COMIRB Protocol

Protocol #: 18-2542
Project title: Enhanced enrollment in the National Diabetes Prevention Program for the underserved: a randomized control trial
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I. Hypotheses and Specific Aims

Type 2 diabetes affects 9.4% of US adults with higher rates among racial/ethnic minorities and individuals of low socioeconomic status.[1] The Diabetes Prevention Program was a successful clinical trial demonstrating that intensive lifestyle support for weight loss reduced diabetes incidence by 58%.[2] The intervention was translated into the National Diabetes Prevention Program (NDPP) and disseminated by the Centers for Disease Control and Prevention as a yearlong group-based program since 2012.[3] Despite successes, a 2017 report found that retention in the NDPP is problematic and leads to suboptimal weight loss.[4] Attendance and weight loss are especially low among Hispanic, non-Hispanic black, and low-income non-Hispanic white participants.[4-6] Strategies to improve NDPP outcomes among these disadvantaged populations are urgently needed.

We previously developed and pilot-tested a novel NDPP enrollment protocol, the Pre-NDPP, that provides a "pre-session" with three components: 1) education about diabetes risks, 2) motivational interviewing (MI) to encourage participation in the NDPP and, 3) problem-solving of barriers to engagement.[7] In a longitudinal cohort study among a diverse and underserved population, outcomes of 75 Pre-NDPP participants who enrolled in the NDPP were compared to 1,065 prior participants using ANCOVA and multivariable logistic regression. Pre-session participants stayed in the NDPP 99.8 days longer ($p<.001$) and attended 14.3% more sessions ($p<.001$) on average than those without a pre-session. Pre-session participants lost 2.0% more weight ($p<.001$) and were 3.5 times more likely to achieve the 5% weight loss target ($p<.001$). Sensitivity analyses were consistent. These findings suggest pre-sessions may be a promising and pragmatic strategy to improve NDPP retention and effectiveness and mitigate disparities in program outcomes. We now propose a large, pragmatic, intent-to-treat randomized controlled trial (RCT) to test effects of the Pre-NDPP enhancement on NDPP attendance and weight loss among a diverse, predominately underserved population with elevated diabetes risks. A RCT is necessary to determine whether Pre-NDPP reliably improves NDPP outcomes. Power calculations based on pilot results indicate that a RCT of 500 participants will allow for a robust test of Pre-NDPP on the primary outcome of percent weight loss.

Aim 1: To evaluate clinical effectiveness of the Pre-NDPP intervention. We will recruit 500 diverse, predominately low-income patients with elevated diabetes risks (e.g., prediabetes) in the Denver Health safety net healthcare system. We will conduct a RCT to compare NDPP attendance and weight loss outcomes between participants randomized to receive the Pre-NDPP enhancement vs. direct enrollment into the NDPP (usual care). Pre-sessions, led by trained Lifestyle Coaches, will focus on providing information on diabetes risks and locally available resources to reduce risk, including the NDPP. Coaches will use MI techniques to help participants identify an actionable plan to reduce risk, such as attending NDPP sessions, and guide participants in identifying barriers and possible solutions that would enable participation. Pre-NDPP participants and usual care NDPP participants will be assigned to separate NDPP classes to prevent contamination of Pre-NDPP effects. We will collect data on demographics, NDPP outcomes (primary outcome is percent weight loss), potential mediators, implementation factors, and cost. We hypothesize that Pre-NDPP participants will have greater engagement and weight loss compared to those who are directly enrolled into the program (usual care).

Aim 2: To examine mediators and moderators of Pre-NDPP outcomes. We will explore potential mediators (perceived risk for developing diabetes and self-efficacy and readiness for weight control) and key sociodemographic variables (race/ethnicity and income level) as potential moderators of intervention effectiveness that are important to understand for future uptake by stakeholders. We hypothesize that a) Pre-NDPP will increase perceived risk, self-efficacy, and readiness, which will mediate relationships between pre-session treatment and NDPP outcomes, and that b) race/ethnicity and income level will moderate Pre-NDPP effectiveness.

Aim 3: To evaluate the implementation factors of Pre-NDPP. In preparation for potential future dissemination, we will evaluate implementation factors following a RE-AIM framework[8], including a qualitative evaluation of pre-sessions from a Lifestyle Coach, clinic provider/personnel, and patient perspective. We will

also evaluate the cost of adding pre-sessions to NDPP delivery and projected return on investment (ROI). We hypothesize that Pre-NDPP will be implementable and yield sufficient projected ROI to justify its cost.

Our future goal is to disseminate a scalable, evidence-based strategy to improve success of the NDPP and reduce disparities in NDPP effectiveness. If found to be effective, this approach can be disseminated to all NDPP providers, including more than 1,700 suppliers[9], and may be supported by current NDPP payers such as Medicare, commercial insurers, and employer groups.[10-12] Thus, this approach has potential for high impact on the burden of type 2 diabetes and related health disparities across the country.

II. Background and Significance

Diabetes in the US. Type 2 diabetes (T2D) affects 9.4% of US adults, imposing a significant public health and economic burden.[13,14] Diabetes prevalence is higher among Hispanics (12.1%) and non-Hispanic blacks (NHBs; 12.7%) than among non-Hispanic whites (NHWs; 7.4%).[13] Low socioeconomic status is also associated with higher prevalence.[1,15] An additional 33.9% of US adults are estimated to have prediabetes,[13] an intermediary condition of elevated blood glucose that is likely to progress to diabetes without intervention. Individuals with impaired fasting glucose experience annual rates of diabetes incidence of 5.6%.[16] Yet only 1 in 10 individuals with prediabetes are estimated to be aware of their risk.[13] Interventions to prevent T2D have been developed and widely disseminated by the Centers for Disease Control and Prevention (CDC), but gaps in participation and effectiveness need to be addressed to improve population health and diabetes-related disparities.

The National Diabetes Prevention Program: Strengths and areas for improvement. The Diabetes Prevention Program clinical trial was highly successful in demonstrating that intensive lifestyle support for weight loss reduced diabetes incidence by 58% over an average of three years.[2] Longitudinal follow up showed that lifestyle intervention benefits can persist up to 15 years.[17,18] The National Diabetes Prevention Program (NDPP), a lower cost translation of the program, has achieved scalability with over 1,700 suppliers[9] and 106,000 participants served[19] since dissemination began in 2012. Successful outcomes have led to health policy change, including reimbursement from payers like Medicare, which began coverage of the NDPP as of April 2018.[10] The NDPP promotes ≥5% weight loss through diet and physical activity, with 16 weekly to biweekly sessions, plus ≥6 monthly sessions, over 12 months. Greater duration and intensity of participation are associated with better weight loss.[4] Incrementally greater weight loss is important to prevent diabetes as each kilogram of weight loss has been associated with a 16% reduction in incidence.[20] Delivering the NDPP in healthcare settings also appears optimal given: 1) access to a provider referral network bolsters initial enrollment of at-risk patients,[21] 2) greater weight loss is achieved when delivered in healthcare vs. community sites,[22] and 3) clinic settings have existing infrastructure for insurer reimbursement. At the same, the CDC has approved of remotely-conducted NDPP sessions (or combined in-person and remotely-conducted classes) since 2018, which has shown promise for improving participant retention with its more flexible approach,[23] and is expressly encouraged in the era of COVID-19.

The NDPP has numerous strengths, yet limitations include suboptimal engagement and weight loss rates,[4,24] that are further disparate among racial/ethnic minorities and low-income NHW participants.[4,5,25] Specifically, a national evaluation showed that Hispanic and NHB participants have similar weight loss (medians of 2.5% and 2.2%, respectively among participants with ≥2 recorded weights), but less than the weight loss achieved by NHW participants (median=4.1%).[4] Low-income NHWs have also been shown to achieve less than half as much weight loss as higher-income NHWs.[25] It is important to develop cost-effective strategies to improve NDPP attendance and weight loss among these disadvantaged populations.

Theoretical model to improve NDPP effectiveness. The Health Belief Model[26] (Fig. 1) is a widely used theory of health behavior change that offers insights toward developing strategies to improve NDPP outcomes. The model posits that perceived risk, benefits of, barriers to and cues to action, and self-efficacy, are factors determining health behavior that can be addressed in targeted interventions. Based on the Health Belief Model, interventions to prevent T2D must focus on increasing risk awareness and exploring pros/cons of available interventions, including the NDPP. Studies have demonstrated that increasing awareness of diabetes risks may lead to risk-reduction behavior. For example, being told of having prediabetes by a healthcare professional was associated with self-reported

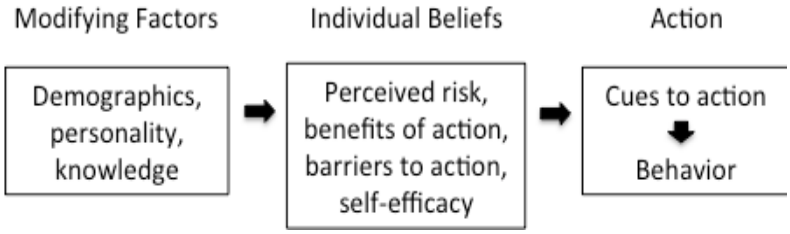

Fig. 1: Health Belief Model, adapted from Champion & Skinner, 2008

weight loss efforts among 52-68% of at-risk individuals in national surveys.[27,28] Motivational interviewing (MI)[29] may also facilitate action-oriented decision-making about NDPP engagement with its empathic coaching style and evocation of "change talk". Multiple systematic reviews support the proposed use of MI in a brief, group-based intervention to improve NDPP effectiveness: A broad review found MI was effective in brief doses as low as 10 minutes (although greater duration appears beneficial), when delivered in group settings (3 of 3 studies showed positive effects), and to support weight loss behavior and outcomes (8 of 10 had positive results).[30] More specifically, a 2001 review found brief MI was particularly effective at enhancing engagement in weight loss interventions.[31] A more recent 2014 review noted overall positive results of MI for weight management.[32] Good evidence was also found for MI as a necessary component for interventions to prevent diabetes.[33]

Pre-NDPP: A theory-driven, pragmatic solution to improve NDPP effectiveness. Implementing a "pre-session" prior to NDPP enrollment (Pre-NDPP) may be a pragmatic strategy for delivering a theory-driven educational and motivational intervention to bolster the NDPP's effectiveness. Pre-sessions have been recommended to increase NDPP engagement,[34] without supporting evidence prior to our recently published pilot study.[35] In brief, we developed and pilot-tested a novel strategy to improve attendance and weight loss in the NDPP in which diverse and predominately underserved participants attended a pre-session that provided 1) education about diabetes risks, 2) brief MI to participate in the NDPP, and 3) problem-solving of barriers to participation, based on well-known findings that sufficient engagement in the NDPP generally yields good weight loss[4,22]. Our pre-session strategy pilot study was highly successful (see Preliminary Data below) but results require confirmation from an adequately powered randomized trial to justify dissemination efforts.

Research gap and scientific rationale of proposed study. NDPP outcomes are suboptimal, especially for disadvantaged populations, which risks further widening of health disparities if not addressed. Pilot data show feasibility and promising results of Pre-NDPP among diverse, underserved patients with elevated diabetes risks, but are limited by small sample size of the intervention group and no concurrently randomized control group. To address the research gap, we propose a randomized controlled trial (RCT) to compare NDPP attendance and weight loss among diverse, predominately underserved participants who receive Pre-NDPP vs. direct enrollment into NDPP (usual care). The primary hypothesis generated by pilot data and above-cited literature is that pre-sessions improve NDPP engagement and weight loss, which will be confirmed if those randomized to Pre-NDPP have better outcomes than those receiving usual care NDPP. A secondary analysis will examine whether only Pre-NDPP participants who go on to NDPP benefit (vs. no benefit for those declining NDPP), which would suggest that pre-sessions screen for individuals likely to participate adequately, and thus benefit from, the NDPP. Screening via pre-sessions may yet be an efficient population health strategy to a) increase risk awareness for the estimated one-third of US adults with prediabetes,[1] b) offer informed decision-making, and c) maximize performance-based reimbursement for suppliers, which supports access[36]. In either case, a brief group model may be optimal as: 1) Individual pre-sessions appear cost-prohibitive, while longer sessions may also be more taxing on vulnerable populations; 2) Uptake by NDPP suppliers likely depends on establishing efficacy in a low-cost, high-reach model; 3) A key goal is supporting engagement in the yearlong NDPP for continued intervention, and thus increasing familiarity with its hour-long, group class format may be important (held remotely and/or in-person as allowable in the era of COVID-19). If effective, greater uptake is expected if NDPP providers and payers can understand how Pre-NDPP achieves an effect and whether their populations are likely to benefit, which will be addressed via mediation and moderation analyses. To prepare for future dissemination, we will also evaluate implementation factors, including cost of adding pre-sessions to NDPP delivery and estimated return on investment (ROI). If effective, this approach may reduce disparities in NDPP effectiveness. It can also be disseminated to all NDPP providers, including more than 1,700 suppliers[9], and may be supported by current NDPP payers such as Medicare, commercial insurers, and employer groups.[10-12] Thus, Pre-NDPP has potential for **high impact** on the burden of T2D and related health disparities across the country.

III. Preliminary Studies/Progress Report

Preliminary data. Our pilot study was conducted at Denver Health (DH), a safety net healthcare system and early NDPP adopter, offering the program since March 2013 per CDC-established guidelines.[7] Bilingual lay health educators received CDC-approved training to serve as NDPP coaches. New NDPP classes began every 3-6 months in DH primary care clinics, in English and Spanish. We used CDC-established NDPP eligibility criteria (e.g., A1c 5.7-6.4).[37] Eligible individuals were identified from medical records and referrals and enrolled through outreach calls, without fees or financial incentives to participate. Following standard NDPP delivery to 1,065 participants through July 2016 cohorts, we found disconcerting evidence of disparities in outcomes, consistent with national data[4] (e.g., only 27% of NHBs with ≥2 recorded weights achieved the ≥5%

weight loss goal in national data, comparable to 23% of NHBs at DH). Thus, we aimed to develop a cost-effective NDPP adaptation by adding an educational and motivational "pre-session" before enrollment. NDPPs launched in September 2016 and January 2017 were preceded by these group-based meetings. In brief, participants received education on diabetes risks and information about locally available resources to reduce risk, including the NDPP. Coaches used MI techniques to help participants identify their preferred plan of action to reduce risk, such as attending the NDPP, and guided participants in identifying barriers and possible solutions to enable participation. Seventy-five participants completed a pre-session before NDPP enrollment. Another 15 individuals (17%) attended a pre-session, but did not enroll, and no further data were collected.

Analysis. Pilot study outcome measures were duration (days) and intensity (percentage of sessions attended) of NDPP participation, percent weight change (based on weight at first/last NDPP sessions attended), and achievement of ≥5% (vs. <5%) weight loss at any point in the program (per Centers for Medicare and Medicaid Services [CMS] performance standards[10]). The primary analysis for this longitudinal cohort study compared outcomes of 75 participants who received a pre-session prior to the NDPP to 1,065 previously enrolled DH participants who did not. We also conducted a sensitivity analysis comparing outcomes of the 75 pre-session participants to outcomes of 42 participants who began the NDPP during the immediately preceding June 2016 cycle, but were not offered a pre-session. This group was selected for the sensitivity analysis to reduce potential influences of differences over time in coaching staff, other modifications in NDPP implementation (e.g., incorporating the revised 2016 NDPP curriculum[3]), and general time trends. Differences in characteristics between intervention groups were assessed using chi-square and t-tests. Differences in NDPP outcomes were analyzed with ANCOVA and multivariable logistic regression. Covariates included age, gender, race/ethnicity, and income (≥/< 133% of federal poverty level).

Results. The majority of participants were female (77.5%), low-income (61.8%), and Hispanic (58.9%). An additional 21.5% of participants were NHW and 19.8% were NHB. Mean age was 48.4 (SD=12.7). There were no significant differences in demographic characteristics between participants who received a pre-session and those who did not, facilitating comparisons of between group outcomes. In adjusted models, pre-session participants attended more sessions (49.3% vs. 35.0%; p<.001) and stayed in the program longer (196.3 vs. 96.5 days; p<.001) on average than participants who were not offered a pre-session. Pre-session participants also achieved more weight loss (3.4% vs. 1.5%; p<.001), and were 3.5 times more likely to achieve ≥5% weight loss (p<.001, 95% CI [2.1-6.1]). Sensitivity analysis results were fully consistent. Pre-NDPP cohorts also met full CDC accreditation criteria,[37] important to both fidelity and reimbursement.[38,39] For example, participants attending the NDPP for ≥9 months exceeded the 5% average weight loss goal (M=5.9%; SD=6.2). The Pre-NDPP group also performed well compared to national data[4] (e.g., only 31% of Hispanic participants with ≥2 recorded weights achieved the ≥5% weight loss goal in national data, vs. 51% of Hispanic participants who received a pre-session before NDPP enrollment at DH).

Summary. A pre-session enhancement to the NDPP showed highly successful results upon initial dissemination in a diverse, predominately low-income population and may be a viable strategy to address suboptimal NDPP outcomes. Our pilot work was an award-winning abstract at the 2018 American Diabetes Association meeting[40] and is now published in the American Journal of Health Promotion.[35] Pilot work also highlights our ability to 1) implement both Pre-NDPP and NDPP, 2) recruit a large underserved population of at-risk patients, and 3) conduct analyses and publish findings.

IV. Research Methods

A. Outcome Measure(s).

Data collection for Aims 1 and 2. This RCT focuses on comparing NDPP outcomes between participants who receive Pre-NDPP vs. direct enrollment into the NDPP. The assessment schedule is shown in Table 1 below. Demographic characteristics will be extracted from EHR databases and verified as needed during the first study visit, including age, gender, race/ethnicity, preferred language, income (above/below 133% of federal poverty level), and education (highest level completed). Body weight will be measured on a high-capacity medical-quality scale at study visits and NDPP sessions. We will also provide study participants with a commercial-grade scale for in-home use (e.g., Inevifit's Premium Bathroom Scale I-BS002; https://www.inevifit.com/product/inevifit-premium-bathroom-scale-w-led-display-silver/) so that they can send us a picture of their weight via text message or email when not meeting in-person. The primary outcome is percent weight change from baseline to 12-months by ITT analysis (without regard to whether participants declined NDPP or had early dropout). We will also calculate percent weight change from the first to last NDPP sessions attended (i.e., last observation carried forward), per CDC guidelines.[37] CMS standards for NDPP reimbursement also emphasize achieving ≥5% weight loss at any point in the program,[10] assessed as a

dichotomous outcome. Attendance in the NDPP will be measured as ≥1 session attended, total number of NDPP sessions attended (including make-up sessions), and duration of participation in the yearlong program. We will also record how many sessions were attended remotely vs. in-person. Rates of completing between-session support calls will also be assessed as an additional indicator of engagement and treatment dose. Per the CDC's NDPP curriculum, participants will self-report weekly minutes of moderate to vigorous physical activity since the last session.[3] Baseline BMI will also be assessed at the initial study visit as kg/m^2. If the initial study visit is held remotely (i.e., due to restrictions to meeting in-person per COVID-19), we will collect BMI by confirming height from a participant's medical record, and mailing a scale to participants for them to send us a picture of their weight within 1-2 weeks.

We will assess potential mediators of perceived risk and self-efficacy, key constructs of the Health Belief Model,[26] as well as readiness for weight loss as an indicator of motivation. Perceived risk for developing diabetes will be assessed with the Risk Perception Survey for Developing Diabetes, a 53-item Likert scale measure with four subscale scores on Comparative Disease Risk, Environmental Risk, Personal Control, and Optimistic Bias.[41,42] Self-efficacy for weight control will be measured with the Weight Efficacy Lifestyle Questionnaire, a 20-item measure of confidence (on a 10-point scale) managing five situational factors related to weight management behavior: negative emotions, availability, social pressure, physical discomfort, and positive activities.[43] We will use validated Spanish-language versions of both measures.[42,44] Weight loss readiness will be assessed with the Stages of Change in Overweight and Obese People (S-Weight), a 5-item survey developed concurrently in English and Spanish by expert consensus.[45,46] Mediators will be measured during an initial assessment at the time of enrollment and 1-2 weeks prior to the first NDPP session (i.e., about one week after pre-sessions are completed for the Pre-NDPP arm, and shortly before NDPP classes begin for both arms). This will determine whether Pre-NDPP results in increased perceived risk, self-efficacy, and readiness compared to the usual care NDPP, and whether changes in these variables mediate outcomes.

Data collection for Aim 3. RE-AIM is a planning and evaluation framework for implementation research that will guide our evaluation of Pre-NDPP delivery and effectiveness.[8] RE-AIM constructs will be assessed through a combination of recruitment data, intervention outcomes, staff logs, observations, and interviews with Lifestyle Coaches, clinic personnel, and patients, as well as cost records (Table 1). Dr. Holtrop holds expertise in implementation research and will lead qualitative data collection with Ms. Connelly (Qualitative Research Assistant; QRA), first developing semi-structured interview guides[47], surveys, and a structured observation template. Health economist Dr. Gritz will lead cost-related data collection.

Observations and interviews with Lifestyle Coaches and clinic personnel will focus on how Pre-NDPP implementation works in practice and where gaps in care processes may be. Semi-structured interview and observation guides will be used. Interviews will seek to understand the context of intervention delivery and mindsets and belief systems that drive thoughts and actions regarding Pre-NDPP. External influences such as financial demands and staff turnover will also be explored as potential challenges. Both Lifestyle Coaches and 3 personnel per each of 8 clinics (focusing on high- and low-referring providers and clinic directors) will be interviewed. The QRA will shadow pre-sessions using the observation template and field notes to determine fidelity to core features of the Pre-NDPP protocol. Patient interviews will focus on discerning similarities and differences in perspectives about the Pre-NDPP and NDPP across 6 groups: those 1) randomized to Pre-NDPP and 2) randomized to usual care, and within these groups, those a) who initially decline to enroll in the NDPP, b) who enroll but complete <6 months of the NDPP, and c) who complete ≥6 months. We will begin with 5 interviews per group and continue until thematic saturation is achieved (i.e., not eliciting new information). Key interview questions include to what extent Pre-NDPP sessions increase motivation, relieve uncertainty about participating in the NDPP, address practical barriers to engagement, support autonomy, and other emergent factors that may influence participation. Patients and clinic personnel will be provided gift-card incentives. Interviews will be recorded with consent and transcribed. Interviews may be completed in-person or by phone/video-conference.

We will measure Pre-NDPP costs using principles of time-driven activity based costing,[48,49] accounting for Lifestyle Coach and supervisor time (including salaries and benefits), supplies and other direct costs, and indirect costs (e.g., facilities and general administrative expenses). To focus on Pre-NDPP, we will exclude other costs associated with standard NDPP delivery and research-related costs (e.g., data collection solely for research purposes). To facilitate accurate estimates of personnel costs, coaches and their supervisor will track time spent on Pre-NDPP activities (e.g., training, outreach, preparing for and conducting Pre-NDPP) and report total hours for each Pre-NDPP activity quarterly. Supplies and other direct costs will also be reported quarterly. Standard cost collection guides will be used by study staff.

Table 1: Measures*

Measure	Description	Method of Collection	Timeframe
Characteristics			
Demographics	Age, gender, race/ethnicity, primary language, income, education, household composition, etc	Collected from EHR and during first study visit	BL
Body mass index	Baseline body mass index (kg/m^2)	Collected during first study visit (or within 1-2 weeks of remotely-conducted initial study visits)	
Main outcomes			
Initial NDPP attendance	≥1 NDPP session attended	Collected during NDPP delivery; Note weight is also measured at an initial study assessment and at a final 12-month study visit (we are setting up a time for all randomized individuals to have their weight measured at these study visits, for which they will receive gift cards). Participants may also text/email a picture of their weight using a study-provided scale for in-home use if not meeting in-person for weight collection.	Ongoing collection
# of sessions attended	1-25 NDPP sessions attended (including virtual vs. in-person sessions)		
Duration in NDPP	1-365 days of NDPP participation		
# of between-session calls completed	1-25 between-session support calls completed		
Physical activity	Average self-reported weekly minutes at each NDPP session		
Percent weight change	Based on a) BL to 12 months (**primary outcome**), and b) first to last NDPP sessions attended		
≥5% weight loss	Achieved at any point in the NDPP		
Mediators			
Risk perception	Risk Perception Survey for Developing Diabetes[42]	Administered by Lifestyle Coaches during first study visit and repeated prior to start of NDPP classes to assess pre-post change	BL and 1-2 weeks prior to start of NDPP classes
Self-efficacy	Weight Efficacy Lifestyle Questionnaire[43]		
Readiness	Stages of Change in Overweight and Obese People[45,46]		
Implementation factors using RE-AIM			
Reach – Absolute number, proportion, and representativeness of individuals who participate	# and characteristics of patients referred, outreached, and express interest, consent, complete Pre-NDPP (intervention group), and attend NDPP (both groups); Reasons for not enrolling or dropout	Demographics and referral data from EHR; enrollment and participation data collected by coaches; reasons for participating or declining collected by QRA interviews with select participants	Ongoing collection
Effectiveness- Intervention impact on key outcomes	Based on main outcomes listed above		
Adoption – Absolute number, proportion, and representativeness of settings and agents willing to initiate intervention	# and characteristics of participating DH clinics; NDPP referrals; Lifestyle Coach participation	Study documentation; EHR data	Monthly abstraction analysis
	Factors influencing adoption	QRA interviews with Lifestyle Coaches and select clinic personnel	BL (for coaches and clinic personnel); 6 months after start of Pre-NDPP (for coaches

			only)
Implementation – Fidelity to intervention protocol, including consistency of delivery (e.g., bias) and time and cost of intervention	Completion of Pre-NDPP and NDPP protocol components	Coach documentation; Pre-session shadowing by QRA; Fidelity checks	Ongoing collection
	Acceptability of Pre-NDPP components, processes and tools; any adaptations made by coaches	Interivew by QRA with Lifestyle Coaches	6 months after start of Pre-NDPP
	Process, barriers, facilitators to implementing Pre-NDPP	QRA interviews with select participants, select clinic personnel and Lifestyle Coaches	12 months after start of Pre-NDPP (for clinic personnel and coaches); 1-2 months after last intervention session attended (for participants)
	Pre-NDPP cost	Lifestyle Coach time and resources survey	Quarterly after each pre-session
Maintenance (potential) – Extent to which intervention becomes routine practice and long-term participant benefits	Plans and intent to continue, or modify/adapt, Pre-NDPP after study; ROI as an indicator of potential sustainability; 12-month weight loss outcomes	QRA interviews with Lifestyle Coaches and select clinic staff; Document review and abstraction of NDPP payment schedules (e.g., Medicare); Above outcome data	Study completion
*EHR=electronic health record; BL=baseline; QRA=qualitative research assistant; ROI=return on investment			

B. Description of Population to be Enrolled. As a pragmatic trial, we will recruit English- and Spanish-speaking adults who meet CDC-established NDPP eligibility criteria, including BMI≥25 (≥23 if Asian) and history of recent prediabetes or former GDM diagnosis.[37] Prediabetes is based on a laboratory test within the past year indicating a fasting blood glucose of 100-125, blood glucose of 140-199 measured 2 hours after a 75gm glucose load, or hemoglobin A1c of 5.7-6.4. GDM is based on past diagnosis in the medical record or self-reported. Patients without known prediabetes or past GDM may also be eligible based on a risk screening tool[50], as administered by Lifestyle Coaches during recruitment. Participants are excluded if pregnant at enrollment or known to have T2D.

C. Study Design and Research Methods.

Recruitment. We will identify potential participants through referrals from healthcare providers at DH, which is known to support initial enrollment in the NDPP.[21] Providers refer through the electronic health record (EHR) per usual practice. Since 2013 over 7,000 at-risk patients were referred by providers to the DH NDPP. If needed to meet recruitment goals, we will also identify participants from a risk registry based on EHR data, which has previously identified over 10,000 NDPP-eligible patients annually. The enrollment process after initial identification will be as follows: 1) Lifestyle Coaches pre-screen via medical record review and contact referrals by phone to verify interest, eligibility, and schedule eligible individuals for an initial screening visit (held in-person or remotely as needed), 2) consenting individuals are randomized to receive Pre-NDPP or usual care NDPP (note we will use Denver Health's e-consent process for any virtually-conducted recruitment visits), and 3) complete an initial assessment (behavioral and anthropometric assessments), 4) the Pre-NDPP group completes a pre-session 1-2 weeks before NDPP classes start, 5) both groups complete a follow up behavioral

assessment 1-2 weeks before NDPP classes start (collected in-person or remotely as needed), and 6) both groups commence yearlong NDPP classes (held in-person or remotely as needed).

We will initially enroll 500 participants, with a goal of 400 randomized participants across both groups attending ≥1 NDPP session as based on statistical power estimates (see Sample Size and Power Calculations below). From previous experience, we expect approximately 50% of referred patients to express interest in participating upon initial outreach. Then after initial assessment, we expect early attrition of approximately 20% of consenting participants. We will seek to recruit 50 individuals every 3 months, for a total of 500 participants recruited over 2.5 years (i.e., 200 participants annually). From 2013-2017, we recruited 300 NDPP participants on average each year. Thus, we expect to fully meet RCT recruitment goals. Demographic characteristics of individuals in this study are expected to approximately match characteristics of all previous NDPP participants at DH: 78.0% female, 58.2% Hispanic, 19.5% NHB, 21.0% NHW, 61.4% low-income (including a majority of low-income individuals within each racial/ethnic group), and a mean age of 48.4 (SD=12.7) years.

Randomization. We will randomize eligible, consenting participants to receive either the enhanced intervention (Pre-NDPP + standard NDPP) or usual care control group (standard NDPP only) in a 1:1 ratio. After defining our randomization parameters, including allocation by varying block sizes and stratification by demographic characteristics, we will use the Randomization Module of the Research Electronic Data Capture system (REDCap) to manage random assignment of participants.

Retention. We aim to have 400 randomized participants across arms attending ≥1 NDPP session. We established initial retention rates during our 2013-2017 NDPP delivery and Pre-NDPP pilot as described above and in Preliminary Data (e.g., 83% [n=75] of participants attended the NDPP after completing a pre-session). We expect similar rates of early retention following the initial assessment in this study. Note dropout does not impede our ability to test main effects of Pre-NDPP on NDPP attendance and weight loss as: 1) NDPP engagement is a main outcome of interest; 2) The primary outcome of percent weight loss from baseline to 12 months will be assessed by intent-to-treat (ITT) analysis. Imputation methods for missingness will be used as appropriate (see Analysis Plan). For generalizability, we will deliver NDPP with only customary retention methods: offering classes at clinics where participants receive their primary care (with an option to join classes remotely, as allowable by the CDC since 2018[23]), facilitating transportation as needed (e.g., providing free parking and information about insurance-provided transportation benefits), offering make-up sessions as needed, and updating participant contact information often. To reduce both participant and study staff burden, make up sessions will be offered primarily as a pre-recorded audio and/or video of the Lifestyle Coach talking through the session content (without other participants present). Coaches will seek to follow up briefly (e.g., 10-15 minutes) with participants via phone to ensure comprehension and address remaining questions. To accommodate additional data collection required of participants in both arms of the trial (above and beyond routine care in the NDPP), we will provide compensation of $25 for completing each of two 30-minute research assessments at the time of initial recruitment and immediately prior to attending the NDPP. We will also provide an additional $25 for all participants to complete a final study visit for weight measurement at 12 months (which may be collected via an in-home, study-provided scale as needed).

Description of the National Diabetes Prevention Program (for both conditions). The yearlong NDPP promotes modest weight loss through diet and physical activity. The curriculum is published by the CDC.[3] We will follow CDC guidelines for implementing the standard group-based NDPP,[37] including 16 weekly to biweekly sessions, followed by ≥6 monthly sessions over a total of one year. The objective of NDPP is achieving ≥5% weight loss. Attending more sessions is associated with greater weight loss,[4,22] and guidelines allow NDPP sites to offer more than the minimum 22 sessions to support this goal. We will offer 25 total NDPP sessions (16 in months 1-6; 9 in months 7-12), held at the same time, day, and location in group visit rooms available at 8 neighborhood primary care clinics. There will also be an option to attend classes virtually via phone or video-conference. In light of COVID-19, in-person group classes will be offered when allowable by public health entities and Denver Health, although a virtual attendance option will remain for participants who prefer to join remotely. Two new NDPP classes will commence quarterly over 2.5 years. To minimize potential contamination, participants in the two study arms will be enrolled in separate NDPP classes. Trained, bilingual lay health educators will lead NDPP classes as Lifestyle Coaches and provide make-up sessions as needed. They will be observed by the research coordinator and/or qualitative research assistant for fidelity and to assess for potential bias in NDPP delivery. Weight is measured at each session on a high-capacity, medical-grade scale, or by reporting their weight from a study-provided in-home scale. As required by the NDPP curriculum, participants are encouraged to achieve a weekly goal of ≥150 minutes of moderate to vigorous intensity physical activity (beginning gradually as needed). Participants are instructed to track start and stop times and report total weekly activity minutes at the following session. The most recent CDC curriculum also

encourages a low-fat diet, but does not require monitoring of dietary adherence.[3,32] Lifestyle Coaches conduct support calls between sessions to support engagement and health behavior change, address individual questions and concerns, and remind participants about upcoming sessions.

Description of the Pre-NDPP protocol. The Pre-NDPP protocol was previously developed in a pilot study funded by the Colorado Department of Public Health and Environment. The protocol is based on the Health Belief Model[26] and extensive stakeholder engagement, including feedback from previous NDPP participants and Lifestyle Coaches. Pre-sessions are intended to increase motivation and readiness to engage in the NDPP, while helping participants become comfortable with the group class format. Content was developed for a 4th grade reading level. Pre-sessions focus on 1) education on diabetes risks, 2) MI to participate in the NDPP, and 3) problem-solving of barriers to engagement. Pre-sessions are scheduled for 1 hour to minimize burden, but are flexible in practice, lasting 60-90 minutes to address individual questions and needs. Pre-sessions will be held 1-2 weeks before NDPP classes start, at the same day, time, and location to facilitate transitions to the NDPP. We will hold pre-sessions remotely when needed per COVID-19 restrictions on in-person meetings. To minimize bias, Lifestyle Coaches will be assigned each quarter to deliver one Pre-NDPP and one usual care NDPP classes, with accompanying fidelity observations. Moreover, there have been no significant differences in NDPP outcomes among coaches (e.g., 1.5% vs. 1.6% mean weight loss among participants attending ≥1 session with Ms. Covarrubias and Ms. Amaro, respectively, p=.475). The research coordinator is also a trained Lifestyle Coach and will assist in all pre-sessions.

Pre-NDPP participants will first receive education on diabetes risks and information about available resources to reduce risk, including a description of the NDPP. Education is informed by the Health Belief Model[26] in which perceived risk, severity, benefits of and barriers to action, and cues to action determine health behavior. Topics include: a) an overview of T2D (e.g., prevalence, common complications) and risks for developing T2D (e.g., prediabetes, sedentary lifestyle, overweight/obesity), b) rates of T2D onset, c) guidance that modest weight loss can reduce risk, and d) evidence-based resources to prevent T2D, including a detailed overview of the NDPP. Guidance is intended to normalize the experience of being at-risk for T2D to reduce anxiety, while focusing on instilling hope that T2D is preventable and making calls to action.

Coaches will then use MI techniques (e.g., reflective listening, evoking ambivalence, rolling with resistance, and eliciting change talk)[29] to help participants identify their preferred plan of action to reduce risk, encouraging participation in NDPP sessions. For example, to create discrepancy, coaches will acknowledge the difficulty of making changes in health behavior and probe for typical experiences of weight loss followed by weight regain or other similar challenges. To counter-balance these challenges, coaches will encourage participants to describe why preventing T2D is important to them (e.g., wanting to live a long and healthful life or setting a positive example for their children and grandchildren). Coaches will also non-judgmentally acknowledge that while the NDPP works well for those who attend regularly, it may be challenging for some individuals to attend a yearlong class, and that it is okay to opt out or choose other risk reduction resources.

Finally, to plan behavior to reduce diabetes risk, participants will be guided toward developing a personalized SMART (Specific, Measurable, Achievable, Realistic, and Time-bound) strategy for attending the NDPP. Coaches will help participants identify their anticipated barriers to attendance (e.g., need for childcare) and possible solutions that would enable participation (e.g., finding other caregivers or bringing children to class on occasion if needed). Participants will also be encouraged that more frequent attendance is associated with greater weight loss, but overall benefits can be achieved despite missing some sessions: attending ≥15 sessions is associated with achieving the ≥5% weight loss goal on average (i.e., each session is associated with 0.31% weight loss[4]). Scaling questions will be used to help individuals identify an appropriate initial goal. For example, although some participants may have limited confidence to make a commitment to attend the yearlong NDPP without having tried it before, they may report a 10 of 10 in confidence to attend at least the first NDPP session. Lastly, participants will complete an individualized action plan that includes their SMART goal and anticipated problem-solving strategies.

Observations and interviews. Observations and interviews with Lifestyle Coaches and clinic personnel will focus on how Pre-NDPP implementation works in practice and where gaps in care processes may be. Interviews will seek to understand the context of intervention delivery and mindsets and belief systems that drive thoughts and actions regarding Pre-NDPP. External influences such as financial demands and staff turnover will also be explored as potential challenges. Both Lifestyle Coaches and 3 personnel per each of 8 clinics (focusing on high- and low-referring providers and clinic directors) will be interviewed. The QRA will shadow pre-sessions using the observation template and field notes to determine fidelity to core features of the Pre-NDPP protocol. Patient interviews will focus on discerning similarities and differences in perspectives about the Pre-NDPP and NDPP across 6 groups: those 1) randomized to Pre-NDPP and 2) randomized to

usual care, and within these groups, those a) who initially decline to enroll in the NDPP, b) who enroll but complete <6 months of the NDPP, and c) who complete ≥6 months. We will begin with 5 interviews per group and continue until thematic saturation is achieved (i.e., not eliciting new information). Key interview questions include to what extent Pre-NDPP sessions increase motivation, relieve uncertainty about participating in the NDPP, address practical barriers to engagement, support autonomy, and other emergent factors that may influence participation. Patients and clinic personnel will be provided gift-card incentives. Interviews will be recorded with consent and transcribed.

We will measure Pre-NDPP costs using principles of time-driven activity based costing,[48,49] accounting for Lifestyle Coach and supervisor time (including salaries and benefits), supplies and other direct costs, and indirect costs (e.g., facilities and general administrative expenses). To focus on Pre-NDPP, we will exclude other costs associated with standard NDPP delivery and research-related costs (e.g., data collection solely for research purposes). To facilitate accurate estimates of personnel costs, coaches and their supervisor will track time spent on Pre-NDPP activities (e.g., training, outreach, preparing for and conducting Pre-NDPP) and report total hours for each Pre-NDPP activity quarterly. Supplies and other direct costs will also be reported quarterly.

D. Description, Risks, and Justification of Procedures and Data Collection Tools.

1) Pre-NDPP and NDPP classes

    a. Description (see above description in section C)

    b. Risks: Discussing diabetes risks may also be emotionally stressful. Muscle soreness or minor injury may occur from engaging in physical activity as recommended in the NDPP. To be safe, we encourage starting slowly with physical activity and checking with a doctor as needed. Participants may experience anxiety or distress related to answering personal questions or having weight collected. The National Diabetes Prevention Program classes are held in groups of other participants. We will ask the class to not share sensitive personal information outside of the group, but privacy cannot be guaranteed.

    a. Why necessary: The one-time Pre-NDPP classes are being studied to see if they increase engagement in NDPP classes.

2) Study visits for survey completion and weight assessment

    a. Description: Study visits will occur for 1) an initial eligibility and baseline assessment held in person (or remotely when needed due to restrictions on in-person meetings), 2) a follow up assessment in person, electronically, by mail, or by phone 1-2 weeks prior to the start of NDPP classes, and 3) a 12-month weight assessment in person (or collected remotely when needed).

    b. Risks: Participants may experience anxiety or distress related to answering personal questions or having weight collected. The study investigators will make every effort to keep records private but it cannot be guaranteed.

    c. Why necessary: Quantitative data collected from these visits will be used to answer research questions about the effectiveness of Pre-NDPP.

3) Interviews

    a. Description: Observations and interviews with Lifestyle Coaches and clinic personnel will focus on how Pre-NDPP implementation works in practice and where gaps in care processes may be. Interviews will seek to understand the context of intervention delivery and mindsets and belief systems that drive thoughts and actions regarding Pre-NDPP. External influences such as financial demands and staff turnover will also be explored as potential challenges. Both Lifestyle Coaches and 3 personnel per each of 8 clinics (focusing on high- and low-referring providers and clinic directors) will be interviewed. Patient interviews will focus on discerning similarities and differences in perspectives about the Pre-NDPP and NDPP across 6 groups: those 1) randomized to Pre-NDPP and 2) randomized to usual care, and within these groups, those a)

who initially decline to enroll in the NDPP, b) who enroll but complete <6 months of the NDPP, and c) who complete ≥6 months. We will begin with 5 interviews per group and continue until thematic saturation is achieved (i.e., not eliciting new information). Key interview questions include to what extent Pre-NDPP sessions increase motivation, relieve uncertainty about participating in the NDPP, address practical barriers to engagement, support autonomy, and other emergent factors that may influence participation. Patients and clinic personnel will be provided gift-card incentives. Interviews will be recorded with consent and transcribed.

b. Risks: Interviewees may experience anxiety or distress related to answering personal questions. The study investigators will make every effort to keep interview records private but it cannot be guaranteed.

c. Why necessary: Qualitative data collected from interviews will be used to answer research questions about the effectiveness of Pre-NDPP and inform future implementation and dissemination.

Please note that a Spanish-language translation of the updated English-language consent form will be submitted pending approval.

E. Potential Scientific Problems. This study is powered on percent weight loss; more limited power is expected to evaluate Pre-NDPP effectiveness among demographic subgroups and mediators/moderators. Although we do not anticipate difficulty meeting recruitment goals via provider referrals, we can identify more eligible participants as needed from an EHR-derived patient registry. Regarding implementation, delivery is limited to a single healthcare system, yet in a variety of different clinics and following CDC standards for NDPP delivery. Economic analysis limitations include reliance on literature-derived estimates of projected cost savings and the relationship between weight loss and T2D incidence. It is possible there will be limited or no effect of Pre-NDPP in an RCT, but pilot results are strong and any clinically meaningful benefit may be worthwhile given Pre-NDPP is expected to be a relatively low-resource intervention. Financial incentives may in fact lead to better outcomes than obtained in previous observational study, but are only offered for study-related assessments and appropriately sized.

F. Data Analysis Plan.

General quantitative approaches. Differences in characteristics between study groups will be assessed using chi-square and t-tests to examine potential sampling bias. Percent weight change is the primary outcome, which has a well-documented association with T2D incidence.[2,20] ITT analyses will include all randomized participants regardless of NDPP participation, including those lost to follow up. Weight loss data for women who become pregnant during the study will be excluded from analyses. Patient-level covariates will be screened in bivariate analyses and included in multivariate analysis if related to the outcome at $p<.2$, differ between treatment arms, or associated with dropout. Covariates and potential moderators will include age, gender, race/ethnicity, primary language, comorbidities, and other demographic and clinical variables. Although primary analyses examine a single outcome per patient (e.g., percent weight loss), for longitudinal analyses (e.g., perceived risk) we will determine whether missingness patterns are ignorable or non-ignorable.[51-54] If so, we will employ likelihood-based methods that use all available data, adjusting for covariates associated with missingness. If missingness is non-ignorable we will use pattern mixture models.[55] If normality assumptions are not met, we will use transformations to normalize distributions, ordinal or Poisson regression where appropriate, and/or the appropriate link function and distribution (e.g., logit link, gamma distribution). We will use general (generalized) linear mixed models to incorporate data structures that may be both hierarchical (patients within groups) and longitudinal (repeated observations over time).[56,57] Hypothesis tests will be two-sided with $\alpha=.05$ or p values reported. Goodness of fit statistics and model fitting diagnostics will be used to assess for influential points, outliers, overdispersion, and heteroscedasticity and to evaluate alternative model specifications.[57] SAS version 9.4 (SAS Institute Inc., Cary, NC) will be used for analyses.

Aim 1: To evaluate clinical effectiveness of the Pre-NDPP intervention.

Hypothesis 1.1. Pre-NDPP participants will experience greater weight loss than those directly enrolled into NDPP. The primary outcome for this analysis will be percent weight change among all randomized participants. As study participation includes groups of individuals in the same study arm, the data structure will be hierarchical, with patients nested within groups. Statistical models are shown in hierarchical notation below.

Likelihood of achieving ≥5% weight loss in the NDPP will also be evaluated (using generalized linear mixed models with logit link), as well as percent weight change from first to last NDPP sessions attended.

Level 1 model. Individual outcomes will be modeled as a function of patient characteristics (fixed effects), such as sociodemographic variables, baseline BMI, and comorbid conditions: $Y_{ij} = \beta_{0j} + \beta_{1j} X_{1ij} + \beta_{2j} X_{2ij} + \ldots + \beta_{pj} X_{pij}$
Level 2 model. Group level models specify relationships between group-level predictors and coefficients in the Level 1 model. The intervention effect is included as 0 if control, 1 if intervention: $\beta_{0j} = \gamma_{00} + \gamma_{01}(\text{intervention}) + u_{0j}$. Thus, for a standardized model, γ_{00} is adjusted mean weight loss for patients in the standard condition (i.e., no pre-session intervention), γ_{01} represents the average increment (decrement) from the mean for groups with intervention patients, and u_{0j} is a group level random effect that reflects between-group variance and is the difference between group means and the predicted mean based on the model, and $u_{0j} \sim N(0,\tau_{00})$. Thus, Hypothesis 1.1 can be tested as H_0: $\gamma_{01}=0$ vs H_1: $\gamma_{01}\neq 0$.

Hypothesis 1.2. Pre-NDPP participants will have greater engagement in the NDPP than those who are directly enrolled into the program. The outcome variables, number of sessions attended and days of participation, will be analyzed using similar approaches. If the distribution of outcomes is non-normal we will use generalized linear mixed models with the appropriate distribution and link function, as described above. We will also examine the dichotomous outcome of ≥1 NDPP session attended using multilevel logistic regression (generalized linear mixed model with logit link and random effect for group).

Aim 2: To examine mediators and moderators of Pre-NDPP outcomes.

Hypothesis 2.1. The Pre-NDPP intervention will increase perceived risk for developing diabetes and self-efficacy and readiness for weight management. Outcomes for these analyses will be patients' perceived risk, self-efficacy, and readiness scores over time. We will use longitudinal models to determine if trajectories differ for patients in control vs. intervention groups, shown below in mixed model notation:

$$Y_{tij} = \gamma_{000} + \gamma_{010}(\text{intervention}) + \gamma_{100}(\text{time}) + \gamma_{110}(\text{intervention x time}) + u_{00j} + r_{0ij} + \varepsilon_{tij},$$

where γ_{000} represents the initial status for control groups; γ_{010} represents the baseline difference between intervention and control groups (should be close to 0); γ_{100} is the change in scores for groups of control patients; γ_{110} is the difference in change for control vs. intervention groups. r_{tij} is a patient random effect and U_{00j} is a group random effect, independent of r_{tij} and assumed to have a bivariate normal distribution over practices; ε_{tij} is residual variance. Thus, the Pre-NDPP effect can be tested as H_0: $\gamma_{110}=0$ vs H_1: $\gamma_{110}\neq 0$.

Hypothesis 2.2. Perceived risk, self-efficacy, and readiness will mediate relationships between Pre-NDPP treatment and outcomes. Outcomes will be weight loss and session attendance, using similar approaches as described above for Hypotheses 1.1 and 1.2. We will include baseline perceived risk, self-efficacy, and readiness as covariates and change in these constructs as primary independent variables to determine if the intervention effect is partially or fully explained by these hypothesized mediators.[58]

Hypothesis 2.3. Pre-NDPP effects will differ for participants with the moderator condition (e.g., Hispanic; low-income) compared to those without the moderator (non-Hispanic; higher income). The effects of moderator analyses involve inclusion of an intervention x moderator fixed effect for models that are not longitudinal (e.g., percent weight loss, number of sessions attended). For longitudinal models (e.g., self-efficacy over time) models will include a main effect for time, arm, moderator variable, time x arm, time x moderator, arm x moderator, and time x arm x moderator interaction term. The 3-way interaction term tests for differential intervention effectiveness in subgroups identified by the moderator variable.

Sample size and power. Pre-NDPP pilot data indicate a 0.36 effect size for percent weight change in the NDPP with an intraclass correlation coefficient (ICC) of 1.44%. To be conservative for our primary outcome of percent weight loss among all randomized participants regardless of NDPP participation, we estimate minimum effect sizes detectable for various sample sizes and ICCs (Table 2), with effect sizes of approximately 0.28 to 0.35 for analyses of the primary outcome with a type-1 error rate of .05. Consequently, we expect that 500 randomized participants will provide adequate power while accounting for expected attrition. Note that mediation and moderation analyses are considered exploratory, as estimated power is unknown.

Table 2: Estimated power to detect treatment differences in percent weight loss.

Groups per arm	Patients per group	ICC	Effective sample size	Detectable difference (effect size)	Power
10	18 (180 per arm)	1%	154	.32	80%
10	18 (180 per arm)	2%	134	.35	82%

10	20 (200 per arm)	1%	168	.31	81%
10	20 (200 per arm)	2%	145	.33	80%
12	20 (240 per arm)	1%	201	.28	80%
12	20 (240 per arm)	2%	174	.31	82%

Aim 3: To evaluate the implementation factors of Pre-NDPP. Qualitative analyses will evaluate Pre-NDPP implementation from a Lifestyle Coach, clinic provider/leadership, and patient perspective. Interviews and observation data will be cleaned and entered into the qualitative software program ATLAS.ti (version 8; Scientific Software Development GmbH, Berlin, Germany) for analysis. Analyses will begin as a small group process for data triangulation to occur and use a grounded hermeneutic editing approach.[59] Dr. Holtrop and Ms. Connelly will read 5-10 interviews and together determine key themes and their definitions and labels ("codes"). Codes will be vetted with the larger study team and stakeholder representatives. After establishing initial codes, analysts will code the data (first together, then independently) as outlined by Addison[59], and will compare and reconcile coding until a high degree (≥80%) of conceptual inter-rater reliability is achieved. Specifically, data from interviews with Lifestyle Coaches and clinic personnel will examine themes related to adoption, feasibility, and acceptability of Pre-NDPP. Did the presence of Pre-NDPP affect referral processes in any way? Did they perceive differences in patients who participated in Pre-NDPP or not? This analysis will determine key underlying characteristics, such as belief systems or mindsets, and/or practical reasons that make Pre-NDPP effective or not, and to what extent. We expect data from patient interviews will more thoroughly explain engagement in the NDPP. We will examine emergent codes across study groups by comparing group-level quotations to determine differential experiences. Did Pre-NDPP availability address practical concerns? Did Pre-NDPP change mindsets about the importance of diabetes prevention? Did it alter participants' experience in the NDPP? Finally, perceived reasons for participation (or non-participation) will be examined alongside actual engagement data to corroborate and explain quantitative results. In ongoing meetings with the larger study team, we will further consider existing literature and associated experiences for corroboration, and seek out additional data as needed to confirm or refute results. After initial analysis has identified data to support one theme or interpretation, effort will be devoted to finding negative or disconfirming evidence. Clinic personnel and Lifestyle Coaches will be selected for member checking and revision of thematic groupings prior to final coding. The final phase consists of preparing interpretive summaries detailing the findings of prior phases. All phases of data processing and analysis will be cross-checked to ensure consistency in application of coding and classification procedures. Observation data will be similarly analyzed.

Pre-NDPP cost and ROI. We will first calculate Pre-NDPP cost as the average expense of each pre-session delivery based on personnel time, supplies and other direct costs, and indirect costs. We will then determine the projected ROI of Pre-NDPP from both provider and payer perspectives. For NDPP providers, ROI will be calculated as the additional payment expected from payers as a result of potentially improved retention and weight loss of Pre-NDPP participants minus the average pre-session cost and divided by pre-session cost. For common reference, payments will be based on the Medicare reimbursement schedule for achievement of NDPP attendance and weight loss milestones.[10] We will compare the average expected reimbursement for participants in both study arms to measure additional payments that may be attributed to Pre-NDPP. We will also conduct a sensitivity analysis by calculating the projected ROI for varying numbers of Pre-NDPP participants with varying demographic characteristics (e.g., race/ethnicity, income), and with other available NDPP payment schedules (e.g., Maryland Medicaid[60]). Sensitivity analysis results will inform Pre-NDPP sustainability by identifying the number of participants needed per pre-session to achieve a positive ROI, the extent to which moderators identified in Hypothesis 2.3 affect ROI, and the extent to which different payment models affect ROI. From the perspective of NDPP payers, ROI will account for the expected reduction in direct healthcare expenditures as a result of covering Pre-NDPP through an additional payment to NDPP providers, as calculated over a 3-year horizon. ROI will be the reduction in projected expenditures minus the average pre-session cost and divided by pre-session cost. Estimates of change in direct healthcare expenditures will be based on the impact of Pre-NDPP on weight loss from Hypothesis 1.1, the known relationship between weight loss and T2D incidence[20], and the difference in expenditures for individuals with prediabetes or T2D over a 3-year horizon.[61] This timeline requires discounting of expected reductions in years 2 and 3 expenditures for which we will apply a standard 3% discount rate. We will also conduct a sensitivity analysis by varying the number of Pre-NDPP participants, their characteristics, and the discount rate. To be conservative, cost and ROI is based on all Pre-NDPP participants, regardless of NDPP attendance.

G. Summarize Knowledge to be Gained. In summary, this proposed RCT of Pre-NDPP may lead to future dissemination of a scalable, evidence-based strategy to improve success of the NDPP, reduce disparities in NDPP effectiveness, and help prevent T2D across the country.

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