

# Effect of an Online Weight Management Program Integrated With Population Health Management on Weight Change

## A Randomized Clinical Trial

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**IMPORTANCE** Online programs may help with weight loss but have not been widely implemented in routine primary care.

**OBJECTIVE** To compare the effectiveness of a combined intervention, including an online weight management program plus population health management, with the online program only and with usual care.

**DESIGN, SETTING, AND PARTICIPANTS** Cluster randomized trial with enrollment from July 19, 2016, through August 10, 2017, at 15 primary care practices in the US. Eligible participants had a scheduled primary care visit and were aged 20 to 70 years, had a body mass index between 27 and less than 40, and had a diagnosis of hypertension or type 2 diabetes. Follow-up ended on May 8, 2019.

**INTERVENTIONS** Participants in the usual care group (n = 326) were mailed general information about weight management. Participants in the online program only group (n = 216) and the combined intervention group (n = 298) were registered for the online program. The participants in the combined intervention group also received weight-related population health management, which included additional support from nonclinical staff who monitored their progress in the online program and conducted periodic outreach.

**MAIN OUTCOMES AND MEASURES** The primary outcome was weight change at 12 months based on measured weights recorded in the electronic health record. Weight change at 18 months was a secondary outcome.

**RESULTS** Among the 840 participants who enrolled (mean age, 59.3 years [SD, 8.6 years]; 60% female; 76.8% White), 732 (87.1%) had a recorded weight at 12 months and the missing weights for the remaining participants were imputed. There was a significant difference in weight change at 12 months by group with a mean weight change of -1.2 kg (95% CI, -2.1 to -0.3 kg) in the usual care group, -1.9 kg (95% CI, -2.6 to -1.1 kg) in the online program only group, and -3.1 kg (95% CI, -3.7 to -2.5 kg) in the combined intervention group ( $P < .001$ ). The difference in weight change between the combined intervention group and the usual care group was -1.9 kg (97.5% CI, -2.9 to -0.9 kg;  $P < .001$ ) and the difference between the combined intervention group and the online program only group was -1.2 kg (95% CI, -2.2 to -0.3 kg;  $P = .01$ ). At 18 months, the mean weight change was -1.9 kg (95% CI, -2.8 to -1.0 kg) in the usual care group, -1.1 kg (95% CI, -2.0 to -0.3 kg) in the online program only group, and -2.8 kg (95% CI, -3.5 to -2.0 kg) in the combined intervention group ( $P < .001$ ).

**CONCLUSIONS AND RELEVANCE** Among primary care patients with overweight or obesity and hypertension or type 2 diabetes, combining population health management with an online program resulted in a small but statistically significant greater weight loss at 12 months compared with usual care or the online program only. Further research is needed to understand the generalizability, scalability, and durability of these findings.

**TRIAL REGISTRATION** ClinicalTrials.gov Identifier: [NCT02656693](https://clinicaltrials.gov/ct2/show/study/NCT02656693)

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For 2015-2016, it was estimated that more than 70% of US adults had overweight (body mass index [BMI; calculated as weight in kilograms divided by height in meters squared] between 25-29.9) or obesity (BMI  $\geq$ 30).<sup>1</sup> Overweight and obesity are associated with increased morbidity and mortality from various chronic conditions.<sup>2</sup> Even small amounts of weight loss (eg, 3%-5% of body weight) can have important health benefits, and clinical guidelines recommend lifestyle interventions and counseling for all patients with obesity and for patients with overweight who have cardiovascular risk factors or obesity-related comorbidities.<sup>3</sup> However, primary care physicians often do not counsel patients about weight due to limited time, training, and systems.<sup>4-6</sup>

Studies have shown that online programs involving web-based lifestyle interventions can help people achieve and maintain weight loss, but there is variability across studies.<sup>7-9</sup> Some studies also show that online programs may be efficacious and cost-effective in primary care.<sup>10,11</sup> However, online programs have not been widely implemented in primary care and it remains unclear whether they are effective and scalable in routine practice.

Population health management is a team-based approach in which nonclinical staff members identify and reach out (typically outside face-to-face visits) to specific groups of patients with unmet preventive and chronic condition care needs.<sup>12,13</sup> Population health management has been increasing across primary care and is associated with improved outcomes,<sup>14,15</sup> but to our knowledge, it has not previously been used for patients with overweight or obesity.

The purpose of this trial was to examine whether integrating an online weight management program with population health management support would enhance its effectiveness and lead to greater weight loss at 12 months among primary care patients compared with the online program only and with usual care.

## Methods

### Study Design and Setting

The methods have been described in detail elsewhere<sup>16</sup> and the trial protocol and statistical analysis plan appear in [Supplement 1](#). The study was conducted within the Brigham and Women's Hospital Primary Care Center of Excellence, a group of 15 primary care practices with approximately 170 primary care physicians. The 15 primary care practices were divided into 24 clinics based on preexisting administrative divisions. The study was approved by the Partners human research committee and informed consent was obtained from participants electronically prior to enrollment.

### Study Population

Eligible patients were aged 20 to 70 years and had a scheduled primary care visit, a BMI between 27 and less than 40, and a diagnosis of hypertension or type 2 diabetes. Eligible patients also had to speak English or Spanish, have internet access, and be motivated to lose weight. We excluded

## Key Points

**Question** Does a combined intervention, including an online weight management program integrated with population health management (additional support and outreach from nonclinical staff), increase weight loss at 12 months among primary care patients compared with the online program only and usual care?

**Findings** In this cluster randomized trial of 840 patients with overweight or obesity and a diagnosis of hypertension or type 2 diabetes, the mean weight loss at 12 months was 1.2 kg in the usual care group, 1.9 kg in the online program only group, and 3.1 kg in the combined online program with population health management group. The difference in weight loss between the combined intervention group and either the usual care group or the online program only group was statistically significant.

**Meaning** Combining population health management with an online program resulted in a small but statistically significant greater amount of weight loss at 12 months compared with usual care or the online program only.

patients who had undergone or were planning to undergo bariatric surgery, had weight loss of 5% or greater of body weight within the past 6 months, were taking weight loss medications, or had contraindications for weight loss (all inclusion and exclusion criteria appear in [Supplement 1](#)). We used the electronic health record (EHR) to identify potentially eligible patients, who were sent a recruitment letter by mail or electronically if they had a patient portal account. Interested patients were screened and a research assistant reviewed the EHR prior to enrollment to confirm that the patient met all criteria.

### Randomization

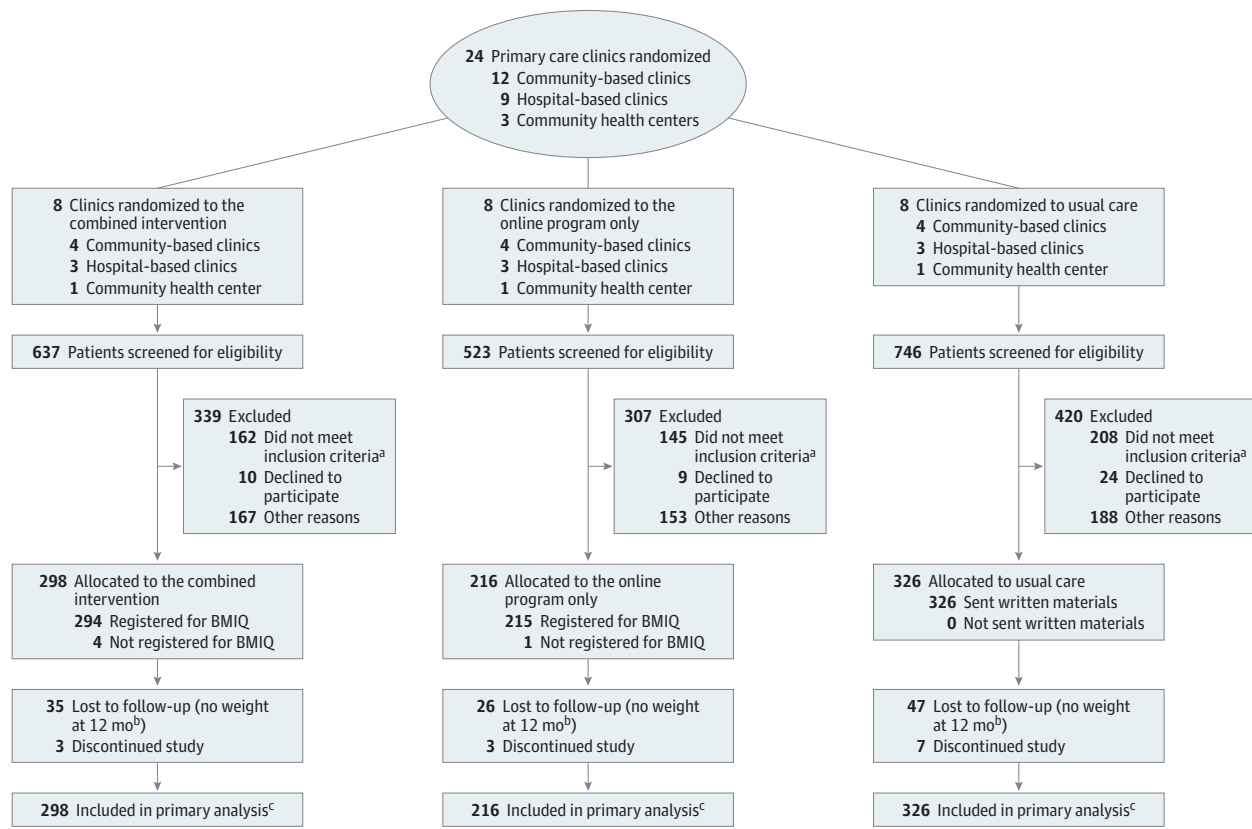
Prior to randomization, the 24 clinics were grouped into 3 strata: hospital-based clinics, community-based clinics, and community health centers ([Figure 1](#)). Randomization was stratified by clinic type to ensure balance across the 3 groups. Using a computer algorithm generated by the study biostatistician (E.J.O.), we randomized the 24 primary care clinics to usual care, the online program only, or the combined intervention.

### Interventions

After enrollment, patients were assigned to 1 of the 3 groups based on their primary care clinic. Patients in the usual care group were sent a 1-time mailing with information about weight management, including general recommendations about diet and physical activity. Patients in the online program only group were registered for the online program, were sent instructions about how to use the program, were provided a brief overview from a research assistant by phone, and were contacted by a research assistant approximately 7 days later to address questions.

Based on patient and stakeholder input,<sup>16,17</sup> we selected and adapted an evidence-based online weight management program called BMIQ (Intellihealth Inc) (eTable 1 in [Supplement 2](#)). This program can be accessed via a computer, tablet,

Figure 1. Flow of Participants



BMIQ (Intellihealth Inc) is the name of the online weight management program.

<sup>a</sup> The most common reasons for exclusion were the body mass index was out of the inclusion range ( $n = 179$ ), lost 5% or greater of body weight within last 6 months ( $n = 98$ ), did not have hypertension or type 2 diabetes ( $n = 71$ ), or had a severe mental health condition ( $n = 63$ ).

<sup>b</sup> At 18 months, weight was not recorded for 44 participants in the combined

intervention group, 43 participants in the online program only group, and 66 participants in the usual care group.

<sup>c</sup> Fully conditional specification multiple imputation with 25 imputations was used to estimate missing weights and other outcomes and covariates and was based on available data for 91 patient variables.

or smartphone and has patient and professional interfaces. The patient interface includes 33 nutrition and behavioral change educational sessions in written and video format (adapted from those used in the Practice-based Opportunities for Weight Reduction at the University of Pennsylvania [POWER-UP] trial<sup>18</sup>) that were released weekly for the first 16 weeks and then every other week. The patient interface also includes exchange-based meal plans and sample menus and tools for tracking weight, food intake, and activity. The professional interface includes patient monitoring and alerts, progress notes, and reporting features. Patients were assigned to a meal plan with a specific calorie goal based on their starting weight and were offered a brief phone consultation with a registered dietitian.

Patients in the combined intervention group received the same components as the online program only group plus additional support from a population health manager (a non-clinical staff member) who works with the primary care practices. We worked with the population health management team to incorporate additional weight-related support that supplemented the support the population health managers

provide as standard care for all patients diagnosed with hypertension or type 2 diabetes. The role of the population health managers was to monitor patients' progress in the online program and to conduct outreach according to a specific protocol.<sup>16</sup> The population health managers did monthly check-in calls with patients and they uploaded a patient summary report from the online program to the EHR every other month. During the monthly calls, the population health managers reviewed patients' progress, addressed questions, and encouraged patients to use the online program regularly. They also offered patients a second brief phone consultation with a registered dietitian approximately 6 months after enrollment. In some situations (eg, if a patient lost  $\geq 7.5\%$  of their body weight), the population health managers would enter a note in the EHR and send direct messages to patients and primary care physicians in case this affected decisions related to care. In addition, the population health managers would reach out to patients who were not logging into the online program regularly (at least every 2 weeks) and encourage them to log in, view the educational sessions, and track their weight.

### Data Collection and Follow-up

The intervention period was 12 months. Patients in all 3 groups received routine care as directed by their primary care physicians and there were no required study visits. If a patient did not have a measured and recorded weight in the EHR at 12 months ( $\pm 90$  days) after enrollment, a research assistant tried to contact the patient to schedule a brief study visit to measure weight. Data on demographic and clinical factors, including measured weight and BMI, were extracted from the EHR at enrollment and at approximately 6, 12, and 18 months after enrollment. Patients in all 3 groups also completed surveys at baseline and at 6, 12, and 18 months after enrollment to assess patient-reported outcomes and satisfaction. Some demographic factors (eg, race/ethnicity using fixed categories) also were assessed on the baseline survey because they could affect weight change, engagement with the interventions, or both. Use of the online program and the number of phone and email contacts with population health managers or other study staff were tracked within the online program.

### Outcomes

The primary outcome was weight change at 12 months ( $\pm 90$  days) after enrollment, which was calculated as the difference (in kilograms) between each patient's measured weight at the initial visit and at the visit approximately 12 months later. Secondary outcomes included weight change at 6 months ( $\pm 60$  days) and at 18 months ( $\pm 90$  days) after enrollment; percentage weight change; weight loss of 5% or greater; changes in measured systolic and diastolic blood pressure level, total cholesterol level, low-density lipoprotein and high-density lipoprotein cholesterol levels, triglycerides level, and hemoglobin A<sub>1c</sub> level; and changes in self-reported weight-related quality of life,<sup>19</sup> diet,<sup>20</sup> physical activity,<sup>21</sup> health status,<sup>22</sup> and confidence in ability to lose weight.<sup>23</sup> We also examined use of and satisfaction with the interventions.

### Power

Although the primary analysis was designed to compare weight change at 12 months across the 3 groups, we calculated the sample size to have 80% power for subsequent pairwise comparisons. Based on previous studies,<sup>24,25</sup> we assumed a mean 12-month weight loss of 0.5 kg in the usual care group, 1.5 kg in the online program only group, and 3.0 kg in the combined intervention group and an SD of 5 kg. Accounting for the within-clinic correlation and assuming 20% attrition, we decided to enroll 840 patients (280 per group), which provided more than 99% power for the primary analysis.

### Statistical Analysis

Participants were analyzed according to randomization group and all participants were included. We used repeated-measures mixed-effects linear regression using weights at baseline and at 12 months (because the primary outcome was weight change at 12 months) first and then using weights at baseline and at 6, 12, and 18 months. We included indicators for group and time along with interaction terms to demonstrate the intervention effect. We adjusted for the prespeci-

fied covariates (including age, sex, race/ethnicity, educational level, and medical conditions) that could affect weight change. We included clinic type as a fixed effect and clinic, physician, and patient as random effects. The same general modeling approach was used to compare changes in continuous secondary outcomes across the 3 groups. For binary outcomes (eg, weight loss  $\geq 5\%$ , excellent or very good health status), we used mixed-effects logistic regression. We used fully conditional specification multiple imputation to estimate missing weights as well as other missing outcomes and covariates.

To determine whether there was a significant difference in weight change at 12 months by group, we used a global *F* test with 2 degrees of freedom to examine the statistical significance of the study group  $\times$  12-month time point interaction term with an  $\alpha$  level of .05. If significant, we proceeded to conduct 2 planned pairwise comparisons to compare weight change in the combined intervention group vs the usual care group and the combined intervention group vs the online program only group.

We used the Holm procedure to account for multiple comparisons with a 2-sided significance level of .025 for the first comparison and level of .05 for the second comparison. Because of the potential for type I error due to multiple comparisons, the findings for the analyses of the secondary end points should be interpreted as exploratory. All analyses were conducted using SAS version 9.4 (SAS Institute Inc).

## Results

### Study Participants

A total of 26 393 potentially eligible patients were sent information about the study, 1906 were screened, and 840 were enrolled from July 19, 2016, through August 10, 2017. Follow-up ended on May 8, 2019. There were 326 patients in the usual care group, 216 in the online program only group, and 298 in the combined intervention group (Figure 1). At baseline, the mean age of the participants was 59.3 years (SD, 8.6 years), the mean weight was 92.1 kg (101.9 kg for males and 85.6 kg for females), the mean BMI was 32.5 (including both males and females), 60% of participants were female, and 76.8% were White (Table 1). Although most characteristics had similar distributions across the 3 groups, there were a few differences (eg, sex, educational level) due to the randomization by clinic.

### Changes in Weight and Other Outcomes

#### Primary Outcome

There were 732 participants (87.1%) with a recorded weight at 12 months ( $\pm 90$  days) and the weights for the remaining participants were imputed. There was a significant difference in weight change at 12 months by group with a mean weight change of -1.2 kg (95% CI, -2.1 to -0.3 kg) in the usual care group, -1.9 kg (95% CI, -2.6 to -1.1 kg) in the online program only group, and -3.1 kg (95% CI, -3.7 to -2.5 kg) in the combined intervention group ( $P < .001$ ; Table 2). The difference in weight change between the combined intervention group and the usual care group was -1.9 kg (97.5% CI, -2.9 to -0.9 kg;  $P < .001$ ) and the

Table 1. Baseline Characteristics of Participants

	Combined intervention	Online program only	Usual care
No. of total participants <sup>a</sup>	298	216	326
<b>Demographic data</b>			
Age, mean (SD), y	60.1 (8.3)	59.1 (8.8)	58.7 (8.6)
Sex, No. (%)			
Male	139 (46.6)	88 (40.7)	109 (33.4)
Female	159 (53.4)	128 (59.3)	217 (66.6)
Race/ethnicity, No./total (%)			
Non-Hispanic White	227/295 (77.0)	169/215 (78.6)	249/326 (76.4)
Non-Hispanic Black	31/295 (10.5)	23/215 (10.7)	39/326 (12.0)
Hispanic	20/295 (6.8)	12/215 (5.6)	24/326 (7.4)
Other <sup>b</sup>	17/295 (5.8)	11/215 (5.1)	14/326 (4.3)
Primary language, No. (%)			
English	288 (96.6)	212 (98.2)	315 (96.6)
Spanish	10 (3.4)	4 (1.9)	11 (3.4)
Highest level of education, No./total (%)			
High school graduate or less	14/258 (5.4)	16/192 (8.3)	23/288 (8.0)
Some college	50/258 (19.4)	45/192 (23.4)	91/288 (31.6)
College graduate	83/258 (32.2)	66/192 (34.4)	102/288 (35.4)
Master's, doctorate, or professional degree	111/258 (43.0)	65/192 (33.9)	72/288 (25.0)
Employment status, No./total (%)			
Employed (full-time or part-time)	169/288 (58.7)	139/213 (65.3)	206/314 (65.6)
Retired	65/288 (22.6)	33/213 (15.5)	63/314 (20.0)
Other	54/288 (18.8)	41/213 (19.3)	45/314 (14.3)
Health insurance, No. (%)			
Private	207 (69.5)	141 (65.3)	217 (66.6)
Medicare	68 (22.8)	50 (23.2)	72 (22.1)
Medicaid or VHA	23 (7.7)	25 (11.6)	37 (11.4)
<b>Anthropometric data, mean (SD)</b>			
Weight, kg	92.9 (13.8)	91.6 (14.4)	91.8 (14.4)
Height, cm	169.2 (9.9)	168.7 (9.9)	167.4 (9.4)
Body mass index <sup>c</sup>	32.4 (3.4)	32.2 (3.2)	32.7 (3.3)
<b>Health and behavior data, No. (%)<sup>d</sup></b>			
Hypertension	287 (96.3)	211 (97.7)	312 (95.7)
Type 2 diabetes	83 (27.9)	49 (22.7)	73 (22.4)
Hypercholesterolemia	56 (18.8)	60 (27.8)	67 (20.6)
Obstructive sleep apnea	56 (18.8)	36 (16.7)	53 (16.3)
Coronary heart disease or atherosclerosis	4 (1.3)	1 (0.5)	2 (0.6)
Non-alcoholic fatty liver disease	3 (1.0)	1 (0.5)	1 (0.3)
Use of glucagon-like peptide-1 receptor agonists or sodium-glucose co-transporter-2 inhibitors	5 (1.7)	1 (0.5)	1 (0.3)
Any previous weight loss attempts, No./total (%)	236/266 (88.7)	182/188 (96.8)	269/291 (92.4)
Motivation to lose weight, mean (SD), points <sup>e</sup>	8.9 (1.1)	8.9 (1.1)	8.8 (1.1)
Internet use, No./total (%)			
≤Once per week	4/260 (1.5)	2/191 (1.0)	6/287 (2.1)
Several times per week	8/260 (3.0)	13/191 (6.8)	14/287 (4.9)
Once per day	14/260 (5.4)	9/191 (4.7)	23/287 (8.0)
≥Several times per day	234/260 (90.0)	167/191 (87.4)	244/287 (85.0)

Abbreviation: VHA, Veterans Health Administration.

<sup>a</sup> Data are expressed as No./total (%) for the rows with missing data.

<sup>b</sup> Includes American Indian/Alaska Native, Hawaiian/Pacific Islander, those who selected multiple categories, and those who selected other for race on the baseline survey but did not provide their race.

<sup>c</sup> Calculated as weight in kilograms divided by height in meters squared.

<sup>d</sup> Unless otherwise indicated.

<sup>e</sup> Assessed on a scale from 1 to 10 where 1 indicates not at all motivated and 10 indicates completely or extremely motivated. Only patients who reported their level of motivation as 7 or higher were included.<sup>26</sup>

difference between the combined intervention group and the online program only group was -1.2 kg (95% CI, -2.2 to -0.3 kg;  $P = .01$ ). There were no significant differences in these effects by sex or educational level (eTable 2 in Supplement 2).

#### Secondary Outcomes

There was a significant difference in the percentage weight change at 12 months by group with mean weight change of -1.4% (95% CI, -2.3% to -0.6%) in the usual care group, -1.9%

Table 2. Mean Changes in Weight-Related Outcomes

	Combined intervention	Online program only	Usual care	P value
No. of total participants	298	216	326	
<b>Primary analysis: changes from baseline to 12 mo<sup>a</sup></b>				
Weight, kg				
At baseline	92.1	91.4	92.3	
Change at 12 mo (95% CI)	-3.1 (-3.7 to -2.5)	-1.9 (-2.6 to -1.1)	-1.2 (-2.1 to -0.3)	<.001 <sup>b</sup>
Weight change at 12 mo, % (95% CI)	-3.0 (-3.8 to -2.1)	-1.9 (-2.8 to -1.0)	-1.4 (-2.3 to -0.6)	<.001 <sup>b</sup>
Participants had ≥5% weight loss at 12 mo, % (95% CI)	32.3 (25.8 to 38.8)	20.8 (14.5 to 27.2)	14.9 (10.2 to 19.6)	<.001 <sup>b</sup>
Confidence in ability to lose weight, points <sup>c</sup>				
At baseline	6.5	6.8	6.8	
Change at 12 mo (95% CI)	0.5 (0.06 to 0.9)	-0.4 (-0.9 to 0.07)	-0.7 (-1.1 to -0.3)	<.001 <sup>b</sup>
<b>Secondary analysis: changes over entire 18-mo follow-up period<sup>d</sup></b>				
Weight, kg				
At baseline	92.1	91.4	92.3	
Change at 6 mo (95% CI)	-2.9 (-3.5 to -2.3)	-2.1 (-2.8 to -1.5)	-1.0 (-1.9 to -0.1)	<.001 <sup>e</sup>
Change at 12 mo (95% CI)	-3.1 (-3.7 to -2.5)	-1.9 (-2.6 to -1.1)	-1.2 (-2.1 to -0.3)	
Change at 18 mo (95% CI)	-2.8 (-3.5 to -2.0)	-1.1 (-2.0 to -0.3)	-1.9 (-2.8 to -1.0)	
Weight change, % (95% CI)				
At 6 mo	-2.8 (-3.8 to -1.8)	-2.0 (-3.1 to -0.9)	-1.0 (-1.9 to 0.03)	.01 <sup>e</sup>
At 12 mo	-2.9 (-3.9 to -2.0)	-1.7 (-2.8 to -0.6)	-1.2 (-2.1 to -0.2)	
At 18 mo	-2.6 (-3.6 to -1.5)	-0.9 (-2.0 to 0.2)	-1.9 (-2.9 to -0.9)	
Participants lost ≥5% of body weight, % (95% CI)				
At 6 mo	29.5 (21.4 to 37.5)	22.1 (14.2 to 30.0)	13.4 (7.8 to 19.0)	.20 <sup>e</sup>
At 12 mo	31.5 (23.4 to 39.5)	20.4 (13.0 to 27.9)	12.7 (7.7 to 17.7)	
At 18 mo	31.3 (23.0 to 39.6)	19.9 (12.5 to 27.3)	20.9 (14.3 to 27.6)	
Aggregate estimate across all 3 time points	30.7 (22.4 to 39.0)	20.8 (13.0 to 28.6)	15.7 (6.2 to 25.1)	<.001 <sup>e</sup>

<sup>a</sup> Used repeated-measures models including baseline and 12-month time points adjusting for age, sex, race/ethnicity, educational level, and medical conditions (type 2 diabetes, hypertension, and hyperlipidemia). Clinic type (community-based clinic, hospital-based, or community health center) was included as a fixed effect. Clinic, physician, and patient were included as random effects. Fully conditional specification multiple imputation with 25 imputations was used to estimate missing weights and other outcomes and covariates and was based on available data for 91 patient variables.

<sup>b</sup> From global *F* tests examining the statistical significance of the study group × 12-month time point interaction term.

<sup>c</sup> Assessed on the baseline and follow-up patient surveys using a 10-point Likert scale where 1 indicates "not at all confident" and 10 indicates "very confident."<sup>23</sup>

<sup>d</sup> Used repeated-measures models including all time points adjusting for age, sex, race/ethnicity, educational level, and medical conditions (type 2 diabetes,

hypertension, and hyperlipidemia). Clinic type (community-based clinic, hospital-based, or community health center) was included as a fixed effect. Clinic, physician, and patient were included as random effects. Fully conditional specification multiple imputation with 25 imputations was used to estimate missing weights and other outcomes and covariates and was based on available data for 91 patient variables. Models also included time × study group interaction terms and no assumption was made that the treatment effects were consistent across time.

<sup>e</sup> From the time × study group interactions. Significant *P* values indicate that the effects of the interventions diverge from each other over time. For the percentage of patients who lost at least 5% of their body weight, the model showed no significant time × study group interaction (ie, the differences among groups were consistent over time). Another model was run without the interaction terms and the aggregate effect across time reflects the overall differences among the study groups.

(95% CI, -2.8% to -1.0%) in the online program only group, and -3.0% (95% CI, -3.8% to -2.1%) in the combined intervention group (*P* < .001; Table 2). There was a significant difference in the percentage of participants with weight loss of 5% or greater by group; 14.9% (95% CI, 10.2% to 19.6%) of participants in the usual care group, 20.8% (95% CI, 14.5% to 27.2%) of participants in the online program only group, and 32.3% (95% CI, 25.8% to 38.8%) of participants in the combined intervention group lost at least 5% of their body weight (*P* < .001; Table 2). In addition, there was a significant difference in change in confidence in the ability to lose weight by group with the mean change of -0.7 points (95% CI, -1.1 to -0.3 points) in the usual care group and -0.4 points (95% CI, -0.9 to 0.07 points) in the online program only group; however, the mean change was 0.5 points (95% CI, 0.06 to 0.9 points) in the combined interven-

tion group (*P* < .001; Table 2). There were no significant differences in other secondary outcomes at 12 months by group (eTable 3 in Supplement 2).

There were significant differences by group in weight change over 18 months (Table 2 and Figure 2). At 18 months, the mean weight change was -1.9 kg (95% CI, -2.8 to -1.0 kg) in the usual care group, -1.1 kg (95% CI, -2.0 to -0.3 kg) in the online program only group, and -2.8 kg (95% CI, -3.5 to -2.0 kg) in the combined intervention group (*P* < .001). The difference in weight change between the combined intervention group and the usual care group was -0.9 kg (95% CI, -1.9 to 0.2 kg; *P* = .10) and the difference between the combined intervention group and the online program only group was -1.6 kg (95% CI, -2.7 to -0.5 kg; *P* = .003). Across the entire 18-month period, the percentage of patients with weight loss of 5% or



**Table 4. Participant Satisfaction With Online Program and Population Health Management Support**

	Combined intervention (n = 298)		Online program only (n = 216)	
	6 mo	12 mo	6 mo	12 mo
No. patients completing survey	196	176	125	127
Satisfaction with online program, No. (%)				
Very satisfied	54 (27.6)	51 (29.9)	25 (20.0)	23 (18.1)
Satisfied	60 (30.6)	48 (27.3)	42 (33.6)	38 (29.9)
Neutral	44 (22.5)	53 (30.1)	33 (26.4)	42 (33.1)
Would recommend online program to family or friends, No. (%)				
Definitely	91 (46.4)	82 (46.6)	53 (52.4)	49 (38.6)
Probably	66 (33.7)	57 (32.4)	42 (33.6)	43 (33.9)
Satisfaction with support or outreach related to online program, No. (%)				
Very satisfied	37 (18.9)	37 (21.0)		
Satisfied	49 (25.0)	42 (23.9)		
Neutral	77 (39.3)	69 (39.2)		

participants in the online program only group (29.9% vs 18.1%, respectively, were very satisfied; **Table 4**).

## Discussion

In this cluster randomized trial among primary care patients with overweight or obesity and a diagnosis of hypertension or type 2 diabetes, there were significant differences in weight change and other weight-related outcomes by group. Participants in the combined intervention group had the greatest weight loss at 12 months, followed by participants in the online program only group and then by participants in the usual care group. There also were significant differences in weight change at 18 months; however, the difference between the combined intervention group and the usual care group was no longer significant due to weight loss in the usual care group between 12 and 18 months. A possible explanation could be that patients in the usual care group may have engaged in other interventions or programs outside the study but this is difficult to evaluate. In addition, the initial weight loss in the online program only group was not sustained over time.

These findings are consistent with previous studies showing that online weight management programs can be effective for helping people achieve and maintain weight loss,<sup>8</sup> including in the primary care setting.<sup>10,27</sup> To our knowledge, this is the first study to demonstrate that an online program can be integrated with existing population health management support delivered by nonclinical staff without any specialized training in nutrition or weight counseling and be implemented in routine primary care.

The low use rates for the online program in this study are consistent with previous studies.<sup>8,28</sup> For example, in a randomized trial of an online weight management program alone or combined with brief telephone coaching, the median number of sessions completed by participants was 1 in both intervention groups.<sup>29</sup> In the current study, use of the online program was not significantly different between the online program only group and the combined intervention

group; however, the number of contacts was higher in the combined intervention group and this suggests that additional contacts may explain the difference in weight change between these groups.

There were no significant differences in changes in cardiovascular outcomes, diet, or physical activity by group and this could be due to lack of power, missing data, or insufficient time for these outcomes. Furthermore, the diet and physical activity measures may not have been sensitive enough to detect small differences across groups. In addition, participants in all 3 groups received general information about weight management, diet, and exercise and all participants were eligible for population health management for hypertension, type 2 diabetes, or both as part of standard care.

These results may have broader implications for health care institutions, primary care physicians, and other clinicians. Although the absolute magnitude of weight loss was small, the interventions were integrated with existing care and delivered by nonclinical staff; therefore, they could have a large effect if they are scalable. Even though the overall weight loss was modest, the mean weight loss among patients in the combined intervention group at 12 months was 3.0%, and approximately one-third of patients had weight loss of 5% or greater, suggesting that the intervention could have an important clinical effect.<sup>3</sup>

This study has many strengths. The interventions were integrated in routine care and leveraged systems-level changes that are now common in primary care. Online weight management programs are generally lower cost and more accessible for patients than face-to-face programs.<sup>30</sup> There was adequate power based on the sample size to detect small but clinically meaningful differences in weight change. Most of the data were collected during routine visits, which reduced patient burden and increased generalizability. Patient-reported outcome measures also were used in addition to clinical outcomes.

## Limitations

This study has several limitations. First, randomization was done by clinic to decrease the potential for contamination;



however, some clinics enrolled patients much faster than other clinics. As a result, the final sample was not equal across the 3 groups and there were some imbalances in characteristics across the groups.

Second, due to the pragmatic nature of the trial, there was heterogeneity in the population health management component of the intervention, as well as limited data on fidelity to the outreach protocol, making it difficult to determine which components of the intervention worked best.

Third, primary care physicians were minimally involved, which may have affected clinical outcomes and patient satisfaction. In addition, the generalizability may be limited, given that the study was conducted at a single institution and the majority of participants were White, well educated, and

English-speaking. Further studies are needed to determine whether the interventions are scalable at other institutions and in other populations.

## Conclusions

Among primary care patients with overweight or obesity and hypertension or type 2 diabetes, combining population health management with an online program resulted in a small but statistically significant greater weight loss at 12 months compared with usual care or the online program only. Further research is needed to understand the generalizability, scalability, and durability of these findings.

### ARTICLE INFORMATION

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**Author Contributions:** Dr Baer had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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**Supervision:** Baer, Halperin, Aronne, Bates.

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Laboratories, Boehringer Ingelheim, Pfizer, Novo Nordisk, Real Appeal, Janssen Pharmaceuticals, and Gelesis; receiving research funding from Aspire Bariatrics, Allurion, Eisai, Eli Lilly, AstraZeneca, Gelesis, Janssen Pharmaceuticals, and Novo Nordisk; having an equity interest in Intellihealth/BMIQ, ERX, Zafgen, Gelesis, MYOS, and Jamieson Laboratories; and serving on the board of directors for MYOS, Intellihealth/BMIQ, and Jamieson Laboratories. Ms Minero reported being employed and having an equity interest in Intellihealth/BMIQ. Dr Bates reported serving as a consultant for EarlySense, which makes patient safety monitoring systems; receiving cash compensation from CDI (Negev) Ltd, which is a not-for-profit incubator for health information technology start-ups; having equity interest in ValeraHealth (which makes software to help patients with chronic diseases), in Clew (which makes software to support clinical decision-making in intensive care), and in MDClone (which takes clinical data and produces deidentified versions of it); and receiving research funding from IBM Watson Health. No other disclosures were reported.

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