



Patient-Centered Goal-Setting in the National Diabetes Prevention Program: A Pilot Study

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OBJECTIVE

Difficulty achieving preset goals (e.g., $\geq 5\%$ weight loss, ≥ 150 min of weekly physical activity) in the yearlong National Diabetes Prevention Program (NDPP) can prompt dropout and diminish benefits. We piloted a more patient-centered NDPP adaptation (NDPP-Flex) that promotes a variety of attainable and individually tailored goals to reduce diabetes risks, along with flexibility to adjust goals each week as needed.

RESEARCH DESIGN AND METHODS

Retention, physical activity, weight, and glycated hemoglobin (HbA_{1c}) were evaluated among diverse participants with diabetes risks who received our pilot of NDPP-Flex beginning in January and July 2018 ($n = 95$), with a planned comparison with standard NDPP delivery in preceding cohorts that launched between September 2016 and October 2017 ($n = 245$). Both the standard NDPP and NDPP-Flex interventions were 1 year in duration and implemented in phases (i.e., nonrandomized).

RESULTS

Average adjusted retention (e.g., 158.90 ± 15.20 vs. 166.71 ± 9.38 days; $P = 0.674$), physical activity (157.97 ± 11.91 vs. 175.64 ± 7.54 weekly min; $P = 0.231$), and weight loss ($1.46 \pm 0.38\%$ vs. $1.90 \pm 0.24\%$; $P = 0.396$) were similar between NDPP-Flex versus standard NDPP. However, NDPP-Flex participants had greater HbA_{1c} reduction on average ($0.22 \pm 0.05\%$ vs. $0.06 \pm 0.03\%$; $P = 0.018$) and were more likely to have normoglycemia at follow-up (odds ratio 4.62; $P = 0.013$ [95% CI 1.38–15.50]) than participants in the standard NDPP.

CONCLUSIONS

An adapted, more patient-centered NDPP that focuses on flexible, self-selected goals may be a promising strategy to improve glycemia even in the absence of substantial weight loss.

Diabetes affects 13.0% of U.S. adults, with higher prevalence among racial/ethnic minorities and individuals of low socioeconomic status (1). Another 34.5% of U.S. adults are estimated to have prediabetes (1) or elevated glycemia (e.g., glycated hemoglobin [HbA_{1c}] 5.7–6.4%) that can progress to type 2 diabetes (2). In response, the Centers for Disease Control and Prevention (CDC) established the National Diabetes Prevention Program (NDPP) in 2010 and continues to issue updated delivery standards and curricula for dissemination (3). The NDPP seeks to

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translate successes from the landmark Diabetes Prevention Program (DPP) trial, in which lifestyle intervention led to 7% weight loss and 0.1% improvement in HbA_{1c} at 1 year, reducing diabetes incidence by 58% within 3 years (4). Lifestyle intervention in the DPP trial was primarily delivered individually to participants with impaired glucose tolerance and impaired fasting glucose, who further had completed a 3-week run-in to ensure compliance (5,6). For scaling, the yearlong NDPP uses lower-cost formats (in-person group classes, online, distance-learning, or combined approaches), uses broader eligibility criteria, and does not require glycemic monitoring (3). Rather, the NDPP primarily targets $\geq 5\%$ weight loss and uses frequent weight monitoring to assess progress (3). Major successes include widespread adoption (e.g., $>3,000$ organizations have delivered the NDPP [3]) and insurance coverage (e.g., Medicare coverage began in 2018 [7]), yet substantial challenges remain to impact diabetes prevalence (8).

Increasing effectiveness of the NDPP is a key objective to reduce diabetes prevalence (8). Concerns include that weight loss outcomes are suboptimal and that weight change alone may be misleading as an indicator of effectiveness. Nearly three-quarters of participants (71.7%) do not achieve the $\geq 5\%$ weight loss target (3), and racial/ethnic minority, low-income, and younger participants lose about half as much weight as their counterparts (9–11). Previous efforts to improve NDPP effectiveness have focused on strategies to address poor attendance (3), such as partnering with health care providers for referrals and providing incentives (12). In turn, greater attendance often leads to more weight loss (3,11,13,14), but is not always sufficient (10,15,16). For example, financial incentives increased attendance but without more weight loss among Medicaid beneficiaries (16). Additional strategies to improve health outcomes, including glycemia, appear needed. Although weight loss was highly protective at first in the DPP (17), follow-up study revealed that more weight loss was paradoxically associated with higher diabetes incidence, attributed to weight regain over time (18,19). However, even a temporary return to normal glucose regulation had substantial lasting benefit, with a 56% reduction in diabetes incidence at ~ 10 years compared with participants who did not attain normal glucose

regulation at least once (18). Moreover, the DPP's lifestyle intervention focused narrowly on weight loss through low-fat diet and moderate physical activity (5), which was extended to the NDPP (20). Yet, newer consensus from the American Diabetes Association (ADA) is that other lifestyle approaches (e.g., Mediterranean diet) can improve glycemia without weight loss and that interventions should be flexible to accommodate personal preferences (21).

Unachieved lifestyle goals may also diminish self-efficacy (a key construct of the Health Belief Model for behavior change [22]), as suggested by the premature dropout of NDPP participants who have difficulty reaching preset goals (23,24). For example, less than half of participants meet the NDPP's preset physical activity goal (including fewer racial/ethnic minority participants) (9), and each week of goal "failure" is associated with 25% lower likelihood of returning to the next session (24). Adapting the NDPP to promote more attainable and individually tailored goals for risk reduction, plus flexibility to adjust goals over time as needed, may help increase effectiveness. The CDC's original NDPP curriculum had the most restrictive and challenging goals, including $\geq 7\%$ weight loss, ≥ 150 min of weekly physical activity, and $\leq 25\%$ of calories from fat. By comparison, the latest curriculum (released in March 2016) does incorporate action planning to set three individualized goals at each session, albeit in addition to preset goals for $\geq 5\%$ weight loss and ≥ 150 weekly min of physical activity (20). To inform future program delivery, we designed a more patient-centered NDPP adaptation without preset goals (NDPP-Flex). In this study, we report on our pilot of NDPP-Flex, including attendance, physical activity, weight loss, and glycemic outcomes, as compared with implementation of the standard NDPP with the latest curriculum.

RESEARCH DESIGN AND METHODS

Design

We designed NDPP-Flex to align with guidelines for conducting patient-centered outcomes research (25), including through: 1) responsiveness to feedback and confirmatory evidence that preset goals deter participation; 2) developing a flexible goal-setting approach that retains other standard NDPP components and without added costs; 3) minimizing participant burden by assessing

glycemic improvement through electronic health records; and 4) assessing the comparative effectiveness of NDPP-Flex versus prior delivery of the standard NDPP. The Colorado Multiple Institutional Review Board approved the program evaluation (16-1093).

Setting

Denver Health is an urban safety-net health care system that is the largest provider of Medicaid and uninsured services in Colorado through its community- and school-based clinics, specialty centers, and hospital in the Denver metropolitan area. Denver Health was an early adopter of the NDPP, receiving federal, state, and intramural funding to provide the NDPP at no cost to patients since 2013.

Participants

We included English- and Spanish-speaking adults who met CDC-established NDPP eligibility criteria, including BMI ≥ 25 kg/m² (≥ 23 kg/m² if Asian) and prediabetes or former diagnosis of gestational diabetes (26). Prediabetes was based on a laboratory test within the past year indicating a fasting blood glucose of 100–125 mg/dL, blood glucose of 140–199 mg/dL measured 2 h after a 75-g glucose load, or HbA_{1c} of 5.7–6.4%. Gestational diabetes was based on past diagnosis in the medical record or self-reported. Individuals without known prediabetes or past gestational diabetes were also eligible based on a risk-screening questionnaire (27). Individuals were excluded if pregnant or known to have type 2 diabetes at enrollment.

Participants were identified primarily through provider referrals and invited to enroll in new classes that were launched every 3–6 months without fees or monetary incentives. This analysis includes participants from two cohorts of classes that began our pilot of NDPP-Flex in January and July 2018 ($n = 95$), with a planned comparison with five preceding cohorts of standard NDPP delivery that launched between September 2016 and October 2017 ($n = 245$). Selecting these comparator groups assures that both arms received the CDC's latest NDPP curriculum (20) (delivered as standard or adapted in NDPP-Flex) and were preceded by an introductory "pre-session" 1–3 weeks before intervention, which

participants with prepost HbA_{1c} records. To minimize potential outlier influence, models included winsorized weight and HbA_{1c} change. Multiple linear and logistic regression models then controlled for baseline characteristics (age, sex, race/ethnicity, baseline BMI, and baseline HbA_{1c}), pre-session attendance, class language, and coach (i.e., three coaches delivered the standard NDPP, two of whom also went on to deliver NDPP-Flex), as well as retention, physical activity, and weight loss as applicable. We report descriptive statistics, including mean, SD, or SE, *P* values, and 95% CIs as applicable. Significance was determined by $\alpha < 0.05$.

RESULTS

Table 1 presents comparisons of between-group characteristics, with results showing that participants were similar in sex, age, race/ethnicity, baseline BMI, and baseline weight. Differences in baseline HbA_{1c} between the standard NDPP (mean 5.89% [SD 0.28]) and NDPP-Flex (mean 5.96% [SD 0.29]) approached significance (*P* = 0.065), although clinically similar in presentation. Frequency and timing of prepost HbA_{1c} testing was otherwise comparable, as was pre-session attendance and average class size.

Table 2 presents comparisons of program outcomes between the standard NDPP and NDPP-Flex. There were no significant differences in retention, physical

activity, or weight loss. Nonetheless, adjusted models showed that NDPP-Flex participants were more likely to have normoglycemia (HbA_{1c} <5.7%) at follow-up (odds ratio 4.62; *P* = 0.013 [95% CI 1.38–15.50]), with 0.22 ± 0.05% average HbA_{1c} improvement (*P* = 0.018). Unadjusted differences for frequency of normoglycemia at follow-up were non-significant (24.2% vs. 31.7%; *P* = 0.171), although in a similar direction. Sensitivity analyses were consistent among participants with prepost HbA_{1c} testing.

Post hoc analyses confirmed that NDPP-Flex participants selected 1.08 goals (SD 0.30) per session on average. NDPP-Flex participants cumulatively chose 3.28 (SD 2.15) different types of goals on average over the course of their participation. The most frequently selected goal was cardiovascular activity (selected at least once by 74.7% of participants), followed by consuming fruits/vegetables (45.3%), more water (41.1%), using a smaller plate (29.5%), and stress management (28.4%). The frequency and type of goal selected (e.g., number of times that a participant selected cardiovascular activity) did not influence glycemia. However, choosing a greater variety of goals over time (e.g., cardiovascular activity, strength training, more fruits/vegetables, and fewer sweets) affected HbA_{1c} improvement, with each additional type of goal selected being associated with 0.06 ± 0.02% HbA_{1c} improvement (*P* = 0.034).

CONCLUSIONS

In order to improve effectiveness of the NDPP for diverse populations, we evaluated a more patient-centered adaptation, NDPP-Flex, that promotes attainable and individually tailored goals to reduce diabetes risks, along with flexibility to adjust goals over time as needed. This study included relatively younger (48 vs. 57 mean years nationally [23]) and more racial/ethnic minority participants (82% vs. 45% nationally [23]) who usually benefit less from standard delivery of the NDPP (3,23). Compared with the standard NDPP, NDPP-Flex did not increase retention, weight loss, or physical activity, but resulted in greater glycemic improvement (0.2% mean HbA_{1c} improvement) and over fourfold likelihood of normoglycemia, which is considered key to diabetes prevention irrespective of weight (18). By comparison, intensive lifestyle intervention in the DPP trial yielded 0.1% mean HbA_{1c} improvement after 1 year (4) and twofold likelihood of normoglycemia at follow-up versus placebo (18). Alternatively, NDPP-Flex may benefit disadvantaged populations by improving glycemia without requiring adherence to preset goals for lifestyle change or completing a full year of intervention. Retention was 170 days in both the standard and adapted approaches, compared with 96 days when previously delivering the NDPP without pre-sessions (28). Longer retention may require removing socioeconomic

Table 1—Characteristics of standard NDPP and NDPP-Flex participants (N = 340)

	Standard NDPP (n = 245)	NDPP-Flex (n = 95)	<i>P</i> value
Age (years)	48.45 (12.91)	47.54 (12.91)	0.552
Female	196 (80.0%)	75 (78.9%)	0.881
Race/ethnicity			
Latino	170 (70.5%)	71 (76.3%)	0.341
Non-Hispanic Black	25 (10.4%)	6 (6.5%)	0.302
Non-Hispanic White	45 (18.7%)	15 (16.1%)	0.637
Baseline weight (kg)	93.28 (23.69)	91.13 (25.78)	0.465
Baseline BMI (kg/m ²)	35.50 (8.03)	35.40 (7.89)	0.931
Baseline HbA _{1c} (%)	5.89 (0.28)	5.96 (0.29)	0.065
Prepost HbA _{1c} records available	127 (51.8%)	46 (48.4%)	0.629
Months before first session when baseline HbA _{1c} measured	3.76 (2.50)	3.97 (2.67)	0.630
Months after last session when follow-up HbA _{1c} measured	5.00 (3.20)	4.72 (3.25)	0.618
Attended pre-session prior to NDPP	216 (88.2%)	86 (90.5%)	0.701
Average class size (number of participants)	15.3 (3.6)	15.8 (5.6)	0.846

Data presented as frequency (%) for categorical variables and unadjusted mean (SD) for continuous variables, with *P* values based on paired *t* tests and χ^2 analyses.

Table 2—Outcomes for delivery of the standard NDPP and NDPP-Flex (N = 340)

	Unadjusted					Covariate-adjusted				
	Standard NDPP		NDPP-Flex		P value	Standard NDPP		NDPP-Flex		P value
	Mean ± SE	n	Mean ± SE	n		Mean ± SE	n	Mean ± SE	n	
Main models										
Duration (1–365 days)	169.90 ± 8.59	245	170.19 ± 13.35	95	0.986	166.71 ± 9.38	206	158.90 ± 15.20	85	0.674
Sessions attended (1–25)	10.84 ± 0.48	245	10.67 ± 0.72	95	0.848	10.57 ± 0.52	206	10.27 ± 0.84	85	0.772
Physical activity (weekly minutes)	177.36 ± 7.38	197	159.90 ± 11.31	82	0.190	175.64 ± 7.54	164	157.97 ± 11.91	72	0.231
Weight loss (%)	1.68 ± 0.20	245	1.20 ± 0.32	95	0.214	1.90 ± 0.24	164	1.46 ± 0.38	72	0.353
HbA _{1c} improvement (%)	0.06 ± 0.03	127	0.21 ± 0.05	46	0.012	0.06 ± 0.03	98	0.22 ± 0.05	40	0.018
Normoglycemia at follow-up (%)	24.2%	165	31.7%	60	0.186	24.2%	99	35.0%	40	0.013
Sensitivity analyses										
For those with prepost HbA _{1c}										
Duration (1–365 days)	175.27 ± 11.99	127	171.83 ± 18.04	46	0.880	175.24 ± 12.44	122	195.59 ± 21.70	45	0.551
Sessions attended (1–25)	11.12 ± 0.69	127	10.98 ± 1.01	46	0.921	11.00 ± 0.69	122	10.64 ± 1.21	45	0.807
Physical activity (weekly minutes)	165.89 ± 8.88	103	167.09 ± 16.56	41	0.946	171.07 ± 8.91	98	152.73 ± 14.73	40	0.313
Weight loss (%)	1.71 ± 0.26	127	1.17 ± 0.47	46	0.303	2.01 ± 0.30	98	1.33 ± 0.50	40	0.267
HbA _{1c} improvement (%)	0.06 ± 0.03	127	0.21 ± 0.05	46	0.012	0.06 ± 0.03	98	0.22 ± 0.05	40	0.018
Normoglycemia at follow-up (%)	25.2%	127	32.6%	46	0.218	24.5%	98	35.0%	40	0.013

Data presented as unadjusted and adjusted mean ± SE and corresponding sample size, with boldface indicating significance at $P < 0.05$. Weight loss and HbA_{1c} improvement were winsorized at the 5th and 95th percentiles. Adjusted models controlled for age, sex, race/ethnicity, baseline BMI, baseline HbA_{1c}, pre-session attendance, class language, and coach, as well as retention, physical activity, and weight loss as applicable. Physical activity was collected starting at the 4th session (when introduced in the curriculum, per delivery guidelines [20]), limiting available data. HbA_{1c} within ±12 months of participation was assessed as available in medical records for approximately half of participants.

barriers (e.g., lack of transportation) (29) and expanding delivery of distance-learning programs upon further study (3).

This pilot study has limitations and lacks generalizability. The study design was nonrandomized, although the similarity of baseline characteristics between groups may support outcome comparisons. Without testing for impaired glucose tolerance and impaired fasting glucose as in the original DPP trial (6), there may be other unknown differences in metabolic risk profiles at baseline. Nonetheless, measuring glycemic improvement both linearly (total change in HbA_{1c}) and dichotomously (normal vs. hyperglycemia) may mitigate this concern, as individuals with higher baseline risk may likely attain greater HbA_{1c} improvement after intervention, whereas participants with lower baseline risk may more likely have normoglycemia at follow-up. Although half of participants lacked prepost laboratory testing of HbA_{1c}, obtaining HbA_{1c} values through medical records remains a relative strength given that glycemic outcomes are understudied in previous NDPP evaluations. Optional HbA_{1c} reporting is newly added to the CDC's revised NDPP delivery guidelines that were released in May 2021 (30), which may help expand evaluation of glycemic outcomes, as well as support ADA recommendations for annual screening (31). Moreover, the

revised guidelines newly allow NDPP participants to focus on glycemic improvement without weight loss and define $\geq 0.2\%$ HbA_{1c} improvement as a successful outcome, coinciding with the average improvement in NDPP-Flex. In contrast, mean HbA_{1c} improvement in our delivery of the standard NDPP was only 0.06%, suggesting that NDPP-Flex may be a preferred approach. Given NDPP-Flex was designed to follow existing CDC guidelines as much as possible, NDPP-Flex participants still received the latest CDC-developed curriculum and may have remained influenced, positively or negatively, by its prescriptive content focusing on weight loss. These participants may have also benefited from reporting goals (i.e., increasing accountability [32]), whereas the standard curriculum does not instruct coaches to collect goals.

A randomized trial of NDPP-Flex appears warranted to confirm findings and underlying mechanisms. For example, glycemic improvement has been linked to self-efficacy and perceived control (33,34), which may result from more patient-centered goal-setting. Goal variety also appeared to improve glycemia in this study. More research on goal-setting to improve glycemia is needed to conclusively inform best practices (35,36), although assessing achievability may be a foremost consideration (32). Above all,

the NDPP has relied on the extensive collaboration of cross-sector stakeholders to establish commendable successes in its first decade (7). Our data suggest that further improvements in the NDPP are possible and may improve impact of this landmark intervention. Concurrent efforts also remain needed to improve other aspects of NDPP delivery, such as more screening to identify and refer at-risk individuals, expanded program access, and greater overall uptake (37–39). If successful upon further study, NDPP-Flex could contribute to these collective efforts with a relatively simple adaptation for use by the many organizations delivering the NDPP to help reduce diabetes prevalence and disparities nationwide.

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