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One-Year Effects of a Group-Based Lifestyle Intervention in Adults with Type 2 Diabetes: A Randomized Encouragement Trial

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Abstract

Aims—To estimate the real-world effects of offering a group-based lifestyle intervention (GLI) to adults with diabetes.

Methods—This randomized encouragement trial included adult primary care patients in metropolitan Chicago with type 2 diabetes and body mass index ≥ 24 kg/m². Participants were randomized to standard care (brief dietary and lifestyle counseling) or standard care plus being encouraged, but not required, to participate in a free-of-charge GLI offered by the YMCA. The GLI was a group-based adaptation of the Look AHEAD lifestyle intervention.

Results—Of 331 participants, 167 were randomized to standard care and 164 to the GLI encouragement arm. About one third of participants were non-Hispanic White (34.4%). In the GLI arm, 75 (45.7%) attended ≥ 1 GLI visits. In the primary intention-to-treat analysis, the effect of GLI encouragement was 0.95% weight loss at six months (95% confidence interval [CI], 0.13–1.77%; $P=0.02$), and 1.20% weight loss at 12 months (95% CI, 0.05–2.36%; $P=0.04$). At 12 months, there was a 0.30% (3.3 mmol/mol) reduction in hemoglobin A1c, but this result did not achieve statistical significance ($P=0.054$). In instrumental variable analysis estimating effects among the subgroup of participants who attended any GLI visits, the effect of GLI attendance was

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2.30% weight loss at six months (95% CI, 0.30–4.30%; $P=0.02$), and 2.07% weight loss at 12 months (95% CI, 0.25–3.88%; $P=0.02$). We detected no significant blood pressure or cholesterol effects.

Conclusions—Among adults with type 2 diabetes, a group-based lifestyle intervention in a community-based setting achieved modest weight loss at 6 and 12 months.

Keywords

Diabetes; cardiovascular risk; weight loss; primary care; minorities

1. INTRODUCTION

More than 30 million Americans have diabetes [1], and diabetes prevalence is predicted to exceed 50 million by 2030 [2]. As new medication therapies have steadily elevated treatment intensity and costs for type 2 diabetes [3, 4], patients have come to view the complexity and stress of intensive diabetes management as a decrease in their quality of life [5, 6]. Additionally, only 14% of patients with diabetes simultaneously meet treatment targets for not smoking along with controlled blood pressure, low-density lipoprotein (LDL) cholesterol and hemoglobin A1c (HbA1c) [7]. There is a need for sustainable approaches to improve physical activity and healthier eating, which improve type 2 diabetes prevention and control, as well as other risk factors for cardiovascular disease and death [8].

In the past decade, the Look AHEAD efficacy trial demonstrated that adherence to resource-intensive lifestyle interventions results in meaningful weight loss, improved cardiovascular risk factor levels and less need for medications for patients carefully selected in academic medical settings [9]. Although traditional efficacy trials such as Look AHEAD are considered the gold standard for making causal inferences, these trials require tightly defined interventions to be provided to highly selected participant samples in optimal surroundings [10]. In the Look AHEAD trial, participants were carefully selected and required to complete multiple self-monitoring tasks prior to randomization [11]. However, since real world populations are unlikely to perfectly adhere to lifestyle interventions [12, 13], complementary effectiveness trials are needed to translate Look AHEAD's findings to everyday clinical settings.

The randomized encouragement trial design can be a powerful tool for enhancing causal inference and the current evidence base [14]. Whereas participants in traditional randomized controlled trials (RCTs) are expected to adhere to assigned treatments, participants in randomized encouragement trials are randomly assigned to an *opportunity* to receive a specific treatment, but allowed to choose whether to receive the treatment [14]. As a result, the randomized encouragement design can be used to account for, and estimate, real-world effects of offering an intervention in everyday clinical settings [15]. Although it is both feasible and effective to offer intensive lifestyle interventions in real-world settings [16, 17], access to and participation in these programs has not yet been integrated into routine healthcare delivery. In this context, the randomized encouragement design can demonstrate how the general public responds to being offered a health behavior change intervention. With this aim, we conducted the Intervening in Diabetes with Healthy Eating, Activity and

Linkages To Healthcare (I-DHEALTH) Study, a randomized encouragement trial that evaluates the effectiveness of offering adult primary care patients with diabetes access to a free-of-charge, community-based intensive lifestyle intervention. The current manuscript presents results from the first year of this study's two-year follow-up period.

2. MATERIALS AND METHODS

I-D-HEALTH is a two-arm, individually randomized encouragement trial comparing standard care alone to standard care plus being offered free-of-charge access to a group-based lifestyle intervention (GLI). Detailed study protocols have been published elsewhere [18]. In brief, the GLI is a low-cost adaptation of the Look AHEAD lifestyle intervention [19] to support modest weight loss and moderate physical activity. The GLI was delivered at two community-based YMCA (i.e. 'the Y') sites in metropolitan Chicago. Recruitment occurred by referral from primary care practices—including federally qualified health centers, independent community practices and academically affiliated practices. Study protocols were registered in the National Clinical Trials Registry (NCT01435603) and approved by Northwestern University's institutional review board (IRB).

2.1. Recruitment and Randomization

Study participants are adults aged ≥ 18 years who have type 2 diabetes and a body mass index ≥ 24 kg/m². Individuals were excluded if they had hemoglobin A1c (HbA1c) ≥ 11.0%, systolic blood pressure (SBP) ≥ 180 mmHg, diastolic blood pressure ≥ 105 mmHg, significant cardiovascular disease, used supplemental oxygen, were pregnant or had a contraindication to regular physical activity. We also excluded individuals who used a medication known to produce hyperglycemia, had a disease besides diabetes that causes abnormal glucose metabolism, or could not read English or Spanish.

Patients were recruited following referral by their primary care provider (PCP) to receive patient-centered information from a community resource hub that provided linkages to local community resources offering support for healthy eating, physical activity or weight loss. After PCP referral, a health promoter from the resource hub called each patient to assess individual goals and preferences and then offer tailored information about community-based lifestyle modification resources. During the call, the health promoter described the I-D-HEALTH study as a means to continue receiving information on resources to improve health. Interested patients were screened for study eligibility, and those who met preliminary eligibility criteria were offered an in-person visit at a participating Y site to complete screening and enrollment. After obtaining informed consent and authorization to collect protected health information, a research assistant assessed final inclusion criteria through height, weight, blood pressure and HbA1c measurements.

Eligible, consented patients were randomized using a computer-generated randomization sequence, stratified by Y study site and participant race (non-Hispanic White; African-American; Hispanic/Other), with 1:1 study arm allocation using a block size of 4. We concealed (i.e., blinded) participants' study arm assignment from RAs and other study staff who completed outcome measurements. Recruitment methods, the randomization approach, and intervention protocols are described in detail elsewhere [18].

The trial used a randomized encouragement design that enabled us to estimate both real-world participation rates and intervention effects. Participants in both study arms received brief lifestyle advice and information on community-based resources. Because randomization protocols imposed no more than minimal risk, participants were not informed that the study involved randomization. Thus, although participants could not be blinded to the resources they were offered, they were not aware that some participants received different interventions than others. This procedure was approved by the Northwestern University IRB and has been used previously by our study team [20–23] to minimize potential biases from participant unblinding when one treatment arm might be perceived to deliver greater benefit.

2.2. Interventions and Outcome Assessment

Participants in both study arms received brief dietary and lifestyle information from a study research assistant at baseline and at follow-up visits at 6 months and 12 months. Participants randomized to the GLI arm also received information about access to a group-based lifestyle intervention at the Y. Within three business days of randomization, a Y intervention coordinator telephoned each GLI arm participant and encouraged her to take part in the GLI at no cost.

The GLI was adapted from the Look AHEAD lifestyle intervention, which encouraged participants to lose 10% (or more) of their initial weight by means of decreasing caloric intake and increasing moderate-intensity physical activity to achieve and sustain 175 minutes per week of exercise [11]. Similar to Look AHEAD [19], the GLI involves face-to-face delivery and uses a cognitive-behavioral skill-based training approach. The goals of the GLI are analogous to those of Look AHEAD [11], including an initial weight loss goal of 10% of baseline weight, 175 minutes of moderate physical activity per week and maintenance of lifestyle changes for at least two years. Like the Look AHEAD intervention, the GLI involves three phases: 1) a 24-session core curriculum over six months, with 60- to 90-minute intervention sessions offered weekly in groups of 5–12 participants; 2) a 12-session transition phase over the next six months and; 3) a 24-session maintenance phase during the second year. As was recommended in the Look AHEAD intervention, GLI staff advised intervention participants to follow a low-calorie, moderate-fat diet (<30% of kcal from fat) and were provided with paper logs (and if interested, advice about available electronic logging methods) to track their diet intake and energy expenditure. All Look AHEAD intervention materials are publicly available in print [19] and online [24].

We made modifications to the Look AHEAD lifestyle intervention including intervention delivery staff qualifications, elimination of meal replacements and a greater emphasis on a group-based format. Whereas Look AHEAD intervention staff included dietitians, behaviorists, and exercise physiologists, the I-D-HEALTH GLI was delivered by wellness instructors employed by the Y. All I-D-HEALTH GLI instructors had a high school diploma or equivalent and at least one-year of prior experience teaching wellness-related classes, but were not required to have training in dietetics, health behavior, or exercise physiology. Look AHEAD intervention staff prescribed and provided meal replacement products at no cost to the intervention participants [11]. In contrast, in the I-D-HEALTH GLI, meal replacements

were neither prescribed nor provided in order to reduce costs and make intervention delivery more feasible for wellness instructors at the Y. Additionally, all I-D-HEALTH GLI intervention sessions were conducted in a group format, whereas during the first year of the Look AHEAD intervention one intervention session per month was conducted as an individual counseling session.

In addition to baseline data collected at the screening/enrollment visit, research assistants collected follow-up data at in-person visits at 6 months and 12 months via written survey, biometric assessments and finger stick blood tests. To reduce participant burden and increase measurement completion, these visits were scheduled at the time of day that was most convenient for the participant; participants were not required to fast for these visits, since fasting was not a requirement for any capillary blood samples used in this study. The primary study outcome was the percent change in body weight between baseline and follow-up. Secondary outcomes included changes in HbA1c, SBP, total cholesterol and HDL cholesterol. HbA1c [25, 26] and cholesterol [27] were measured from capillary blood samples. Blood pressures were assessed as the average of two resting measurements. Percent body fat, waist circumference, and aerobic fitness were not measured due to participant burden and cost considerations.

2.3. Statistical Power and Analysis

Given the study's encouragement trial design, we assumed as few as 30% of participants in the GLI arm would actually attend the intervention [12, 13] and sample attrition of 20% at 12 months. Under these assumptions, a sample size of 328 provided more than 80% power at the $\alpha=0.05$ significance level to detect a between-group mean difference of 4.75% (SD 6.5%) weight loss at 12 months. A sample size of 328 also provided 80% power to detect between-group differences in HbA1c of 0.64% (SD 0.99) and SBP of 3.55 mmHg (SD 19.98).

The randomized encouragement design enabled us to observe GLI participation levels when offered in a real-world context and to conduct two complementary regression analyses: 1) intention-to-treat analysis to estimate effects based on study arm randomization, regardless of GLI attendance and; 2) instrumental variable analysis to estimate the complier-average treatment effect for participants who received (i.e. attended) the GLI [28–31].

All statistical tests were performed using two-sided tests with $\alpha=0.05$. Intention-to-treat analysis was conducted using SAS, version 9.4 (SAS Institute; Cary, NC). Other analyses were conducted using Stata/SE, version 14.2 (StataCorp; College Station, TX).

2.3.1. Intention-to-treat Analysis—We fit generalized estimating equations (GEE) with an independent correlation structure and robust variance estimates to produce marginal population-averaged estimates for each outcome. The primary outcome was percent weight change from baseline to 6- and 12-month time points, and the main independent variable was a binary indicator of randomization assignment to GLI encouragement (versus standard care). Weight loss interventions typically have non-linear effects over time, so we treated time as a factor (i.e. categorical) variable rather than a continuous variable. We assessed treatment effect at each time point by including a treatment-time interaction term. Covariates

included continuous age and categorical variables for sex, race/ethnicity (non-Hispanic White; non-Hispanic African-American; Hispanic/Other), income, intervention site, and baseline insulin use (yes/no).

In addition to the primary outcome of percent weight change, we fit GEE models for weight change in kilograms and a binary measure of $\geq 5\%$ weight loss, a common weight loss threshold in type 2 diabetes [32, 33]. GEE models were also used for change in secondary outcomes from baseline to 6 and 12 months, including HbA1c (%; mmol/mol), SBP (mmHg), total cholesterol (mg/dL) and HDL cholesterol (mg/dL). Regression models adjusted for all covariates listed in the prior paragraph, as well as baseline use of medications that affect each respective outcome of interest (weight models adjusted for use of insulin, glucagon-like peptide 1 [GLP1] receptor agonists and sulfonylureas; the HbA1c model adjusted for insulin, non-insulin antidiabetic agents and statins; the SBP model adjusted for antihypertensives; cholesterol models adjusted for statins and other antilipidemics)

This regression analysis was conducted under the intention-to-treat principle such that all randomized subjects were included in the analysis. Although we engaged in substantial efforts to minimize attrition in this diverse, low-income participant sample, weight data were missing for 82 participants (24.8%) who did not attend study follow-up visits at six months and 74 participants (22.4%) at 12 months ($P = 0.66$ for chi-square tests comparing proportions of missing data between randomization arms). Similar proportions of follow-up data were missing for secondary outcomes. There were no significant differences in baseline study outcomes among participants with missing weight data ($P = 0.37$ versus those with complete data). Household income was the lone demographic characteristic where those with missing data differed from those with complete data ($P=0.002$); while the majority of those with complete data reported at least \$25,000 of income, the majority of those with missing data reported income of less than \$25,000 or ‘Refused.’

GEE can produce valid estimates under the assumption of data missing at random (MAR), but in accordance with pre-specified analysis protocols [18] we conducted multiple imputation (MI) for all missing data, employing Markov chain Monte Carlo estimation with an expectation maximization algorithm using 50 imputations [34]. MI was conducted separately for each stratum in the experimental design (race/ethnicity and site) and for each outcome. Variables used for MI included baseline, 6-month and 12-month values of the outcome, age, sex, treatment arm and baseline medications appropriate to each regression model. Estimates from the 50 iterations were combined using the “PROC MIANALYZE” package in SAS.

2.3.2. Instrumental Variable Analysis—In accordance with the trial’s randomized encouragement design, some participants randomized to the GLI arm did not attend the GLI intervention at the Y. To estimate the effect of GLI *participation* among the subgroup of ‘attenders,’ we conducted a pre-specified [18] two-stage instrumental variable analysis for all continuous outcomes. In this modeling approach, an ‘instrument’ (i.e. randomization assignment) makes the exposure of interest (i.e. GLI participation) more or less likely but does not affect the outcome of interest beyond its impact on the exposure. This application of instrumental variables has been extensively outlined in the experimental design [15, 28,

29] and epidemiology [30] literature, and used in trials of behavioral economics [31] and health services research [23] interventions in leading academic publications.

Instrumental variable models used random treatment assignment (GLI encouragement versus standard care) as the instrumental variable, and a binary indicator for GLI participation (1 GLI visits) as the exposure. Instrumental variable models adjusted for the same covariates as intention-to-treat models, and similarly modeled effects at both 6 and 12 months. We used Stata's 'xtivreg' command to compute instrumental variable estimates for panel data with a patient-level random effect estimator. The first stage of each IV regression used random treatment assignment to predict the probability of GLI attendance, and the second stage used predicted values from the first stage to estimate the effect of attendance. To our knowledge, there are no imputation methods that produce reliable results for instrumental variable regression; as such, we assumed missing data were missing at random for instrumental variable analysis.

3. RESULTS

Trial recruitment began in January 2013 and concluded in July 2014. Six-month follow-up visits began in July 2013 and 12-month outcome data collection concluded in June 2015. Among 2,957 total patients referred to this study or identified in clinical databases as having diabetes, 331 (11.2%) were eligible, enrolled and randomized into the final study cohort (Figure 1); 167 participants were randomized to the standard care arm and 164 to the GLI encouragement arm.

Baseline demographic and cardiometabolic characteristics, shown in Table 1, reflect the trial cohort's racial/ethnic and socioeconomic diversity. The mean age was 56.9 years (standard deviation [SD] 11.4), and a majority of participants were racial/ethnic minorities, including 101 (30.5%) non-Hispanic African-Americans and 116 (35.1%) Hispanic/Other. One hundred and eighteen participants (35.6%) reported a total household income below \$25,000, while 80 (24.2%) reported an income over \$75,000.

Cardiometabolic risk factors were modestly elevated. Mean weight was 99.7 kilograms (SD 24.2), and mean body mass index was 35.6 kg/m² (SD 7.6). Mean SBP was 126.5 mmHg (SD 16.8), and mean HbA1c was 7.2% (SD 1.2%) (55 mmol/mol). Mean total cholesterol was 171.7 mg/dL (SD 44.9), while mean HDL cholesterol was 44.1 mg/dL (SD 13.1).

At baseline, 24.5% of participants used insulin and 81.0% used any non-insulin antiglycemic medications. Compared to participants in the standard care arm, GLI arm participants had higher baseline use of non-insulin antiglycemics (87.2% versus 74.8%). Overall, more than three-fourths of participants used antihypertensive medications, and over half used statins.

Of the 164 participants randomized to GLI encouragement, 75 (45.7%) attended one or more GLI group visits at the Y. Among these 75 attenders, the mean number of GLI visits during the first six months was 5.3 visits (SD 6.0) and the median was 2 visits (interquartile range [IQR], 1–8). Over 12 months, they had a mean of 10.3 visits (SD 10.8) and a median of 5 visits (IQR, 1–18).

Mild hypoglycemia, severe hypoglycemia, cardiovascular events (myocardial infarction, percutaneous transluminal coronary angioplasty or bypass surgery, congestive heart failure, arrhythmia and stroke), fractures and deaths were monitored as potential harms/unintended intervention effects. There were no significant differences in rates of these adverse events between the two treatment groups ($P = 0.16$; results available from authors upon request).

3.1. Intention-to-treat Analysis

In intention-to-treat analysis, there were statistically significant intervention effects for continuous weight outcomes (Table 2; $n=331$). At six months, the intention-to-treat effect—i.e. the average effect of randomization to the GLI encouragement arm—was 0.95% weight loss (95% CI, 0.13 to 1.77%; $P=0.02$). At 12 months, the intention-to-treat effect was 1.20% weight loss (95% CI, 0.05 to 2.36%; $P=0.04$). In kilograms, the intention-to-treat effect was 1.09 kilograms of weight loss at 6 months (95% CI, 0.27 to 1.91; $P=0.01$) and 1.42 kilograms of weight loss at 12 months (95% CI, 0.21 to 2.63; $P=0.02$). There was no significant difference between trial arms in the odds of 5% weight loss at 6 months ($P=0.06$) or 12 months ($P=0.13$).

In models for secondary outcomes, the intention-to-treat effect for HbA1c was not statistically significant at 6 months ($P=0.18$); at 12 months, there was a 0.30% (3.3 mmol/mol) reduction in HbA1c, but this result did not achieve statistical significance ($P=0.054$). We did not detect statistically significant intention-to-treat effects on SBP, total cholesterol or HDL cholesterol at either 6 months ($P = 0.24$) or 12 months ($P = 0.10$).

3.2. Instrumental Variable Analysis

In instrumental variable analysis, we detected statistically significant weight effects among participants who attended GLI group visits at the Y (Table 3; $n=271$). At 6 months, the average effect of GLI attendance was 2.30% weight loss (95% CI, 0.30 to 4.30%; $P=0.02$). At 12 months, the average effect of GLI attendance was 2.07% weight loss (95% CI, 0.25 to 3.88%; $P=0.02$). In kilograms, the effect of GLI attendance was a 2.60 kilogram weight loss at 6 months (95% CI, 0.37 to 4.84; $P=0.02$) and a 2.64 kilogram weight loss at 12 months (95% CI, 0.61 to 4.66; $P=0.01$).

In models for secondary outcomes, GLI attendance reduced HbA1c by 0.53% (5.8 mmol/mol) over 12 months, but—similar to our intention-to-treat results—the effect approached but did not achieve statistical significance ($P=0.06$). We also did not detect statistically significant effects of GLI attendance on SBP or cholesterol outcomes at either 6 months ($P = 0.15$) or 12 months ($P = 0.12$).

4. DISCUSSION

In this randomized encouragement trial, we investigated the effects of a group-based lifestyle intervention among adults with type 2 diabetes. Compared to controls, participants who were *offered* the GLI lost about 1% of body weight over 6 months and maintained this weight loss at 12 months, regardless of their level of intervention engagement. Although participants in the GLI encouragement arm reduced hemoglobin A1c by 0.30% (3.3 mmol/mol) over 12 months, this result narrowly failed to achieve statistical significance at $P<0.05$.

In instrumental variable analysis, the effect of GLI participation was a loss of about 2% of body weight, or 2.6 kilograms, over both 6 months and 12 months. The GLI had no statistically significant effects on SBP or cholesterol outcomes over this same time period.

Although this study's one-year weight effects are smaller than those from the Look AHEAD study [9], they should be interpreted in the context of the I-D-HEALTH study's design, participant sample and low resource intensity of the intervention. The Look AHEAD Research group evaluated the efficacy of an intensive lifestyle intervention offered to participants who were screened for characteristics that improve adherence to protocols [11] and demonstrated adherence during a two-week run-in period [35]. In contrast, in the current trial, we evaluated adoption and effectiveness of the GLI when offered through a primary care-community linkage [18], and I-D-HEALTH participants were not required to demonstrate ability to adhere to the assigned treatment. I-D-HEALTH also targeted participants who were more likely to have low income (over one third had household income below \$25,000) or to be racial/ethnic minorities; these characteristics were associated with comparatively less weight loss in prior lifestyle interventions [36, 37]. Although only 46% of I-D-HEALTH participants randomized to GLI encouragement attended any intervention group visits, this attendance rate exceeds that of many prior referral-based lifestyle interventions [12, 13]. Finally, unlike Look AHEAD, the I-D-HEALTH GLI did not include meal replacements, which can increase weight loss [38, 39] but cost nearly \$800 per participant in the Look AHEAD intervention's first year [40].

This study's external validity is potentially very high. In many ways, the I-D-HEALTH participant cohort reflects the diversity of type 2 diabetes prevalence across the United States. Also, the YMCA has broad national reach in both urban and non-urban settings. Importantly, participants randomized to the GLI arm were offered the intervention free-of-charge, which is consistent with a recent U.S. Preventive Services Task Force 'B' recommendation [41] requiring full coverage of this type of lifestyle intervention for adults with overweight or obesity and an additional cardiovascular risk factor such as diabetes [42].

This study is not without limitations. First, outcome data was missing for about one-fifth of participants. Although we imputed missing data in intention-to-treat analysis, we cannot be certain of the study outcomes among those lost to follow-up. Second, we only present results on intervention effects over the first 12 months; future analyses will report changes in weight, secondary cardiometabolic outcomes and medication use over the trial's full two-year follow-up period. Third, an in-person GLI program is not necessarily suitable for all patients. Additional research is needed to assess the comparative effectiveness and cost effectiveness of lifestyle interventions across numerous demographic subpopulations and intervention delivery formats, such as clinic-based group interventions [43], online interventions or telephone-based group interventions. Fourth, intervention effects approached statistical significance for some secondary outcome measures, such as HbA1c reductions ($P=0.054$ for 12-month effect). Since this trial was not powered to detect this small of an HbA1c effect, we are unsure whether an HbA1c reduction of this magnitude would have been statistically significant in a larger trial cohort. Further research is warranted here, particularly for potential HbA1c effects that might mirror one-year glycemic reductions from the Look AHEAD trial [9].

This study demonstrates the achievement of modest weight loss in a group-based lifestyle intervention delivered in a community-based setting. Future research by our team will address longer-term effects of the intervention under study, including potential changes in medication use and intervention costs.

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Highlights

- This trial evaluated effects of offering a group-based lifestyle intervention (GLI) to patients with Type 2 diabetes
- Participants offered a GLI lost about 1% of body weight over 6 months, and maintained this weight loss at 12 months
- The subgroup of participants who attended any GLI visits lost about 2% of body weight

Figure 1. CONSORT Diagram

Boxes and arrows indicate the flow of potentially eligible patients as deemed approachable, eligible, enrolled and randomized; side arrows provide reasons for non-approach, ineligibility and non-enrollment

Abbreviations: EHR, electronic health record; PCP, primary care provider; BMI, body mass index; HbA1c, hemoglobin A1c

Table 1

Baseline Characteristics of the Randomized Cohort

Characteristic	Total		Standard Care		GLI	
	N=331		n=167		n=164	
Age, mean (SD)	56.9	(11.4)	56.6	(12.2)	57.1	(10.6)
Female, n (%)	166	(50.2)	81	(48.5)	85	(51.8)
Race/Ethnicity, n (%)						
White non-Hispanic	114	(34.4)	58	(34.7)	56	(34.1)
African-American non-Hispanic	101	(30.5)	51	(30.6)	50	(30.5)
Hispanic/Other	116	(35.1)	58	(34.7)	58	(35.4)
Household Income, n (%)						
<\$25,000	118	(35.6)	57	(34.1)	61	(37.2)
\$25,000 – \$74,999	105	(31.7)	53	(31.8)	52	(31.7)
\$75,000	80	(24.2)	47	(28.1)	33	(20.1)
Refused	28	(8.5)	10	(6.0)	18	(11.0)
Weight (kg), mean (SD)	99.7	(24.2)	98.3	(23.9)	101.2	(24.5)
BMI (kg/m ²), mean (SD)	35.6	(7.6)	34.9	(7.3)	36.2	(7.8)
BMI (kg/m ²), n (%)						
24 – 29.99	94	(28.4)	51	(30.5)	43	(26.2)
30 – 34.99	84	(25.4)	44	(26.3)	40	(24.4)
35 – 39.99	76	(23.0)	37	(22.2)	39	(23.8)
40	77	(23.2)	35	(21.0)	42	(25.6)
HbA1c						
NGSP units, % (SD)	7.2	(1.2)	7.1	(1.3)	7.3	(1.2)
IFCC units, mmol/mol (SD)	55	(13)	54	(14)	56	(13)
Systolic blood pressure (mmHg), mean (SD)	126.5	(16.8)	127.0	(17.6)	126.0	(16.0)
Total cholesterol (mg/dL), mean (SD)	171.7	(44.9)	169.6	(44.2)	173.9	(45.7)
HDL cholesterol (mg/dL), mean (SD)	44.1	(13.1)	43.2	(13.4)	45.0	(12.8)
Antiglycemic medications, n (%)						
Insulin	81	(24.5)	36	(21.6)	45	(27.4)
Non-insulin antiglycemics (any)	268	(81.0)	125	(74.8)	143	(87.2)
Sulfonylureas	88	(26.6)	40	(24.0)	48	(29.3)
GLP1 receptor agonists	16	(4.8)	5	(3.0)	11	(6.7)
SGLT2 inhibitors	0	(0)	0	(0)	0	(0)
Antihypertensive medications, n (%)	260	(78.6)	128	(76.6)	132	(80.5)
Statin medications, n (%)	184	(55.6)	87	(52.1)	97	(59.2)

Abbreviations: BMI, body mass index; GLP1, glucagon-like peptide 1; GLI, group-based lifestyle intervention; HbA1c, hemoglobin A1c; HDL, high-density lipoprotein; IFCC, International Federation of Clinical Chemistry; NGSP, National Glycohemoglobin Standardization Program; SD, standard deviation; SGLT2, sodium-glucose co-transporter 2

Table 2

Results of Intention-to-treat Regression Models Estimating Effect of Randomization to the GLI Study Arm

Outcome	6 Month Effect (95% CI)	<i>P</i> value	12 Month Effect (95% CI)	<i>P</i> value
Weight				
Percent	−0.95 (−1.77, −0.13)	0.02	−1.20 (−2.36, −0.05)	0.04
Kilograms	−1.09 (−1.91, 0.27)	0.01	−1.42 (−2.63, −0.21)	0.02
5% weight loss ^a	2.96 (0.95, 9.24)	0.06	1.71 (0.85, 3.47)	0.13
HbA1c				
NGSP units (%)	−0.18 (−0.45, 0.09)	0.18	−0.30 (−0.61, 0.01)	0.05 ^b
IFCC units (mmol/mol)	−2.0 (−4.9, 1.0)	0.18	−3.3 (−6.7, 0.1)	0.05 ^b
Systolic blood pressure (mmHg)	1.02 (−2.75, 4.79)	0.60	−1.36 (−5.30, 2.59)	0.50
Total cholesterol (mg/dL)	−4.96 (−13.29, 3.37)	0.24	−5.69 (−13.76, 2.38)	0.17
HDL cholesterol (mg/dL)	0.36 (−1.74, 2.46)	0.74	1.67 (−0.30, 3.64)	0.10

Abbreviations: CI, confidence interval; GLI, group-based lifestyle intervention; HbA1c, hemoglobin A1c; HDL, high-density lipoprotein; IFCC, International Federation of Clinical Chemistry; NGSP, National Glycohemoglobin Standardization Program

^aLogistic regression model estimated odds ratio of 5% weight loss in the GLI arm, compared to the standard care arm. Other intention-to-treat models used linear regression models to estimate effects on continuous outcomes

^b $P=0.054$

Table 3

Results of Instrumental Variable Regression Models Estimating Effect of GLI Participation Among Those who Attended Intervention Visits

Outcome	6 Month Effect (95% CI)	P value	12 Month Effect (95% CI)	P value
Weight				
Percent	−2.30 (−4.30, −0.30)	0.02	−2.07 (−3.88, −0.25)	0.02
Kilograms	−2.60 (−4.84, −0.37)	0.02	−2.64 (−4.66, −0.61)	0.01
HbA1c (%)				
NGSP units (%)	−0.29 (−0.91, 0.32)	0.35	−0.53 (−1.09, 0.03)	0.06
IFCC units (mmol/mol)	−3.2 (−9.9, 3.5)	0.35	−5.8 (−11.9, 0.3)	0.06
Systolic blood pressure (mmHg)	1.79 (−6.36, 9.95)	0.67	−2.21 (−9.67, 5.26)	0.56
Total cholesterol (mg/dL)	−13.34 (−31.57, 4.88)	0.15	−13.24 (−29.80, 3.33)	0.12
HDL cholesterol (mg/dL)	0.07 (−4.32, 4.46)	0.98	3.04 (−0.99, 7.06)	0.14

Abbreviations: CI, confidence interval; GLI, group-based lifestyle intervention; HbA1c, hemoglobin A1c; HDL, high-density lipoprotein; IFCC, International Federation of Clinical Chemistry; NGSP, National Glycohemoglobin Standardization Program