Title

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Journal

The Annals of Family Medicine, 21(3)

ISSN

1544-1709

Authors

McCarthy, William J
Rico, Melvin
Chandler, Maria
et al.

Publication Date

2023-05-01

DOI

10.1370/afm.2964

Peer reviewed

Randomized Comparative Effectiveness Trial of 2 Federally Recommended Strategies to Reduce Excess Body Fat in Overweight, Low-Income Patients: MyPlate.gov vs Calorie Counting

William J. McCarthy, PhD[1,2]
Melvin Rico[3]
Maria Chandler, MD[4]
Dena R. Herman, PhD[5]
Cindy Chang, MS[4]
Thomas R. Belin, PhD[6]
Stephanie Love[4]
Evangelina Ramirez[7]
Lillian Gelberg, MD, MSPH[8,9]

[1]Center for Cancer Prevention & Control Research, Fielding School of Public Health, University of California-Los Angeles, Los Angeles, California

[2]Department of Psychology, University of California-Los Angeles, Los Angeles, California

[3]Charles R. Drew University Postgraduate Medical School, Los Angeles, California

[4]The Children's Clinic of Long Beach, Long Beach, California

[5]College of Health and Human Development, California State University-Northridge, Northridge, California

[6]Department of Biostatistics, Fielding School of Public Health, University of California-Los Angeles, Los Angeles, California

[7]Kalula Transport, Hemet, California

[8]Department of Family Medicine, David Geffen School of Medicine, University of California-Los Angeles, Los Angeles, California

[9]Department of Health Policy and Management, Fielding School of Public Health, University of California-Los Angeles, Los Angeles, California

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Conflicts of interest: authors report none.

CORRESPONDING AUTHOR

William J. McCarthy
Center for Cancer Prevention & Control Research
UCLA Fielding School of Public Health
A2-125 CHS; Box 690015
Los Angeles, CA 90095-6900
wmccarth@ucla.edu

ABSTRACT

PURPOSE Since 2011, US authorities have supported the following 2 approaches to healthier body fat composition: the Centers for Disease Control and Prevention National Diabetes Prevention Program's calorie counting (CC) approach and the US Department of Agriculture's MyPlate (adherence to federal nutrition guidelines). The purpose of this study was to compare the effect of CC vs MyPlate approaches on satiety/satiation and on achieving healthier body fat composition among primary care patients.

METHODS We conducted a randomized controlled trial comparing the CC and MyPlate approaches from 2015 to 2017. The adult participants were overweight, of low income, and were mostly Latine (n = 261). For both approaches, community health workers conducted 2 home education visits, 2 group education sessions, and 7 telephone coaching calls over a period of 6 months. Satiation and satiety were the primary patient-centered outcome measures. Waist circumference and body weight were the primary anthropometric measures. Measures were assessed at baseline, 6 months, and 12 months.

RESULTS Satiation and satiety scores increased for both groups. Waist circumference was significantly decreased in both groups. MyPlate, but not CC, resulted in lower systolic blood pressure at 6 months but not at 12 months. Participants for both MyPlate and CC reported greater quality of life and emotional well-being and high satisfaction with their assigned weight-loss program. The most acculturated participants showed the greatest decreases in waist circumference.

CONCLUSIONS A MyPlate-based intervention might be a practical alternative to the more traditional CC approach to promoting satiety and facilitating decreases in central adiposity among low-income, mostly Latine primary care patients.

Ann Fam Med 2023;21:213-219. https://doi.org/10.1370/afm.2964

INTRODUCTION

New strategies are needed to improve the success of obesity treatment in the primary care setting.[1] The dominant behavioral intervention approach to treating obesity has emphasized energy restriction via calorie counting (CC) and portion size limits.[2] This approach has yielded consistent short-term weight-loss benefits including among low-income primary care patient populations.[1,3] Despite this success, the prevalence of obesity in the United States has continued to increase, with a prevalence of 42.4% in 2017-2018.[4] Focusing more on enhancing satiety and less on calorie counting might be a practical alternative for sustaining primary care patients' efforts at reducing excess body fat.[5,6] Shifting the emphasis to optimizing satiation/satiety can be achieved by encouraging consumption of fiber-rich foods, particularly fresh fruits and vegetables.[6,7] Satiation refers to physiologic processes that terminate an eating occasion.[8,9] Satiety refers to feeling free of hunger during the period initiated by the end of a meal and terminating when hunger triggers a desire to start the next meal.[9] This shift in emphasis addresses goals expressed by patients to lose excess fat while feeling satisfied with their meals (satiation) and without feeling hungry (satiety).

Research on the effects of specific foods on self-ratings of hunger, meal satisfaction, and fullness after meals have identified minimally processed, fiber-rich

plant foods as satiating or promotive of satiety.[10-12] The Dietary Approaches to Stop Hypertension (DASH) diet,[13] featured in federal nutrition guidelines (MyPlate; www.myplate.gov), prescribes a minimum of 8 servings of fruits and vegetables a day, nearly double the typical US fruit and vegetable consumption.[14] A 2011 clinical trial of a DASH-based weight-loss approach involving low-income primary care patients with obesity[15] reported that DASH doubled the percentage of patients sustaining 2-year weight loss of at least 5% (38.2%) compared with the self-care control condition (18.8%; $P < .001$).

In the present study, we adapted CC and MyPlate interventions to the cultural and clinical context of predominantly Latine primary care patients served by a federally qualified health center,[16] based on input from patients, primary care clinicians, clinic staff, and community partners. We compared the CC to MyPlate interventions at 1 year on key patient-centered and anthropometric outcomes. Regarding the anthropometric measures, we designed this study as a noninferiority clinical trial comparing 2 distinct government-supported behavioral approaches to reducing excess body fat in overweight patients. Whereas the 2 conditions were expected to yield comparable body fat reduction, the cognitively simpler[17] MyPlate approach was expected to rely on greater satiation and satiety[6,7,18] to sustain a healthier daily calorie intake. The primary patient-centered outcomes consisted of 3 visual analog scale measures of satiation and satiety. The primary anthropometric outcome measures were waist circumference and body weight. Interest also focused on acculturation as an effect modifier. Secondary outcomes included dietary quality and health-related quality of life.[19]

METHODS

Study Design

We conducted a parallel-group, randomized, controlled, comparative-effectiveness trial with equal numbers allocated to each experimental condition. The Consolidated Standards of Reporting Trials diagram in Figure 1 outlines study progress through the 1-year follow-up. The interventions were open label, but research assistants were blind to participants' experimental assignment. This study was approved by the University of California-Los Angeles Institutional Review Board (IRB #14-001360) and fully registered on Aug 4, 2015 at clinicaltrials.gov (NCT02514889).

Interventions and Comparability of Intervention Exposure

Community health workers (CHWs) were trained to provide lifestyle-change coaching for study participants. Intervention details are reported elsewhere.[16] In brief, both behavior-change approaches are built on social cognitive theory[20] and use motivational interviewing.[21] Consistent with previous National Diabetes Prevention Program protocols,[22] the CC approach focused on helping patients achieve a daily calorie deficit. The MyPlate approach focused on helping patients adhere to the DASH dietary pattern and did not encourage calorie counting;[15] the focus was on adhering to MyPlate principles by making minimally processed fruits and vegetables one-half of their daily food intake and whole-grain foods and quality protein sources each one-quarter of their daily intake.

Both interventions featured 11 health education sessions over a period of 6 months, comparable to prior primary care–based weight-loss trials.[23] These included 2 home visit sessions, 2 group education sessions, and seven 15-minute telephone coaching calls, all within 6 months of enrollment. Community health workers were nested within intervention condition, with 2 delivering MyPlate coaching and 2 delivering CC coaching. Weekly debriefing calls between investigators and CHWs optimized CHW adherence to intervention protocols, thereby reinforcing intervention fidelity.

Intervenors

Community health workers employed by the clinic partner were the behavior change agents. The 4 CHWs, 2 of whom were Spanish bilingual, received 2 days of behavioral weight-loss training adapted from prior calorie restriction[22] or DASH diet[15] weight-control intervention protocols, respectively. All CHWs were trained in motivational interviewing[24] and in cognitive-behavioral behavior change strategies.[25] The CHWs' mastery of these strategies was reinforced during weekly debriefing sessions throughout the active intervention phase.

Participants

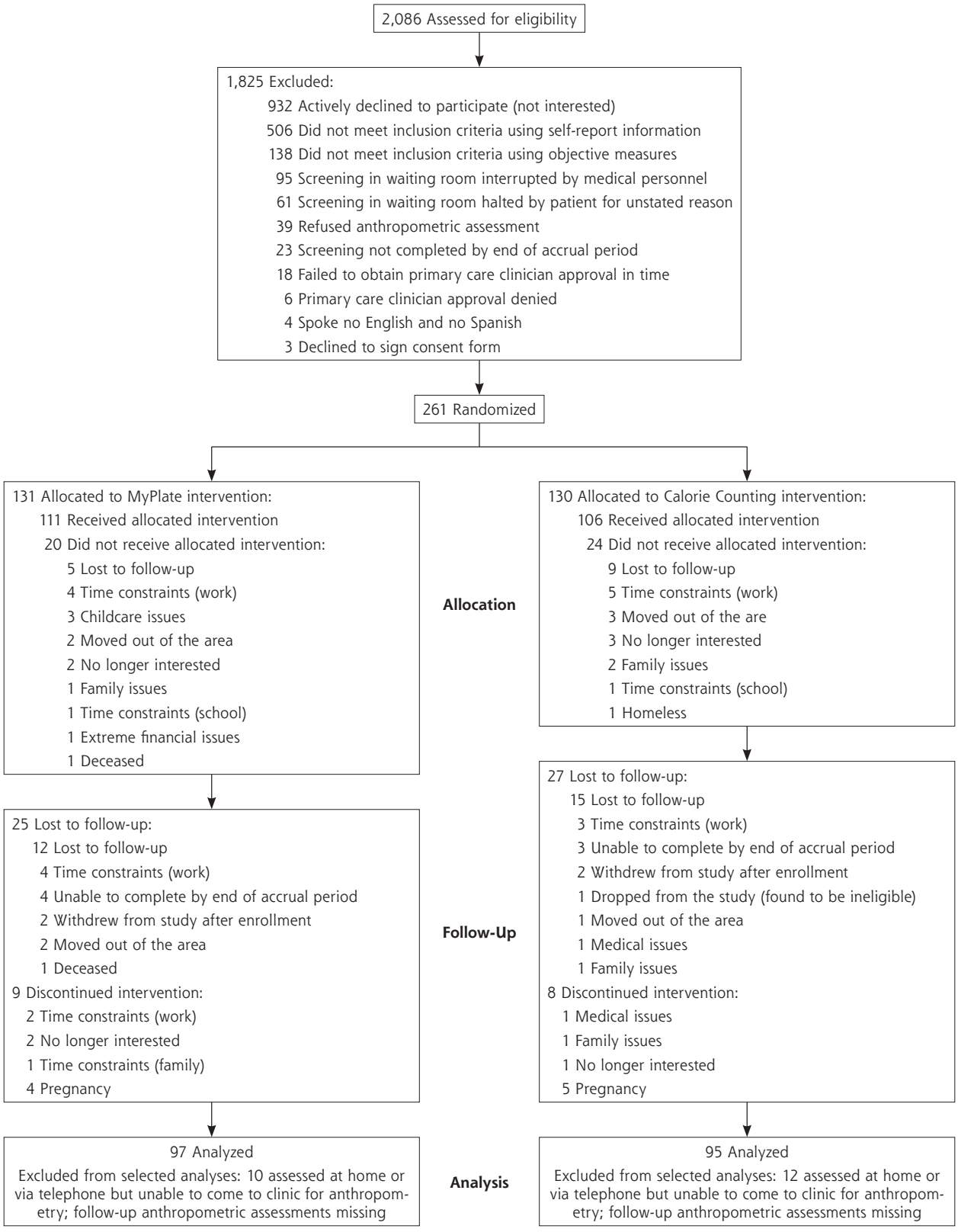
Patients were eligible if they were adults, had a baseline body mass index of 27 to 40, and spoke English or Spanish. Patients with uncomplicated type 2 diabetes were eligible contingent on approval from their primary care clinician. Patients were excluded if they were insulin dependent, were pregnant or planning to become pregnant, used weight-loss drugs in the past 6 months, currently smoked, reported problem drinking, or had a blood pressure >160/100 mm Hg. We used a computer-generated random number algorithm to assign participants to each experimental condition after determination of eligibility.

Measures

Study measure details are reported elsewhere.[16] In brief, data on anthropometric, psychosocial, and lifestyle behavior measures were obtained at baseline, 6 months, and 12 months after enrollment. Food frequency questionnaires were completed at baseline and 12 months only. Assessments were performed in a private room in the clinic and required 1 hour. The Block Food Frequency Questionnaire[26] was typically completed at home or by telephone.

We used a 100-mm visual analog scale[18] to assess satiation/satiety. Participants were instructed to mark the visual analog scale to indicate the satiety measure of hunger and the 2 measures of satiation (feeling of fullness and meal satisfaction).[27] These questions were worded as follows: (1) "How hungry

Figure 1. CONSORT flow diagram showing reasons for study attrition.



CONSORT = Consolidated Standards of Reporting Trials.

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)?"

Participants were asked 6 standard US Department of Agriculture (USDA) questions about food insecurity.[28,29] Using a USDA-recommended scoring algorithm,[28] we included the summative score as a covariate.

Primary patient anthropometric outcomes included the following 2 indicators of body fat composition: waist circumference (cm) and body weight (kg). Waist circumference was assessed using a Gulick anthropometric tape.[30] For participants averse to partial disrobing, the research assistant measured waist circumference over minimal clothing and recorded the measures as taken over clothing. Body weight was assessed using a digital scale (Tanita, model BWB 800S) calibrated weekly. The baseline vs 12 months follow-up differences for satiation/satiety were the primary patient-centered outcomes, and corresponding differences for waist circumference and body weight were the primary patient anthropometric outcomes.

Prespecified Secondary Outcome Measures

DASH Score

We evaluated adherence to DASH guidelines using an existing instrument,[31] assigning points for high intake of fruit, vegetables, nuts and legumes, low-fat dairy products, and whole grains according to quintile rankings.

Health-Related Quality of Life and Mental Health

We used the 12-item Short Form Survey (SF-12) health-related quality of life scale[32,33] and the Mental Health Inventory-5 (MHI-5) mental health scale.[33] High scores represent better quality of life and greater emotional well-being, respectively.

Systolic Blood Pressure

Resting blood pressure was measured using an A&D Medical UA-767 Plus digital sphygmomanometer (A&D Company) following the National Health and Nutrition Examination Survey protocol.[30]

Statistical Analysis

On the basis of power analyses described elsewhere,[16] the sample size target was 300. Timeline constraints halted accrual at n = 261.

We performed longitudinal analyses using random-intercept mixed-effects models.[34] For analysis of the satiation/satiety outcomes, we evaluated predicted differences in expected intervention-induced changes over time by testing a predicted-treatment-by-time interaction.[35] Demographic covariates included sex, age, ethnicity, educational attainment, and marital status. Models had included the USDA measure of food insecurity,[28] but this covariate had negligible effect on outcomes and was not retained in final analyses (Supplemental Table 1).

For intention-to-treat analyses, missing primary and secondary outcomes at follow-up were multiply imputed 20 times using the Stata mi procedure (StataCorp LLC)[36] and a multivariate-normal joint modeling assumption. For analyses involving the 3 indicators of satiation/satiety, we used a false-discovery rate of q = 0.05 to correct for multiple hypothesis testing.[37,38] For analyses involving the 2 anthropometric indicators of body composition, we set the critical *P* value to .025 to correct for multiple hypothesis testing.[38] Analyses were repeated with exposure to planned intervention sessions grouped at 3 levels (0 sessions, 1-6 sessions, 7-11 sessions) to assess the effect of increasing intervention exposure. Similar covariate-adjusted analyses considered whether tertiles of acculturation moderated the effect of the intervention on outcomes. All full-sample analyses were replicated for the subgroup of women-only and the subgroup of Latine-only participants to assess robustness of findings when excluding the 12 men or 30 non-Latine participants in the study (Supplemental Table 2 and Supplemental Table 3).

RESULTS

Baseline Characteristics

As described previously,[16] a total of 261 overweight/obese participants were randomized to each condition (CC or MyPlate). Most participants were female (95%) and Latine (86%); the remaining were African American (8%), White (4%), Asian-Pacific Islander (2%), or other (1%). Mean age was 42 years (range, 18-72 years). Most participants (82%) were foreign born; 74% preferred speaking in Spanish. Demographic characteristics and baseline outcome measures did not differ between experimental conditions[16] (Table 1). Accrual began on June 29, 2015 and ended February 29, 2016.

Study Attrition

Cases with complete follow-up data did not differ from those with incomplete follow-up data on outcome measures (all $P > .15$). The only baseline characteristic that differed between complete and incomplete cases was age (incomplete: 37.6

Table 1. Baseline Marginal Means for Primary Outcome Measures, by Condition, Among 261 Adult Low-Income Primary Care Patients of a Partnering Federally Qualified Health Center

	MyPlate	Calorie Counting	Group Difference
Outcome Measure	Baseline Mean (SE)	Baseline Mean (SE)	*P* Value
Hunger, mm	47.09 (2.16)	50.75 (2.17)	.30
Meal satisfaction, mm	66.91 (2.54)	69.31 (2.55)	.54
Feeling full, mm	65.96 (2.31)	69.89 (2.32)	.26
Waist circumference, cm	100.47 (0.81)	103.30 (0.81)	.054
Body weight, kg	80.85 (0.99)	83.03 (1.00)	.31

DASH = Dietary Approaches to Stop Hypertension.

Note: Mean values reflect statistical adjustments for participant age, sex, marital status, educational attainment, race/ethnicity, and DASH score.

years, 95% CI, 34.5-40.7 years; complete: 43.0 years, 95% CI, 41.5-44.6 years). Age was not significant in any analysis showing significant changes in study outcomes. As shown in in Figure 1, 77.9% of MyPlate participants and 75.4% of CC participants participated in 12-month follow-up assessments.

Intervention Exposure

Overall, 83% of study participants had ≥1 intervention session, 33% engaged in 1 to 5 sessions, an additional 39% participated in ≥6 sessions, and 14% engaged in all 11 sessions. The home visit sessions were the most popular (83% participated), followed by the group education sessions (76% participated) and the telephone coaching calls (72% participated). Regardless of experimental condition, participants overwhelmingly (92%) reported being somewhat or very satisfied with their body-fat reduction program.

Primary Patient-Centered Outcomes

All 3 satiation/satiety measures improved from baseline to 12 months for both conditions, although the decrease in hunger in the MyPlate group was not significant after taking multiplicity of hypothesis testing into account (Table 2). We had predicted significant increases in satiation/satiety with the MyPlate condition and nonsignificant changes in satiation/satiety with the CC condition. We expected this difference in change over time to yield a significant treatment-by-time interaction effect.[35]

Primary Anthropometric Outcomes

The hypothesized absence of a treatment-by-time interaction for reduction in waist circumference was confirmed, that is, the differences between treatment conditions did not differ significantly at different assessment intervals. However, a within-treatment analysis showed a significant reduction in MyPlate participants' waist circumference from baseline to 12 months (difference = −1.86 cm; 95% CI, −3.26 to −0.46 cm; $P = .009$) (Table 2). Calorie counting participants' reduction in waist circumference (difference = −1.71 cm, 95% CI, −3.16 to −0.26 cm; $P = .02$) was also significant but not significantly different from the MyPlate mean. Most (73%) of the waist circumference measures were taken over clothing, per participant preference. A mean 3.34-cm (95% CI, 1.71-4.98 cm) difference was observed between waist circumference measured over clothing vs measured against the skin. Sensitivity analyses recalculated the waist circumference measures after subtracting 3.34 cm when the measurement was taken over clothing. These analyses resulted in larger decreases in waist circumference from baseline to follow-up for both conditions (MyPlate b = −3.15; 95% CI, −4.54 to −1.77; $P < .001$; CC b = −2.72; 95% CI, −4.16 to −1.29; $P < .001$). Sensitivity analyses of alternative offsets of 1 cm, 2 cm, and 3 cm yielded comparable results (data not shown).

Although both groups included more people who lost weight than gained weight from baseline to 12 months (MyPlate = 59.1%; CC = 53.5%), neither intervention yielded a significant reduction in body weight (MyPlate difference: −0.34 kg, 95% CI, −1.27 to 0.59 kg; CC difference: −0.75 kg; 95% CI, −1.72 to 0.23 kg).

Intention-to-treat analyses after multiple imputation of missing primary outcome values yielded similar results (data not shown). The MyPlate reduction in waist circumference

Table 2. Marginal Mean Differences From Baseline to 6 and 12 Months Follow-Up for Primary Outcome Measures, by Condition, Among 261 Adult Low-Income Primary Care Patients of a Partnering Federally Qualified Health Center

	MyPlate			Calorie Counting				
Measure	6 Months (95% CI)	12 Months (95% CI)	12-Months Difference *P* Value	6 Months (95% CI)	12 Months (95% CI)	12-Month Difference *P* Value	Group Difference[b]	Group Difference *P* Value
Hunger, mm	−3.76 (−9.41 to 1.89)	−6.17 (−11.85 to −0.50)[a]	.03[a]	−8.29 (−14.22 to −2.36)[a]	−9.64 (−15.41 to −3.87)[a]	.001[a]	−3.47	.51
Meal satisfaction, mm	12.05 (5.01 to 19.09)[a]	17.13 (10.07 to 24.20)[a]	<.001[a]	9.46 (2.09 to 16.83)[a]	12.80 (5.62 to 20.0)[a]	<.001[a]	2.59	.69
Feeling full after meal, mm	5.81 (−0.68 to 12.30)	12.64 (6.12 to 19.15)[a]	.001[a]	4.89 (−1.90 to 11.68)	8.13 (1.51 to 14.75)[a]	.016[a]	4.51	.61
Waist circumference, cm[c]	−1.42 (−2.75 to −0.08)[a]	−1.86 (−3.26 to −0.46)[a]	.009[a]	−0.39 (−1.82 to 1.04)	−1.71 (−3.16 to −0.26)[a]	.02[a]	−0.15	.54
Waist circumference, cm[d]	−2.18 (−3.50 to −0.85)[a]	−3.15 (−4.54 to −1.77)[a]	<.001[a]	−0.94 (−2.36 to 0.47)	−2.72 (−4.16 to −1.29)[a]	.0002[a]	−0.43	.45
Body weight, kg	−0.23 (−1.11 to 0.66)	−0.34 (−1.27 to 0.59)	.48	−0.55 (−1.50 to 0.41)	−0.75 (−1.72 to 0.23)	.13	0.41	.81

Note: Mean values reflect statistical adjustments for participant age, sex, marital status, educational attainment, and race/ethnicity. Changes in outcomes observed for participants who participated in 7-11 sessions were greater than changes observed for participants who participated in ≤6 sessions.

[a]Significant change from baseline at the $P < .025$ for body composition measures (Bonferroni-corrected nominal *P* value) and at the q = .05 (false-discovery rate) correction for multiplicity of hypothesis testing for the 3 satiety measures.
[b]Group-by-time interaction (group difference in differences from baseline to 12 months follow-up).
[c]Waist circumference not corrected for variation in measurement over clothing.
[d]Waist circumference corrected for variation in measurement over clothing.

at 12 months remained significant for the full sample, female-only, and Latine-only participant analyses when waist circumference measures were adjusted to correct for those instances when waist circumference was measured over clothing instead of against the skin.

Increased participation in intervention sessions was associated with greater changes in desired outcomes. Participants exposed to zero sessions showed no changes; participants exposed to 1 to 6 sessions experienced modest but not significant improvements in satiation/satiety and body composition measures. MyPlate participants exposed to 7 to 11 sessions showed significant improvements in 2 of 3 measures of satiation/satiety and in waist circumference at 12 months (Supplemental Table 4) as well as a nonsignificant decrease in body weight (b = −1.38 kg; 95% CI, −2.70 to −0.06 kg; $P = .0402$) after correcting for multiple hypothesis testing. Calorie counting participants exposed to 7 to 11 sessions showed significant improvement in meal satisfaction, hunger, and waist circumference but no significant improvement in feeling full after a meal and body weight at 12 months (Supplemental Table 4). Neither group showed a significant decrease in systolic or diastolic blood pressure at 12 months, although MyPlate participants did experience an average decrease in systolic blood pressure at 6 months from 123 mm Hg to 120 mm Hg (95% CI, −5.44 to −0.53; $P = .0171$); the corresponding 1-mm Hg decrease for CC participants was not significant.

Health-Related Quality of Life and Mental Health

MyPlate and CC participants experienced increases from baseline to follow-up in health-related quality of life and mental health. The mean SF-12 score increased from 73.99 (95% CI, 70.8-77.2) to 77.8 (95% CI, 74.3-81.2; $P = .0149$) for MyPlate and from 73.8 (95% CI, 70.6-77.1) to 79.9 (95% CI, 76.3-83.4; $P = .0032$) for CC. In addition, MHI-5 scores increased from 75.9 (95% CI, 72.7-79.0) to 82.1 (95% CI, 78.7-85.5; $P = .0014$) for MyPlate and from 78.3 (95% CI, 75.1-81.4) to 84.4 (95% CI, 81.0-87.9; $P = .0025$) for CC.

Intermediate Endpoints/Moderating Variables

Prespecified Moderator: Acculturation

Acculturation was influenced by whether the participant was US born or foreign born ($P < .001$). Even after controlling for demographic variables, baseline acculturation was inversely associated with participant baseline DASH score, a measure of dietary quality ($P < .001$). As reflected in Supplemental Table 5, only the MyPlate participants in the top tertile of acculturation reduced their waist circumference significantly at 12 months (b = −3.42, 95% CI, −6.40 to −0.45; $P = .0243$).

DISCUSSION

This comparison of MyPlate to CC for addressing excess body fat in low-income, mostly Latine primary care patients suggests that both intervention approaches offer satiation/satiety-enhancing and body fat–reduction benefits. The simpler MyPlate approach might be a practical alternative to the more cognitively demanding calorie restriction approach in primary care settings.[17] The disproportionate benefit experienced by the most acculturated tertile suggests that more nuanced tailoring of the intervention is needed for recent immigrants to encourage them to retain their baseline healthier dietary habits.[39]

The continuing reduction of central adiposity observed among MyPlate participants 6 months after the active intervention phase had ended is consistent with interventions that focus on high-satiety foods.[40,41] Similar approaches have yielded reductions of central adiposity without a corresponding loss of body weight, as observed in the present study.[40,42] Whereas additional research is needed to confirm the hypothesized intervention components, the results of the present study align with recommendations favoring a diet rich in diverse, fiber-rich foods.[43]

Strengths of this study include comparing 2 existing, government-recommended dietary interventions, involvement of low-income Latine primary care patients, acceptable study retention, a 6-months no-intervention follow-up period to evaluate behavior change sustainability, and use of clinic-employed bilingual CHWs as change agents. Study limitations include reliance on self-reports of dietary change with no biomarker validation and generalizability limited to low-income Latine primary care patients living in Long Beach, California. More research is warranted to investigate satiety-enhancing approaches to desirable weight control in diverse populations and the use of CHWs as change agents.

Read or post commentaries in response to this article.

Key words: clinical trial; obesity treatment; nutrition intervention; Latine; immigrant

Submitted July 7, 2022; submitted, revised, November 18, 2022; accepted December 13, 2022.

Funding support: Patient-Centered Outcomes Research Institute CER-130601150.

Disclaimer: The authors had exclusive and full access to and control of study data. The decision to submit this manuscript for publication was exclusively a decision by the authors. The sole funder of the research reported in this manuscript was the Patient-Centered Outcomes Research Institute (PCORI). The authors were solely responsible for the study design, data collection, analysis of data, and writing of this manuscript; PCORI was not responsible for any of these roles.

Previous presentation: North American Primary Care Research Group 45th Annual Meeting; November 17-21, 2017; Montreal, Quebec, Canada

Trial registration: This study is registered at www.clinicaltrials.gov (NCT02514889), posted Aug 4, 2015.

Acknowledgments: We would like to thank all of the patients, primary care physicians, and staff who participated in this study. We also thank the community members who helped guide the development of this study and who assisted in the interpretation of study results.

Supplemental materials

Replication data: Available at https://doi.org/10.7910/DVN/JO6OG9

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