One-Year Results of the Think Health! Study of Weight Management in Primary Care Practices

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The Think Health! study evaluated a behavioral weight loss program adapted from the Diabetes Prevention Program (DPP) lifestyle intervention to assist primary care providers (PCPs) and auxiliary staff acting as lifestyle coaches (LCs) in offering weight loss counseling to their patients. In a randomized trial conducted at five clinical sites, study participants were randomly assigned in a 1:1 ratio within each site to either “Basic Plus” (n = 137), which offered PCP counseling every 4 months plus monthly LC visits during the first year of treatment, or “Basic” (n = 124), which offered only PCP counseling every 4 months. Participants were primarily (84%) female, 65% African American, 16% Hispanic American, and 19% white. In the 72% of participants in each treatment group with a 12-month weight measurement, mean (95% CI) 1-year weight changes (kg) were −1.61 (−2.68, −0.53) in Basic Plus and −0.62 (−1.45, 0.20) in Basic. P (difference: 0.98 (−0.36, 2.33)).

RESULTS

In a descriptive, nonrandomized analysis that also considered incomplete visit attendance, mean weight change was −3.3 kg in Basic Plus participants who attended ≥5 LC visits vs. + 0.53 kg in those attending <5 LC visits. We conclude that the Basic Plus approach of moderate-intensity counseling by PCPs and their staff can facilitate modest weight loss, with clinically significant weight loss in high program attenders.

INTRODUCTION

Obesity and its cardiovascular and other health consequences are common problems presenting in primary care settings (1). Approximately one-third of US men and women are obese, with even higher prevalence in African Americans and Hispanic Americans, and women more affected than men (2). Basic principles for facilitating weight loss are well established. When achieved, even modest weight losses are beneficial for reducing associated comorbidities (3–5). The potential for health benefits of lifestyle weight loss interventions was underscored by the results of the Diabetes Prevention Program (DPP), which showed a substantial reduction in the occurrence of diabetes in high risk individuals and similar benefits among ethnically diverse adults of both sexes (4). However, the DPP and prior similar trials with state of the art behavioral weight loss interventions were designed as efficacy studies (6–8) rather than for direct practical application. The challenge is to adapt and evaluate approaches used in such trials to facilitate weight loss among overweight and obese adults in the general population.

Primary care practices are an important route of access to the general population, but too few primary care clinicians offer weight control counseling as recommended by current guidelines (9). Several studies have demonstrated the potential for primary care providers (PCPs), when given appropriate training, to provide effective counseling for a variety of behavior change targets, including smoking, alcohol, nutrition, physical activity, and weight control (10–13). These studies indicate that counseling outcomes vary by behavior, frequency of contact and other programmatic variables, and by the nature of the study population (e.g., whether unselected vs. selected on risk factor or disease status). Effectiveness may also be influenced by a combination of the authority and credibility that PCPs...
have with their patients, as well as the level of engagement evidenced by their ability to build on a supportive and ongoing provider-patient relationship. Whether it is practical to offer behavioral counseling may be determined by the amount of available clinician time.

Think Health! A Personal Weight Management Program, or “Vive Saludable! Un programa personalizado de control de peso” (referred to as Think Health!) was developed and evaluated to contribute to the still inadequate evidence base for practical weight loss counseling models applicable to primary care practices generally (14) and with relevance to practices that reach African Americans and Hispanics (15,16). The DPP Lifestyle Balance Program used Social Learning Theory-based principles for fostering changes in dietary and physical activity behaviors to promote weight loss and weight loss maintenance in an ethnically diverse population (6). The goal for Think Health! was to create a simplified version of the DPP approach suitable for implementation by providers who were not specialists in lifestyle behavior change, within the logistical and time constraints of busy primary care practices. This article describes the 1-year weight change results of a randomized controlled trial (RCT) that compared moderate- and low-intensity versions of the Think Health! program. Using the definitions suggested by the US Preventive Services Task Force, moderate (or medium) intensity was defined as monthly contact, and low intensity was defined as less than monthly contact (14). To date, evidence for the utility of moderate-intensity interventions has been insufficient. As described below, the Think Health! moderate-intensity version involved auxiliary practice staff acting as lifestyle coaches (LCs) to augment PCP counseling.

METHODS AND PROCEDURES

Study design
A detailed description of the Think Health! design, recruitment and start up has been published (17). Briefly, clinical sites were five primary care practices in the Philadelphia, Pennsylvania area, recruited between November 2006 and January 2008. Study participants identified from billing lists and clinician referrals were recruited within these sites between October 2007 and November 2008. Eligible participants were men and women ages 18–70 years, with a BMI ≥27 kg/m² and ≤55 kg/m² and weighing less than 182 kg (400 lb), who had been patients at the practice for at least 1 year or seen at the practice at least twice. Exclusions were: being pregnant or lactating; being nonambulatory; taking systemic steroids, second generation anti-psychotics, or mood stabilizing agents (for which weight gain is often a side effect); undergoing active cancer treatment; and having unstable cardiovascular disease or significant mental health conditions. Eligible participants, stratified by gender and age (≤53 or over 35 year) were randomized to one of two treatment groups in a 1:1 ratio with randomly permuted blocks (block sizes of 2–6). Random assignments were concealed from both participant and study staff prior to implementation. The principal study hypothesis was that participants in the moderate-intensity version of the program (Basic Plus) would achieve a net greater weight loss than those in a low-intensity version (Basic), with assessment of the initial phase of intervention at 1 year post randomization. The low-intensity version was intended to approximate a standardized usual care condition and was not expected to result in significant weight loss. Several providers were already attempting some level of counseling on their own. We were concerned that offering no treatment would be less than the ethical standard of care and would also limit both provider and patient motivation. Total follow up lasted up to 2 years. The targeted sample size was 240 participants to detect a relative advantage for Basic Plus over Basic of 2.4 kg. The Institutional Review Boards (IRBs) of the University of Pennsylvania and the Albert Einstein Healthcare Network approved all study procedures. IRB approval was obtained from or on behalf of all participating primary care practices.

Treatment approach
Think Health! advised a dietary pattern consistent with the US Dietary Guidelines (18) while reducing dietary fat and other sources of calories. Recommended calorie levels were 1,200–1,499 for individuals weighing less than 100 kg (220 lb) and usually 1,500–1,800 kcal/d for those weighing more than 100 kg. The weight loss goal was 5–10% of initial weight; the physical activity goal was to achieve at least 150 min of moderate activity per week. The 16 core DPP sessions were modified based on a prior DPP adaptation (19) (see Supplementary Appendix online). Some DPP core content was put in supplemental handouts, and some was shifted to the maintenance period in the second year of treatment. The amount of content conveyed per session was reduced to a set of key points that could be summarized in a two-page handout (19). These handouts were packaged in participant manuals (see Figure 1), which also included a CD with audio narration of the first 12 sessions, supplemental handouts, and food and activity record forms (Keeping Track logs), along with a calorie counter and resistance band to assist with adherence. Handouts and the audio narration were in both English and Spanish.

For Think Health! the initial intervention period was extended to 1 year rather than the 24 week core in DPP. The DPP initially offered high-intensity contact (30–60 min sessions, weekly, for about 6 months, or 8–16 contact hours over 6 months). Contact was then tapered to every-other-month at a minimum for the remainder of the first year. By contrast, the moderate-intensity Think Health! condition (“Basic Plus”) offered about 2–4h total contact over an entire year (10–15 min sessions every 4 months with the PCP and similarly brief contacts with a LC monthly. The comparison condition (“Basic”) offered only the brief PCP counseling every 4 months and was, therefore, not expected to result in significant weight loss (11).

Weight measurements were taken in association with all treatment visits. PCPs were trained to deliver brief counseling sessions, beginning with an initial session at which they gave the participant the manual, reviewed
the weight measurement, program goals and session 1–4 handouts, and helped the participant set a short-term, realistic goal to accomplish before the next program-related PCP visit. Visits 2 and 3 with the PCP followed a similar format, focusing on sessions 5–8 or 9–12, respectively. Visit 4 was devoted to a year 1 review but otherwise followed the same format. The LC component was implemented by a medical assistant or other staff member with the appropriate level of interest and interpersonal skill. Staff identified as LCs were trained to conduct sessions following lesson materials for that month and, where applicable, for any prior missed visits. The LC also reviewed weight change from the prior visit, as well as food and activity records, and helped the participant select behavioral goals for the ensuing month.

**Treatment implementation**

All five clinical sites were retained. Two of 14 PCPs who participated initially left their respective practices; 1 was replaced by another provider at that site and 1 other PCP joined the study briefly but did not rejoin after returning from leave, for a net of 13 who continued. There were 10 participating LCs initially. Turnover of LC staff occurred at four of the five sites (i.e., staff left the practice or were reassigned and LC duties were assumed by another staff member). The largest site reduced the number of LCs from four to three LCs, for a net of 9 continuing. The year 1 treatment protocol was implemented as intended, although not all treatment visits were completed with all patients due to nonattendance (see Results). Observations by research staff, who were at clinical sites at least once per week, indicated that PCP visits were sometimes conducted separately from billable patient visits. This was within protocol but left to the discretion of the practice. The timing of visits often deviated from the intended schedules of every 4 months (PCP visits) or every month (LC visits), due to various reasons that included characteristics of scheduling systems, PCP, and LC availability, and participant factors. Procedures for scheduling visits at clinical practice sites did not allow scheduling as far as 4 months in advance. This meant that clinical staff (or patient) initiative was required to schedule PCP follow-up visits. To maintain the natural flow of treatment to the extent possible, research staff were instructed to refrain from involvement with the treatment process, including scheduling. However, in some cases research staff assisted sites in preparing postcards sent by the practice to remind participants to schedule study visits. In response to early provider feedback, the original plan to have the PCPs distribute materials for four sessions at each of the first three visits was altered so that all handouts were placed in the participant manuals distributed at the first PCP visit. To accommodate participant interests and to account for missed visits, LCs were permitted to address more than one topic at a given session, rather than necessarily one session per month in sequential order.

**Data collection**

Data collection procedures have been described (17). Research staff obtained baseline measurements and questionnaire data on demographic and personal characteristics during eligibility determination at the patient’s primary care practice site. Dietary behavior was assessed with a 30-item questionnaire for which scores were previously found to correlate with weight change in a study of African American women (20). The Paffenbarger questionnaire, which consists of questions about walking, climbing stairs, and sport or recreational activities, was used to estimate physical activity (21). Data used for the 1-year interim analysis of weight change included participant characteristics, height and weight measurements collected during recruitment, follow-up weight measurements obtained around the time of the participant’s 1-year post randomization anniversary date (at the annual measurement visit), weight measurements associated with treatment visits, and participant feedback provided on a questionnaire completed at the annual measurement visit. Weights from the participant’s medical record were used to fill in missing data (22). To encourage attendance at treatment and research measurement visits, study participants who attended the annual measurement visit were paid a sum equivalent to $5 for visits attended up to that point.

**Data analysis**

All analyses were performed using SAS (v 9.2) and Stata (v 11.1). We conducted both descriptive analyses and modeling of attendance at scheduled PCP visits and LC visits (number and percent of possible visits attended) and mean weight change, and descriptive analyses of percent weight change. Descriptive analyses of mean and percent weight change compared treatment group differences using only weights obtained at 12 months ± 7 weeks post randomization. Comparing weights (treat ment visit or medical record weight minus weight measured by research staff) for the 98 participants who had a weight from each source within the same month showed small intraperson differences (mean difference = 0.1 kg, range, +4.2 kg to −2.6 kg) that were not biased toward either source. Mean differences between Basic (0.04 kg) and Basic Plus (0.14 kg) were similar and very small. Repeating final regression models omitting medical record weights confirmed that using this method had no impact on results.

Mean weight change was modeled with mixed effects linear regression using all available weight measures through month 12 and assumed that data were missing at random (23,24). The actual date the measurement was taken was included to permit treatment group contrasts based on estimated weight at 0 and 12 months. Participant level analyses were “as randomized” (intention to treat) (25). Using a main effect for treatment and time and a time by treatment interaction term, models estimated the relative difference in change over time among the participants assigned to Basic Plus vs. Basic. Random effects accounted for individual variation in baseline weights. Random "slopes" allowed for individual weight trajectories over time to vary around the common mean (23,26,27). In addition, models included clinical site, gender, and age (stratification variables in randomization) and the following baseline factors: married or living with partner (yes, no); full time employed (yes, no); education (high school or less vs. more than high school); cigarette smoking status (yes, no); alcohol drinker (yes, no); race/ethnicity (Black-non-Hispanic, Hispanic, and others); self-rated health (excellent or very good vs. less than very good); and having any one of the following comorbid conditions (hypertension, cardiovascular disease, chronic obstructive pulmonary disease, musculoskeletal disease, and diabetes).

To assess the association of attendance at treatment visits with weight change, we compared mean weight change across categories of attendance at PCP or LC visits. To further examine factors of attendance in Basic Plus while avoiding the bias associated with this type of “as treated” analysis, we adapted the method of Nagelkerke (28) (see Supplementary Appendix online) to estimate the effect of Basic Plus (compared to Basic) among those who complied, according the number of LC visits the participants attended.

### RESULTS

**Participant characteristics**

Randomization resulted in 52.5% (n = 137) of participants assigned to Basic (range 50.8–54.1% across clinical sites) and 47.5% (n = 124) to Basic Plus (range 46.0–49.2% across sites). Table 1 shows baseline participant characteristics overall and by treatment assignment. There were no apparent differences by treatment assignment. Participants were 47 years of age on average, mostly female (84%) and African American (65%), with 16% Hispanic. Average BMI (37.2 kg/m²) was in the class 2 obese range (i.e., 35–40 kg/m²). More than 40% reported a medical history of high blood pressure, and 18% reported having diabetes. Fourteen participants—seven in each treatment arm—had withdrawn by 12 months post randomization (see Figure 2). No study related serious adverse events were reported.

### Program attendance

A total of 116 (85%) of 137 randomized participants in Basic and 118 (95%) of the 124 participants in Basic Plus initiated treatment by attending at least one visit with a PCP or LC within their first 12 months in the study. As shown in Table 2,
more than half (58 and 66%, respectively) of Basic and Basic Plus participants attended at least two of the four possible year 1 PCP visits, and about 40% in each treatment group attended at least three of four visits. In Basic Plus, 44% of participants attended at least five of the possible 13 LC visits.

Weight change
Descriptive data on weight change at 1 year are shown in Table 3. Mean 1-year weight change was larger for participants in Basic Plus vs. Basic: mean (95% confidence interval (CI)) = −1.61 kg (−2.68, −0.53) vs. −0.62 kg (−1.45, 0.20), but the treatment group difference was not statistically significant: 0.98 kg (−0.36, 2.33); \( P = 0.15 \). Using all weight measures from all participants, and adjusting for potential imbalances between groups, the comparable difference in weight change was 1.08 kg (−1.56 for Basic Plus vs. −0.48 for Basic, \( P = 0.093 \)) using a mixed effects linear model with random intercept and slopes to adjust for variability across participants.

The percent of participants with a weight loss of at least 5% of initial weight was greater in Basic Plus than in Basic (22.5 vs. 10.2%, respectively; \( P = 0.022 \)) (bar graph in Figure 3, and Table 3). Percentages generated using all observations with the same mixed effects model described previously, adjusting for confounders, were 16.9% for Basic Plus and 5.8% for Basic.
Lifestyle coach visits to obesity Plus and was observed for both PCP and LC visits, separately.

This effect was clearest and statistically significant only in Basic.

Greater among participants who attended more study visits.

In a secondary analysis, we found that weight change was associated with program attendance.

The association of weight change and program attendance was interdependent for the two types of visits: Basic Plus participants who attended more LC visits also attended more PCP visits. For example, 73% of those who attended nine or more LC visits in year 1 attended all of their PCP visits. Our formal, model-based analyses of the effect of the Basic Plus intervention among those who complied by attending LC visits that made use of participants’ randomization assignments arrived at similar results. Using thresholds for attendance at LC visits ranging from 30 to 60% in the Basic Plus intervention, the model-based expected differences in weight change (of Basic Plus over Basic) over the 12 months ranged from −2.6 to −3.2 kg for these compliers. Consistent with the model-based and adjusted results, the observed 1-year weight change in Basic Plus participants who attended ≥5 LC visits was a loss of 3.3 kg vs. a gain 0.53 kg in those attending <5 LC visits. As expected, this estimated range of weight loss in Basic Plus in relation to Basic exceeded the model-based, as randomized estimate of the treatment group effect (1.08 kg) because it considers the fact that those participants who attended more lifestyle sessions tended to lose more weight.

Table 2 Distribution of attendance at year 1 treatment visits

<table>
<thead>
<tr>
<th>No. of visits completed</th>
<th>Basic (n = 137)</th>
<th>Basic Plus (n = 124)</th>
<th>Lifestyle coach visits</th>
<th>Basic Plus (n = 124)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of participants</td>
<td>15</td>
<td>5</td>
<td>None</td>
<td>7</td>
</tr>
<tr>
<td>1</td>
<td>26</td>
<td>29</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>18</td>
<td>25</td>
<td>1–4</td>
<td>48</td>
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<tr>
<td>3</td>
<td>20</td>
<td>22</td>
<td>5–8</td>
<td>25</td>
</tr>
<tr>
<td>4*</td>
<td>20</td>
<td>19</td>
<td>9–13</td>
<td>19</td>
</tr>
<tr>
<td>100</td>
<td>100</td>
<td>100</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 2 Participant recruitment, withdrawals, and collection of weight measurements through 1-year post randomization.

Figure 3 Table 2 Distribution of attendance at year 1 treatment visits

Phase 1 treatment lasted for 12 months post randomization; for participants who withdrew, visits completed prior to the time of withdrawal were counted.

*Not applicable to Basic. \*In one case the 5th PCP visit occurred within the 12-month anniversary window.

respectively (line graph in Figure 3). Some participants in both treatment groups gained weight. Similar proportions of Basic Plus (6.7%) and Basic (5.0%) participants gained 5% or more of their baseline weight, although the overall distribution of weight change in Basic Plus was more favorable.

**Association of weight change and program attendance**

In a secondary analysis, we found that weight change was greater among participants who attended more study visits. This effect was clearest and statistically significant only in Basic Plus and was observed for both PCP and LC visits, separately and combined (Figure 4). The association of weight change in Basic Plus with visit attendance was interdependent for the two types of visits: Basic Plus participants who attended more LC visits also attended more PCP visits. For example, 73% of those who attended nine or more LC visits in year 1 attended all of their PCP visits. Our formal, model-based analyses of the effect of the Basic Plus intervention among those who complied by attending LC visits that made use of participants’ randomization assignments arrived at similar results. Using thresholds for attendance at LC visits ranging from 30 to 60% in the Basic Plus intervention, the model-based expected differences in weight change (of Basic Plus over Basic) over the 12 months ranged from −2.6 to −3.2 kg for these compliers. Consistent with the model-based and adjusted results, the observed 1-year weight change in Basic Plus participants who attended ≥5 LC visits was a loss of 3.3 kg vs. a gain 0.53 kg in those attending <5 LC visits. As expected, this estimated range of weight loss in Basic Plus in relation to Basic exceeded the model-based, as randomized estimate of the treatment group effect (1.08 kg) because it considers the fact that those participants who attended more lifestyle sessions tended to lose more weight.

**Participant feedback**

Participant perceptions of the program were obtained from the 62% of participants who attended the annual measurement visit, completed the feedback questionnaire, and had attended at least one treatment visit (referred to as “respondents”): 64% in Basic (n = 88) and 60% (n = 74) in Basic Plus. Responses, which were
similar by treatment, confirmed that sessions with PCPs involved distribution of study materials and goal setting. In response to a question asking which of six activities PCPs could do “to help keep you motivated to manage your weight”, the most frequent responses, each chosen by about 65% of respondents, were “keep me up to date about how my weight relates to my health” and “encourage me to keep following the program.” “Help me with managing stress” and “make it easy for me to schedule appointments for our visits” were each chosen by about one third of respondents. About 20% of respondents also indicated that reviewing some of the information with the LC could be helpful. Basic Plus respondents were also asked how the LC could help keep them motivated. The three responses offered—providing encouragement, facilitating scheduling, and reviewing some program information—were chosen, respectively, by 74%, 41%, and 30% of respondents. Three-fourths or more of respondents in both treatment groups found the calorie counter useful. More Basic Plus than Basic respondents indicated the usefulness of the binder (87 vs. 71%, \( P = 0.015 \)), session materials (78 vs. 61%; \( P = 0.02 \)), additional handouts (61 vs. 46%, \( P = 0.051 \)), and Keeping Track logs (62 vs. 41%, \( P = 0.01 \)). About 25% indicated that the audio CD, and 50% that the resistance band, was useful. This was similar by treatment.

**DISCUSSION**

The present results are encouraging with respect to the acceptability and general feasibility of our intervention as a primary care counseling strategy. However, the findings suggest that Basic Plus is associated with only modest weight loss overall, and with clinically significant weight loss for a relatively small proportion. The mean 1-year weight loss in Basic Plus was less than 2 kg. This was larger than the weight loss in Basic, by 1.1 kg in adjusted analysis, which was not statistically significant (\( P = 0.093 \)). The noteworthy proportion of participants in both groups with no weight change or with weight gain provides one explanation for the modest mean weight losses. In studies reviewed by Christian et al., most lower intensity interventions reported relatively small mean weight change (range −1 to −3 kg), with substantial proportions losing 5–10% or greater, but also 20–65% with no change or gain (29). An advantage of Basic Plus over Basic was suggested by the finding that significantly more Basic Plus than Basic participants achieved a clinically significant weight loss (at least 5% of baseline weight) (23 vs. 10%, respectively; \( P = 0.022 \)) at 1 year. Even more suggestive of some potential utility for the Basic Plus approach was the gradient of larger weight loss associated with higher program attendance. A loss of 3.3 kg in Basic Plus participants who attended at least 5 of their LC visits was observed, compared to a gain of 0.5 kg in those attending fewer than 5 visits. In addition, participant feedback was consistent with expectations with respect to intervention delivery, receptivity to the approach, and importance of PCPs and LCs in providing encouragement (and of PCP’s providing health-related feedback).

Only about a fifth of participants attended all of their PCP visits or, in Basic Plus, most of their LC visits. This may have related in part to LC turnover or to scheduling and billing issues. Conducting study visits apart from routine PCP visits departs from what would presumably occur were the intervention integrated into routine care. This undoubtedly increased the burden for patients, administrative staff, and PCPs. Participant feedback confirmed impressions of research staff that scheduling problems may have been a deterrent to attendance for some participants. We are unable to directly assess the impact of these factors on study outcomes. In the pilot study that informed the design of Think Health! (and that reported better attendance and retention than was observed here), only

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**Table 3 Weight change at 1 year by treatment group for participants with a 12-month weight measurement**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Treatment assignment</th>
<th>Difference*</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year weight change (kg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± s.d.</td>
<td>−0.62 ± 4.1</td>
<td>−1.61 ± 5.1</td>
<td>0.98 ± 4.6</td>
</tr>
<tr>
<td>Median (25th and 75th percentiles)</td>
<td>−0.80 (−2.8; 1.7)</td>
<td>−1.30 (−4.70; 1.60)</td>
<td>—</td>
</tr>
<tr>
<td>% Who lost &gt;5% of baseline weight</td>
<td>10.2</td>
<td>22.5</td>
<td>12.3</td>
</tr>
</tbody>
</table>

*Value for Basic Plus minus value for Basic. *For participants with a 12-month weight measurement. \( \chi^2 (df = 1) = 5.212 \).
patients with obesity-related comorbidities were enrolled, and PCP visits were billable visits that focused on management of these comorbidities (19). This approach may be preferable when possible but would not apply to prevention of comorbidities in obese patients unless third party payors were to cover weight loss counseling itself. Nevertheless, particularly given the positive association of attendance and weight loss in Basic Plus, the impact of Think Health! on an overall patient population would probably be improved if visit attendance could be improved. This might help to reduce the proportions with no weight change or significant weight gain. Because moderate-intensity interventions have fewer or less frequent contact opportunities than interventions with higher intensity, the effect of missing visits is magnified.

Other trials of moderate- or low-intensity, physician-delivered weight loss counseling have also reported relatively modest 1-year results. This includes some trials with more than monthly initial contact or with other enhancements to PCP counseling. The Worcester Area Trial for Counseling in Hyperlipidemia study, in which physicians were trained to counsel patients with hyperlipidemia, reported a −1.0 kg weight change in the treatment group that provided only PCP counseling, which was not significantly different from the 0.0 kg weight change in the usual care group (13). Weight loss in a third study arm that provided the PCPs with systematic office support was 2.3 kg, significantly different from usual care. A study in patients with Type 2 diabetes evaluated an intervention in which quarterly counseling visits with trained and prompted physicians were supplementary to computerized individual assessment and behavior change materials. The comparison was a usual care condition in which patients were seen as needed and received no special counseling (loss of 1.4 kg vs. gain of 0.3 kg, respectively; \( P = 0.01 \)) (31). Differences between groups were no longer significant by 12 months: −1.4 kg and −0.16 kg in treatment and control, respectively, \( (P = 0.10) \) (32). Our results can also be compared with 1-year results of the aforementioned randomized pilot study conducted by two of the authors (A.G.T. and T.A.W.), which informed the DPP adaptation and general approach used in Think Health! (19). Patients at two primary care practices were assigned to quarterly PCP visits supplemented by 2 bi-weekly and then 5 monthly counseling sessions with medical assistants, or to usual care supplemented by written weight loss materials only. Similar to the Martin et al. study cited above, the intervention resulted in a significant treatment vs. control difference in weight change at 6 months (−4.4 vs. −0.9 kg; \( P < 0.0001 \)) but a smaller, nonsignificant difference at 12 months (−2.3 vs. −1.1 kg; \( P = 0.31 \)). Together with our findings, these results suggest that treatment augmentation may be needed for programs like Think Health!, although not necessarily by increasing contact frequency.

Methodological strengths of this study for evaluating the moderate-intensity intervention include the within-site randomized design, a protocol with professionally packaged materials that may be feasible for use in many primary care practices, robustness of the protocol to implementation without major modifications, excellent PCP engagement and retention, a high rate of treatment initiation, the validated use of medical record weights to supplement missing outcome data, and statistical analyses that controlled for factors related to nonattendance. Limitations include the difficulty of separating research and practice issues related to feasibility and effectiveness. Research procedures needed to study effectiveness of translation into primary care settings, although an essential step in the translation process, add a layer of complexity. Research procedures altered the flow of patients into treatment compared to what would occur in routine care because of the required hurdles of screening, informed consent, and randomization, and study visits were generally outside of the usual flow. We also cannot assess the impact of other clinical site or provider variables that might be relevant, such as different from usual care. A study in patients with Type 2 diabetes evaluated an intervention in which quarterly counseling visits with trained and prompted physicians were supplementary to computerized individual assessment and behavior change materials. The comparison was a usual care condition in which patients were seen as needed and received no special counseling (loss of 1.4 kg vs. gain of 0.3 kg, respectively; \( P = 0.01 \)) (31). Differences between groups were no longer significant by 12 months: −1.4 kg and −0.16 kg in treatment and control, respectively, \( (P = 0.10) \) (32). Our results can also be compared with 1-year results of the aforementioned randomized pilot study conducted by two of the authors (A.G.T. and T.A.W.), which informed the DPP adaptation and general approach used in Think Health! (19). Patients at two primary care practices were assigned to quarterly PCP visits supplemented by 2 bi-weekly and then 5 monthly counseling sessions with medical assistants, or to usual care supplemented by written weight loss materials only. Similar to the Martin et al. study cited above, the intervention resulted in a significant treatment vs. control difference in weight change at 6 months (−4.4 vs. −0.9 kg; \( P < 0.0001 \)) but a smaller, nonsignificant difference at 12 months (−2.3 vs. −1.1 kg; \( P = 0.31 \)). Together with our findings, these results suggest that treatment augmentation may be needed for programs like Think Health!, although not necessarily by increasing contact frequency.

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as prior experience with conducting research studies, and other practical implementation issues. For example, we do not have data on time spent in counseling or quality of PCP or LC counseling provided. We also cannot assess possible differences in how PCPs counseled participants in Basic vs. Basic Plus (based on their inadvertent knowledge of the participant’s randomization assignment) and do not know the degree of individual tailoring that occurred within counseling sessions. Although materials were standardized, PCPs were encouraged to use their own styles of working with patients generally and with the particular patient. In addition, the absence of an unstructured usual care condition limits the ability to estimate the achieved weight loss that would have occurred in the absence of any counseling or in the presence of the counseling that PCPs would have provided if not adhering to the ‘Think Health’ protocol. The participating PCPs were highly motivated to provide weight loss counseling, and some might have otherwise provided a similar level, although differently.

In conclusion, we note that Think Health! is only one adaptation of the DPP lifestyle intervention. The DPP program has been adapted for translation, with some promising results, using individual, group, or combined counseling approaches with various study designs, populations, and provider types, in other clinical or community settings (33–37). The Think Health! DPP-based, but much less intensive approach, evaluated within the logistical and time constraints of a typical primary care practice, may be inadequate for weight loss management without additional enhancements to improve attendance and strengthen treatment. A key challenge for increasing the impact of this type of program on a primary care patient population is finding ways to identify those who are sufficiently motivated to enroll but are then relatively less likely to participate or participate consistently. Although community programs cannot substitute for effective support of weight control in primary care settings, combining community-based weight loss or exercise programs with primary care encouragement and support may be worth exploring.

SUPPLEMENTARY MATERIAL
Supplementary material is linked to the online version of the paper at http://www.nature.com/oby

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DISCLOSURE
The authors declared no conflict of interest.

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REFERENCES