A Virtual Diabetes Prevention Program tailored to increase participation of Black and Latino Men: Protocol for a Randomized Controlled Trial

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Abstract

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Objective: This study was designed to 1) Assess the effect of Power-Up (a men-centered virtual NDPP program) vs. standard care, mixed-gender virtual NDPP on percent weight loss among racial and ethnic minority men at risk for diabetes; 2) Compare engagement of racial and ethnic minority men at risk for diabetes in Power-Up vs. standard care NDPP; and 3) Evaluate the reach, effectiveness, adoption, implementation, and costs of Power-Up. We hypothesize that men randomized to Power-Up will achieve significantly greater weight loss (% weight loss from baseline) at 16-weeks and 1-year than men randomized to the standard, mixed-gender NDPP group. Men randomized to Power-Up will also have significantly greater engagement and retention than men randomized to the standard care NDPP.

Methods: Using the electronic health record (EHR) systems of a large academic medical center and a network of small to medium independent primary care practices throughout New York City, we identified Black and Latino men that meet the eligibility criteria for NDPP.

Results: We enrolled 301 participants through our health system partners. Men were randomized 1:1 to either the Power-Up intervention arm or to a standard, mixed-gender NDPP.

Conclusions: This manuscript describes the Power-Up trial design and allocation of participants to NDPP groups. Clinical Trial: ClinicalTrials.gov NCT04104243

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Abstract

Background. A clinic-based National Diabetes Prevention Program (NDPP) tailored to Black and Latino men has the potential to address prior limitations of NDPP implementation and reduce gender-based diabetes disparities. Objectives. This study was designed to 1) Assess the effect of *Power-Up* (a men-centered virtual NDPP program) vs. standard care, mixed-gender virtual NDPP on percent weight loss among racial and ethnic minority men at risk for diabetes; 2) Compare engagement of racial and ethnic minority men at risk for diabetes in *Power-Up* vs. standard care NDPP; and 3) Evaluate the reach, effectiveness, adoption, implementation, and costs of *Power-Up*. We hypothesize that men randomized to *Power-Up* will achieve significantly greater weight loss (% weight loss from baseline) at 16-weeks and 1-year than men randomized to the standard, mixed-gender NDPP group. Men randomized to *Power-Up* will also have significantly greater engagement and retention than men randomized to the standard care NDPP. Methods. Using the electronic health record (EHR) systems of a large academic medical center and a network of small to medium independent primary care practices throughout New York City, we identified Black and Latino men that meet the eligibility criteria for NDPP. Results. We enrolled 301 participants through our health system partners. Men were randomized 1:1 to either the *Power-Up* intervention arm or to a standard, mixed-gender NDPP. Conclusions. This manuscript describes the *Power-Up* trial design and allocation of participants to NDPP groups. [ClinicalTrials.gov NCT04104243]

Introduction

The prevalence of diabetes and its risk factors disproportionately affects low income, and racial and ethnic minority populations.[1,2] Black and Latino populations are 2-3 times more likely to die of diabetes-related complications than their White population counterparts. [2] In general, more men than women have prediabetes and fewer men are aware of their condition than women.[3] Men are more likely than women to be hospitalized for long-term complications of diabetes and more than twice as likely as women to have a leg or foot amputated. [4] Compared to women, and compared to other men, men of color have significantly poorer health and higher rates of hospitalization related to diabetes.[5] Latino men are twice as likely to die from diabetes as men identifying as White, and men identifying as Black are three-times as likely to need treatment for diabetes-related kidney disease.[2] Compared to men identifying as White, racial and ethnic minority men are significantly more likely to have a lower limb amputation. [4,6] Despite these striking disparities, men of color are rarely the focus of research, policy, or practice focused on prevention of diabetes or other chronic diseases. [7-9]

The Diabetes Prevention Program randomized trial (DPP; 32% male participants) clearly

established the efficacy of lifestyle change for weight loss and type 2 diabetes prevention [10,11]. There have been many efforts to translate the DPP into “real world” settings, but they mostly reach women. [12] Evaluation of the National Diabetes Prevention Program (NDPP) showed that men comprise fewer than 20% of participants. [12] Men of color are particularly underrepresented in NDPPs. [12-14] However, when men do participate, they achieve equivalent or better weight loss than women. [12] Low rates of participation of men of color in the NDPP are consistent with low levels of engagement in other healthful activities and health promotion programs.[15,16] Although the body of literature on minority male health and health programs is still limited,[17] researchers attribute low participation in healthful activities to competing priorities that are compounded by the impact of structural, contextual, and life course factors, including discrimination, poverty, and a cycle of limited education and limited employment opportunity. [17,18] Poor engagement of men has been attributed to the framing of existing programs [19,20] and masculine ideals and societal expectations that men be self-reliant, suppress signs of weakness, and avoid seeking help. [21,22] Men-focused programming is a promising method for reaching and engaging men and achieving behavior change. [23] Men-only group-based programming may facilitate behavior change, may increase openness with respect to health concerns, and can act as an incentive for participation.[24] Retaining and tracking health outcomes of men in these programs is essential to evaluating success and sustainability. Men of color are particularly underrepresented in NDPPs. This randomized controlled trial evaluates weight loss and engagement outcomes for Black and Latino men in *Power-Up*, an adaptation of the NDPP tailored to the needs and preferences of racial and ethnic minority men. [25-27]

Specific Aims

The delivery of *Power-Up* included a men-only, virtual, group-based model with men as coaches and NDPP curriculum designed to be attentive to the concerns and needs of men. The intervention was delivered virtually to participants recruited through clinical settings and available in English and Spanish. The aims of the project were to: 1) Assess the effect of *Power-Up* vs. NDPP on weight loss among racial and ethnic minority men at risk for diabetes; 2) Compare engagement of racial and ethnic minority men at risk for diabetes in *Power-Up* vs. NDPP; and 3) Evaluate the reach, effectiveness, adoption, implementation, and costs of *Power-Up*. The results of this study will help to fill an important gap in health promotion and diabetes prevention for men and specifically for men of color.

Methods

Study Development

The *Power-Up* study (ClinicalTrials.gov NCT04104243) was developed in partnership with our study team at Einstein/Montefiore in collaboration with partners at the New York City Department of Health and Mental Hygiene (DOH) Primary Care Improvement Project (PCIP). Montefiore is a large hospital system in the Bronx, New York, and the largest provider of health care in Bronx County. The PCIP program is a collection of health care practices throughout NYC that are supported by the DOH particularly, as it relates to this study, in the delivery of diabetes prevention and management programs. In 2019 when the *Power-Up* study was funded, it was designed to be delivered in-person and the curriculum had been updated from the pilot delivery [25-27] to be consistent with the new Prevent T2

guidelines. Approximately six months into the study development phase of the randomized trial, the first cases of COVID-19 reached New York City and shortly after the city was shut down. The delivery of DPP, which was a priority of quality health care within our hospital system and through our DOH community clinic partners, was eclipsed by the pandemic, which utilized all available resources. The Bronx bore the heaviest burden of the early wave of the pandemic in NYC and NYC more generally became the epicenter of the pandemic accounting for a large share of the mortality from the virus. In the months that followed, it became clear that in-person delivery of DPP would not be possible for at least a year, or longer. A decision was made to convert the study to virtual delivery. This process meant the training of coaches in virtual delivery including the use of virtual platforms for both the *Power-Up* coaches and all coaches delivering the control condition in collaboration with our DOH partners and their affiliated clinical partners. We chose the Zoom platform due to comfort and ease of use by our coaches and participants. It also meant that eligibility criteria had to be changed to include patients that had access to a stable internet connection (although participants could attend occasionally via phone) and were comfortable with accessing the Zoom platform. It also meant that curriculum materials were shared digitally via email or on paper via mail delivery, if requested. The aims of the *Power-Up* study remained the same and the study became even more important as we learned of the increased risk of mortality that COVID-19 would have among people with diabetes.

Setting

Study materials and procedural development took place in our study offices at Einstein and DOH and at local clinical sites of participating practices from the PCIP and MMG networks. Recruitment, eligibility screening (Table 1), and enrollment procedures were conducted by study staff/prevention outreach specialists located at Einstein-Montefiore and PCIP/ DOH offices. Data collection from electronic health record (EHR) systems took place at the respective clinical site locations. All engagement data were collected during NDPP sessions. Survey data were collected by phone at baseline when randomization took place and during routine calls from study staff at 16 weeks and 12 months. The weight measurements were collected via Wi-Fi enabled weight scales (BodyTrace Inc.) When participants did not attend virtual NDPP sessions, where weights are primarily collected via weight scale, weights were recorded as missing. In data analysis, missing weights were managed using multiple imputation from time points near NDPP session delivery from Wi-Fi scale weights, weights extracted from EHR, and self-reported weights.

Table 1: Inclusion/Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Identified as Hispanic/Latino and/or African American/Black as indicated in electronic health record	Previously diagnosed with diabetes
Identifying as a man via electronic health record and self-identification	Inability to join most sessions via virtual platform or by phone
Age 18 or older	Unable to participate in either English or Spanish
BMI ≥ 25 (within last 6 months) AND Most recent HbA1c: 5.7%-6.4% (within last year) OR CDC pre-diabetes risk score of 5 or higher	Previous participation in DPP
Valid residential address and telephone contact information	Inability to join during session time or day
Plan to remain in NYC area for at least a year or more	
Received care at a NYC-based PCIP health care clinic or at Montefiore Medical Group within last 12 months.	

Participant recruitment

Our recruitment strategies are informed by our experience with the pilot and prior health behavior change and lifestyle intervention studies conducted by our team involving longitudinal follow-up of participants over time. The strategies included regular data queries from our clinical sites to identify eligible men for participation. Men who met the eligibility criteria based on information available in the EHR (e.g., weight, height, and HbA1c) were called and invited to participate once other eligibility criteria were established (see Table 1). Along with these recruitment strategies, we provided monetary incentives for the completion of telephone surveys and for the collection of weights at initial baseline interview, as well as +/- 1 week from the date of delivery of the16th core session and the final maintenance session at 12 months.

At the MHS sites, we used EHR search capabilities to generate lists of men who: 1) meet all the following NDPP criteria based on EHR data – at least 18 years old, most recent BMI ≥ 25 (within last year), most recent HbA1c: 5.7%-6.4% (within last 12 months); and 2) received care at a Bronx-based MHS site in the past 12 months. We contacted eligible men by phone to tell them more about the study and to obtain their consent to participate. To be fully eligible, men must: 1) self-identify as an African American, Black, Hispanic or Latino during telephone screening; 2) have no plans to change their primary care provider or move from their current address in the next year; 3) must agree that they are physically able and willing to attend virtual, group-based diabetes prevention classes; 4) must complete the baseline survey assessment and be willing to complete follow-up study surveys and procedures for collecting study weights; and 5) must provide informed consent by telephone, including consent for study participation, data collection, and random assignment to *Power-Up* or standard care NDPP.

DOH engaged small primary care practices (PCP) that serve predominantly Black and Latino populations to identify eligible individuals receiving care in the last 12 months at a PCIP health care clinic for recruitment into the *Power-Up* study. After securing an agreement from PCP, DOH facilitators provided on-site technical assistance to participating PCPs to generate a patient report using their EHR systems to apply study eligibility criteria every 6 months. DOHMH facilitators were instructed to generate eClinicalWorks Business Optimizer (eBO) reports at each PCPs clinical location. These eBO reports use a prewritten query already saved at each practice EHR that identify individuals that meet study eligibility criteria (be 18 years or older, have a BMI of 25 or higher and have an A1C in the prediabetes range 5.7–6.4%). The query retrieves a comprehensive set of data for each eligible individual that includes full name, date of birth, date of last office visit, sex, race/ethnicity, preferred language, address, phone number, last HbA1c value and date measured, height, weight, and body mass index (BMI). Generated reports were transferred to an excel document and securely transmitted to DOH data staff. To confirm eligibility criteria, DOHMH data staff reviewed eBO reports and assigned eligible individuals for telephonic outreach.
Due to technical issues and limited resources to resolve them during the COVID-19 public health emergency, the DOHMH temporarily shifted their recruitment strategies to an alternative search approach that was more prone to error and misidentify BMI and/or HbA1C inclusion requirements. We addressed this by modifying our inclusion criteria to require that all men meet the NDPP prediabetes risk test score of 5 or above.[28]

Randomization into intervention arms

The *Power-Up* study was designed to recruit 300 men with 150 randomly assigned to the men-only *Power-Up* condition run by the Einstein study team and another 150 into a mixed-gender NDPP comparison condition run by the PCIP partners. In order to keep the comparison condition ratio of men to women similar to the upper limit of male participation in current NDPP implementation across our partnering health systems, we monitored the percentage of men assigned/referred to these groups during recruitment and worked with our health system partners to refer additional eligible women, through EHR-based searches and outreach so as to ensure that the percentage of men in standard care NDPP groups did not rise substantially above 33%. We distributed the randomized men in the comparison condition over 4 mixed-gender groups to reduce the likelihood that the percentage of men in any of those groups would be higher than 33%. Thus, for every *Power-Up* men-only group there were four mixed-gender groups running concurrently, with four times as many women recruited for those groups as men (see Table 3).

Separate randomized sequences of treatment group assignments for English and Spanish language-preferring participants, in balanced blocks of sizes 4 or 8 in random order, was computer-generated using Stata version 16.1, and maintained securely at a remote site by the data analyst, who had no contact with the patients. Upon obtaining consent to participate from a patient, a randomization center was contacted to assign treatment group. Random assignment and final enrollment into the study occurred after telephone screening, obtaining informed consent, and completion of baseline surveys.

THE *POWER-UP* AND STANDARD NDPP CONDITIONS

LIFESTYLE COACHES. The DOH provided NDPP master training for all coaches. The first training occurred for one coach mid-year 1, before beginning interventions, and a second training was offered to three coaches at the end of year 2. The training curriculum included instructions on data collection for all coaches (1/2 day). Men coaches implementing *Power-Up* received additional training in the adapted curriculum and using a toolbox for men-tailored behavioral approaches (extra 1 1/2 days). Supervision was available by experienced co-investigators to ensure fidelity to the protocol. Additional periodic training was given to coaches to ensure they were up to date with current strategies to administer DPP. Study staff conducted regular meetings with coaches from both the standard NDPP and the *Power-Up* conditions to be sure session delivery and all trainings were consistent between the conditions. All coaches facilitated either the standard *Power-Up* or NDPP conditions, with no crossover of coaches. Because many of the patient population in our clinical catchment areas are more comfortable communicating in Spanish, we offered both NDPP conditions in Spanish as well as English.

DESCRIPTION OF THE STANDARD NDPP CONDITION AND *POWER-UP* CONDITION

Both *Power-Up* and the standard NDPP follow the PREVENT T2 curriculum which included modifications to the previous curriculum by including: beginning core sessions with a focus on physical activity, rather than healthy eating; de-emphasizing tracking fat grams; adding a session on heart health; developing more content on replacing sugary drinks with low-calorie drinks; emphasizing coping strategies throughout. All NDPP programs included 16 core sessions delivered over 6 months and 8-10 additional maintenance sessions delivered

over the subsequent 6 months for a total of 24 sessions over one year. The standard NDPP curriculum is delivered virtually at a standard time and day of the week that is responsive to standard work schedules and took place typically in the evenings. After the first session, the day of week and time could be changed to accommodate most of participant's schedules. One make-up session was offered per week for any missed session by participants. The sessions were delivered in either English or Spanish depending on the preferred language of the participants, which was determined at baseline interview. The sessions between the standard condition and *Power-Up* condition were coordinated so they started within at least 2 weeks of each other. Participants were given the session curriculum digitally and/or by paper copy mailed out to them upon request. All participants received activity, food, and weight logs digitally and/or by mail. The sessions were delivered by a trained lifestyle coach at no charge to participants.

THE EXPERIMENTAL *POWER-UP* CONDITION. Adaptations focused on making the program more appealing and motivating to men, more consistent with their priorities, group dynamics and behaviors, and to be more likely to affect lifestyle change. These adaptations were made to the Prevent T2 curriculum based on our pilot work [25-27] and updated review of the literature. The *Power-Up* sessions differ from the standard NDPP in that they are run my men coaches, include only participants identifying as men, and the PREVENT T2 curriculum was adapted to focus on men using men-centric vignettes, illustrations, and health-related information. Our goal was to develop an adaptation based on the input of men who participated in the pilot, [25-27] that would meet Center for Disease Control and Prevention (CDC) criteria as a recognized program (Table 3). Recruitment strategies included messaging emphasizing that the program was specifically designed for racial and ethnic minority men and facilitated by men coaches.

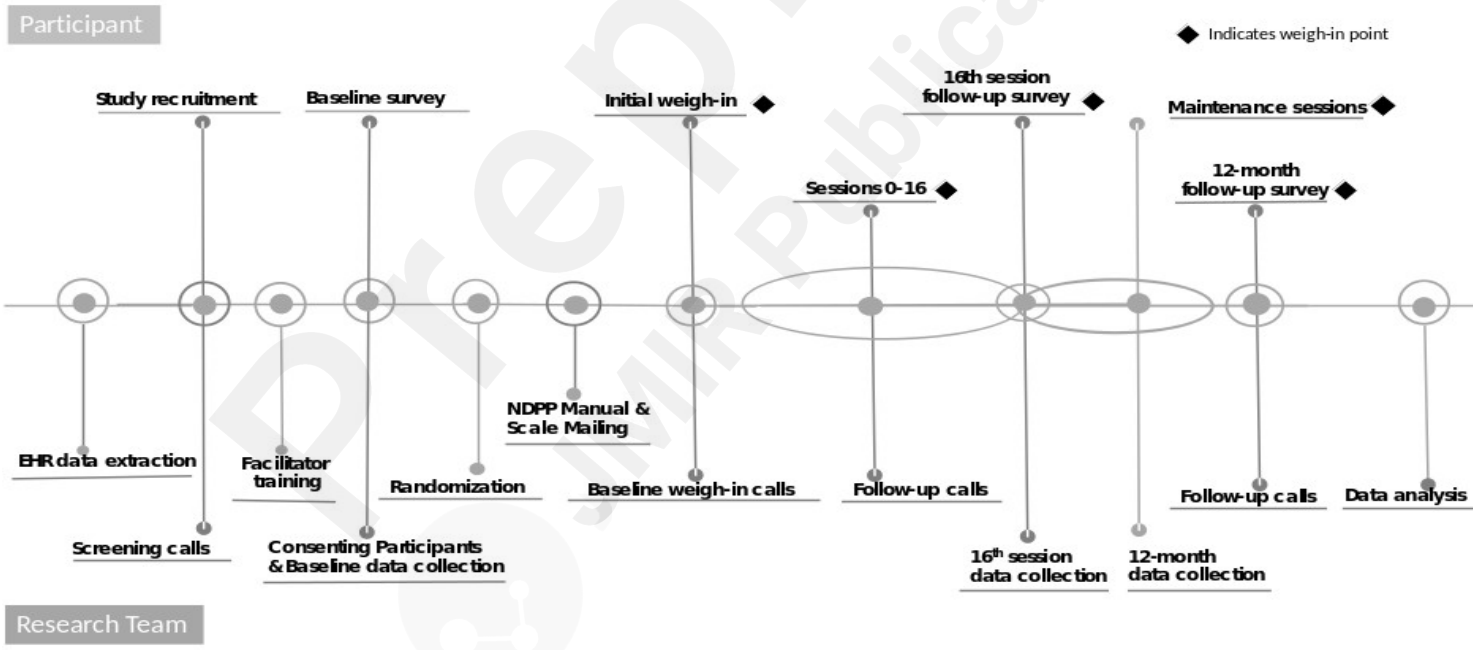
Table 3. *Power-Up* Curriculum Content

Session	Session Topic	Session Focus
1	Welcome to *Power-Up*	This introductory session helps men at risk for diabe change their lifestyles by moving them from the thinking phase to the action phase.
2	Get Active to Stay Active	This session introduces the concept of getting active.
3	Be Safe, Be Active, Keep on Track	This section provides detailed instructions on how to tra your activities and how to exercise safely.
4	Build Your healthy Plate	This session introduces the concept of healthy eating.
5	Track Your Food	This session provides detailed instructions on how to tra the food you eat.
6	Being Active- A Way of Life	This session focuses on how to become more physica active as a lifestyle choice.
7	Find your Tipping Point: Burn more calories than you take in	Teaches participants how to burn more calories than th take in.
8	Eating from Shopping to Cooking	This session focuses on how to become more physica active as a lifestyle choice.
9	You Can Manage Stress	This session teaches participants how to reduce and d with stress.
10	Four Keys to Healthy Eating Away from Home	Teaches participants how to stay on track with their eat goals at restaurants and social events.
11	Jump Start Your Activity Routine	This session teaches participants how to find time for fitnes
12	Taking Charge of What is Around You	This session teaches participants how to cope with triggers unhealthy behaviors.

13	*Power-Up* Your Heart	This session teaches participants how to keep their he healthy.
14	Talk Back to Your Negative Thoughts	This module teaches participants how to replace harm thoughts with helpful thoughts.
15	Getting Support	This module teaches participants how to get support for th healthy lifestyle.
16	Stay Motivated to Prevent Diabetes	This module helps participants reflect on their progress a helps them to keep making positive changes over the n six months.
17 (Maintenance Session)	Staying Active for the Long Haul	This session teaches participants how to start losing wei and to cope with some challenges of staying active.
18 (Maintenance Session)	Take A Fitness Break	This session teaches participants how to overcome barri to taking fitness breaks.
19 (Maintenance Session)	Staying Active Away from Home	This session teaches participants how to stay on track w their fitness goal when they travel for work or pleasure.
20 (Maintenance Session)	Understanding Carbs	This module gives participants a deeper understanding carbs.
21 (Maintenance Session)	Have Healthy Food You Enjoy	This module teaches participants how to have healthy fo that they enjoy.

Data Collection

Figure 1 Data Collection Timeline



Outcome measures

Weight was the primary outcome measurement. Participants used study-supplied Wi-Fi enabled scales (https://www.bodytrace.com/medical/) to measure and transmit their weight to coaches and study team. To maximize the completeness of these data, incentives were provided to participants who transmit weight measurement at sessions or provide a self-reported weight. When a weight measurement was not available using these scales at the 16 week and 12-month sessions (primary outcome measurement time points) then a self-reported weight by telephone or by search of EHR on a visit close to the session dates was

collected. The primary outcome measure was percent change in weight at the end of the Core (16 weekly) sessions and at the end of 12 months. Study staff and trained coaches collected and managed all primary data. Body mass index (BMI) was determined through weight and height measurements identified in the EHR measured prior to baseline interview. Weight was measured thereafter at each *Power-Up* or NDPP session attended, with primary data points for this outcome captured at approximately 16-weeks (end of core sessions), and 12-months (final post-core maintenance session; Figure 1).

Survey questionnaires

Surveys of validated self-report questionnaires for psychosocial and behavioral variables were conducted by telephone by study staff at our Einstein study offices. These surveys occurred at baseline/enrollment (immediately prior to randomization), at approximately 16-weeks (goal to conduct this survey within a window of +/- 1 month of the 16-week intervention session), and 12-months (goal of +/- 1 month of the 12-month final maintenance session). Table 4 shows the survey domains for the study including data collected at baseline, 16-weeks, and 12-months.

Table 4. Survey Domains & Data Collection Time Points

Survey Domains	Baseline	16 week follow up	12 month follow up	Measure
Demographics*	X			Power Up 1.0
Insurance	X			NYC Community Health Survey (CHS) [29]
Housing Insecurity	X		X	Study of Latinos Mobility Study
Housing Composition		X		Affordable Housin as an Obesity Moderating Environment Questionnaire
Social Needs + Food Insecurity	X		X	Adapted from Health Leads [30]; Hager et al. [31]
Health History	X	X	X	Hispanic Community Healt Study/ Study of Latinos (HCHS/SOL) [32]
Body Image Perception	X	X	X	National Physical Activity and Weigh Loss Survey [33]
Sleep	X	X	X	Pittsburgh Sleep Quality Index [34]
Sedentary Behavior	X	X	X	International Physical Activity Questionnaire [35]
Physical Activity	X	X	X	NYC CHS [29]
Diet	X	X	X	NYC CHS [29]
Risk Perception	X	X		Risk Perception Survey-DD [36]
Self-rated Health	X	X	X	National Health and Nutrition

				Examination Survey (NHANES [37]
Depression	X	X	X	Patient Health Questionnaire-8 [3]
Tobacco Use	X			HCHS/SOL [32]
Alcohol	X			NYC CHS [29]
Neighborhood Environment	X	X	X	Power Up 1.0
Discrimination	X			Everyday Discrimination Scale [39]
Machismo	X			HCHS/SOL [32]
*Age, gender, race and Hispanic ethnicity, education, employment, income.				

SECONDARY OUTCOMES: ENGAGEMENT AND RETENTION.

Evaluation of engagement and retention for Aim 2 were based on attendance records for *Power-Up* and standard NDPP sessions electronically collected by trained coaches and monitored by study staff. We followed standards for NDPP evaluation where engagement is defined as ≥ 4 core sessions attended and retention is defined as ≥ 9 sessions attended. We will examine several process and moderating variables based on a survey measures validated for English and Spanish language and telephonic administration.

DATA ANALYSIS

The nature of our study intervention makes it impossible to blind participants and coaches to their study arm, however we did not directly disclose our hypotheses to them. The data management and analysis protocols we outline below may be modified based on unanticipated data anomalies that must be resolved in some way. To ensure that these decisions are undertaken without bias, our statistician will be given an end-of-study data set that designates the arms neutrally as Group 1 and Group 2. Until all data management and analyses are complete, the statistician will not be told which group is *Power-Up* and which NDPP. A future manuscript will present descriptive statistics by arm for end-of-study variables including percent weight loss and retention.

Analysis Plan

SPECIFIC AIM 1: WEIGHT LOSS. The primary intention to treat (ITT) analysis will contrast the percentage weight loss across study arms using mixed effects linear regression models of 16-week and 12-month percentage weight loss with study arm as a predictor, and random intercepts at the program group and practice levels. Because of the large sample size and random assignment to groups, it is very unlikely that adjustment for confounding variables will be required. If, however, our descriptive statistics identify variables that differ appreciably between arms and are associated with outcomes, they will be adjusted as covariates. A secondary per protocol analysis using only those participants who have completed at least four sessions will be carried out using models similar to the primary ITT analyses. Because per protocol analyses do not preserve randomization, we will re-analyze and carefully compare the baseline attributes across arms to seek out confounders to be included as covariates. For these analyses limited to successfully engaged participants we expect equivalence of *Power-Up* and Standard NDPP and will interpret these results by examining whether the 95% confidence limits of the difference in percentage weight loss fall

within 2.5 percentage points of zero.

Missing scale weights will be principally managed using multiple imputation by chained equations.

SPECIFIC AIM 2: ENGAGEMENT AND RETENTION. Engagement and retention outcomes will be analyzed with ITT mixed-effects logistic regression models using the same predictors and random intercepts. In all instances, we will report the model-predicted expected values with 95% confidence intervals as well as the expected difference in outcomes with its 95% confidence interval calculated by the delta method. The p-values from Wald tests of the null hypothesis of no difference between arms will also be shown. We do not expect missing data for these outcomes, as we will conduct ongoing monitoring of coach-recorded data.

Any data entry errors or missing recordings will be rectified immediately through contact with coaches. Thus, we do not expect any missing data at the participant level for measures of engagement or retention. If, in this unlikely scenario where attendance for a particular participant cannot be determined by contact with the coach or participant, any unexpected missing data will be dealt with first by excluding cases with missing data from analysis and second by using multiple imputation procedures similar to those described above. If these approaches yield differing outcomes, both will be reported in our outcome paper. For all analyses, we will report the model predicted expected values with 95% confidence intervals as well as the expected difference in outcomes with its 95% confidence interval calculated by the delta method. The p-values from Wald tests of the null hypothesis of no difference between arms will also be shown.

Power calculations

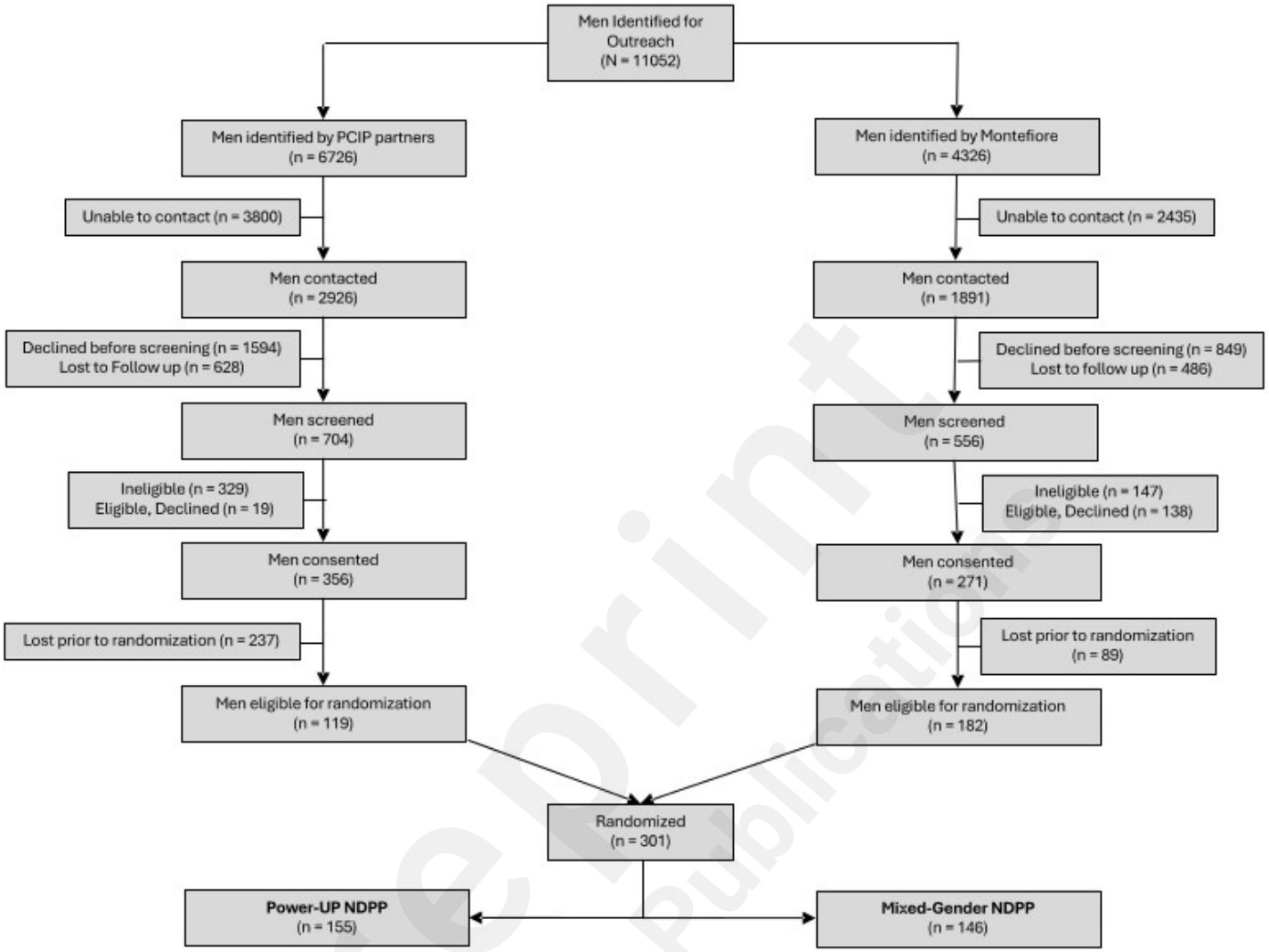
Our target sample size was 300 men. Power calculations assumed, based on earlier studies, a standard deviation of 4.7 percentage points in percent weight loss, and an intraclass (intra program group) correlation of 0.05. Assuming 80% of participants provided complete data for analysis, we would have 90.5% power to detect a 2.5 ppt difference in weight loss between the study arms, as well as providing 80% power to detect a Cohen-d of completion and engagement outcomes of 0.21 and 0.18, respectively. Power to detect a 5-percentage point difference in weight loss between the study arms would be > 99.9%.

As a worst-case sensitivity analysis, we considered the possibility that the standard deviation of percentage weight loss could be as high as 5.9 percentage points, and the intraclass correlation as high as 0.10. Under these adverse circumstances we would still retain 81.4% power to detect the 2.5 percentage point difference at the .05 significance level. Power for the engagement and retention outcomes was not appreciably affected by changes in these parameters.

RESULTS

Of the 301 men randomized in our study (Figure 2), we identified 11,052 potentially eligible men based on clinical weight and Hb A1c information identified in the EHR. Of the men identified, 43.5% were contacted and asked to participate in a yearlong NDPP. Of the men contacted to participate, 6.2% agreed to participate and were ultimately randomized.

Figure 2. Consort Diagram for Study



Men in the control condition were included in mixed-gender NDPP classes. The distribution of men into each arm and the gender distribution by cohort are shown in Table 2.

Table 2. Participation and Gender Distribution in *Power-Up* and NDPP Control Cohorts

Cohort		Gender Distribution	Gender Ratio
Power-Up 1	Male	12	
	Female	0	
NDPP Control 1	Male	12	10%
	Female	103	90%
Power-Up 2	Male	29	
	Female	0	
NDPP Control 2	Male	25	8%
	Female	283	92%
Power-Up 3	Male	18	
	Female	0	
NDPP Control 3	Male	16	7%
	Female	219	93%
Power-Up 4	Male	28	
	Female	0	

NDPP Control 4	Male	25	14%
	Female	160	86%
Power-Up 5	Male	26	
	Female	0	
NDPP Control 5	Male	29	21%
	Female	110	79%
Power-Up 6	Male	25	
	Female	0	
NDPP Control 6	Male	23	21%
	Female	53	79%
Power-Up 7	Male	17	
	Female	0	
NDPP Control 7	Male	16	30%
	Female	93	70%

Discussion

Prior delivery of NDPP has struggled to reach men, particularly men of color. A prior report of NDPP delivery using data from all accredited CDC programs showed that men are only 20% of NDPP participant nationwide.[12] However, the reach of NDPP and uptake of the NDPP programs more generally is largely unknown since most studies start measuring engagement at the point of study recruitment or attendance at first NDPP session. carried-forward to account for missing outcomes, may lead to biased estimates of effectiveness.[40] While we do not yet know the rate of engagement in *Power-Up* post randomization, to recruit the 301 men randomized in our study, approximately 4800 men were contacted and only 6% agreed to participate. This rate of engagement is low but may not be low for NDPPs more broadly as there are many reports of the high cost of resources needed to recruit eligible participants and deliver NDPP. [41,42] Studies show that delivery of NDPP in clinical settings may not be fiscally feasible given the cost of delivery even when reimbursement by Medicare or Medicaid is considered.[43-45] Furthermore, a recent report in poor rural areas of the US showed that this disparity of uptake in poorer communities may exacerbate diabetes disparities. [46] This is of particular concern in poor urban settings like the Bronx where even with cost of NDPP offered free of charge uptake of the intervention is low. [47,48] Despite these challenges to NDPP delivery, there may be benefits to delivering NDPP tailored for men in that once enrolled in the program their retention rates may be better than mixed-gender approaches. Lastly, our use of EHR-captured clinical weights to inform multiple imputation of missing outcomes for intention to treat analyses will provide an unbiased estimate of effectiveness to inform dissemination strategies in the future.

The *Power-Up* study is unique in that the recruitment was conducted from patients identified in the EHR system of clinics and so has a known denominator for recruitment. An analysis using the true denominator facilitated evaluation of true reach and representativeness of the recruited sample, as compared to the eligible population. Evaluations that limit outcome analyses to successfully engaged participants, that rely on per-protocol outcome analyses, or that use last-observation. *Power-Up* was designed to leverage past success of NDPP delivery through the clinical care setting by identifying and recruiting eligible men seen in primary care practices of a large hospital system in the Bronx, NY and primary care settings supported by the DOH. This approach also allowed for the identification of potential participants through the EHR systems facilitating data collection on important outcomes such as weight and Hemoglobin A1C. In the *Power-Up* study, we proposed to test an innovative adaptation of the NDPP tailored for racial and ethnic minority men and based on quantitative and qualitative results and lessons learned from a successful pilot study.[25-27] The *Power-Up* intervention was tailored to the needs and preferences of men and used: a) men coaches; b) men-only groups; c) messaging tailored to be appreciated and motivational to men; and

d) adapted content that highlighted issues relevant to men. Further, *Power-Up* was delivered virtually during the beginning of the COVID-19 pandemic in early 2020. The virtual format through the Zoom platform was designed to facilitate ease of attendance by participants given the attendance challenges of in-person NDPP delivery and eliminate the risk induced by delivering a group based DPP during a viral pandemic.

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Author contributions
ECC and JAG are responsible for study design and implementation, and writing of manuscript. CS, EG, and KD contributed to data collection and analysis. All authors reviewed and provided revisions of the manuscript.

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