Randomized Trial of a Lifestyle Intervention for Urban Low-Income African Americans with Type 2 Diabetes

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BACKGROUND: African Americans suffer more than non-Hispanic whites from type 2 diabetes, but diabetes self-management education (DSME) has been less effective at improving glycemic control for African Americans. Our objective was to determine whether a novel, culturally tailored DSME intervention would result in sustained improvements in glycemic control in low-income African-American patients of public hospital clinics.

RESEARCH DESIGN AND METHODS: This randomized controlled trial ($n = 211$) compared changes in hemoglobin A1c (A1c) at 6, 12, and 18 months between two arms: (1) Lifestyle Improvement through Food and Exercise (LIFE), a culturally tailored, 28-session community-based intervention, focused on diet and physical activity, and (2) a standard of care comparison group receiving two group DSME classes. Cluster-adjusted ANCOVA modeling was used to assess A1c changes from baseline to 6, 12, and 18 months, respectively, between arms.

RESULTS: At 6 months, A1c decreased significantly more in the intervention group than the control group (-0.76 vs -0.21%, $p = 0.03$). However, by 12 and 18 months, the difference was no longer significant (12 months -0.63 intervention vs -0.45 control, $p = 0.52$). There was a decrease in A1c over 18 months in both the intervention ($\beta = -0.026$, $p = 0.003$) and the comparison arm ($\beta = -0.018$, $p = 0.048$) but no difference in trend ($p = 0.472$) between arms. The intervention group had greater improvements in nutrition knowledge (11.1 vs 6.0 point change, $p = 0.002$) and diet quality (4.0 vs -0.5 point change, $p = 0.018$) while the comparison group had more participants with improved medication adherence (24% vs 10%, $p < 0.05$) at 12 months.

CONCLUSIONS: The LIFE intervention resulted in improved nutrition knowledge and diet quality and the comparison intervention resulted in improved medication adherence. LIFE participants showed greater A1c reduction than standard of care at 6 months but the difference between groups was no longer significant at 12 and 18 months.

NIH TRIAL REGISTRY NUMBER: NCT01901952

Compared to non-Hispanic whites, African Americans are more likely to have type 2 diabetes (T2DM), are more likely to suffer and die from diabetes-related complications, and experience higher diabetes hospitalization rates.[1,2] Improved glycemic control in African Americans would result in fewer microvascular complications as well as reduced healthcare utilization and costs.[3]

Extensive evidence suggests that diabetes self-management education (DSME) interventions are effective at reducing hemoglobin A1 (A1c) for up to 12 months.[4–7] However, a recent meta-analysis found that DSME has not been effective at reducing A1c in African Americans.[8] There is limited evidence to inform effective strategies for improving long-term diabetes self-management in African Americans.

The Lifestyle Improvement through Food and Exercise (LIFE) intervention[9] is an intensive, group-based DSME intervention to help low-income African Americans with uncontrolled T2DM improve glycemic control through changes to diet and physical activity. The LIFE intervention was designed using a novel cultural-tailoring strategy in which educational information about nutrition was reframed to match the pre-existing beliefs of low-income African-American patients to facilitate the learning process and improve knowledge retention.[9] A pilot study showed that the LIFE intervention was effective at reducing A1c at 6 months,[10] and the current study tests whether the LIFE intervention can achieve sustained changes in A1c to 12 and 18 months.

The primary study aim was to examine whether the LIFE intervention resulted in greater long-term improvements in glycemic control than a comparison intervention consisting of two group classes taught by a registered dietitian (RD). We

hypothesized that intervention participants would show a greater A1c reduction at 12 months than comparison participants and that the difference would be sustained 6 months after the conclusion of the intervention (at 18 months).

RESEARCH DESIGN AND METHODS

Design and Procedures

The LIFE study used a single-blind randomized controlled trial design comparing effectiveness of two DSME approaches to achieving sustained improvements to glycemic control among low-income African Americans with T2DM. Patients randomized to the intervention received a culturally tailored group-based DSME intervention of 28 group sessions delivered by a registered dietitian (RD) in a community setting and peer supporter phone calls over 12 months. Patients randomized to the comparison arm received two DSME sessions, delivered in the clinic, in the first 6 months of the study period. Both arms were taught the seven core DSME content areas as defined by the American Association of Diabetes Educators: healthy eating, being active, monitoring, medication, problem-solving, reducing risks, and healthy coping.[11] Full assessments were conducted at baseline and 12 and 18 months and an abbreviated assessment was conducted at 6 months. Blinded research staff conducted all assessments at the patients' clinic. The primary study outcome was change in A1c at 12 months. Research staff also telephoned participants every 3 months to collect information about healthcare utilization (e.g., hospitalizations, ER visits) and update contact information. Participants received $100 for each full assessment and $25 for brief assessments.

Participants

Participants were recruited from five outpatient primary care community clinics that are part of the Cook County Health and Hospitals System (CCHHS) which is the public, safety-net hospital system serving residents of Cook County, Illinois. Patients were recruited in six cohorts of 30 to 40 patients each. Each cohort was recruited within a single clinic, with one clinic providing two separate cohorts. At each clinic, potentially eligible patients were identified through a medical record review, contacted and prescreened by study staff, and invited to attend a group information session at their clinic. Eligible patients provided informed consent and were randomized into intervention vs. control arms following completion of the baseline assessment. A total of 211 participants were randomized. Within each cohort, patients randomized to the intervention were assigned to the same DSME class, thereby forming a cluster among the study participants. Recruitment took place from March 2012 to April 2014 and intervention groups were conducted from August 2012 to August 2015. More details about recruitment are available elsewhere.[12] The study was approved by the Rush University Medical Center and Cook

County Health and Hospitals System (CCHHS) Institutional Review Boards. All participants gave written informed consent. The trial was monitored by an independent Data and Safety Monitoring Board and prospectively registered with ClinicalTrials.gov (NCT01901952).

Inclusion criteria included uncontrolled T2DM (HbA1c $\geq$ 7.0%), African-American race, age $\geq$ 18, seen at least once in the past 12 months at a CCHHS primary care clinic, and available to attend group sessions during specific hours.

Participants were excluded if they had any of the following: BMI < 18.5 kg/m^2, end-stage renal disease (GFR < 15 mL/min/1.73 m^2), history of stroke with paresis, congestive heart failure (New York Heart Association class 2–4), major end-organ T2DM complications, or any conditions limiting probable lifespan to less than 4 years, current pregnancy, diagnosis of a major psychiatric condition or impaired cognitive function, prednisone use in the prior 3 months, history of weight loss surgery, inability to walk two blocks without stopping, lack of telephone access, lack of provider clearance for study participation, and cohabitation with an active study participant.

The LIFE Intervention

The intervention was delivered in 28 group sessions over 12 months: weekly for the first 4 months, biweekly for the second 4 months, and monthly for the third 4 months. Two additional maintenance sessions were held at months 15 and 18. Sessions were held in a community setting proximate to the patients' clinic with 15–20 participants per group. The intervention had four main components: (1) culturally tailored diabetes nutrition education delivered by an RD, (2) physical activity, (3) self-monitoring of blood glucose (SMBG), and (4) social support.

An RD delivered the intervention content and an experienced African-American group facilitator and African-American peer supporters led the social support component. Peer supporters, who were community members with T2DM, telephoned participants at the same frequency as the group sessions.

The bulk of the LIFE intervention curriculum focused on diet change, which is the most challenging diabetes self-management behavior.[13] Participants were encouraged to maintain consistent carbohydrate intake levels throughout the day and eat a diet consistent with the American Diabetes Association guidelines. The nutrition education curriculum was culturally tailored to match pre-existing cultural beliefs about diet and health, as described in prior studies.[9] Cultural adaptations incorporated into the intervention included a culturally tailored nutrition education curriculum and use of peer supporters who were African-American women with diabetes. Tailoring of the curriculum was informed by cognitive anthropology studies with low-income African-American women that indicated (a) awareness of the impact of macronutrients but limited knowledge of macronutrient content of foods (especially carbohydrates), (b) conceptual organization of

foods into functional categories (i.e., meals and snacks) rather than nutrient profiles, and (c) a category of natural foods (fruits and vegetables) frequently labeled "God's food." The curriculum focused on increasing declarative knowledge of macronutrient content of foods (e.g., memorizing which foods are carbohydrates) and procedural knowledge about how to construct a healthy meal or snack, using a modified version of the plate method.[14] In addition, we used the concept of "God's food" to encourage consumption of whole grains. Sensitivity to literacy was reflected in use of simple teaching materials and use of interactive and hands-on teaching methods.

Each session consisted of nutrition education, a short physical activity, a healthy snack, and a group discussion about goals, progress, and barriers to behavior change. Participants also set behavioral goals for diet, physical activity, and SMBG at each session and used logs and pedometers to self-monitor those behaviors between sessions. Logs and pedometers were reviewed at group sessions and during peer supporter phone calls. RDs helped participants to individually tailor their diet in response to recorded blood glucose levels. During the group discussion, participants were guided in informal problem-solving focused on overcoming barriers to behavior change, such as social pressure to eat unhealthily and financial stressors. Social support was provided in sessions by interventionists, peer supporters, and other group members.

Comparison Group

The comparison group received the DSME content in two RD-taught group sessions in the first 6 months of the study period. Both classes were offered three times to maximize attendance and participants received reminder calls. This level of DSME is what is currently reimbursable by CMS following the first year of diagnosis and therefore constitutes standard of care.

Participants received $10 per attended class for transportation and other costs. More intervention details are available elsewhere.[9]

Measures

All assessments were conducted in the patients' primary care clinic by research assistants blinded to participant treatment status. Full assessments consisted of two visits 1 week apart conducted at baseline and 12 and 18 months. All measures are described in Table 1. At the first visit, participants completed a 24-h food recall, measurement of A1c, height, weight, blood pressure, and study questionnaires and were given an accelerometer to wear for 7 days. At the second visit, participants returned the accelerometer and completed a second 24-h food recall. At each assessment, participants received their current A1c and blood pressure values along with the target ranges. A1C, weight, blood pressure, and a subset of study questionnaires were completed at 6 months. Follow-up diet and physical activity assessments were conducted at 12 and 18 months. Prescribed medication was collected by self-report and reconciled with the electronic medical record. Two antiglycemic medication scores were calculated for each participant at 12 months. The first score was a sum of the total number of units of each type of medication (sulfonylureas, insulin, and metformin), where unit is defined as the minimally effective dose, and the second was the percent of each medication's maximum daily dosage, adjusted for median absolute decrease in A1c.[32]

Statistical Analysis

Basic group-specific descriptive analyses were performed using means ± SD for approximately normal continuous measures; median, first, and third quartiles for non-normal data; and frequencies and percentages for categorical measures. Each cohort was viewed as a cluster with patient as the randomization unit. The resulting intraclass correlation coefficient (ICC) was computed to assess the impact of clustering. Data analysis strategies were employed to account for the clustering study design. Differences in patient characteristics between the study arms were assessed using cluster-adjusted analysis of covariance (ANCOVA) for approximately normal data and cluster-adjusted Friedman's rank ANCOVA modeling for non-normal data. For categorical data, a cluster-adjusted chi-square test was used for cell counts ≥ 5 and Fisher's exact test was used when counts were < 5. Cluster-adjusted ANCOVA modeling was used to assess A1c changes from baseline to 6, 12, and 18 months, respectively, between arms. Mixed effects modeling with unstructured covariances was used to assess trends in A1c change over time. Models included cluster as a random effect as well as a treatment group indicator, time (since baseline), and a treatment-by-time interaction. A priori specified covariates added to this model and assessed using backwards stepwise elimination with a cut point of $p < 0.20$ included age, gender, baseline A1c, diabetes duration, insulin-use, and PHQ-9 score which was found to be significantly different between arms at baseline ($p = 0.03$). In subsequent analyses, a three-way interaction term (consisting of treatment group indicator and time) was added to the mixed effects models to assess the following potential treatment moderators: age, gender, baseline A1c, health literacy, and depressive symptoms (see Table 1). Time-to-event analyses of secondary outcomes were performed using cluster-adjusted logrank tests. All statistical tests were two-sided with a p value of < 0.05 and performed using SAS software (SAS Institute Inc. SAS 9.4 Help and Documentation. Cary, NC: SAS Institute Inc., 2011).

RESULTS

Recruitment and Attrition

As indicated in the CONSORT diagram (Fig. 1), the research team screened 822 of 3048 patients with T2DM from participating clinics. Of those, 211 were randomized and the primary outcome (A1c) was collected from the following number of participants at the three follow-up visits: 198 (94%) at

Table 1 List of Measures

Variable	Measure
Participant demographic information	Self-reported demographic questionnaires including questions about income, education, employment, and insurance.
Glycemic control	Hemoglobin A1c levels. Blood samples were collected via finger stick and processed through the Afinion AS100 Hemoglobin A1C Analyzer System.[15]
Blood pressure	Blood pressure was measured by research staff using Omron Digital Blood Pressure Monitor (Omron Healthcare, Inc. Lake Forest, Illinois). Final value was average of three readings taken 2 min apart while participant was seated.
Body mass index	Weight was measured using a balance beam digital scale (Health O Meter), reported to 1/10 kg (5 min). Height was measured using wall mounted stadiometer. BMI was calculated by dividing weight (kilograms) by height (meters squared).
Medications	Participants brought all medications to assessment visit and RA recorded medication and dosage. Congruence between self-reported medications and pharmacy records for low-income adults = 91% for major drug classes.[16] Diabetes medications were also confirmed via chart review.
Medical history	Self-reported participant medical history information such as duration diabetes age of onset, number of diabetic complications, and comorbidities, ER visits in past 6 months, etc.
Diet	Dietary intake was measured using the Nutrition Data System for Research 24-Hour Dietary Recall (NDSR; Nutrition Coordinating Center, University of Minnesota), a computer-based software application that facilitates the collection of standardized dietary recalls using a multiple-pass interview approach.
Alternative Healthy Eating Index (AHEI)	Alternative Healthy Eating Index 2010 (AHEI)[17] is associated with reduced cancer, CVD, and all-cause mortality. It is comprised of 11 subscales ranging from 1 to 10 for a total range of 0–110.
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.[18, 19] 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).
Nutrition knowledge	An adapted version of the Nutrition Knowledge Questionnaire[20, 21] and the AdultCarbQuiz[22] 62 items with response format: yes, no, I do not know. Score range 0–62. Higher scores indicate greater nutrition knowledge.
Medication Adherence	Morisky Medication Adherence Scale (MMAS)-8, 8-item self-report measure: MMAS-8 score < 6 signifies low medication adherence.[23–26]
Depression	The Patient Health Questionnaire (PHQ-9)[27] has nine items with a response format from 0 to 3 (*Not at all* to *nearly every day*). Higher scores indicate greater depression severity. Scores range from 0 to 27. Score ≥ 10 suggests moderate or severe depression.
Perceived social support	The Support Received subscale from Diabetes Care Profile[28–30] is 6 items with a response format ranging from 1 to 5 (*strongly disagree* to *strongly agree*). Higher scores indicate more social support.
Diabetes-specific quality of life	The Social and Personal Factors subscale from Diabetes Care Profile[28–30] has 13 items and a response format ranging from 1 to 5 (*strongly disagree* to *strongly agree*). Lower scores indicate higher quality of life.
Self-efficacy	The Self-care ability subscale from Diabetes Care Profile[28–30] has 4 items and a response format ranging from 1 to 5 (*strongly disagree* to *strongly agree*). Higher scores indicate greater self-efficacy.
Health literacy	The Newest Vital Sign (NVS)[31] has 6 items with a yes-no response format and higher scores indicate greater health literacy. Limited health literacy is defined as a score of 0–1.

6 months, 196 (93%) at 12 months, and 190 (90%) at 18 months. By study end, 4 patients had died and 13 patients were lost to follow-up (6%). There were no study-related adverse events.

Patient Characteristics

Participants had a mean age of 55, most were uninsured at baseline (65%) and 43% reported an annual household income below the federally defined poverty level. Participants had been diagnosed with diabetes for a mean of 9.4 years, 45.5% were taking insulin and 28.4% screened positive for depression. Baseline characteristics appear in Table 2. No statistically significant differences were found between the groups at baseline except a between-group difference in the median PHQ-9 score (7.0 vs. 5.0, $p = 0.03$).

Changes in HbA1c

Figure 2 displays the marginal means and standard errors for A1c change at each time point. The mean change from baseline to 12 months, the primary endpoint, was not significantly different between arms ($p = 0.52$, see Table 3). At 6 months, A1c decreased significantly more in the intervention than in

the comparison group (intervention mean 6-month change = − 0.76, SD = 1.70; control mean 6-month change = − 0.21, SD = 1.74; $p = 0.03$), but by 12 and 18 months, the difference was no longer significant (Table 3). Mixed effects modeling over all four time points (0, 6, 12, 18 months) showed a statistically significant A1c decrease over 18 months in the intervention group ($\beta = -0.026$, $p = 0.003$) and a significant, but lesser, decrease in the comparison group ($\beta = -0.018$, $p = 0.048$). There was no difference in trend ($p = 0.47$) between arms. No intervention moderators were detected.

Changes in Secondary Outcomes

Table 3 shows changes in secondary outcome variables from baseline to 12 and 18 months (diet and PA were not collected at 6 months). Nutrition knowledge improved more in the intervention vs. comparison group at 12 months (11.1 vs 6.0 point change, $p = 0.002$, $d = 1.46$) but the difference was only marginally significant at 18 months ($p = 0.06$). Similarly, diet quality (AHEI) improved more in the intervention vs comparison group at 12 months (4.0 vs − 0.5 point change, $p = 0.018$, $d = 1.27$). This difference was not maintained at 18 months. The proportion of individuals who improved their medication
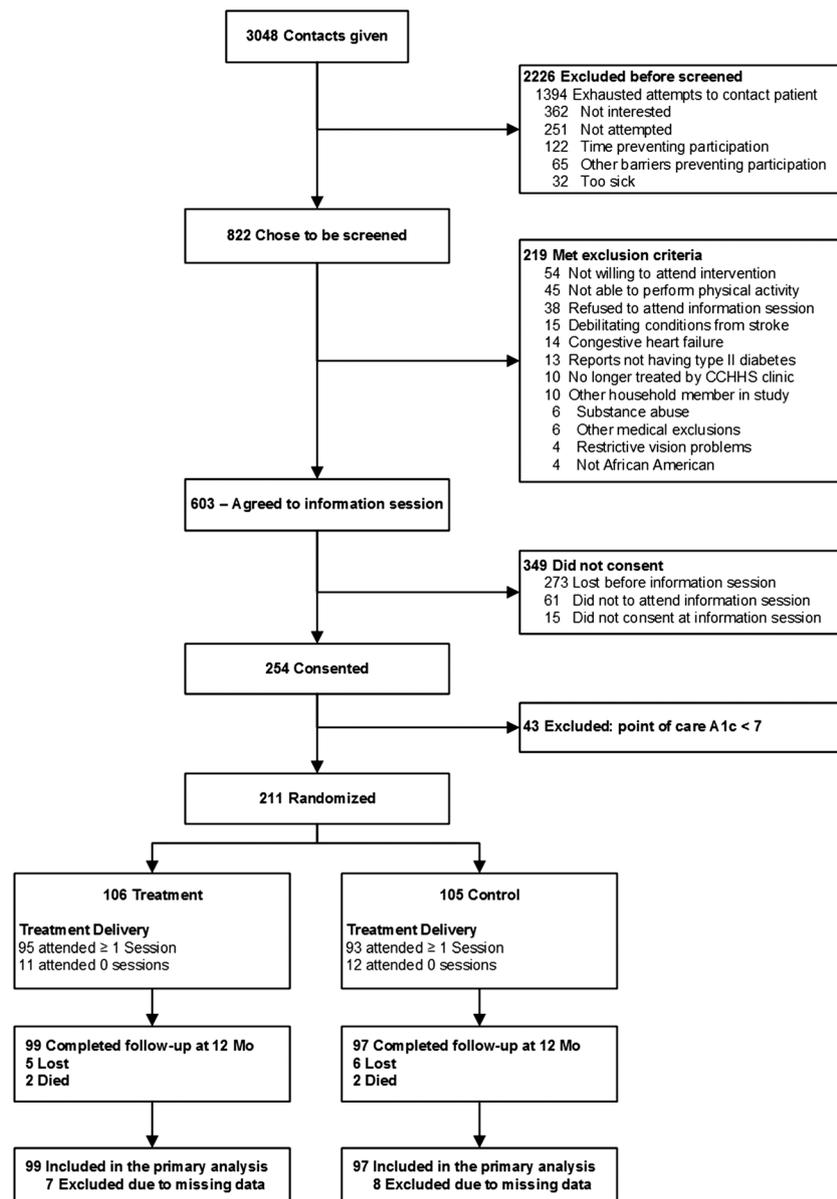
Figure 1 Participant flow diagram.

adherence from baseline was greater in the comparison group than the intervention group at 12 months (24% vs 10%, $p = .021$) but not 18 months. There was no difference between groups in changes to physical activity, emergency room or hospital utilization, or antiglycemic medication scores (change in total units score, $p = 0.26$; change in adjusted dosage score, $p = 0.71$).

Process Measures

The average number of group sessions attended by intervention participants was 13.8 out of a possible 28; 51% attended at least 60% of sessions and 25% attended at least 80% of sessions. At least half of the planned peer supporter phone calls were completed by a majority (73%) of participants. The percent of intervention classes attended in the

first 6 months was associated with 6-month A1c change ($r = -0.31$, $p = 0.002$), but neither 12- nor 6-month attendance was associated with 12-month A1c change. Intervention participants brought their pedometers to 76.7% of attended sessions and brought their food logs to 41% of attended sessions.

A majority (68.6%) of control participants attended both classes, 20% attended one class, and 11% attended no classes. The percent of control group classes attended was associated with 12-month HbA1c change ($r = -0.21$, $p = 0.04$).

CONCLUSIONS

The current study tested the hypothesis that the LIFE intervention would result in greater improvements to

Table 2 Participant Characteristics at Baseline

Characteristics	Total ($N = 211$)	Comparison ($N = 105$)	Treatment ($N = 106$)
Demographics			
Age, mean (SD)	55.0 (10.3)	54.8 (9.0)	55.1 (11.5)
Female, n (%)	148 (70.1)	73 (69.5)	75 (70.8)
Education, n (%)			
Less than high school	28 (13.3)	17 (16.2)	11 (10.4)
High school	69 (32.7)	35 (33.3)	34 (32.1)
Some college/technical school	87 (41.2)	40 (38.1)	47 (44.3)
≥ College degree	27 (12.8)	13 (12.4)	14 (13.2)
Relationship status, n (%)			
Single	109 (51.7)	50 (47.6)	59 (55.7)
Lives with partner/spouse	50 (23.7)	29 (27.6)	21 (19.8)
Lives separately from partner/spouse	14 (6.6)	7 (6.7)	7 (6.6)
Divorced	21 (10.0)	12 (11.4)	9 (8.5)
Widowed	17 (8.1)	7 (6.7)	10 (9.4)
Annual income[a], n (%)			
<$9999	68 (32.2)	29 (27.6)	39 (36.8)
$10,000–$19,999	67 (31.8)	39 (37.1)	28 (26.4)
$20,000–$39,999	56 (26.5)	26 (24.8)	30 (28.3)
> $40,000	11 (5.2)	6 (5.7)	5 (4.7)
Refused/do not know	9 (4.3)	5 (4.8)	4 (3.8)
Below poverty ratio, n (%)	87 (43.1)	39 (39.0)	48 (47.1)
Insurance, n (%)			
Uninsured	138 (65.4)	71 (67.6)	67 (63.2)
Medicare only	29 (13.7)	13 (12.4)	16 (15.1)
Medicaid only	24 (11.4)	12 (11.4)	12 (11.3)
Medicare plus Medicaid	8 (3.8)	2 (1.9)	6 (5.7)
Private	8 (3.8)	5 (4.8)	3 (2.8)
Other	4 (1.9)	2 (1.9)	2 (1.9)
Employment, n (%)			
Full-time employment	25 (11.9)	16 (15.2)	9 (8.5)
Part-time employment	26 (12.3)	12 (11.4)	14 (13.2)
Unemployed	72 (34.1)	38 (36.2)	34 (32.1)
Retired	48 (22.8)	20 (19.1)	28 (26.4)
Too ill to work	27 (12.8)	9 (8.6)	18 (17.0)
Other/refused	13 (6.2)	10 (9.5)	3 (2.8)
Medical factors			
Time since diabetes diagnosis (year), median (q1, q3)	9.4 (4.6, 15.0)	9.1 (4.4, 15.7)	9.6 (4.7, 15.0)
Diabetic medications, n (%)			
Insulin[b]	96 (45.5)	51 (48.6)	45 (42.5)
Oral agent only	111 (52.6)	53 (50.5)	58 (54.7)
Diet control only	4 (1.9)	1 (1.0)	3 (2.8)
Diabetes comorbidities, n (%)			
Heart disease	10 (4.7)	6 (5.7)	4 (3.8)
Hypertension[c]	192 (91.0)	94 (89.5)	98 (92.5)
Total number of diabetes comorbidities[d], n (%)			
0	15 (7.1)	6 (5.7)	9 (8.5)
1–2	101 (47.9)	46 (43.8)	55 (51.9)
≥3	95 (45.0)	53 (50.5)	42 (39.6)
Other comorbidities[e,f], n (%)			
0	82 (38.9)	40 (38.1)	42 (39.6)
1–2	108 (51.2)	56 (53.3)	52 (49.1)
≥3	21 (10.0)	9 (8.6)	12 (11.3)
Hemoglobin A1c (%), median (q1, q3)	8.5 (7.8, 9.8)	8.4 (7.6, 9.7)	8.6 (7.8, 9.9)
Hemoglobin A1c > 9%, n (%)	80 (37.9)	42 (40.0)	38 (35.9)
Body mass index, median (q1, q3)	34.7 (29.3, 40.2)	34.8 (29.3, 40.5)	34.6 (29.3, 39.9)
Systolic blood pressure (mmHg), median (q1, q3)	130.5 (120.5, 143.5)	130.5 (120.5, 144.5)	130.5 (120.5, 142.5)
Diastolic blood pressure (mmHg), median (q1, q3)	81.0 (74.0, 87.0)	81.5 (75.0, 88.0)	79.3 (73.5, 88.5)
Health knowledge factors			
Nutrition knowledge[g], median (q1, q3)	35 (27, 40)	35 (27, 39)	34 (26, 40)
Low health literacy[h], n (%)	83 (39.3)	39 (37.1)	44 (41.5)
Behavioral factors			
Daily dietary intake, median (q1, q3)			
Total kcal	1749 (1335, 2236)	1714 (1297, 2176)	1769 (1398, 2329)
Total vegetable servings	0.6 (0.3, 0.9)	0.6 (0.3, 0.9)	0.6 (0.3, 0.9)
Non-starchy vegetables (excluding potatoes, corn, legumes, peas)	0.1 (0.0, 0.2)	0.1 (0.0, 0.2)	0.1 (0.0, 0.2)
Percent kcal from carbohydrate, mean (SD)	45.5 (8.8)	45.8 (8.3)	45.1 (9.2)
Percent kcal from protein	17.0 (14.0, 19.6)	17.3 (14.3, 19.9)	16.8 (14.0, 19.6)
Percent kcal from fiber	7.9 (5.8, 10.6)	8.0 (5.8, 10.8)	7.6 (6.0, 10.0)
Alternative Healthy Eating Index, mean (SD)	48.8 (10.7)	50.4 (11.2)	47.2 (10.0)
Physical activity			
Daily average steps, median (q1, q3)	3614 (2468, 4984)	3819 (2705, 5205)	3548 (2366, 4761)
Weekly moderate intensity activity (min), mean (SD)	38.7 (92.0)	37.7 (73.7)	39.6 (107.6)
Daily sedentary minutes, mean (SD)	516.1 (96.0)	507.9 (93.8)	524.3 (97.9)
Low medication adherence at baseline[i], n (%)	77 (36.5)	41 (39.1)	36 (34.0)

Table 2. (continued)

Characteristics	Total ($N = 211$)	Comparison ($N = 105$)	Treatment ($N = 106$)
Psychosocial			
PHQ-9 score[j], median (q1, q3)	6.0 (2.0, 10.0)	7.0 (3.0, 12.0)	5.0 (1.0, 9.0)
Moderate or severe depression (PHQ-9 ≥ 10),[k] *n* (%)	60 (28.4)	37 (35.2)	23 (21.7)
Diabetes-specific social support[l], median (q1, q3)	3.0 (1.7, 4.0)	3.0 (2.0, 4.0)	2.9 (1.2, 4.0)
Diabetes-specific quality of life[m], median (q1, q3)	2.4 (2.0, 3.0)	2.4 (2.0, 3.1)	2.4 (2.0, 2.9)
Diabetes-specific self-efficacy[n], median (q1, q3)	3.0 (2.3, 3.5)	3.0 (2.3, 3.5)	2.8 (2.3, 3.5)

Friedman's rank ANCOVA with adjustment of clinical site used for comparing non-normal data, chi-square used for categorical data, ANCOVA with adjustment of clinical site used for normally distributed continuous data

[a]*Total family annual income before taxes*

[b]*Participant uses insulin only or insulin plus oral medication for diabetes management*

[c]*Self-reported hypertension, > 140(s)/or > 90(d) mmHg, or currently talking blood pressure lowering medications*

[d]*Diabetic 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*

[e]*History of cancer, arthritis, lung, cirrhosis or liver disease, depression, asthma, sleep apnea, neurological diseases, HIV or AIDs, serious mental illness*

[f]*Although the two groups have equal medians, Wilcoxon test showing statistically significant gender differences because the ranges differ between men and women reaching a higher number of chronic conditions*

[g]*Nutrition Knowledge Questionnaire, 46 items, response format: yes, no, I do not know. Score range 0–46. Higher scores indicate greater nutrition knowledge*

[h]*Health 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*

[i]*Morisky Medication Adherence Scale (MMAS)-8; use of the ©MMAS is protected by US copyright laws. Permission for use is required. A license agreement is available from Donald E. Morisky, MMAS Research, LLC 14725 NE 20th St., Bellevue, WA, 98007*

[j]*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*

[k]*PHQ-9 score ≥ 10*

[l]*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*

[m]*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*

[n]*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*

glycemic control than standard of care DSME. Intervention participants achieved significant A1c reductions at 6 months that were largely sustained at 12 and 18 months. A1c also decreased in the comparison group from baseline to 6, 12, and 18 months. While the A1c change was greater in the intervention group than the comparison group at each follow-up assessment, the difference between arms was only statistically significant at 6 months.

Recent meta-analyses of DSME interventions across a range of populations have reported mean A1c changes ranging from − 0.16 to − 0.53 at 6 months and − 0.14 to − 0.46 at 12–14 months.[4–7] The magnitude of the A1c change achieved by the LIFE intervention is consistent with DSME intervention effects reported by those meta-analyses, but greater than the non-significant A1c change of − 0.08 reported by a meta-analysis of DSME interventions targeting African Americans.[8] The current study was not powered to detect the effect size observed by this study at 12 months (− 0.18). LIFE is a resource-intensive intervention which requires extensive time and commitment from participants. To justify the cost of the intervention, we felt it should result in at least a clinically significant reduction in A1c (≥− 0.5).[33]

We did not include an untreated arm in this study because we wanted to measure the LIFE intervention against standard of care, rather than usual care. Because there was no untreated arm in this study, we cannot identify with full assurance what contributed to the A1c reduction experienced by the comparison arm. This study was conducted during a time of great change in the healthcare system, both nationally and at CCHHS. The Affordable Care Act (ACA) Medicaid expansion was implemented for Cook County adults in January of 2014, which was prior to the 12-month follow-up for approximately half of study participants. Simultaneously, some of the CCHHS community clinics were experimenting with patient-centered medical home models and group visits for diabetes. It is possible that those system-level changes, which were intended to increase access to care, were
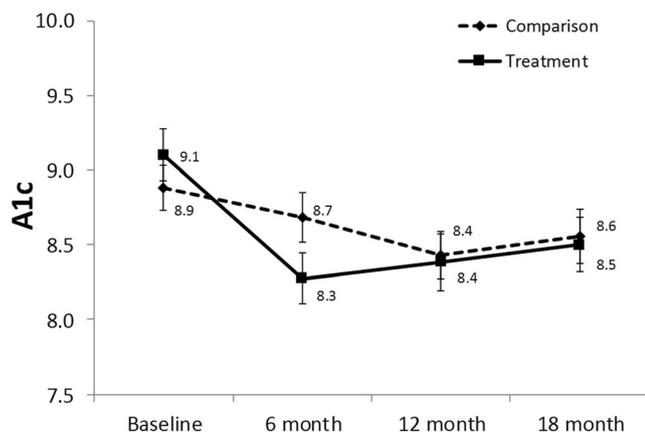

Figure 2 Means and 95% confidence intervals for HbA1c at baseline and 6, 12, and 18 months.

Table 3 Changes in Secondary Outcome Variables from Baseline to 12 and 18 Months*

Outcomes	Change at 12 months		Change at 18 months	
	Comparison	Treatment	Comparison	Treatment
	$N = 99$	$N = 97$	$N = 96$	$N = 94$
Medical outcomes				
Hemoglobin A1c (%), mean (SD)	−0.45 (1.68)	−0.63 (1.83)	−0.33 (1.75)	−0.58 (1.96)
Body mass index, median (q1, q3)	−0.2 (−2.1, 0.8)	−0.7 (−2.2, 0.7)	−0.8 (−2.4, 0.8)	−0.5 (−2.1, 1.0)
Systolic blood pressure (mmHg), mean (SD)	−0.1 (19.1)	−0.9 (19.1)	−3.9 (19.2)	1.7 (16.8)[†]
Diastolic blood pressure (mmHg), mean (SD)	0.6 (13.3)	−0.3 (13.1)	−0.7 (12.6)	0.0 (11.8)
Health knowledge outcomes				
Nutrition knowledge, mean (SD)	6.0 (11.8)	11.1(12.9)[‡]	4.5 (10.0)	7.7 (12.7)
Behavioral outcomes				
Daily dietary intake				
Total kcal, median (q1, q3)	−184 (−548, 214)	−288 (−754, −32)	−66 (−484, 190)	−360 (−773, 184)
Total vegetable servings (c), median (q1, q3)	0.1 (−0.4, 0.3)	0.1 (−0.3, 0.4)	0.0 (−0.3, 0.4)	0.0 (−0.2, 0.4)
Non-starchy vegetables (excluding potatoes, corn, legumes, peas) (c), median (q1, q3)	0.0 (−0.1, 0.1)	0.0 (−0.1, 0.3)	−0.0 (−0.2, 0.2)	0.0 (−0.1, 0.1)
Percent kcal from carbohydrate, median (q1, q3)	−0.4 (−9.1, 5.8)	−1.9(−7.8, 6.4)	−0.8 (−10.7, 5.2)	0.3 (−7.8, 7.4)
Percent kcal from protein, median (q1, q3)	0.7 (−2.0, 4.0)	2.1 (−2.1, 5.7)	0.1 (−2.4, 5.1)	2.1 (−1.8, 6.3)
Percent kcal from fiber, median (q1, q3)	0.2 (−2.4, 3.1)	0.6 (−1.7, 3.3)	−0.4 (−2.3, 2.8)	0.8 (−1.7, 3.6)
Alternative Healthy Eating Index, mean (SD)	−0.5 (13.1)	4.0 (12.0)[†]	0.3 (12.9)	2.8 (13.3)
Physical activity				
Average daily steps/week, median (q1, q3)	309 (−327, 1009)	93 (−481, 1025)	−373 (943, 508)	−215 (−909, 629)
Weekly moderate intensity activity (min), median (q1, q3)	0.0 (−14.0, 10.0)	0.0 (−15.5, 0.0)	0.0 (−9.0, 9.0)	0.0 (−10.0, 0.0)
Daily sedentary minutes, mean (SD)	31.9 (95.2)	38.1 (111.0)	33.4 (85.1)	69.3 (105.6)[†]
Medication adherence, n (%)[a]				
Low to high	24 (24.0)	10 (10.1)[†]	20 (21.1)	14 (14.4)
Stayed the same	61 (61.0)	74 (74.8)[†]	62 (65.3)	65 (67.0)
High to low	15 (15.0)	15 (15.2)[†]	13 (13.7)	18 (18.6)
Psychosocial outcomes				
Depression symptoms, mean (SD)	−3.6 (5.5)	−1.5 (6.2) [†]	−2.0 (6.1)	−1.7 (5.3)
Diabetes-specific social support, mean (SD)	0.5 (1.7)	0.3 (1.8)	0.2 (1.6)	0.3 (1.6)
Diabetes-specific quality of life, mean (SD)	−0.1 (0.9)	0.0 (0.9)	−0.2 (0.9)	−0.2 (0.8)
Diabetes-specific self-efficacy, mean (SD)	0.4 (1.0)	0.5 (1.0)	0.5 (1.1)	0.6 (1.0)

*Friedman's rank ANCOVA with adjustment of clinical site used for comparing non-normal data, Mantel_Haenszel test used for categorical data, ANCOVA with adjustment of clinical site used for normally distributed continuous data

[†]*p value < 0.05*

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responsible for improved glycemic control in both intervention groups. However, some evidence supports that the improved glycemic control in the comparison group resulted from the DSME classes. The majority (89%) of comparison arm participants attended at least one DSME class, and individuals who attended more classes achieved better glycemic control. In addition, comparison arm participants, but not intervention participants, improved medication adherence at 12 months. These findings add to evidence that all patients should receive standard of care DSME.[34]

At 12 months, the intervention group showed an increase in nutrition knowledge as well as an increase in diet quality. Both interventions addressed diet and medication adherence but the LIFE intervention placed disproportionately more emphasis on diet. The attention directed toward diet among LIFE participants may have resulted in a decreased focus on medication adherence. For intervention participants, a key motivation for improving diet was to reduce diabetes medications. Unlike comparison participants, they may have viewed diet and medication as alternative strategies for improving glycemic control.

The advantage of using diet to improve glycemic control is that a healthy diet has a cascade of health benefits. While the amount of improvement in diet quality achieved by LIFE intervention participants was not associated with statistically significant changes to weight and blood pressure in the current study, the magnitude of increase on the AHEI achieved by LIFE participants in this trial at 12 months (~8% increase from baseline) has been associated with reduced risk of diabetes and cardiovascular disease in large, observational studies.[17,35–38] However, the improvement to diet observed at 12 months was not sustained at 18 months.

Changing diet and physical activity may be especially challenging for low-income patients, such as those in the current study. Evidence suggests that neighborhood deprivation is related to a number of cardiometabolic risk factors, including diabetes prevalence and higher A1c.[39–41] Conditions in impoverished neighborhoods, such as high levels of food insecurity, few safe areas to engage in physical activity, and high stress associated with poverty and violence, may have made it difficult for LIFE participants to attend intervention sessions and/or achieve and sustain the diet and activity changes targeted by the

intervention. DSME interventions may need to address environmental and social factors that influence behavior change in order to achieve sustained health benefits, particularly for low-income populations. In the short term, a brief intervention focused on medication adherence may be a resource-efficient strategy by which to achieve improved glycemic control among low-income African Americans.

One study limitation is that we did not measure diet and physical activity at 6 months, so we cannot be certain that the difference between the arms at 6 months was related to differences in diet and physical activity behavior. Another limitation is that our measure of diet was self-report and therefore potentially subject to bias. Also, we conducted only two dietary recalls per participant and did not always measure a weekend day and weekday as recommended.

In sum, the current study found that low-income African-American participants in a novel, culturally tailored and literacy sensitive, intensive DSME intervention achieved sustained improvements in glycemic control, but did not perform meaningfully better than those receiving two DSME sessions. Findings from this study underscore the urgent need for research to discover effective behavior change interventions for improving long-term glycemic control within this patient population.

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Compliance with Ethical Standards:

The study was approved by the Rush University Medical Center and Cook County Health and Hospitals System (CCHHS) Institutional Review Boards. All participants gave written informed consent.

Conflict of Interest: The authors declare that they do not have a conflict of interest.

Disclaimer: The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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