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Design, Recruitment and Start Up of a Primary Care Weight Loss Trial Targeting African American and Hispanic Adults

Shiriki Kumanyika, PhD, MPH^{a,*}, Jennifer Fassbender, MS^a, Etienne Phipps, PhD^b, Susan Tan-Torres, MD^{c,1}, Russell Localio, PhD^a, Knashawn H. Morales, ScD^a, David B. Sarwer, PhD^d, Tina Harralson, PhD^{b,2}, Kelly Allison, PhD^d, Lisa Wesby, MS^{a,3}, Ronni Kessler, MEd^{a,3}, Adam Gilden Tsai, MD, MSCE^{d,4}, and Thomas A. Wadden, PhD^d

^a Center for Clinical Epidemiology and Biostatistics, 8th Floor Blockley Hall, 423 Guardian Drive, University of Pennsylvania School of Medicine, Philadelphia, PA, USA, 19104-6021 Kumanyika (skumanyi@mail.med.upenn.edu); Fassbender (jfassben@mail.med.upenn.edu); Localio (rlocalio@mail.med.upenn.edu); Morales (knashawn@mail.med.upenn.edu); Wesby (wesby@mail.med.upenn.edu); Kessler (rsk@mail.med.upenn.edu)

^b Center for Urban Health Policy and Research, Albert Einstein Healthcare Network, 5501 Old York Road, Philadelphia, PA, USA, 19141; Phipps (phippst@einstein.edu); Harralson (tharralson@polarishealth.com)

^c Independence Blue Cross, 1901 Market Street, Philadelphia, PA USA 19103–1480 Tan-Torres (srtantorres@hotmail.com)

^d Center for Weight and Eating Disorders, 3535 Market Street, Suite 3018, University of Pennsylvania School of Medicine, Philadelphia, PA, USA, 19104; Sarwer (dsarwer@mail.med.upenn.edu); Allison (kca@mail.med.upenn.edu); Tsai (adam.tsai@ucdenver.edu); Wadden (wadden@mail.med.upenn.edu)

Abstract

Primary care offices are critical access points for obesity treatment, but evidence for approaches that can be implemented within these settings is limited. The Think Health! (¡Vive Saludable!) Study was designed to assess the feasibility and effectiveness of a behavioral weight loss program, adapted from the Diabetes Prevention Program, for implementation in routine primary care. Recruitment of clinical sites targeted primary care practices serving African American and Hispanic adults. The randomized design compares (a) a moderate-intensity treatment consisting of primary care provider counseling plus additional counseling by an auxiliary staff member (i.e., lifestyle coach), with (b) a low-intensity, control treatment involving primary care provider counseling only. Treatment and follow up duration are 1 to 2 years. The primary outcome is

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* Corresponding Author Center for Clinical Epidemiology and Biostatistics, 8th Floor Blockley Hall, 423 Guardian Drive, University of Pennsylvania School of Medicine, Philadelphia, PA, USA, 19104-6021: skumanyi@mail.med.upenn.edu; Phone: 1-215 898 2629 Fax 1-215 573-5311.

¹Present address: Community Health Collaborative, 2130 N. Palethorpe St., Philadelphia, PA USA 19122

²Present address: Polaris Health Directions, Inc.; 444 Oxford Valley Rd., Suite 300; Langhorne, PA, USA, 19047

³Present address: Division of General Internal Medicine, University of Pennsylvania School of Medicine, Blockley Hall, Philadelphia, PA, USA, 19104

⁴Present address: Division of General Internal Medicine & Center for Human Nutrition, University of Colorado Denver, Campus Box C263, North Pavilion, Room 317 Denver, Colorado, USA, 80220.

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weight change from baseline at 1 and 2 years post-randomization. Between November 2006 and January 2008, 14 primary care providers (13 physicians; 1 physician assistant) were recruited at five clinical sites. Patients were recruited between October 2007 and November 2008. A total of 412 patients were pre-screened, of whom 284 (68.9%) had baseline assessments and 261 were randomized, with the following characteristics: 65% African American; 16% Hispanic American; 84% female; mean (SD) age of 47.2 (11.7) years; mean (SD) BMI of 37.2(6.4) kg/m²; 43.7% with high blood pressure; and 18.4% with diabetes. This study will provide insights into the potential utility of moderate-intensity lifestyle counseling delivered by motivated primary care clinicians and their staff. The study will have particular relevance to African Americans and women.

Keywords

Obesity; Counseling; Female; Ethnic Groups; Office Visits; Patient Education

1. Introduction

About one- third of U.S. adults are obese (body mass index [BMI] of 30 kg/m² or above), and another third are overweight (BMI between 25 and 30 kg/m²) [1]. Obesity is clearly linked to the increased occurrence of type 2 diabetes, cardiovascular and pulmonary diseases, certain cancers, and musculoskeletal conditions [2]. Even modest weight loss may help to delay the onset or improve the management of these conditions. Given that obesity requires continuing care, there is a critical need to identify effective, sustainable treatment approaches that are available to affected adults, particularly those with obesity related co-morbidities. An expert panel has recommended that obesity treatment be offered routinely in primary care, directly or by referral [3]. However, evidence for weight loss treatment approaches that can be effectively implemented within primary care offices is lacking. Approaches that are efficacious in specialized research settings are generally not transferable. This is because the higher program intensity and delivery by expert staff, which are common elements of such treatment, are not replicable or feasible in the typical primary care office. Studies are needed to determine how typical practices might offer obesity treatment, as well as justify insurance coverage of such care [4, 5].

Studies of how to provide effective obesity treatment for African American and Hispanic primary care populations are especially lacking [3, 4] and are critically needed. African American and Hispanic adults, particularly women, have higher obesity prevalence than non-Hispanic whites [1], and this contributes to higher prevalence of obesity-related co-morbid conditions [6, 7]. For example, national data for 2007-2008 indicate that 50% of black women and 43% of Hispanic women have a BMI $\geq$ 30 kg/m², compared to 33% of white women [1]. The numbers of primary care office visits for African American and Hispanic adults are substantial, in spite of relatively lower rates of health insurance coverage [8, 9].

Recent multi-center efficacy trials of lifestyle modification for obesity have reported clinically significant weight loss results for African American and Hispanic adults [10-12], presenting an excellent opportunity for translation to practical use. The Think Health! Study addresses this opportunity. Think Health! assesses the feasibility and effectiveness of a behavioral weight loss program by adapting the Diabetes Prevention Program [12, 13] intervention for implementation in routine primary care, with a particular focus on practices reaching African American or Hispanic adults. This article reports the study design, recruitment and preparation of primary care practices, training of primary care providers and auxiliary staff to deliver the program, patient recruitment, and clinical site and patient baseline characteristics. Start-up and recruitment were completed in November 2008.

2. Materials and Methods

2.1 Study Design

2.1.1. Aim and Hypothesis—The study assesses the feasibility and effectiveness of a moderate-intensity weight loss program compared with a lower intensity version of the same program, implemented in primary care practices over 1 to 2 years. A moderate-intensity intervention is defined as providing approximately monthly treatment contacts [3]. Primary care providers (PCPs) (usually physicians) and auxiliary staff trained to act as lifestyle coaches counsel patients in their own practices. The design is a parallel group, randomized, controlled trial with 1:1 assignment of patients to treatments, stratified by practice. Weight is the primary outcome, with blood pressure and waist circumference as secondary outcomes. The hypothesis tested is that assignment to the moderate-intensity program will be associated with greater weight loss at 1 and 2 years.

2.1.2. Sample Size—The study was designed to detect differences between treatment groups in weight change (from baseline to 24 months) of >2.4 kg (approximately 2.4% of body weight) (0.8 standard deviations of weight change) with 80% power, requiring recruitment of 240 patients, assumed to be distributed evenly across several sites. This sample size was considered feasible with the resources available. A weight loss difference of >2.4% was considered adequate for inferring greater clinical utility of the moderate- vs. the low intensity treatment [2, 14] and is comparable to differences observed in prior lifestyle weight loss studies that compared two active treatments or an active treatment with usual care [15-17]. Sample size calculations assumed that at least 180 of 240 study patients (75%) would return for a final assessment visit (i.e., up to 25% loss to follow up). Due to a rolling enrollment period and fixed study end date, we assumed that two-thirds of study patients would be administratively censored earlier than 24 months after randomization. This approach to estimating power is conservative because, in the proposed analysis, patients who remain during part of the study for any length of time after baseline will contribute information and thus augment the statistical power of the study. All sample size calculations were performed by simulations specifically designed for this study and implemented in Stata v 10 (Stata Corp., College Station, TX).

2.1.3. Setting—The study was conducted in Philadelphia, Pennsylvania, a city of approximately 1.5 million with a racial/ethnic distribution that is 45% black, 47% white, < 1% American Indian, and approximately 5% Asians or Pacific Islanders. Ten percent of the population is of Hispanic ethnicity. Primary care coverage is 131 physicians per 100,000 population [18]. All study procedures were approved by the Institutional Review Boards of the University of Pennsylvania and the Albert Einstein Healthcare Network.

2.1.4. Treatments

2.1.4.1. Treatment approach and materials: The counseling program entitled: *Think Health! A Personal Weight Management Program*, or “*¡Vive Saludable! Un programa personalizado de control de peso*,” was adapted in content and approach from the Diabetes Prevention Program (DPP) lifestyle intervention [13]. DPP was a randomized controlled efficacy trial among ethnically diverse adults with impaired glucose tolerance. The behavioral counseling program was found effective in inducing a loss of 7% of initial weight and in preventing the development of Type 2 diabetes [19]. For ThinkHealth! the DPP counseling materials were modified by the research team using an approach found to be effective in a primary care pilot study [20].

Goals to be achieved over the course of the study are addressed in the first session and include a weight loss of 5% to 10% (to be achieved in the first 6 to 12 months) and 30

minutes of physical activity on five days per week. Subsequent sessions address the importance of recording calorie and fat intake, as well as physical activity; tenets of healthy eating (two sessions); benefits and strategies for increasing physical activity (two sessions); addressing negative thoughts and stimulus control (two sessions); successfully negotiating the food environment; stress management; and working with social cues for eating and exercise. Intake goals are 1200 to 1500 calories per day with 30 g of fat for participants who weigh ≤ 250 pounds and 1500 to 1800 calories daily with 40 g of fat for participants weighing > 250 pounds. A commercially available calorie counter (Calorie King™) is provided to support self monitoring of food intake. Walking or other types of aerobic activities are recommended, depending on access to equipment and individual preferences, with guidelines for increasing heart rate to a moderate level. Examples and illustrations of exercises are included in the materials, including stretching, exercise band routines, and free weight exercises. An elastic resistance band is provided to encourage strength training.

As in the DPP, materials are provided in both English and Spanish. Key topics are presented as a series of two-page handouts in a colorful, professionally-produced patient manual, with supplemental information on additional pages in the back of the manual. English language handouts were adapted from materials developed for a 6-month primary care pilot study led by two of the authors [20] and then translated into Spanish. The first 12 topics are also provided in narrated audio formats on a CD, in both languages. Materials are the same for the moderate- and low-intensity treatments.

2.1.4.2. Moderate-intensity treatment: The moderate-intensity treatment (“Basic Plus”) involves counseling by the PCP every four months and additional support sessions with a Lifestyle Coach. PCP visits, which last about 10-15 minutes, include review of obesity-related health complications and weight management topics based on the written materials. Four sessions are reviewed with the patient at each PCP visit. Lifestyle Coach counseling is offered monthly for 12 months and then bi-monthly for the remaining duration of follow up. Lifestyle coach visits, which also last 10-15 minutes, use the same written materials to provide support and motivation for adherence. The structure of lifestyle coaching sessions is as follows: 1) review of food and exercise records, as well as goals set from the previous visit; 2) delivery of the content of the session and any supplemental materials; and 3) summary and setting of goals for next session.

To facilitate long term weight management (after the first year), all patients receive a physical activity resource guide with a basic description of recommended types of activities and a locality-specific list and map of 175 relevant facilities, outdoor locations, and resources for instruction in the Philadelphia area. Participants also receive automated telephone reminders every other month during the second year to reinforce the program’s principles of weight management. Patients are provided modest compensation to offset out of pocket costs for study visits. This compensation is paid in a lump sum at the outcome data collection visits (see section 2.5.2.) and covers all study visits attended since the baseline or annual visit, as appropriate.

2.1.4.2. Low-intensity treatment: The low-intensity, comparison condition (“Basic”) provides the every-four-month PCP counseling visits but no lifestyle coach visits. Participants in this arm of the study receive the same manuals and other resources, including the automated telephone reminder calls during the maintenance phase.

2.2. Primary Care Practices

2.2.1. Eligibility—To be eligible, a practice was required to: 1) have at least one PCP interested in participating in the study; 2) identify one or more staff members to be trained

as a Lifestyle Coach; 3) agree to study administrative and logistical requirements; and 4) accept the level of financial compensation offered to the practice in return for study participation. Recruitment targeted practices that were typical of those that served the community at large, and gave priority to engaging practices with substantial numbers of African American or Hispanic patients. It was assumed that most practices would serve primarily individuals with health insurance, although practices open only to individuals with a specific type of health insurance were not considered. Prior experience with research studies was not required. Having a range of practice types and characteristics is useful for assessing program implementation and outcomes in different organizational and administrative scenarios.

2.2.2. Practice Recruitment—Local university- or hospital-affiliated primary care practices, as well as independent individual or group physician practices, were identified by investigators associated with the study (through their personal knowledge or word of mouth) and were approached about potential participation. The study was described to practices as a research project, funded by a grant from the Commonwealth of Pennsylvania, that would provide opportunities to: 1) obtain PCP and staff training in weight loss counseling approaches; 2) explore the feasibility and effectiveness of offering the program in their routine practice; and 3) offer the program to other non-study patients at their discretion once study recruitment had been completed, with additional patient materials provided at cost. Follow up of initial verbal or e-mail contacts included sending a letter and study fact sheet to the practice administrator or lead physician, with subsequent in-person meetings when the practice expressed sufficient interest. Issues discussed by study staff and practices related to practice eligibility, staffing and operating models, willingness and ability to collect data, volume of visits, demographic characteristics of patients, and financial compensation for study participation (see Table 1). Financial compensation was based on available study funds, which were described as modest and not necessarily sufficient to offset all costs. To increase feasibility, practice administrators were allowed flexibility in how study funds were used subject to their relevant institutional approvals. Compensation to practices did not include research funds reserved to reimburse study participants for out of pocket costs associated with attendance at treatment or data collection visits.

The process of recruiting practices began in November 2006 and was completed in January 2008. Practices owned by two health systems that initially expressed interest when the grant application was submitted subsequently declined participation. A new pool of 15 potential sites, including practices owned by other health systems, as well as independent practices, yielded discussions with 10, of which 6 agreed to participate. As judged by the investigators, practice or provider motivations for going forward included: awareness of the importance of obesity in their practice and wanting to offer services to their patient population; interest in enhancing their knowledge and skills about obesity and weight management; and interest in being part of a collaborative study. Practices that did not participate had unresolved concerns that staff (both physicians and office staff) would not have time to take on additional responsibilities related to the study or other, higher-level health system issues that were not discussed directly with the research team. Explicit refusals based on the level of financial compensation were not typical, although there were indirect references to factors such as inability to cover the study responsibilities without funds for additional staff.

The six sites recruited included one independent practice, two university health system practices, and three community-based practices owned by a different health care system; three were family practices and three were internal medicine practices. Two of the health care system practices merged while participant recruitment was underway and were subsequently considered as one practice, reducing the number of separate practices to five.

Four of the five practices had substantial proportions or a majority of African American patients, and one had a large proportion of Hispanic patients.

All clinical sites were asked to commit to recruiting at least 50 participants, allowing for some over-recruitment in case of shortfalls at other sites or site attrition. Once verbal agreement was reached, a memorandum of understanding outlining roles and expectations of the practice staff and research team was executed. Up to 7 months from the beginning of initial discussions was needed to obtain a memorandum of understanding. All practice staff who committed to be directly involved with the study signed these agreements. Minimal additional descriptive information about practice characteristics was subsequently collected by interview with practice administrators or staff.

2.2.3. PCP and Lifestyle Coach Recruitment and Training—Within a practice, all interested PCPs (i.e. physicians and other clinicians with primary responsibilities for patient care) were eligible to participate if they were regular staff (i.e., not medical residents). Any medical assistant or other auxiliary staff member at the practice was eligible for consideration as a Lifestyle Coach. The practices were given a list of desirable characteristics for coaches with respect to motivation, interpersonal skills, and available time and space to conduct Basic Plus visits. Research team members were directly involved in final coach selection.

PCPs and lifestyle coaches were required to complete training sessions, arranged separately at the convenience of each practice. PCP training for treatment delivery involved one 3-hour session conducted by study investigators, who were psychologists or physicians experienced in providing behavioral weight loss treatment. This session began with a presentation with the following learner objectives: 1) to understand the scope of the obesity problem in the United States; 2) to review physiological and environmental contributions to obesity; 3) to discuss the efficacy of popular diets, as well as self-help and commercial weight loss programs; 4) to review the tenets of behavioral weight loss treatment; 5) to discuss the challenges to obesity treatment in primary care practices; and 6) to review more specific clinical considerations in providing weight loss treatment in a primary care setting. This allowed the clinicians to appreciate the scope of the obesity problem, the rationale for the study and the targeted population, and the rationale behind the behavioral treatment to be provided. The patient manual was reviewed for the first four Basic sessions, with additional materials for review during the course of the study. PCPs first observed the investigators role-play delivery of sessions. PCPs then were observed while delivering a session to a fellow trainee (or to the trainer) who acted as the patient. Sample scripts were provided for the first 12 sessions.

The same trainers conducted an initial, 3-hour training for lifestyle coaches on the initial 12, monthly, brief behavioral counseling sessions. The opening presentation covered the same content areas as the PCP session, but lifestyle coaches received more specific instruction in how to deliver each counseling session. In addition, the trainers stressed the fundamentals of good counseling practices, including the importance of maintaining fidelity to the materials and being non-judgmental. Initial training focused on the first two sessions, with review of additional sessions to continue throughout the first year of treatment delivery in conjunction with discussions of patient progress, clinical concerns, and practical examples from patients being counseled.

Human subjects' research training was required for each clinician and lifestyle coach for regulatory compliance. This online training took approximately 3 hours to complete. A 1-hour logistical training session was also held with study providers to review study visit flow and visit data collection.

2.2.4. Equipment—Each practice was provided a digital scale for measuring weights at study visits (TANITA BWB-627A; 600 pound capacity; Tanita Corporation; Tokyo, Japan or Health-O-Meter® 752KL; 500 pound capacity; Pelstar, LLC; Alsip, IL). Wall-mounted stadiometers (Seca 216 Accu-Hite; Seca; Hanover, Maryland) were installed to allow the research staff to measure heights at baseline and final assessment visits. A mobile study cart was provided for storage of participant files and program materials, and as a location for practice staff to leave communications for research staff.

2.3. Recruitment of Study Participants

2.3.1. Eligibility—Eligible participants were men and women, ages 18 to 70 years, with a body mass index $\geq 27 \text{ kg/m}^2$ and $\leq 55 \text{ kg/m}^2$ who weighed $< 182 \text{ kg}$ ($< 400 \text{ lb}$). Participants with a BMI $> 55 \text{ kg/m}^2$ were excluded because they were considered likely to require a more intensive treatment approach than available in Think Health! Because of the interest in studying a representative primary care population, other exclusions were limited to those considered necessary for safety, program participation (i.e., being non-ambulatory (unable to walk one block or climb one flight of stairs without assistance)), and clear interpretation of weight loss outcomes. Exclusion criteria included: pregnancy or lactation; weight loss $> 5 \text{ kg}$ in the previous 3 months; current use of weight loss medications; use of medications known to result in significant weight gain (e.g., oral steroids or second generation antipsychotics); psychiatric disorders including untreated major depression, psychosis, bulimia nervosa, and substance abuse; active chemo- or radiation therapy; and unstable renal, hepatic, or cardiovascular disease, including malignant arrhythmias and recent (past 3 months) history of myocardial infarction, stroke, or congestive heart failure. Persons with type 2 diabetes, hypertension, hyperlipidemia, and other obesity-related conditions were eligible.

2.3.2. Referral and Prescreening—Patient recruitment began in October 2007 and was closed at the end of November 2008. Potential study participants were identified through listings from billing systems and direct referrals from providers. At the practice where all clinicians were participating, patients self-referred based on advertisements placed in the waiting or exam rooms. Listings were sampled systematically (every 10th name) to phase contact over several weeks. PCPs authorized initial contacts by signing recruitment letters. Letters were followed by eligibility pre-screening, usually by telephone, for those who could be reached. Signed PCP confirmation of potential medical eligibility was obtained for those pre-eligible after prescreening, and a baseline data collection visit was scheduled. Recruitment and retention data for each practice were used for periodic feedback and guidance.

2.3.3. Baseline Data Collection—Research staff assessed height, weight, waist circumference, and blood pressure at a scheduled in-person visit at the patient's practice. Weight (to the nearest 0.1 kg) and height (to the nearest 0.1 cm) were measured with participants wearing light clothing and shoes removed. Waist circumference was measured with a no-stretch, retractable tape (Gulick Plus II tape; Country Technologies, Gays Mills, WI) to the nearest 0.1 cm at the midpoint between highest point of the iliac crest and lowest part of the costal margin in the mid-axillary line. Blood pressure was taken with an automatic device (OMRON HEM 907XL; Omron Healthcare, Inc, Bannockburn, Illinois 60015), as the average of two readings from the right arm, using measured arm circumference to determine appropriate cuff size and with participants seated after a 5-minute rest [21].

Participants completed questionnaires for demographic and personal information, medical history, and selected psychosocial information not obtained during prior screening. Weight-

related dietary behaviors were assessed with a 30-item questionnaire for which resulting scores were correlated with weight change in a prior study of African American women [22]. Physical activity was assessed with the Paffenbarger questionnaire, which permits calculation of kilocalories expended per week based on responses to questions about walking, climbing stairs, and sport or recreational activities [23]. Social support for eating and exercise were assessed with measures developed by Sallis et al [24]. Cohen's 4-item measure was used to assess perceived stress [25]. Health related quality of life was assessed with the 8-item version of the Medical Outcomes Survey, Short Form (SF-8™ Health Survey Standard – United States (English Version 1.0))[26]. The baseline questionnaire also included the following variables potentially related to adherence: access to free or other exercise facilities and safe outdoor parks; exercise space at home; most common form of transportation; access to a car for food shopping; access to a refrigerator at work; and cooking options at home. Participants were also asked where they usually purchased food, and whether there was a farmer's market near their home. Availability and accessibility of supermarkets and affordable opportunities for physical activity were of particular interest based on evidence that these factors are less favorable in neighborhoods with a high proportion of African American and Hispanic residents [27, 28].

A food diary form and instructions also were provided to orient potential participants to self-monitoring required by the lifestyle modification program. Before randomization, any remaining medical eligibility issues were clarified with the PCP, and participants were re-contacted to review their experiences with the food diary and reconfirm willingness to be randomized.

2.3.4. Randomization—Treatment assignment to Basic or Basic Plus was implemented by the study coordinator. A randomization algorithm provided by a study biostatistician was electronically administered by assigning treatment group after key eligibility data were entered. Participants were equally allocated between treatments within each practice after suitable stratification (by site) and permuted blocks with unequal block sizes on patient-level factors (age and gender). The age cut off was <35 vs 35 years and over. This cutoff was chosen based on the potential difference in prevalence of comorbidities below and above this age. This cutoff also seemed useful in minimizing differential drop out, since a prior study indicated a higher level of drop out among younger participants [29]. This procedure facilitated balance of patient characteristics between treatment conditions while blinding both patient and staff to treatment allocations.

2.4. Treatment Monitoring and Quality Control

The study coordinator, in consultation with the medical director and other members of the research team, monitors and facilitates PCP intervention delivery and overall protocol adherence at the practices through telephone and email contacts and on-site meetings. Two PhD-level clinical psychologists, experienced in behavioral weight loss treatment, conduct monthly meetings with the lifestyle coaches at each site. During these meetings they review individual patient progress, discuss strategies lifestyle coaches can use to help patients who are having difficulty adhering to the intervention, and review upcoming sessions from the treatment protocol.

2.5. Follow up Data Collection

2.5.1. Intervention Data—Clinicians and lifestyle coaches are asked to complete the appropriate visit form after their respective counseling sessions to note what occurred at the visit. Weights are measured at all intervention visits and later extracted by research staff for transfer to the data base. Research staff track other aspects of treatment implementation and study logistics through regular chart reviews and telephone and on-site meetings.

2.5.2. Outcome Data—Research staff collect outcome data at assessment visits at each site. Follow up occurs at 1 year post randomization and again at 2 years post randomization or earlier, at the time of administrative censoring. Patient compensation, paid in conjunction with the data collection visit, includes compensation for all treatment visits attended up to that time. Measurements include weight, height (final visit only), waist circumference, and blood pressure. Questionnaires update health and medical status, the aforementioned psychosocial variables, and recent (past 6 months) life changes related to work, home and family, financial, or personal and social factors, and elicit feedback about the treatment process.

2.5.3. Feasibility and Implementation—Intervention dose delivered will be assessed as attendance at treatment visits by site, patient, PCP and, where applicable, by lifestyle coach. Treatment delivery assessment for the maintenance phase will include patient-specific data for number of completed automated telephone calls. Qualitative data will include field notes on implementation, administrative and staff changes within or affecting the practices, quality control, and problem solving. Closeout interviews with PCPs, lifestyle coaches and administrative staff will assess their reactions to participation in the study, perceived strengths and weaknesses of the program, suggestions for program modification, and plans to continue offering the program.

2.6. Data Management and Statistical Analysis

The data management system consists of a centralized, custom-designed Oracle database with distributed web-based data entry. All data are collected on paper forms and entered manually. Research staff collect PCP and lifestyle coach intervention process forms from each practice site at least weekly. They directly complete or obtain case report forms when they conduct outcome data collection visits.

Statistical analyses are performed in SAS (v 9.2), Stata (v 11) and R (v 2.6). Our general analytic approach reflects the longitudinal, repeated measures, parallel group multi-site design. This design, with a baseline measurement and up to 6 follow-up periods per person for the principal endpoint (weight, obtained at 4, 8, 12, 16, 20, and 24 months intervention or assessment visits), allows for comparisons within individuals over time, as well as across individuals (within or across treatment groups). All patients will be analyzed initially according to the treatment to which they were randomized. Thus, if patients drop out and are still followed, they will continue to be analyzed by initial treatment assignment [30].

The main analyses will compare observed or modeled weight losses at 12 months and 24 months between treatment groups. To allow for different trajectories of weight loss and gain and to afford flexibility in making contrasts within patients over time and across patients, while simultaneously controlling for potential confounding factors, we will use a person-specific, mixed effects linear model. With this approach, the mean response (weight, for example) depends on the covariates of interest (treatment assignment, patient characteristics) and the random effect represents the unobserved factors that lead to variation of the individual's weight from the mean. Random effects for each individual (random intercepts) permit modeling of natural variation across individuals at baseline in their weight or other physical measurements or responses. Random "slopes" for the trajectory of each individual's weight over time, allow for variation of each individual around a mean for all individuals. Although less robust to model misspecification, when dropout and missed visits lead to unbalanced groups, this model has fewer assumptions about missing data than do alternatives.

Missing weight data may occur because a participant leaves the study or does not attend treatment or measurement visits at which weights are taken. When this occurs, the use of

non-study related medical record weights will be evaluated by comparing such weights with study weights taken around the same time period. Mixed effects models for longitudinal data analysis assume missingness at random, and they use all available data, including the weight change in early months from those subjects who eventually dropped out. Sensitivity analyses will be performed to estimate the potential impact of missing data on overall program success assuming that those with no weight measurements were faring worse than those who remained in the program [31]. Sensitivity analyses to estimate the effect of the intervention if subjects adhere fully to the program of regular visits with clinicians and life-style coaches will be implemented using methods of instrumental variables [32]. The target of inference is the person-specific response to treatment over time [33-35].

As is standard for multi-site trials, primary care practice site will be treated as a fixed effect. Effect modification at the site level will be estimated to compensate for the effects of unobserved site-level factors that explain treatment success over time.

3.0. Results

3.1. Participating Practices and Providers

Table 2 shows selected characteristics of the five practices, including numbers and gender of participating providers. There was a mix of small, medium, and large practices based on number of clinicians, total staff size, or estimated patient volume, with length of operation varying from 4 to 43 years. Across all sites approximately half (14 of 27) of eligible clinicians participated in the study; both eligible clinicians participated at 1 site. Participating clinicians were evenly divided by gender. Practices identified one to four lifestyle coaches, all female.

The total time needed to complete start up (defined as having fully trained study PCPs and lifestyle coaches eligible to counsel the first participant) with 5 practices spanned 15 months. Within practices, the time from initial discussions to start up ranged from 4.5 to 12 months.

3.2. Participant Recruitment and Baseline Characteristics

A total of 261 participants was recruited, 21 more than the targeted sample size. As shown in Table 2, some practices exceeded and some did not attain the 50-per-site target. Participant flow from eligibility prescreening through randomization is shown in the Figure. Of the 412 individuals prescreened, 69% (284 of 412) were further screened for eligibility, of whom 92% (261 of 284) were randomized. Of the other 23, 19 were ineligible, and 4 were no longer interested. Allocation to Basic Plus was 46% to 49% across sites (site-specific data not shown) and 48% overall (124 of 261). Table 3 shows baseline participant characteristics. Eighty-one percent of participants were African American or Hispanic and 84% were female. The mean BMI was 37.2 kg/m². High blood pressure and diabetes were the most common chronic conditions. About a third of participants reported low activity levels, and about one-fifth reported being very active.

4.0. Discussion

The hybrid design of the Think Health! Study combines objectives that prioritize internal validity (as in efficacy studies) with those that explore feasibility and give more priority to external validity and potential sustainability (as in effectiveness studies) [36, 37]. This type of trial is a useful precursor to a practical trial that would require full adoption and institutionalization within primary care settings. Clinical site recruitment focused on community-based practices, most of which had little previous involvement in research or in lifestyle change research. The five participating practices included the two major primary

care specialties (internal medicine and family medicine) and were also diverse with respect to organizational structures, size, and longevity. Targeting African Americans and Hispanics at the practice level, and emphasizing the importance of including these groups from a research perspective, was effective; 81% of randomized participants were members of one of these two groups. The percent of male participants recruited was lower than desired for generalizability. Men are typically underrepresented in weight loss programs [3], and men make fewer visits than women to primary care physicians [38]. Hypertension, the most common obesity-related comorbidity in our sample, is also the most common diagnosis associated with primary care visits [38].

The major study challenge in the start-up phase was the time needed to complete the process of negotiating participation agreements for the required number of sites. Ellis and colleagues, based on analyses of yield and cost associated with 10 strategies used to recruit primary care practices to a randomized trial related to cardiovascular disease risk factor management, reported that in-person meetings and previous relationships were the most cost efficient [39]. These are essentially the strategies that we used, but the time needed for the decision making process at practices was quite extended, except for the independent practice, in which all decisions were made within the practice itself. This delay may raise a crucial issue for lifestyle change interventions in primary care, for which the time commitment of clinicians and involved ancillary staff is presumably greater than for pharmacologic interventions. The compensation we offered was sufficient for some incentives for existing staff, but not enough to allow practices to increase their staff.

The legislation authorizing the Think Health! study funding required that all project funds be used within 4 years. The delay in beginning patient recruitment required that the protocol be revised to allow for administrative censoring as early as 16 months post randomization, rather than follow all participants for 24 months as originally intended. Once underway, patient recruitment was completed in a timely manner. Advertising the study practice-wide (e.g., in waiting and exam rooms) might have shortened the time needed for patient recruitment. However, in Think Health! this was only appropriate for the site in which both clinicians were engaged in the study.

In conclusion, studies to identify effective models for obesity treatment in primary care offices are generally lacking and are especially needed for ethnic minority adults who, on average, have a higher risk of obesity-related chronic diseases than whites [6, 7]. A systematic review of randomized controlled trials in which behavioral weight loss interventions were provided in primary care identified only 10 qualifying RCTs [4]. Four studies were based on brief PCP lifestyle counseling without adjunctive medication, of which one involved primarily African Americans (low-income women) [40] and one included 50% Latinos with type 2 diabetes [41]. The logistical and feasibility aspects of studies conducted in natural settings such as primary care practices differ from those in studies in which researchers maintain control over the process and alter natural settings to align with research needs. The Think Health! study is designed to determine what might be possible when a simplified version of the Diabetes Prevention Program lifestyle intervention is delivered individually to primary care patients with minimal departures from an approach that is potentially replicable in usual care settings that reach high risk ethnic minority adults.

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NON-STANDARD ABBREVIATIONS

PCP	Primary Care Provider
PA	Physician Assistant

References

- [1]. Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among US adults, 1999–2008. *JAMA*. 2010; 303:235–41. [PubMed: 20071471]
- [2]. Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults--The Evidence Report. National Institutes of Health. *Obes Res*. 1998; 6(Suppl 2):51S–209S. [PubMed: 9813653]
- [3]. Screening for obesity in adults: recommendations and rationale. *Ann Intern Med*. 2003; 139:930–2. [PubMed: 14644896]
- [4]. Tsai AG, Wadden TA. Treatment of obesity in primary care practice in the United States: a systematic review. *J Gen Intern Med*. 2009; 24:1073–9. [PubMed: 19562419]
- [5]. Tsai AG, Asch DA, Wadden TA. Insurance coverage for obesity treatment. *J Am Diet Assoc*. 2006; 106:1651–5. [PubMed: 17000198]
- [6]. Must A, Spadano J, Coakley EH, Field AE, Colditz G, Dietz WH. The disease burden associated with overweight and obesity. *Jama*. 1999; 282:1523–9. [PubMed: 10546691]
- [7]. Smith SC Jr, Clark LT, Cooper RS, Daniels SR, Kumanyika SK, Ofili E, et al. Discovering the full spectrum of cardiovascular disease: Minority Health Summit 2003: report of the Obesity, Metabolic Syndrome, and Hypertension Writing Group. *Circulation*. 2005; 111:e134–9. [PubMed: 15769755]
- [8]. Schappert SM, Rechtsteiner EA. Ambulatory medical care utilization estimates for 2006. *Natl Health Stat Report*. 2008;1–29. [PubMed: 18958997]
- [9]. Ferrer RL. Pursuing equity: contact with primary care and specialist clinicians by demographics, insurance, and health status. *Ann Fam Med*. 2007; 5:492–502. [PubMed: 18025486]
- [10]. Wadden TA, West DS, Neiberg RH, Wing RR, Ryan DH, Johnson KC, et al. One-year weight losses in the Look AHEAD study: factors associated with success. *Obesity (Silver Spring)*. 2009; 17:713–22. [PubMed: 19180071]
- [11]. Hollis JF, Gullion CM, Stevens VJ, Brantley PJ, Appel LJ, Ard JD, et al. Weight loss during the intensive intervention phase of the weight-loss maintenance trial. *Am J Prev Med*. 2008; 35:118–26. [PubMed: 18617080]
- [12]. West DS, Prewitt T Elaine, Bursac Z, Felix HC. Weight loss of black, white, and Hispanic men and women in the Diabetes Prevention Program. *Obesity (Silver Spring)*. 2008; 16:1413–20. [PubMed: 18421273]
- [13]. The Diabetes Prevention Program (DPP): description of lifestyle intervention. *Diabetes Care*. 2002; 25:2165–71. [PubMed: 12453955]
- [14]. Dattilo AM, Kris-Etherton PM. Effects of weight reduction on blood lipids and lipoproteins: a meta-analysis. *Am J Clin Nutr*. 1992; 56:320–8. [PubMed: 1386186]
- [15]. Martin, P Davis; Rhode, PC.; Dutton, GR.; Redmann, SM.; Ryan, DH.; Brantley, PJ. A primary care weight management intervention for low-income African-American women. *Obesity (Silver Spring)*. 2006; 14:1412–20. [PubMed: 16988084]
- [16]. Mayer-Davis EJ, D'Antonio AM, Smith SM, Kirkner G, Martin S Levin, Parra-Medina D, et al. Pounds off with empowerment (POWER): a clinical trial of weight management strategies for black and white adults with diabetes who live in medically underserved rural communities. *Am J Public Health*. 2004; 94:1736–42. [PubMed: 15451743]

- [17]. Womble LG, Wadden TA, McGuckin BG, Sargent SL, Rothman RA, Krauthamer-Ewing ES. A randomized controlled trial of a commercial internet weight loss program. *Obes Res.* 2004; 12:1011–8. [PubMed: 15229342]
- [18]. Community Health Status Report for Philadelphia County Pennsylvania. 2008.
- [19]. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002; 346:393–403. [PubMed: 11832527]
- [20]. Tsai AG, Wadden TA, Rogers MA, Day SC, Moore RH, Islam BJ. A primary care intervention for weight loss: results of a randomized controlled pilot study. *Obesity (Silver Spring).* 2010; 18:1614–8. [PubMed: 20019680]
- [21]. Perloff D, Grim C, Flack J, Frohlich ED, Hill M, McDonald M, et al. Human blood pressure determination by sphygmomanometry. *Circulation.* 1993; 88:2460–70. [PubMed: 8222141]
- [22]. Anderson CA, Kumanyika SK, Shults J, Kallan MJ, Gans KM, Risica PM. Assessing change in dietary-fat behaviors in a weight-loss program for African Americans: a potential short method. *J Am Diet Assoc.* 2007; 107:838–42. [PubMed: 17467382]
- [23]. Paffenbarger RS Jr, Wing AL, Hyde RT. Physical activity as an index of heart attack risk in college alumni. *Am J Epidemiol.* 1978; 108:161–75. [PubMed: 707484]
- [24]. Sallis JF, Grossman RM, Pinski RB, Patterson TL, Nader PR. The development of scales to measure social support for diet and exercise behaviors. *Prev Med.* 1987; 16:825–36. [PubMed: 3432232]
- [25]. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav.* 1983; 24:385–96. [PubMed: 6668417]
- [26]. QualityMetric Incorporated. Health Survey. <http://www.sf-36.org/tools/sf8.shtml> Copyright © 1998, 1999
- [27]. Powell LM, Slater S, Mirtcheva D, Bao Y, Chaloupka FJ. Food store availability and neighborhood characteristics in the United States. *Prev Med.* 2007; 44:189–95. [PubMed: 16997358]
- [28]. Powell LM, Slater S, Chaloupka FJ, Harper D. Availability of physical activity-related facilities and neighborhood demographic and socioeconomic characteristics: a national study. *Am J Public Health.* 2006; 96:1676–80. [PubMed: 16873753]
- [29]. Kumanyika SK, Shults J, Fassbender J, Whitt MC, Brake V, Kallan MJ, et al. Outpatient weight management in African-Americans: the Healthy Eating and Lifestyle Program (HELP) study. *Prev Med.* 2005; 41:488–502. [PubMed: 15917045]
- [30]. Ellenberg JH. Intent-to-treat analysis versus as-treated analysis. *Drug Information J.* 1996; 30:535–44.
- [31]. Pauler DK, McCoy S, Moynour C. Pattern mixture models for longitudinal quality of life studies in advanced stage disease. *Stat Med.* 2003; 22:795–809. [PubMed: 12587106]
- [32]. Joffe MM, Ten Have TR, Brensinger C. The compliance score as a regressor in randomized trials. *Biostatistics.* 2003; 4:327–40. [PubMed: 12925501]
- [33]. Carlin JB, Wolfe R, Brown CH, Gelman A. A case study on the choice, interpretation and checking of multilevel models for longitudinal binary outcomes. *Biostatistics.* 2001; 2:397–416. [PubMed: 12933632]
- [34]. Fitzmaurice, GM.; Laird, NM.; Ware, JH. *Applied Longitudinal Analysis.* John Wiley & Sons; New York: 2004.
- [35]. Diggle, PJ.; Heagerty, PJ.; Liang, K-Y.; Zeger, SL. *Analysis of Longitudinal Data.* 2nd ed. Oxford University Press; Oxford, England: 2002.
- [36]. Glasgow RE. What types of evidence are most needed to advance behavioral medicine? *Ann Behav Med.* 2008; 35:19–25. [PubMed: 18347901]
- [37]. March JS, Silva SG, Compton S, Shapiro M, Califf R, Krishnan R. The case for practical clinical trials in psychiatry. *Am J Psychiatry.* 2005; 162:836–46. [PubMed: 15863782]
- [38]. Cherry DK, Hing E, Woodwell DA, Rechtsteiner EA. National Ambulatory Medical Care Survey: 2006 summary. *Natl Health Stat Report.* 2008; 1–39. [PubMed: 18972720]

- [39]. Ellis SD, Bertoni AG, Bonds DE, Clinch CR, Balasubramanyam A, Blackwell C, et al. Value of recruitment strategies used in a primary care practice-based trial. *Contemp Clin Trials*. 2007; 28:258–67. [PubMed: 17030154]
- [40]. Martin PD, Dutton GR, Rhode PC, Horswell RL, Ryan DH, Brantley PJ. Weight loss maintenance following a primary care intervention for low-income minority women. *Obesity* (Silver Spring). 2008; 16:2462–7. [PubMed: 18787526]
- [41]. Christian JG, Bessesen DH, Byers TE, Christian KK, Goldstein MG, Bock BC. Clinic-based support to help overweight patients with type 2 diabetes increase physical activity and lose weight. *Arch Intern Med*. 2008; 168:141–6. [PubMed: 18227359]

Figure 1.
Flow of patient recruitment from prescreening through randomization

Table 1

Issues considered during recruitment of primary care practices

Issue	Topics Covered and Relevance to Practice Recruitment
Practice eligibility	Whether involved in a similar intervention (would disqualify practice) Significant number of African American or Hispanic patients (highly desirable) Clinicians see patients six days per week (highly desirable) Primary language spoken to patients in the practice (English or Spanish required) Clinicians or staff speak Spanish (highly desirable at practices with Hispanic patients)
Feasibility of implementation at practice level	Number and type of medical staff (i.e., MD, DO, RN, PA ^a) (descriptive) Practice hours (adequacy and flexibility for scheduling study visits) Volume of weekly visits overall and by clinician (adequacy to support study needs) # of patient visits Location of the practice (access by patients and research staff) Space layout of the practice (to accommodate lifestyle coach visits) Patient contact preferences (by mail, phone, or e-mail) Record keeping methods (electronic or otherwise; ability to incorporate study documentation) Availability of fax machine and copier (for study-related forms) Ability to work within available financial compensation
Feasibility of implementation at PCP level	Counseling schedule; willingness and ability to fit Primary Care Provider (clinician) visits into existing schedule # of clinicians who would offer counseling for Think Health! Clinician prior research experience Requirements for training in study implementation and research with human subjects
Basic Plus Implementation	Administrative and logistical challenges in implementing the Basic Plus counseling Requirements for Lifestyle Coaches; ability to identify staff (e.g., medical assistant) to be trained as Lifestyle Coaches Requirements for Lifestyle Coach training in study implementation and research with human subjects
Participant recruitment and treatment	Expectation to recruit and counsel at least 50 eligible patients Proposed recruitment methods Length of recruitment period
Data Collection	Willingness to complete data collection forms and take weight measurements at each study visit
Language	Need for written materials in English or Spanish Perceived need for audio-narrated counseling material
Community Resources	Local community resources that would be valuable for patients to utilize, i.e. fitness center, grocery store

^aPA = physician assistant

Table 2

Characteristics of participating primary care practices

Practice Identifier	Primary Care Providers (Potential clinicians)		Other practice staff (Potential Lifestyle Coaches)		Estimated size of practice (volume of patients)	Years in operation ^c	Individual Participant Recruitment	
	Total Eligible PCPs ^a	# in study Total [# males/ # females]	Total other staff eligible	# in study ^b			# randomized ^d	Recruitment duration (months)
A	5	2 [0/2]	17	1	~7000	7	52	5
B	11	5 [2/3]	19	4	~6000	17	66	9.5
C	5	3 [2/1]	14	2	~4000	12	65	8.5
D	2	2 [2/0]	4	2	~2000	43	41	9.5
E	4	2 [1/1]	9	1	<2000	4	37	10

^a 2 of the eligible clinicians were nurse practitioners and 1 was a physician assistant; other eligible clinicians were MDs or DOs

^b All staff identified as Lifestyle Coaches were female

^c At the start of clinical site recruitment in 2006

^d All sites were asked to recruit at least 50 participants

Table 3

Baseline characteristics of randomized participants overall and by treatment arm

Variable	Total Sample n= 261)
Race/ethnicity (%)	
-White	18
-African American	65
-Hispanic/Latino	16
-Asian	1
Age (years) ^a	47.2 ± 11.7
> 12 yrs education (%)	69.4
Female (%)	84.3
Married (%)	44.4
Current smoker (%)	17.6
Current alcohol drinker (%)	33.0
Self-rated health (%)	
- excellent or very good	14.6
- fair or good	75.1
- poor or very poor	10.3
Physical activity level (%)	
- low (<500kcal/week)	36.2
- moderate (500 to 1999 kcal/week)	40.8
- high (2000+ kcal/week)	23.1
Reported history of:	
- Cardiovascular disease	9.2
- High blood pressure	43.7
- Respiratory problems	1.9
- Diabetes	18.4
- Musculoskeletal problems	14.9
Weight (kg) ^a	101.2 ± 19.9
BMI (kg/m ²) ^a	37.2 ± 6.4
Waist circumference (cm) ^{a*}	111.4 ± 15.1
Diastolic blood pressure ^a	74.3 ± 10.3
Systolic blood pressure ^a	119.2 ± 15.5

^a mean ± SD

* n=195; not measured for the first 66 participants