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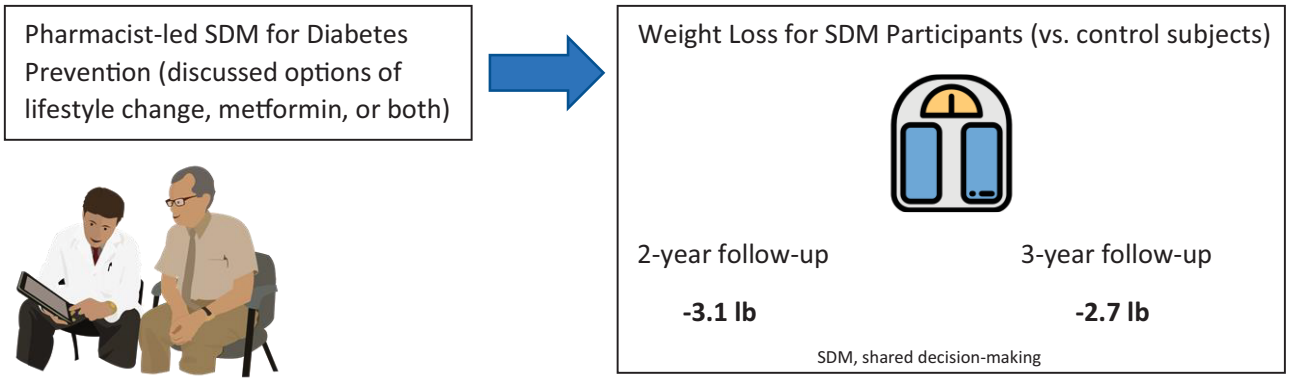

ARTICLE HIGHLIGHTS

- A pharmacist-led randomized trial of shared decision-making in diabetes prevention led to modest weight loss in participants with prediabetes.
- Weight loss was sustained up to 3 years.
- Study participants who chose both lifestyle change and metformin had the greatest long-term weight loss.
- However, shared decision making did not result in lower diabetes incidence.

The Effectiveness of Shared Decision-making for Diabetes Prevention: 24- and 36-Month Results From the Prediabetes Informed Decision and Education (PRIDE) Trial

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BRIEF REPORT

OBJECTIVE

We conducted a cluster-randomized, shared decision-making (SDM) trial offering lifestyle change, metformin, or both options, to adults at risk for diabetes in a primary care network (*n* = 20 practices).

RESEARCH DESIGN AND METHODS

We used propensity score matching to identify control patients and used electronic health record data to compare weight loss at 24 and 36 months of follow-up and diabetes incidence at 36 months of follow-up.

RESULTS

In adjusted post hoc analyses, SDM participants (*n* = 489) maintained modestly greater 24-month weight loss of −3.1 lb and 36-month weight loss of −2.7 lb versus controls (*n* = 1,430, both comparisons *P* < 0.001). SDM participants who chose both lifestyle change and metformin sustained weight loss at 36 months of −4.1 lb (*P* < 0.001 vs. controls). We found no differences in incident diabetes (15% of SDM participants, 14% of control participants; *P* = 0.64).

CONCLUSIONS

This is one of the first studies to demonstrate weight loss maintenance up to 36 months after diabetes prevention SDM.

Randomized controlled trials, including the Diabetes Prevention Program (DPP), have demonstrated that lifestyle change and metformin both prevent or delay type 2 diabetes among patients at risk (1–4). Therefore, prediabetes is "preference-sensitive," a condition for which the evidence supports multiple options (5). Shared decision-making (SDM) is a patient-centered approach for preference-sensitive conditions that incorporates evidence-based information, provider experience, and patient values and preferences (6). SDM uses decision aids (DAs) to guide decision-making and can reduce decisional conflict while improving care satisfaction (7). However, prior evidence of clinical improvement is limited. Diabetes prevention guidelines do not explicitly include SDM (8).

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Our research team previously implemented a cluster-randomized trial of pharmacist-led diabetes prevention SDM, the Prediabetes Informed Decision and Education (PRIDE) trial. We showed increased uptake of DPP/lifestyle change (23% vs. 0.4%) and metformin (19% vs. 1.6%) at 4 months and greater weight loss at 12 months for SDM participants versus control subjects (−5.3 lb vs. −0.2 lb, $P < 0.001$) (9). In the current analysis, we examined post hoc weight loss outcomes at 24 and 36 months and diabetes incidence at 36 months for SDM participants versus control subjects.

RESEARCH DESIGN AND METHODS

The PRIDE study design has been described elsewhere (9). In brief, we included patients between 18 and 74 years with overweight/obesity and prediabetes. We excluded patients with diabetes, chronic kidney disease stage 4 or higher, active eating disorder(s), or who were pregnant or planning to become pregnant in the next year. Eligible patients in intervention practices received a study invitation letter signed by their primary care provider. The study was approved by the University of

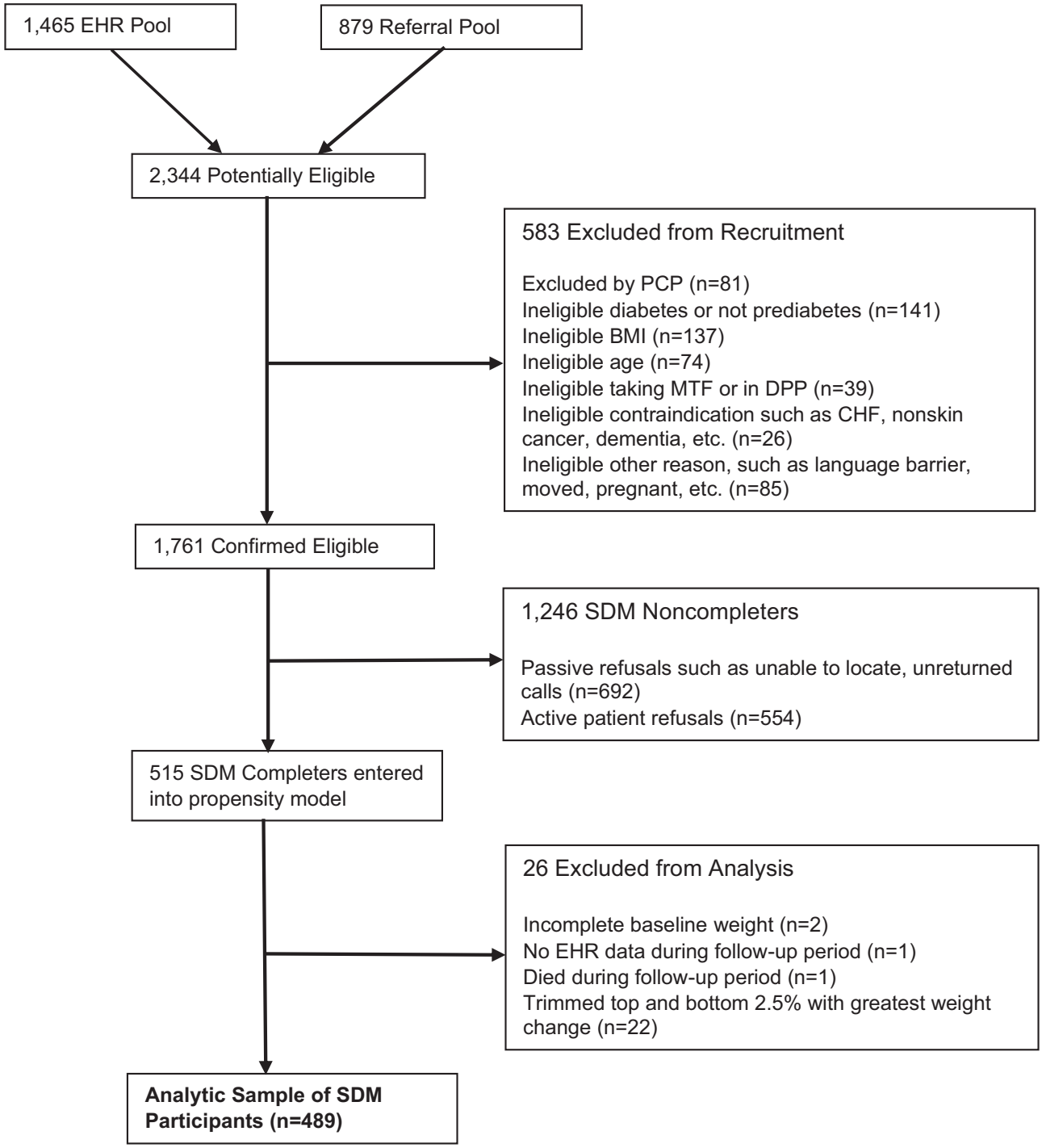

Figure 1—Consolidated Standards of Reporting Trials (CONSORT) flow for intervention practices. CHF, congestive heart failure; MFT, metformin; PCP, primary care provider.

California, Los Angeles Institutional Review Board (IRB no. 15-000310) and was registered at ClinicalTrials.gov (NCT02384109).

Intervention

The in-person intervention was delivered by pharmacists trained in motivational interviewing, SDM, and use of the Healthwise diabetes prevention DA, "Prediabetes: Which Treatment Should I Use?" (10). During SDM, patients chose one of four options: *1*) DPP/intensive lifestyle change, *2*) metformin, *3*) DPP/intensive lifestyle change plus metformin, or *4*) usual primary care. At 4 months, 23.4% of SDM intervention patients had enrolled in DPP/lifestyle change, 18.8% had started metformin, and 38.2% had initiated both (9). Of patients who chose the DPP, 30% completed fewer than nine sessions, while 11% completed nine or more sessions.

Outcomes of Interest

In this pragmatic trial, we recruited intervention participants with a documented electronic health record (EHR) weight in the 90 days prior to recruitment, although we primarily used the weight measured at their SDM visit as baseline. We set the window for EHR weight measurement among matched control subjects to 1 year prior to the SDM date of the intervention participant to which each control subject was matched (or within 2 weeks after). Of note, 86% of control subjects had an EHR weight within 90 days before or 2 weeks after their proxy date, which was used as their baseline. Given this difference in weight ascertainment, we controlled for the interval between the weight measurement and the SDM visit date in all models. We used available weight measures closest to the anniversary of the SDM visit within 21 and 28 months to define the 24-month weight outcome, and within 32 and 40 months to define the 36-month weight outcome. If no weight was available within those windows, weight change was considered missing.

We measured incident type 2 diabetes using EHR data, defined as *1*) an inpatient or outpatient *International Classification of Diseases* billing code for diabetes, *2*) any HbA_{1c} value $\geq$6.5%, or *3*) any antiglycemia medication other than metformin.

Statistical Analyses

We estimated the required sample size for the study using an interclass correlation coefficient of 0.007 for practice-level clustering, based on prior literature (11). For the main analyses, we used an intention-to-treat approach with outcomes assessed universally regardless of the SDM option selected. In hypothesis-generating analyses, we examined weight loss among subgroups based on uptake of diabetes prevention and completion of DPP sessions. We defined our control sample using a propensity score that modeled eligible, contacted patients in intervention practices to predict the likelihood of SDM participation (enrollment). As EHR weights are prone to data entry errors, we trimmed the top and bottom 2.5% with the greatest and smallest weight change from our intervention and control samples (Fig. 1). We had similar frequencies of missing follow-up weights for the intervention (23% missing at 24 months, 30% at 36 months) and control participants (23% missing at 24 months, 28% at 36 months). To address missing weight data, we used pattern-mixture modeling with control-based pattern imputation.

We used generalized linear mixed-effects models to compare weight change and a Cox proportional hazards model to estimate differences in incident diabetes in a survival analysis. Weight change models included fixed effects for time, treatment group, and time-treatment interactions, and random effects for patients and practices to account for repeated measurements within patients and practice clustering. We adjusted for sex, race, and ethnicity, along with days from baseline weight to start of the study window as this differed by study arm. Cox proportional hazard models also controlled for HbA_{1c}, BMI, and age. Analyses were done using SAS 9.4 software (SAS Institute).

RESULTS

Intervention (n = 489) and control (n = 1,430) participants had relatively similar baseline BMI, HbA_{1c}, and age values (Table 1). There were nonsignificant racial and ethnic differences between groups, for Black race (15% intervention vs. 11% control, standardized mean difference [SMD] = 0.19 for test of overall racial differences), Latino/Hispanic ethnicity (16% intervention vs. 13% control, SMD = 0.19), as well as sex (55% women in intervention vs. 61% women in control, SMD = 0.12).

Overall, intervention participants had greater unadjusted weight loss at 24 months versus matched control subjects (−4.0 lb vs. −0.7 lb, $P < 0.001$). As shown in Table 2, the adjusted difference in mean weight loss at 24 months between the groups was −3.1 lb (95% CI −4.2, −1.9; $P < 0.001$). Intervention participants maintained greater unadjusted weight loss at 36 months versus matched control subjects (−4.3 lb vs. −1.1 lb, $P < 0.001$). Similarly, the adjusted difference in mean weight loss at 36 months between the groups was −2.7 lb (95% CI −3.9, −1.4; $P < 0.001$). Weight loss was greatest among participants who completed nine or more DPP sessions and was relatively sustained at 36 months (−4.1 lb; 95% CI −6.4, −1.8; $P < 0.001$) (Table 3). Weight loss at 36 months was similar for participants who completed fewer than nine DPP sessions (−1.9 lb), started

Table 1—Demographic characteristics of the study population

	Intervention (n = 489)	Matched control subjects (n = 1,430)	SMD (absolute value)
Age, years, mean (SD)	55.5 (11.5)	56.8 (11.0)	0.12
Female sex, %	55	61	0.12
Race, %			0.19
Asian/Pacific Islander	19	19	
Black	15	11	
White	47	55	
Other	16	13	
Unknown	3	2	
Ethnicity, %			0.19
Latino/Hispanic	16	13	
Not Latino/Hispanic	79	85	
Unknown	4	3	
Baseline BMI, kg/m^2, mean (SD)	30.2 (5.1)	30.3 (5.8)	0.02
Baseline HbA_{1c}, % (SD)	6.0 (0.2)	5.9 (0.2)	0.09

Table 2—Adjusted weight change overall at the 24- and 36-month follow-up visits

Outcome	SDM participants (n = 489)	Matched control subjects (n = 1,430)	Difference	P value
Weight change at				
24 months	−3.7 (−4.6, −2.7)	−0.6 (−1.2, −0.0)	−3.1 (−4.2, −1.9)	<0.001
36 months	−3.8 (−4.9, −2.7)	−1.1 (−1.7, −0.5)	−2.7 (−3.9, −1.4)	<0.001

Data are presented in lb (95% CI).

metformin only (−2.3 lb), or had no uptake of either strategy (−2.3 lb). In terms of incident diabetes, 15% of intervention participants (n = 71) developed diabetes over 36 months compared with 14% of control subjects (n = 195), and this difference was not statistically significant (P = 0.64).

CONCLUSIONS

We found that participation in diabetes prevention SDM led to greater weight loss at both the 24- and 36-month follow-up among patients with overweight/obesity and prediabetes, but we found no differences in diabetes incidence. This is one of the first longitudinal studies to demonstrate modest, persistent weight loss after brief diabetes prevention SDM, and the results support a potential role for SDM in diabetes prevention.

Diabetes prevention SDM matches patients to prevention options that most closely align with their preferences and values. This is important in the context of low uptake and retention for lifestyle change programs. Only 5–15% of patients with prediabetes are advised by their health care providers to participate in a weight loss or diabetes prevention program, and of that group, only 35–40% actually participate (12). A recent analysis of two health systems found that 72% of referred patients never showed up to the DPP, while 13% attended one to three sessions and only 15% attended four or more sessions (13). Interactive patient engagement with SDM is similar to "session zero" preprogram activities that have increased retention and clinical outcomes for the DPP and other chronic disease self-management programs (14,15).

Our study had several limitations. First, the SDM intervention was conducted in a single health system with pharmacists embedded within primary care practices, which may limit generalizability.

Second, intervention patients who opted in for SDM may have been more motivated to lower their diabetes risk than nonparticipants. To help address possible selection bias, we created a propensity score predicting the likelihood of study enrollment and used this to identify comparable control patients who would have a similar propensity to enroll.

Finally, this pragmatic study collected weight outcomes from the EHR, resulting in data missingness for patients who did not have follow-up clinical encounters in our study window. However, rates of data missingness were very similar for intervention and control participants, which make differential bias by study arm less likely, and we used a conservative approach of pattern-mixture modeling with control-based pattern imputation in our study analyses. Still, it is not possible to entirely eliminate bias due to nonrandom missingness, and our results should be interpreted in that context.

In conclusion, we found that diabetes prevention SDM that includes both lifestyle change and metformin as evidence-based diabetes prevention options is associated with weight loss at 24 and 36 months of follow-up in a diverse population of patients with prediabetes. While we did not detect a reduction in diabetes incidence, our finding of modest, sustained weight loss for up to 3 years in a real-world setting supports SDM as a potentially effective approach to diabetes prevention for high-risk patients with prediabetes.

Table 3—Adjusted weight change by diabetes prevention uptake among SDM participants at 12-, 24-, and 36-month follow-up visits

	Follow-up (months)	Weight change vs. matched control subjects*	P value
Completed ≥9 DPP sessions, with or without metformin (n = 96)	24	−4.7 (−7.0, −2.5)	<0.001
	36	−4.1 (−6.4, −1.8)	<0.001
Completed <9 DPP sessions, with or without metformin (n = 42)	24	−4.3 (−7.6, −1.0)	0.01
	36	−1.9 (−5.5, +1.6)	0.28
Metformin only (n = 59)	24	−4.8 (−7.7, −1.9)	0.001
	36	−2.3 (−5.3, +0.8)	0.15
No uptake (n = 285)	24	−2.1 (−3.6, −0.7)	0.004
	36	−2.3 (−3.9, −0.7)	0.004

*Data are presented in lb (95% CI).

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reviewed and edited the manuscript. R.M. provided supervision for the intervention and reviewed and edited the manuscript. K.C.N. reviewed and edited the manuscript. T.M. conceptualized the study and reviewed and edited the manuscript. O.K.D. 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.

Prior Presentation. Parts of this study were presented as a poster at the 82nd Scientific Sessions of the American Diabetes Association, virtual and at New Orleans, LA, 3–7 June 2022.

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