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Diabetes Prevention Program Translation in the Veterans Health Administration

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Abstract

Introduction: This clinical demonstration trial compared the effectiveness of the Veterans Affairs Diabetes Prevention Program (VA-DPP) with an evidence-based usual care weight management program (MOVE!®) in the Veterans Health Administration health system.

Design: Prospective, pragmatic, non-randomized comparative effectiveness study of two behavioral weight management interventions.

Setting/participants: Obese/overweight Veterans with prediabetes were recruited from three geographically diverse VA sites between 2012 and 2014.

Intervention: VA-DPP included 22 group-based intensive lifestyle change sessions.

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Main outcome measures: Weight change at 6 and 12 months, hemoglobin A1c (HbA1c) at 12 months, and VA health expenditure changes at 15 months were assessed using VA electronic health record and claims data. Between-group and within-group comparisons for weight and HbA1c were done using linear mixed-effects models controlling for age, gender, race/ethnicity, baseline outcome values, and site. Analyses were conducted in 2015–2016.

Results: A total of 387 participants enrolled (273 VA-DPP, 114 MOVE!). More VA-DPP participants completed at least one (73.3% VA-DPP vs 57.5% MOVE! $p=0.002$), four (57.5% VA-DPP vs 42.5% MOVE!, $p=0.007$), and eight or more sessions (42.5% VA-DPP vs 31% MOVE!, $p=0.035$). Weight loss from baseline was significant at both 6 ($p<0.001$) and 12 months ($p<0.001$) for VA-DPP participants, but only significant at 6 months for MOVE! participants ($p=0.004$). Between groups, there were significant differences in 6-month weight loss (-4.1 kg VA-DPP vs -1.9 kg MOVE!, $p<0.001$), but not 12-month weight loss (-3.4 kg VA-DPP vs -2.0 kg MOVE!, $p=0.16$). There were no significant differences in HbA1c change or outpatient, inpatient, and total VA expenditures.

Conclusions: VA-DPP participants had higher participation rates and weight loss at 6 months, but similar weight, HbA1c, and health expenditures at 12 months compared to MOVE! participants. Features of VA-DPP may help enhance the capability of MOVE! to reach a larger proportion of the served population and promote individual-level weight maintenance.

INTRODUCTION

Prediabetes, or abnormally elevated blood sugar levels that do not yet meet the threshold for Type 2 diabetes, is prevalent and associated with significant risk of progression to Type 2 diabetes.^{1–4} However, evidence from RCTs, including the Diabetes Prevention Program (DPP) Study, shows progression to diabetes can be prevented with intensive lifestyle interventions involving dietary change, physical activity, and weight loss.^{1,2,5–7} Thus, numerous studies have evaluated translations of DPP-based lifestyle interventions into real-world settings.^{8–11} However, important evidence gaps remain in real-world DPP effectiveness as most studies have used uncontrolled pre–post, single-site study designs and very few have examined diabetes-related outcomes or expenditures.^{8–11}

To address these important gaps, the authors conducted a multisite clinical demonstration trial in the Veterans Affairs (VA) that assessed change in weight, hemoglobin A1c (HbA1c), and health expenditures. This was a pragmatic comparative effectiveness trial of two group-based lifestyle interventions that varied in content, intensity, and delivery (Appendix Table 1): the VA-DPP and the usual care MOVE!® weight management program (MOVE!). VA-DPP included more sessions (i.e., higher intensity), had closed groups led by a single instructor, and standardized goals for all participants, which might increase group cohesion. Therefore, it was hypothesized that VA-DPP would lead to greater weight loss and improved HbA1c over 12 months among overweight/obese participants with prediabetes versus MOVE!.¹²

METHODS

Study Sample

This was a prospective, pragmatic, non-randomized comparative effectiveness trial conducted from 2012 to 2015. This non-randomized design reflects the challenge of implementing VA-DPP with high fidelity balanced against the pragmatic need to adapt to local clinical context.^{13,14} A Transparent Reporting of Evaluations with Nonrandomized Designs statement is provided in Appendix Table 2.¹⁵ The degree to which pragmatic considerations drove study design decisions was assessed along the nine dimensions of the Pragmatic–Explanatory Continuum Indicator Summary (PRECIS) tool¹⁶ based on ratings for from five VA-DPP team members and ten investigators not affiliated with VA-DPP (scale 1=explanatory and 5=pragmatic, Appendix Figure 1).

The implementation of VA-DPP was deemed a quality improvement initiative using de-identified outcomes data and did not require approval by IRBs dominate predictor.¹⁴ (M AuYoung J Smith, VA Ann Arbor, unpublished observations, 2016). However, the clinical demonstration trial itself was IRB approved at all involved Veterans Health Administration (VHA) sites. More-detailed methods are reported elsewhere.¹⁷

Within VHA, patients who are obese (BMI ≥ 30 kg/m²) or overweight (BMI ≥ 25 kg/m²) with at least one obesity-related condition can be provider- or self-referred to an orientation session for a national weight loss program known as MOVE!. Patients with prediabetes at three VA sites who attended a MOVE! orientation session were eligible to participate. Prediabetes was defined as either:

1. impaired fasting glucose or impaired glucose tolerance documented in the electronic health record; or
2. laboratory confirmation of prediabetes (HbA1c between 5.7% and 6.4% or fasting plasma glucose [FPG] between 100 and 125 mg/dL) within the previous 6 months.

Participants had to live within 1-hour travel time of their local VA site because both programs included weekly face-to-face sessions. Participants with diabetes, defined as HbA1c $\geq 6.5\%$, FPG ≥ 126 mg/dL, or for whom anti-glycemic medication (including metformin) was documented in VA pharmacy records within the previous 6 months, were excluded.

Initially, sites assigned the first 20 eligible patients to VA-DPP and the next 20 patients to MOVE!, forming a new cohort every 2 months.

The VA-DPP used the Group Lifestyle Balance curriculum^{18,19} with 22 sessions over 12 months (16 core sessions in the first 6 months followed by six monthly maintenance sessions). MOVE!, whose design was informed by DPP, is considered the standard of care for overweight/obese patients in VHA,^{20–23} and includes eight to 12 core weekly sessions (the number varies by site) followed by monthly maintenance sessions. MOVE! participants have multiple options of days/times because sessions are delivered as independent topics, in contrast to one specified class time, iterative sessions, and same coaches with VA-DPP. At

two of three study sites, MOVE! cohorts were open; that is, new patients could join at any time. As MOVE! is widely accessible across all VHA sites, it is possible that VA-DPP participants may have also attended MOVE! sessions.

Measures

The RE-AIM framework,²⁴ designed to enhance the translation of evidence-based programs into practice, informed outcome selection in this trial. RE-AIM comprises five domains that identify multifaceted benefits important to policymakers and practitioners. This study examined outcomes related to:

1. **reach**, defined as the degree to which the study sample represented the intended population and participated in the intervention;
2. comparative **effectiveness** of the clinical program;
3. **adoption** of VA-DPP by targeted settings and staff;
4. **implementation** consistency and adaptations; and
5. **maintenance** of program benefits over time.

Reach, comparative **effectiveness**, and individual-level **maintenance** of VA-DPP are presented here. **Adoption**, **implementation**, and organizational-level **maintenance** are reported elsewhere.^{17,25–27}

The primary outcome for this intention-to-treat (ITT) analysis was assessing effectiveness as change in weight (kg) at 6 months and individual-level maintenance at 12 months because studies have shown that weight loss is an important predictor of diabetes risk reduction.^{28–30} Secondary outcomes included HbA1c at 12 months and VHA health expenditures at 15 months. VA claims data were aggregated to the patient level and inflation adjusted for inpatient expenditures, outpatient expenditures, and total expenditures. Reach was assessed by degree to which eligible participants represented the intended population and participated in the intervention.³¹ Because 75% of VHA patients are overweight/obese, the intended population (reach) included obese/overweight VHA patients with prediabetes. Participation metrics included the proportion of eligible participants who attended at least one session and those who attended four or more sessions (based on the Centers for Disease Control and Prevention standards for the Diabetes Prevention Recognition Program).¹⁹

Data on weight, HbA1c, age, gender, comorbidities, and site were obtained from the VHA Corporate Data Warehouse, a national data repository comprising data from local VHA electronic health records. Race and ethnicity data were obtained from self-report or the Corporate Data Warehouse (if self-report was missing); participants were first categorized by ethnicity then race. Weight is routinely assessed and documented at every VHA clinic visit, as well as at all VA-DPP and MOVE! sessions. Patients who did not have a 12 to 14-month follow-up weight documented as part of routine care were asked to come in for a follow-up weight assessment. All but six patients had a baseline HbA1c or FPG within 6 months of enrollment (four patients had laboratory tests outside of the required 6-month window and two patients had discordant HbA1c and FPG values to indicate prediabetes). All

patients were asked to repeat their HbA1c testing at 10–14 months, if not already assessed as part of routine care.

Statistical Analysis

A sample size of 720 participants ($n=360$ in each group) was estimated to be sufficient to detect, with 80% power, an average marginal effect of an additional 1.7 kg of weight change for individuals in VA-DPP compared with MOVE!, based on a two-sided test using a model adjusting for baseline values of weight ($\alpha=0.05$). The study assumed an SD of 3.16 kg weight loss at 12 months (corresponding to a 5-kg SD of weight and a within-person correlation in baseline and 12-month weight of 0.8) and an intragroup correlation coefficient of 0.014. Baseline characteristics of VA-DPP and MOVE! participants were compared using independent sample *t*-tests. Linear mixed-effects regression models were used to test the association between study arm and change in baseline weight at 6 and 12 months of follow-up, as well as 12-month change from baseline HbA1c. The analytic cohort for each outcome variable included all participants with at least one follow-up outcome value. The primary predictor was study arm. Owing to the non-randomized design, the analytic plan required the models to adjust for key baseline values of the outcome variable. Both the weight and HbA1c analytic models were adjusted for age, gender, and race/ethnicity.

Analyses were conducted based on ITT principles, including all available weights (baseline through 14 months) for all individuals assigned to each study arm in the weight outcome model. Because of non-linear trajectories of individuals' weights, the model also included days, days squared, days cubed, interaction of days by study arm, interaction of days squared by study arm, and interaction of days cubed by study arm. Participant and site were included as random intercepts to adjust for within-participant and within-site correlations of the repeated outcome measures. The weight model predicted 6- and 12-month changes in baseline weight by study arm, and tested for differences between VA-DPP and MOVE!. Similarly, the HbA1c model predicted 12-month change from baseline HbA1c by study arm.

Generalized linear models with a gamma distribution and log-link link function assessed changes in VA outpatient and total expenditures. VA inpatient expenditures were estimated using a marginalized two-part model³² because a high proportion of Veterans were outpatients and there was interest in generalizing results to the entire study cohort (not the subset of hospitalized Veterans in each treatment). Expenditure regressions adjusted for age, sex, baseline weight (kg), baseline HbA1c (%), race (Caucasian versus other race and African American versus other race), and diagnosis of selected comorbid conditions (hypertension, coronary artery disease, mental health, congestive heart failure). Given skewness of data distributions, Wilcoxon rank-sum tests compared baseline total and outpatient expenditures. A chi-square test compared the probability of inpatient admission between VA-DPP and MOVE! participants. It was not possible to blind participants or study staff from the arm to which participants were assigned. All analyses were conducted in 2015 and 2016 using Stata, version 14.0.

RESULTS

Between August 2012 and January 2014, a total of 1,830 patients were assessed for eligibility (Figure 1).^{26,27} An additional 20 patients were contacted but excluded from analyses because of incomplete screening information. A total of 387 eligible individuals were systematically assigned to VA-DPP ($n=273$) or MOVE! ($n=114$). The number of participants assigned to VA-DPP was higher than that assigned to MOVE! because the number of candidate participants often failed to reach 40 within the 2-month recruiting intervals. During many recruitment intervals, 20 were assigned to VA-DPP as planned but <20 were available to assign to MOVE!. In response to low numbers, two sites switched from bimonthly to monthly intervals, assigning the first ten patients to VA-DPP and the second ten to MOVE!. Additionally, all sites assigned any eligible participants to MOVE! for 2 or 3 months to ensure a sufficient number assigned to MOVE!. Of the 273 participants assigned to VA-DPP, 36% ($n=98$) explicitly declined to participate; their data were included with all DPP-assigned participants consistent with an ITT analysis. After excluding one patient without a baseline weight, the final analytic sample comprised 386 participants (VA-DPP, $n=273$; MOVE!, $n=113$). In HbA1c analyses, six patients who did not have a baseline HbA1c or FPG within 6 months of enrollment and 70 participants who did not complete a follow-up HbA1c test were excluded, leaving a final analytic sample of 310 participants (VA-DPP, $n=210$; MOVE!, $n=100$).

Trial participants were representative of the overall VHA population, which tends to be male dominated and overweight/obese, and reflected the racial/ethnic diversity at the study sites. Participants were mostly men (89%) with a mean age of 58 (range, 28–88) years, and mean BMI (range, 25.2–57.2) kg/m²; all had prediabetes (Table 1). All baseline characteristics and expenditures were comparable between groups, except the proportions of MOVE! participants included more Hispanics and fewer non-Hispanic black and non-Hispanic white participants ($p=0.04$).

Overall, participation rates were higher in VA-DPP than MOVE! (Figure 2). More VA-DPP participants completed one or more sessions (73.3% VA-DPP vs 57.5% MOVE!, $p=0.002$), at least four sessions (57.5% VA-DPP vs 42.5% MOVE!, $p=0.007$), or eight or more sessions (42.5% VA-DPP vs 31% MOVE!, $p=0.035$) (Figure 2).

Based on adjusted outcomes within groups, VA-DPP participants had significant weight loss at 6 months (−4.1 kg, $p<0.001$) and 12 months (−3.4 kg, $p<0.001$) whereas MOVE! participants only had significant weight loss at 6 months (−1.9 kg, $p=0.004$; 12-month results: −2.0 kg, $p=0.07$) (Table 2). In adjusted comparisons between groups, VA-DPP participants lost significantly more weight at 6 months (−4.1 kg VA-DPP vs −1.9 kg MOVE!, $p<0.001$) (Table 2). By 12 months, the difference in weight loss was no longer statistically significant (−3.4 VA-DPP vs −2.0 kg MOVE!, $p=0.16$). On average, African Americans lost slightly less weight relative to non-Hispanic whites ($\beta=0.88$, $p=0.003$) (Appendix Table 5). Based on adjusted models, 12-month HbA1c did not significantly change from baseline within or between groups (0.1% VA-DPP vs 0.0% MOVE!, $p=0.41$) (Table 2). Inpatient, outpatient, and total expenditures were similar between VA-DPP and MOVE! participants (Appendix Table 3).

DISCUSSION

This study found that VA-DPP resulted in significantly more 6-month weight loss than MOVE!, but these differences were not significant at 12 months, nor were differences in HbA1c or VA expenditures. Based on a recent systematic review of DPP translation studies, the VA-DPP compares favorably with the minority (41%) of studies included in the review that succeeded in achieving moderate or high weight loss (>2.4 kg).¹⁰ However, this was a comparative effectiveness trial, which included an active comparator (MOVE!) as the “control” group. Although it is more difficult to achieve statistically significant difference between two active intervention arms, VA-DPP did result in significantly higher weight loss at 6 months. In addition, the ITT analyses for weight outcomes included data from 36% of participants who had explicitly declined to participate in VA-DPP. These two key factors likely contributed to more-conservative findings.

All nine PRECIS dimensions were rated as more pragmatic than explanatory, indicating that study findings may be highly relevant for translations of DPP into other clinical settings. Outcomes were assessed using systemwide electronic health record clinical data, participants were recruited using existing clinical processes with little additional criteria, and the trial was conducted in busy clinical settings with minimal contact beyond participation in their respective programs. Moreover, participants were mostly middle-aged, overweight/obese men, who are traditionally under-represented in both DPP translational⁸ and weight loss studies.³³ Only 32.3% of DPP trial participants and 30.0% of DPP translational study participants have been men, further emphasizing the importance of generating knowledge of the impact, reach, and uptake of lifestyle interventions for male participants.¹

The VA-DPP participants were representative of the VHA population; their participation rates must also be considered in context. Prior studies have shown that men tend to have lower engagement and poorer outcomes in real-world weight loss interventions compared with women.^{34,35} Study participants were also Veterans receiving care in VHA who tend to be older, of lower SES, and more burdened by multiple chronic conditions than the general population.^{36,37} Together, these factors may have contributed to lower participation and individual-level maintenance in this cohort. Despite this, VA-DPP participation rates were generally higher than MOVE! (Table 2) and nearly all Centers for Disease Control and Prevention Diabetes Prevention Recognition Program standards were met (Appendix Table 4).

Reaching the targeted populations and engaging them in DPP interventions remains an important challenge in diabetes prevention efforts nationwide.⁹ Regularly attending sessions may present a challenge for patients. Therefore, more research is needed to assess the efficacy and effectiveness of DPP delivery options that increase convenience and flexibility for participants.^{38–40} Fewer in-person sessions or hybrid models (combining in-person, online, or mobile applications) may also yield meaningful weight changes over time. More research is needed to bolster reach by identifying efficient recruitment methods and supporting meaningful engagement of high-risk patients who are most likely to benefit.

This head-to-head comparison of VA-DPP and MOVE! was a design quite relevant to VHA, a public payer seeking to identify and deploy the most effective population-level behavioral weight management strategy. Although 12-month differences in weight change and HbA1c were not significantly different, participation in VA-DPP was higher and prior work indicated higher satisfaction compared with MOVE!.^{25,27} Program differences (Appendix Table 1) included VA-DPP use of closed cohorts, a single coach per cohort, and more sessions during the initial intensive phase of the program. Based on early results, guidance for MOVE! delivery was updated to align more closely with VA-DPP to enhance reach and participation of this population-based program.⁴¹

Limitations

There are several limitations to acknowledge. First, this trial was conducted in VHA, which may limit generalizability to other clinical settings and populations. However, the sample population was geographically and racially/ethnically diverse. The racial/ethnic difference in weight outcomes merits further investigation. Second, 19% of participants did not complete follow-up HbA1c testing but this may be expected for a clinical demonstration in the real world. Third, participants were not randomized but the risk of selection bias appears to be minimal given the similar population characteristics in both groups. Fourth, it was not possible to track the extent to which VA-DPP participants attended MOVE! sessions because this was a pragmatic trial that relied on existing documentation processes. Estimated differences between the two programs may be biased toward the null, depending on the extent to which this occurred. Because the VA-DPP coach occasionally covered for the MOVE! program at two of three sites, spillover effects are possible, further biasing differences toward the null. Lastly, the target sample size was not reached, partly because this highly pragmatic trial relied on existing clinical recruitment processes. (e.g., no incentives). The smaller sample size did not allow for tests of differences among recruitment cohorts over time but the 12-month duration of the trial should minimize potential seasonal effects on outcomes. A larger sample size may have been able to detect a statistically significant difference in weight loss at 12 months. Nonetheless, it provides important insights into a well-acknowledged challenge in engaging targeted patients in programs like DPP.¹⁰

CONCLUSIONS

A pragmatic trial of VA-DPP resulted in higher participation rates with significantly greater 6-month weight loss and a non-significant trend toward greater 12-month weight loss compared with MOVE!. Thus, MOVE! may be enhanced by aligning more closely to VA-DPP to augment the reach (for at-risk individuals) and individual-level effectiveness (of individual weight loss). This is one of the first studies to include a predominantly male cohort and highlights the continued difficulty in recruiting and maintaining patients in population-based intensive lifestyle interventions.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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MLM reported ownership of Amgen stock due to his spouse's employment. CB reported personal fees from Novo Nordisk and personal fees from Enteromedics outside of the submitted work. No other financial disclosures were reported by the authors of this paper.

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Figure 1.

CONSORT flow diagram of participant flow through the study.

^aDiabetes was defined by HbA1c > 6.4% or FPG > 125 mg/dL, diabetes medications or diagnosis.

VA-DPP, VA Diabetes Prevention Program; BL, baseline; ITT, intent to treat; FPG, fasting blood glucose; HbA1c, Hemoglobin A1c

Figure 2.

Proportion of participants who attended each session by intervention arm (N=386).

Notes: Figure 2 provides a visual comparison of the percent of participants in each arm who attended cumulative sessions. For example, 73% of VA-DPP participants attended 1 or more sessions compared to 57.5% of MOVE! participants ($p=0.002$).

VA-DPP includes 16 core weekly sessions followed by biweekly sessions in first 6 months, as well as 6 monthly maintenance sessions in second 6 months. MOVE! typically includes 8–12 core weekly sessions followed by monthly maintenance sessions. VA-DPP, Veterans Affairs Diabetes Prevention Program; MOVE!, national weight loss program in the VA

Table 1.

Comparison of Baseline Characteristics Between MOVE! and VA-DPP Participants

Characteristic	MOVE! N=113	VA-DPP N=273	p-value
Female, n (%)	9 (8.0%)	32 (11.7%)	0.28
Age, years, mean (SD)	58.9 (10.0)	57.7 (10.0)	0.29
Weight, kilograms, mean (SD)	106.3 (19.0)	109.0 (19.8)	0.22
BMI, Kg/m ² , mean (SD)	34.3 (4.9)	35.1 (5.4)	0.19
Ethnicity/Race, n (%) ^a			0.04
Hispanic	10 (8.8%)	9 (3.3%)	
Non-Hispanic black	41 (36.3%)	119 (43.6%)	
Non-Hispanic white	45 (39.8%)	122 (44.7%)	
Non-Hispanic other	3 (2.7%)	6 (2.2%)	
Missing	14 (12.4%)	17 (6.2%)	
Comorbidities, n (%)			
HTN	77 (68.1%)	183 (67.0%)	0.83
CAD	15 (13.3%)	37 (13.6%)	0.94
Mental health ^b	54 (47.8%)	149 (54.6%)	0.22
Outpatient expenditures (mean, SD)	\$12,746 (\$12,670)	\$13,507 (\$14,034)	0.63
Probability of admission	17.7%	16.9%	0.84
Inpatient expenditures for admitted Veterans (mean, SD)	\$18,976 (\$17,636)	\$22,403 (\$40,500)	0.42
Total expenditures (mean, SD)	\$16,105 (\$18,675)	\$17,281 (\$26,696)	0.60
	N=112	N=269	
HbA1c %, mean (SD)			
N=HbA1c 5.7–5.9%	6.0 (0.2) %	6.0 (0.2) %	0.41
			0.13
Higher risk HbA1c 6.0–6.4%, n (%)	64 (57.7%)	132 (49.1%)	0.13
Missing HbA1c but used glucose, n (%)	2 (1.8%)	4 (1.5%)	0.83

Note: Boldface indicates statistical significance ($p < 0.05$).

^aData on race and ethnicity were obtained from either CDW or self-report. Self-report or CDW status of Hispanic ethnicity was categorized before race (if identified as Hispanic ethnicity, no racial category was assigned).

^bIncludes: Post-traumatic Stress Disorder (PTSD), Depression, Schizophrenia, Bipolar, and Anxiety.

VA-DPP, VA Diabetes Prevention Program; HTN, hypertension; CAD, coronary heart disease; CHF, congestive heart failure; HbA1c, Hemoglobin A1c; kg/m², kilogram per meter squared

Table 2.

Adjusted Primary and Secondary Outcomes For All Participants (Intent-to-Treat Analyses)

Outcomes	MOVE!	VA-DPP	<i>p</i> -value
Participation in first 6 months (%)	N=113	N=273	
Completed 1+ sessions (%)	57.5	73.3	0.002
Completed 4+ sessions (%)	42.5	57.5	0.007
Completed 8+ sessions (%)	31.0	42.5	0.035
Mean change in weight (kg)	N=113	N=273	
Kg weight loss at 6 months (95% CI)	-1.9 (-3.3, -0.6)	-4.1 (-5.2, -2.9)	<0.001
Kg weight loss at 12 months (95% CI)	-2.0 (-4.0, 0.2)	-3.4 (-5.2, -1.6)	0.16
Mean change in weight (%)	N=113	N=273	
% weight loss at 6 months (95% CI)	-1.6 (-2.7, -0.5)	-3.7 (-4.6, -2.7)	<0.001
% weight loss at 12 months (95% CI)	-1.7 (-3.5, 0.1)	-3.0 (-4.5, -1.5)	0.11
Mean change in HbA1c (%)	N=100	N=210	
HbA1c % change at 12 months (95% CI)	0.0 (-0.2, 0.2)	0.1 (-0.1, 0.2)	0.41

Note: Boldface indicates statistical significance ($p < 0.05$).

VA-DPP, VA Diabetes Prevention Program; Kg, kilogram; HbA1c, Hemoglobin A1c