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The Lifestyle Intervention for the Treatment of Diabetes Study (LIFT Diabetes): design and baseline characteristics for a randomized translational trial to improve control of cardiovascular disease risk factors

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Abstract

The prevalence of type 2 diabetes continues to increase in minority and underserved patients, who are also more likely to have poorer control of diabetes and related risk factors for complications. Although The Look AHEAD trial has demonstrated improved risk factor control among overweight or obese diabetes patients who received an intensive lifestyle intervention, translating such findings into accessible programs is a major public health challenge. The purpose of this paper is to report the design and baseline characteristics of the Lifestyle Interventions for the Treatment of Diabetes study (LIFT Diabetes). The overall goal is to test the impact of a community-based lifestyle weight loss intervention (LWL) adapted from Look AHEAD on cardiovascular disease risk at 12-months and 24-months among minority and lower income diabetes patients. Secondary outcomes include body weight, physical activity, medication use, cost, resource utilization, and safety. The primary hypothesis being tested is that the LWL will result in 10% relative reduction in CVD risk compared to the DSM. We have randomized 260 overweight or obese adults with diabetes one of two 12-month interventions: a LWL condition delivered by community health workers or a diabetes self-management education (DSM)

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condition. The baseline demographic characteristics indicate that our sample is predominantly female, obese, low income, and ethnic minority. Translating evidence-based, lifestyle strategies, and targeting minority and underserved patients, will yield, if successful, a model for addressing the burden of diabetes and may favorably impact health disparities.

Keywords

diabetes; lifestyle; weight loss; cardiovascular disease risk

1. Introduction

The prevalence and incidence of Type 2 diabetes mellitus (T2D) has increased dramatically in recent years [1, 2]. Approximately 29.1 million US adults, representing 9.3% of the population, have T2D and 1.7 million additional patients are diagnosed yearly [3]. The burden of T2D is particularly high for racial/ethnic minorities. From 2008–2012, the incidence rates among non-Hispanic black and Hispanic adults increased at rates significantly greater than for non-Hispanic white adults [2]. Furthermore, ethnic minorities also have a higher incidence of many diabetes-related complications [4–8]. These complications can be reduced or delayed by intensive management of glycated hemoglobin (A1C), blood pressure (BP), and lipids [9]. Unfortunately, control of risk factors and complications among adults with T2D is suboptimal [10, 11], particularly among minority and underserved patients [12, 13].

Diabetes self-management education (DSME) and lifestyle changes are integral components of successful care for individuals with T2D [14]. The Action for Health in Diabetes (Look AHEAD) study tested the impact of an intensive lifestyle intervention program (ILI) on incident cardiovascular disease (CVD) compared to a control condition of diabetes support and education (DSE) in 5145 overweight and obese adults with T2D [15]. Over the course of more than 9 years of follow-up, participants randomized to ILI lost more body weight (−4 kg); reduced waist circumference (−3.2 cm); and reduced glycated hemoglobin (−0.22%) as compared to those in DSE [15]. Additionally, the improvements in risk factors led to a reduction in estimated 10-year CVD risk of 15% [16]. This was achieved with lower use of medical services and medications and, over 10 years, the healthcare cost savings in the ILI group was $5,280 [17]. Despite these benefits, there were no between group differences in incident CVD. However, the trial demonstrated several, long-term health benefits resulting from lifestyle weight loss in adults with T2D. Unfortunately, numerous barriers to widespread dissemination of lifestyle weight loss interventions exist, particularly for minority and underserved populations [18–20].

To address both cost and community level barriers to access to behavioral weight loss programs, the Healthy Living Partnerships to Prevent Diabetes (HELP PD) study [21] tested a community-based translation of the Diabetes Prevention Program (DPP) [22]. HELP PD involved the partnering of a Diabetes Education Program (DEP) with community health workers (CHWs) in the delivery of a group-based lifestyle intervention. HELP PD randomly assigned 301 overweight and obese adults with pre-diabetes to a 24-month lifestyle weight

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loss intervention (LWL) or an enhanced usual care (UC) condition. LWL participants experienced significantly greater decreases in fasting glucose, insulin, body weight, and waist circumference than the UC participants at 2 years [23]. HELP PD exceeded the average effects found across all DPP translational studies [24] with direct costs at about one-third of the DPP intervention ($850 vs. $2631) [25]. It is unknown whether this community-based model would be an effective method to deliver a lifestyle intervention for adults with T2D. The Lifestyle Intervention for Treatment of Diabetes (LIFT Diabetes) was designed to address this uncertainty in a diverse sample.

2. Primary Research Goals

LIFT Diabetes seeks to determine whether an adaptation of the lifestyle weight loss intervention (LWL) developed in Look AHEAD implemented using the community-based delivery model developed by HELP PD can improve CVD risk factor control, compared to a group-based DSME intervention based on the American Association of Diabetes Educators seven self-care behaviors [26] that target glycemic control. Because both arms might be expected to improve glycemic control as well as impact other CVD risk factors such as blood pressure and lipids, we selected a composite endpoint, the United Kingdom Prospective Diabetes Study (UKPDS) estimated CVD risk score [27]. The design was also influenced by our goals to recruit a diverse sample, the knowledge that DSME can improve diabetes control, and the desire to offer an alternative intervention to participants.

The primary hypothesis of LIFT Diabetes is that a lifestyle weight loss intervention (LWL) that is administered and delivered through community-based resources will have beneficial and clinically relevant impact on UKPDS-estimated CVD risk at 12 and 24 months. Secondary endpoints include individual risk factor control, body weight, physical activity, medication use, safety measures, and process measures (adherence, knowledge). LIFT Diabetes will also examine the costs and resource utilization associated with delivering both interventions.

3.Study Design

3.1. Overview

A total of 260 participants with T2D diabetes have been recruited over a 21-month recruitment period (June 2013 to March 2015) and randomized to either a CHW-led LWL or a clinic-based DSM group. Our comparison intervention is an enhanced version of standard care involving 12-months of monthly group contact facilitated by a professional health educator and is designed to exceed the usual care provided in normal clinical practice. DSM participants also receive two additional individual contacts with the study health educator. The LWL intervention has been adapted from HELP PD and Look AHEAD and was designed to produce modest yet achievable (≥7%) weight loss through healthy eating and alterations in energy balance. LWL sessions are conducted in group format and facilitated by CHWs. The contact schedule involves 2 phases, with an intensive phase (1 group session per week) and a 6-month maintenance phase (1 group session per month). Follow-up data collection of primary and secondary outcomes occurs at 12 and 24-months. Medical history,

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medications, resource use, and adverse events are collected at baseline, 6, 12, 18, and 24 months.

3.2. Eligibility

The objectives guiding the selection of the eligibility criteria were to obtain a sample of participants that: a) had diagnosed diabetes; b) had no medical contraindications to participate in a lifestyle intervention that included unsupervised physical activity and weight loss; and c) was free from existing cardiovascular disease (see Table 1 for a complete list of eligibility criteria). We also sought to recruit a sample that was at least 50% ethnic minority. Our eligibility criteria are modeled after Look AHEAD. However, due to the translational nature of this study, as well as design features including the use of CHWs, LIFT included several important changes. LIFT includes all adults aged 21 or over with no upper age limit. We also did not include an upper BMI limit. Many advocate weight loss surgery for patients with BMI>40 kg/m^2, however patients typically must first demonstrate they can comply with dietary changes and lose weight prior to surgery. We accepted all classes of obesity provided participants met other criteria. We excluded those with CVD due to safety considerations, as the intervention would be largely delivered by CHWs. We utilized the American Diabetes Association's (ADA) 2010 criteria to identify potentially eligible individuals with type 2 diabetes mellitus [28], however, these patients must first have had a primary care physician (PCP) initiate treatment. We excluded those with poor control of risk factors for cardiovascular disease (Table 1) as such individuals urgently need enhanced pharmacologic approaches and/or determination if compliant with prescribed regimens. Pregnant women and/or nursing mothers were excluded because weight loss in the setting of pregnancy or breast-feeding is not advised, and T2D management in pregnancy is complex. Other exclusion criteria (Table 1) were designed to limit participation by those unable or unwilling to give informed consent, participate in the interventions, or remain active participants for two years.

3.3. Recruitment

Participant recruitment was organized in four phases: i) identification of potentially eligible individuals; ii) completing a telephone screen to assess initial eligibility; iii) completing a clinic screening visit to assess final eligibility; and iv) completing a baseline visit and eventual randomization. The primary recruitment source was the electronic medical record system of Wake Forest Baptist Health in Winston Salem, North Carolina, supplemented by direct referrals, media advertisements and community health screenings. The overall recruitment yield was 23.6% (30.2% for whites and 21.4% for African Americans/blacks). Details about the recruitment process, recruitment yield and associated costs are reported elsewhere (Effoe et al., In review).

3.4. Informed Consent

The LIFT Diabetes protocol and consent forms were approved by the institutional review board (IRB) of the Wake Forest School of Medicine prior to the start of recruitment. To comply with the guidelines of the Health Insurance Portability and Accountability Act (HIPAA), a limited waiver to access medical records was also approved by the IRB. A

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signed informed consent, including HIPAA authorization, was obtained from all participants prior to the screening process.

3.5. Randomization

Eligible participants were randomly assigned to either the LWL or the DSM arm using a web-based data management system that verifies eligibility and utilizes a variable block length randomization paradigm that was not stratified. SAS 9.3 was used to conduct the random allocation. Neither the participants nor the data collectors were masked to treatment assignment.

3.6. Measures

LIFT assessments were modeled after Look AHEAD to facilitate comparison. Assessments of primary and secondary outcomes are performed at baseline, 12-, and 24-months post-randomization. Psychosocial measures were self-administered and trained study staff completed the remaining measures.

3.6.1. Clinical and Laboratory Measures—All clinical and biochemical measurements were obtained by trained technicians. Weight was measured to the nearest 0.1 lb using a digital scale (Tanita WB-100A Class III). Two measurements of weight were obtained at each study visit and the average of the two was used. Height was measured once at baseline to the nearest 0.1 inch using a wall-mounted height rod (Tanita HR-200). Waist circumference was measured to the nearest 0.1 cm at each study visit at the level of the umbilicus with the participant in the upright position. Two initial measurements were obtained, and if the difference was > 0.5 cm, a third measurement was obtained. The average of the two measurements was used. Seated blood pressure was measured after at least 15 minutes of rest at the arm using a digital blood pressure monitor (OMRON Intelli^{TM} sense HEM-907XL). Two readings were obtained with a one-minute interval between the two. The average of both readings was used.

A blood sample was collected on all participants after an overnight fast of at least eight hours. All biochemical measurements were performed by LabCorp using a Roche Cobas C701 analyzer. Serum glucose, total cholesterol, triglycerides and HDL-cholesterol were analyzed by enzymatic method. Serum creatinine was analyzed by the Kinetic Jaffe method. A1C is analyzed on EDTA whole blood by the Roche Tina Quant method. Serum LDL-cholesterol and VLDL-cholesterol were calculated.

3.6.2. Costs—The use of medical resources (i.e. number and type of hospitalizations, ambulatory visits, medications, procedures) and participants' time spent in shopping, cooking and exercising is assessed from participants' self-report by forms completed at 6-month intervals. The cost per type of hospitalization, outpatient encounter, etc. will be estimated using available US data and aggregated to estimate total direct medical costs for each intervention arm. The costs of the intervention will be estimated by periodic reports of clinic time spent by staff on the intervention. Other costs not recorded by participants or interventionists, such as personnel and medical tests, are recorded and maintained by the project manager. In addition to direct medical costs, the project manager will estimate

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selected indirect costs. The methods being used here have been adapted from Look AHEAD [29].

3.6.3. Health Behaviors and Physical Activity—Participants reported on their weight control practices, physical activity, and use of tobacco and alcohol and frequency of self-monitoring blood glucose at baseline, year 1, and year 2. Measures of weight control practices, tobacco use, alcohol, and frequency of self-monitoring of blood glucose were adapted from Look AHEAD [29]. Physical activity is assessed using a modified version of the International Physical Activity Questionnaire (IPAQ) short form, an internationally reliable and valid 7-item instrument for assessing physical activity during the seven days prior to administration of the survey. [33].

3.6.4. Quality of Life—The SF-36 [34] is a generic measure of health status/health-related quality of life that consists of two norm-based composite T-scales, mental health and physical function, and 8 subscales: physical functioning, mental health, role-physical, role-emotional, bodily pain, general health, vitality, and social functioning. There has been extensive data published in support of the psychometric properties of this instrument [34]. This measure has been used in the study of obese persons [35] and has been found to be sensitive to physical activity and dietary interventions [36]. The Satisfaction with Life Scale (SWL) [37] is also used to assess participants' global cognitive evaluation of satisfaction with life (5 items). This measure has been widely used in a variety of contexts, including cross-cultural analyses, and has excellent psychometric properties [38]. These measures are completed at baseline and months 12 and 24.

3.6.5. Psychosocial process measures—Four brief measures based on social cognitive theory [39] are measured at baseline,12 and 24 months. These are: 1) barriers efficacy for physical activity [40] and weight loss,[41] 2) task efficacy related to specific physical capacities, weight loss [42], and diabetes self-management, 3) satisfaction with physical function and body appearance [43], and 4) the desire to be physically competent and to lose varying percentages of weight [44].

3.6.6. Quality Adjusted Life Years (QALYS)—QALYs is measured with two instruments at baseline,12 months and 24 months. The EuroQol Feeling Thermometer is a visual analog scale that assesses participant's perception of their current health status. The Health Utilities Index (HUI) [45] is a generic preference-based systems for measuring comprehensive health status and health-related quality of life (HRQL). HUI scoring functions are based on preference measurements from random samples of the general population and are appropriate for calculating quality-adjusted life years (QALYs) in cost-effectiveness and cost-utility analyses.

3.6.7. Technology use—At baseline, participants will be asked questions about use of technology to assist with diabetes/medical care/weight management practices, including the internet, personal health portal, smartphones, and social media [29].

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3.7. Interventions

3.7.1. Aspects common to both study arms—Participants attended a one-hour individual visit with a study interventionist following randomization and prior to the start of the intervention. This session provided basic education about diabetes, with particular emphasis on aspects of diabetes care related to the trial such as management of hypoglycemia and cardiovascular disease symptoms. Participants at risk of hypoglycemia were encouraged to use blood glucose self-monitoring equipment. Study interventionists stressed the importance of a healthy diet and physical activity for both weight loss and improvement of glycemic control. Current smokers were encouraged to stop smoking and were provided with self-help materials and/or referral to local programs, as appropriate. Participants in both interventions and their physicians were given results from study examinations after each annual examination. Participants received medical care and medical management of diabetes from their usual source of medical care, not from study staff. Interventionists also inquired about the participants' past history with diabetes self-management, physical activity, and diet and provided a brief orientation to the intervention to which they were randomized. Table 2 displays key characteristics of each treatment arm.

3.7.2. Diabetes Self-Management (DSM) Education Intervention—The comparison group in LIFT Diabetes is an enhanced diabetes self-management (DSM) education program delivered in a group format at a clinic that serves lower socioeconomic neighborhoods was guided by evidence-based standards [46]. A trained, master's level nurse health educator facilitated these sessions and the groups met one time per month for 12 months. DSM education seeks to support informed decision-making, self-care behaviors, problem-solving and active collaboration with the health care team. The DSM education intervention is designed based on the Look AHEAD control condition (diabetes support and education), the Standards for Diabetes Care-2014 [14], the National Standards for Diabetes Education as well as the American Association of Diabetes Educators AADE7 Self-care behaviors program [14, 46]. The AADE7 [26] are self-care behaviors that are essential for improved health status and greater quality of life for patients with diabetes [46] and include healthy eating, being active, monitoring, taking medication, problem solving, healthy coping, and reducing risks. The content of the DSM education sessions was adapted from Look AHEAD by the LIFT Intervention committee.

3.7.2.1. Hemoglobin A1C Goals: The objective of the DSM comparison arm is the management of blood glucose. As such the DSM focuses on lowering A1C to <7% [14]. A1C goals are based on the 2014 ADA Standards for Medical Care and may be tailored to the unique needs of the participant. A1C <7% is the primary goal because lowering A1C to below or around 7% has been shown to reduce microvascular complications of diabetes, and if implemented soon after the diabetes diagnosis is associated with long-term reduction in macrovascular disease. However, the ADA suggests that more stringent A1C goals (such as <6.5%) may be appropriate for some patients, if this can be accomplished without significant hypoglycemia or other adverse effects. We encouraged this goal in patients who are high functioning, with recent diagnosis of diabetes, and long life expectancy. The ADA also suggests that A1C goals may be raised (such as <8%) for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or cardiovascular

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complications, and extensive comorbid conditions and for those with longstanding diabetes in whom the A1C goal is difficult to attain despite diabetes self-management education, appropriate glucose monitoring, and effective doses of multiple glucose-lowering agents including insulin. However, many patients for whom an A1C goal of <8% is appropriate would not meet entry criteria for this trial. We accept a goal of <8% for participants if their primary care provider recommends this.

3.7.3. Community Lifestyle Weight Loss (LWL)—The LWL was a community-based translation of the Look AHEAD lifestyle intervention [47] that utilized the translational model developed in the HELP PD study [21, 23] for implementation. Community health workers facilitated group behavioral weight loss sessions and these sessions took place in community settings (e.g., parks and recreation facilities, non-profit organizations). This intervention sought to induce weight loss by creating negative energy balance through decreasing caloric intake and increasing caloric expenditure through physical activity. Information related to safety of weight loss intervention in individuals with diabetes (e.g. hypoglycemia and foot care) is presented.

The intervention utilized strategies that have been shown to be most effective for long-term weight loss and weight loss maintenance [47]. These include a portion-controlled diet (i.e., a diet that includes portions of food with a fixed calorie content) during the initial phase of weight loss, a multi-component approach to intervention (including behavioral techniques, diet modification, physical activity, and social support), and ongoing regular contact throughout the follow-up period. Advanced behavioral strategies were offered in later months of the weight loss program for participants having difficulty achieving or maintaining weight loss.

A treatment manual developed by the LIFT Diabetes investigators contains lessons and materials for the participants and an accompanying guide for the CHWs. In addition CHWs were trained by the Lifestyle Intervention Committee and monitored to ensure that they deliver the intervention as designed. These procedures help ensure standardization of the intervention across groups and CHWs. The intervention has been designed to allow individual flexibility in the use of tailored toolbox strategies. This is primarily accomplished by the use of individual sessions with the study registered dietitian in combination with group meetings. Individual participants select the specific foods they wish to consume and the types of physical activities in which they would like to engage. The CHWs and Intervention Committee work with participants not adhering to the intervention to help identify the barriers and to utilize the strategies that they feel will be most helpful to them in overcoming these barriers.

3.7.3.1. Weight Loss Goals: The objective of the LWL is to reduce CVD risk and complications associated with DM; these goals will be achieved primarily through weight loss and increased physical activity. The primary LWL goal is to induce ≥7% weight loss through controlling caloric intake and increasing caloric expenditure through moderate intensity physical activity. Individuals are encouraged to lose >10% of their initial body weight, with the expectation that —aiming high will enable more participants to achieve 7% weight loss.

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3.7.3.2. Diet: Calorie goals are 1200–1500 kcal/day for individuals weighing <250 lbs. and 1500–1800 kcal/day for those >250 lbs. [47]. These calorie levels should promote approximately 1–2 lbs. weight loss per week. The composition of the diet is based on ADA guidelines [48]. Because the LWL seeks to induce long-term behavior change, participants must determine how to structure their diets so as to stay under their calorie goals in a way that is sustainable in the context of his/her unique experience.

3.7.3.3. Physical Activity: LIFT Diabetes focuses on unsupervised moderate intensity physical activity, such as walking and other large muscle activities. Participants are encouraged to formulate their own personal physical activity goals with the assistance of the CHW and to gradually progress toward a goal of 5 days per week of non-occupational moderate intensity physical activity totaling 180 minutes by the end of the first six months. Exercise bouts of ten minutes and longer are counted toward this goal. To enhance adherence, participants are able to tailor the exercise programs based on their capabilities, preferences, and safety issues. These physical activity goals and methods are consistent with the American College of Sports Medicine and the ADA [49].

3.7.3.4. Behavioral Strategies and Group Sessions: LWL included training in cognitive behavioral strategies developed from social cognitive theory to help produce and maintain changes in dietary intake and physical activity [50–53]. All participants were asked to self-monitor their caloric intake and physical activity minutes throughout the first six months and periodically thereafter. Key behavioral strategies such as stimulus control techniques, problem solving, and relapse prevention were taught during the first six months. Individual sessions focused primarily on goal setting, problem solving, and motivational interviewing.

Group sessions included 8–12 participants, were coordinated and facilitated by the CHW, and were conducted at community locations (e.g. municipal recreation centers) during daytime or early evening hours. Group sessions were held weekly for the first 6 months (Phase 1). Participants also received 3 individual visits with the study registered dietitian (RD) during phase 1. During months 7–12, groups met once per month and participants received a monthly phone call from the CHW . Individual visits with the study RD were scheduled as needed to address medical or adherence issues.

The LWL sessions lasted 60 minutes and included four segments. The first segment was a private weigh-in where participants discussed with the CHW the progress they had achieved and identified any problems that they might have encountered. Good progress was highlighted with strong positive feedback. Difficulties were acknowledged and briefly discussed. The second segment was a group discussion of participants' progress in implementing the strategies recommended for changing their eating habits and physical activity. Success was celebrated and encouraged and barriers were dealt with through group support and problem solving. The third segment focused on skill training related to cognitive-behavioral self-management skills (e.g., goal setting, self-monitoring), nutrition training (e.g., recognizing the caloric and fat contents of food), or exercise science (e.g., minimizing the risk of injuries). This core content was delivered and discussed via a structured DVD series adapted from HELP PD. Optional educational materials were available in a —toolbox to enhance the educational activities. In the final segment, each

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participant was asked to identify specific behavioral goals for the next period and received feedback and encouragement from the group.

3.7.3.5. Content of Group Sessions: Participants received manuals (written at the 8th grade level, adapted from HELP PD and Look AHEAD) that contained specific objectives for each meeting; methods to accomplish the objectives; and illustrative handouts. The continuous care problem-solving model served as the foundation of this intervention [54]. This approach assumes that problems are a normal part of weight loss and solutions must be tailored to each individual. This procedure involves 5 steps: (1) problem orientation, (2) problem definition and formulation, (3) generation of alternatives, (4) systematic decision-making, and (5) implementation and verification. Each group session focused on a relevant topic, such as counting calories, eating out, maintaining physical activity, preparing for holidays, overcoming barriers, building social support and coping with relapse. Additionally, the group discussion of progress allowed for the tailoring of content to address minority participant preferences. To minimize the burden of specialized scientific knowledge in core content areas on the CHWs and to promote community-based resources, we included presentations from a clinic representative and community experts (e.g., YMCA or local grocery store staff). CHWs are also provided with a —toolkit of relevant handouts and resources (e.g., examples of portion sizes, meal replacement samples, coupons for local athletic stores) to be used during group sessions.

3.7.3.6. Community Health Workers (CHWs): Community Health Workers represent an effective mechanism for delivering diabetes prevention and management interventions [55–57]. They are defined as —…lay members of communities who work either for pay or as volunteers in association with the local health care system in both urban and rural environments and usually share ethnicity, language, socioeconomic status and life experiences with the community members they serve (p. 3)[58]. CHW models are advantageous because of the lower costs associated with disseminating information through volunteers with extant social networks [25]. Furthermore, CHWs share common demographic and cultural traits with the target population and tend to have a close understanding of the community served. Additionally, the effectiveness of some CHW interventions is attributed to their natural helping abilities, ability to model targeted behaviors, and empathic abilities [23]. Based on HELP PD, we sought patients with type 2 DM with well-controlled A1C, and a history of healthy eating, physical activity, and weight loss to be CHWs. Other preferred CHW skills include organizational abilities, strong public speaking skills, and a desire to help others. CHWs were compensated nominally ($100/week in months 1–6, $200/month in months 7–12) for their participation. CHWs were recruited from local diabetes care clinics by the study investigators.

CHW training occurred during the start-up phase of the LIFT Diabetes study and was largely modeled after the HELP PD protocol [21]. Selected CHWs received 36 hours of training over a two-month period that included didactic instruction, peer mentoring, and observation. The training included instruction on a) study protocol; b) intervention philosophy, goals, and procedures; c) weight loss (energy balance); d) physical activity basics; e) nutrition basics; f) group facilitation; g) cognitive-behavioral principles; h) participant monitoring and tool box

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methods; i) the structure/goals of telephone contacts; and j) data entry. To provide experiential learning, CHWs participated in an abridged form of the intensive phase of the lifestyle intervention in which they were required self-monitor calories and physical activity, track weight, and participate in group sessions. The first behavioral session presented was conducted as an actual intervention session; the others in didactic format. In the final session, investigators and lead study interventionist observed each CHW conduct a mock group in a formal certification process, with the other CHWs and Interventionist as group members. Using a simple 5-point scale ranging from 1 (needs improvement) to 5 (excellent), the investigators rated the CHWs' performance on (a) group facilitation skills, (b) knowledge of the intervention protocol and use of the treatment manual, and (c) competence in completing requisite forms. CHWs also received feedback and coaching based on their performance. To ensure fidelity, the interventionist acted as a mentor (for the first two months) for newly trained CHWs, periodically observed sessions, and provided feedback and coaching. The lead interventionist continued to support the CHW on a regular basis thereafter, with weekly telephone contact and periodic attendance at group troubleshooting sessions. In addition, we conduct monthly meetings with the CHWs to discuss intervention implementation and participant progress in order to maintain consistency across CHWs. Our real-time web-based data reporting system enables us to monitor intervention delivery by the CHWs, as reflected by participant attendance, adherence measures, and, eventually, outcomes.

3.7.3.7. Monitoring LWL Implementation: To monitor the fidelity of intervention delivery, we monitored and tracked the following: a) adherence to group meetings and make-up sessions, b) weight at all sessions, c) self-monitoring data from the participants concerning dietary intake and physical activity behaviors, and d) phone contacts during the maintenance phase of the study. The lead interventionist supervised the CHWs, collated data from CHW interactions with participants, and provided graphical and verbal feedback to CHWs that can be shared with participants. Additionally, the CHW Support and Monitoring Group functioned as a working group of the Intervention Committee to provide ongoing support and to monitor the activities of the CHWs, thereby providing additional access to expertise in the exercise, nutrition and behavioral sciences on an ongoing basis. In addition, we held monthly meetings with the CHWs to discuss intervention implementation and participant progress in order to maintain consistency across CHWs.

3.8. Data Analysis

The primary outcome measure for this trial is change from baseline in UKPDS CVD risk score. Mean differences for groups based on treatment assignment will be contrasted using t-tests, following the intention-to-treat principle. The symmetry of the distribution of changes will be examined and, if warranted, data will be transformed to improve symmetry. If there are marked differences between groups with the following baseline characteristics, covariates will be included in supporting analyses: age, body mass index, gender, and race/ethnicity. Data following pregnancies and bariatric surgery will be censored. No interim analyses for futility or efficacy will be conducted due to the relatively short (12-month) follow-up for the primary endpoint.

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Supporting analyses will compare rates and identify predictors of missing data. Propensity scores will be adopted in these analyses to examine the potential influence these may have on results. Additional analyses will characterize measures of adherence and patterns of weight loss, based on data from intervention tracking. Three subgroup analyses are pre-specified and will be assessed using tests of interaction, based on race/ethnicity (African American, Hispanic, and White/other), gender, and baseline BMI (below vs. ≥ 35 kg/m^2); these factors were related to achieved weight losses in Look AHEAD [59].

Analyses of other measures (e.g. individual risk factors, costs, satisfaction) will be conducted using parallel approaches. The inter-relationships among measures will be examined using multivariate approaches. Data collected at the 24-month visit will be used to examine the longer-term effects of the 12-month intervention using general linear models. The relationships between 12-month changes and 24-month maintenance will be characterized using regression analyses. Online reports to track participant safety will provide the basis for continual monitoring and regular reports to the IRB and Data and Safety Monitoring Board.

The primary economic hypotheses in this proposed study are that: 1) the ratio of discounted costs per QALY saved (measured from the participants' perspective) is significantly less than an acceptable ceiling ratio in general use at end of study (determined a priori); and 2) the ratio of discounted costs per QALY (measured from a societal perspective) is significantly less than an acceptable ceiling ratio in general use at end of study (determined a priori). These will be confirmed if the net health benefits of those in the CHW intervention arm (calculated using a current and acceptable ceiling ratio at end of study) are greater than those in group-based clinic intervention arm ($p < 0.05$). To evaluate differences in costs, the dependent regression variable will either be costs or the natural log of costs (based on statistical tests of the cost distribution). If log costs are utilized, a smearing retransformation (101) will be used to estimate the absolute cost difference between intervention groups. Independent variables will include the intervention arm (the coefficient for which will provide a measure of the cost difference associated with that intervention) and other covariates correlated with the outcome being analyzed. Whether or not the covariates are differentially distributed across groups will not be a factor considered in their selection. Net health benefits are calculated by multiplying the difference in effects by the currently acceptable ceiling ratio and netting out the difference in costs. Confidence intervals (95%) will be calculated using a bootstrap procedure. In addition to evaluating net health benefits/cost-effectiveness, we will test whether the incremental costs and the incremental QALYs (calculated using both participant and societal preferences) associated with the two interventions are greater than $0. The statistical tests of these additional hypotheses will be derived from the results of the multiple regression analysis of costs and QALYs that were performed to construct net health benefits and the cost-effectiveness ratio. A test of whether the incremental hospitalizations associated with the each intervention will be less than zero will also be performed using multiple regression analysis. As above, we will determine the form of the dependent variable and which independent variables will be included our models. Multiple regression analyses will be used to test whether participants assigned to each intervention have higher summary health-related quality of life and significantly higher physical function, energy/fatigue, role-emotional, and pain domain scores than each other.

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3.9. Sample Size and Power

LIFT targeted a sample of 260 based on the following factors: the assessment risk factors in 90% at one year and applied standard expressions for 2-tailed assessment with Type 1 error at 0.05. This sample size provides 72% power to detect a mean difference of 2% (10% relative reduction associated with randomization to the LWL vs. DSM) for changes in the 10-year UKPDS CVD risk [27] over the first year of intervention between arms. A relative mean difference of 2.5% (12.5% reduction) will provide 89% power. We have framed our trial to detect differences between interventions rather than equivalence. Marked differences could provide data to influence decisions on allocation of resources, reimbursement, and policy. If no marked differences in risk are found (i.e., we do not reject the null hypothesis), intervention recommendations would depend on considerations such as local resources or costs/reimbursement. Follow-up is designed to assess longer-term adherence, satisfaction, and maintenance.

3.10. Participant Safety

Participant manuals and staff training emphasized safety, focusing on preventing hypoglycemia and musculoskeletal injuries. LIFT adapted the Look AHEAD algorithm for minimizing hypoglycemia. Participants were educated about signs and symptoms of hypoglycemia, how to self-treat, and when to seek medical assistance. All participants were assisted with monitoring blood glucose if they do not have supplies during the initial weight loss period. We maintained an intervention —toolbox with funds that were used for testing supplies. Participants were instructed to do daily foot and skin infections, and to exercise using appropriate socks and shoes. Participants were instructed about symptoms of CVD and asked to stop physical activity and seek care if they should have these symptoms.

3.10.1. Glucose abnormalities related to LWL—For patients who may be susceptible to hypoglycemia because they are using insulin or oral diabetes medications that increase insulin secretion, weight loss interventions have the potential to increase the risk of hypoglycemia, especially during the time when diet and/or physical activity interventions are implemented. During the initial intensive weight loss phase, clinical study staff reduced medications according to a standard algorithm based on glucose levels and symptoms. Changes in diabetic regimens were communicated to the participant’s primary care physician. If patients continued to have significant hypoglycemia, intervention was suspended until study medical staff reviewed glycemic management and consulted with the patient and primary care physician. Overall management of diabetes medications remained under the control of the participant’s primary care physician. Intervention staff and participants were also educated about symptoms suggestive of hyperglycemia (excessive thirst, frequent urination), indicating that blood glucose levels should be checked. Participants reporting excessive hyperglycemia (frequent glucose levels>400mg/dl) were referred to their health care provider/clinic for further management.

3.10.2. Other safety concerns—Participants were instructed to report any cardiovascular events (including heart attack, stroke, revascularization, heart failure, or evaluation for chest pain) to their interventionist, who contacted a study physician. In such an event, the interventionist instructed the participant to suspend unsupervised physical

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activity and caloric restriction. The physician communicated with the participant, and if needed, reviewed medical records to ascertain if an event has occurred. If it had not, the participant was instructed to resume unsupervised physical activity. Caloric restriction could be continued and/or resumed after consultation with the participant's primary care physician. Weight loss could reduce blood pressure. Clinic staff contacted the personal care provider of any participants receiving medication for blood pressure control who develop symptomatic hypotension to discuss adjustment or discontinuation of these medications. If a personal care provider could not be contacted in a timely manner, study physicians could elect to adjust these medications and the personal care provider would be notified by phone and follow-up letter. Participants at risk for foot ulceration secondary to peripheral neuropathy, peripheral vascular disease, or for other reasons were advised to limit weight bearing exercises. Participants were helped to identify other types of non-weight-bearing physical activities, such as swimming or bicycling.

There is uncertainty regarding the safety and effectiveness of weight loss in obese women during pregnancy in general, and limited information regarding weight loss and concurrent diabetes management in pregnant women with T2D. The ADA recommends strict attention to glucose control, avoiding most if not all oral diabetes medications, and continued exercise to improve outcomes in pregnancy among women with T2D, and also notes limiting weight gain may be considered [60]. Among non-diabetic obese women, some available data suggest weight loss decreases some pregnancy complications associated with obesity, but also reduces birth weight. However, a small (<5 kg) weight loss in class II and III obese women (BMI 35.0–39.9 kg/m^2 and BMI ≥40 kg/m^2, respectively) appears to have more benefits than risks, and may not increase the risk of having a small for gestational age infant [61–63]. Systematic reviews and meta-analyses have mostly pointed out that there is much additional research needed, although there is not significant evidence from trials that lifestyle interventions are harmful [61–63].

Because of the complexity of pregnancy in diabetes, we did not expect CHWs to be able to advise participants, nor did we feel confident in promoting weight loss; advice must be tailored individually, and beyond the scope of this study. We excluded women who are pregnant or planning on becoming pregnant, by performing a pregnancy test at screening in women of childbearing potential. However, once enrolled, we did not continue to perform pregnancy tests. We included in the consent form that birth control is recommended. The available evidence suggests that women (and fetuses) are unlikely to be harmed by dietary changes and exercise early in pregnancy, particularly if the goal is limiting weight gain rather than weight loss. Therefore, women of child bearing potential who are suspected of being pregnant were referred to their health care provider for a pregnancy test and specific glucose targets. If confirmed (or if women report a positive home pregnancy test), no medication adjustments were made by LIFT personnel. The intervention was tailored in accordance with ADA recommendations for pregnant women with type 2 diabetes, specifically concerning weight gain, dietary changes, and physical activity. We continued to provide information about nutrition, hypoglycemia, and exercise that is consistent with ADA guidelines for pregnancy. Intervention staff and LIFT medical personnel will refer pregnant participants to their physician for specific glucose targets. They were asked to remain participants for follow-up phone calls (6 & 18 months) and follow-up visits (12 & 24

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months). These included body weight and blood draws at 12 and 24 months while being further evaluated and managed by their primary care and/or obstetrical provider. Participants will receive a copy of Appendix 7 entitled *American Diabetes Association (ADA) Recommendations Type 2 Diabetes and Pregnancy* (http://www.diabetes.org/living-with-diabetes/complications/pregnancy/prenatal-care.html).

4. Baseline Characteristics

Recruitment was completed in March 2015 and the baseline demographic characteristics of the study sample can be found in Table 3. As can be seen in the table, our recruitment goals were largely achieved. Two hundred sixty participants were randomized to the LWL or the DSM study conditions and there are no statistically significant between group differences in any of the demographic variables with the exception of education attainment. The DSM group appears to have more participants that have attained —>College while the LWL group appears to have more participants that have attained —Associate/Bachelor degree. The majority of the sample is female (67.3%), minority or other race (53.8%), and low income (61.4% report annual income <$50,000; 38.5% <$30,000). The mean age of the sample is about 56 years and the mean BMI is over 37 kg/m^2, indicating class 2 obesity. Additionally, the vast majority of the sample reported taking medication for diabetes, hypertension, and/or to control lipids. The mean levels of A1C (7.6), systolic blood pressure (126.2 mmHg), diastolic blood pressure (76.1 mmHg), triglycerides (147.4), creatine (0.85), cholesterol (172.7), HDL (47.4), LDL (97.3), and VLDL (26.7) indicate that diabetes and cardiovascular risk factors were well-controlled in this sample. Additional analyses of our recruitment process and the racial characteristics of the sample have been reported elsewhere [64].

5. Discussion

Although the rising prevalence and incidence of diabetes has leveled off in recent years, rates continue to rise in minority and underserved populations. Moreover, minorities also have a higher incidence of many diabetes-related complications [4–8] and are more likely to have poorer processes of care measures and control of diabetes [12, 13]. These health inequities may be due to the inability to effectively translate and disseminate cost-effective, cutting edge therapies to minority and underserved populations. The purpose of LIFT is to test an adaptation of the Look AHEAD lifestyle weight loss program that is implemented using the community-base delivery model developed in HELP PD. The primary outcome is CVD risk as determined by the UKPDS risk engine and secondary outcomes include risk factor control, social cognitive process variables, and cost and resource utilization.

Look AHEAD was terminated early because it would not find significant differences between conditions in the primary outcome (composite of death from cardiovascular causes, nonfatal myocardial infarction, nonfatal stroke, or hospitalization). As such, some may question whether it should be translated and disseminated. Despite the early termination, the Look AHEAD ILI arm produced greater reductions in A1C, greater improvements in cardiorespiratory fitness and numerous cardiovascular risk factors,[15] and reduction in incidence of very-high-risk chronic renal disease[65] compared to DSE. Moreover, the Look

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AHEAD lifestyle participants had fewer hospitalizations, fewer medications, and lower health-care costs [17]. Thus, it appears that lifestyle weight loss programs may provide widespread benefits for patients with diabetes.

To our knowledge there is only one other study that is translating the Look AHEAD lifestyle weight loss intervention. Krukowski and colleagues [66] are testing the Look AHEAD intervention in the United States Air Force. Currently in progress, this study is comparing an adapted, individual-based version of the ILI to a self-paced version of the same intervention in a randomized controlled design with weight change as the primary outcome and a sample of over 200 members of the United States Air Force. However, participants are not required to have diagnosed diabetes.

It should be noted that LIFT has incorporated some translational adaptations of the Look AHEAD ILI that were developed in HELP PD to increase community-based dissemination and increase financial feasibility. First, as noted, whereas Look AHEAD used professional health care providers to deliver the LWL intervention, in the present study CHWs deliver the LWL in community-based settings. Second, LIFT does not provide meal replacements or meal plans to contain costs. These items were administered on a case-by-case basis as part of the —toolbox to tailor the intervention to the unique needs of the participants. Third, LIFT requires participants to self-monitor calories and physical activity, but not fat grams. This was done because recent research suggests that simplified approaches can result in more consistent self-monitoring and significant weight loss [67]. Additionally, recent evidence indicates that the relationships among low fat diets, CVD risk, and weight loss are not clear [68].

The baseline demographic characteristics indicate that we successfully accomplished our recruitment goals in terms of total number (260), equal distribution across treatment conditions, and a sample that is >50% minority. Additionally, the sample also appears to have well-controlled diabetes (M A1C = 7.6) and cardiovascular risk factors despite high levels of obesity. This is likely due to our recruitment methods, which included extensive use of electronic medical records and physician referrals. That is, we primarily recruited participants that were engaged in medical system. As such, the vast majority of the sample were taking medications for either diabetes, hypertension, and/or hyperlipidemia.

An area of ongoing uncertainty is the cost effectiveness of lifestyle interventions designed for the primary prevention of T2D. Because lifestyle change was more effective than metformin, despite the lower intervention cost associated with the drug therapy, the DPP intervention was deemed cost-effective [69]. Moreover, a recent review of fifty-six studies examining the cost-effectiveness of interventions to prevent and control T2D concluded that lifestyle interventions targeting individuals with impaired glucose tolerance were very cost-effective [70]. However, another recent analysis reported an estimate of $62,600 per QALY gained from a societal perspective and $143,000 per QALY gained from a health plan's perspective from a DPP style program for patients at-risk for T2D, which the authors deemed too expensive, and delaying lifestyle intervention until after DM develops would be somewhat more cost-effective (cost/QALY $24,500) [71]. These discrepancies have generated both useful discussion about cost-effectiveness analyses, and consensus about the

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need for less expensive, community-based models for translation of lifestyle interventions into routine practice. Although PCPs provide 85%-90% of DM care in the US, current systems lack the resources needed to provide continuous care (e.g. telephone management of glycemia, behavioral interventions, risk factor reduction, health promotion and periodic examination for complications) [72]. The National Ambulatory Medical Care Survey (NAMCES) indicates that half of all visits made by US adults lacked either height or weight and thus could not calculate BMI; among those with both and a BMI>30 kg/m^2, 70% were undiagnosed and 63% received no lifestyle counseling [72, 73]. NAMCES also suggests African Americans are less likely to receive weight loss and physical activity advice from either African American or white physicians [74]. Commercial approaches are available (e.g., Weight Watchers®); these promote modest weight loss, however, adherence typically is low, and they do not focus on DM management [18, 19]. Furthermore, U.S. minorities are more likely to live in —food deserts, areas with fewer healthy food outlets [20]. Differential access to healthier foods and physical activity facilities contributes to the etiology of DM and is likely to affect DM as well [75].

The results of the HELP PD study suggest that partnerships between existing clinical and community-based resources, including the use of CHWs as intervention facilitators [23], have great potential to reduce costs and increase accessibility to lifestyle behavior change interventions. CHWs appear to be powerful agents of behavior change in light of their inherent understanding of the community, shared cultural experience, and their similarity with intervention participants. Furthermore, CHWs may also provide a cost-effective alternative to professional health care providers, thus potentially increasing the reach of a single provider while controlling costs. Diabetes education programs may also be logical delivery channels for lifestyle weight loss programs, as there are more than 3,000 ADA-recognized programs in the US.

It is possible that the LWL being tested in the present study may not yield significantly greater reductions in CVD risk, weight loss, and control of risk factors as compared to the DSM. However, LIFT is also equipped to examine differences in adherence, costs, and health care utilization. Our community-based LWL is held in community-based settings after normal working hours whereas the DSM is delivered in a health care setting during normal clinic hours. Thus, in light of the contact schedule required in a chronic care model, the LWL may be more accessible for patients. Additionally, the use of CHWs and community-based resources may result in lower cost and health care utilization. The results of LIFT will aid in our understanding of the translational process and the potential to implement lifestyle weight loss interventions for patients with diabetes in a manner that may decrease health disparities.

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Table 1

LIFT Eligibility Criteria

Inclusion Criteria	
Demographics	Adults ≥ 21 years of age residing in the Forsyth County, NC region
English Proficiency	Able to read/understand English at or above a level sufficient to comprehend recruitment and intervention materials
Type II Diabetes	Diagnosis of Type II DM with physician evaluation to confirm its presence
Mellitus	in 21–30 year olds; all others will be identified by the use of oral agents and/or age of onset after 30; if taking insulin, no clinical features of Type I DM can be present.
Hemoglobin A1c	5% ≤ HbA1c ≤ 11% in persons on hypoglycemic medications 6.5% ≤ HbA1c ≤ 11% in persons not on hypoglycemic medications
BMI	≥ 25 kg/m^2 or ≥ 27 kg/m^2 if on insulin
Blood Pressure	Resting BP of ≤ 160/100 mmHg
Primary Care	Persons must have a source for ongoing care and a primary physician
Physician	that can sign a medical clearance form, indicating that they are aware of the patient's participation in the program
Exclusion Criteria	
History of CVD	Clinical history or new diagnosis of cardiovascular disease (CVD) including myocardial infarction, heart failure, ischemic heart disease, stroke, and other vascular disease
Weight Loss	Currently involved in a supervised medical or surgical weight loss program or history of prior weight loss surgery
Pregnancy	Women who are currently pregnant, planning to become pregnant within the next 12 months, or who recently gave birth and are breastfeeding
Serious Illness	Presence of serious illness with anticipated decreased life expectancy during the 24 month intervention
Inability to Exercise	Patients who are wheelchair bound, have had an amputation, are undergoing treatment for lower extremity infections, or self-report inability to ambulate 400 meters without assistance
Renal Disease	Advanced stage 3 chronic renal disease: Estimated glomerular filtration rate (GFR) < 45 ml/min
Other	Criteria likely to interfere with participation and acceptance of randomized assignment, including the following: inability or unwillingness to give informed consent, major psychiatric or cognitive problems, alcohol abuse (> 14 drinks/week for men or > 7 drinks/week for women or adults ≥ 65 years of age, and participation in another research study involving interventions that would affect any component of cardiovascular risk.

Note: BMI = body mass index; DM = diabetes mellitus, CVD = cardiovascular disease, BP = blood pressure, HbA1c = hemoglobin A1c

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Table 2

Treatment Arm Comparison

	Diabetes Self-management Education	Lifestyle Weight Loss
Goals	Control of glycemia: A1C < 7%	Weight loss: 7% weight loss at 6 months
Content	AADE 7 *; standard DSME • Diabetes disease process and treatment options • Nutritional management • Physical activity • Medication • Blood glucose self- monitoring and decision making • Acute complications • Chronic complications • Psychosocial concerns • Personal strategies for behavior change	Look AHEAD/HELP PD curriculum • Energy balance • Nutrition/calories • Physical activity • Goal setting • Mindfulness • Problem-solving • Emotions/stress • Healthy Eating • Portion Sizes
Theoretical Foundation	Self-efficacy theory, empowerment, problem-solving	Self-efficacy theory, empowerment, problem-solving
Delivery Personnel	Clinic staff	Community Health Worker (CHW)
Staff Training Time	8 hours	36 hours
Setting	Clinic	Community Locations
Contact Schedule: Phase 1 (Months 1–6)	Monthly group meetings (6); 3 individual meetings with Interventionist/CDE	Weekly group meetings (24); 3 individual meetings with Interventionist/CDE
Contact Schedule: Phase 2 (months 7–12)	Monthly group meetings; individual meetings PRN (in person or telephone)	Monthly group meetings; individual meetings PRN; 1 phone or email contact/month (CHW)
Total Intervention Contact Time	12 hours	30 hours

Note:

* = America Association of Diabetes Educators 7 Self-care behaviors.

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Table 3

Baseline demographic and CVD characteristics[1].

Variables		LWL	DSM	Total	p[2]
Total n		130	130	260	
Gender					0.23
	Male	38 (29.2)	47 (36.2)	85 (32.7)	
	Female	92 (70.8)	83 (63.9)	175 (67.3)	
Race					0.19
	Hispanic	5 (3.9)	1 (0.8)	6 (2.3)	
	Non-Hispanic Black	67 (51.5)	58 (44.6)	125 (48.1)	
	Non-Hispanic White	54 (41.5)	64 (49.2)	118 (45.4)	
	Other	4 (3.1)	7 (5.4)	11 (4.2)	
Ethnicity					0.21
	Unknown	0	0		
	Hispanic	5 (3.9)	1 (0.8)	6 (2.3)	
	Non-Hispanic	125 (96.2)	129 (99.2)	254 (97.7)	
Education					0.03
	<high school	5 (3.9)	4 (3.1)	9 (3.5)	
	high school diploma	22 (16.9)	22 (16.9)	44 (16.9)	
	some college	34 (26.2)	47 (36.2)	81 (31.2)	
	Associate/Bachelor	49 (37.7)	27 (10.8)	76 (29.2)	
	> College	20 (15.4)	30 (23.1)	50 (19.2)	
Income					0.75
	$0–$29,999	41 (41.0)	37 (36.3)	78 (38.6)	
	$30,000–$49,999	21 (21.0)	25 (24.5)	46 (22.8)	
	$50,000 or more	38 (38.0)	40 (39.2)	78 (38.6)	
Age (years)		56.3±10.4	56.2±11.1	56.3±10.7	0.93
BMI (kg/m^2)		37.7±8.5	37.7±8.3	37.7±8.4	0.99
Diabetes Medication					0.64

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Variables		LWL	DSM	Total	p[2]
	No	11 (8.5)	9 (6.9)	20 (7.7)	
	Yes	119 (91.5)	121 (93.1)	240 (92.3)	
Anti-hypertensive Medication					0.86
	No	20 (15.4)	19 (14.6)	39 (15.0)	
	Yes	110 (84.6)	111 (85.4)	221 (85.0)	
Lipid Lowering Medication					0.70
	No	52 (40.0)	49 (37.7)	101 (38.9)	
	Yes	78 (60.0)	81 (62.3)	159 (61.2)	
A1C (%)		7.63±1.4	7.57±1.3	7.60±1.3	0.91
GFR (ml/min)		92.9±19.7	92.1±20.4	92.5±20.0	0.83
SBP (mmHg)		127.5±15.9	124.9±15.5	126.2±15.7	0.26
DBP (mmHg)		76.7±10.0	75.5±10.5	76.1±10.3	0.50
Triglycerides (mg/dl)		146.9±88.7	147.8±110.8	147.4±100.2	0.21
Creatinine (mg/dl)		0.84±0.21	0.86±0.23	0.85±0.22	0.49
Cholesterol (mg/dl)		175.9±38.3	169.5±34.1	172.7±36.3	0.26
HDL (mg/dl)		48.0±12.1	46.8±14.1	47.4±13.1	0.30
LDL (mg/dl)		98.9±31.4	95.7±28.7	97.3±30.1	0.72
VLDL (mg/dl)		27.5±13.0	25.8±14.2	26.7±13.6	0.10
Vigorous Activity (minutes/week)		31.9±63.6	36.6±68.8	34.2±66.1	0.44
Moderate Activity (minutes/week)		34.1±56.0	35.0±61.8	34.5±58.8	0.91
Walking (minutes/week)		56.9±66.8	70.9±75.8	63.9±71.7	0.12
Total Activity (minutes/week)		112.8±131.3	132.6±150.4	122.5±141.1	0.31

Note:

[1] = data are reported as number and percentage for categorical variables and means ± standard deviations for continuous variables;

[2] = Between group differences were tested using Chi Square for categorical data and independent samples t-tests for continuous data; GFR = Glomerular filtration rate; SBP = Systolic blood pressure; DBP = Diastolic blood pressure; HDL = High density lipoproteins; LDL = Low density lipoproteins; VLDL = Very low density lipoproteins