Published in final edited form as:

J Health Care Poor Underserved. 2017 ; 28(1): 463–486. doi:10.1353/hpu.2017.0034.

Recruitment and Baseline Characteristics of Participants in the Lifestyle Improvement Through Food and Exercise (LIFE) Study

Elizabeth Lynch, PhD,

Department of Preventive Medicine, Rush University Medical Center

Laurin J Mack, PhD,

Department of Behavioral Sciences, Rush University Medical Center

Kelly Karavolos, MS,

Department of Preventive Medicine, Rush University Medical Center

Elizabeth Avery, MS,

Department of Preventive Medicine, Rush University Medical Center

Rebecca Liebman, MPH,

Department of Preventive Medicine, Rush University Medical Center

Kathryn S Keim, PhD, RD, LDN,

Clinical Nutrition, Rush University Medical Center

Crystal M Glover, PhD, and

Department of Preventive Medicine, Rush University Medical Center

Leon Fogelfeld, MD

Department of Diabetes & Endocrinology, John H. Stroger, Jr. Hospital

Abstract

African Americans experience poorer diabetes outcomes than non-Hispanic Whites. Few clinical trials of diabetes self-management interventions specifically target African Americans, perhaps due to well-documented barriers to recruitment in this population. This paper describes strategies used to successfully recruit 211 low-income African Americans from community clinics of a large, urban public hospital system to a randomized clinical trial of an 18-month diabetes self-management intervention. Diabetes-related physiological, psychosocial, and behavioral characteristics of the sample are reported. The sample was 77% female, mean age = 55, mean A1C = 8.5%, 39% low health literacy, 28.4% moderate/severe depression, and 48.3% low adherence. Participants ate a high-fat diet with low vegetable consumption. Relative to males, females had higher BMI, depression, and stress, and better glycemic control, less physical activity, and less alcohol consumption. Males consumed more daily calories, but females consumed a greater proportion of carbohydrates. Gender-specific diabetes self-management strategies may be warranted in this population.

Keywords

African American; type 2 diabetes; self-management intervention; health disparities; community-based intervention

African Americans experience greater prevalence of type 2 diabetes mellitus (T2DM),^{1,2} higher rates of disease-related complications,^{3–7} and earlier death^{7,8} than non-Hispanic Whites. These disparities are due in part to poorer glycemic control among African Americans.^{9,10} Although T2DM can be effectively managed with medication, diet, and exercise,^{11,12} individuals of lower socioeconomic status who live in disadvantaged neighborhoods face significant challenges in adhering to recommended diabetes self-care practices.¹³ Failure to attain glycemic control increases the risk of heart disease, stroke, vision loss, renal failure, and neuropathy.^{14–16}

Diabetes self-management interventions have been successful at improving glycemic control among individuals with T2DM, at least in the short-term.¹⁷ However, despite serious disparities in T2DM prevalence and outcomes, the majority of T2DM self-management interventions have been conducted with non-Hispanic Whites.^{17,18} This is not unique to T2DM self-management interventions: African Americans are under-represented in clinical trials across a range of diseases and interventions.^{19,20} In order to reduce Black-White disparities in T2DM and other diseases, it is critical to increase representation of African Americans in clinical trials.

An extensive body of literature documents barriers to clinical trial participation for African Americans.^{21–24} A number of studies indicate that African Americans perceive that research will benefit Whites only, or the medical institution, rather than benefitting communities of color.^{20,25–28} Other barriers to participation include distrust of the medical system based on personal experience of poor quality of care,^{20,29,30} the time commitment necessary to participate,^{26,31,32} and concern about potential side effects of the intervention.^{26,27,32} An additional barrier is a negative view of randomization and a desire to avoid being assigned to a control group in a trial.²⁸ Suggested strategies to address these barriers include assuring cultural congruence among participants and research staff, providing adequate and appropriate information about the purpose of the study, focusing on altruism as motivation for participation (e.g., how participation could benefit the community and future generations), and increasing the convenience of participation (e.g., covering transportation cost).²⁶

Recruitment from community clinics may facilitate enrollment of African American patients because clinic staff are more familiar and therefore potentially more trustworthy to patients.³² However, significant barriers to research participation exist on the part of community clinics.³³ The most significant barrier is the lack of sufficient staff time to participate in the research, and concern about loss of productivity and income due to participation in research activities.³⁴ Recommended strategies to address these barriers involve creation of a collaborative research environment by assessment of resources and needs of the clinics, and establishment of clear expectations.^{33,35}

This paper describes strategies that led to the successful recruitment of urban, low-income African American adults with uncontrolled T2DM for the Lifestyle Improvement through Food and Exercise (LIFE) study. The LIFE study was a randomized controlled trial that evaluated the effectiveness of an 18-month community-based culturally-tailored intervention that was designed to help low-income urban African American adults with T2DM improve glycemic control via diet, exercise, and self-management skills. Participants were recruited from community clinics of the Cook County Health and Hospital System (CCHHS), one of the largest safety-net public hospital systems in the United States. We also report on the physical, behavioral, and psychosocial baseline characteristics of the study sample. Understanding disease-specific, behavioral, and psychosocial characteristics of low-income African Americans with T2DM will facilitate identification of factors that contribute to health disparities. Further, understanding characteristics of this high-risk population is necessary to inform development of appropriately tailored interventions.³⁶

Methods

Intervention

The LIFE study was designed to compare the effectiveness of culturally-tailored group-based self-management sessions and telephonic peer support with standard of care diabetes self-management education. The intervention consisted of 28 group sessions over 12 months, and two maintenance sessions over the subsequent six months. The control arm consisted of two sessions in the first six months. The target enrollment for the study was 210 participants, with 105 per treatment arm. Participants randomized to the intervention arm were assigned to one of six self-management groups of 15–20 participants. Groups were organized by clinic—all participants who attended the same group were from the same clinic.

Partnership with community health system

Study participants were patients of the CCHHS outpatient community clinics. The CCHHS is the public safety-net hospital system covering Cook County, Illinois and has one of the highest volumes of annual outpatient diabetes visits in the country.³⁷

Formal partnerships were created between Rush University Medical Center (RUMC), the academic research institution leading the research, and two entities of the CCHHS. First, a partnership was established with the Ambulatory and Community Health Network (ACHN), which coordinates community clinics for the CCHHS throughout Cook County, Illinois. Funding was provided from RUMC via subcontract to the ACHN for staff time and for incentives to clinics for participation in the study. The ACHN provided space in the clinics for study research assistants (RAs) to recruit patients and conduct all patient assessments for the study.

A second partnership, also funded through a subcontract, was established with the Division of Endocrinology, Diabetes and Metabolism within the CCHHS Department of Medicine. The Division chair served as a co-Investigator and Medical Director on the study, and a

Division dietitian served on the intervention team. The ACHN worked with the Division to identify potentially eligible patients.

Eligibility criteria

Eligibility criteria were designed to be as inclusive as possible to maximize the generalizability of results while assuring that patients were healthy enough to safely benefit from the lifestyle intervention. Inclusion criteria included a diagnosis of type 2 diabetes mellitus, uncontrolled diabetes (A1C $\geq 7.0\%$), African American race, age 18 or older, and seen at least once in the past 12 months by a primary care physician in a designated CCHHS primary care clinic. Participants were required to be available at the time the group sessions were scheduled. Intervention and control group sessions were held at the same day and time.

Exclusion criteria included BMI < 18.5 kg/m², end-stage renal disease (glomerular filtration rate [GFR] <15 mL/min/1.73 m²), stroke with paresis, congestive heart failure (New York Heart Association class 2–4) or major end-organ complications of diabetes, conditions limiting future life expectancy to less than four years, current pregnancy, diagnosis of a major psychiatric condition, use of prednisone (“steroids”) in the prior three months, weight loss surgery, lack of access to telephone, inability to walk two blocks without stopping, impaired cognitive function, not cleared for participation by a primary care physician, or living in the same household as an active study participant. Medical questions related to eligibility and participant safety were adjudicated by the study endocrinologist.

Recruitment

Participants were recruited from five outpatient community clinics within the CCHHS. The five recruitment clinics were those that had the largest population of African Americans in the CCHHS ACHN. Four of the clinics were in Chicago and had predominantly African American patient populations, and one clinic was located in a suburb south of Chicago and had a patient population of mixed race and ethnicity. Of the four urban clinics, three were located in high-poverty, high-segregation neighborhoods and the fourth was located in a neighborhood undergoing rapid gentrification. The suburban clinic was located in a neighborhood undergoing gradual racial/ethnic integration.

The staged recruitment process included: (1) a medical record review, (2) a prescreening interview, (3) information session and screening visit, and (4) two baseline assessment visits and (5) randomization. The study was approved by the institutional review boards at Rush University Medical Center and CCHHS.

Medical record review—Staff of the ACHN identified adult patients who were 18 years of age or older with clinically diagnosed T2DM, A1C $\geq 6.5\%$, and seen at one of the recruitment clinics during the prior calendar year. Staff of the CCHHS Division of Endocrinology, Diabetes and Metabolism reviewed medical records of each of these patients. Patients were considered potentially eligible if they were African American, able to perform daily activities, and had type 2 diabetes based on type of diabetes medications and diagnosis in the clinical notes. They were also required to have GFR > 15 ml/min. Lists of

potentially eligible patients were sent to RUMC study staff, along with dates and times of scheduled clinic appointments.

Prescreening interview—Research assistants (RAs) who were involved in recruitment were African American and both came from communities similar to those of study participants. Research assistants worked from offices within the clinics. RAs contacted patients, either in the clinic waiting room or by telephone, to conduct a prescreening interview. When recruiting by phone, RAs called patients from the clinic telephone so the number on the caller ID was familiar to the patients, and described the study as a collaborative effort between the clinic and RUMC. The objectives of the prescreening interview were 1) to describe the study to patients, 2) to assess interest in and availability to participate, and 3) to collect further information about health status to ensure eligibility. Eligible and interested patients were invited to a group information session at the clinic to learn more about the study. The information session also served as the final screening visit.

The study required that intervention participants be assigned to six groups of 15–20 people (to meet the intervention arm enrollment target of 105 participants). To achieve this within a randomized design, recruitment took place in six waves. Within each recruitment wave, eligible patients were not invited to the information session until at least 30–40 patients were identified as willing and able to attend the classes. Within each wave, participants were randomly assigned to either the intervention or control group in a 1:1 ratio so that approximately 20 patients would be assigned to each. We used a blocked randomization scheme supervised by the study statistician, alternating block sizes of four and six to ensure equal allocation to the two groups. Two recruitment waves were completed at one clinic and the remaining four recruitment waves were completed at four separate clinics. This recruitment process required that some participants wait a number of months before enrollment.

Information session and screening visit—The information session was conducted by RAs and an intervention staff member who was African American and from a similar community as participants. At the information session, study staff explained the rationale and the goals of the study and requirements for participation. Study staff described a number of potential cons of the study, including: 1) participants could not control the treatment arm to which they would be assigned, 2) one treatment arm would require an extensive time commitment (30 two-hour group sessions over 18 months), and 3) participants would be asked to participate in four extensive assessments over 18-months. Potential benefits were also described to participants, including: 1) they would receive education on how to care for their diabetes, and 2) their participation would help doctors better understand how to help African Americans manage their diabetes and, therefore, potentially help reduce disparities in diabetes outcomes. Patients were also informed that they would receive \$10 per group session and remuneration for in-person assessments (\$100 for three long assessments consisting of two visits and wearing the accelerometer for a week, and \$25 for one short assessment) in order to address transportation and other costs of participation. Patients were asked to discuss pros and cons of participation amongst themselves and share any questions or concerns with study staff.³⁸ At the end of the information session, interested patients

completed the informed consent process and were given a Point-of-Care A1C test. If A1C was $\geq 7.0\%$, RAs scheduled patients for a baseline assessment visit at the primary care clinic.

Baseline assessment visits and randomization—All participants were required to complete two assessment visits prior to enrollment. At the first visit, participants completed a 24-hour food recall, anthropomorphic measures, various questionnaires, and were given an accelerometer to wear for a week. All patients returned to the clinic approximately one week later to return the accelerometer and complete a second 24-hour food recall. After the second visit, patients were paid a cash incentive for completing the assessment process. Patients were enrolled in the study after completing both visits and randomized.

Measures

All assessments were conducted at the patients' primary care clinic by study RAs blinded to participant group assignment. A1C point of care was measured using capillary blood samples collected via finger stick. Blood pressure was measured with patient sitting using an Omron Digital Blood Pressure Monitor (Omron Healthcare, Inc. Lake Forest, Illinois) which averaged three readings taken over a 10-minute period. Dietary intake was measured using two in person 24-hour dietary recalls using the Nutrition Data System for Research software (Nutrition Coordinating Center, University of Minnesota, Minneapolis, Minnesota). The software uses the multiple-pass interview method and data collection is standardized by built-in software interview prompts. Physical activity was measured using an accelerometer worn around the hip or waist. Participants were asked to wear the device for seven days for at least 10 hours per day. Sedentary behavior was defined as the number of minutes out of the first 10 hours of valid wear time (which included waking hours only) in which accelerometer-derived vector magnitude counts ≤ 200 .³⁹ Daily minutes of moderate intensity activity was calculated by summing all minutes of moderate intensity activity per day. All outcome measures are listed in Box 1.* Additional details about study data collection procedures, variables and statistical analysis are described elsewhere.⁴⁰

Results

Recruitment

Recruitment began in March 2012 and was completed by April 2014. Figure 1 presents a consort diagram of the recruitment process. Based on medical record review, CCHHS identified 3,048 patients who met initial screening criteria. Study staff attempted to contact 2,797 (92%) of the potentially eligible patients. Patients were not contacted when recruitment goals for their clinic had been met. Of the patients attempted, RAs were unable to reach 1,394 (49.8%) of the prescreened patients after three attempts or because the telephone number was disconnected. Of the 1,403 patients who were successfully contacted, 822 (58.6%) agreed to be screened and 603 of the screened patients (73.3%) met eligibility criteria and agreed to attend information sessions. Of those who agreed to attend the information session, 269 (44.6%) attended, and a majority of those ($n = 254$, 94%) chose to

*Box 1 includes citations. Those citations appear along with all the other references at the end of this paper. The numbering of the citations in the box starts where the numbering of the citation in the whole text ends (i.e., it starts with #50).

participate and provided consent. Of those, 43 patients were excluded due to point-of care A1C < 7%. The remaining 211 participants completed baseline assessments and were randomized into the study.

Baseline characteristics

The baseline demographic and clinical characteristics of the total sample of randomized participants are presented in Tables 1 and 2. Participants were African American adults whose average age at randomization was 55 years old. A majority of the participants were female (70.1%) and single (51.7%) and had an annual household income less than \$40,000 (90.5%), and 54% completed some college. Most participants were unemployed (34.1%) or retired (22.8%), and were uninsured (65.4%). Physical, behavioral, and psychosocial baseline characteristics for the entire sample are presented in Table 3. Participants had high rates of obesity (70.1%) and a majority had hypertension (91%). Virtually all participants (97.6%) reported use of insulin and/or oral medication and 48.3% reported low medication adherence. Participants consumed higher than recommended amounts of total fat (37.9% of daily calories) and saturated fat (11.3%) and fewer vegetable servings than recommended (1.1 servings/day).^{41,42} The sample had low rates of physical activity—71% of the accelerometer minutes were classified as sedentary for both males and females. Finally, 28.4% of the sample reported experiencing moderate to severe depression over the prior two weeks.

Gender differences in baseline characteristics

There were no differences between females and males on age, income, education, marital status, employment status, or insurance status (see Table 1). Males had higher A1C values (9.2 vs 8.3, $p = .006$) and lower BMI (32.1 vs. 35.8, $p = .017$) than females (Table 2). Women were more likely than men to have hypertension (93.9% vs. 84.1%, $p = .023$) and had a greater number of non-diabetes-related co-morbid conditions (Table 2). Gender differences in behavioral and psychosocial factors were also noteworthy (see Table 3). Relative to females, males consumed a greater number of total daily calories (1947.5 vs. 1632.3, respectively, $p = .0002$), a greater number of total grain (6.3 vs. 5.3, $p = .02$) and protein (7.8 vs. 6.4, $p = .0005$) servings and more cholesterol per day (322.0 vs. 259.8 mg, $p = .03$). However, females consumed a greater percent of calories from carbohydrate (47.2 vs. 43.2%, $p = .026$) than males. Males were more physically active than females, with more minutes of moderate intensity physical activity (18 vs. 13, $p = .0003$) and a greater number of daily steps (3991 vs. 3461, $p = .02$). However, males and females had an equally high level of sedentary activity. Males were more than twice as likely to report consumption of two or more alcoholic drinks weekly, but females endorsed more depression, more stressful events in the past year, and a greater number of PTSD symptoms, as well as higher levels of religiosity, than males (see Table 3). Women had greater diabetes-related nutrition knowledge than did men (35 vs. 32, $p = .029$) and men reported a greater number of days meeting physical activity goals (2.5 versus 1.5 days per week, $p = .029$).

Discussion

Recruitment for this study included a number of strategies to address barriers to participation for both participants and community clinics. Use of these strategies resulted in successful and timely achievement of recruitment targets for an 18-month randomized controlled trial within the allotted two-year recruitment time period.

A number of strategies were utilized in order to address the well-documented distrust experienced by African Americans regarding medical research. First, all recruitment, both in-person and telephonic, was conducted from the patients' own clinic (i.e., the telephone number on caller ID was familiar to patients as it came from the clinic), and all assessment visits were conducted at the clinic. Second, all recruitment staff were African Americans who were culturally similar to participants. Third, participants were provided extensive information about the study prior to being asked to consent, including pros and cons of participation, and were invited to discuss pros and cons amongst themselves. Fourth, participants were provided financial assistance to cover transportation and other costs of participation, including payment for their time during the assessment visits.

Recruitment was facilitated by a successful partnership arrangement between the researchers and the community clinics and the Division of Endocrinology in the Department of Medicine at CCHHS. Literature suggests that concerns about the costs of participation can serve as a barrier to participating in research for community clinics. This barrier was addressed through a partnership agreement which defined expectations of each CCHHS entity and specified the costs of any services provided by the CCHHS. The ACHN was remunerated for clinic space for the RAs, potential costs of physician time to provide permission for patients to participate and additional patient visits that might be required to address changes in medication due to improved glycemic control from lifestyle changes of participating patients, and finally, for ACHN staff time to identify eligible patients and to problem-solve issues that arose among clinic staff. Division of Endocrine staff participated as paid members of the research and intervention teams and Division staff were compensated for medical record screening of potential participants. These strategies resulted in a collaborative partnership in which key CCHHS staff participated as equal members of the research team.

Characteristics of patients in this study suggest a need for tailoring of interventions to address the distinct needs of African American men and women. While both men and women could benefit from interventions to improved diet and exercise, women may especially benefit from interventions to manage depression and increase physical activity. In the LIFE sample, female participants endorsed higher rates of depression and stress compared to males. Given the association between depression and increased risk of diabetes complications,⁴³ and mortality,⁴⁴ mood could be an important target for further tailoring of the intervention for women.⁴⁵ In contrast, interventions focused on men may need to address higher rates of alcohol use. In fact, men may be more likely to be excluded from trials due to excessive use of alcohol as an exclusion criterion.²⁹ Finally, men and women appear to have distinct dietary patterns, suggesting a potential need for tailoring of nutrition education.

The differences between males and females extended also to BMI and glycemic control. Males had significantly lower BMI and worse glycemic control; half of the males had very poor glycemic control (A1c $\geq 9\%$). This may be counterintuitive because obesity is known to increase insulin resistance. The fact that males who were less obese had worse glycemic control may be explained by poorer self-management in males or by worse beta cell function. In a study conducted in a similar population it was suggested that lean males with diabetes may have accelerated decline of beta cell function associated with higher rate of alcohol consumption and smoking.⁴⁶

Study limitations

A limitation of the recruitment process was that we were more successful recruiting females than males. As in many studies with African Americans, men are under-represented in our study.⁴⁷ As indicated by our baseline data, men and women in our target population differed on a number of important clinical, behavioral, and psychosocial characteristics. Most of the men who enrolled in the study came from one clinic which had a special sub-clinic for African American men, staffed primarily by African American male physicians. Staff of this program worked with us to facilitate recruitment of men in that clinic. This suggests that recruitment of African American males may require additional strategies, including the use of African American male research staff and recruitment materials specifically targeting males.⁴⁷ Further research is needed to address underrepresentation of African American males in clinical trials.

In sum, strategies described here resulted in successful recruitment of low-income patients living in a range of urban areas, including highly segregated and impoverished neighborhoods. Recruitment results and characteristics of participants differed by gender, indicating that gender-specific intervention studies may be warranted in this population. Minority and lower socioeconomic status are associated with higher prevalence of T2DM, poorer T2DM clinical outcomes, higher rates of T2DM complications, and mortality.^{48,49} Inclusion of these individuals in a T2DM self-management intervention is challenging, but critical in order to increase knowledge about how best to address poor glycemic control among disadvantaged African Americans and reduce disparities in T2DM outcomes.

Acknowledgments

This research was supported by the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health under Award number RO1DK092271 and was part of the Rush Center for Urban Health Equity, which was funded by the National Institutes of Health (NIH) through the National Institute for Heart Lung and Blood (NHLBI), grant number 1P50HL105189-01. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. Tangula Jefferson, Candace Nicks, and Syed Quadri provided assistance with data collection. Jadwiga Miernik and Rajeev Mehrotra provided assistance with recruitment. Abdul Basith assisted with data management.

References

1. Narayan KM, Boyle JP, Thompson TJ, et al. Lifetime risk for diabetes mellitus in the United States. *JAMA*. 2003 Oct 8; 290(14):1884–90. <https://doi.org/10.1001/jama.290.14.1884>. [PubMed: 14532317]
2. Centers for Disease Control and Prevention (CDC). National Diabetes Statistics Report: estimates of diabetes and its burden in the United States, 2014. Atlanta, GA: U.S. Department of Health and

Human Services; 2014. Available at: <https://www.cdc.gov/diabetes/pdfs/data/2014-report-acknowledgments.pdf>

3. Davis SK, Liu Y, Gibbons GH. Disparities in trends of hospitalization for potentially preventable chronic conditions among African Americans during the 1990s: implications and benchmarks. *Am J Public Health*. 2003 Mar; 93(3):447–55. <https://doi.org/10.2105/AJPH.93.3.447>. [PubMed: 12604494]
4. Cook CB, Hentz JG, Tsui C, et al. Poor glycemic control increases risk of hospitalization in urban African Americans with diabetes. *Ethn Dis*. 2006 Autumn;16(4):880–5. [PubMed: 17061741]
5. Cook CB, Naylor DB, Hentz JG, et al. Disparities in diabetes-related hospitalizations: relationship of age, sex, and race/ethnicity with hospital discharges, lengths of stay, and direct inpatient charges. *Ethn Dis*. 2006 Winter;16(1):126–31. [PubMed: 16599360]
6. Karter AJ, Ferrara A, Liu JY, et al. Ethnic disparities in diabetic complications in an insured population. *JAMA*. 2002 May 15; 287(19):2519–27. <https://doi.org/10.1001/jama.287.19.2519>. [PubMed: 12020332]
7. McBean AM, Li S, Gilbertson DT, et al. Differences in diabetes prevalence, incidence, and mortality among the elderly of four racial/ethnic groups: whites, blacks, hispanics, and asians. *Diabetes Care*. 2004 Oct; 27(10):2317–24. <https://doi.org/10.2337/diacare.27.10.2317>. [PubMed: 15451894]
8. Mokdad AH, Ford ES, Bowman BA, et al. Diabetes trends in the U.S.: 1990–1998. *Diabetes Care*. 2000 Sep; 23(9):1278–83. <https://doi.org/10.2337/diacare.23.9.1278>. [PubMed: 10977060]
9. Harris MI, Eastman RC, Cowie CC, et al. Racial and ethnic differences in glycemic control of adults with type 2 diabetes. *Diabetes Care*. 1999 Mar; 22(3):403–8. <https://doi.org/10.2337/diacare.22.3.403>. [PubMed: 10097918]
10. Heisler M, Faul JD, Hayward RA, et al. Mechanisms for racial and ethnic disparities in glycemic control in middle-aged and older Americans in the health and retirement study. *Arch Intern Med*. 2007 Sep 24; 167(17):1853–60. <https://doi.org/10.1001/archinte.167.17.1853>. [PubMed: 17893306]
11. Norris SL, Engelgau MM, Venkat Narayan KM. Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes Care*. 2001 Mar; 24(3): 561–87. <https://doi.org/10.2337/diacare.24.3.561>. [PubMed: 11289485]
12. Powers MA, Bardsley J, Cypress M, et al. Diabetes self-management education and support in type 2 diabetes: a joint position statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. *Clin Diabetes*. 2016 Apr; 34(2):70–80. <https://doi.org/10.2337/diaclin.34.2.70>. [PubMed: 27092016]
13. Nothwehr F, Stump T. Health-promoting behaviors among adults with type 2 diabetes: findings from the Health and Retirement Study. *Prev Med*. 2000 May; 30(5):407–14. <https://doi.org/10.1006/pmed.2000.0658>. [PubMed: 10845750]
14. Stratton IM, Adler AI, Neil HA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): Prospective observational study. *BMJ*. 2000 Aug 12; 321(7258):405–12. <https://doi.org/10.1136/bmj.321.7258.405>. [PubMed: 10938048]
15. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). UK Prospective Diabetes Study (UKPDS) Group. *Lancet*. 1998 Sep 12; 352(9131):854–65. [https://doi.org/10.1016/S0140-6736\(98\)07037-8](https://doi.org/10.1016/S0140-6736(98)07037-8). [PubMed: 9742977]
16. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group. *Lancet*. 1998 Sep 12; 352(9131):837–53. [https://doi.org/10.1016/S0140-6736\(98\)07019-6](https://doi.org/10.1016/S0140-6736(98)07019-6). [PubMed: 9742976]
17. Norris SL, Lau J, Smith SJ, et al. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes care*. 2002 Jul; 25(7):1159–71. <https://doi.org/10.2337/diacare.25.7.1159>. [PubMed: 12087014]
18. Ali MK, Echouffo-Tcheugui J, Williamson DF. How effective were lifestyle interventions in real-world settings that were modeled on the Diabetes Prevention Program? *Health Aff (Millwood)*. 2012 Jan; 31(1):67–75. <https://doi.org/10.1377/hlthaff.2011.1009>. [PubMed: 22232096]

19. Murthy VH, Krumholz HM, Gross CP. Participation in cancer clinical trials: race-, sex-, and age-based disparities. *JAMA*. 2004 Jun 9; 291(22):2720–6. <https://doi.org/10.1001/jama.291.22.2720>. [PubMed: 15187053]
20. Scharff DP, Mathews KJ, Jackson P, et al. More than Tuskegee: understanding mistrust about research participation. *J Health Care Poor Underserved*. 2010 Aug; 21(3):879–97. <https://doi.org/10.1353/hpu.0.0323>. [PubMed: 20693733]
21. Williams DR, Neighbors HW, Jackson JS. Racial/ethnic discrimination and health: findings from community studies. *Am J Public Health*. 2008 Sep; 98(9 Suppl):S29–37. https://doi.org/10.2105/AJPH.98.Supplement_1.S29. [PubMed: 18687616]
22. Sampsel CM. Nickel-and-Dimed in America: underserved, understudied, and underestimated. *Fam Community Health*. 2007 Jan-Mar; 30(1 Suppl):S4–14. <https://doi.org/10.1097/00003727-200701001-00003>. [PubMed: 17159631]
23. Stahl SM, Vasquez L. Approaches to improving recruitment and retention of minority elders participating in research: examples from selected research groups including the National Institute on Aging's Resource Centers for Minority Aging Research. *J Aging Health*. 2004 Nov; 16(5 Suppl):9S–17S. <https://doi.org/10.1177/0898264304268146>. [PubMed: 15448284]
24. Corbie-Smith G, Thomas SB, St George DM. Distrust, race, and research. *Arch Intern Med*. 2002 Nov 25; 162(21):2458–63. <https://doi.org/10.1001/archinte.162.21.2458>. [PubMed: 12437405]
25. Armstrong K, McMurphy S, Dean LT, et al. Differences in the patterns of health care system distrust between Blacks and Whites. *J Gen Intern Med*. 2008 Jun; 23(6):827–33. Epub 2008 Feb 26. <https://doi.org/10.1007/s11606-008-0561-9>. [PubMed: 18299939]
26. George S, Duran N, Norris K. A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders. *Am J Public Health*. 2014 Feb; 104(2):e16–31. Epub 2013 Dec 12. <https://doi.org/10.2105/AJPH.2013.301706>.
27. Corbie-Smith G, Thomas SB, Williams MV, et al. Attitudes and beliefs of African Americans toward participation in medical research. *J Gen Intern Med*. 1999 Sep; 14(9):537–46. <https://doi.org/10.1046/j.1525-1497.1999.07048.x>. [PubMed: 10491242]
28. Yancey AK, Ortega AN, Kumanyika SK. Effective recruitment and retention of minority research participants. *Annu Rev Public Health*. 2006; 27:1–28. <https://doi.org/10.1146/annurev.publhealth.27.021405.102113>. [PubMed: 16533107]
29. Shavers-Hornaday VL, Lynch CF, Burmeister LF, et al. Why are African Americans under-represented in medical research studies? Impediments to participation. *Ethn Health*. 1997 Mar-Jun; 2(1–2):31–45. <https://doi.org/10.1080/13557858.1997.9961813>. [PubMed: 9395587]
30. Shoff C, Yang TC. Untangling the associations among distrust, race, and neighborhood social environment: a social disorganization perspective. *Soc Sci Med*. 2012 May; 74(9):1342–52. Epub 2012 Feb 24. <https://doi.org/10.1016/j.socscimed.2012.01.012>. [PubMed: 22425069]
31. Penberthy L, Brown R, Wilson-Genderson M, et al. Barriers to therapeutic clinical trials enrollment: differences between African-American and White cancer patients identified at the time of eligibility assessment. *Clin Trials*. 2012 Dec; 9(6):788–97. Epub 2012 Oct 2. <https://doi.org/10.1177/1740774512458992>. [PubMed: 23033547]
32. Swanson GM, Ward AJ. Recruiting minorities into clinical trials toward a participant-friendly system. *J Natl Cancer Inst*. 1995 Dec 6; 87(23):1747–59. <https://doi.org/10.1093/jnci/87.23.1747>. [PubMed: 7473831]
33. Davis RM, Hitch AD, Nichols M, et al. A collaborative approach to the recruitment and retention of minority patients with diabetes in rural community health centers. *Contemp Clin Trials*. 2009 Jan; 30(1):63–70. Epub 2008 Sep 16. <https://doi.org/10.1016/j.cct.2008.09.007>. [PubMed: 18824135]
34. Beeson T, Jester M, Proser M, et al. Engaging Community Health Centers (CHCs) in research partnerships: the role of prior research experience on perceived needs and challenges. *Clin Transl Sci*. 2014 Apr; 7(2):115–20. <https://doi.org/10.1111/cts.12150>. [PubMed: 24774327]
35. Bower P, Wallace P, Ward E, et al. Improving recruitment to health research in primary care. *Fam Pract*. 2009 Oct; 26(5):391–7. <https://doi.org/10.1093/fampra/cmp037>. [PubMed: 19549623]

36. Sims M, Diez Roux AV, Boykin S, et al. The socioeconomic gradient of diabetes prevalence, awareness, treatment, and control among African Americans in the Jackson Heart Study. *Ann Epidemiol.* 2011 Dec; 21(12):892–8. Epub 2011 Jul 7. <https://doi.org/10.1016/j.annepidem.2011.05.006>. [PubMed: 21737303]
37. Regenstein, M., Huang, J., Cummings, L., et al. Caring for patients with diabetes in safety net hospitals and health systems. New York, NY: The Commonwealth Fund; 2005. Available at: <http://www.commonwealthfund.org/publications/fund-reports/2005/jun/caring-for-patients-with-diabetes-in-safety-net-hospitals-and-health-systems>
38. Goldberg JH, Kiernan M. Innovative techniques to address retention in a behavioral weight-loss trial. *Health Educ Res.* 2005 Aug; 20(4):439–47. Epub 2004 Dec 14. <https://doi.org/10.1093/her/cyg139>. [PubMed: 15598664]
39. Aguilar-Farias N, Brown WJ, Peeters GM. ActiGraph GT3X+ cut-points for identifying sedentary behaviour in older adults in free-living environments. *J Sci Med Sport.* 2014 May; 17(3):293–9. Epub 2013 Aug 8. <https://doi.org/10.1016/j.jsams.2013.07.002>. [PubMed: 23932934]
40. Lynch EB, Liebman R, Ventrelle J, et al. Design of the Lifestyle Improvement through Food and Exercise (LIFE) study: a randomized controlled trial of self-management of type 2 diabetes among African American patients from safety net health centers. *Contemp Clin Trials.* 2014 Nov; 39(2): 246–55. <https://doi.org/10.1016/j.cct.2014.09.003>. [PubMed: 25245954]
41. Evert AB, Boucher JL, Cypress M, et al. Nutrition therapy recommendations for the management of adults with diabetes. *Diabetes Care.* 2014 Jan; 37(Suppl 1):S120–43. <https://doi.org/10.2337/dc14-S120>. [PubMed: 24357208]
42. Vitolins MZ, Anderson AM, Delahanty L, et al. Action for Health in Diabetes (Look AHEAD) trial: baseline evaluation of selected nutrients and food group intake. *J Am Diet Assoc.* 2009 Aug; 109(8):1367–75. <https://doi.org/10.1016/j.jada.2009.05.016>. [PubMed: 19631042]
43. Woods VD, Montgomery SB, Herring RP. Recruiting Black/African American men for research on prostate cancer prevention. *Cancer.* 2004 Mar 1; 100(5):1017–25. <https://doi.org/10.1002/cncr.20029>. [PubMed: 14983498]
44. Lin EH, Rutter CM, Katon W, et al. Depression and advanced complications of diabetes: a prospective cohort study. *Diabetes Care.* 2010 Feb; 33(2):264–9. Epub 2009 Nov 23. <https://doi.org/10.2337/dc09-1068>. [PubMed: 19933989]
45. Katon WJ, Rutter C, Simon G, et al. The association of comorbid depression with mortality in patients with type 2 diabetes. *Diabetes Care.* 2005 Nov; 28(11):2668–72. <https://doi.org/10.2337/diacare.28.11.2668>. [PubMed: 16249537]
46. Walker RJ, Smalls BL, Campbell JA, et al. Impact of social determinants of health on outcomes for type 2 diabetes: a systematic review. *Endocrine.* 2014 Sep; 47(1):29–48. Epub 2014 Feb 15. <https://doi.org/10.1007/s12020-014-0195-0>. [PubMed: 24532079]
47. Coleman NJ, Miernik J, Philipson L, et al. Lean versus obese diabetes mellitus patients in the United States minority population. *J Diabetes Complications.* 2014 Jul-Aug; 28(4):500–5. Epub 2013 Nov 27. <https://doi.org/10.1016/j.jdiacomp.2013.11.010>. [PubMed: 24581791]
48. Parrinello CM, Rastegar I, Godino JG, et al. Prevalence of and racial disparities in risk factor control in older adults with diabetes: the atherosclerosis risk in communities study. *Diabetes Care.* 2015 Jul; 38(7):1290–8. <https://doi.org/10.2337/dc15-0016>. [PubMed: 25852205]
49. Chatterji P, Joo H, Lahiri K. Racial/ethnic- and education-related disparities in the control of risk factors for cardiovascular disease among individuals with diabetes. *Diabetes Care.* 2012 Feb; 35(2):305–12. Epub 2011 Dec 21. <https://doi.org/10.2337/dc11-1405>. [PubMed: 22190677]
50. Wood JR, Kaminski BM, Kollman C, et al. Accuracy and precision of the Axis-Shield Afinion hemoglobin A1c measurement device. *J Diabetes Sci Technol.* 2012 Mar 1; 6(2):380–6. <https://doi.org/10.1177/193229681200600224>. [PubMed: 22538150]
51. Parmenter K, Wardle J. Development of a general nutrition knowledge questionnaire for adults. *Eur J Clin Nutr.* 1999 Apr; 53(4):298–308. <https://doi.org/10.1038/sj.ejcn.1600726>. [PubMed: 10334656]
52. Parmenter K, Wardle J. Evaluation and design of nutrition knowledge measures. *J Nutrition Education.* 2000 Sep; 32(5):269–77. [https://doi.org/10.1016/S0022-3182\(00\)70575-9](https://doi.org/10.1016/S0022-3182(00)70575-9).

53. Sasaki JE, John D, Freedson PS. Validation and comparison of ActiGraph activity monitors. *J Sci Med Sport*. 2011 Sep; 14(5):411–6. Epub 2011 May 25. <https://doi.org/10.1016/j.jsams.2011.04.003>. [PubMed: 21616714]
54. Fitzgerald JT, Davis WK, Connell CM, et al. Development and validation of the Diabetes Care Profile. *Eval Health Prof*. 1996 Jun; 19(2):208–30. <https://doi.org/10.1177/016327879601900205>. [PubMed: 10186911]
55. Anderson RM, Fitzgerald JT, Wisdom K, et al. A comparison of global versus disease-specific quality-of-life measures in patients with NIDDM. *Diabetes Care*. 1997 Mar; 20(3):299–305. <https://doi.org/10.2337/diacare.20.3.299>. [PubMed: 9051376]
56. Fitzgerald JT, Anderson RM, Gruppen LD, et al. The reliability of the Diabetes Care Profile for African Americans. *Eval Health Prof*. 1998 Mar; 21(1):52–65. <https://doi.org/10.1177/016327879802100103>. [PubMed: 10183339]
57. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care*. 2000 Jul; 23(7):943–50. <https://doi.org/10.2337/diacare.23.7.943>. [PubMed: 10895844]
58. Morisky DE, Ang A, Krousel-Wood M, et al. Predictive validity of a medication adherence measure in an outpatient setting. *J Clin Hypertens (Greenwich)*. 2008 May; 10(5):348–54. <https://doi.org/10.1111/j.1751-7176.2008.07572.x>. [PubMed: 18453793]
59. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med*. 2001 Sep; 16(9):606–13. <https://doi.org/10.1046/j.1525-1497.2001.016009606.x>. [PubMed: 11556941]
60. Boardman JD, Finch BK, Ellison CG, et al. Neighborhood disadvantage, stress, and drug use among adults. *J Health Soc Behav*. 2001 Jun; 42(2):151–65. <https://doi.org/10.2307/3090175>. [PubMed: 11467250]
61. Mills K, Teesson M, Darke S, et al. Reliability of self-reported trauma exposure among people with heroin dependence: a longitudinal investigation. *J Trauma Stress*. 2007 Jun; 20(3):313–23. <https://doi.org/10.1002/jts.20219>. [PubMed: 17598137]
62. Lang AJ, Stein MB. An abbreviated PTSD checklist for use as a screening instrument in primary care. *Behav Res Ther*. 2005 May; 43(5):585–94. <https://doi.org/10.1016/j.brat.2004.04.005>. [PubMed: 15865914]
63. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav*. 1983 Dec; 24(4):385–96. <https://doi.org/10.2307/2136404>. [PubMed: 6668417]
64. Sharp LK, Kimmel LG, Kee R, et al. Assessing the Perceived Stress Scale for African American adults with asthma and low literacy. *J Asthma*. 2007 May; 44(4):311–6. <https://doi.org/10.1080/02770900701344165>. [PubMed: 17530531]
65. Krieger N, Smith K, Naishadham D, et al. Experiences of discrimination: validity and reliability of a self-report measure for population health research on racism and health. *Soc Sci Med*. 2005 Oct; 61(7):1576–96. Epub 2005 Apr 21. <https://doi.org/10.1016/j.socscimed.2005.03.006>. [PubMed: 16005789]
66. Taylor TR, Kamarck TW, Shiffman S. Validation of the Detroit Area Study Discrimination Scale in a community sample of older African American adults: the Pittsburgh healthy heart project. *Int J Behav Med*. 2004; 11(2):88–94. https://doi.org/10.1207/s15327558ijbm1102_4. [PubMed: 15456677]
67. Underwood LG, Teresi JA. The daily spiritual experience scale: development, theoretical description, reliability, exploratory factor analysis, and preliminary construct validity using health-related data. *Ann Behav Med*. 2002 Winter; 24(1):22–33. https://doi.org/10.1207/S15324796ABM2401_04. [PubMed: 12008791]
68. Skarupski KA, Fitchett G, Evans DA, et al. Race differences in the association of spiritual experiences and life satisfaction in older age. *Aging Ment Health*. 2013; 17(7):888–95. Epub 2013 Apr 29. <https://doi.org/10.1080/13607863.2013.793285>. [PubMed: 23627686]
69. Weiss BD, Mays MZ, Martz W, et al. Quick assessment of literacy in primary care: the newest vital sign. *Ann Fam Med*. 2005 Nov-Dec; 3(6):514–22. <https://doi.org/10.1370/afm.405>. [PubMed: 16338915]

Box 1**LIST OF MEASURES USED IN THE LIFESTYLE IMPROVEMENT THROUGH FOOD AND EXERCISE (LIFE) STUDY**

Demographic Characteristics	Measures
Participant demographic information	Self-reported demographic questionnaires, which included questions about income, education, employment and insurance.
Physical Characteristics	Measures
Glycemic control	Hemoglobin A1c levels. Blood samples were collected via finger stick and processed through the Axis-Shield Afinion A1CPOC device. ⁵⁰
Blood pressure	Blood pressure was measured using Omron Digital Blood Pressure Monitor (Omron Healthcare, Inc. Lake Forest, Illinois). Final value was average of three readings taken 2 minutes apart while participant was seated.
Body Mass Index	Weight measured using a balance beam digital scale (Health O Meter), reported to 1/10 kilograms (5 min). Height measured using wall mounted stadiometer. BMI calculated by dividing weight (kilograms) by height (meters squared).
Waist circumference	Nearest cm at narrowest part of torso, above iliac crest, below rib cage
Medications	Participants brought all medications to assessment visit and Research assistant recorded medication and dosage.
Medical History	Self-reported participant medical history information such as duration diabetes age of onset, number of diabetes complications and comorbidities, Emergency Room visits in past 6 months, etc.
Behavioral Characteristics	Measures
Diet	Dietary intake was measured using the Nutrition Data System for Research 24-Hour Dietary Recall (NDSR; Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN), a computer-based software application that facilitates the collection of standardized dietary recalls using a multiple-pass interview approach.
Nutrition knowledge	Adapted version of the sources of nutrients subscale of the General Nutrition Knowledge questionnaire ^{51,52}
Physical Activity.	Mean weekly minutes of moderate level activity, daily steps, and sedentary time were measured with the Actigraph GT3X, a tri-axial accelerometer measuring acceleration in three axes (vertical, anteroposterior, mediolateral) and step count. Classifications of daily light, moderate, vigorous, very vigorous physical activity minutes and minutes in sedentary behavior were determined based on previously published thresholds. ^{39,53} The accelerometer data were scored using PC-SAS (SAS Institute Inc., Cary, NC) version 9.2, partly using sample codes from NHANES accelerometer data analysis (http://riskfactor.cancer.gov/tools/nhanes_pam).
Perceived social support	Support received subscale from Diabetes Care Profile ^{54–56}
Diabetes-specific quality of life	Social and Personal Factors subscale from Diabetes Care Profile ^{54–56}
Self-efficacy	Self-care ability subscale from Diabetes Care Profile ^{54–56}
Diabetes self-care behaviors	The Summary of Diabetes Self-Care Activities Measure ⁵⁷
Medication adherence	Morisky Medication Adherence Scale (MMAS) -8 item ⁵⁸
Depression	Patient Health Questionnaire (PHQ-9) ⁵⁹
Stressful events (experienced over past year)	Past Stressor Events Form (PSE) ⁶⁰

Stressful events (experienced over lifetime)	Traumatic Stress Checklist ⁶¹
Posttraumatic Stress Disorder	PCL-Civilian Short Form ⁶²
Perception of stress	Perceived Stress Scale (PSS) 4 item version ^{63,64}
Perceived discrimination	Perceived Discrimination Scale ^{65,66}
Religiosity	Selected items from the Daily Spiritual Experiences Scale ^{67,68}
Health Literacy	Newest Vital Sign (NVS) ⁶⁹

Figure 1.
Consort diagram of the recruitment process

Table 1**DEMOGRAPHIC CHARACTERISTICS OF PARTICIPANTS IN THE LIFESTYLE IMPROVEMENT THROUGH FOOD AND EXERCISE (LIFE) STUDY**

Variable	Total Sample (N = 211)	Females (N = 148)	Males (N = 63)	p-value ^a
Age, mean (std)	55.0 (10.3)	55.7 (10.2)	53.4 (10.5)	.139
African American race, n (%)	211 (100.0)			
Education, n (%)				.376
Less than HS	28 (13.3)	20 (13.5)	8 (12.7)	
High School	69 (32.7)	43 (29.1)	26 (41.3)	
Some College/Technical School	87 (41.2)	65 (43.9)	22 (34.9)	
College +	27 (12.8)	20 (13.5)	7 (11.1)	
Low health literacy ^b , n (%)	83 (39.3)	54 (36.5)	29 (46.0)	.194
Relationship status, n (%)				.373 ^c
Single	109 (51.7)	78 (52.7)	31 (49.2)	
Lives with partner/spouse	50 (23.7)	30 (20.3)	20 (31.7)	
Lives separately from partner/spouse	14 (6.6)	12 (8.1)	2 (3.2)	
Divorced	21 (9.9)	15 (10.1)	6 (9.5)	
Widowed	17 (8.1)	13 (8.8)	4 (6.3)	
Annual income ^d , n (%)				.024 ^c
<\$9,999	68 (32.2)	46 (31.1)	22 (34.9)	
\$10,000–\$19,999	67 (31.8)	56 (37.8)	11 (17.5)	
\$20,000–\$39,999	56 (26.5)	33 (22.3)	23 (36.5)	
>\$40,000	11 (5.2)	8 (5.4)	3 (4.8)	
Refused/Do not know	9 (4.3)	5 (3.4)	4 (6.4)	
Insurance, n (%)				.975 ^c
Medicare only	29 (13.7)	22 (14.9)	7 (11.1)	
Medicaid only	24 (11.4)	18 (12.2)	6 (9.5)	
Medicare plus Medicaid	8 (3.8)	6 (4.1)	2 (3.2)	
Private	8 (3.8)	6 (4.1)	2 (3.2)	
Other	4 (1.0)	3 (3.2)	1 (1.6)	
Uninsured	138 (65.4)	93 (62.8)	45 (71.4)	
Employment, n (%)				.612 ^c
Full time employment	25 (11.9)	19 (12.8)	6 (9.5)	
Part time employment	26 (12.3)	15 (10.1)	11 (17.5)	
Unemployed	72 (34.1)	53 (35.8)	19 (30.2)	
Retired	48 (22.8)	35 (23.6)	13 (20.6)	
Too ill to work	27 (12.8)	17 (11.5)	10 (15.9)	
Other/refused	13 (6.2)	9 (6.1)	4 (6.3)	

^aWilcoxon used for comparing non-normal data, Chi-square used for categorical data, t-tests used for normally distributed continuous data.

^bHealth literacy measured by the Newest Vital Sign, 6 items, yes-no response format, higher scores indicate greater health literacy, limited health literacy is defined as a score of 0–1.

^c Fisher's exact test used for categorical data with cell counts < 5.

^d Total family annual income before taxes.

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

Table 2**PHYSICAL CHARACTERISTICS OF PARTICIPANTS IN THE LIFESTYLE IMPROVEMENT THROUGH FOOD AND EXERCISE (LIFE) STUDY**

Variable	Total Sample (N = 211)	Females (N = 148)	Males (N = 63)	p-value ^a
Time since diabetes diagnosis, median (25 th , 75 th perc)	9.4 (4.6, 15.0)	9.5 (5.0, 15.7)	7.8 (3.5, 15.0)	.205
Diabetes diagnosis within past year, n (%)	7 (3.3)	4 (2.7)	3 (4.8)	.424
Age of diabetes diagnosis, median (25 th , 75 th perc)	47.0 (36.0, 53.0)	46.5 (36.0, 53.5)	47.0 (36.0, 52.0)	.702
Body weight, (kg), median (25 th , 75 th perc)	96.6 (83.5, 112.0)	95.0 (82.4, 110.4)	101.2 (86.6, 115.7)	.160
Body mass index, median (25 th , 75 th perc)	34.7 (29.3, 40.2)	35.8 (30.5, 41.2)	32.1 (28.2, 37.3)	.004
Body mass index categories, n (%)				.073
0 BMI<25	15 (7.1)	8 (5.4)	7(11.1)	
25 BMI<30	48 (22.8)	28 (18.9)	20 (31.8)	
30 BMI<35	46 (21.8)	32 (21.6)	14 (22.2)	
35 BMI<40	49 (23.2)	38 (25.7)	11 (17.5)	
BMI 40	53 (25.1)	42 (28.4)	11 (17.5)	
Waist circumference (in), mean (std)	44.3 (6.4)	44.4 (6.2)	44.1 (6.9)	.747
Hemoglobin A1c, median (25 th , 75 th perc)	8.5 (7.8, 9.8)	8.3 (7.6, 9.6)	9.2 (8.0, 10.7)	.006
Systolic blood pressure (mm Hg), mean (std)	133.3 (17.6)	132.0 (17.5)	136.4 (17.7)	.099
Diastolic blood pressure (mm Hg), mean(std)	80.9 (10.8)	80.2 (10.4)	82.4(11.8)	.188
Diabetic medications, n (%)				.835 ^b
Insulin ^c	103 (48.8)	71 (48.0)	32 (50.8)	
Oral Agent only	107 (50.7)	76 (51.4)	31 (49.2)	
Diet control only	1 (0.5)	1 (0.7)	0 (0.0)	
History of hypertension ^d , n (%)	192 (91.0)	139 (93.9)	53 (84.1)	.023
Frequency of self-reported hypoglycemic incidents, n (%)				.163 ^b
0 times/month	82 (39.4)	51 (34.7)	31 (50.8)	
1–3 times/month	93 (44.7)	70 (47.6)	23 (37.7)	
4–6 times/month	19 (9.1)	14 (9.5)	5 (8.2)	
>=7 times/month	14 (6.7)	12 (8.2)	2 (3.3)	
Number of diabetes complications and comorbidities ^e , median (25 th , 75 th perc)	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)	1.0 (0, 2.0)	.137
Total Number of other chronic conditions ^{f,g} , median (25 th , 75 th perc)	1.0 (0, 2.0)	1.0 (0, 2.0)	1.0 (0, 1.0)	.004
Emergency Room admission in past 6 months, n (%)	43 (20.4)	27 (18.2)	16 (25.4)	.238

^aWilcoxon used for comparing non-normal data, Chi-square used for categorical data, t-tests used for normally distributed continuous data.

^bFisher's exact test used for categorical data with cell counts < 5.

^cParticipant uses insulin only or insulin plus oral medication for diabetes management.

^dSelf-reported hypertension, >140(s) /or >90(d) mm Hg, or currently taking blood pressure lowering medications.

^eDiabetic complications and comorbidities include history of hypertension, dialysis, heart attack or myocardial infarction, heart failure, stroke, renal insufficiency, dialysis, diabetes related eye-damage, 4+ hypoglycemic incidents per month.

^fHistory of cancer, arthritis, lung, cirrhosis or liver disease, depression, asthma, sleep apnea, neurological diseases, HIV or AIDs, serious mental illness.

^gAlthough the two groups have equal medians, Wilcoxon test showing statistically significant gender differences because the ranges differ between men and women with women reaching a higher number of chronic conditions.

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

Table 3

BEHAVIORAL CHARACTERISTICS (DIET, EXERCISE, SUBSTANCE USE, PSYCHOSOCIAL) OF PARTICIPANTS IN THE LIFESTYLE IMPROVEMENT THROUGH FOOD AND EXERCISE (LIFE) STUDY

Variable	Total Sample (N = 211) ^a	Females (N = 148)	Males (N = 63)	p-value ^b
Diet, median (25 th , 75 th perc)				
Total kcal	1749.1 (1335.3, 2235.6)	1632.3 (1299.9, 2103.5)	1947.5 (1642.4, 2680.6)	.0002
Percent kcal from carbohydrate	45.1 (38.9, 51.1)	47.2 (40.5, 51.9)	43.2 (37.9, 47.3)	.026
Percent kcal from protein	17.0 (14.0, 19.6)	16.7 (13.7, 19.6)	17.2 (14.2, 20.0)	.298
Percent kcal from total fat	37.9 (32.2, 41.9)	37.0 (31.6, 41.5)	39.2 (34.9, 43.2)	.096
Percent kcal from sat fat	11.3 (9.4, 13.2)	11.1 (9.1, 13.2)	11.7 (9.9, 13.2)	.478
Percent kcal from trans fat	1.3 (0.9, 1.9)	1.3 (0.9, 1.9)	1.2 (0.7, 2.0)	.398
Dietary cholesterol (mg)	280.4 (175.3, 391.8)	259.8 (164.2, 372.4)	322.0 (208.1, 444.2)	.030
Sodium/1000 kcal (g)	1.7 (1.4, 2.1)	1.7 (1.4, 2.1)	1.7 (1.4, 1.9)	.364
Total dietary fiber/1000 kcal (g)	7.9 (5.8, 10.6)	8.2 (6.0, 10.7)	7.6 (5.5, 9.7)	.335
Total grains (oz)	5.5 (3.9, 7.1)	5.3 (3.8, 6.6)	6.3 (4.1, 8.6)	.020
Total protein servings (oz)	6.8 (4.7, 9.4)	6.4 (4.4, 8.4)	7.8 (6.0, 12.2)	.0005
Total dairy servings (c)	0.5 (0.3, 1.1)	0.5 (0.3, 1.0)	0.5 (0.3, 1.2)	.857
Total fruit servings (c)	0.3 (0, 0.7)	0.3 (0, 0.7)	0.3 (0, 1.0)	.142
Total vegetable servings (c)	1.1 (0.6, 1.8)	1.1 (0.7, 1.7)	1.2 (0.5, 2.4)	.704
Non-starchy vegetables (excluding potatoes, corn, legumes, peas) (c)	0.2 (0.02, 0.5)	0.2 (0.02, 0.5)	0.2 (0.01, 0.4)	.632
Nutrition knowledge ^c , median (25 th , 75 th perc)	35.0 (27.0, 40.0)	35.0 (29.5, 41.5)	32.0 (24.0, 38.0)	.029
Physical activity, median (25 th , 75 th perc)				
Daily moderate intensity activity (minutes)	14.6 (7.8, 23.9)	13.0 (6.2, 20.8)	18.0 (11.5, 33.9)	.0003
Daily sedentary minutes	427 (364, 483)	428 (365, 484)	422 (362, 483)	.897
Daily average steps	3614 (2468, 4984)	3461 (2378, 4808)	3991 (2785, 5508)	.020
Current smoker, n (%)	47 (22.3)	31 (20.9)	16 (25.4)	.477
Alcohol beverages consumed in past year, n (%)				.027 ^d
Never	113 (53.5)	82 (55.4)	31 (49.2)	
Monthly or less	67 (31.7)	50 (33.8)	17 (27.0)	
Two to four times a month	19 (9.0)	12 (8.1)	7 (11.1)	
Two or more times per week	12 (5.7)	4 (2.7)	8 (12.7)	
Drug use in past 30 days ^e , n (%)	1 (0.5)	0 (0.0)	1 (1.6)	n/a
Drug use ever, n (%)	47 (22.3)	28 (18.9)	19 (30.2)	.072
Diabetes specific social support ^f , mean (std)	3.3 (1.2)	3.4 (1.2)	3.2 (1.2)	.473
Diabetes specific quality of life ^g , mean (std)	2.5 (0.8)	2.5 (0.8)	2.5 (0.7)	.678
Diabetes specific self-efficacy ^h , mean (std)	2.9 (0.8)	2.9 (0.9)	2.9 (0.8)	.814
Diabetes self-care behaviors ⁱ , median (25 th , 75 th perc)				
General Diet Adherence	3.0 (1.0, 4.0)	3.0 (1.0, 4.0)	2.5 (0.0, 4.5)	.561

Variable	Total Sample (N = 211) ^a	Females (N = 148)	Males (N = 63)	p-value ^b
Specific Diet Adherence	3.0 (2.0, 4.0)	3.0 (2.0, 4.0)	2.5 (1.5, 4.0)	.165
Exercise Adherence	2.0 (0.0, 3.5)	1.5 (0.0, 3.5)	2.5 (0.0, 4.0)	.029
Glucose Self-monitoring Adherence	3.0 (0.0, 7.0)	3.0 (0.0, 6.8)	3.0 (1.0, 7.0)	.228
Foot Care Adherence	4.5 (3.5, 7.0)	4.5 (3.5, 7.0)	4.0 (3.0, 7.0)	.658
Low medication adherence ^j , n (%)	77 (36.5)	57 (38.5)	20 (31.8)	.435
PHQ-9 ^k , median (25 th , 75 th perc)	6.0 (2.0, 10.0)	6.5 (2.0, 12.0)	5.0 (2.0, 8.0)	.015
Moderate/severe depression ^l , n (%)	60 (28.4)	52 (35.1)	8 (12.7)	.001
Stressful events (past year) ^m , median (25 th , 75 th perc)	2.0 (1.0, 4.0)	3.0 (2.0, 4.0)	2.0 (1.0, 3.0)	.013
Stressful events (lifetime) ⁿ , median (25 th , 75 th perc)	2.0 (1.0, 4.0)	2.0 (1.0, 3.0)	3.0 (1.0, 4.0)	.102
PTSD ^o , median (25 th , 75 th perc)	7.0 (6.0, 12.0)	8.0 (6.0, 12.0)	7.0 (6.0, 10.0)	.025
Perceived stress ^p , mean (std)	4.2 (3.3)	4.3 (3.4)	4.0 (3.1)	.604
Perceived discrimination ^q , mean (std)	1.0 (0.8)	1.1 (0.8)	1.0 (0.8)	.604
Religiosity ^r , mean (std)	4.3 (0.9)	4.4 (0.8)	4.1 (0.9)	.007

^a n = 210 for dietary variables.

^b Wilcoxon used for comparing non-normal data, Chi-square used for categorical data, t-tests used for normally distributed continuous data.

^c Nutrition Knowledge Questionnaire, 46 items, response format: yes, no, I don't know. Score range: 0–46. Higher scores indicate greater nutrition knowledge.

^d Fisher's exact test used for categorical data with cell counts < 5.

^e Drug queries include cocaine (coke, crack), methamphetamine (speed, crystal meth, ice), hallucinogens (LSD, acid, mushrooms, PCP, Special K, ecstasy), street opioids (heroin, opium), prescription opioids (fentanyl, oxycodone [OxyContin, percocet], hydrocodone [Vicodin], methadone, buprenorphine).

^f Support attitudes subscale from Diabetes Care Profile, 6 items, response format: range 1–5 (*strongly disagree* to *strongly agree*). Higher scores indicate more social support.

^g Social and personal factors subscale from Diabetes Care Profile, 13 items, response format: range 1–5 (*strongly disagree* to *strongly agree*). Lower scores indicate higher quality of life.

^h Self-care ability subscale from Diabetes Care Profile, 4 items, response format: range 1–5 (*strongly disagree* to *strongly agree*). Higher scores indicate greater self-efficacy.

ⁱ Summary of Diabetes Self-Care Activities Measure, 5 domains, 10 items, response format: range 0–7 (number of days performed activity). Higher scores indicate greater adherence to diabetes self-care behaviors.

^j Morisky Medication Adherence Scale, 8 item, response format: yes-no. MMAS score = 3.

^k Patient Health Questionnaire-9, 9 items, response format: range 0–3 (*Not at all* to *nearly every day*). Higher scores indicate greater depression severity. Score range: 0–27.

^l PHQ-9 score = 10.

^m Past Stressor Events Form, 10 items, response format: yes, no, refuse. Higher score indicates experiencing more stressful events over past year.

ⁿ Traumatic Stress Checklist, 11 items, response format: yes, no, don't know, refuse. Higher score indicates experiencing more stressful events over a lifetime.

^o Short Form of the PTSD CheckList—Civilian Version, 6 items, response format: range 1–5 (*not at all* to *extremely*). Higher scores indicate more severe symptoms of PTSD. Score range: 0–30.

^p Perceived Stress Scale, 4 items, response format: range 1–5 (*never* to *very oft en*). Higher scores indicate higher levels of perceived stress.

^q Perceived Discrimination Scale, 10 items, response format: range 1–4 (*never* to *oft en*). Higher scores indicate higher levels of perceived discrimination.

^r Items from the Daily Spiritual Experiences Scale, 4 items, response format: range 1–6 (*many times a day* to *once a year or less*). Higher scores indicate higher levels of religiosity.