Comparing Calorie Counting versus MyPlate Recommendations for Weight Loss

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Abstract

Background: For patients with obesity seeking weight loss, federal authorities recommend either calorie restriction of standard food choices/calorie counting (CC) or adopting the MyPlate (MyP) distillation of the Dietary Guidelines for Americans. MyPlate recommends increasing fruit and vegetable consumption, making half of grain choices whole grain, replacing sugary drinks with water, limiting sodium intake, and restricting empty calorie intake. Comparing the effectiveness of these 2 approaches in low-income patients to reduce excess body fat long-term is innovative.

Objectives: Conduct a comparative effectiveness trial of the CC and MyP approaches. Primary patient-centered hypothesis: The MyPlate approach to weight loss will yield greater satiety (indicators: feeling hungry, meal satisfaction, feeling full). Primary medical hypothesis: Both approaches will yield similar reductions in body fat (indicators: weight, waist circumference) at 12-month follow-up. Secondary hypotheses: Mental health, satisfaction with program, and quality of life will increase more in MyP participants than in CC participants. Systolic blood pressure will decrease more in MyP participants.

Methods: Study design: 261 study participants randomly assigned to the CC (n = 130) or MyP (n = 131) conditions. For the 6-months intervention phase, all participants had the opportunity to participate in two 1-hour home health education sessions, two 1-hour group education sessions, and seven 20-minute telephone coaching sessions. Additionally, MyP participants were invited to attend two 1-hour cooking demonstrations. Trained bilingual community health workers delivered the interventions. Study population: Predominantly low-income Latino and African American patients recruited from a federally qualified health center in Long Beach, California. They were 95% female, 86% Latino, 8% African American, and 4% white. Mean age was 41 years. Assessment periods: baseline, 6-, and 12-month follow-ups. Assessments included questionnaire measures, anthropometry, and food frequency questionnaires. Intervention sessions and assessments were conducted in English or Spanish, depending on participant preference. Analyses: Key outcome analyses involved random intercept mixed-effects modeling of repeated measures across the 3 assessments.

Results: Study retention was 77% at 12-month follow-up. The MyP and CC conditions both yielded improved satiety on 2 measures; only the CC condition yielded reduced hunger, contrary to prediction. Both conditions yielded reduced waist circumference for overall sample and for female and Latino participant subgroups but neither condition yielded significant weight loss. MyP yielded reduced systolic blood pressure at 6 months but not at 12-month follow-up; CC participants experienced no change in blood pressure. Both conditions yielded improvements in mental health, health-related quality of life, and satisfaction with their respective weight loss program.
**Conclusions:** Both intervention approaches yielded beneficial changes in satiety, quality of life, and reduction in excess body fat. Patient satisfaction with the program was high in both conditions. For a predominantly low-income, Latino patient population, the simpler MyP approach to reducing excess body fat may be as efficacious as the more complex traditional calorie restriction approach to reducing excess body fat.

**Limitations and subpopulation considerations:** Many participants missed 5 or more intervention sessions, which diminished intervention impact. Acculturation was an important moderating influence on outcomes, with the least-acculturated participants experiencing less intervention benefit than more acculturated participants.
Background and Significance

In the United States, 33.9% of adults are overweight but not obese (between 25 and 29.9 kg/m²) and an additional 35.1% are obese (BMI > 30 kg/m²). Hispanics appear to be at especially high risk (35.1% overweight but not obese, 42% obese), followed closely by non-Hispanic African Americans (28.5% overweight, 47.8% obese). The lifetime medical cost burden of overweight and obese patients is substantial and could be reduced through early treatment and prevention. Through a variety of mechanisms, obesity increases the risk of cardiovascular disease. The American Heart Association and other organizations recommend weight loss and regular physical activity for the prevention and treatment of obesity-related diseases. More particularly, abdominal obesity increases the risk of type 2 diabetes, especially in ethnic minority groups. Lifestyle change efforts promoting weight loss in patients with obesity through increased physical activity and healthier food choices can reduce the risk of type 2 diabetes. Latinos and African Americans are particularly at risk of having type 2 diabetes.

Two rigorous trials of successful weight loss interventions administered to patients recruited from community health centers were reported in 2011. Both trials featured a lifestyle change intervention with no adjuncts such as meal replacement products or use of weight-loss drugs. One of these lifestyle interventions featured a conventional energy restriction approach to weight loss but also featured the Dietary Approach to Stop Hypertension (DASH) diet, a model dietary pattern explicitly recommended by the Dietary Guidelines for Americans for consumption by all healthy Americans, regardless of weight status. The other lifestyle intervention was patterned after the energy-restrictive, behavioral intervention used in the Diabetes Prevention Program (DPP). The DPP lifestyle change approach seeks to create a calorie deficit in overweight patients by increasing energy expenditure in daily physical activity and limiting daily intake of calories. In the DPP, this approach yielded 7% weight loss over 2.8 years and a 58% reduction in risk of diabetes compared with usual care. In the 2011 trials, however, the DASH-like diet yielded a 5.4 kg weight loss at 1 year compared with the 3.4 kg weight loss observed in the DPP-like intervention. This difference in impact of the 2 weight-loss approaches resembled the results of another trial in which a fruit- and vegetable-supplemented fat-restricted diet yielded slightly better 1-year weight loss than a standard fat-restrictive weight-loss regimen. The commercial weight loss program Weight Watchers has achieved success in part by encouraging clients to eat more fruits and vegetables in addition to restricting total daily calorie intake. Other research is confirming the weight control–facilitating benefits of daily consumption of fresh fruits and vegetables.
Table 1. Defining Features of the Calorie Counting and MyPlate Approaches to Desirable Weight Loss

<table>
<thead>
<tr>
<th>Feature</th>
<th>Diabetes Prevention Program&lt;sup&gt;a&lt;/sup&gt;</th>
<th>DASH&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Calorie Counting Approach</th>
<th>MyPlate Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restricts total calories per day</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Requires monitoring of calorie intake throughout the day</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Recommends 8+ servings of fruits and vegetables per day</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Recommends limits on sodium intake</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Recommends limits on saturated fat intake</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Recommends limits on sugary beverage consumption</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Recommends limiting snacks and sweets even if within calorie limits</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Requires restraint when still hungry after eating full meal</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Recommends accompanying exercise ~30+ min. MVPA per day</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Abbreviation: MVPA, moderate to vigorous (aerobic) physical activity.

Both lifestyle change approaches were designed to result in reduced daily energy intake. The classical calorie counting (CC) approach (see Table 1 for a detailed comparison of conditions) focuses on using psychological self-regulatory strategies to motivate adherence, including social support, self-
reward to maintaining desirable weight, and encouragement by trusted counselors, but makes little attempt to alter participant food choices in order to minimize hunger or feeling of deprivation.\textsuperscript{27} Consistent predictors of weight loss maintenance under the CC approach are dietary restraint and disinhibition, neither of which are thought to be dependent on the nature of one’s food choices but rather are thought to be a nearly exclusive function of participant motivation.\textsuperscript{28} By contrast, the DASH diet investigators\textsuperscript{17} focused their lifestyle change efforts on increasing patients’ adherence to the DASH dietary pattern, a dietary pattern sufficiently different from the typical US dietary pattern that good adherence requires major changes in daily food choices.\textsuperscript{29} A defining feature of the DASH dietary pattern (see Table 1 for details) is it encourages daily intake of twice the quantity of fruits and vegetables as is typically consumed in the usual American diet.\textsuperscript{30}

Despite the priority that the DASH diet investigators placed on weight loss,\textsuperscript{17} participants were encouraged to increase their intake of minimally processed fruits and vegetables. The recommendation to eat a greater quantity of minimally processed fruits and vegetables daily has recently been given more prominence as 1 of 7 dietary recommendations associated with www.MyPlate.gov,\textsuperscript{31} the federal initiative that replaced the food pyramid with a food plate as the nation’s leading nutrition education icon (see Figure 1). MyPyramid was the predecessor to MyPlate, included 6 food groups versus 5 for MyPlate; required knowing what a standard serving size was for each food group; encouraged consumption of more grain-rich foods than fresh produce; and seemed to encourage consumption of refined oils, sweets, and other problem food components by including them at the top of the pyramid.

MyPlate (MyP) is simpler, focused on only 5 food groups on the plate and dairy on the side, shows fruits and vegetables as occupying twice the space on the plate as (whole) grains, and highlights that only one-quarter of the plate should be occupied by high-quality protein sources. The specific recommendation is for Americans to fill half their plate with minimally processed fruits and vegetables (fruit juice not included). Counterintuitively, interventions that induce overweight individuals to increase their consumption of minimally processed fruits and vegetables are consistently (but not always) associated with reduced body weight at 6-month,\textsuperscript{18} 12-month,\textsuperscript{22} 2-year,\textsuperscript{32} and 4-year follow-up.\textsuperscript{33} Increased obesity risk has been associated with consuming fruit in the form of fruit juice.\textsuperscript{34} Fruit and vegetable juices typically exclude the dietary fiber that had been in the original fruit/vegetable,\textsuperscript{34} which thereby removes substrate that could have fueled commensal gut microbial generation of short chain fatty acids.\textsuperscript{35} Increased short chain fatty acids, in turn, stimulate increased satiety signaling, thereby reducing appetite.\textsuperscript{36} An additional satiating benefit of consuming more fruits and vegetables is the lower
energy density of minimally processed fruits and vegetables (they are 70% to 94% by weight water), permitting DASH trial participants to increase their total daily gram weight intake of food by 24% even while decreasing their daily energy intake by 10%.37

Figure 1. MyPlate Icon, Downloaded From www.choosemyplate.gov

While both the DPP and DASH dietary approaches reduced excess body weight short term, the ability of patients to maintain these approaches successfully for a lifetime remains to be determined. Short-term emotional well-being is typically increased during adherence to calorie-restriction regimens38-40 but is usually not enough to sustain the desired weight loss beyond 5 years.41 We partly designed this study to address this gap by focusing on the satiety/hunger consequences of food choices and the downstream impact on quality of life and mental health. Previous research has shown that a fruit- and vegetable-supplemented weight-loss program yielded less hunger and greater weight loss at 1-year follow-up compared with a traditional calorie restriction approach.22

The investigators took several steps to adapt the DPP and DASH interventions to ensure the intervention effects for either intervention condition could be sustained over the long term. One step replaced the masters-level health educators with community health workers. The social modeling of Social Cognitive Theory42,43 and experience44 suggest that the predominantly low-income Latino immigrant patient population composing the study population can relate to Latino community health workers better than they can to bilingual but non-Latino masters- or doctoral-level counselors.44 African American type 2 diabetes patients as well as Latino patients have benefited from use of community health workers as behavior change agents.45,46
A second step fixed the maximum coaching sessions at 11 contacts (2 in-home, 2 group education sessions, and 7 telephone coaching sessions) to approach the number of individual-level contacts used in previous clinic-originated weight-loss efforts.\textsuperscript{16,17,47-51} This expanded opportunities for participant–coach problem solving and participant trialing of specific lifestyle change strategies and capitalized on the motivational benefits of monitoring by health care professionals.\textsuperscript{52} The clinic-based study employing the DASH approach included 9 individual sessions, 3 phone contacts, and 12 group sessions in the first 6 months.\textsuperscript{17} The clinic-based study employing the DPP approach included 8 individual or phone contact sessions in the first 6 months.\textsuperscript{16}

A third step devoted more intervention resources to ensuring the participant’s home environment was optimally supportive of healthier lifestyle choices. Two-thirds of calories are typically consumed in the home.\textsuperscript{53} Both physical (eg, type of food available) and social (eg, support from family) factors in this setting have been associated with weight, dietary habits, and activity patterns.\textsuperscript{54,55} A fourth feature (in the MyP condition only) included taste testing to get participants to like a greater range of minimally processed, palatable fruits and vegetables.\textsuperscript{33,56-59} A fifth feature conjoined the nutrition messages from both dietary approaches with the recommendations from the Physical Activity Guidelines for Americans.\textsuperscript{60} For the MyPlate approach, increased daily physical activity engendered greater appetite for minimally processed\textsuperscript{61} water-rich plant foods and minimized intestinal inflammation,\textsuperscript{62} a prerequisite to fiber-induced satiety signaling.\textsuperscript{63} For the calorie counting approach, additional physical activity increased the energy expenditure side of the energy balance equation.\textsuperscript{60}

In sum, this study compared the intervention impact of 2 government-sanctioned weight-control approaches on satiety, a patient-centered outcome, and on body fatness, a conventional medical outcome. We expected the new MyP high-satiety/high-satiation approach to desirable weight loss to yield increasing satiety over time, over and above whatever increases in satiety might be observed in the more traditional CC condition. We expected the increased satiety, in turn, to engender increased mental health and increased quality of life, 2 correlates of long-term adherence to desirable lifestyle changes.\textsuperscript{64,65} Even though we expected the MyP arm to yield greater satiety, we expected it to be as effective in reducing body fat at 12-month follow-up as the more traditional deprivation-focused CC weight-loss approach.
Participation of patients and other stakeholders in the design and conduct of research and dissemination of findings

Patient representatives. Maria Chandler, MD, MBA, chief medical officer of The Children’s Clinic of Long Beach (TCC), California, agreed that TCC would participate as a partner in the proposed comparative effectiveness trial of 2 government-sanctioned approaches to weight control. She identified 2 patient representatives familiar with TCC. One was Ms. Evangelina Ramirez, a Spanish-bilingual community organizer and member of TCC’s community advisory board. The other was Ms. Stephanie Love, a clinic manager/vocational nurse and articulate representative of the local African American community. Their input was critical to the design of the intervention protocol. For example, at their insistence childcare was included as part of the group education offerings, to make it possible for low-income mothers to attend the group education sessions while somebody else looked after their child/children. They participated in the study’s community advisory board meetings and were available as needed throughout the study. When accrual was lagging relative to what was expected, they were instrumental in identifying a second recruitment site and reassuring the research assistance staff that nothing about the recruitment protocol was inadvertently alienating possible study recruits. They helped address the perennial problem of study retention with their respective patient populations and were important advocates for higher incentives to boost participant completion of the 12-month follow-up assessment. Their input enabled the research staff to achieve 80.1% retention (when including 9 women who became pregnant and were therefore not included in analyses) at 12-month follow-up, thereby optimizing the study’s internal validity by minimizing selection bias. They actively participated toward the end of the study in interpreting the results and suggesting practical strategies for disseminating the results to their respective communities.

Community advisory board. With input from Dr. Chandler, the study patient representatives, and TCC’s director of community outreach, the investigators identified 15 members who constituted the community advisory board (CAB). In addition to Dr. Chandler and the patient representatives, the CAB included 15 members representing a broad cross-section of the Long Beach, California, community, including physicians; dietitians; community gardening specialists; 2 patient representatives; the local YMCA; a pastor; a health educator, and, ex officio, the UCLA principal investigator. They first met in June 2014 to discuss the aims, protocol, and instruments. This CAB was reconvened in March 2017 to discuss the study’s preliminary results and to assist the investigators in interpreting the results and suggesting
how to build on lessons learned.

**Focus groups and key stakeholder interviews.** Most of the focus group participants and key stakeholders who were interviewed were identified by members of the community advisory board. The investigators conducted 2 focus groups, one consisting of Spanish-speaking obesity patients, the second consisting of English-speaking obesity patients. Criteria for focus group participant selection were similar to the criteria expected in recruiting study participants to ensure comparability of demographic characteristics between focus group participants and study participants. The investigators also interviewed 6 community stakeholders, none of whom were patients from TCC but who were actively engaged members of the Long Beach community. The key stakeholder interviewees included a pastor, a community activist, and other community leaders knowledgeable about the dietary practices and physical activity habits of Long Beach residents and knowledgeable about the health promotion resources available in Long Beach.

The discussion guide that directed the focus group discussion and key stakeholder interviews asked 6 questions about the interlocutors’ attitudes toward food choices, 5 questions about their attitudes toward physical activity, and 8 questions about strategies to improve both the quality of their food choices and their daily level of physical activity. The discussion guide preamble stated the participants’/interviewees’ answers would help the investigators design a better weight-loss intervention for TCC patients who were overweight or obese and wanted to lose some of their excess weight. The questions for the discussion guide were based on the investigators’ previous experience with promotora-led, home-based dietary intervention with Latinos. The focus group discussion lasted 1 hour and took place in a community setting operated by the Long Beach Health Department. The key stakeholder interviews lasted approximately 35 minutes. All participants were rewarded with a $20 gift card following their participation. Seven of the 8 focus group participants were women; 4 of the 6 key stakeholder interviewees were women.

A Spanish-speaking bilingual, bicultural Latina graduate student well experienced in the collection of qualitative data facilitated the focus groups. The notetaker was also a bilingual female graduate student. Although the discussions were audio-recorded they were not transcribed. The content analyses used the notetaker’s notes as the source of the data. When questions arose concerning the meaning of the notetaker’s notes, the content analysts consulted the audio record. The analysis protocol used to sort the themes was based on the protocol described in Krueger and Casey.66

Results suggested that the original design of the MyPlate community health worker–based
home environment–focused lifestyle change intervention was sound but needed minor modifications. Participants in the Spanish-speaking focus group were particularly receptive to the idea of a community health worker coming into the home to advise residents about visual cues, home equipment, and family routines that could, if adopted, increase residents’ adherence to federal nutrition and physical activity recommendations. While participants in the English-speaking focus group were more ambivalent about a community health worker coming into the home, when it came to specific behavioral strategies they were equally supportive. All key stakeholder interviewees supported the idea of having a community health worker making home visits to advise residents on ways to increase their adherence to recommended guidelines, some of them enthusiastically so. The overall impression from all of these data, then, was support for the general concept of the original MyPlate intervention design, but specific cautions about employing certain intervention strategies, such as (1) insisting on starting every day with a healthy breakfast, (2) serving only noncaloric beverages to guests, (3) having household members do gardening every week (if a garden was available), and (4) insisting that household members needed to sleep 7 to 8 hours a night.

The MyPlate approach resonated with focus group members as a particularly appropriate vehicle for communicating nutritional priorities to the mostly low-income, Latino TCC patient population because it requires minimal literacy and numeracy skills. The CC approach, by contrast, requires the ability to read food labels (literacy) and the ability to track and add up daily calories consumed (numeracy). Moreover, the MyPlate emphasis on fruits, vegetables, legumes, and nuts accorded well with immigrants raised on the traditional Mesoamerican diet of maize, beans (eg, black, pinto), and squash (eg, pumpkin, acorn squash). Using bilingual, bicultural community health workers as the change agents rather than masters-level health educators was also consistent with community health practices in low-income Latino communities.

Methods

1. Study design. The investigators conducted a parallel group, a randomized controlled comparative effectiveness trial comparing MyP with calorie counting partly to help reconcile 2 conflicting messages from government-sanctioned sources about practical strategies for losing excess body weight. More specifically, should individuals engage in portion control and restricting calories from all foods (as originally recommended by the Diabetes Prevention Program) or should they eat MORE fruits and vegetables (as recommended by MyPlate consumer messages), even as they try to reduce overall daily
calorie intake to match what their bodies need for daily metabolic needs? If the study was well implemented (ie, high fidelity and low study attrition) and if results confirmed the hypothesis that increased consumption of fiber-rich plant foods (as recommended by MyPlate/DASH) facilitated weight loss measured at 12-month follow-up, this randomized controlled trial would permit confident causal inferences about the weight-control benefit of encouraging low-income Americans to eat MORE fruits, vegetables, legumes, whole grains, and nuts.

2. **Forming the study cohort.** African American and Latino adults in the United States have the highest age-adjusted rates of obesity relative to other major ethnic groups. The investigators therefore partnered with TCC, whose baseline population of adult patients was 76% Latino and 13% African American. Eligibility criteria included (1) body mass index of between 27 and 40, (2) ability to communicate either in English or Spanish, (3) aged 18 years or older, (4) willingness to change diet and exercise patterns, (5) willingness to accept randomization to either intervention group, and (6) ability to give informed consent. Exclusion criteria included (1) pregnancy, (2) major cardiac event or stroke-related medical procedure in the past 6 months, (3) prior or planned bariatric surgery, (4) use of prescription medication for weight loss in the past 6 months, (5) chronic use of medications likely to cause weight gain or weight loss (eg, antidepressants, mood stabilizers), (6) glucose control diabetes medications, (7) corticosteroids, (8) antiseizure medications, (9) beta-blockers, (10) current cigarette smoking, (11) problem alcohol use, (12) psychiatric hospitalization in the past year, (13) plans to move from the area in the next 12 months, (14) unstable angina, and (15) blood pressure greater than 160/100 mm. The most common reason for these exclusions is that patients with these conditions would have difficulty adhering to intervention recommendations. Patients with uncomplicated type 2 diabetes could participate in the trial but only after being permitted to do so by their primary care provider. We included this last proviso at the behest of physicians who argued that patients newly diagnosed with diabetes could benefit from participation in a behavioral weight loss program and should not be barred from participation if they had not yet experienced complications from their disease.

To achieve satisfactory statistical power to detect the expected experimental difference in satiety, we relied on past literature involving use of a fruit-and-vegetable approach to facilitate weight loss. With an effect size ([(mean baseline − mean follow-up)/mean standard deviation] of 0.52 ([53.5 − 46.7]/13.2 = 0.52), the estimated per-condition sample size needed to detect an effect at 12-month follow-up was n = 72 (Cohen, 1992 #6905). To have the power necessary to evaluate differences in body fat
assessment at 12-month follow-up, we relied on the 3 studies cited above, which yielded per-condition sample size estimates of n = 103 to n = 135. For the proposed 2-arm study and allowing for 20% attrition at 12 months, we set the prudent sample size target at N = 300. We halted accrual at N = 261 because of slower than expected accrual. Accrual was slower than anticipated despite the planned contingency of slightly enlarging BMI-contingent eligibility from 30 > BMI < 40 to 27 > BMI < 40. We made this change in BMI eligibility retroactively to include potential recruits who had originally been told that their BMI was too low but whose BMI was larger than 27.
Figure 2. CONSORT flow diagram showing reasons for study attrition

Assessed for eligibility (n= 2,086)

Excluded (n=1,825)
- Actively declined to participate (not interested) (n=932)
- Screening in waiting room interrupted by medical personnel (n=95)
- Screening in waiting room halted by patient for unstated reason (n=61)
- Screening not completed by end of accrual period (n=23)
- Not meeting inclusion criteria using self-report info (n=506)
- Not meeting inclusion criteria using objective measures (n=138)
- Refused anthropometric assessment (n=39)
- PCP approval denied (n=6)
- Spoke no English & no Spanish (n=4)
- Declined to sign consent form (n = 3)
- Failure to get primary care provider approval in time (n=18)
- Lost to follow-up (n=25)
  - Lost to follow-up: 12
  - Time constraints (work): 4
  - Unable to complete by end of accrual period: 4
  - Patient withdrew from study post-enrollment: 2
  - Moved out of the area: 2
  - Deceased: 1

Allocated to MyPlate intervention (n=131)
- Received allocated intervention (n=111)
- Did not receive allocated intervention (n= 20)
  - Lost to follow-up: 5
  - Time constraints (work): 4
  - Childcare issues: 3
  - Moved out of the area: 2
  - No longer interested: 2
  - Family issues: 1
  - Time constraints (school): 1
  - Extreme financial issues: 1
  - Deceased: 1

Allocated to Calorie Restriction intervention (n=130)
- Received allocated intervention (n=106)
- Did not receive allocated intervention (n=24)
  - Lost to follow-up: 9
  - Time constraints (work): 5
  - Moved out of the area: 3
  - No longer interested: 3
  - Family issues: 2
  - Time constraints (School): 1
  - Homeless: 1

Discontinued intervention (n=9)
- Time constraints (work): 2
- No longer interested: 2
- Time constraints (family): 1
- Pregnancy = 4

Lost to follow-up (n=27)
- Lost to follow-up: 15
- Time constraints (work): 3
- Unable to complete by end of accrual period: 3
- Patient withdrew from study post-enrollment: 2
- Dropped from the study (found to be ineligible: 1
- Moved out of the area: 1
- Medical Issues: 1
- Family issues: 1

Discontinued intervention (n=8)
- Medical Issues: 1
- Family issues: 1
- No longer interested: 1
- Pregnancy = 5

Analyzed (n=102)
- Excluded from selected analyses: 10 were assessed at home or via phone but unable to come to clinic for anthropometry; their f-up anthropometric assessments are missing

Analyzed (n=98)
- Excluded from selected analyses: 12 were assessed at home or via phone but unable to come to clinic for anthropometry; their f-up anthropometric assessments are missing
All participants were recruited in TCC waiting rooms. Bilingual male and female research assistants approached 2,086 adult patients, regardless of perceived corpulence, as they waited for their appointment with their health care provider (see CONSORT flow diagram, Figure 2). The order in which waiting room patients were selected was determined by computer-generated random numbers to ensure representativeness of the TCC patient population. Overall, 44.7% (932 of 2,086) declined to be screened for eligibility for the trial, and among the 364 who appeared to be eligible, 28.3% (103 of 364) declined to participate in the trial. The most common reason for declining to participate was lack of interest (45%). Another 24% were found ineligible based on self-report anthropometric and blood pressure information. Subsequent assessment—using objective anthropometric measures or use of a sphygmomanometer led to an additional 7% being found ineligible. Of potential recruits, 7% were unable to complete the screening, generally because registration desk staff announced that the patient’s primary care provider was now available to meet with him or her. The remainder were ineligible for other reasons, such as not speaking either English or Spanish.

3. Study setting. Although initial contact with the patient was in the clinic waiting room, most of the health education sessions occurred offsite. Two of the sessions took place in the patient’s home because those sessions focused on how to make the home environment more supportive of healthier lifestyle choices. One group education session took place in the grocery store because that session focused on strategies to make typical food shopping more supportive of healthy food choices. Most of the coaching sessions took place by phone at times convenient to the study participant. Group cooking sessions took place at TCC or at community sites close to TCC.

4. Interventions/Choice of comparators. It has been established that overweight patients are highly interested in receiving advice from their primary care physicians about effective lifestyle change approaches to losing excess weight. The investigators chose to compare 2 government-recommended lifestyle change approaches to healthy weight loss with somewhat conflicting recommendations. Calorie counting approach. The traditional government recommendation given to clinicians about effective advice for patients wanting to lose excess weight is well-reflected by the information at http://win.niddk.nih.gov/publications/talking.htm#staff or at http://www.healthfinder.gov/prevention/ViewTopic.aspx?topicId=25. This information focuses on getting the patient to deliberately adhere to an energy-deficit diet, where energy expenditure exceeds energy intake. The behavioral pathways to achieving a daily energy deficit include increased physical
activity, careful monitoring of energy intake (ie, calorie counting), and deliberate reduction of food portions commonly consumed to ensure adherence to lower-than-usual daily calorie intake. While there is some mention of substituting low-calorie foods such as fruits and vegetables for high-calorie foods, the focus is on reducing the amount of current food choices rather than on changing the nature of the foods consumed. With a couple of exceptions (see Table 1), the defining features of the calorie counting approach were identical to the defining features of the diet prescribed in the Diabetes Prevention Program. At the insistence of community members composing our community advisory board, the calorie counting approach now explicitly encourages eating more fruits and vegetables regardless of calorie limits and discourages consuming sugary beverages.

Community dietitians who counsel their overweight patients to engage in calorie restriction said their counseling nonetheless included recommendations to patients that they consume more fruits and vegetables and that they limit sugary beverage consumption. They said not including these departures from the traditional calorie restriction approach would be unethical, withholding from the patient behavioral strategies now widely recognized as helpful in facilitating weight loss. More specifically, participants in the CC condition were prescribed a daily calorie goal based on body weight. Following the Diabetes Prevention Program, participants who weighed ≤ 114 kg (≤250 lb) were prescribed 1200 to 1499 kcal/d and those > 114 kg (>250 lb) were prescribed 1500 to 1800 kcal/d. All participants were encouraged to aim for the lower end of their range.

MyPlate Approach. By contrast, the www.MyPlate.gov initiative explicitly calls for changing the proportion of one’s plate that is devoted to different food groups, eating more minimally processed fruits and vegetables relative to other food groups, favoring whole grains when grains are consumed, replacing high-fat dairy with low-fat or nonfat dairy, replacing sugary drinks with water, and choosing lower-sodium alternatives. The defining features of the MyPlate approach were the defining features of the DASH dietary pattern (See Table 1). These included encouragement to consume fewer snacks and sweets. The behavioral pathways to achieving a daily energy deficit using the MyPlate approach include doubling typical intake of (minimally processed) fruits and vegetables, limiting intake of caloric beverages, engaging in moderate physical activity every day, and limiting sodium intake. The message that Americans can achieve a healthier weight by eating more of some foods is a relatively new message and one that would benefit from comparative assessment with the government’s more traditional calorie counting, portion-control approach. Study attrition did not differ by experimental condition in a clinical trial of overweight adult women and we did not expect differential attrition to be a problem in here. Protocols for both approaches have been well detailed in recent clinical trials and have been
associated with good study retention (78%-86%) at 1-year follow-up.\textsuperscript{16,17}

Participants were randomly allocated to the MyPlate or calorie counting condition only after providing informed consent to participate and completing all baseline assessment questionnaires. The research staff were thus kept blind to the patient’s experimental condition during enrollment activities and baseline assessment. Once baseline activities were concluded, the REDCap online survey program generated the random assignment to experimental condition.

Comparability of intervention exposure. Both conditions entailed the same number of contacts between the community health workers conducting the lifestyle change coaching and the study participants regardless of assignment to condition. These contacts included 2 health education sessions in the home setting, 2 health education sessions in a group setting, and 7 telephone coaching calls, all to be completed within 6 months of enrollment. Weekly debriefing calls between the investigators and the community health workers and the nesting of community health workers in each intervention ensured optimal adherence to the intervention protocols. Process questions were asked of study participants concerning number of sessions completed and satisfaction with different components of the intervention that enabled assessment of the impact of participant compliance to the intervention protocol.

5. **Follow-up.** In this prospective 1-year trial, follow-up assessment occurred at 6 and 12 months after the enrollment date for most measures. At each assessment, the questionnaire and anthropometric measures took 60 minutes to complete; the addition of program evaluation questions at follow-up increased the assessment time to 80 minutes. Ideally, the 20-minute food frequency questionnaire (FFQ) assessment took place concurrently with the questionnaire and anthropometric assessment, but in practice participants preferred to complete the FFQ by phone with a trained nutritionist. Food frequency questionnaire assessments were limited to baseline and 12-month follow-up. Despite its desirability, collection of food frequency data at the 6-month follow-up was thought to pose an excess burden on study participants and was considered less important than 12-month follow-up for documenting intervention-related dietary change. For most participants, exposure to all study intervention activities had ceased by the 6-month follow-up assessment. They were expected to continue adhering to their respective lifestyle change prescriptions and knew that their level of adherence would be assessed at 12-month follow-up. To accommodate unexpected interruptions in some participants’ lives, make-up intervention sessions were permitted for several weeks after the 6-month assessment.
6. **Study outcomes.** The conventional primary outcome in previous trials of clinic-based weight-loss interventions has been body weight.\textsuperscript{16,17,80,81} Successfully reduced body weight achieved at 12-month follow-up has not been enough to sustain a healthier body weight for 4 years or more,\textsuperscript{82} in part because the calorie restriction approach has been accompanied by increased hunger relative to a fruit- and vegetable-supplemented approach.\textsuperscript{22} For dietary changes to be sustained for a lifetime, not only does the excess weight need to be lost but the successful weight loss regimen also needs to leave the patient feeling satisfied after each day’s meals.\textsuperscript{83,84} Hence, the investigators chose to include the hunger scale used in previous research\textsuperscript{22} as well as 2 additional questions about meal satisfaction and a feeling of fullness\textsuperscript{85} as primary endpoints. We evaluated the choice of terms for assessing these facets of the satiety construct using cognitive interviewing techniques to ensure study participants correctly comprehended the meaning ascribed to these terms by the investigators. These terms were also vetted by focus group participants, the patient representatives, and members of the community advisory board.

The published intervention trial that comes closest to the study proposed here was a comparison between a standard low-fat energy restriction (only) approach compared with a low-fat energy restriction approach accompanied by encouragement to consume more fruits and vegetables (F&V). A key finding in this study was that the F&V intervention yielded greater 1-year weight loss but significantly LESS daily feeling of hunger than the more conventional low-fat energy restriction approach.\textsuperscript{22} This trial used “How hungry did you feel today?” The trial also used a visual analogue scale (VAS). The VAS consisted of a 100-mm line anchored at either extreme by “Not at all hungry” and “Extremely hungry.” Participants placed a hash mark on the line that represented the level of hunger they remembered having experienced after the preceding day’s last meal. We scored each VAS by measuring the distance from the left end of the line to the participant’s hash mark.\textsuperscript{86,87} In this trial, the 3 satiety items were prefaced by “Take a moment to remember the last meal you ate yesterday.” The wording of the hunger item was “Thinking about yesterday, how hungry did you feel during the day?” The VAS scale was anchored by “Not at all hungry” on the left and “ Extremely hungry” on the right. The wording of the meal satisfaction item was “Thinking about the last meal you ate, how satisfied were you after you ate that meal?” The VAS scale was anchored by “Very satisfied” on the left and “Very unsatisfied” on the right. For analysis purposes, this scale was reverse-scored, so high scores connoted satisfaction. Finally, the fullness item was “Thinking about the last meal you ate, how full did you feel after you ate that meal?” The VAS scale was anchored by “Completely full” on the left and “Not at all
full” on the right. For analysis purposes, this scale was reverse-scored, so high scores connoted fullness.

We originally assumed that these 3 measures of satiety would be sufficiently similar to justify including them in a single scale, to avoid the problem of inflation of type 1 error associated with multiple hypothesis testing, but the internal consistency (Cronbach $\alpha = 0.43$) was unacceptably low. However, all 3 measures have been used in nutrition research to represent the satiety construct to good effect,²²,⁸⁵,⁸⁸ so we retained all 3. To correct for the inflation of type 1 error in multiple comparisons,⁸⁹ we used the Bonferroni correction to set the nominal critical $P$ value to $p = 0.0167$ instead of $p = 0.05$.

While the hypothesis was that the MyPlate diet, with its doubling of fruits and vegetables, would yield greater satiety and reduced feeling of daily hunger than the DPP-like diet, a confounding contributor to feeling hunger is meal skipping, both voluntary and involuntary. The lifestyle change coaches were trained to encourage breakfast eating in both conditions and to discourage meal skipping. Patients dependent on government food assistance may also experience periods of involuntary hunger. Two questions about food insecurity were asked of all participants and used as covariates to help control for the hunger-generating effects of periodic meal skipping. In this study, food insecurity means a household-level economic and social condition of limited or uncertain access to adequate food.⁹⁰ The specific questions were the following: “In the last 12 months, did you ever eat less than you felt you should because there wasn’t enough money to buy food?” “In the last 12 months, were you ever hungry but didn’t eat because you couldn’t afford enough food?” The answer options were “Yes,” “No,” “Refused,” or “Don’t know.”

**Primary patient medical outcome included 2 indicators of body fat composition:** weight (kg) and waist circumference.

Anthropometric measures of body fatness are conventionally used to assess the impact of clinic-based weight-loss interventions.¹⁶,¹⁷ Weight (kg) was measured at each assessment in the clinic setting. Weight in light indoor clothes without shoes was recorded by trained, certified staff using a high-quality digital scale (Tanita). Duplicate measurements were made to ensure reliability. Weight was measured in pounds for ease of interpretation by the participants and subsequently converted to kilograms for data analysis. Scales were calibrated weekly using Troemer standardized weights (Thorofare, New Jersey). The weight at screening/baseline determined eligibility (27.0 ≤ BMI ≤ 40.4). The difference between body weight obtained at screening/baseline and 12-month follow-up was the primary patient medical outcome.

Although easily measured by patients, body weight is an imperfect gauge of metabolically
Waist circumference is arguably a better reflection of abdominal fat, which is a more consistent risk factor for metabolic disease than subcutaneous fat.\textsuperscript{92-95} Participants’ waist circumference was therefore measured at each assessment. Waist circumference (cm) was measured by trained staff using an anthropometric measuring tape (Gulick anthropometric tape) at a horizontal plane around the abdomen just above the uppermost lateral border of the right iliac crest (ie, the top of the hip bone).\textsuperscript{96} Obesity cut points of 88 cm (women) and 102 cm (men)\textsuperscript{96} were considered cut points separating those at risk of obesity-related disease from those not at risk.

**Prespecified secondary outcome measures.** To replicate DASH trial blood pressure outcomes\textsuperscript{18,19} for the MyP condition, we included measurement of resting systolic blood pressure at each assessment for study participants in both experimental conditions. The study participant rested for 5 minutes before having the first blood pressure assessment using an automated sphygmomanometer that was calibrated regularly against a Life Source UA-767 Plus, A&D Medical digital blood pressure monitor. Blood pressure was obtained by trained data collectors according to a standard protocol, adapted from that used by the Center for Disease Control.\textsuperscript{9} Two measures were taken 1 minute apart. If these 2 measures varied by more than 5 mm, then a third measure was taken and averaged with the preceding 2 in analyses.

**Intervention check.** Using the MyPlate icon (at www.choosemyplate.gov) the community health workers in the MyP intervention stressed the importance of filling half of one’s plate with (minimally processed) fruits and vegetables. CC participants were also encouraged to consume more fruits and vegetables but only because of their low energy density. All participants answered questions about how much of their average plate they filled with fruits and vegetables. The answer options were as follows: “None,” “Quarter plate,” “Half plate,” “Three-quarters plate,” and “Full plate.”

**Health-related quality of life and mental health.** In theory, the high-satiety approach of the MyPlate approach should lead, over time, to a lower sense of deprivation and hunger during active weight-control efforts than traditional calorie restriction approaches and to enhanced health-related quality of life\textsuperscript{39} and lower risk of depressiveness.\textsuperscript{98} We therefore included the SF-12 health-related Quality of Life Scale\textsuperscript{99,100} and the Mental Health Index-5 (MHI-5) mental health scale.\textsuperscript{100} All items of both scales had originally come from the SF-36.\textsuperscript{101} For the SF-12 health-related quality of life measure, the convention is to take the 12 items, with answer options ranging from dichotomous items to 6 ordered options, and scale them such that the maximum score for each item is 100. High scores represent a high quality of life; low scores represent a low quality of life.

Three of the MHI-5 items were taken from the SF-12 and the remaining 2 items were taken from
The MHI-5 items included the following questions: “How much of the time during the last month have you (1) been a very nervous person?; (2) felt downhearted and blue?; (3) felt calm and peaceful?; (4) felt so down in the dumps that nothing could cheer you up?; and (5) been a happy person?” All items included the following answer options: (1) “All the time,” (2) “Most of the time,” (3) “A good bit of the time,” (4) “Some of the time,” (5) “A little of the time,” and (6) “None of the time.” Items were reverse-coded, as necessary, so that high scores represented greater mental health.

Secondary outcome measures (not prespecified). The scientific literature on behavior change weight-loss programs includes a variety of behavioral, psychological, and social measures as covariates. To optimize the comparability of our results with the results reported in the literature, we included the following covariates: (1) self-reported physical activity, (2) television watching as a proxy for sedentary behavior, (3) family support for healthy eating, (4) family support for leisure time physical activity, (5) food frequency questionnaire assessment of typical food choices in the last year, and (6) acculturation. We included acculturation in part because the investigators were aware that many TCC patients were immigrants. The food frequency questionnaire was administered at baseline and 12-month follow-up. All the other covariates were administered at baseline and at 6- and 12-month follow-up. We determined inclusion of specific covariates in regression analyses by theory, not by stepwise methods. Information about how these covariates were coded when included in regression analyses is below.

Physical activity (2 indicators: self-reported minutes of moderately vigorous-equivalent minutes of physical activity per week and heart rate). Advice to increase daily physical activity to at least 30 minutes of moderate to vigorous physical activity at least 5 days a week was given to participants in both conditions. Participants in both conditions received a “gym in the bag” that included a 10-minute “Instant Recess™” DVD featuring fun dance routines, resistance bands, a pedometer, and charts with which to monitor progress. Self-report questions were taken from the International Physical Activity Questionnaire—short version\textsuperscript{102} to assess the frequency and duration of different moderate and vigorous forms of physical activity. This 7-item questionnaire collects information on the time (ie, number of days and average time per day) spent being physically active and measures vigorous-intensity activity, moderate-intensity activity, walking activity, and sitting in the past 7 consecutive days. An aggregate weekly number of moderately vigorous physical activity-equivalent minutes were calculated from these responses and entered into regressions as a continuous measure after truncation of outliers.

Objective measure reflective of physical fitness: heart rate. Heart rate has been used as a proxy measure of physical fitness that covaries reasonably well with peak oxygen uptake, the gold standard for fitness assessment.\textsuperscript{103} The resting heart rate was obtained automatically during the blood pressure...
assessment, following a 5-minute rest and expressed in beats per minute. When included in regression analyses, the resting heart rate was given as an integer between 40 and 110 beats per minute.

TV watching. Reducing time spent watching TV was particularly encouraged in the MyP condition because of evidence that fruit and vegetable intake was inversely associated with number of hours of TV watching per day.\textsuperscript{104} This was a self-report item that asked, “Over the past 30 days, on average how many hours per day did you sit and watch TV or videos?” Answer options were 0 hours, <1 hour, 1 hour, 2 hours, 3 hours, 4 hours, and 5 or more hours. When included in regression analyses, this measure was represented by dummy values ranging from 1 (0 hours) to 7 (5+ hours) because they were normally distributed.

Family social support for healthy eating. Study participants completed 8 items adapted from measures of family support for healthy eating,\textsuperscript{105} yielding a scale with acceptable reliability (Cronbach $\alpha = 0.81$). The stem was “During the last 3 months, my family (or members of my household) . . .” Various examples of supportive or unsupportive behaviors were then listed (eg, “Encouraged me not to eat ‘unhealthy foods’ [cake, salted chips] when I’m tempted to do so,” and “Commented if I went back to my old eating habits”). Answer options were (1) “None,” (2) “Rarely,” (3) “A few times,” (4) “Often,” and (5) “Very often.” As appropriate, items were reverse-scored so that high scores denoted high family social support for healthy eating. When included in regressions, this covariate was represented by its dummy values because its values were normally distributed.

Family social support for increased physical activity. Participants also completed 9 items adapted from measures of family support for daily physical activity,\textsuperscript{105} yielding a scale with acceptable reliability (Cronbach $\alpha = 0.81$). The stem was “During the past 3 months, my family (or members of my household) . . .” Various examples of supportive or unsupportive behaviors were then listed (eg, “Exercise with me,” or “Complained about the time I spend exercising.”). Answer options were (1) “None,” (2) “Rarely,” (3) “A few times,” (4) “Often,” and (5) “Very often.” As appropriate, items were reverse-scored so that high scores denoted high family social support for leisure time physical activity. When included in regressions, this covariate was represented by its dummy values because its values were normally distributed.

Food and beverage choices. The Block FFQ\textsuperscript{106} was administered to participants at baseline and 12-month follow-up but not at 6-month follow-up. Hence, analyses including the food and beverage consumption data from the FFQs necessarily ignored the 6-month anthropometric and survey data. However, specific questions about sugary beverage consumption on the survey questionnaire overlapped with questions asked on the FFQ. For these survey questions, it was possible to model
changes in consumption of sugary beverages at both 6 months and 12 months. Most FFQ items were expressed in mean grams consumed per day, or per week, after taking into consideration the mean amount of the food consumed and the frequency with which it was consumed. In some cases, the vendor for the questionnaire created aggregate variables derived from aggregating the consumption data involving specific categories of foods, such as all sweet-tasting foods or all sugar-sweetened beverages. In these 2 instances, the metric was not grams per day consumed but percentage of total calories represented by the specific food/beverage category.

Finally, in order to control for variations in participants’ daily food consumption, the grams of total fruit- and vegetable-derived fiber were divided by the total grams of food consumed daily and multiplied by 1000 to yield a fruit and vegetable fiber index per kilogram of food consumed daily.107 Because many of the variables derived from the Block Food Frequency Questionnaire were not normally distributed, they were subjected to log transformation to make the resulting values more consistent with the assumption that all predictors were normally distributed when included as covariates in regression analyses.

Acculturation as a moderator variable (not prespecified). Acculturation to US cultural practices was assessed by 7 psychometrically well-established language-focused questions,108,109 such as “I speak English at home,” “I write in Spanish (eg, letters, emails),” and “I watch Spanish-language movies on television.” Answer options were “Never,” “Rarely,” “Sometimes,” “Usually,” and “Always.” These 7 items had high internal consistency (Cronbach $\alpha = 0.94$). They were subjected to a principal components analysis with 1 factor summarizing the shared variance. We then used this factor to evaluate the impact of acculturation on study outcomes. For some analyses we categorized this acculturation factor into tertiles. Although not prespecified in the planned analyses, the investigators included these items at baseline because of consistent literature indicating that acculturation to US dietary practices entrained less adherence to components of the MyPlate prescription (eg, less daily fruit intake, less legume intake, greater consumption of sugar in food and beverages)110 and because the investigators anticipated that most of the study participants would be immigrants. Measures of language preferences, as used here, are useful proxies for assessing acculturation but not the only way for researchers to assess study participants’ acculturation level. Other ways to assess acculturation include an acculturation score, years lived in the United States, birthplace, and self-described generational status, in addition to language preference.111 A 2008 review of studies evaluating the association between acculturation and dietary practices found consistent inverse associations between diet quality and acculturation despite variations in how acculturation was measured.110
Satisfaction with the weight control program. We included process measures in the 6- and 12-month follow-up assessments to gauge participant satisfaction with the weight-loss intervention program to which they had been randomly assigned. There were 2 overall indicators of participants’ satisfaction with their weight-control program. One consisted of the question “How useful was the Healthy Weight Loss Program for helping you to lose weight?” Answer options were “Very useful,” “Somewhat useful,” and “Not useful.” The other consisted of the question “Would you recommend this program to your family members or friends?” Answer options were “Definitely,” “Maybe,” and “No.” The latter question is considered to be unusually effective in predicting the success of a commercial product or service. These variables lacked variability because the participants were almost universally highly satisfied with their experience, so we did not include these variables as covariates in regression analyses.

To recap, the primary patient-centered outcome was satiety, represented by 3 indicators; the primary medical outcome was body fat composition, represented by 2 indicators; prespecified secondary outcomes included systolic blood pressure, mental health, health-related quality of life, daily intake of fruits and vegetables, and satisfaction with the weight-loss program.

7. Data collection and sources. Participants were typically phoned a week before the due date to remind them about their 6- or 12-month follow-up assessments. If they were unreachable by phone, a postcard was sent to them, asking them to call one of the research assistants. After securing permission from the IRB and participants for HIPAA-consistent access to their medical records, clinic records yielded information about patients who had moved away. More specifically, our strategy was to work with clinic front office staff to inquire about information relevant to patient retention (eg, patients’ last clinic visit, updated contact information such as telephone number or home address). From prior research, it was known that maintaining regular contact with study participants optimizes retention. The nature of the 2 interventions being compared here—namely 11 contacts over 6 months—provides a sufficient frequency of contact that retention is likely to be high. Reminder calls and birthday cards were sent periodically to remind participants they were considered continuing participants in the study until completion of their 12-month follow-up assessment, even if they had been unable to complete all proposed health education sessions during the intervention period or if they did not complete any sessions at all. Patients were considered adherent to the program if they were reachable for their scheduled health education session within 5 contact attempts made by their community health educator. If more than 5 contact attempts were made for a session then patients were labeled as hard-
to-reach. To ensure good participation at the baseline, 6-month, and 12-month assessments, the investigators employed additional strategies to facilitate patient retention. Some were providing $20, $30, and $50 incentives, respectively; having full-time staff members available during all clinic business hours; and making the clinic the primary workspace. If a patient came to the clinic for a medical appointment, staff was available to reach the patient and update contact information. Patients were offered the option of meeting at their preferred time to complete follow-up assessments (eg, after work, after school, on the weekends) and at a location of their preference in their community if unable to attend the clinic (eg, local coffee shops, their homes, community centers). All data were coded by a unique study identifier specific to each participant to ensure linkage of disparate sources of data, including participant questionnaires, research assistant records of anthropometry and blood pressure measures, and food frequency questionnaires. Assessment research staff were blind to participants’ experimental assignment at the time of assessment.

8. **Analytical and statistical approaches.** We conducted most of the cross-time analyses as random-intercept mixed-effects models because, in contrast to repeated measures analysis of variance, parameter estimates generated by mixed-effects modeling are robust in the presence of data missing at random. Cases with no missing follow-up data did not differ from study “dropouts” on either baseline demographic or outcome measures (all \( p > 0.15 \)) except for the demographic age. The mean age of study dropouts was 37.6 (95% CI, 34.5-40.7) years compared with 43 years (95% CI, 41.5-44.6) for cases with no missing follow-up data. Age was not a significant correlate in any of the regression models showing significant changes over time and is probably not a confounding influence on observed experimental effects. For intent-to-treat analyses, we also analyzed missing primary and secondary outcome measures at follow-up by carrying forward previous values under the assumption that those participants who were missing at follow-up had not benefited from exposure to the intervention since the past assessment and therefore had experienced no (additional) improvement in their satiety or body fatness measures. As an alternative to the last-observation-carried-forward approach to imputing missing data, we used a regression approach assuming multivariate normality to impute missing data on the primary outcome measures and found a similar pattern of findings. For all regression analyses, covariates included age, sex, race/ethnicity, educational attainment, and participant marital status as standard demographic covariates used in comparable studies.

9. **Conduct of the study.** A revised final study protocol was previously submitted. We conducted
most of the trial as envisaged in the original protocol. Changes included expanding eligibility to include patients with a BMI between 27 and 30, not only those with a BMI between 30 and 40 as originally planned. This change accommodated patient interest in participating in the study and to facilitate accrual. Another change increased the incentive at 12-month follow-up from $40 to $50 to facilitate participant retention at the final assessment. A third change included access to patients’ medical records to facilitate follow-up and provide information corroborative of weight status and health conditions in the event the patient was missing at follow-up. The informed consent form was revised to reflect these changes and approved by the IRB before we implemented the changes.

Results

An updated CONSORT flow diagram is described in Figure 2. As recorded in clinicaltrials.gov, the last 12-month follow-up assessment occurred on March 23, 2017 (#NCT02514889).

Table 2. Descriptive Characteristics of the Baseline Sample (N = 261)*

<table>
<thead>
<tr>
<th>Measure</th>
<th>Total</th>
<th>MyPlate</th>
<th>Calorie Counting</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Number of respondents</td>
<td>261</td>
<td>100%</td>
<td>131</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>12</td>
<td>4.6%</td>
<td>5</td>
</tr>
<tr>
<td>Female</td>
<td>249</td>
<td>95.4%</td>
<td>126</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td>20</td>
<td>7.7%</td>
<td>10</td>
</tr>
<tr>
<td>Asian or Asian American</td>
<td>2</td>
<td>0.8%</td>
<td>1</td>
</tr>
<tr>
<td>White/Caucasian</td>
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<td>3.8%</td>
<td>7</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
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<td>86.2%</td>
<td>112</td>
</tr>
<tr>
<td>Native American</td>
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<td>0.4%</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
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<td>1</td>
</tr>
<tr>
<td>Educational attainment</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Never attended/kindergarten only</td>
<td>6</td>
<td>2.3%</td>
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<tr>
<td>Less than high school</td>
<td>120</td>
<td>46.0%</td>
<td>57</td>
</tr>
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<td>High school/GED</td>
<td>76</td>
<td>29.1%</td>
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</tr>
<tr>
<td>Some college</td>
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<td>20.3%</td>
<td>33</td>
</tr>
<tr>
<td>College degree</td>
<td>5</td>
<td>1.9%</td>
<td>2</td>
</tr>
<tr>
<td>Some grad school/postcollege degree</td>
<td>1</td>
<td>0.4%</td>
<td>0</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-29 years</td>
<td>43</td>
<td>16.5%</td>
<td>23</td>
</tr>
<tr>
<td>30-39 years</td>
<td>65</td>
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<td>32</td>
</tr>
<tr>
<td>40-49 years</td>
<td>90</td>
<td>34.5%</td>
<td>44</td>
</tr>
<tr>
<td>50-59 years</td>
<td>44</td>
<td>16.9%</td>
<td>23</td>
</tr>
</tbody>
</table>
Baseline characteristics. Table 2 includes participant baseline characteristics for the 261 participants who were fully enrolled in the trial. The table shows no statistically significant differences between experimental conditions on any demographic characteristics on the primary or secondary measures listed. The proportion of African American participants was only 8%, well below the estimated
13% expected based on publicly available TCC demographic statistics. The proportion of Latino participants was 86%, well above the estimated 78% expected. Initial estimates were that one-third of participants would be men but, as is commonly observed in community-based weight loss interventions, men were under-represented, with male participants composing just 5% of the study sample. We tested all major hypotheses for all participants as well as within subgroups defined by ethnicity (Latino participants only) and by gender (women only). Because women were such an overwhelming percentage (95%) of participants, results for women only were generally similar to results involving the full sample. Similarly, because Latinos were 86% of the total sample, results for Latinos rarely differed from results for the full sample. Unless otherwise highlighted, the findings of significance obtained for the sample as a whole were also obtained for the 95% of the sample who were women and the 86% of the sample who were Latinos.

Table 3. Number of Patients by Number of Sessions Completed (11 Possible Sessions), Los Angeles Area Federally Qualified Health Center, 2015-2016

<table>
<thead>
<tr>
<th>Number of Sessions Completed</th>
<th>Percentage of Patients</th>
<th>Cumulative Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>All sessions</td>
<td>13.4% (n = 35)</td>
<td>13.4% (n = 35)</td>
</tr>
<tr>
<td>10 sessions</td>
<td>11.5% (n = 30)</td>
<td>24.9% (n = 65)</td>
</tr>
<tr>
<td>9 sessions</td>
<td>11.5% (n = 30)</td>
<td>36.4% (n = 95)</td>
</tr>
<tr>
<td>8 sessions</td>
<td>5.4% (n = 14)</td>
<td>41.8% (n = 109)</td>
</tr>
<tr>
<td>7 sessions</td>
<td>3.0% (n = 8)</td>
<td>44.8% (n = 117)</td>
</tr>
<tr>
<td>6 sessions</td>
<td>6.1% (n = 16)</td>
<td>50.9% (n = 133)</td>
</tr>
<tr>
<td>5 sessions</td>
<td>5.0% (n = 13)</td>
<td>55.9% (n = 146)</td>
</tr>
<tr>
<td>4 sessions</td>
<td>6.5% (n = 17)</td>
<td>62.4% (n = 163)</td>
</tr>
<tr>
<td>3 sessions</td>
<td>6.9% (n = 18)</td>
<td>69.3% (n = 181)</td>
</tr>
<tr>
<td>2 sessions</td>
<td>7.3% (n = 19)</td>
<td>76.6% (n = 200)</td>
</tr>
<tr>
<td>1 session</td>
<td>6.5% (n = 17)</td>
<td>83.1% (n = 217)</td>
</tr>
<tr>
<td>No sessions</td>
<td>16.9% (n = 44)</td>
<td>100.0% (n = 261)</td>
</tr>
</tbody>
</table>

**Intervention exposure.** Table 3 shows 44 study enrollees (17%) were exposed to none of the intervention sessions despite saying during eligibility screening that they were interested in participating. Of these enrollees, 51% were exposed to at least 6 sessions and 13% participated in all 11 sessions. Of the 3 types of sessions, the home visit education sessions were the most popular (93% participated), the group education sessions were the least popular (76% participated), and the phone coaching calls were intermediate (participants completed about half of the telephone coaching sessions). Whether they participated in a few sessions or many sessions, more than 92% said they were
either somewhat or very satisfied with the weight-control program to which they were assigned. There was no difference in participants’ high level of satisfaction with the program between the 2 experimental conditions. We assessed the variability in exposure to the planned intervention content as a moderating influence on the outcome and to gauge its threat to the internal validity of the study.

**Primary outcomes.** The primary patient-centered outcome was the satiety construct, represented by 3 measures of satiety measured on 100 mm visual analog scales: (1) How hungry did you feel (yesterday)? (2) How full did you feel after your last meal (yesterday)? (3) How satisfied were you after your last meal (yesterday)? We regressed these 3 indicators onto standard demographic variables and set the critical \( P \) value to \( p = 0.017 \) to correct for multiple comparisons using the conservative Bonferroni correction.\(^8\) The demographic variables were those typically included in other clinical trials of behavioral weight-control programs and included sex, age, ethnicity, educational attainment, and whether the participant living with or without a partner. We reran the models including 2 food insecurity questions that asked about cutting back on food because of lack of money. Although these questions had a correlation of 0.57, we decided to include both as covariates rather than assuming they reflected the same underlying construct. There was a marginally insignificant reduction in reported hunger in the MyPlate condition (mean diff = –5.99; 95% CI, –11.64 to –0.34; \( p = 0.04 \)) but unexpectedly a significant reduction in reported hunger within the calorie counting condition (mean diff = –9.99; 95% CI, –15.73 to –4.25; \( p = 0.004 \)) (see Figure 3). The addition of the 2 food insecurity covariates decreased the magnitude of the reduced hunger over time in both conditions but the reduction in hunger from baseline to 12-month follow-up remained significant for calorie counting participants (mean diff = –9.57; 95% CI, –15.32 to –3.82). Figure 3 illustrates the monotonically declining levels of reported hunger experienced the previous day. Similar trends were observed for the sample excluding men and for the sample excluding non-Latinos.

Comparisons between experimental conditions in estimated mean changes are also given in Table 4, showing no statistically significant difference between conditions.
Figure 3. Experimental effect on everyday hunger as measured on a 100-mm visual analogue scale, where 0 was not at all hungry and 100 was extremely hungry (yesterday). In addition to the standard demographic covariates, the mixed-effects modeling included a covariate to control for individual differences in food insecurity. Twelve-month follow-up values were significantly lower in the calorie counting condition and marginally insignificantly lower in the MyPlate condition than corresponding baseline values.

Table 4. Comparison Between CC and MyPlate Conditions in Estimated Mean Change in Primary Patient-centered Outcomes Over 12-month Period in the Intention-to-Treat Population

<table>
<thead>
<tr>
<th>Measure</th>
<th>Calorie Counting</th>
<th>MyPlate</th>
<th>P Value&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of hunger after last meal yesterday</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At month 6</td>
<td>–10.65 ± 3.71</td>
<td>–11.51 ± 3.58</td>
<td>0.87</td>
</tr>
<tr>
<td>At month 12</td>
<td>–13.79 ± 3.65</td>
<td>–16.58 ± 3.59</td>
<td>0.58</td>
</tr>
<tr>
<td>How satisfied were you feeling after last meal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>yesterday?</td>
<td>5.45 ± 3.42</td>
<td>5.73 ± 3.30</td>
<td>0.95</td>
</tr>
<tr>
<td>At month 6</td>
<td>8.69 ± 3.36</td>
<td>12.55 ± 3.31</td>
<td>0.41</td>
</tr>
<tr>
<td>How full did you feel after last meal yesterday?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At month 6</td>
<td>8.70 ± 2.99</td>
<td>3.57 ± 2.87</td>
<td>0.21</td>
</tr>
<tr>
<td>At month 12</td>
<td>9.99 ± 2.93</td>
<td>5.99 ± 2.88</td>
<td>0.33</td>
</tr>
</tbody>
</table>

<sup>a</sup> Plus–minus values are means ± SE; N = 261; covariates = sex, age, ethnicity, educational attainment, marital status.

<sup>b</sup> P value for contrast between calorie counting and MyPlate.

Figure 4 illustrates the significant increase in reported satiety as measured by meal satisfaction reported
not only by MyP participants (difference = 16.58; 95% CI, 9.54-23.63) but also by the CC participants (difference = 13.79; 95% CI, 6.65-20.94). The MyP result was predicted; the CC result was not. Results were similar for the women and Latino subsamples. Comparisons between conditions in estimated mean changes are also given in Table 4, showing no difference between conditions.

![Figure 4. Experimental effect on meal satisfaction using a 100-mm visual analogue scale, where 0 was not at all satisfied/full after eating and 100 was extremely satisfied/full after eating (yesterday). Twelve-month follow-up values were significantly greater in each condition than corresponding baseline values.](image-url)
Figure 5 illustrates the significant increase in reported satiety as measured by “feeling full after last meal” reported not only by MyP participants (difference = 12.54; 95% CI, 6.05-19.04) but also by the CC participants (difference = 8.69; 95% CI, 2.10-15.28). Results were similar for the women and Latino subsamples. Comparisons between conditions in estimated mean changes are also given in Table 4, showing no difference between conditions.
Table 5. Comparison Between CC and MyPlate Conditions in Changes Over Time in Estimated Mean Waist Circumference, Body Weight, and Body Mass Index Over 12-month Period in the Intention-to-Treat Population

<table>
<thead>
<tr>
<th>Measure</th>
<th>Calorie Counting</th>
<th>MyPlate</th>
<th>P Value&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in waist circumference (cm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At month 6</td>
<td>–0.49 ± 0.69</td>
<td>–1.50 ± 0.66</td>
<td>0.29</td>
</tr>
<tr>
<td>At month 12</td>
<td>–1.96 ± 0.68</td>
<td>–1.91 ± 0.67</td>
<td>0.96</td>
</tr>
<tr>
<td>Weight loss (kg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At month 6</td>
<td>–0.46 ± 0.47</td>
<td>–0.23 ± 0.44</td>
<td>0.72</td>
</tr>
<tr>
<td>At month 12</td>
<td>–0.63 ± 0.46</td>
<td>–0.30 ± 0.45</td>
<td>0.60</td>
</tr>
<tr>
<td>Body-mass index (kg/m&lt;sup&gt;2&lt;/sup&gt;)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At month 6</td>
<td>0.13 ± 0.19</td>
<td>0.30 ± 0.18</td>
<td>0.50</td>
</tr>
<tr>
<td>At month 12</td>
<td>0.16 ± 0.18</td>
<td>0.30 ± 0.18</td>
<td>0.57</td>
</tr>
</tbody>
</table>

<sup>a</sup> Plus–minus values are estimated means ± SE; N = 261; covariates = sex, ethnicity, age, educational attainment, marital status.

<sup>b</sup> P value for contrast between calorie counting and MyPlate.

**Primary medical outcomes.** With 2 primary medical outcome measures, we set the critical P value at \( p = 0.025 \) to correct for multiple comparisons, using the conservative Bonferroni correction.<sup>89</sup>

Table 5 reports between-condition differences in within-condition weight difference scores observed from baseline through 6- and 12-month follow-up.

MyP participants experienced a one-third kilogram reduction in **body weight** (difference = –0.37; 95% CI, –1.30-0.56) from baseline to 12 months; the corresponding CC reduction was three-quarters of a kilogram (difference = –0.74; 95% CI, –1.72-0.23). These statistically insignificant results were replicated for the women-only and Latino-only subsamples, and are illustrated in Figure 6. Because of consistent evidence that acculturation to US dietary practices increases immigrants’ risk of obesity and because 82% of baseline respondents were foreign-born, we explored the possibility that acculturation was a moderating influence on the outcomes. When participants were stratified by acculturation tertile, the middle tertile among CC participants only experienced a 2-kilogram decrease in body weight from baseline to 12-month follow-up (difference = –2.11; 95% CI, –3.78 to –0.44; \( p = 0.01 \)).

The body weight decline for this group at 6 months was similar to that observed at 12 months (difference = –2.00; 95% CI, –3.64 to –0.37; \( p = 0.02 \)) (see Figure 7).
Figure 6. Experimental effect on body weight. Twelve-month follow-up values were insignificantly lower in each experimental condition compared with corresponding baseline values.

Figure 7. Experimental effect on body weight for only participants in the middle tertile of acculturation. Six- and 12-month follow-up values were insignificantly lower in the MyPlate experimental condition but more than 2 kilograms lower in the CC condition compared with corresponding baseline values.
As illustrated in Figure 8, MyP participants enjoyed a nearly 2-cm reduction in their **waist circumference** (difference = –1.90; 95% CI, –3.29 to –0.50; \( p \lt 0.01 \)). CC participants also experienced a significant reduction in their waist circumference from baseline to 12-month follow-up (difference = –1.67; 95% CI, –3.11 to –0.23; \( p = 0.02 \)). Ideally, all waist circumference measures would have been taken against the skin, not over clothing. In practice, most (73%) of the waist circumference measures were taken over clothing due to patient preference because most of the participants were female and often the research assistant taking the anthropometric measures was male. The additional length of measuring tape required to accommodate the clothing (mean increased waist circumference = 3.34 cm; 95% CI, 1.71 to 4.98) could have introduced systematic error inasmuch as it was the participant’s decision, not the investigator’s decision, to opt for their waist circumference being measured over clothing. In other words, the 3.34-cm difference may have reflected other, unmeasured differences between the groups. The waist circumference analyses were therefore redone, subtracting 3.34 cm from the waist circumference measures taken over clothing for those participants whom the research assistants recorded as having the waist circumference measure taken over clothing. The resulting 12-month follow-up difference scores increased in absolute magnitude from 58% to 113% (MyP difference = –3.18 cm, 95% CI, –4.55 to –1.80, \( p < 0.001 \); CC difference = –2.70 cm, 95% CI, –4.13 to –0.71, \( p < 0.001 \)). For sensitivity analysis purposes, differences of 1 cm, 2 cm, and 3 cm were also evaluated, with similar patterns of results intermediate between 0 correction and 3.34-cm correction of the waist circumference measures. These results were replicated in the women- and Latino-only subsamples. Table 5 reports between-condition differences in within-condition waist circumference difference scores observed from baseline through 6- and 12-month follow-up.
Figure 8. Experimental effect on waist circumference using measures unadjusted for some respondents having had their waist measured over light clothing instead of against the skin. Adjusting for the average 3.44-cm increase in waist circumference contributed by clothing changed the absolute values downward but barely changed the relative differences. Twelve-month follow-up values were significantly lower in each experimental condition compared with corresponding baseline values.

While mixed-effects modeling generates parameter estimates that are robust in the presence of data missing at random, another way to address the potentially confounding issue of attrition-related selection bias is to conduct an intent-to-treat analysis. In the obesity field, a common strategy for imputing missing outcome data is to carry the last observation forward under the assumption that study dropouts are less likely to have lost weight in the interim than continuing participants. Making the assumption that dropouts had failed to reduce their waist circumference relative to their baseline weight systematically biases follow-up results in favor of the null hypothesis. Nonetheless, after imputing the missing waist circumference data this way, the cross-time MyP and CC results remained significant (p < 0.025) for the full-sample, women-only, and Latino-only analyses.

We observed a significant decline in systolic blood pressure for MyP participants at 6-month follow-up, from 123 mm to 120 mm (difference = –3.08 mm; 95% CI, –5.61 to –0.54) but not for CC participants, whose systolic blood pressure dropped only 1 mm, from 123 mm to 122 mm (difference = –1.07; 95% CI, –3.75-1.61) (see Figure 9). By 12 months, the decline in systolic blood pressure was
statistically insignificant for both conditions (MyP difference = –1.81 mm, 95% CI, –4.46-0.82; CC difference = –1.04, 95% CI, –3.77-1.70). We observed no decline in diastolic blood pressure for participants in either condition.

Figure 9. Experimental effect on systolic blood pressure values over time was significant only at 6 months and only for MyP participants.

**Intervention check.** Using the MyPlate icon (at www.choosemyplate.gov) the community health workers in the MyP intervention stressed the importance of filling half of one’s plate with (minimally processed) fruits and vegetables. CC participants were also encouraged to consume more fruits and vegetables but only because of their low energy density. All participants answered questions about how much of their average plate they filled with fruits and vegetables. The respondents were given 5 choices for indicating how much of their usual plate was filled with fruits, vegetables, or whole grains. The choices were (1) none, (2) one-quarter plate, (3) one-half plate, (4) three-quarters plate, and (5) whole plate. The marginal mean at 12-month follow-up for the MyP condition was 2.98 (approximately one-half plate); the marginal mean at baseline for the MyP condition was 2.37 (closer to one-quarter plate than to one-half plate), for a difference of 0.61. MyP participants significantly increased the proportion of their plate they devoted to vegetables over time (difference = 0.61; 95% CI, 0.41-0.82), as did the CC participants (difference = 0.42; 95% CI, 0.22-0.63) (see Figure 10). In plate
surface percentage terms, these represented 15.4% (from 32.9% to 48.4%) and 10.6% (from 34.1% to 44.7%) increases for the MyP and CC conditions, respectively. They reported a corresponding increase in plate space devoted to fruit as well (MyP difference = 0.62, 95% CI, 0.41-0.82 versus CC difference = 0.40, 95% CI, 0.20-0.60) (see Figure 11). In plate surface percentage terms, these represented 13.9% (from 30.5% to 44.4%) and 9.2% (from 31.8% to 41.0%) increases for the MyP and CC conditions, respectively. Analysis of the women-only and Latino-only subsamples yielded similar results.

![Graph showing experimental effect on portion of plate filled with vegetables.](image)

**Figure 10.** Experimental effect on the proportion of the typical plate that the participant reports devoting to vegetables. The response options included 5 Likert items, including none of the plate on the lower end and all of the plate at the higher end. Twelve-month follow-up values were significantly greater in each condition than corresponding baseline values.
Figure 11. Experimental effect on the proportion of the typical plate that the participant reported devoting to minimally processed fruit (no juices). The response options included 5 Likert items bounded on the lower end by “None of the plate” and bounded on the upper end by “All of the plate.” Twelve-month follow-up values were significantly greater in each condition than corresponding baseline values.

Internal validity. Primary outcome results were moderated by exposure to the intervention. We documented participant exposure to intervention sessions. We used a prespecified categorical variable to represent an ordered classification of exposure to intervention sessions with 0 representing those participants who had participated in 0 sessions (17.3%), those who participated in 1 to 5 sessions (32.6%), and those who participated in 6 to 11 sessions (50.2%). The a priori expectation was that exposure to 0 sessions should be associated with the least change in satiety; exposure to more than half of all sessions should be associated with the greatest change in satiety; and exposure to some but not more than half of all sessions should be associated with an intermediate change in satiety. All 3 indexes of satiety were significantly related to intervention exposure, controlling for participant age, gender, educational attainment, ethnicity, and marital status. For example, participants’ feeling of hunger during the previous day did not change significantly for either 0 sessions (−4.53; 95% CI, −9.53-0.47; p = 0.08) or
1 to 5 sessions (−2.28; 95% CI, −5.20-0.63; \( p = 0.12 \)) but did change significantly for 6 to 11 sessions (−3.64; 95% CI, −5.83 to −1.44; \( p = 0.001 \)). Similarly, participant meal satisfaction did not increase significantly for 0 sessions (4.57; 95% CI, −1.47-10.62; \( p = 0.14 \)); did increase somewhat for 1 to 5 sessions (6.3; 95% CI, 2.74-9.87; \( p = 0.0005 \)); and increased the most for 6 to 11 sessions (7.4; 95% CI, 4.71-10.11; \( p = 0.0000 \)). Changes over time in waist circumference were also significantly related to intervention exposure, controlling for the usual covariates. Participants who had participated in 0 sessions experienced no decrease in waist circumference (−0.06 cm; 95% CI, −1.65-1.54; \( p = 0.94 \)); those who participated in 1 to 5 sessions experienced some decrease in waist circumference (−0.68 cm; 95% CI, −1.48-0.11; \( p = 0.09 \)); and those who participated in 6 to 11 sessions experienced the greatest decrease in waist circumference (−1.03 cm, 95% CI, −1.57 to −0.50, \( p = 0.0002 \)).

**Health-related quality of life and mental health.** In theory, the high-satiety approach of the MyPlate approach should lead over time to a lower sense of deprivation and hunger during active weight-control efforts than traditional calorie restriction approaches and therefore lead to enhanced health-related quality of life and lower risk of depressiveness. Thus, we included the SF-12 health-related Quality of Life Scale and the Mental Health Index-5 mental health scale. Both were acceptably reliable (baseline SF-12 Cronbach \( \alpha = 0.79 \); baseline MHI-5 Cronbach \( \alpha = 0.76 \)) Measures on both scales improved significantly for both MyP and CC participants by 12-month follow-up in all samples (MyP SF-12 difference = 0.17, 95% CI, 0.07-0.26; CC SF-12 difference = 0.22, 95% CI, 0.12-0.31; MyP MHI-5 difference = 0.31, 95% CI, 0.14-0.48; CC MHI-5 difference = 0.33, 95% CI, 0.16-0.51) (see Figures 12 and 13). There was a near-significant interaction effect for improvement in health-related quality of life at 6-month follow-up favoring the CC condition (beta = 4.50; 95% CI, −0.67-9.67; \( p < 0.09 \)), but the quality of life ratings for the 2 intervention conditions converged at the 12-month assessment. Mental health ratings steadily increased for both conditions, with no appreciable difference between the 2. Similar results were obtained for the women-only and Latino-only subsamples.

**Physical activity.** Advice to increase daily physical activity to at least 30 minutes of moderate to vigorous physical activity most days of the week was given to participants in both conditions. Participants in both conditions received a “gym in the bag” that included a 10-minute “Instant Recess™” DVD featuring fun dance routines, resistance bands, a pedometer, and charts with which to monitor progress. None of these strategies for stimulating increased physical activity seemed to have had much impact, either on self-reported physical activity using the International Physical Activity Questionnaire—short version (see Figure 14) or on a proxy measure for physical fitness, namely research assistant–assessed heart rate (see Figure 15).
**Acculturation.** To examine the possible moderating impact of acculturation on change in waist circumference, especially in the Latino subsample, study participants completed 7 language preference questions used in previous research\(^\text{108}\) that together yielded an acculturation scale with high reliability (Cronbach \(\alpha = 0.94\)). We subjected these items to a principal components analysis with 1 factor summarizing the shared variance. We then used this factor to evaluate the impact of acculturation on study outcomes. For some analyses, we categorized this acculturation factor into tertiles. Figure 16 illustrates for MyP participants only the higher risk of central obesity faced by the most acculturated but also shows a significant decline in waist circumference over 12 months in the most acculturated (difference = –3.50 cm; 95% CI, –6.17 to –0.83) in contrast to no significant decline in the less acculturated MyP participants over 12 months. We observed no corresponding decline in CC participants.

![Figure 12. Experimental effect on mental well-being as measured by the Mental Health Index-5 items. High scores represented increased mental health; low scores represented impaired mental health. Twelve-month follow-up values for better mental health were significantly greater in each condition than corresponding baseline values.](image-url)
Figure 13. Experimental effect on health-related quality of life as measured by the SF-12, composed of 12 items that assessed social and physical function as well as psychological health. Lower scores indicated lower health-related quality of life; higher scores indicated higher health-related quality of life. Twelve-month follow-up values were significantly greater in each condition than corresponding baseline values.

Figure 14. Experimental effect on daily physical activity as assessed by items from the International Physical Activity Questionnaire—short form. Answers were converted to moderately vigorous physical activity—equivalent minutes per week. Values at 12-month follow-up were not statistically different from baseline values.
Figure 15. Experimental effect on heart rate, measured as beats per minute after at least 5 minutes of sitting in a chair, at rest. Values at 12-month follow-up were not statistically different from baseline values.

Figure 16. Patient acculturation level moderates change in waist circumference over time. Among MyP participants, the most acculturated (highest tertile) had more central adiposity to reduce than less acculturated participants at baseline and were observed to have the largest drop in waist circumference from baseline to 12-month follow-up.
**TV watching.** At baseline participants in both conditions reported watching TV an average of fewer than 2 hours a day. Reducing time spent watching TV was particularly encouraged in the MyP condition but, contrary to prediction, TV watching declined in both the MyP condition (difference = −0.88; 95% CI, −1.18 to −0.58) and the CC condition (difference = −0.45; 95% CI, −0.75 to −0.14). The reduction was equivalent to 37 minutes fewer watching TV per day in the MyP condition and 32 minutes fewer watching TV per day in the CC condition. The condition by assessment interaction was significant (p = 0.04) and is illustrated in Figure 17.

![Figure 17. Experimental effect on amount of TV watching per day. Ordinal categories of hours of TV watching per day declined significantly in both conditions from baseline to 12-month follow-up but more so in the MyP condition, resulting in a significant condition by time interaction (p = 0.04).](image)

**Family social support for healthy eating.** The scales were formed from the mean of the dummy values for the available items and generally varied between 2 and 4, with the higher numbers denoting higher levels of family support for healthy eating. We found the scale scores were found to be normally distributed and were therefore not subjected to transformation or dichotomization.

Both experimental conditions succeeded in boosting social support for healthy eating for the duration of the study, as depicted in Figure 18, and did not differ from each other. Mean social support
for healthy eating ratings increased from 3.08 to 3.36 in the MyPlate condition and from 3.11 to 3.28 in the CC condition.

**Family social support for increased physical activity.** The scales were formed from the mean of the dummy values for the available items and generally varied between 2 and 4, with the higher numbers denoting higher levels of family support for leisure time physical activity. Family social support for leisure time physical activity increased only in the MyP condition for the first 6 months, from 2.82 to 3.06, which remained elevated through 12-month follow-up (mean = 3.10). We observed an insignificant increase in social support in the CC condition, from 2.82 to 2.95 at 6-month follow-up, remaining insignificantly elevated at 2.95 at 12-month follow-up, as depicted in Figure 19. Family social support for leisure time physical activity did not differ between conditions.

![Experimental effect on family support for healthy eating](image)

*Figure 18. Experimental effect on family social support for healthy eating. Family social support for healthy eating showed significant increases in both conditions from baseline to 12-month follow-up.*
Figure 19. Experimental effect on family social support for exercise. Family social support for exercise increased significantly for MyPlate condition only by the 6-month assessment and remained significantly.

**Food and beverage choices paralleling the decline in waist circumference.** The FFQ was administered to participants at baseline and 12-month follow-up but not at 6-month follow-up. Hence, analyses including the food and beverage consumption data from the FFQs necessarily ignored the 6-month data. However, questions about sugary beverage consumption on the main questionnaire overlapped with questions on the FFQ. For these questions it was possible to model changes at 6 months and 12 months in consumption of sugary beverages.

**Main questionnaire food and beverage choices.** As Figure 20 illustrates, sugary beverage consumption dropped 50% in the MyP condition from an initial fourth-fifths drink per day to two-fifths drink per day and 50% in the CC condition from an initial one and one-sixth drinks per week to drinks per day between baseline and 6-month follow-up but then reverted to baseline in the MyP group by the 12-month follow-up. Conversely, as Figure 19 illustrates, plain water consumption increased in both conditions, increasing 14.9% (linear effect chi square[1] = 19.10; \( p < 0.0001 \)) from an initial 4.24 times/day to 4.9 times/day in the MyP condition and 8.7% (linear effect chi square[1] = 6.65; \( p < 0.01 \)) from an initial 4.41 times/day to 4.80 times/day in the CC condition through 12 months.
Analyses of the FFQ data showed significant decreases in the proportion of food choices identified by the Block FFQ as sweet-tasting foods (MyP difference = –2.67, 95% CI, –4.51 to –0.82; CC difference = –2.25, 95% CI, –4.18 to –0.33). Relatedly, the FFQ data confirmed what we had observed using participant self-reported frequency of sugary beverage consumption on the main questionnaire, that the percentage of calories consumed as sugary beverages dropped significantly in both conditions (MyP difference = –17.87, 95% CI, –30.58 to –5.17; CC difference = –22.94, 95% CI, –36.21 to –9.68).

**Figure 20.** There was an experimental effect on sugary drink consumption such that the number of sugary drinks consumed daily decreased significantly in both conditions from baseline to 6-month follow-up but then reverted to baseline levels in the MyP group by the 12-month follow-up.

**Water intake.** The survey questionnaire included the item “How often do you drink water on a typical day?” The answer options were (1) “I don’t drink water,” (2) “I drink water once per day,” (3) “I drink water twice per day,” (4) “I drink water 3 to 4 times per day,” and (5) “I drink water 5 or more times per day.” At baseline, 55% said they drank water 5 or more times per day; the corresponding percentages at 6- and 12-month follow-up were 60% and 72%, respectively. Because of the negatively skewed distributions, these measures were dichotomized, with the dummy value of 0 representing those who drank water fewer than 5 times per day and the dummy value of 1 representing those who drank water 5 or more times per day. Figure 21 illustrates increasing water consumption in both
conditions from baseline through 12-month follow-up. In the MyPlate condition, the probability of participants who drank water 5 or more times per day increased from 53% at baseline (95% CI, 44.6%-61.6%) to 72.5% at 12-month follow-up (95% CI, 63.9%-81.1%); in the CC condition, the probability of participants who drank water 5 or more times per day increased from 58% at baseline (95% CI, 49.7%-66.6%) to 71.2% at 12-month follow-up (95% CI, 62.2%-80.1%).

Figure 21. Experimental effect on daily intake of plain water. Daily plain water intake increased markedly across assessments in the MyPlate condition and less markedly but still significantly in the calorie counting condition from baseline through 12-month follow-up.

Total gram weight of solid food consumed. One of the derived measures generated by the vendor of the Block FFQ was an estimate of the total gram weight of solid food consumed each day by each participant. As expected, participants in the CC condition reduced consumption of solid food, from 1125 grams at baseline (95% CI, 1035-1213) to 1015 grams at 12-month follow-up (95% CI, 908-1023). Unexpectedly, participants in the MyPlate condition also reduced consumption of solid food, from 1188 grams at baseline (95% CI, 1100-1277) to 1044 grams at 12-month follow-up (95% CI, 942-1147). These declines are illustrated in Figure 22.

Bean intake. Curiously, despite MyP participants being encouraged to eat more beans, consumption of refried beans dropped significantly in both conditions (MyP difference = –5.55 g/day, 95% CI, –10.99 to –0.12; CC difference = –6.65 g/day, 95% CI, –12.34 to –0.96). Similarly, tortilla
consumption dropped significantly in both conditions (MyP difference = –15.46 g/day, 95% CI, –24.23 to –6.70; CC difference = –10.11 g/day, 95% CI, –19.29 to –0.94).

Figure 22. Total daily gram weight of solid food consumed declined in the MyP condition but not in the CC condition from baseline to 12-month follow-up.

Figure 23. The percentage of calories from sugary beverages was inversely associated with the ratio of fruit and vegetable grams of fiber to total grams of solid food per day observed both at baseline and 12 months later. The relative intake of fruit and vegetable fiber was significantly lower for study participants who consumed a high level of sugary beverages daily (100 or more kilocalories/day).
FFQ data on sugary beverage intake in relation to consumption of fiber from fruits and vegetables. Figure 23 depicts box plots for both baseline and 12-month follow-up data showing an inverse association between categorical levels of daily sugary beverage intake and the ratio of fruit and vegetable fiber (g) per kilogram of solid food weight. Relative to participants who drank no sugary beverages, participants who drank between 1 and 99 kilocalories of sugary beverages a day consumed 1.27 fewer grams of fruit and vegetable fiber per kilogram of food (95% CI, −2.26 to −0.28) and participants who drank 100 or more kilocalories of sugary beverage a day consumed 2.43 fewer grams of fruit and vegetable fiber per kilogram of food (95% CI, −3.53 to −1.33). Figure 21 shows the same data but in relation to change over time. Fruit and vegetable fiber intake was highest in the participants who consumed no sugary beverages and remained highest at 12-month follow-up but participants who consumed a low level of sugary beverage intake (1 to 99 kilocalories per day) increased their fruit and vegetable fiber intake significantly over time (difference = 0.64 g/kg food; 95% CI, 0.28-1.00) in contrast to participants who drank 100 or more kilocalories of sugary beverages per day, whose daily consumption of fruit and vegetable fiber remained unchanged and well below the levels of the other 2 groups.

Figure 24. The consumption of sugary beverages appears to influence whether participants consume proportionately more fruit and vegetable fiber from baseline to 12-month follow-up with low-level consumers enjoying significant intervention benefit in terms of increasing fruit and vegetable fiber intake. High-level consumers of sugary beverages had significantly lower levels of fruit and vegetable fiber intake throughout the study period compared with the other groups.
Figure 25. The consumption of sweet-tasting foods is associated cross-sectionally with significantly inverse proportions of fruit and vegetable fiber intake per kilogram of food consumed both at baseline and at 12-month follow-up. Prospectively, it was the participants consuming the highest proportion of calories from sweet-tasting foods at baseline who consumed a significantly greater proportion of calories from fruit and vegetable fiber at 12-month follow-up compared with baseline.

**Inverse associations between percent of calories from FFQ sweet food choices (added sugars) and fiber-bearing foods.** Figure 24 summarizes the consistently inverse relationship between the proportion of calories from sweet-tasting food choices that are categorized by the Block FFQ as sweets or desserts (i.e., added sugar) and the proportion of fruit and vegetable grams of fiber consumed per kilogram of solid food, termed here the *F&V fiber ratio*. The F&V fiber ratio was theoretically the most parsimonious way of assessing the impact of overall fruit and vegetable intake on satiety because the accumulating literature on the gut microbiome has identified fruit and vegetable fiber as critical determinants of satiety signaling. For ease of presentation we converted the percentage of calories from added sugar to a 3-way classification distinguishing participants who adhered to the American Heart Association (AHA) recommendation to consume fewer than 5% of calories of added sugar from participants who adhered to the USDA’s recommendation to consume
fewer than 10% of calories of added sugar and from participants whose added sugar intake exceeded both added sugar recommendations (10%+). Both at baseline and at follow-up the participants who adhered to the AHA 5% added sugar recommendation had the highest F&V fiber ratio (baseline adjusted mean = 11.61; 95% CI, 11.04-12.19); adherents to the USDA 10% added sugar recommendation were intermediate (baseline adjusted mean = 10.55; 95% CI, 9.90-11.20); and participants whose added sugar intake exceeded both recommendations had the lowest F&V fiber ratio (baseline adjusted mean = 8.19; 95% CI, 7.61-8.77) (see Figure 25). This generic inverse association between percentage of calories from sweet foods and F&V fiber ratio was replicated in significant inverse associations observed between percent of calories from sweet foods and the following fruits and vegetables: bananas, apples, pears, carrots, green salad, and tomatoes (all $p < 0.04$). The percentage of calories from sweet foods was also positively associated with salty snacks, tortillas, and, of course, sugary beverages (all $p < 0.001$). In contrast to the results for sugary beverage intake, for which the highest consumers experienced no intervention benefit in terms of increasing intake over time in fruit and vegetable fiber, in the case of sweet-tasting solid food the high consumers showed the most intervention benefit (difference = 0.55 g/kg; 95% CI, 0.09-1.00).

The F&V fiber ratio, in turn, was inversely associated with feeling hunger the previous day (difference between < 9 g fiber/kilogram of food and ≥12 g fiber/kilogram = –8.64; 95% CI, –16.62 to –0.65) (see Figure 26). The participants’ F&V fiber ratio also moderated the change in their feeling full after meals from baseline to follow-up (see Figure 27). Feeling full as measured by a 100-mm visual analogue scale increased significantly from baseline to follow-up in study participants whose daily intake of fruit and vegetable fiber was 9+ grams of fiber per kilogram of solid food (baseline to 12-month follow-up difference, medium fiber ratio = 11.66, 95% CI, 2.83-20.48; difference, high fiber ratio = 12.67, 95% CI, 3.71-21.64) but did not increase significantly in participants whose baseline fruit and vegetable fiber intake was than 9 grams of fiber per kilogram (difference, low fiber ratio = 6.48; 95% CI, –4.02-16.98).

The effect of increasing intake of water-rich foods on repeated hunger ratings over 1 year was also statistically significant, with a moderate estimated effect size (Cohen’s effect size = (53.5 – 46.7)/13.2 = 0.52).22
Figure 26. Association between the ratio of fruit and vegetable grams of fiber and participant-reported level of hunger experienced during the previous day. Perceived hunger as measured by 100-mm visual analogue scale was significantly higher in study participants whose daily intake of fruit and vegetable fiber was less than 0.9% of total solid food weight compared with participants whose daily intake of fruit and vegetable fiber exceeded 1.2% of solid food weight.

Figure 27. Association between the ratio of fruit and vegetable grams of fiber and participant-reported feeling full after yesterday’s last meal. Feeling full as measured by 100-mm visual analogue scale increased significantly from baseline to follow-up in study participants whose daily intake of fruit and vegetable fiber was 9 grams of fiber per kilogram of solid food, but it did not increase significantly in participants whose baseline fruit and vegetable fiber intake was fewer than 9 grams of fiber per kilogram.
Discussion

In brief, the CC and MyP interventions failed to reduce body weight significantly but both were associated with significant declines in central body fat, as predicted. Both interventions yielded similar improvements in satiety, an outcome that we expected for the MyPlate condition but not the CC condition. Higher satiety scores in both conditions were associated with reductions in sugary beverage intake and increased proportional fruit and vegetable fiber intake. Participants in both conditions reported higher quality of life, better mental health, and higher levels of satisfaction with their respective weight-loss programs.

The lack of concordance between the body weight data and the waist circumference data is a concern. Body weight is known to be an imprecise measure of body adiposity, but other researchers have nonetheless achieved significant reductions in body weight as well as reductions in participants’ waist circumference.16,17 The MyPlate approach did yield a statistically significant reduction in systolic blood pressure at 6-month follow-up, as one would expect in exposing patients to the DASH diet,18,19 but MyP participants’ reversion to baseline systolic blood pressure values suggests that behavioral reinforcement is needed to optimize long-term adherence to the DASH diet.

As expected, food insecurity moderated the effect of the interventions, rendering the association between rated feeling of postmeal hunger and exposure to the MyPlate condition marginally insignificant but leaving still significant the association of reduced postmeal hunger with exposure to the CC condition. In theory, refraining from consuming calories because of impaired access to food should have the same biological impact as refraining from consuming calories because of intentional calorie restriction. In practice, however, involuntary restriction of calories may shift appetite to favor more energy-dense forms of carbohydrates, thereby undermining adherence to MyPlate recommendations that favor consumption of fruits and vegetables, the least energy-dense forms of carbohydrate-rich food.117

Decisional context. This study’s inquiry was prompted by findings from 3 decades of research on calorie restriction approaches to treating obesity, calling attention to the consistent difficulty that most patients wanting to lose excess body fat have had in sustaining long term the weight loss achieved during the active intervention period with the calorie restriction approach.118 This study’s central question was whether the new MyPlate approach could achieve at least equal weight loss success as the CC approach but without the increased hunger commonly associated with weight loss through
nonketogenic calorie restriction approaches to desirable weight loss.\textsuperscript{26,119} Low-carbohydrate ketogenic diets do appear to suppress feelings of hunger during active avoidance of carbohydrates, but increased hunger reappears immediately following restoration of any amount of carbohydrate consumption.\textsuperscript{120} A confluence of findings from the bariatric literature,\textsuperscript{121} the gut microbiome literature,\textsuperscript{122} and literature on the use of fruits and vegetables to promote satiety\textsuperscript{22} suggested that the new MyPlate approach introduced by the federal government in 2011 could yield at least equivalent weight loss with potentially less postmeal hunger and more satiation/satiety than the nonketogenic, conventional calorie restriction approach used in the Diabetes Prevention Trial.\textsuperscript{12} If results were limited to comparing intervention effects on body weight, the 2 interventions would be judged a failure. If results include the slow but monotonically decreasing measure of waist circumference, then the results presented here suggest that both approaches yielded body fat reduction benefit measurable at 12-month follow-up, as hypothesized. The parallel increases in satiety in the 2 conditions were unexpected but not surprising in light of the spontaneous, compositional changes in the food choices made by participants in the calorie counting condition. Instead of just cutting back on everything they had been eating before, the calorie counting participants proportionately increased their fruit and vegetable intake, much as the participants in the MyPlate condition were instructed to do.

To be consistent with previous literature and this study’s dietary data,\textsuperscript{22} the most parsimonious explanation is that proportionately increased fruit and vegetable intake—whether as part of a calorie restriction approach or a MyPlate/DASH approach—represents a gentle, user-friendly approach to reducing central adiposity in low-income patients, with satiety benefits enduring at least through 12 months of follow-up. The significant reduction in central obesity associated with exposure to both conditions was accompanied by increased satiety after meals even as participants actively engaged in weight-control efforts. Increased satiety-signaling during calorie restriction for weight loss was not expected based on past literature.\textsuperscript{81} This reduction in central adiposity was also accompanied by increased mental health and health-related quality of life, which are commonly observed short term during adherence to calorie restriction regimens.\textsuperscript{38-40} More than 90\% of participants enjoyed participating in the intervention and “definitely” would recommend it to their friends and relatives. Because the intervention failed to change participants’ levels of self-reported physical activity, the observed benefits are more reasonably attributed to the observed changes in food choices during the 1-year study period. The principal dietary changes associated with the observed reduction in central adiposity were reductions in the percent of calories from added sugar, especially by reducing sugary beverage consumption, and by the proportionally increased consumption of minimally processed fruits.
and vegetables, as reflected by fruit and vegetable fiber intake (no juices). The percentage of calories from added sugar was strongly and inversely associated with the ratio of fruit and vegetable fiber grams relative to total grams of solid food consumed. The fruit and vegetable fiber ratio, in turn, was inversely associated with patient reports of everyday hunger experienced the previous day, consistent with the higher satiety signaling expected with increased intake of prebiotics such as fruit and vegetable polysaccharides.123

The study results in context. Study results confirmed recent findings124 that calorie counting is not required to achieve significant reduction in central adiposity comparable to that achieved by the traditional calorie counting approach as long as one adheres to a DASH-style dietary pattern18 and limits consumption of inflammatory foods such as junk food,125 highly processed foods with emulsifiers,126 processed meats,127 foods high in sodium,128 and foods high in saturated fat.21 While statistically significant, the 12-month follow-up waist circumference reduction was smaller in magnitude than that reported in a previous low-income, predominantly African American clinic population.16 The seeming equivalence between intervention approaches in waist circumference reduction effectiveness seen in the results presented here could be different if the clinic population were predominantly Philadelphia African Americans rather than predominantly Long Beach Latinos. More dissemination and implementation research is needed to evaluate the relative waist circumference reduction effectiveness of these 2 approaches.

The satiety results for the calorie counting control group, while unexpected, may reflect the decision made before trial onset to permit the CC community health workers to include strong and consistent encouragement to eat more fruits and vegetables.22 While the classic calorie restriction approach treated all sources of calories as equivalent, the most popular commercial weight loss program, namely Weight Watchers, has popularized the notion that fruits and vegetables were particularly helpful food choices during weight loss efforts because of their low-calorie density.24 During the study design phase, our community advisory board objected to implementing the classic calorie restriction approach as being inconsistent with how calorie restriction approaches are implemented. We therefore permitted inclusion of a focus on encouraging CC participants to eat more fruits and vegetables, even though doing so reduced the distinctiveness of the 2 weight-loss approaches. This change in CC intervention content may at least in part explain the surprising increase in satiety observed in CC participants at 12-month follow-up. The community advisory board insistence that the CC condition encourage patients toward more fruit and vegetable consumption as a strategy to lose excess
weight was borne out of the July 2017 Diabetes Prevention Program’s release of its “Lifestyle Balance” program. The latest version of the DPP explicitly and repeatedly encourages consumption of MORE fruits and vegetables even as it continues to encourage consumption of FEWER calories in order to achieve a healthier weight.

The use of community health workers instead of highly trained behavior change specialists can yield good weight loss results, as previously demonstrated by peer leaders in Weight Watchers–style interventions. Throughout the study, all 4 community health workers were employed by TCC; 3 of them had years of prior experience working with TCC patients and were well prepared to make patient referrals to other TCC medical services, as needed. The high participant satisfaction with both of the intervention programs in this study suggests that the community health workers were successful in establishing rapport and providing culturally appropriate lifestyle change coaching. The high community support and patient-centeredness that characterized participants’ experiences in both intervention conditions could be partially confounding influences in explaining why we observed similar intervention benefits in both trials but would not be parsimonious explanations for why proportionally higher intake of fruits and vegetables would be associated with satiety ratings. More research is needed to disentangle the separate contributions of dietary change, community support, and the patient-centeredness of the interventions to increased satiety and reduced central adiposity.

The investigators were surprised at the dearth of literature on the use of behavioral economics in the home setting to create a home environment more supportive of healthier lifestyle choices. The most recent federal nutrition guidelines explicitly embrace a socioecological model approach to changing food choices, implicitly acknowledging the importance of the food environment for influencing population food choices. In the one major study that made changing the food in the home the focus of the intervention, desirable weight loss was achieved. In the present study the community health workers were somewhat resistant to ask participants to complete the home environment audit. They were resistant in part because they believed it to be an intrusion on the participants’ privacy. In theory, the participants were expected to be more receptive to changing physical features of their home environment than they were to changing their lifestyle practices. In practice, however, changing physical features of the home environment was challenging because there were typically multiple stakeholders in the household, not all of whom shared the same perceived benefits of changing home environmental cues to make them more supportive of healthier food choices.

Implementation of study results. TCC health care providers, according to TCC’s senior
administrators, were happy with the MyPlate intervention staff’s minimally intrusive approach to apprise the providers of patient eligibility for participation in the trial and to obtain provider approval for the patient to be enrolled in the intervention. Using community health workers as change agents relieved the health care providers of managing the treatment of those patients who needed to lose excess body weight. Because the community health workers were actual TCC employees and not UCLA employees, they used their knowledge of TCC to obtain clinic resources that were not among those provided by the PCORI contract, such as referrals for mental health issues. Because TCC has a long-standing policy against using incentives to motivate patients to participate in health education offerings, no incentive was offered to induce participation in intervention sessions. Transportation vouchers were provided, however, to cover the costs associated with attending the group health education sessions at the clinic or at a local grocery store where nutrition education occurred. TCC provided childcare at the group health education sessions, allowing participants to devote their full attention to the health education. Participation in the phone coaching sessions and the group health education session was nonetheless low, suggesting that small per-session incentives (eg, $5 per session) might increase patient participation. The UCLA assessment staff used incentives to optimize participation in the assessments ($20 for baseline assessment, $30 for 6-month assessment, and $50 for 12-month assessment), resulting in 80% retention at 12-month follow-up (if the 9 participants not included in analyses because they became pregnant are included). If incentives worked so well for motivating participation in the assessments, they may also have motivated participation in the intervention sessions.

**Generalizability.** Because 86% of the participants were Latino, results may not be generalizable to African Americans, whites, or other ethnic groups. Because 95% of the participants were women, results may not be generalizable to men. Because all participants were patients receiving medical care at a community clinic serving a low-income, urban population, results may not generalize to patients in other clinics in Los Angeles, in other cities, in rural populations, or to higher-income patients. These caveats notwithstanding, there may be benefits to clinics adopting some of the intervention strategies employed in this study, such as the use of home health education sessions, the use of community health workers as change agents, the use of cooking demonstrations, the use of home environmental audits, and the provision of a community resource guide to facilitate patient access to resources that may help them improve their food choices and increase their daily level of physical activity.

**Subpopulation considerations.** The identifiable subgroups the investigators planned to examine
closely in this study included men and African Americans. Unfortunately, instead of the projected 30% of participants being men, the observed proportion was only 5% (n = 12). Instead of the projected 13% of participants being African American, only 8% (n = 20) enrolled in the study. Hypothesis testing with samples of 20 or fewer is nearly futile.

These subgroups are nonetheless useful for hypothesis-generating purposes and represent future study populations in which to conduct MyPlate-type interventions culturally tailored to address their group's specific needs. Because 86% of the enrollees in this study were low-income Latinos, often with immigrant backgrounds (82% born outside of the United States), potentially important lessons could emerge from analyses of the data regarding the impact of acculturation on receptivity and responsiveness to the MyPlate intervention. Indeed, exploratory subgroup analyses indicated that intervention impact was greatest on the moderately (second tertile) US-acculturated participants, whose food choices departed significantly more from federal nutrition guidelines at baseline relative to the minimally acculturated participants.

**Study Limitations.** We based most of the measures used in this study on self-report, which is typically subject to greater measurement error than biological measures. To optimize the patient-centeredness of trial procedures, we included no venipuncture to assess changes in diet or satiety hormones and conducted no maximal treadmill testing for assessing changes in fitness. The patient-centered decision to obtain waist circumference measures over clothing if patients objected to partial disrobing introduced measurement error but adjusting for that error did not meaningfully change the results, despite exhaustive sensitivity analysis testing. The failure of the hypothesis testing to confirm the expected experimental condition by time interaction on satiety was attributable to the calorie counting condition yielding results that differed from results obtained in past calorie-restriction participants, possibly because the CC condition included strong encouragement to eat more fruits and vegetables, because of contamination from inadvertent exposure of CC patients to the MyPlate condition by talking to other patients, or because of contamination from inadvertent exposure of the community health workers nested in the CC condition hearing about strategies being used by their community health worker colleagues nested in the MyPlate condition. Increased imprecision and possible selection bias might have resulted from the 33% of baseline participants not included in the 12-month follow-up analyses. The 261 baseline participants were selected at random from the participating clinic’s patient population, but this small number may not fairly represent the millions of low-income patients living in California. From an ethical perspective, the investigators are pleased that participants
in both conditions enjoyed similar satiety benefits but the reduction in feeling of hunger after eating in the calorie restriction condition is in contrast to a previous randomized controlled trial showing significantly greater hunger in the calorie restriction arm compared with the fruit- and vegetable-supplemented arm.22 The 12-month follow-up waist circumference outcomes of either intervention condition are impressive relative to secular trends toward increasing waist circumference over time in healthy middle-aged adults.132 Because follow-up of participants ended at 12 months, extrapolation of results to longer time intervals is problematic.

Eating is embedded in a web of daily influences ranging from variations in health status to variations in menstrual cycling, daily physical activity level, and income-related access to food, only some of which this study measured. Moreover, physiological functioning is not necessarily the primary determinant of food choices. Hedonic hunger and liking/wanting of highly palatable foods, regardless of feelings of fullness, could also influence eating duration and quantity of calories consumed.133 The generalizability of this study’s findings is necessarily constrained by the limited number of covariates that could be included without overburdening the study participant.

**Future Research.** Beneficial intervention features unique to each of the approaches studied here could be combined for greater impact. This, in fact, was accomplished implicitly in a recent weight-loss intervention targeting adults with serious mental illness.124 The authors of that study built on the nutrition approach pioneered by the DASH trials18,19 much as the investigators did with the MyPlate approach. However, they also included recommendations to restrict portion sizes and calorie-dense foods as commonly done in calorie restriction programs but explicitly rejected the calorie monitoring approach of traditional calorie restriction programs. The modest 1.5 kg weight-loss advantage observed in the intervention group compared with controls at 6-month follow-up became a 2.6 kg advantage at 1 year and a 3.2 kg advantage at 18-month follow-up, a pattern of continuing improvement rarely seen in the calorie restriction literature.81 Unsurprising inflammation-reducing benefits of calorie restriction have recently been identified in studies of the murine gut microbiota,134 providing conceptual support for restricting consumption of pro-inflammatory foods (eg, processed foods with emulsifiers, processed meats, foods high in saturated fat),135 even as patients are encouraged to eat more daily servings of minimally processed fruits, vegetables, whole grains, legumes, seeds, and nuts.21 In other words, there may be therapeutic benefits to including both caloric restriction (of pro-inflammatory foods) and the MyPlate recommendations (to eat more fiber-rich foods, to limit sodium-added, sugar-added, saturated fat-rich foods).
Conclusions

Results were conditionally supportive of initial hypotheses. Six- and 12-month follow-up declines in body weight and a 6-month follow-up decline in systolic blood pressure in the MyPlate US-acculturated subgroup provide some admittedly limited corroboration of the primary medical hypotheses. The fact that the CC arm experienced more hunger-diminishing and equally satiety-enhancing benefits as the MyP arm, contrary to hypothesis, suggests that CC participants’ proportionally increased intake of fruit and vegetable fiber may have contributed to their increased satiety levels over time. The observed intervention effect on reducing the percent of calories from sweet-tasting solid foods and follow-on effect of reduced percentage of calories from sweet-tasting solid food on level of fruit and vegetable fiber intake do offer plausible physiological and metabolic mechanisms for how the reduction in waist circumference was achieved in both conditions. The overall negligible drop in body weight in either intervention condition was smaller than expected but correlated with the waist circumference outcomes, which yielded significant cross-time effects for both conditions.

The waist circumference results are more impressive when viewed in the context of the secular trend for central obesity risk to increase with age in middle-aged, low-income Americans. Even more impressive, from a patient-centered outcome perspective, is that the significant reduction in central adiposity was achieved concurrently with increases in quality of life, mental health, and satiation/satiety. When engaging in desirable lifestyle behaviors leads to intrinsically rewarding outcomes, it is much easier to imagine lifelong adherence to those behaviors than if the desired behaviors are associated with the need for continual vigilance against relapse and more frequent feelings of postmeal hunger as previously observed in the calorie restriction literature.

This study demonstrated that when intervention and research assistant personnel gained the trust of participants, good follow-up is possible and participants will generally permit the personnel into their homes. So-called hard-to-reach populations such as low-income, immigrant Latinos are not difficult to recruit and retain when the intervention and assessment personnel are familiar with the community and share cultural and linguistic ties with the study participants.

A possible reason for steadily improving weight-loss outcomes observed in trials that emphasize eating more fruits, vegetables, whole grains, legumes, seeds, and nuts rather than emphasizing calorie restriction is that consumption of these minimally processed plant foods is associated with increased satiety-signaling despite active weight loss, but the resulting daily calorie
deficit is small. Using portions of the plate instead of calories as the metric for gauging relative quantities of food consumed is likely more user-friendly for low-literacy, low-numeracy populations than asking them to read food labels and track their daily calorie intake. Despite the initially modest obesity-reduction benefit of the MyPlate approach, its relatively low cost and user-friendliness—and the demonstrated benefit of inducing adults to eat proportionately more fruits and vegetables, minimally processed foods, whole grains, legumes, seeds, and nuts—argues for follow-on studies to see if a modified form of the MyPlate approach that avoids the tedium of calorie counting but encourages limits on the amount of processed food consumed each day might work as well (or better) in other low-income communities as traditional calorie restriction approaches to desirable weight loss.
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