Balance: A Pragmatic Trial of a Digital Health Intervention to Prevent Weight Gain in Primary Care

STUDY PROTOCOL, INFORMED CONSENT & STATISTICAL ANALYSIS PLAN

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STUDY PROTOCOL

1. Research Design

Overall study aim: This will be a pragmatic, patient-randomized controlled effectiveness trial. We will randomize up to 455 overweight and obese adult participants to a 12-month weight gain prevention intervention (Balance, or *Equilibrio* in Spanish) or to usual care. Our primary outcome will be weight gain prevention over 24 months, defined as ≤3% change in initial body weight over 24 months. We will gather all follow-up patient data to assess outcomes from their Piedmont electronic health record. We will not have any intervention contact with participants during the final 12 months, with the exception of a Balance intervention satisfaction survey. Funding for this trial was provided by the National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases on May 13, 2016. Funding continued through April 30, 2023.

Background: Up to 50% of obese patients are not interested in, or ready for, weight loss. Clinical practice guidelines clearly recommend that these patients avoid gaining weight. Doing so might contain, or even attenuate, the adverse cardiometabolic risks that accrue with additional weight gain. However, despite this clinical guideline, weight gain prevention interventions are not available in primary care practice. This evidence gap disproportionately affects medically vulnerable patients -- those who are low-income, often racial/ethnic minority, and may reside in rural settings. These patients have the highest rates of obesity and weight gain, but the least interest in, readiness for, and success with weight loss. The implications for these patients are clear: without intervention, most will continue to gain weight and incur cardiometabolic risks. For obese medically vulnerable patients, weight gain prevention is a priority but treatment options do not exist.

Pragmatic Effectiveness Trial: This will be a pragmatic effectiveness trial to test the Balance intervention in rural community health centers. We will randomize up to 455 overweight and obese adults to either: 1) usual care, or 2) a 12-month weight gain prevention intervention, including mHealth self-monitoring and feedback, skills training videos, and responsive coaching from a clinic dietitian. Our primary outcome is weight gain prevention at 24 months.

Usual Primary Care Condition: Usual Primary Care participants will receive the standard primary care offered by their providers; mailed study materials (pedometer, self-help materials such as NHLBI's "Aim for a Healthy Weight"); as well as automated (non-tailored) text messages with health information/skills training for six months. At least annually, our team presents an update on obesity treatment at a medical staff meeting attended by all providers. We will conduct these trainings at study kickoff, and will continue them throughout the trial. We will not influence usual primary care in any other way.

Weight Gain Prevention Intervention Condition: Intervention participants will receive: 1) tailored behavior change goals, 2) self-monitoring using connected scales and mobile technologies, 3) responsive coaching, and 4) tailored feedback and skills training. We describe each below:

iOTA — the interactive obesity treatment approach (iOTA): We developed iOTA and have used it in several recent primary care-based obesity treatment trials.[51,54,55,58] iOTA creates an energy deficit by having participants achieve simple, straightforward, and concrete behavior change goals (e.g., no fast food, no sugary drinks, walk 10k steps per day).[51,54,55,58] We designed iOTA in response to the frequent finding of poorer trial outcomes and less intervention engagement among medically vulnerable populations when traditional weight loss intervention approaches are used. We think that traditional treatments are less successful in the medically vulnerable because of their literacy/numeracy requirements, cognitive complexity, and resource assumptions. In contrast, iOTA is straightforward and does not require expert knowledge or expensive resources. Participants simply take a short survey, are assigned tailored behavior change goals, self-monitor their adherence to those goals using their phones,

and receive immediate tailored feedback, regular skills training, and dietitian counseling that is informed by their tracking data.

Behind the scenes, iOTA is very sophisticated. All iOTA components are delivered using digital health technologies. iOTA uses a series of interconnected algorithms and content libraries. After participants take their initial surveys, our prescription algorithm assigns up to 4 tailored behavior change goals from our vast goal library. Participants use their phones to self-monitor goal adherence. A feedback algorithm tailors feedback, selecting content from a vast feedback content library. From our skills training library, we send videos to assist behavior change efforts. When participants speak to their dietitian coaches, our coaching algorithm uses self-monitoring data and real-time weight data to tailor the counseling protocol.

Theoretical framework: iOTA is grounded in social cognitive theory,[59] from which we selected self-efficacy as our primary psychosocial mediator. There is strong and consistent evidence that self-efficacy is positively associated with weight-related behavior change.[60-62] Bandura identified four primary factors[63] that influence self-efficacy: 1) Mastery experiences: We will enhance mastery by teaching behavioral skills. Regular self-monitoring with tailored feedback and interventionist support (which emphasizes long-term change success vs. quick wins) will help to reinforce mastery experiences; 2) Social modeling: Skills materials feature narratives of those who have been successful with similar behavior change; 3) Social persuasion: Behavioral counseling will boost efficacy by teaching behavioral skills and validating behavior change efforts; 4) Somatic and emotional reactions. Self-efficacy among obese, sedentary patients may be reduced quickly through intense physical activity changes. We have structured our recommendations to progressively increase activity. Tailored feedback and counseling are designed to boost positive emotions. Interventionists teach basic stress coping skills to prevent undermining efficacy and the adoption of stress eating. Social cognitive theory also indicates that behavior change can be facilitated through self-regulatory processes that we will target in the intervention, including self-monitoring,[64-66] goal setting,[60,67] and social support.[68,69]

Behavior change goals: Successful weight gain prevention requires the creation of a slight energy deficit (100-200 kcal/day). This is a small change on an absolute basis. However, challenges abound in creating this deficit over an extended period, especially in a population that is often in positive energy balance, has low weight loss motivation, limited literacy/numeracy, and sociocultural, psychosocial, and contextual barriers. iOTA assigns 4 concrete goals that create a slight energy deficit. Our iOTA prescription algorithm selects goals from a large library, prioritizing behaviors in highest need of change, those for which the participant has high self-efficacy and readiness, and those that achieve the intended caloric deficit. To minimize habituation, we rotate participants' goals at 8-week intervals, or when goals have been successfully maintained for 4 consecutive weeks. To prescribe new goals, the prescription algorithm considers previous performance, weight change to date, and necessary caloric deficit. We will leverage the goal libraries from Shape (Protocol 2628) and Track (Protocol B0033), translate them, and adapt them for the broader Balance patient population. Our behavior goals help patients to easily create an energy deficit, even in resource-constrained settings.

Self-monitoring and tailored feedback: Participants self-monitor adherence to their behavior change goals each week. To maximize engagement, we allow participants to choose either interactive voice response or text messaging for self-monitoring; they can switch between these channels as often as they like. In previous studies, we found that participants who chose to switch channels had the greatest intervention engagement.[55] Both of these channels are phone-based — the most widely used technology channel by all populations, particularly among the medically vulnerable. Through both channels, we contact participants weekly, request self-monitoring data, and immediately provide automated tailored feedback. Feedback messages describe trends in progress, reinforce successes, and offer motivational strategies. We also provide short skills training tips. Our interactive voice response system calls participants weekly (at their

chosen number) and allows them to self-monitor with their keypads or voices. The system is similar to those used by banks and airlines. We have hundreds of hours of audio content (recorded by professional actors) that we piece together seamlessly during the call. This means that participants hear a human voice (rather than a digitized voice) that requests tracking data and delivers tailored feedback. We have a complex callback protocol when calls do not connect; this protocol produced 72% adherence at 12-months in Shape. Our text messaging system is also fully automated. After participants self-monitor their goal adherence, we provide tailored, real-time feedback on progress via text. Both of these mHealth channels are high reach, low-cost, easily usable, proximal to the user, and requires no expert user knowledge. Both are inexpensive to develop and to scale. This makes them ideal for use in primary care.

Responsive coaching: In this study, we will use an innovative strategy to vary the frequency, intensity, content and modality of coaching. We designed responsive coaching for two reasons. First, most obesity interventions use a one-size-fits-all approach, delivering content with a fixed schedule and intensity. This approach may miss important windows of opportunity to impact behavior change. It may also deliver too much or too little of an intervention dose. Digital health technologies can help us to better meet participants' counseling needs at the time they are needed. Our responsive coaching model has several steps.

Step 1. Participants weigh weekly: Intervention participants will be asked to weigh themselves daily, and at least weekly, with a cellular-connected scale. Co-Investigator, Dr. Steinberg has been a leader in establishing the evidence for regular self-weighing.[70] As in our previous studies, participants will use scales from BodyTrace. These scales transmit weight data directly through the cellular network; they do not require a computer, Internet, Bluetooth or wifi connection. We will use weekly weight change data to trigger our counseling activities. If participants do not weigh themselves at least once weekly, we will send automated texts (e.g., "Looks like you didn't weigh yourself this week…"). Specific verbiage for engagement messages will come from libraries used in our prior trials. We used escales in Track, which had a similar patient population. On average, Track participants were weighing 3.6 (+/- 2.1) days each week.

Step 2. Algorithms stage participants: Each week, our system places participants into one of 3 intervention zones, depending on their average weight change (based on averages of daily weights on a weekly basis) from baseline, similar to the approach used in the Stop Regain weight maintenance trial.[71] However, we will categorize participants in a fully automated manner and will then use the zones to select the frequency, intensity, and mode of counseling.

- **Green zone (<0-1.5kg change from baseline)**: These patients will continue to track their goals and receive weekly automated feedback and tailored skills training. They will receive no coaching but will receive one automated text message each week with positive reinforcement.

- **Yellow zone text counseling (+1.6-2.9 kg change from baseline)**: Using protocols for email counseling in weight management, a Piedmont registered dietitian will deliver brief counseling via text messaging in English or Spanish. The goal of counseling is to raise awareness about weight gain, to enhance motivation and efficacy for behavior change, and/or to engage problem solving. Coaches will have a library of special yellow zone skills training materials that they can offer participants. Coaches have discretion to change a participant's goals if necessary.

  Text messaging functionality is built into our coaching dashboard, where coaches can access data on their yellow zone patients to use in tailoring their counseling text messages. The system stores all counseling text messages. While texting has been traditionally limited to 160 characters, modern platforms do not have such limits. This allows us to have more robust interactions via text. That said, the intervention protocol will emphasize that coaching should be limited to 4

messages total (2 inbound, 2 outbound) per week. In contrast to similar channels (e.g., email), text messaging offers greater population penetration (>90% at Piedmont), immediate delivery, and is frequently used. Texting has been critical to our intervention and evaluation activities in this population.

- **Red zone phone counseling**: We will activate the red zone protocol for participants who gain >3.0+ kg from baseline. Red zone participants will receive automated weight messages on a weekly basis and telephone counseling, based on our previously-tested telephone counseling protocol and/or text messaging interactions with the Balance dietitian, as described above. When notified that a participant has entered the red zone, his/her coach will make a counseling call attempt or send a text message within 24 hours. will use our previously-tested callback protocol if we do not immediately reach the patient. This protocol produced a call completion rate of 84% in Shape and Track. We will set a call ceiling a total of 12 calls over the 1-year intervention, for the Balance dietitian to distribute using his or her discretion. Each 15-20 minute counseling call will be designed to assess and enhance motivation and efficacy for behavior change, deliver in-depth behavioral skills training, and provide social support. Counseling will be guided by principles of motivational interviewing (MI).[73,74] MI enhances self-efficacy, increases recognition of inconsistencies between actual and recommended behaviors, and teaches dissonance reduction skills.[73] On each call, coaches will: 1) review weight change and self-monitoring data; 2) discuss problem solving strategies; 3) deliver skills training content, and; 4) discuss engaging community resources. We have extensive experience supporting health center dietitians to deliver MI-based weight management counseling.

Tailored skills training videos: We have produced videos for each of the goals in our library. For example, for those assigned a fast food reduction goal, we provide skills training materials on eating out, social eating, and lunch packing. We also have a library of general behavior change lessons (e.g., stimulus control, problem solving, social cues, stress management) and condition-specific materials (e.g., hypertension, diabetes). Our materials include narratives, as well as information about cost and community resources. We use expectancy priming throughout to heighten salience of materials.[75] In Shape, we produced a set of printed materials at baseline and then sent participants additional materials every 3 months. This was successful but costly, and the printed materials still presented literacy challenges. In Balance, we will deliver skills training videos that we have implemented with success on Track. We will be able to leverage much of the Track content, given overlap in our skills training content. We will translate these videos into Spanish during study startup. We will share these videos with intervention participants at baseline and deliver additional skills training, as necessary.

Intervention fidelity: The study dashboard presents each session's call script, allows for note taking, and provides access to self-monitoring IVR and SMS data. The system also automatically records coaching calls/texts and stores call process data (e.g., date/time, call disposition, duration). Drs. Bennett and Steinberg will oversee coach training, which will consist of two days of didactics and role-playing, using training materials from previous studies.[50,76] Coaches will be trained to detect clinical events that require provider referral. We will certify coaches at the close of training and re-certify them bi-annually. Drs. Bennett and Steinberg will review 5% of calls, selected randomly. Coaches will have bi-weekly supervision with Dr. Steinberg. Note that Piedmont believes that similar interventions can be sustainable only if delivered by core staff. Incorporating dietitians as coaches (vs health educators, case managers, CHWs) has been successful in Shape and Track; dietitians are familiar with the patient population, have excellent intervention fidelity, with call completion rates of >84%. Incorporating dietitians also has future reimbursement potential.

Study start-up: During the first 6 months of Year 1, we will update the goal library, skills training materials, all content libraries, and algorithms. We will translate all intervention materials into Spanish. We will conduct all staff training activities. We will also update all technology systems, which are currently operational.

Data collection: Research data will be collected from several sources. The baseline survey will be administered by the research assistant (See Appendix B) via phone or in-person in a private location. We will gather self-monitoring data from intervention arm participants via weekly IVR calls/text messages for self-monitoring, via coaching texts and calls (See Appendix H for sample content) and via daily weight data from the BodyTrace escales. All other clinical data (e.g. blood pressure, lipids, and glucose screenings; co-morbidities; medications, etc.) will collected from Piedmont Health's EHR, to assess the 24 to 30-month outcomes of the intervention. Per the signed HIPAA authorization form, pre-baseline data (12-18 months prior to randomization) will also be collected from the Piedmont Health medical record. (See below). In keeping with our practices on prior trials, only trained and certified research staff will obtain data. All research staff are required to have human subjects training. All gathered data will be used specifically for research purposes.

Data from the Balance satisfaction survey will be collected via an online Duke Qualtrics survey link that will be texted, emailed and/or called (or survey read aloud on the phone to participants who don't have a smart phone who agree to participate) to currently-enrolled previously-randomized Intervention arm Balance participants after they complete the 12-month active intervention period. Up to 80 active Balance participants will be randomly-selected from the Spanish-speaking and English-speaking participants from the Intervention arm (up to 40 in each language group) after they complete the active intervention period. For smart phone users, a survey link will be sent via email and/or text message that will contain more information on this satisfaction survey (and a phone call attempt may be made to encourage participation); or will be read the script aloud if the participant doesn't have a smart phone and/or email address. The survey link will be emailed or texted to smart phone users from our system up to a total of 4 times within a 3-week period: twice during the first week they reach the 12-month completion mark, spread out with at least 2-3 days in between each attempt; and then twice over the remaining 2 weeks. After the 4 attempts, if there is no response, we will consider them not interested in the survey and will not follow up further. We will follow the same process for phone calls to those without smart phones (up to 4 attempts over a 3-week period) and will try calling on different days at different times, spread out by at least 2-3 days in between. If there is no response from participants (ie call, text or email back) after 4 contact attempts over the 3-week period, we will consider them not interested and will not contact again. (See Appendix M for the process). The survey will be administered through Qualtrics (See Appendix N for survey content). Our REDCap project may also be used to link the participant data and Duke Box will be used to store any reports from Qualtrics and any reports generated from doing both statistical and qualitative analyses of the resulting data.

To assess the implementation of Balance within the primary care setting at Piedmont Health, we will conduct confidential in-person or phone interviews with Piedmont Health providers and staff. Up to 25 Piedmont Health employees will be invited to volunteer their time for the interviews. Preliminary emails will be sent to Piedmont Health employees to assess their interest in interview participation, and if interested, to schedule a time for the informed consent process (Appendix P). If the participant consents to participate in the interview, research staff will document their verbal consent in Duke REDCap. Balance research staff will ask participants to fill out a brief paper survey with demographic questions and then will conduct the semi-structured interview (See Appendix Q). The interviews will last approximately 30-45 minutes and will occur in a private location. The interviews will be digitally-recorded on encrypted recorders; professionally-transcribed by a HIPAA-compliant vendor, with names removed from the transcripts prior to analyses; and coded using NVivo software.

To assess the degree to which the design/implementation of Balance is pragmatic, data collected from the Balance Pragmatic Design survey will be collected via an online Duke Qualtrics survey, approximately 10-15 minutes in length. A Qualtrics survey link will be emailed to the Balance research team, comprised of Duke and Piedmont Health staff. Up to 25 members of the Balance research team will be invited to complete this voluntary survey. The survey asks participants to score the level of pragmatism (on a scale of 1 to 5, with 1 being the least pragmatic and 5 being the most pragmatic) based on the descriptions provided and their knowledge of Balance for 10 trial design domains (see Appendix S). An average score for each domain will be created, based on the total number of responses received from the Balance research team.

Baseline Assessment: After receiving signed written HIPAA authorization form from a potential participant, to conduct the baseline screen/consent, Balance research staff will describe the study, determine eligibility for the study through a brief screen (See Appendix C), and if eligible and interested, obtain verbal consent, and administer a phone/in-person baseline survey. This will be conducted via phone or in-person in a private space at the clinic. A staff member will then randomly assign the participant to either Intervention or Usual Care arms. For those in the intervention arm, the staff member will deliver the iOTA survey, also by phone, in Spanish or English (see Appendix B for complete survey). The eligibility screen, verbal consent, and baseline survey will be administered via phone (in Spanish or English) or in-person, and entered into the Balance study database and within a secure platform such as Qualtrics and/or REDCap. Study surveys will eliminate or define medical terms, and use simple sentence structure and vocabulary.

Follow-up Data Collection: Given our pragmatic trial design, we will gather 12 to 18-month pre-randomization data, as well as 24 to 30-month follow-up data directly from Piedmont's EHR; we have a great deal of experience and well-established protocols in use. For each participant, we will assess the following data through 24 to 30 months following randomization: demographics (that were not asked at the baseline assessment including insurance status, poverty and marital status), and clinical data such as weight, blood pressure, smoking status, diagnostic codes, appointment dates, visit notes, lab tests (e.g. glucose and lipids), and medications. To receive the EHR follow-up data for evaluation purposes on enrolled Balance participants, we will utilize a Duke-provisioned Box folder to receive the data on enrolled participants from the Piedmont Health data manager/IT manager as follows:

Per the request of Piedmont Health, to collect our evaluation data from the EHR, we will provide Piedmont Health with lists of enrolled participants in a spreadsheet format for whom we need pre-baseline and follow-up data for Balance evaluation purposes. The participants will be identified in spreadsheets with their names, dates of birth, and Piedmont Health patient ID numbers (which will be extracted from our Balance Duke REDCap project for enrolled participants) to ensure we are receiving the correct participant data from the record. These spreadsheets will only be stored and accessed within a restricted Duke-provisioned Box folder and within a protected subfolder with restricted access granted to the necessary personnel at Piedmont Health and the Duke research team. Piedmont Health will directly upload the evaluation reports into this designated Duke Box folder, or will send the reports via their encrypted email system to the Balance study coordinator. If securely emailed, the Balance study coordinator will access the encrypted files, promptly save the reports in the designated Duke Box folder and delete the emails. When subsequent analyses are conducted by the Balance biostatisticians utilizing these datasets, the names, dates of birth and Piedmont Health patient ID numbers will be redacted, and only study IDs will be used to identify participants.

The processes for data collection and data elements that will be collected from the participant's medical record will be explained to the participant as part of the consent process (See Appendix A) and in the written HIPAA Authorization Form (See Appendix D). At the 12-month timepoint, we will mail a completion letter in English or Spanish to active study participants and provide a certificate of completion

or a revised letter thanking them for their participation (if they were in the program for at least 6 months but may not have completed the full 12 months of Balance). (See Appendix O). We will not have any intervention contact with participants during the final 12 months.

At Piedmont, weight and blood pressure are measured at all visits, including for acute care. Our proposed lab tests are also commonly administered. We will closely monitor patients' medical visits during the 24 to 30-month follow-up period. We have extensive experience retaining medically vulnerable patients, consistently reporting retention rates in the 90% range. We are thus confident that we will have adequate follow-up data to conduct our outcome analyses.

2. Subject Selection

Inclusion Criteria: The study involves males and females aged ≥ 21 years who are English and Spanish-speaking patients at a Piedmont Health Services primary care health center; and with a BMI between 25-40 kg/m^2 and weight less than 380 pounds. Eligible participants will have had a non-urgent visit to a Piedmont Health clinic within the last 2 weeks. Eligible participants will also have a cell phone and be willing to receive study-related text messages (3-12 messages per week).

Exclusion Criteria: Potential participants cannot: be a current Piedmont Health employee; currently or recently (within the past six months) pregnant or planning on becoming pregnant in the next 12 months; be currently or recently (past 2 months) lactating; have prior or planned bariatric surgery; have a diagnosis contraindicating weight loss (e.g., active malignancy); have a history of a cardiovascular event (stroke, MI); or have been hospitalized for a mental health issue in the last 12 months; have a diagnosis of end-stage kidney disease (ESRD) in the medical record; or due to investigator discretion for a potential health or safety issue. Potential participants who have a history of a coronary artery revascularization (in last 12 months) will be allowed to participate in the study with provider approval (See Appendix C).

Sample size: We will recruit up to 455 adult men and women, who speak either English or Spanish. At least 30% of the sample will be male (we recently recruited a 31% male sample in Track). The sample size calculation is based on the primary aim examining differences in the time to gain ≥ 3% of baseline weight between intervention and control groups. Based on Shape's clinical data, we assume a 5% sample loss for each group per month of the study. A sample of N=192 per group (Total N=384) allows us to test the difference between the two distributions with greater than 80% power. Factoring in an additional expected sample loss of 15% (those with no clinical data past baseline) gives a final sample size of N=221 per group (Total N=442, with the possibility of enrolling up to 455).

For the qualitative Balance implementation sub-study, we will recruit up to 25 Piedmont Health employees in varying roles and across the participating sites and leadership team.

For the Balance pragmatic design survey, we will invite via email up to 25 current or former Balance research team members at Duke and Piedmont Health Services staff (including leadership and dietitians) to complete the voluntary online Qualtrics survey (See Appendix R for the recruitment email template).

Recruitment: To enhance the pragmatic design, study recruitment will occur via two methods: 1) provider referral and 2) mailed materials to potentially-eligible patients based on lists run by Piedmont Health (See Appendices J-L).

1) Recruitment via Provider Referral: This approach was suggested and preferred by the Piedmont Health medical director and associate medical director/medical informatics director and is a current practice at Piedmont Health. Recruitment will occur as follows:

During regular outpatient appointments, Piedmont Health providers will introduce Balance to their patients and gauge their interest in being contacted by Duke research staff to learn more about the study (See Appendix E). Patients who express interest in Balance will be informed that a HIPAA authorization form needs to be signed to allow Duke research staff to access their information and contact them for follow-up. The provider will then give patients a brochure and HIPAA authorization form, written in Spanish or English. The study brochure and HIPAA authorization form will be reviewed with patients by a Piedmont staff member and signed copies returned via the following methods: placed in a lockbox in the clinic; securely scanned by the Piedmont Health provider or staff member and uploaded to a restricted Duke Box folder set up in a Duke-provisioned Box account; or emailed the Balance study Duke email address or the Duke email address of authorized study personnel, such as the lead research assistant or study coordinator. The forms may also be returned in-person to a Duke research assistant, if in the clinic at time of referral. (See Appendix I for research assistant script). A copy of the IRB-approved verbal consent document will also be reviewed and given to patients to review and take home, if interested. Any questions about the study will also be addressed. Duke research assistants will then confirm eligibility of patients who have signed the HIPAA authorization form by reviewing their electronic medical record and create a new participant record in the Duke REDCap Balance project with the details from the HIPAA form (e.g. name, DOB, contact phone numbers, signature date, HIPAA form recruitment method, primary health center, etc.) into the REDcap project for the study. At the same time, s/he will also enter the patient ID number from the medical record into REDCap. This is to ensure duplicate records for the same participant are not created within our study database during the estimated two-year recruitment timeline. Because of how the REDCap project was created for the purposes of Balance, matching new patients with patients who are already in the database by the unique identifier of patient ID at time of data entry will be the only way to prevent duplicate records for the same person (i.e. when people go back for appointments in the future during our active recruitment period and could be accidentally re-recruited in the health center).

If eligible based on chart review, the Duke research assistant will then contact the patient via phone or in-person at the clinic. The patient will be screened, and if interested and still eligible to participate, will be verbally consented and enrolled, on the phone or in-person, by the research assistant. Trainings regarding the study purpose, directions about participant eligibility, intervention components, and processes to refer to the study will be conducted at participating Piedmont Health sites with involved staff.

2) Recruitment via Mail: To enhance our recruitment success and expand recruitment to other, more rural Piedmont Health clinic locations, we plan to reach out to potentially-eligible patients via mail in advance of their medical appointments. (Please also see Appendix J for the partial HIPAA authorization waiver). This will occur as follows:

Once or twice per month, Piedmont Health staff will run a report of all patients who are ≥ 21 years old; not currently pregnant; do not have end-stage renal disease, have a last recorded BMI and weight within our target range; speak English or Spanish as their primary language; and who have an upcoming medical appointment within the next 4-6 weeks at one of the participating Piedmont Health community health centers. The Piedmont report will be exported as a spreadsheet and securely sent (via their encrypted email system that they use to send sensitive emails/email that contains ePHI or via a restricted folder in within the Balance Duke Box folder) to the Balance study coordinator with the following information: patient name; gender (for letter salutation purposes); Date of Birth; mailing address; telephone number(s); email address; preferred language (Spanish/English); primary community health center; and upcoming appointment date. From this list, we would send a cover letter (See Appendix K); Balance study information (See Appendix F); and two copies of the HIPAA authorization form (See Appendix D) via postal mail. We would request that interested patients sign and return one copy of the form to us via mail to our office or printed, signed, scanned and returned as an attachment via email to our Duke Balance

email address. The patient would also have the option of returning the form to us during or immediately after their medical appointment at the clinic. The other copy of the HIPAA form would be for the patient to keep for his/her records.

In the cover letter, we would explain the study and the waiting period of 10 days before we would contact the patient for follow-up. During those first 10 days, if patients contact us via mail, phone or email and state they wish to be removed from our list, we will document their lack of interest in the study and not contact the participant further.

If after 10 days, the participant has not opted out of contact, a Duke research assistant or Piedmont provider will contact the participant via phone or email (See Appendix L). We will contact participants no more than twice per week via phone and/or email before their appointment and no more than twice a week following their scheduled appointment time. The reason for contacting participants after the appointment time is that participants remain eligible up to 14 days after their appointment. If we do not receive a signed form within 14 days after the appointment date, we will not follow up with them again via mail at that timepoint. If the participant expresses disinterest within 14 days post-appointment, we will document this in our database and no future follow-up contact would occur.

During the recruitment phase of the study, it is necessary to keep participant names, dates of birth and contact information to cross-check previous recruitment and enrollment lists. These lists will be stored in Duke Box or within our Balance REDCap project. We will keep these lists for our recruitment period to ensure we do not inadvertently contact the same patient multiple times; contact participants who have told us they do not wish to be contacted; or contact participants who have already been screened, consented and/or enrolled at another time point. Once the recruitment phase is over and we have enrolled all participants in Balance, we will redact the PHI from these recruitment lists.

If we receive a signed HIPAA authorization form from this recruitment method, we will complete the same study procedures as for the provider referral method, i.e. a brief chart screen, phone screen, verbal consent, and phone enrollment, as described previously and below.

For both recruitment methods, we will screen participants, consent those to Balance who meet eligibility criteria over the phone or in-person in the clinic, and conduct survey and randomization activities as outlined above in the Data Collection section: Baseline Assessment. Study surveys will eliminate or define medical terms and use simple sentence structure and vocabulary. As in previous trials[55] we will offer all recruitment, enrollment, and assessment activities in both English and Spanish in order to maximize the representativeness of the study sample. For both recruitment methods, we will reach out to potential participants via phone call, text message and/or email to assess interest in the study, and if interested, for phone screening, consent and enrollment.

We will randomize participants in permuted blocks, stratified by health center to balance assignment by community health center. With our design, research staff and participants cannot reasonably be blinded to allocation. However, to reduce the potential for biased outcomes, we take steps to segregate research staff from those involved in intervention design and evaluation. Our work demonstrates the feasibility of this methodology; indeed, we designed this strategy together with Piedmont and they agree that it will be minimally burdensome to clinic operations.

Patients who sign the HIPAA authorization form but are ineligible for the study based on screen will be informed they are not eligible for Balance. If the only reason a participant is ineligible for the study is too high based on BMI/weight from their chart (i.e. BMI was above 40 kg/m^2; and/or weight was greater than 380 lbs), s/he will be mailed a cover letter; copy of health education materials based on the NHLBI's "Aim for a Healthy Weight" booklet; and a printed copy of an IRB-approved Charge study recruitment

flyer (Duke Campus IRB Protocol Number D0752) with information about how to sign up for that trial, if interested (for English-speakers only), during the time that Charge is actively recruiting. (See Appendix C for eligibility screen).

To recruit up to 25 Piedmont Health providers and staff for the qualitative sub-study, we will first reach out to individual stakeholders who were involved in the implementation of the project via email and assess their interest in possibly participating. If the employee declines possibly participating, we will not follow up further. If s/he expresses interest, we will coordinate a date and time to conduct the verbal consent process (See Appendix P) and semi-structured interview (See Appendix Q), either in-person or on the phone.

3. Risks and Benefits

This is a minimal risk study, and thus we do not anticipate problems beyond our control that involve risks to subjects and others happening.

No clinical assessments will be taken by research staff. Clinical data will be extracted from the EHR system at Piedmont as described above for evaluation and for participant study safety monitoring at 6, 12 and 24-month timepoints and will reflect their processes for routine screenings based on current clinical practice guidelines.

Physical activity: Risks from increased physical activity will be minimized by: 1) recommending physical activity in line with national guidelines; 2) encouraging moderate activity; and 3) directing participants to their physicians when appropriate. If exercise-related symptoms are reported, we will advise participants to get clearance from their PCPs before they can restart physical activity.

Participants will be counseled to change behaviors that will maintain or reduce weight. If individuals follow this advice and decide to change their health behaviors, there should be few risks or side effects. The materials and counseling will provide guidance on preventing and managing the side effects of health behavior change.

Data confidentiality: We will use the standard operating procedures that have been used on our prior trials for survey conduct and data management. All paper files related to the study will be stored in a secure location at Duke University in a locked file cabinet accessible only to key study personnel. The privacy, security, and durability of accumulated personal health information are of paramount importance. Physical access to computing resources (hard drives, servers, networking equipment) is secure, audited, and restricted to skilled personnel; virtual access (login and system administration) is encrypted, audited, and limited to skilled personnel; all databases are encrypted and access from the public Internet is precluded; staff will be assigned unique login IDs and follow Duke standards for choosing passwords. We will also implement multifactor authentication to protect logins to databases. All communication between our software and third-party software is encrypted using SSL. Personnel must have access to perform regular maintenance duties. However, this constituency is limited to senior system administrators and the director of the research group. Surveys for enrollment, intervention goal assignment or intervention satisfaction will utilize Duke's secure HIPAA-compliant survey platform, Qualtrics and/or REDCap, that only authorized research staff can access. For the qualitative sub-study, verbal consent and participant information (name and assigned ID code number) will be stored within REDCap. Paper demographic surveys will contain the associated ID code number for the participant. Responses from the paper survey will be entered into the REDCap project that is linked to the participant after the interview. Original audio recordings will be transferred from the encrypted recorders to Duke Box for storage and then deleted from the recorders. Audio files will then be securely transferred to a HIPAA-compliant vendor to transcribe. When the transcripts are received from the vendor, they will be stored and accessed within Duke Box.

Prior to analyses in NVivo, participant names will be removed from the transcripts. Any written notes taken during the interviews will be securely stored in a locked file cabinet within a locked office and disposed of after analyses.

For the voluntary pragmatic design survey, we will utilize Duke Qualtrics to collect the survey data. The survey does not require participants to enter their names or other identifying information.

Breach of confidentiality: All participant information collected in the context of this study, and even the fact that an individual is participating in the study, will be considered confidential. Confidentiality will be assured through several mechanisms. First, each participant will be assigned an anonymous study ID that will be used on all study forms. Second, all study forms and paper records that contain participant information (e.g., HIPAA authorization forms) will be kept in secured, locked areas or in encrypted databases. In addition, such materials, when in use, will be kept away from public scrutiny. Materials that need to be discarded will be destroyed. Third, access to all participant data and information will be restricted to authorized personnel. In the case of computerized study data, access to data will be password-protected and staff members will be assigned individualized passwords that allow them access to only those elements of the data management system to which they are authorized. In addition, all study personnel will maintain certification with the Duke IRB that they have completed training in research ethics, which includes training on confidentiality. Finally, participants will not be identified by name in any reports or publications, nor will data be presented in such a way that the identity of individual participants can be inferred. All information obtained in the course of the study that identifies an individual will be treated as confidential in accordance with section 903C of the Public Health Service Act (42 U.S.C.299a-1). We will strip all identifiers from analytic data sets after data merging and will keep all personal identifiers in a separate location from the analytic data. No individual participant will be identified in any reports from the study. Data storage will involve computer files that will be password protected and encrypted and will be accessible only to personnel who need to contact participants.

In order to send and receive text messages, we will use a software engine that uses Twilio, Heroku, and Amazon S3. The engine will receive self-monitoring data that participants send via interactive voice response (IVR) and text message as well as weight data when they step on the BodyTrace scale. The data will be automatically analyzed each week according to algorithms we embed. Study staff will log into a password-protected database using multi-factor authentication to view and edit participant information. We will use Twilio to send text messages to participants each week. We will use Heroku to process data for the engine. We will use Amazon S3 to store data; data will be encrypted when it is stored. At times, we will transfer data from the engine to/from the participants and BodyTrace servers, and we will use Heroku and Twilio to do this. If data are disclosed by these companies or their business partners, it may no longer be covered under the Duke privacy protections. Text messaging does not provide a completely secure and confidential means of communication. Participants will be made aware of these risks as well as those that are inherent in using consumer-based products such as BodyTrace, telephone (IVR), and text messaging during the informed consent process. We used these processes on several previous studies conducted in this population.

Potential Benefits: Potential benefits for study participants include improved lifestyle, lower blood pressure and consequent reduction in cardiovascular risk. An additional benefit for some participants may be personal satisfaction in being part of a study that may have major public health implications for the community. No benefit from participation can be guaranteed. Potential benefits to others include the possibility that this research will lead to the dissemination of an intervention that can help maintain weight, with consequent reduction in the risks associated with diagnoses of diabetes, high cholesterol, and hypertension. Of particular importance is the fact that this project aims to provide an intervention in a culturally appropriate and sustained manner through use of intervention materials at an appropriate

reading level for the target population. The minimal health risks to participants listed above are offset by the potential benefits to them and to society.

4. Confidentiality

In the present study, we will collect identifying demographic information including: names, addresses, telephone numbers, and email addresses. We will use the standard operating procedures that have been used on our prior trials for survey conduct and data management. All paper files related to the study will be stored in a secure location at Duke University in a locked file cabinet accessible only to key study personnel and within a temporary lockbox or locked filed drawer within an office at Piedmont Health (for HIPAA authorization forms that are in the clinic for the research assistant to pick up). The privacy, security, and durability of accumulated personal health information are of paramount importance. Physical access to computing resources (hard drives, servers, networking equipment) is secure, audited, and restricted to skilled personnel; virtual access (login and system administration) is encrypted, audited, and limited to skilled personnel; all databases are encrypted and access from the public Internet is precluded; staff will be assigned unique login IDs and follow Duke standards for choosing passwords. We will also implement multifactor authentication to protect logins to databases. All personnel must have access to perform regular maintenance duties. However, this constituency is limited to senior system administrators and the director of the research group.

Strategies for protecting electronic PHI: Study staff will enter all participant information into the study database, which is hosted and maintained in a remote data center. All software and servers are reachable only via logging in using multi-factor authentication and all communication between our software's application programming interface (API) and third-party software is encrypted using a protocol called Secure Sockets Layer (SSL). As described above, physical access to computing resources (hard drives, servers, networking equipment) is secure, audited, and restricted to skilled personnel; virtual access (login and system administration) is encrypted, audited, and limited to skilled personnel; all databases are encrypted and access from the public Internet is precluded; all software and servers are reachable only via a virtual private network (VPN) or multi-factor authentication; and all communication between our software's application programming interface (API) and third-party software is encrypted using SSL. In addition, Duke-provided HIPAA-compliant resources such as Qualtrics, REDCap and/or Duke Box may be used to collect and store research data for the study. Only research staff who have received CITI Certification and are listed on the Duke University Institutional Review Board protocol will have access to the study database. Information in the database will not be shared with anyone outside the research team.

On the study verbal consent script (Appendix A) and the Piedmont Health employee qualitative sub-study (Appendix P), we inform participants that we do collect identifying information and that we take all appropriate measures to minimize the risk of unintentional breach of confidentiality. In the Balance pragmatic design survey, we will inform participants about the potential loss of confidentiality and how we will mitigate those risks.

We will communicate with participants' providers at Piedmont Health about certain clinically relevant situations. We would communicate with providers for few reasons: 1) to obtain provider assent for patients with certain health conditions that do not make them ineligible, but that we are concerned about (example: mild cardiac condition); 2) to notify providers of situations we encounter during the regular course of the trial that are of particular concern to our staff. Examples of these situations include: participants with significant and dramatic weight loss or to discuss emergent, serious diagnoses in participants that may compromise their suitability for the trial. In clinically relevant situations, study staff will notify study participants of the concerning data (e.g. extreme weight loss) and advise them to follow

up with their providers according to the Data Safety Monitoring protocol. In addition, study staff will notify participants when there will be communication with their providers. Unless the clinical situation is serious and time-sensitive, we will communicate with Piedmont Health providers using "flags" in their EHR. The "flags" in Piedmont's EHR system function as secure, internal emails. If the situation is clinically serious, we will contact the participant's provider by phone. We have included information about this communication in the informed consent verbal script (Appendix A).

The information generated by this study will be kept for seven years after the date of last publication. Then it will be destroyed by shredding the paper copies and by securely deleting the computer files.

Data management will take place under the supervision of Dr. Bennett. Our group has developed extensive quality assurance procedures, including on-going quality control checks.

After data analysis, we plan to disseminate the results of the study via journal publications and presentations.

We will not collect information about illegal activities. Further, we do not expect that participants will reveal information subject to reporting because our coaches are instructed to maintain close adherence to a protocol that involves discussing only behavior change efforts related to diet and exercise.

All of the same privacy measures and confidentiality procedures described above will also be adopted for the Balance satisfaction survey with patients and qualitative assessment with Piedmont Health employees. The online survey will be administered through Qualtrics. The qualitative assessment with Piedmont Health will be conducted in a private location (either in-person or on the phone). Collected survey and interview data and subsequent analyses will be stored within the Duke Box web application and/or REDCap that only authorized research staff at Duke will be able to access. To keep the Balance participants' information private, we will use their study ID number and their Balance phone number only to identify their responses. To keep Piedmont Health employee responses confidential, we will remove names from interview transcripts, and identifying information linking their names to the code numbers on their interview and the demographic survey will be stored only within the restricted REDCap project.

5. Compensation

Balance patient participants will not receive monetary compensation as part of their participation, as the baseline assessment will be brief and conducted primarily by phone. All participants, regardless of which program they are randomized to, will receive important health information/program materials as part of their participation as well as a pedometer. The main incentive for participation in this study (in either study arm) is to receive health information, materials and support for maintaining a healthy weight.

For the Balance satisfaction survey, to thank them for their time to take the survey (estimated to be 15-20 minutes), participants who decide to participate and complete the entire survey online will be compensated with a $20 Amazon online gift card. The e-gift card will be texted or emailed to the participant, based on their preference. The incentive will be offered to mitigate the time burden involved with filling out the survey. Please see the attached script/process for the survey (Appendix M).

For the qualitative assessment, we will offer a $25 Amazon online gift card to participating Piedmont Health employees in appreciation for their time (estimated to be 30-45 minutes). Similar to the satisfaction survey, the e-gift card will be texted or emailed to the participant, based on preference stated at the conclusion of the interview. (See Appendix P).

6. Informed Consent

Please see the attached verbal consent script (Appendix A).

7. Deception

Deception will not be used in the present study.

8. Debriefing

We do not anticipate a need for debriefing.

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INFORMED CONSENT

Appendix A

Informed Consent
Duke University
Verbal Consent Script for participation in *Balance*

After determining participant is eligible, ask the participant: "Do you have around 30 minutes now to go through study information?"

- *If YES, continue with the information below, going through bullets.*
- *If NO, ask "Are you interested in scheduling another time to go through this study information and see if you want to participate?"*
    - *If not interested, document in the database. No follow-up occurs.*
    - *If interested in scheduling another time, call back at that time and go through the script below.*

What is *Balance*?

- *Balance* is a research study. Researchers at Duke University are doing this study. The goal of the study is to find the best way to help men and women maintain their weight and take care of their health.
- *Balance* is open to men and women who are 21 years old or older and within a certain height and weight range.
- A total of 442 patients will be invited to take part in this study.

What is the reason for this information?

- We are inviting you to join *Balance.* We are working with Piedmont Health community health centers on this project.
- I will go through the information about the study and your part in it, if you decide to participate.
- Feel free to stop me and ask any questions at any time.
- If you decide to take part in the study, you are a volunteer. You can join the study now and stop later if you change your mind.
- You may quit the study at any time. If you have health insurance, your benefits won't change. Your relationship with your doctor and health center will stay the same.

What will happen if you join the study?

- If you decide to join, a computer will place you in one of two Balance programs. The computer will pick your program by chance, like flipping a coin. This is done by chance because no one knows if one program is better or worse than the other. Neither you, your doctor, or the study staff can choose the program you will be in. You will have an equal chance of being placed in either program.

  Your participation will last around two years. This includes 1 year for participation in one of the two Balance programs and around another year to access your health information from your medical record to see if the study was successful.

  If you are assigned to Program 1:

  - You will be asked to answer questions about your health and background. You can refuse to answer any questions that make you feel uncomfortable.
  - You will receive information about ways to be healthy, including training videos, materials and a pedometer to track your steps, at no charge to you. We will provide you with an electronic scale for regular weight tracking.
  - You will receive 4 health goals to work on a time.
  - Once a week, the study will call you on the phone. The calls will come from a computer and will ask you about your goals. You will answer these questions by pressing the buttons your phone. The calls will last about 2-3 minutes each.
  - You can also choose to respond to us via text messages once a week. You will answer the questions by pressing numbers on your cell phone and texting back your answers. As a reminder, you will need a cell phone for the study that can receive 3-12 text messages a week.
  - You may get text messages or phone calls from a Balance dietitian every now and then to discuss your goals and your weight and to help with any problems you might be having.
    - If you and a Balance dietitian text with each other, we will keep a record of these text messages.

  - We will ask for your permission to record the weekly computerized calls and calls with a Balance dietitian. These calls may be reviewed for quality assurance and training purposes. You may say no if you don't want these calls to be recorded.
  - A research staff member might contact you 2-3 more times.

If you are assigned to Program 2:

- You will be asked to answer questions about your health and background.You can refuse to answer any questions that make you feel uncomfortable.

- You will receive materials about how to maintain your weight and health and a pedometer to track your steps.

- You will also receive a few text messages per week for the next six months with health tips. You will not be asked to respond to these text messages.

- You will not be asked to do anything else different than what you normally do.

- You might be contacted by our research staff 2-3 more times.

What are the risks or discomforts of the study?

- The study will help you follow general health guidelines from the National Institutes of Health. The activities we ask you to do (such as walking more, eating healthy foods) have very little risk to your body.

- We may ask you to get more exercise as part of this study. You will mostly be asked to do activities, like walking, that usually do not cause injuries. However, sometimes injuries like muscle strains and sprains can happen. We will talk with you about ways to not get hurt.

- Most people do not have problems when they get more physical activity. If you have any pain from exercise, we would want you to see a doctor right away.

- If you become pregnant, we will ask you to leave the study. Changes in diet and weight may not be healthy for a baby during pregnancy.

- If study investigators think you should not continue in the study for health reasons, we will ask you to leave the study.

- If we learn of certain health-related information during the course of the study that we feel is important to share with your doctor at Piedmont Health, we will communicate that information to your doctor. That communication will be secure, private, and will not become a permanent part of your medical record.

- We have many ways to protect your privacy. The information we collect will be kept in locked files and password-protected computers at Duke University. Only research staff at Duke will be able to see the information.

- To see if this program helps you maintain your weight and improve your health, we will need to access your health information from your medical record at Piedmont Health. All of this information will be kept confidential and only authorized people who work on the study will be able to see this information. You can decide that you do not want this information shared and still receive the Balance program. If you decide later on that you do not want us to access your medical record, you can write to us and remove yourself from that part of the study.

- You can refuse to take part in any part of the study. You can also refuse to answer any questions that make you uncomfortable. You can drop out of the study at any time, and your relationship with Piedmont Health, your healthcare providers, and your health insurance will not change.

What are the benefits of taking part in the study?

- We cannot promise that you will you will not gain weight while participating in our study. But, by taking part, we hope that you will learn ways to be healthy.

- Participation in this study helps us learn more about ways to keep men and women in your community healthy.

How will my privacy be protected?

- To keep your information private, we will use code numbers on all data collected as part of the study including your surveys. We will only report information about the whole study group, not about individual people.

- During the study, we will collect personal information, including health information and contact information. This information will be encrypted and stored in a remote database. Except for information that we may share with your provider, the information we collect will be used only for this study.

- Every effort will be made to keep your information private; however, this cannot be guaranteed. The information we gather will be kept in databases on password-protected computers at Duke and within a special network folder at Duke that has extra layers of security that only study personnel can access. The information we collect will be used only for this study. Only study staff approved by the Duke Institutional Review Board (IRB) will be able to see your information. None of your data will ever be sent to third parties except as described in this consent form, with your permission, or as may be required by law.

- We realize that no data security system is completely safe, but we will take all appropriate measures to minimize the risk of violating your privacy.

- In both programs, we will communicate with you by text message. In Program 1, we will also communicate with you by phone and we will ask you to weigh yourself on a cellular-connected scale. To send and receive phone calls and text messages, and to store your study information and weights, we use companies such as Twilio, Heroku, Amazon S3, and BodyTrace. These companies will take measures to keep information safe on their servers (such as keeping the data encrypted), but no system is completely safe.

- When we talk to you on the phone, we will speak to you in a private space.

- We will destroy copies of all personal health information and other study information seven years after the date of last publication.

What will I receive if I'm in this study?

- All materials we send you (health information, pedometer, videos, etc.) will be provided at no cost to you.

- The only potential cost from participating is from your cell phone use. Depending on your cell phone plan, you might see extra charges on your bill because of text messages you send and receive, or cell phone minutes you use from speaking with us. We unfortunately will not be able to reimburse participants if these extra charges occur.

Will the study pay if there is an injury?

- If you get hurt from taking part in this study, you should contact Miriam Berger at (919-681-5829), after contacting a health professional (like first aid, your primary care provider, or emergency treatment). However, the study will not pay for the treatment. Your health insurance may be billed for the cost.

Where can I get more information?

For questions about your rights as a research participant, please call:
Chair
Duke University
Institutional Review Board
(919) 684-3030

For questions about the study, please call:

Ms. Miriam Berger
Project Coordinator
Duke University

(919) 681-5829

What does my agreement on the phone mean?

- If you agree to participate in the study:
  - You understand what will be asked of you
  - You have been given an opportunity to ask questions.
  - You agree to join the study as a volunteer

I will now read this statement out loud to you:
"I have been told about this research study and its possible benefits, risks, and discomforts. I agree to take part in this research as a subject. I know that I am free to change my mind and quit this project at any time."

Ask participant: "Do you agree with this statement?"

_____[Participant name] has been informed of the nature and purpose of the procedures described above, including any risks involved with participation in the study. He or she has been given time to ask any questions, and these questions have been answered to the best of the investigator's ability. A copy of this study information will be provided to the subject with the mailed materials.

I verbally consented this participant: [Will be documented within study database]

_____Research Assistant Name

Date _____ Time_____ am/pm

STATISTICAL ANALYSIS PLAN

Statistical Analysis Plan

Baseline variables were summarized by the intervention arm as means and SDs for continuous variables and as counts and percentages for categorical variables. We used a 2-stage modeling strategy to answer our primary hypothesis. All analyses were intent-to-treat. For the first stage, we estimated the intervention effect on weight using a constrained longitudinal linear mixed effects model, using all available data from between 18 months pre-enrollment through 30.5 months postenrollment. We explored nonlinearities for the fixed effects of time and random effects of time in the models, guided by the Bayesian Information Criterion and likelihood ratio tests. The model included fixed effects for time and interactions between time segments and intervention, with a random intercept and random slopes for time. The covariance between random effects was modeled using an unstructured covariance matrix. Randomization was stratified by CHC; thus, we adjusted for CHC in the analyses but did not adjust for other variables. Using this linear mixed effects model, we estimated mean weight change by intervention arm, and the difference between intervention arms in mean weight change, at 6, 12, 18, and 24 months.

Second, we compared the percentage of ≤3% weight gain, our primary outcome, in each arm at 24- months postrandomization using individual empirical best linear unbiased predictors (EBLUPs) from the mixed model. To ensure good predictions, we only used individual EBLUPs from participants with at least 1 EHR weight documented within a 6-month window centered on the 24-month time point (ie, between 21 and 27 months postenrollment). We compared the percentage of ≤3% weight gain in intervention and usual care arms using both a log-binomial model and linear risk model on the EBLUP output, in order to obtain both risk ratios and risk differences, which provide estimates of relative and absolute efficacy, respectively. The extra variability induced by the EBLUPs being predicted from the model was taken into account using a resampling procedure, explained further in the Multimedia Appendices 1 and 2. Sensitivity to the 21- to 27-month window was assessed by obtaining predictions after expanding the window. We additionally used EBLUPs to compare the percentage of ≤3% weight gain in each arm at 6-, 12-, and 18-months postrandomization.

Additional sensitivity analyses included adjusting the model for baseline variables imbalanced across arms, by weight measured in the primary time window ($P<.10$) and removing telehealth visits from the analysis. We also explored effect modification by adding interactions to the primary model with age tertiles; gender; BMI class; race and ethnicity; and preferred language (English or Spanish), each in a separate model. Additionally, in post hoc analyses we added the completion date of the study (pre- or post-COVID) as an effect modifier to examine the potential impact of COVID-19 on the intervention effect.