	.025
Fitness	-0.168	-0.493 to 0.158	-0.207	-0.532 to 0.118	.392
PrimeScreen	0.013	-0.050 to 0.076	0.055	-0.009 to 0.119	.232
SF-12 mental score	-0.077	-0.270 to 0.116	0.078	-0.120 to 0.276	.356
HealthState	1.602	-3.248 to 6.452	0.304	-4.627 to 5.235	.802

The models were adjusted for repeated measures, clustering of patients within practices, age, comorbidities, education, sex, income, marital status, race, and ethnicity.

\*Multivariate model:  $P < .05$ , time by patient group interaction.

†Coefficients are in terms of differential change from baseline by the enhanced feedback group compared to the limited feedback group.

BMI, body mass index; SF-12, 12-item Short Form.

groups. However, at 10 months only the enhanced feedback group showed an improvement in quality of life from baseline.

#### Health State

Results indicated no significant change in health state over time among patients in the study or between the limited and enhanced groups. However, estimation of the difference between 10-month and baseline averages using one degree of freedom hypotheses tests indicated patients from both the limited and enhanced feedback groups improved from their baseline values at 10 months.

#### Categorized Weight Change

Table 4 shows the weight change as a percentage of initial weight among the 374 patients in the limited and enhanced feedback groups who completed both the baseline and 10-month surveys. There was no statistical difference in the proportion of the patients losing  $\geq 5\%$  of their initial weight between the enhanced and traditional patient groups (18% vs 15%;  $P = .20$ ).

#### Discussion

There were only minimal differences in the outcomes of interest for patients who received enhanced versus limited feedback in the AIM-HI study. Behavioral change is difficult to achieve without intensive interventions. This study did not rely on intensive behavioral therapy because it was not a covered benefit for obesity or poor physical

fitness at the time of this study. The AIM-HI approach focuses on promoting small changes in a manner consistent with routine primary care. This study added differential feedback to the AIM-HI tools to determine whether patients who received information about calculated insulin resistance and lipoprotein profiles and more frequent feedback would have better BMI, systolic blood pressure, physical activity, dietary intake, and quality of life than those who received limited feedback or standard care. At 10 months, systolic blood pressure and quality of life were improved in the enhanced feedback group but not in the limited feedback group. Dietary intake and health state were improved at 10 months in both groups, with no difference between the 2 groups. Furthermore, there was no difference between groups in the percentage of people who achieved clinically significant weight loss.

Systolic blood pressure and quality of life improved in the enhanced feedback group at 10 months. Systolic blood pressure improved by 2.5 mmHg from a baseline level that was not considered elevated. Whether the magnitude of change would increase with higher baseline blood pressures is unknown. The clinical significance of a 2.5-mmHg drop in blood pressure is unclear; however, given that antihypertensives generally lower blood pressure by 5 mmHg,<sup>24</sup> and considering that it may have dropped more among people with higher baseline pressures, the change could be clinically useful.

The study was designed to explore the effect of providing patients with feedback on specific biomarkers that theoretically would change rapidly with either weight loss or improved physical fitness. Unfortunately, the effect of the feedback was minimal. The lack of effect could be related to the level of responsiveness of the biomarkers to improvements in weight or physical activity or to the inability of people to understand the implications of small changes in the biomarkers in relation to overall behavior change and improved health. Patients in the study did not lose much weight, possibly because they may not have received enough behavior change counseling. The US Preventive Services Task Force recommends that weight loss counseling occur at least twice per month for the first 3 months.<sup>25</sup> The actual amount of counseling patients received in our study is unknown but was unlikely to meet the recommended levels in this real-world study.

Of note, patients in both feedback groups did show some improvements in their health habits, specifically dietary intake and perceived health state. PrimeScreen scores improved for participants in both groups. The PrimeScreen was designed to measure the dietary risks for developing cardiovascular disease, cancer, and osteoporosis and not specifically to measure weight-modifying behaviors,<sup>20</sup> which may explain why the improvements in dietary intake were not associated with weight loss. Improved PrimeScreen scores may have indicated that patients' eating habits had improved with regard to their risk for developing chronic diseases but may not have reduced overall caloric intake. Perceived health state was significantly improved in both groups at 10 months. It is possible that participants felt their health was improved because they saw their providers more frequently than usual, which may have caused them to feel healthier. They may also have derived some perceived benefit from actively working to improve their health using the AIM-HI tools.

The limitations of the current study may account for the lack of difference between study groups. While we attempted to mimic real-world intervals in follow-up in the limited feedback group, which was the de facto standard of care in our study, there was no control group. Therefore, the changes we found in both the limited and enhanced groups may have been different from a true control group. We also sought to identify novel

indicators of improved fitness that may be more responsive to a wider range of change efforts than the standard lipid panels and hemoglobin A1c tests to provide early feedback on efforts to enhance nutrition and increase exercise. In this study, feedback with the novel test results did not provide any added benefit over standard care. This may have been because the biomarkers did not move as quickly as expected with changes in fitness or that the changes were not of big enough magnitude. Compared with US Preventive Services Task Force guidelines, the AIM-HI intervention with enhanced feedback may have occurred too infrequently to affect weight loss<sup>25</sup> or was the wrong modality to increase physical activity.<sup>26</sup> The resulting intervention may have met the needs of the practices but was ineffective at improving the outcomes of interest.

Although population level clinical outcomes did not change dramatically from the intervention, there is some good news: 40% of the people in the limited feedback group and 52% of the people in the enhanced feedback group either maintained or lost weight at 10 months. Furthermore, a number of individuals lost  $\geq 5\%$  of their initial weight (15% in the limited feedback group and 18% of in the enhanced feedback group; Table 5). This is in contrast to the average American adult, who tends to gain up to 2 pounds per year.<sup>27,28</sup> Since 68% of adults in the United States are either overweight or obese,<sup>29</sup> prevention of weight gain can be viewed as an accomplishment, particularly with an intervention that took a "nondiet" approach to weight management. Such a finding indicates a need for more study of nondiet interventions delivered in primary care settings.

**Table 5. Weight Change as a Percentage of Initial Weight**

	Limited (n = 183)	Enhanced (n = 191)	P value
Weight loss			.2
0–<5	25	34	
$\geq 5$	15	18	
Weight gain			
0–<5	46	37	
$\geq 5$	13	12	

Data are percentages. Columns do not total 100% because of rounding.



## References

1. Centers for Disease Control and Prevention. Overweight and obesity facts. April 27, 2012. Available from: <http://www.cdc.gov/obesity/data/facts.html>. Accessed November 21, 2012.
2. The World Health Report 2002. Reducing risks, promoting healthy life. Geneva: World Health Organization; 2002. Available from: [http://www.who.int/whr/2002/en/whr02\\_en.pdf](http://www.who.int/whr/2002/en/whr02_en.pdf). Accessed November 6, 2013.
3. McGinnis JM, Foege WH. Actual causes of death in the United States. *JAMA* 1993;270:2207–12.
4. Baker RC, Kirschenbaum DS. Weight control during the holidays: highly consistent self-monitoring as a potentially useful coping mechanism. *Health Psychol* 1998;17:367–70.
5. Rooney B, Smalley K, Larson J, Havens S. Is knowing enough? Increasing physical activity by wearing a pedometer. *WMJ* 2003;102:31–6.
6. Cifuentes M, Fernald DH, Green LA, et al. Prescription for health: changing primary care practice to foster healthy behaviors. *Ann Fam Med* 2005;3(Suppl 2):S4–11.
7. American Academy of Family Physicians. Americans In Motion–Healthy Interventions (AIM-HI). Available from: <http://www.aafp.org/online/en/home/clinical/publichealth/aim.html>. Accessed November 6, 2013.
8. Glasgow RE, Emont S, Miller DC. Assessing delivery of the five “As” for patient-centered counseling. *Health Promot Int* 2006;21:245–55.
9. Prochaska JO, DiClemente CC, Norcross JC. In search of how people change. Applications to addictive behaviors. *Am Psychol* 1992;47:1102–14.
10. Pace WD, Lanigan AM, Staton EW, et al. Effectiveness of 2 methods of promoting physical activity, healthy eating, and emotional well-being with the Americans in Motion–Healthy Interventions approach. *Ann Fam Med* 2013;11:371–80.
11. Wing RR, Phelan S. Long-term weight loss maintenance. *Am J Clin Nutr* 2005;82(1 Suppl):222S–5S.
12. Shimbo D, Pickering TG, Spruill TM, Abraham D, Schwartz JE, Gerin W. Relative utility of home, ambulatory, and office blood pressures in the prediction of end-organ damage. *Am J Hypertens* 2007;20:476–82.
13. YMCA. YMCA’s Diabetes Prevention Program. About the program. Available from: <http://www.ymca.net/diabetes-prevention/about.html>. Accessed June 29, 2012.
14. Mitchell D. Early study results show AIM-HI can help patients make, sustain lifestyle changes: AAFP’s fitness initiative offers docs free resources, framework for success. Available from: <http://www.aafp.org/online/en/home/publications/news/news-now/obesity/20100517aim-hi.html>. Accessed May 20, 2013.
15. Erskine J, Lanigan A, Emsermann CB, Manning BK, Staton EW, Pace WD. Use of the Americans in Motion–Healthy Intervention (AIM-HI) to create a culture of fitness in family practice. *J Am Board Fam Med* 2012;25:694–700.
16. Golding LA. YMCA fitness testing and assessment manual. 4th ed. Champaign, IL: Human Kinetics; 2000.
17. Weyer C, Bogardus C, Mott DM, Pratley RE. The natural history of insulin secretory dysfunction and insulin resistance in the pathogenesis of type 2 diabetes mellitus. *J Clin Invest* 1999;104:787–94.
18. Kraus WE, Houmard JA, Duscha BD, et al. Effects of the amount and intensity of exercise on plasma lipoproteins. *N Engl J Med* 2002;347:1483–92.
19. Shadid S, LaForge R, Otvos JD, Jensen MD. Treatment of obesity with diet/exercise versus pioglitazone has distinct effects on lipoprotein particle size. *Atherosclerosis* 2006;188:370–6.
20. Rifas-Shiman SL, Willett WC, Lobb R, Kotch J, Dart C, Gillman MW. PrimeScreen, a brief dietary screening tool: reproducibility and comparability with both a longer food frequency questionnaire and biomarkers. *Public Health Nutr* 2001;4:249–54.
21. Levesque CS, Williams GC, Elliot D, Pickering MA, Bodenhamer B, Finley PJ. Validating the theoretical structure of the Treatment Self-Regulation Questionnaire (TSRQ) across three different health behaviors. *Health Educ Res* 2007;22:691–702.
22. Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. *Ann Med* 2001;33:337–43.
23. Ware J, Kosinski M, Keller SD. A 12-item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;34:220–33.
24. Collins R, MacMahon S. Blood pressure, antihypertensive drug treatment and the risks of stroke and of coronary heart disease. *Br Med Bull* 1994;50:272–98.
25. U.S. Preventive Services Task Force. Screening for obesity in adults: recommendations and rationale. *Ann Intern Med* 2003;139:930–2.
26. U.S. Preventive Services Task Force. Guide to clinical preventive services. 2nd ed. Washington, DC: Office of Disease Prevention and Health Promotion; 1996.
27. Hill J, Wyatt H, Reed G, Peters J. Obesity and the environment: where do we go from here? *Science* 2003;299:853–5.
28. Simkin-Silverman LR, Wing RR, Boraz MA, Kuller LH. Lifestyle intervention can prevent weight gain during menopause: results from a 5-year randomized clinical trial. *Ann Behav Med* 2003;26:212–20.
29. Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among US adults, 1999–2008. *JAMA* 2010;303:235–41.