



# Evaluating the Implementation of a Digital Diabetes Prevention Program in an Integrated Health Care Delivery System Among Older Adults: Results of a Natural Experiment

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The purpose of this natural experiment study was to assess the effectiveness of a 12-month digital Diabetes Prevention Program (DPP) for adults aged 65–75 years with prediabetes and obesity within a large, integrated health care system. Adjusting for propensity scores and covariates, patients who enrolled and participated in the digital DPP had a mean weight loss of 8.6 lb over 12 months and 5.7 lb by 24 months, compared with a steady, minimal weight loss of 1.3 lb over 12 months and 2.8 lb by 24 months among patients not enrolled. There was a significant difference in mean change in A1C between enrolled and nonenrolled patients over 12 months (–0.10%), but not by 24 months (–0.06%). Digital DPP appears to be an effective weight loss option and potential diabetes prevention intervention for older adults at high risk for type 2 diabetes.

Diabetes disproportionately affects older adults in the United States—25% of individuals  $\geq 65$  years of age compared with 9% in the U.S. population overall (1). An even larger number of older adults—23 million—are affected by prediabetes, of whom 5–10% will typically develop diabetes each year (1,2). Individuals with type 2 diabetes require lifelong clinical management (2) and have medical costs that are  $\sim 2.3$  times greater than those of individuals without diabetes (3). Alarmingly, overall estimated costs of diabetes increased by 26% from 2012 to 2017 as a result of both increased prevalence and higher costs per person, primarily among those  $\geq 65$  years of age (3).

Fortunately, efficacious prevention interventions exist. The seminal Diabetes Prevention Program (DPP) clinical trial conclusively demonstrated that an intensive behavioral lifestyle intervention consisting of improved nutrition, physical activity, and behavioral counseling produced clinically significant weight loss and reduced diabetes incidence, particularly among participants  $\geq 60$  years of age, who experienced a 71% reduction in incidence of type 2 diabetes (4). Since the DPP trial, several translational studies have established the effectiveness of lifestyle change programs modeled on the DPP trial for older adults delivered across different settings (5–11).

Beginning in April 2018, the Centers for Medicare & Medicaid Services (CMS) began to reimburse clinical and community-based settings that provided the Centers for Disease Control and Prevention's (CDC's) National Diabetes Prevention Program (National DPP) curriculum (12) to Medicare beneficiaries and Medicaid recipients in some states. However, despite select online digital DPPs achieving CDC recognition and studies supporting the effectiveness of digital DPPs (6,7,13–16), Medicare coverage has been limited to in-person, group-based programs. Uptake of the CMS in-person DPP benefit has been low (12,17,18), and national advocacy organizations and U.S. senators alike have called for the expansion of DPP via telehealth—especially since the start of the coronavirus disease 2019 (COVID-19) pandemic. Nonetheless, CMS has not yet

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offered coverage for digital DPPs (19,20), citing the need for further evidence of their effectiveness among the Medicare population.

In 2017, Kaiser Permanente Northwest (KPNW), a large, integrated health system, implemented a digital DPP using a population-based approach among its adult members who were  $\geq 65$  years of age and at risk for diabetes. Using a natural experiment study design, we assessed the effects of the digital DPP on change in weight and A1C at 12 and 24 months.

## Research Design and Methods

### Setting

KPNW is a nonprofit, group model, integrated health care system providing comprehensive prepaid health care to >600,000 members in Oregon and southwest Washington. All patient contacts within the system and all services referred outside are recorded in a single, comprehensive electronic health record (EHR; KP HealthConnect, based on Epic). Approximately 30% of KPNW members have prediabetes, 12% have diabetes, and >40% have obesity. This study was approved by the KPNW Institutional Review Board.

### Participant Recruitment and Enrollment

Based on a population-level query of the KPNW EHR conducted in March 2017, patients were eligible to participate in the digital DPP if they were a current KPNW member aged 65–75 years, had an A1C of 39–46 mmol/mol (5.7–6.4%) documented within the prior 12 months, had a BMI  $\geq 30$  kg/m<sup>2</sup> based on weight documented within the prior 12 months, and had no prior diagnosis of type 1 or type 2 diabetes. In addition, patients had to use the KPNW electronic patient portal; 74% of members had an active account at the time of this query. These eligibility criteria are comparable to the Medicare DPP eligibility criteria but differ in the BMI requirement (BMI  $\geq 25$  kg/m<sup>2</sup> or 23 kg/m<sup>2</sup> for those self-identifying as Asian for Medicare DPP) (21) and the need to have access to the electronic patient portal. KPNW focused on members with both prediabetes and obesity, as these individuals have more than a 15% probability of developing diabetes within 2 years (22). A total of 4,148 patients were identified as potentially eligible to participate in the digital DPP.

Once these patients were identified, primary care providers were asked to remove any of their patients they thought should not be included for any reason. In April 2017, the 4,132 potentially eligible patients whose

providers did not opt out were sent a secure message through the KPNW patient portal inviting them to enroll in the digital DPP by clicking on a unique web link embedded in the message. KPNW planned to offer the digital DPP once as part of an implementation pilot and, because of limited resources, offer only 500 enrollment slots. Those who were unable to enroll plus those who did not try to enroll formed the comparison group, which received usual care. Enrollment was tracked via a unique code, and Omada Health (the digital DPP vendor) provided enrollment data back to KPNW.

### Intervention

KPNW patients were offered the Omada Health program (formerly called “Prevent”), a CDC-recognized (12) translation of the DPP trial’s lifestyle intervention in a digital format (23). A full description of the program has been previously published (13,23). In brief, the program consisted of a 12-month behavior change curriculum (12); health coaching from lifestyle coaches trained using a CDC-approved training mechanism (24); virtual, small-group support; and electronic behavioral tracking tools for nutrition, physical activity, and weight. The Omada digital DPP program was offered to KPNW members for only 12 months, but at no cost as part of the implementation pilot, which has been described previously (25).

### Data Collection and Outcomes

All data used in the analyses were collected as part of standard clinical practice and health care operations within the KPNW health system and recorded in the EHR. The primary outcome was change in weight over 12 months. Secondary outcomes were change in weight over 24 months and change in A1C over 12 and 24 months. Baseline measurements were defined as the weight and A1C documented in the EHR within the 12 months prior to the month that the invitation was sent (April 2017). We used the measurement closest to April 2017 if there were multiple values. All weight and A1C measurements recorded in the EHR over the 24 months after the invitation were included in analyses. Over the full 24 months, patients had a mean of 7.5 (SD 6.3) weight measurements recorded in the EHR and a mean of 2.0 (SD 1.2) A1C values recorded.

### Statistical Analyses

Demographic characteristics of the study participants were assessed and presented as mean  $\pm$  SD for continuous variables or *n* (%) for categorical variables.

Comparisons of characteristics between enrolled and nonenrolled participants were conducted using two-sample *t* tests for the normally distributed continuous variables and  $\chi^2$  tests for the categorical variables.

The following variables were identified a priori as covariates: age (modeled continuously), race and ethnicity (non-Hispanic White, non-White), sex, self-reported minutes of exercise per week during routine visits (0, 10–140, or  $\geq 150$  minutes), Charlson Comorbidity Index score (0, 1, 2, or 3+) (26), baseline tobacco use (current, former, or never), census tract-level proportion completing high school or less, census tract-level median household income, baseline weight and A1C, and metformin use (treated as time-varying with “no” or 0 and then always “yes” or 1 after the first dispensing of the medication). To further control for potential confounding, models were adjusted for propensity score. Propensity scores for enrolling in the digital DPP were estimated by fitting a logistic regression model with enrollment status as the outcome and the following variables as predictors: all covariates previously mentioned, health care utilization (number of primary care visits, specialty care visits, emergency department visits, hospitalizations, primary care visit no-shows, and laboratory tests) up to 12 months prior to DPP recruitment, and presence of a chronic comorbidity or mental health condition at baseline (hypertension, heart disease, dyslipidemia, chronic kidney disease, depression, anxiety, or bipolar disorder). To test the robustness of primary findings, propensity score-matching was conducted as a sensitivity analysis. Using standard practice (27), we matched 1:1, without replacement, enrolled patients to nonenrolled patients on logit propensity score using a caliper of 20% of the pooled logit propensity score SD; only one digital DPP-enrolled participant was not matched (Supplementary Figure S1).

Weight trajectories over 12 and 24 months were modeled using a linear mixed effects analysis, using time since baseline as the time axis. Because of the “check mark” phenomenon that is often seen in behavioral weight loss studies (28) and observed in our data using visual inspection of a scatter plot of weights, we used a piece-wise linear spline function with a knot at 7 months. We also tested a model with an additional knot at 12 months (the end of the digital DPP) to examine weight change over a 1-year follow-up period. Random effects for the intercept and slope(s) were included in the model to allow for person-specific trends in weight trajectories. The correlation structure for the random effects was determined based on best model fit using

the Akaike information criterion and Bayesian information criterion values.

To compare the time trend of weight trajectories between patients enrolled and not enrolled in the digital DPP, our models included a two-way interaction term between time and digital DPP enrollment status. Furthermore, a two-way interaction for time by weight at enrollment and a three-way interaction for time by mental health condition at baseline by enrollment status were included. Two-way and three-way interactions for time by sex and time by sex by enrollment status were not significant and therefore not included in the final model. Model assumptions were checked by examining residuals and predicted values cross-sectionally and over time. Marginal means (95% CIs) and model-estimated weights averaged over all covariates in the model (i.e., all covariates were held constant at their means) were estimated at baseline and months 7, 12, and 24. The primary contrasts of interest were the differences in estimated weight change from time of recruitment between enrolled and nonenrolled patients over 12 months and over the full 24 months.

A1C trajectories for 12 and 24 months were modeled similarly to weight with a linear mixed effects model using time since baseline as the time axis. We included the same covariates as the weight model but excluded the interactions. During the study period, after baseline data were extracted, there was a change in the calibrator and reagent lot used for the A1C test in the KPNW laboratory. To mitigate differences in A1C resulting from this change in measurement method, we calibrated A1C values by adding 0.22% to each patient's A1C measured after the laboratory method change.

Missing data were handled using full-information maximum likelihood. All analyses were evaluated using a two-tailed  $\alpha$  level of 0.05 and 95% CIs and conducted using Stata/IC, v. 15.1 (Stata Corp., College Station, TX), or SAS, v. 9.4 (SAS Institute, Cary, NC), statistical software.

## Results

As shown in Figure 1, of the 4,132 patients invited to participate in the digital DPP, 511 successfully enrolled within 48 hours; an extra 11 were allowed because they signed up before enrollment was closed. For analyses, we excluded patients who did not allow access to their clinical data ( $n = 3$ ), were in the diabetes registry ( $n = 22$ ), had a cancer

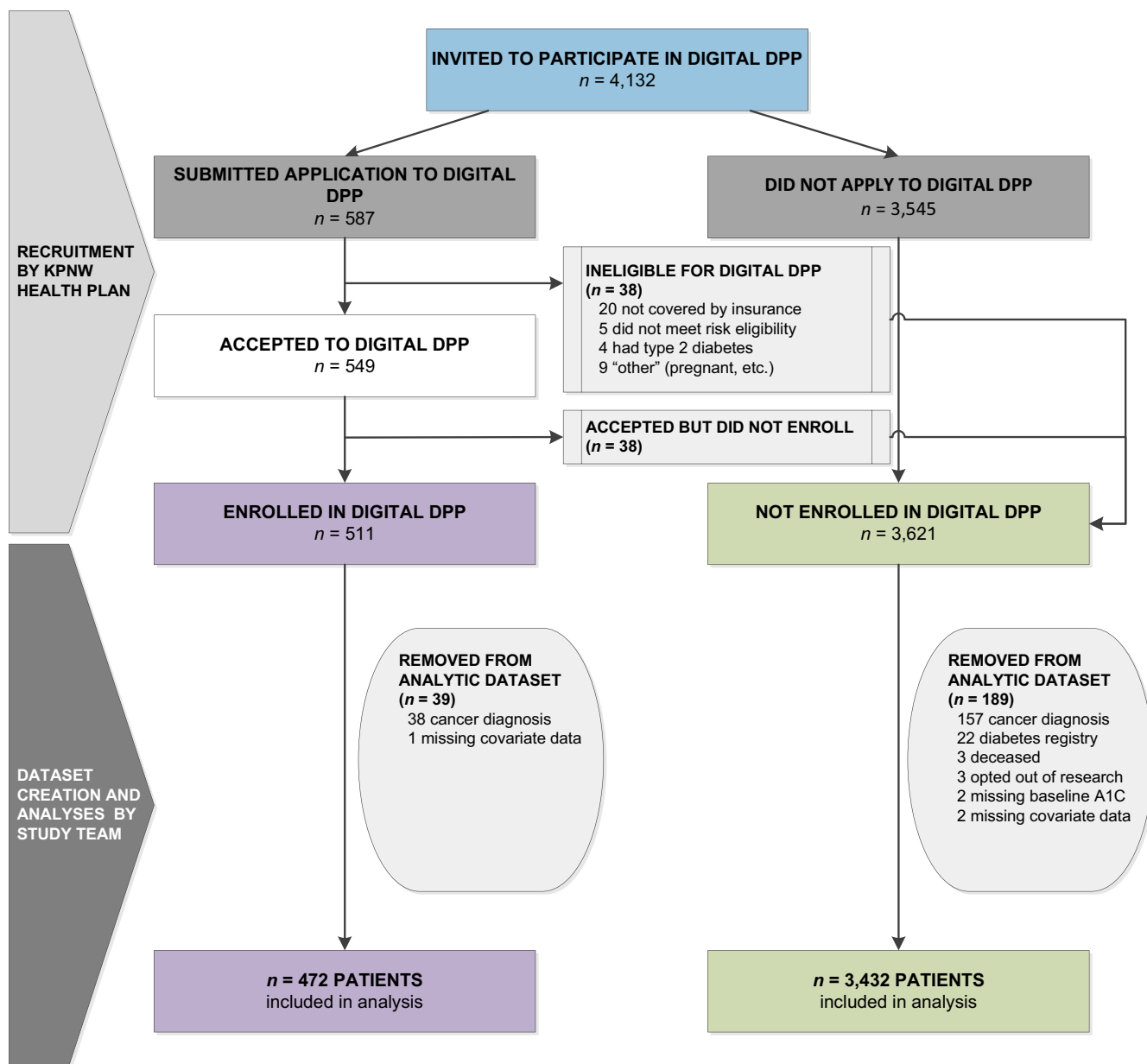


FIGURE 1 Recruitment, enrollment, and analytic dataset flow diagram.

diagnosis ( $n = 195$ ), had missing data for one of the covariates ( $n = 5$ ), or were deceased ( $n = 3$ ). A total of 3,904 patients were included in analyses (472 enrolled and 3,432 not enrolled). Those who enrolled in the digital DPP were slightly younger, more likely to be women, and more likely to live in neighborhoods with both a higher median household income and a higher level of education (Table 1).

### Weight Change Over 12 and 24 Months

Figure 2 displays the weight trajectories for enrolled and nonenrolled patients over 24 months. Adjusting for propensity scores and covariates, patients who enrolled

and participated in the digital DPP had a mean weight loss of 8.6 lb (95% CI 6.8–10.4 lb) over 12 months and a loss of 5.7 lb (95% CI 3.7–7.6 lb) over the full 24 months. The mean percentage weight loss among enrolled patients over 12 months was clinically significant (4.0% [95% CI 3.2–4.8%]), but not over the full 24 months (2.3% [95% CI 1.4–3.2%]). Patients who did not enroll in the digital DPP had a steady, minimal weight loss of 1.3 lb (95% CI 0.8–1.9 lb) over 12 months and 2.8 lb (95% CI 2.1–3.5 lb) over 24 months. Based on the mixed effects models, estimated weight and weight change with 95% CI for the overall patient population and by sex, as well as percentage weight

**TABLE 1** Baseline Demographics Overall and by Digital DPP Enrollment Status

	Total (N = 3,904)	Not Enrolled (n = 3,432)	Enrolled (n = 472)	P
Age, years	69.2 ± 2.9	69.3 ± 2.9	68.7 ± 2.8	<0.001
Female sex	2,155 (55.2)	1,865 (54.3)	290 (61.4)	0.004
Race/ethnicity				0.07
Black/African American	41 (1.1)	32 (0.9)	9 (1.9)	
Hispanic	58 (1.5)	53 (1.5)	5 (1.1)	
Other*	123 (3.2)	114 (3.3)	9 (1.9)	
Non-Hispanic White	3,682 (94.3)	3,233 (94.2)	449 (95.1)	
A1C, %	5.94 ± 0.18	5.94 ± 0.18	5.93 ± 0.18	0.31
Height, inches	66.3 ± 3.9	66.3 ± 3.9	65.9 ± 3.9	0.02
Weight, lb	221.5 ± 37.5	221.8 ± 37.4	219.5 ± 38.3	0.22
BMI, kg/m <sup>2</sup>	35.4 ± 5.1	35.4 ± 5.0	35.5 ± 5.2	0.58
Charlson Comorbidity Index				0.26
0	2,328 (59.6)	2,030 (59.1)	298 (63.1)	
1	858 (22.0)	756 (22.0)	102 (21.6)	
2	446 (11.4)	401 (11.7)	45 (9.5)	
3+	272 (7.0)	245 (7.1)	27 (5.7)	
Tobacco use				<0.001
Never	2,131 (54.6)	1,840 (53.6)	291 (61.7)	
Former	1,605 (41.1)	1,431 (41.7)	174 (36.9)	
Current	168 (4.3)	161 (4.7)	7 (1.5)	
Percentage of neighborhood with high school degree or less	0.34 ± 0.14	0.34 ± 0.14	0.31 ± 0.15	<0.001
Median neighborhood household income, \$1,000s	63.3 ± 21.5	62.9 ± 21.3	66.9 ± 22.4	<0.001
Exercise per week (self-report at visits), minutes				0.06
0	1,895 (48.5)	1,693 (49.3)	202 (42.8)	
10-140	825 (21.1)	717 (20.9)	108 (22.9)	
≥ 150	881 (22.6)	758 (22.1)	123 (26.1)	
Missing	303 (7.8)	264 (7.7)	39 (8.3)	
Chronic kidney disease	438 (11.2)	389 (11.3)	49 (10.4)	0.54
Hypertension	2,115 (54.2)	1,867 (54.4)	248 (52.2)	0.45
Dyslipidemia	1,219 (31.2)	1,075 (31.3)	144 (30.5)	0.72
Cardiovascular disease†	50 (1.3)	47 (1.4)	3 (0.6)	0.18
Mental health diagnosis‡	899 (23.0)	782 (22.8)	117 (24.8)	0.33
Primary care visits	2 (1-3)	2 (1-3)	2 (1-3)	0.26
Specialty care visits				<0.001
0	709 (18.2)	655 (19.1)	54 (11.4)	
1	847 (21.7)	736 (21.4)	111 (23.5)	
2+	2,348 (60.1)	2,041 (59.5)	307 (65.0)	
Emergency department visits				0.22
0	3,308 (84.7)	2,899 (84.5)	409 (93.2)	
1+	596 (15.3)	533 (15.5)	63 (13.3)	

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**TABLE 1** Baseline Demographics Overall and by Digital DPP Enrollment Status (Continued)

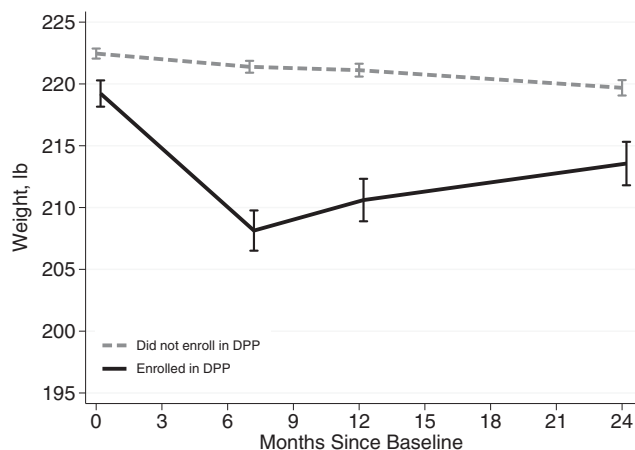
	Total (N = 3,904)	Not Enrolled (n = 3,432)	Enrolled (n = 472)	P
Inpatient visits				0.88
0	3,633 (93.1)	3,193 (93.0)	440 (93.2)	
1+	271 (6.9)	239 (7.0)	32 (6.8)	
Prescribed metformin				0.86
No	3,817 (97.8)	3,355 (97.8)	462 (97.9)	
Yes	87 (2.2)	77 (2.2)	10 (2.1)	
Propensity score	0.11 (0.08-0.15)	0.11 (0.08-0.15)	0.14 (0.10-0.18)	<0.001

Data are mean ± SD, n (%), or median (interquartile range). \*Includes Native Americans, Alaskan Natives, Native Hawaiian/Pacific Islander, Asian, and patients who endorsed “other.” †Includes coronary artery disease, congestive heart failure, and/or stroke. ‡Includes depression, anxiety, and bipolar disorder.

change for the overall patient population are presented in Supplementary Tables S1 and S2, respectively.

### A1C Change Over 12 and 24 Months

Figure 3 presents the estimated A1C trajectories for enrolled and nonenrolled patients, adjusting for propensity scores as well as covariates, including use of metformin. There was a significant difference in mean change in A1C between enrolled and nonenrolled patients over 12 months (−0.10% [95% CI −0.18 to −0.02%]), but not over the full 24 months (−0.06% [95% CI −0.13 to 0.01%]). This finding did not differ by sex. Enrolled patients were less likely to be diagnosed with type 2 diabetes than those who were not enrolled, but this finding was not statistically significant (odds ratio 0.65; 95% CI 0.31–1.36). Estimated A1C and A1C change are provided in Supplementary Table S3.



**FIGURE 2** Estimated (95% CI) weight trajectories by digital DPP enrollment status.

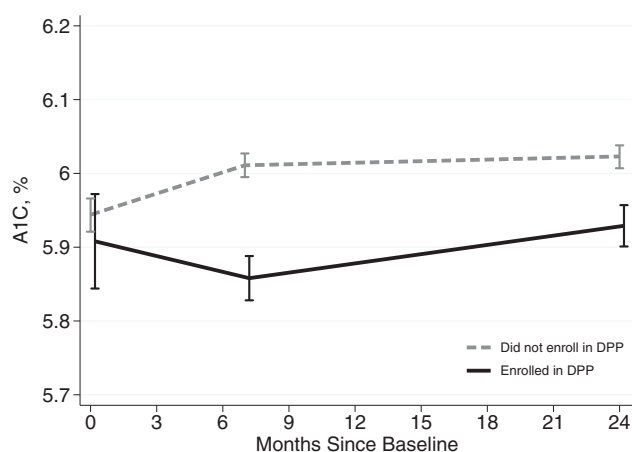
### Participant Engagement in the Digital DPP

Among the 511 older adult patients who enrolled in the digital DPP, 471 (92%) completed at least four weekly lessons, and 385 (75%) completed all 16 weekly lessons. Among participants who completed at least four lessons, engagement in other features of the program was also high, including a weekly average of 22.5 log-ins, 7.3 weigh-ins, 11 food/activity tracking episodes, and 1 private message with the health coach. Furthermore, 455 (89%) of those enrolled participated in the digital DPP program for the full 12 months.

### Discussion

In this natural experiment, older adults with prediabetes and obesity who chose to participate in a digital DPP had significantly greater weight loss over 12 and 24 months than patients who did not enroll. There were no significant differences in weight loss by sex. Furthermore, there was a significant difference in mean change in A1C between enrolled and nonenrolled patients over 12 months. Although not statistically significant, enrolled patients had a lower probability of being diagnosed with type 2 diabetes than nonenrolled patients over 24 months. Overall, these results demonstrate the effectiveness of a digital DPP in mitigating the risk of diabetes among high-risk older adults receiving care at a large, integrated health system.

The mean weight loss among patients enrolled in the digital DPP in this study (~9 lb [4%] over 12 months) is comparable to those reported in other studies of the Omada digital DPP in older adults. For example, Castro Sweet et al. (7) reported a mean weight loss of ~13–14 lb (7.5%) over 12 months among 501 Medicare



**FIGURE 3** Estimated (95% CI) A1C trajectories by digital DPP enrollment status.

beneficiaries, and Lee et al. (29) reported a weight loss of 12.2 lb (5.6%) among 61 veterans. Our findings are also similar to other studies that have examined the effectiveness of a digital DPP (not limited to the Omada Health program) among middle-aged to older adults, with a mean weight loss of 4% over 12–15 months (16,30,31). These weight outcomes may be perceived as modest compared with previous intensive in-person lifestyle interventions; however, our results are on par with results of a National DPP study (32), which found a mean weight loss of 4% among in-person participants. The weight regain experienced by enrolled patients after the first 6 months highlights the need to provide ongoing, continuous support for relapse prevention and long-term weight loss maintenance (33).

To our knowledge, this is one of only two studies to examine change in A1C among patients participating in a digital DPP compared with a control condition (34). Our finding of a significant  $-0.10\%$  mean change difference in A1C between enrolled and nonenrolled patients over 12 months provides further evidence in support of a digital DPP for diabetes prevention, particularly at the population health level.

### Study Strengths

Our study has some strengths worth noting. First, our findings further contribute to the evidence that DPPs delivered in a digital format are effective for weight loss among older adults. We established this finding in a real-world context. Second, we followed patients for 2 years; only one other study has examined weight outcomes beyond 1 year (14). The weight regain among enrolled patients led KPNW to establish ongoing weight

management support via phone-based health coaching, an effective approach (35). Third, we captured weight and A1C data longitudinally; these data not only help us understand the effectiveness of a digital DPP on maintenance of weight loss, but also can be used to determine what adjunctive clinical services may be needed. Fourth, we used the EHR to capture weight and A1C—data that are used in clinical practice and decision-making daily. Finally, we included all enrolled patients in analyses and did not limit our analyses to patients who attended a certain number of sessions, therefore increasing the generalizability of our findings.

### Study Limitations

Our study also has several limitations. First, although we tried to address the common limitations of natural experiments by adjusting for propensity scores and numerous demographic and clinical covariates, we may not have included all potential confounders. Second, similar to previous studies (7,16,29,30), our overall study population was primarily White and more highly educated, which limits the generalizability of the findings. However, our 12-month weight loss outcomes are similar to those of previous studies with more diverse samples, including a study of Oregon Medicaid recipients, which showed a mean weight loss of 4.4% over 12 months (15,36). Third, we relied on the EHR for weight data, which are known to be accurate (37–40) but may not be optimal in capturing timely intervention-related weights for enrolled patients. However, by using this approach, we ensured that we had a common source for outcome data for both enrolled and nonenrolled patients. Also, we were able to extract, on average, 7.5 weight measurements per patient, allowing us to capture weights at several stages.

### Conclusion

Digital DPPs appear to be an effective weight loss option and potential diabetes prevention intervention for older adult patients at high risk for type 2 diabetes. Furthermore, the demand for digital DPPs is high, as evidenced by the 511 patients who enrolled in our digital DPP within just 48 hours of receiving an invitation. With promising results pending from the largest randomized trial of a digital DPP (34) and the demand for digital/online health and wellness programs (especially during the COVID-19 pandemic), CMS and other payers should take these factors into account when considering expanding coverage for digital/online DPPs.

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## DUALITY OF INTEREST

No potential conflicts of interest relevant to this article were reported.

## AUTHOR CONTRIBUTIONS

S.L.F., N.S., W.M.V., V.J.S., S.K.G., and S.P.F. contributed to the development of the study. S.L.F. and S.P.F. conceived of the study and overall study design in consultation with W.M.V., V.J.S., and S.K.G. A.M.R., N.S., and D.B.N. developed and contributed to writing the statistical analysis plan. S.L.F., M.M., and A.M.R. developed the manuscript draft. All authors contributed to the editing of the manuscript and have read and approved the final version. S.L.F. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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