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An AI-Powered Lifestyle Intervention vs Human Coaching in the Diabetes Prevention Program:

A Randomized Clinical Trial

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Abstract

IMPORTANCE: Prediabetes is common, yet evidence-based lifestyle interventions are underutilized.

OBJECTIVE: To determine whether referral to an exclusively artificial intelligence (AI)-led lifestyle intervention based on the Diabetes Prevention Program (DPP) is noninferior to referral to a human-led DPP in achieving recommended thresholds for weight loss, hemoglobin A_{1c} (HbA_{1c}) reduction, and weekly physical activity among adults with prediabetes and overweight or obesity.

DESIGN, SETTING, AND PARTICIPANTS: This phase 3, parallel-group, pragmatic, noninferiority randomized clinical trial was conducted from October 11, 2021, to December 16, 2024 (last follow-up) at 2 US clinical sites in Baltimore, Maryland, and Reading, Pennsylvania. Adults 18 years or older with prediabetes and overweight or obesity were enrolled.

INTERVENTIONS: Participants were randomized in a 1:1 ratio to receive either a referral to an AI-powered DPP lifestyle intervention delivered via a mobile app and Bluetooth-enabled digital scale or a referral to a human coach-led DPP lifestyle intervention delivered remotely. Both interventions were delivered independently of the study team over a 12-month period.

MAIN OUTCOMES AND MEASURES: The primary outcome was a composite of maintaining an HbA_{1c} less than 6.5% throughout the study and achievement of at least 5% weight loss, at least 4% weight loss plus at least 150 minutes of weekly physical activity (assessed with actigraphy), or an absolute reduction in HbA_{1c} of at least 0.2 percentage points at 12 months. Noninferiority

of referral to the AI-led DPP compared with referral to the human-led DPP was prespecified to be determined if the 1-sided 95% CI lower boundary of the risk difference did not cross –15%.

RESULTS: A total of 368 participants were included (median [IQR] age, 58 [50-65] years; 71% were female, 27% were Black, 6% were Hispanic, and 61% were White; median [IQR] BMI, 32.3 [28.5-37.1]). After referral, 171 of 183 participants (93.4%) initiated the AI-led DPP and 153 of 185 (82.7%) initiated the human-led DPP. The primary outcome was achieved by 58 of 183 participants (31.7%) in the AI-led DPP group and 59 of 185 (31.9%) in the human-led DPP group (risk difference, –0.2% [1-sided 95% CI, –8.2%]), meeting the criterion for noninferiority. Findings were consistent across individual components of the composite end point and in sensitivity analyses.

CONCLUSIONS AND RELEVANCE: Among adults with prediabetes and overweight or obesity, referral to a fully automated AI-led DPP was noninferior to referral to a human-led DPP in achieving a composite outcome based on weight reduction, physical activity, and HbA_{1c}.

TRIAL REGISTRATION: [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT05056376) Identifier: [NCT05056376](https://clinicaltrials.gov/ct2/show/study/NCT05056376)

Prediabetes affects approximately 38% of US adults and has a growing global prevalence.^{1,2} It represents a stage between normal glucose tolerance and diabetes, and is independently associated with an increased risk of vascular complications.^{1,3} Of the approximately 460 million adults worldwide with prediabetes, about 20% to 50% are projected to develop diabetes within 5 years,⁴ highlighting the need for effective prevention strategies.

The Diabetes Prevention Program (DPP) lifestyle intervention is the criterion standard for reducing the risk of diabetes in individuals with prediabetes, demonstrating 58% risk reduction over 3 years.^{5,6} However, implementation is limited by program availability and low participation following referral. There are 1549 Centers for Disease Control and Prevention (CDC)-recognized DPPs nationwide, translating to 1 program for every 63 000 adults with prediabetes, and only about 35% of those referred ultimately participate.⁷ Travel (for in-person DPPs), scheduling conflicts, and limited cohort availability constrain participation.⁸

Digital DPPs present a promising approach to increase utilization by enabling asynchronous, app-based delivery.⁹⁻¹¹ Artificial intelligence (AI) may further enhance scalability of digital programs by personalizing behavioral change support and reducing the need for human coaches.^{12,13} Although previous randomized trials have assessed digital adaptations of the DPP, none had experimental groups that were fully automated and AI-based and none used a human-led DPP control group.¹⁴⁻¹⁹ The AI-based DPP studies reported to date have been single-group or other nonrandomized designs.^{12,20,21}

This pragmatic randomized clinical trial (RCT) was conducted to evaluate whether referral to a fully automated AI-powered DPP is noninferior to referral to a human coach-based DPP in achieving a composite of at least 5% weight loss, at least 4% weight loss plus at least 150 minutes of physical activity per week, or an absolute HbA_{1c} reduction of at least 0.2% at 12 months, while maintaining an HbA_{1c} less than 6.5% throughout the study.

Methods

Study Design

The original trial protocol, statistical analysis plan, and amendments are available in Supplement 1; the trial protocol has been summarized previously.²² Briefly, we conducted a phase 3, un-masked, parallel-group, noninferiority, randomized clinical trial from October 11, 2021, to December 16, 2024, at Johns Hopkins Hospital (Baltimore, MD) and Reading Hospital Tower Health (Reading, PA). After providing written informed consent, participants were randomly assigned in a 1:1 ratio to receive a referral to either an AI-based DPP or a CDC-recognized human-coached DPP. The trial was conducted in accordance with the Declaration of Helsinki.²³ We received approval from the institutional review boards at each site and adhered to the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline.²⁴

Participants

Eligible participants had prediabetes diagnosed using standard laboratory criteria and overweight or obesity using race-specific body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) cutoffs.²² Exclusion criteria included a prior diabetes diagnosis, severe cardiovascular conditions, factors affecting HbA_{1c} accuracy, cognitive or psychiatric barriers, and conditions or medications impacting body weight or blood glucose.²²

Randomization

Eligible participants underwent block randomization using centrally administered REDCap software.²² Randomization was stratified by baseline HbA_{1c} level (< 6.0% or 6.1%-6.4%) and recruitment site, using randomly permuted block sizes of 2, 4, or 8. The REDCap system concealed the randomization sequence from the research coordinators who enrolled and assigned participants.

Interventions

This trial was designed as an effectiveness study of referral of patients to lifestyle programs. The research team did not deliver or manage the interventions and had no role in supporting participant engagement beyond initiating the referral.

Participants were permitted to receive usual medical care; however, participation in other trials or structured programs related to nutrition, weight, or diabetes and use of medications that could affect glucose levels or body weight were prohibited.

AI-Based DPP: Participants in the AI-led DPP group were referred to Sweetch Health, Ltd, and received a digital health kit within 8 to 12 days after randomization, which included a Bluetooth scale and app registration instructions. The app delivered personalized push notifications for weight management, physical activity, and nutrition, informed by both actively collected data (eg, weight measurements, meal logging) and passively collected data (eg, geolocation, accelerometry). Physical activity was tracked via smartphone or wearable

devices, meals were logged through a food library or photo-based detection, and weight was recorded either automatically through the scale or manually.

The AI used in the intervention consisted of a reinforcement learning algorithm that did not use large language models. It personalized messaging by continuously learning which prompts, timing, and content elicited greater user engagement. Examples are provided in the Box and eFigure 1 in Supplement 2. The app also delivered location- and goal-specific nutrition education and included gamification elements and educational resources.^{25,26} A full description and visuals of the AI-led DPP can be found in the eMethods and eFigures 1 and 2 in Supplement 2. The manufacturer was permitted to implement updates to the app during the trial (eTable 1 in Supplement 2).

This platform was previously tested in a pilot trial involving adults with prediabetes, which included an initial calibration cohort to optimize its reinforcement learning algorithm.¹² Details on this algorithm are publicly available and summarized in Supplement 2.²⁷

Human Coach–Based DPP: Participants in the human-led DPP group were referred to 1 of 4 12-month accredited lifestyle change programs. All 4 participating DPPs had full plus recognition status from the CDC (ie, the highest designation within the Diabetes Prevention Recognition Program, awarded for effectiveness in achieving weight loss/physical activity outcomes and participant retention benchmarks; eTable 2 in Supplement 2). Due to COVID-19, all sessions transitioned from in-person to synchronous distance learning through group video conferences. Trained lifestyle coaches led sessions based on the CDC's PreventT2 curriculum, covering healthy eating, food tracking, physical activity, behavior modification, and long-term weight management, with an initial core phase (16 weekly sessions) and a subsequent core maintenance phase (biweekly to monthly sessions) to complete the 12-month intervention. Study participants joined DPP cohorts that included standard enrollees who were not participants in this trial.

Data Collection and Management

Baseline data were collected prior to intervention assignment. Race and ethnicity information was collected by participant self-report at baseline to characterize the enrolled population. All weight and HbA_{1c} measurements were obtained during study visits by trained research coordinators as described in Supplement 1; no weight data collected outside of study visits were used for outcome assessment. Actigraphy data were collected using a wrist-worn monitor (ActiGraph, Inc) for 7 consecutive days each month, with baseline physical activity collected prior to initiation of either intervention. Actigraphy processing details are available in Supplement 2. Baseline diet quality was assessed using a brief dietary assessment.²⁸

Staff in the human-led DPP group provided session attendance data through a REDCap database, while app usage data for the AI-led DPP group was tracked automatically and accessed from a secure dashboard.

Outcomes

The primary outcome was defined as maintaining an HbA_{1c} less than 6.5% throughout the study plus 1 or more of the following outcomes at 12 months: weight loss of greater than or equal to 5%, weight loss of greater than or equal to 4% combined with at least 150 weekly minutes of moderate to vigorous physical activity, or an absolute decrease in HbA_{1c} of at least 0.2 percentage points. The composite outcome, as defined by the CDC in its 2021 standards,²⁹ comprises elements that have each been associated with reduced risk of progression to diabetes.³⁰⁻³⁴ The change in HbA_{1c} end point was applicable only to participants with baseline HbA_{1c} of 5.7% to 6.4%.

Reported prespecified secondary outcomes include individual components of the primary composite outcome, program completion, incident HbA_{1c} greater than or equal to 6.5%, and continuous measures of body weight (absolute and percentage change from baseline), HbA_{1c} (absolute change from baseline), and mean weekly physical activity at 12 months. Secondary outcomes not reported include objective vs subjective physical activity correlation, engagement levels, acceptability, changes in well-being, analysis of participant characteristics associated with response to the intervention, cost-effectiveness, and other physical activity metrics.

There was no prespecified definition of adherence to the referred program. Program initiators were defined as participants who registered and used the app (AI-led DPP group) or attended at least 1 in-person session (human-led DPP group). Program completers engaged with the app for at least 8 weeks during months 1 to 6 with a span of at least 9 months between initiation and last engagement in the AI-led DPP group and attended at least 8 sessions in months 1 to 6 that spanned at least 9 months in the human-led DPP group.³⁵ The AI-led DPP delivers low-touch, asynchronous support that may allow for lighter but more continuous use, whereas the human-led DPP involves scheduled, synchronous sessions that may require more concentrated effort. As a result, progression categories may not reflect equivalent intensity or effort across groups.

Post hoc outcomes included program initiation rates and subgroup analyses of the primary outcome by recruitment site, sex, age group, baseline HbA_{1c} category, and BMI category.

Sample Size Calculation

This noninferiority trial aimed to demonstrate that referral to an AI-led DPP is not worse than referral to a human-led DPP, with a prespecified noninferiority margin of 15 percentage points. The composite end point used in this trial has not been previously assessed. To inform the margin, we referenced the landmark DPP trial, in which 47% of participants in the intensive lifestyle intervention group achieved at least 5% weight loss at 12 months compared with 0.3% in the placebo group, yielding a risk difference of 46.7% (95% CI, 43.1%-50.2%).³⁶ Preserving 50% of the control effect, as recommended by US Food and Drug Administration guidance, would correspond to a margin of 23 percentage points; however, we selected a more conservative margin of 15 percentage points to ensure clinical acceptability.

A sample of 276 participants (138 per group) was calculated to provide 80% power at a 1-sided significance level of .05. Accounting for a 25% attrition rate, target enrollment was 368 participants (184 per group).

Statistical Analysis

Primary Outcomes: The primary analysis was conducted using an intention-to-treat approach in all randomized participants. Those who did not attend the 12-month study visit were classified as not achieving the primary composite outcome. The risk difference was estimated using binomial regression. Noninferiority was defined a priori as the lower bound of the 1-sided 95% CI for the risk difference being greater than or equal to -15% .

Five post hoc sensitivity analyses were conducted: (1) an analysis that included multiple imputation using chained equations to address missing 12-month outcomes under a missing-at-random assumption; (2) an analysis that adjusted for baseline covariates that were imbalanced after randomization; (3) analyses that applied alternative assumptions regarding actigraphy derived physical activity; (4) a pattern mixture model sensitivity analysis assuming data were missing not at random; and (5) analyses using cluster-robust standard errors to account for potential intragroup correlation due to shared program exposure.

A restricted analysis was conducted in participants with 12-month outcome data who did not initiate prohibited medications during the trial. Additional exploratory subgroup analyses of the primary outcome were conducted.

Secondary Outcomes: Secondary outcomes were considered exploratory; therefore, no adjustments were made for multiple comparisons, and all CIs and *P* values are interpreted descriptively. The individual components of the primary composite end point were analyzed using binomial regression models to estimate risk differences. Program initiation and completion rates and the percentage of participants with incident HbA_{1c} levels greater than or equal to 6.5% during the study were compared between groups using χ^2 tests. In the participants with 12-month outcome data who did not initiate prohibited medications, 12-month changes in weight, HbA_{1c}, and physical activity levels were summarized descriptively. All analyses were conducted using R (R Foundation for Statistical Computing) and Stata version 17.0 (StataCorp).

Results

Study Participants

Among 427 individuals screened for eligibility, 368 adults met eligibility criteria, were randomized, and were included in the primary analysis (Figure 1). The Table and eTable 3 in Supplement 2 summarize baseline characteristics, with 66% of participants recruited from Johns Hopkins Hospital (urban/suburban population) and 34% from Reading Tower Health (suburban/rural population). Participants had a median (IQR) age of 58 (50-65) years and 70.7% were female, 27.2% were Black, 5.4% were Hispanic, and 61.0% were white. The median (IQR) BMI was 32.3 (28.5-37.1); 72.3% of participants were classified as having obesity and 27.7% were classified as having overweight. At baseline, 67.7% met the moderate to vigorous physical activity guideline of at least 150 minutes per week via

actigraphy and 31.8% had poor diet quality. Baseline characteristics were balanced between intervention groups, except for age. The prevalence of additional eligibility criteria by group is provided in eTable 4 in Supplement 2. Participants from Reading, PA, were older, more frequently White and married, and had lower educational attainment than those from Baltimore, MD (eTable 5 in Supplement 2). There were no clinically significant differences between participants with HbA_{1c} end point–eligible (baseline HbA_{1c} of 5.7% to 6.4%) and ineligible individuals in factors affecting weight loss or physical activity (eTable 6 in Supplement 2).

A total of 313 participants completed the 12-month study and had complete outcomes data (eTable 7 and eTable 8 in Supplement 2), resulting in a study retention rate of 85.1% and high adherence to the follow-up schedule (eTable 9 in Supplement 2). Of these participants, 13 initiated prohibited medications (eTable 10 in Supplement 2), leaving 300 participants included in the restricted analysis (eTable 11 in Supplement 2).

Primary Analysis

The primary end point of achievement of a composite of at least 5% weight loss, at least 4% weight loss plus at least 150 minutes of weekly physical activity (assessed with actigraphy), or an absolute reduction in HbA_{1c} of 0.2% at 12 months in participants who maintained an HbA_{1c} less than 6.5% throughout the study was achieved by 31.8% of participants overall, with 58 of 183 participants (31.7%) in the AI-led DPP group and 59 of 185 participants (31.9%) in the human-led DPP group. The risk difference was –0.2% (1-sided 95% CI: –8.2%; Figure 2), demonstrating that the AI-led DPP intervention met the noninferiority margin of –15.0%. eTable 12 in Supplement 2 disaggregates the individual components among the 117 participants who achieved the composite outcome (58 in AI-led DPP group and 59 in human-led DPP group).

Secondary Outcomes

The risk differences for the 3 individual components were directionally consistent with the primary analysis (Figure 2). Additionally, the percentage of participants with HbA_{1c} greater than or equal to 6.5% did not significantly differ between the groups (AI-led DPP group: 4.4%; human-led DPP group: 3.8%; $P = .78$; eTable 13 in Supplement 2). Figure 3 and eTable 14 in Supplement 2 display continuous components of the composite primary outcome.

A higher percentage of referred participants initiated the AI-led DPP compared with the human-led DPP (93.4% vs 82.7%; $P = .001$). Additionally, a higher percentage of AI-led DPP participants met engagement criteria for program completion (63.9% vs 50.3%; $P = .008$). Similar engagement–outcome relationships were observed for both groups (Figure 4), with higher outcome achievement in program completers. Outcome achievement was observed in 25% vs 28% of participants who were referred but did not initiate, 22% vs 28% of those who initiated but did not complete, and 37% vs 35% of those who completed the AI-led and human-led DPPs, respectively. Among those who achieved the outcome, 5% vs 15% were referred but did not initiate, 21% vs 29% initiated but did not complete, and 74% vs 56% completed the AI-led and human-led DPPs, respectively.

Exploratory Analyses

Restricted analyses of participants with 12-month data who did not initiate prohibited medications (eTable 15 in Supplement 2) and sensitivity analyses (eFigure 3, eTables 16-19 in Supplement 2) were consistent with the primary analysis. In the subgroup analysis, the AI-led DPP appeared less effective at the Baltimore, MD, site, among older participants, and in lower BMI strata, yet had better performance in those at the Reading, PA, site and in those with severe obesity (eFigure 4 in Supplement 2).

Adverse Events

Although there were more adverse events reported in participants randomized to the AI-led DPP group, there were no study-related adverse events in either group (eTable 20 in Supplement 2).

Discussion

This RCT demonstrated that the percentage of participants achieving a composite outcome of weight loss, physical activity, and HbA_{1c} reduction at 12 months following referral to an AI-driven DPP delivered without human intervention was noninferior to that of participants referred to a traditional human coach-based DPP. Despite CDC recognition of digital DPPs since 2015, limited RCT evidence has evaluated their effectiveness, with no trials comparing them directly to the criterion-standard DPP.^{14-19,37} To the authors' knowledge, this is the first RCT to compare a fully automated DPP to standard care and adds to the limited evidence evaluating AI interventions against established standards in medicine.^{38,39}

The asynchronous mobile delivery of personalized coaching may address barriers to implementation of human coach-based models. Participants referred to the AI-led DPP had higher rates of program initiation, likely due to the greater accessibility and convenience of asynchronous, on-demand engagement. In this trial, some participants achieved the outcome despite not initiating their assigned program. This was more common in the human-led DPP group due to a greater number of noninitiators. It is possible that individuals who chose to participate in this trial were more motivated to pursue alternative behavioral change strategies than the general population of patients with prediabetes.

Outcome achievement rates were similar between the groups among program initiators and program completers. However, the engagement level distribution among outcome achievers differed between groups. In the AI-led DPP group, a larger percentage of outcome achievers were program completers compared with the human-led DPP group (74% vs 56%). This suggests that intervention exposure may play a more central role in the AI-led DPP, which depends on continuous, self-directed engagement, whereas the human-led DPP's structured, coach-led format may allow participants to derive benefit with less time spent on the program. The AI-led DPP's advantage in facilitating higher engagement appeared to be offset by the human-led DPP's ability to confer benefit even among partial completers, resulting in comparable overall effectiveness.

Despite guideline recommendations,⁴⁰ only 3% of adults in the US with prediabetes participate in DPPs.⁴¹ Usual care typically involves brief lifestyle advice without structured

counseling. Insufficient program availability and low retention limit the DPP's population health impact.⁴² The AI-based DPP evaluated in this trial, with its scalable, on-demand format, addresses these barriers and may reach individuals who currently receive no structured intervention. However, among those able to access and participate in traditional DPPs, the AI-led DPP did not show greater benefit, suggesting its value lies in scalability rather than superiority. As AI continues to evolve and new digital interventions emerge, AI-based approaches to behavioral change should continue to be compared with traditional models. Further study is required to evaluate effectiveness of the AI-led intervention across participant subgroups.

The intervention evaluated in this trial was designed to be simple and accessible; however, a baseline level of digital comfort may have been required, and the role of digital literacy in moderating the effectiveness of AI-based DPPs warrants further study. Because this intervention involved no human in the loop, findings from this trial could support revisiting current CDC standards for DPP recognition, which do not allow digital programs to use AI in place of human lifestyle coaching.⁴³

The control group of this trial was modeled on the intensive lifestyle intervention from the original DPP trial and delivered via CDC-recognized programs with full recognition status. While the original DPP reported at least 5% weight loss in 44% of participants at 12 months, community-based programs report this degree of weight loss in 13.5% to 35.5% of participants.^{44,45} In this trial, 20.0% of participants in the human-led DPP group in the primary analysis and 22.1% in the analysis of completers who did not initiate prohibited medications achieved at least 5% weight loss, falling within the expected range for community-based programs. This supports the adequacy of DPP delivery in the human-led DPP group and its use as an appropriate control group.

Although this trial was initially designed to compare the AI-led DPP with delivery of the DPP in-person, all sessions in the human-led DPP group were delivered remotely due to the COVID-19 pandemic. This shift may have reduced typical barriers to in-person participation, such as transportation and scheduling, as suggested by the higher-than-typical participation rates observed in the human-led DPP group. The shift toward delivering the DPP through distance learning makes the results in this study relevant to contemporary DPPs. Synchronous remote DPPs follow the same CDC-approved structure as in-person programs. In a study of more than 330 000 participants of the national DPP, there were similar rates of greater than or equal to 5% weight loss with in-person and distance learning formats (34.3% vs 37.2%) and, in the UK National Health Service DPP, synchronous remote delivery produced slightly greater weight loss than prepandemic in-person sessions (2.40 kg vs 2.01 kg).^{46,47}

Adverse events were more common in the AI-led DPP group, though none were attributed to the intervention. This may reflect uncaptured baseline differences in health status, older age in the AI-led DPP group, or behavioral effects of the interventions. Unlike the human-led DPP, which may have included discussions about pandemic precautions, the AI DPP app was not programmed to incorporate COVID-19 pandemic-specific behaviors and may have encouraged more public physical activity.

Strengths of this trial include its randomized design, criterion-standard active control, 12-month duration, high retention, objective physical activity assessment, and pragmatic approach to DPP delivery.

Limitations

This study has several limitations. First, it was not masked and used surrogate outcomes rather than incidence of diabetes. Second, despite CDC recognition for adherence to DPP standards, delivery of the human-based DPP may have varied across sites. Third, while the AI algorithm for push notifications remained unchanged, the impact of interface or feature updates to the app on engagement or outcomes is unknown. Fourth, study visits and actigraphy were conducted outside of standard DPP exposures.

Fifth, referrals did not originate from participants' primary care clinicians as in standard practice. Sixth, missing 12-month data may have influenced results, though findings were consistent across sensitivity analyses. Seventh, physical activity estimates may have been affected by assumptions on nonwear time and sampling adequacy, although sensitivity analyses suggested minimal impact on outcomes. Eighth, delivery of the human-led DPP was changed due to the COVID-19 pandemic, and engagement and outcomes may also have been influenced. Ninth, participants were motivated volunteers with high baseline physical activity levels and high educational attainment from only 2 sites, limiting generalizability to the broader population of patients with prediabetes with overweight or obesity.

Conclusions

Among adults with prediabetes and overweight or obesity, referral to a fully automated AI-led DPP was noninferior to referral to a human-led DPP in achieving a composite outcome based on weight reduction, physical activity, and HbA_{1c}. Further studies are warranted to assess incidence of diabetes, generalizability to other AI-based programs, cost-effectiveness, implementation across diverse populations, and patient preference.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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See Supplement 4.

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Key Points

Question

How does referral to a lifestyle intervention exclusively driven by artificial intelligence (AI) compare with referral to a human coach–led Diabetes Prevention Program (DPP) lifestyle intervention?

Findings

In this randomized clinical trial involving 368 adults with overweight or obesity and prediabetes, 31.7% of participants randomized to referral to an AI-led DPP and 31.9% of participants randomized to referral to a human-led DPP group achieved the primary composite outcome (5% weight loss, 4% weight loss plus 150 minutes of physical activity per week, or an absolute hemoglobin A_{1c} reduction of 0.2 percentage points with hemoglobin A_{1c} maintained at <6.5% throughout the study duration) at 12 months, a difference that met the prespecified noninferiority criterion of 15%.

Meaning

Among adults with prediabetes and overweight or obesity, a fully automated AI-led DPP may be a viable alternative to a DPP led by human coaches.

Box.**Example Personalized Push Notifications in the Artificial Intelligence–Led Diabetes Prevention Program****Physical Activity**

“Hey Sam—your gym is nearby, and it’s been a few days. 30 minutes is all it takes to boost your energy and progress. Ready to jump back in?”

“Hi Rita—rainy days make it tough, but 10 minutes of movement still counts. You have a short break between meetings now—let’s try some indoor stretching!”

Nutrition

“Headed to your usual lunch spot, Sam? Try choosing a meal with protein + fiber to help stay full longer—like grilled chicken with veggies. Want a few quick ideas?”

“Looks like you’re at the grocery store, Rita! Want a quick list of high-fiber snacks or smart swaps to stay on track this week?”

Weight Tracking

“It’s been a while since your last weigh-in, Sam. It looks like you’re working from home today—how about stepping on the scale to restart your streak?”

“You’ve made great food choices this week, Rita. A quick weigh-in today can help reinforce the momentum. Every step counts.”

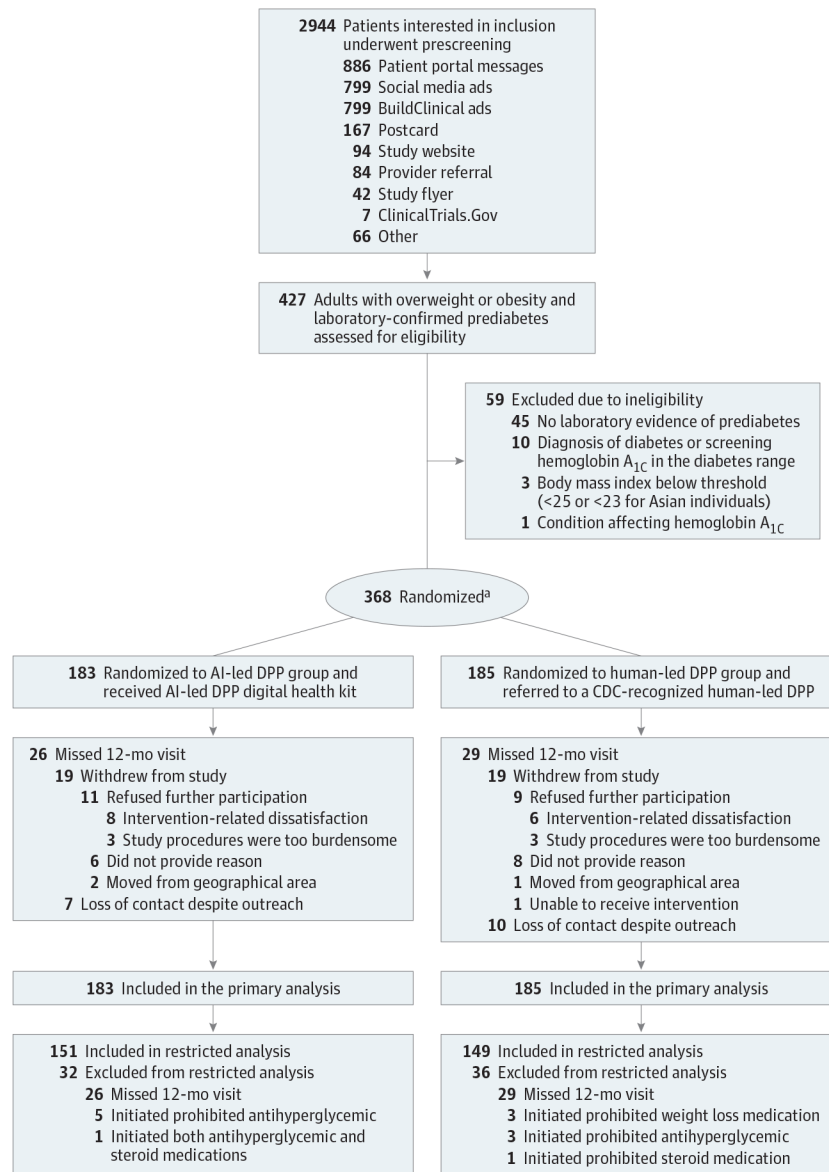


Figure 1. Participant Flow in a Trial of Interventions for Prediabetes

^aRandomization was stratified by baseline hemoglobin A_{1C} (6.0% vs 6.1%-6.4%) and by recruitment site (Johns Hopkins vs Reading Hospital).

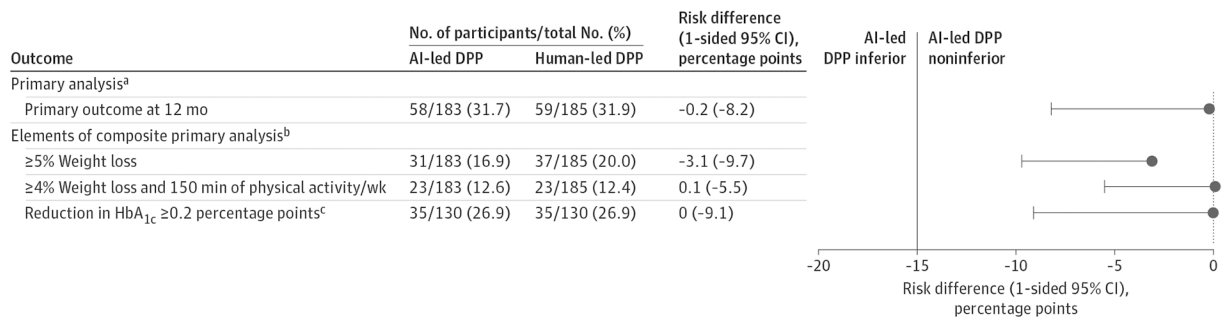


Figure 2. Plot of Binary Outcome Differences

^aThe plot presents risk differences (percentage points) with 1-sided 95% CIs for the primary and elements of the composite primary analysis at 12 months. The reference line at -15 percentage points represents the noninferiority margin. The AI-led DPP intervention is considered noninferior to human-led DPP if the 1-sided 95% CI does not cross this threshold. Negative risk difference values indicate a lower outcome achievement frequency in the AI-led DPP group compared with the human-led DPP group.

^b95% CIs for elements of the composite primary analysis outcomes are presented for descriptive purposes only. No multiplicity adjustment was applied because these analyses are exploratory and not intended for formal hypothesis testing.

^cAnalysis of the hemoglobin A_{1c} (HbA_{1c}) reduction of 0.2 percentage points outcome applies only for participants with HbA_{1c} in the prediabetes range at the study baseline visit (AI-led DPP: n = 130; human-led DPP: n = 130).

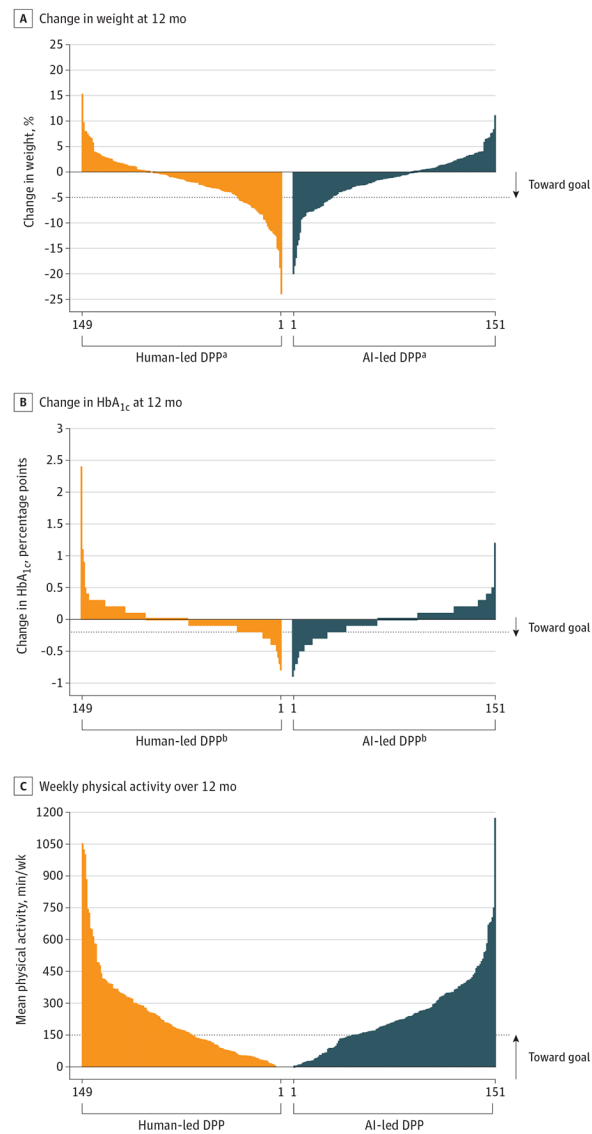


Figure 3. Percent Weight Change, HbA_{1c} Change, and Physical Activity at 12 Months

^aBaseline median (IQR) weight: 32.2 (28.2-35.9) kg/m² in the AI-led DPP group and 32.5 (29.3-37.7) kg/m² in the human-led DPP group.

^bBaseline mean (SD) hemoglobin A_{1c} (HbA_{1c}), 5.8% (0.3%) in both groups.

A AI-led DPP (n=183)

	Referred, not initiated	Initiated, not completed	Completed	Total by outcome achievement status
Did not achieve outcome	9	42	74	125
Achieved outcome	3	12	43	58
Total by engagement level	12	54	117	183

B Human-led DPP (n=185)

	Referred, not initiated	Initiated, not completed	Completed	Total by outcome achievement status
Did not achieve outcome	23	43	60	126
Achieved outcome	9	17	33	59
Total by engagement level	32	60	93	185

Figure 4. Outcome Achievement at Varying Levels of Engagement by Group

Matrix plots illustrating the distribution of participants by program engagement level and 12-month outcome. Between-group engagement categories are based on discrete program milestones and exposure to the program and may not fully correspond to equivalent levels of intensity or effort. A, In the AI-led DPP, outcome achievement was observed in 25% of those referred but did not initiate, 22% who initiated but did not complete, and 37% who completed.

Among those who achieved the outcome, 5% were referred but did not initiate, 21% initiated but did not complete, and 74% completed. B, In the human-led DPP, outcome achievement was observed in 28% of those referred but did not initiate, 28% who initiated but did not complete, and 35% who completed. Among those who achieved the outcome, 15% were referred but did not initiate, 29% initiated but did not complete, and 56% completed.

Table.
Baseline Characteristics of Randomized Participants

Characteristic ^a	Diabetes Prevention Program	
	AI-based (n = 183)	Human coach-based (n = 185)
Site, No. (%)		
Johns Hopkins Hospital (Baltimore, MD)	120 (65.6)	123 (66.5)
Reading Tower Health (Reading, PA)	63 (34.4)	62 (33.5)
Age, median (IQR), y ^b	60.0 (51.0-68.0)	57.0 (50.0-63.0)
Sex, No. (%)		
Female	121 (66.1)	139 (75.1)
Male	62 (33.9)	46 (24.9)
Race, No. (%) ^c		
American Indian or Alaska Native	0	1 (0.5)
Asian	11 (6.0)	16 (8.6)
Black or African American	51 (27.9)	49 (26.5)
White or Caucasian	114 (62.3)	111 (60.0)
More than 1 race	3 (1.6)	5 (2.7)
Other	4 (2.2)	2 (1.1)
Declined to answer	0	1 (0.5)
Ethnicity, No. (%) ^c		
Hispanic or Latino	5 (2.7)	15 (8.1)
Not Hispanic or Latino	176 (96.2)	167 (90.3)
Declined to answer	1 (0.5)	1 (0.5)
Unknown	1 (0.5)	2 (1.1)
Marital status, No. (%)		
Married/partnered	120 (65.6)	121 (65.4)
Previously married (divorced/separated/widowed)	27 (14.8)	26 (14.1)
Single/other	36 (19.7)	38 (20.5)
Educational attainment, No. (%)		
High school or less	23 (12.6)	19 (10.3)
Some college/associate's degree	38 (20.8)	36 (19.5)
Bachelor's degree	53 (29.0)	55 (29.7)
Graduate/professional degree	69 (37.7)	74 (40.0)
Declined to answer	0	1 (0.5)
BMI, median (IQR)	32.2 (28.2-35.9)	32.5 (29.3-37.7)
Medical history, No. (%) ^d		
Dyslipidemia	85 (46.4)	86 (46.5)
Hypertension	82 (44.8)	78 (42.2)
Back pain	52 (28.4)	44 (23.8)

Characteristic ^d	Diabetes Prevention Program	
	AI-based (n = 183)	Human coach-based (n = 185)
Mood disorder	39 (21.3)	43 (23.2)
Osteoarthritis	39 (21.3)	32 (17.3)
Asthma/COPD	31 (16.9)	28 (15.1)
BMI classification, No. (%)		
Overweight (BMI, 25.0-29.9)	55 (30.1)	47 (25.4)
Class I obesity (BMI, 30.0-34.9)	70 (38.3)	57 (30.8)
Class II obesity (BMI, 35.0-39.9)	33 (18.0)	47 (25.4)
Class III obesity (BMI 40.0)	25 (13.7)	34 (18.4)
HbA _{1c} , mean (SD), % ^e	5.8 (0.3)	5.8 (0.3)
Actigraph-measured MVPA, median (IQR), min/wk ^f	237.0 (106.0-374.0)	239.0 (104.0-462.0)
Actigraphy-measured MVPA <150 min/wk, No. (%) ^g	54 (29.5)	65 (35.1)
Diet quality score, No. (%) ^h		
Healthiest diet (1-5)	70 (38.3)	73 (39.5)
Moderately healthy diet (6-10)	50 (27.3)	58 (31.4)
Least healthy diet (11-16)	63 (34.4)	54 (29.2)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); COPD, chronic obstructive pulmonary disease; MVPA, moderate to vigorous physical activity.

^aValues for nonnormally distributed continuous characteristics are presented as median (IQR). Additional characteristics provided in eTable 4 (overall), eTable 6 (by site), and eTable 7 (by baseline hemoglobin A_{1c} [HbA_{1c}] status) in Supplement 2.

^bAge differed significantly between the study groups ($P = .01$); all other baseline characteristics were similar ($P > .05$).

^cRace and ethnicity were self-reported in single-choice questions with explicit categories derived from the Epic electronic medical record.

^dMedical history collected via participant self-report at baseline.

^eHbA_{1c} reference ranges were defined as <5.7% for normoglycemia, 5.7%-6.4% for prediabetes, and ≥6.5% for diabetes.

^fActigraph-measured MVPA refers to objectively measured moderate-to-vigorous physical activity using a wrist-worn accelerometer. For participants with no valid baseline Actigraphy data (n = 3), MVPA was imputed as 0 minutes/week to reflect likely inactivity following repeated prompting to wear the device.

^gMVPA less than 150 minutes per week corresponds to not meeting the recommended physical activity guidelines for prediabetes.

^hDiet quality at baseline was scored using the Starting the Conversation dietary survey,²⁸ with lower scores indicating healthier dietary patterns. Scores range from 0 to 16, based on responses to 8 items assessing key dietary behaviors (eg, intake of fast food, fruits, vegetables, sugary drinks, chips, desserts, beans, and margarine or butter), and each item scored from 0 (most healthful) to 2 (least healthful). For 1 participant, a missing response was imputed with a midrange value (1 of 0-2) to allow diet quality score calculation.