Obesity

Randomized Controlled Trial of a Nationally Available Weight Control Program Tailored for Adults with Type 2 Diabetes

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Objective: Modest weight loss from clinical interventions improves glycemic control in type 2 diabetes (T2DM). Data are sparse on the effects of weight loss via commercial weight loss programs. This study examined the effects on glycemic control and weight loss of the standard Weight Watchers program, combined with telephone and email consultations with a certified diabetes educator (WW), compared with standard diabetes nutrition counseling and education (standard care, SC).

Methods: In a 12-month randomized controlled trial at 16 U.S. research centers, 563 adults with T2DM (HbA_{1c} 7–11%; BMI 27–50 kg/m^2) were assigned to either the commercially available WW program (regular community meetings, online tools), plus telephone and email counseling from a certified diabetes educator, or to SC (initial in-person diabetes nutrition counseling/education, with follow-up informational materials).

Results: Follow-up rate was 86%. Twelve-month HbA_{1c} changes for WW and SC were −0.32 and +0.16, respectively; 24% of WW versus 14% of SC achieved HbA_{1c} <7.0% (P = 0.004). Weight losses

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Author contributions: Authors from MUSC (PMO, PWT, LEB) and WWI (KM-K, SLR) designed the study with input from several outside consultants, some of whom are authors (KF, PLH, RFK, TAW). MUSC provided trial management (PMO, LEB) and medical monitoring (KLH, NDS) and served as the data coordinating center. TAW, KF, PLH, RFK, WTG, DMR, RJM, DW, WJR, and JLS served as site principal investigators. Outside contractors provided central laboratory (PPD Global Central Laboratories; Highland Heights, KY), randomization (Randomize.net; Ottawa, ON), and electronic data capture services (Clinical Ink; Winston-Salem, NC). Clinical Ink collected all data from the research sites and the central lab and provided them to the MUSC coordinating center. MUSC staff (LEB, PWT, PMO) had complete control of the data and provided all data management and analyses independently of the funding source and its employees. WWI's roles in the conduct of the study were limited to: (1) providing subjects in the Weight Watchers condition with access to meetings, online tools, and certified diabetes educators via telephone and email and providing MUSC with data on participant usage of the educators and online services, and (2) funding the outside contractors who provided central laboratory and electronic data capture services. Neither WWI as the sponsor nor WWI authors played any role in the collection, management, analysis, or interpretation of the data. PMO wrote the initial draft of the manuscript. All authors including WWI authors reviewed, edited, and approved the manuscript. As the sponsor, nonauthor WWI staff reviewed the manuscript but had no approval authority.

*KM-K and SLR are no longer with WWI.

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were −4.0% for WW and −1.9% for SC (*P*s < 0.001). 26% of WW versus 12% of SC reduced diabetes medications ($P < 0.001$). WW participants had greater reductions in waist circumference ($P < 0.001$) and C-reactive protein ($P = 0.02$) but did not differ on other cardiovascular risk factors.

Conclusions: Widely available commercial weight loss programs with community and online components, combined with scalable complementary diabetes education, may represent accessible and effective components of management plans for adults with overweight/obesity and T2DM.

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Introduction

The prevalence of diabetes among adults in the United States is high and growing. In 2012 it was estimated to be 12.3%, an increase from 9.3% only 10 years earlier (1,2). Only 72% of adults with diabetes are diagnosed, and of them, only 57% achieve targets for glycemic control [hemoglobin A_{1c} (HbA_{1c}) <7.0%] (3,4). The majority (90–95%) of cases are type 2 diabetes mellitus (T2DM), which is associated with obesity and overweight. Indeed, more than half of the cases of all diagnosed diabetes occur among people with obesity (BMI >30 kg/m^2), and 85% of all cases occur among people with overweight or obesity (BMI >25 kg/m^2) (3).

Weight loss via clinical interventions has been shown to improve glycemic control in T2DM, whether the loss is achieved by intensive diet and exercise (lifestyle change) programs, weight loss medications, or bariatric surgery (5-15). However, such interventions are not options for many overweight diabetic individuals because of limited availability, affordability, or acceptability. For example, in the landmark Look AHEAD trial, the first year of the lifestyle intervention required weekly group and individual treatment sessions for the first 6 months and three sessions per month for the second 6 months, delivered by a multidisciplinary professional staff in tertiary care medical centers (16). Such intensive, multidisciplinary lifestyle change interventions, even those not restricted to diabetic participants, are not widely available and where available are employed by only a minority of individuals who consider them (17).

Even modest weight loss (2–5% of initial body weight) improves glycemic control (6,15). Commercial weight loss programs, comparatively more affordable and accessible than clinic-based modalities, can produce weight losses in this range, although they typically do not offer diabetes-specific counseling (18-20). Recently an enhancement of one such program, Weight Watchers, has been developed to provide additional support and education for participants with T2DM. The standard Weight Watchers program, as offered in the community and online, is utilized in conjunction with coordinated telephone and email consultations with a certified diabetes educator (CDE). The present 12-month, multisite, randomized controlled trial examined the effects on glycemic control and weight loss of this combined program compared with usual diabetes nutrition counseling and education. We hypothesized that the combined program would produce better glycemic control and weight loss.

Methods

Study design

This was a prospective, randomized, parallel-group clinical trial conducted at 16 U.S. sites across 13 states (see Supporting Information for list of sites). The Medical University of South Carolina Institutional Review Board and those of each of the trial sites approved the study. Subjects were randomized to either the standard Weight Watchers program supplemented with telephone and email CDE counseling (WW) or to one session of face-to-face T2DM nutritional counseling by a registered dietitian with follow-up written information (standard care; SC). Randomization was 1:1 and stratified by study site, gender, and HbA_{1c} (<8.5% vs. ≥8.5%), with treatment allocation in blocks of four subjects. Participants were monitored at 3-, 6-, 9-, and 12-month follow-up visits.

Participants

Major inclusion criteria were: participant-reported diagnosis of T2DM; $HbA_{1c} = 7–11\%$; fasting blood glucose (FBG) <240 mg/dL (13.3 mmol/L); BMI 27 to 50 kg/m^2; age 18 to 70 years; diabetes management by a non-study physician; stable regimen of all medications for at least 3 months; and willingness to attend weekly Weight Watchers meetings in the community and to use Weight Watchers online tools. Use of any diabetes medications, including insulin, was permitted but was not required.

Major exclusion criteria were type 1 diabetes; active cardiovascular/coronary heart disease; blood pressure >160/110 mm Hg; weight loss >5 kg in the previous 3 months; severe depression within the previous year; use of prescription or over-the-counter weight loss medications within 4 weeks before screening; participation in a weight control program within the prior 3 months; and previous weight loss surgery (complete list of inclusion/exclusion criteria is in Supporting Information).

Participants classified their race/ethnicity using the following categories: African-American, Asian, Caucasian, Hispanic, Native American, Pacific Islander, other (self-described). Because of low numbers, some groups were combined, resulting in the following categories for analyses: African-American, Caucasian, Hispanic, and other.

Interventions

WW participants were provided free access to the ongoing, weekly, in-person Weight Watchers meetings in their communities and the standard online tools. Weight Watchers meeting staff were unaware participants had diabetes or were in a clinical trial. Other than providing initial instruction in how to access the meetings and online tools, *study* staffs were not involved in the WW intervention. In two scheduled telephone consultations, a CDE advised on adapting the standard Weight Watchers program to enhance the participant's management of her/his T2DM. Included in this education was guidance regarding risk factors for and symptoms of hypoglycemia and recommendations

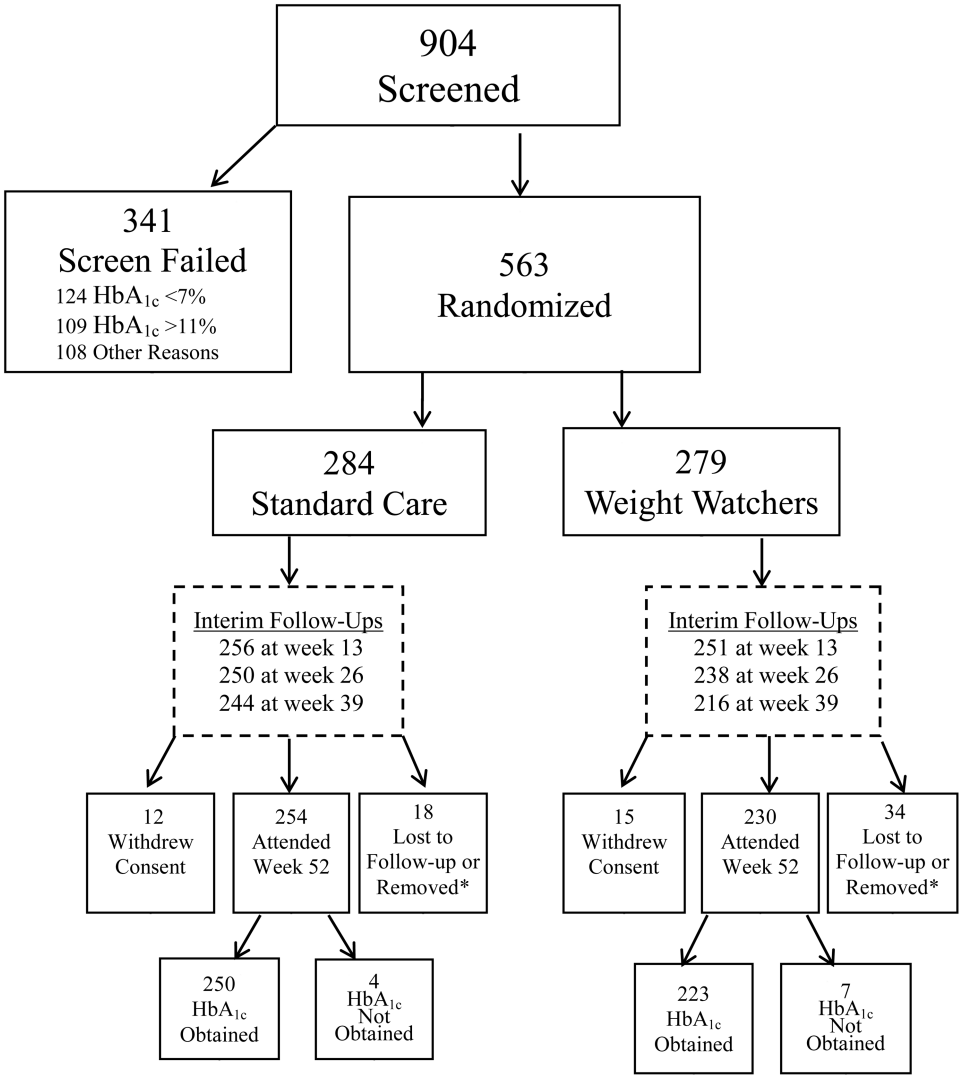

Figure 1 Participant disposition by groups. Participants missing any intermediate follow-up visit(s) were encouraged to attend all subsequent ones. HbA_{1c} values were not available for 11- to 12-month follow-up attendees (four SC, seven WW) because of inadequate samples, spoiled samples, or shipping failures, leaving 250 for analysis in the SC group and 223 in the WW group. Of those with 12-month weight data, 438 (230 SC, 208 WW) had weight data at all prior visits. Of those with week 52 HbA_{1c} values, 415 (217 SC, 198 WW) provided HbA_{1c} data at all prior visits. *Two participants reported intercurrent events requiring elimination of their data from the time of reporting onward: SC participant reporting a recent diagnosis of throat cancer at week 26 visit and WW subject who underwent sleeve gastrectomy before week 13 visit. WW, Weight Watchers group; SC, standard care group.

for preventing and treating any such occurrences. All CDEs were also registered dietitians and followed a treatment protocol. Subjects received weekly emails discussing that week's meeting topic as it related to T2DM, including reminders concerning the possibility of hypoglycemia; in any given week, all U.S. Weight Watchers meetings have the same content. Subjects could also have unlimited additional phone and email CDE consultations on demand.

At the baseline visit, participants in the SC condition received one session of in-person T2DM nutrition counseling with a registered dietitian, with additional written materials at follow-up visits, based on guidelines in effect at the time (21). They were instructed to consume a hypocaloric (~500 kcal/day deficit), carbohydrate-controlled, fiber-rich diet, with nutritional guidance for diabetes control. SC participants were promised a post-study 1-year membership in the standard Weight Watchers program (in-person and online) and an initial CDE telephone consultation if they completed the study. The SC intervention was intended to be compatible with the amount of diabetes education commonly received by people with diabetes in the general population, rather than to control for factors such as amount of attention or frequency or duration of contact.

Study procedures

Eligibility screening took place in one or two visits, including baseline fasting blood samples. Randomization occurred during the week

TABLE 1 Baseline demographics and diabetes medications

	Standard care (*N* = 284)		Weight Watchers (*N* = 279)	
	N	Percent	*N*	Percent
Demographics				
Gender				
Female	199	70	201	72
Male	85	30	78	28
Ethnicity				
African-American	108	38	100	36
Caucasian	125	44	128	46
Hispanic	31	11	28	10
Other	20	7	22	8
Diabetes medications				
Metformin	202	71.1	192	68.8
Insulin	104	36.6	111	39.8
Sulfonylureas	88	31.0	102	36.6
DPP-4 inhibitors	29	10.2	27	9.7
GLP-1 agonists	25	8.8	30	10.8
Combination oral medications	25	8.8	21	7.5
Thiazolidinediones	24	8.5	16	5.7
Meglitinides	2	0.7	2	0.7
Amylin mimetics	1	0.4	0	0.0
No medications	13	4.6	15	5.4

Because many participants were on multiple medications, percentages sum to more than 100%.

0 visit; treatment assignment was not known by either staff or participants until this time.

Participants underwent follow-up assessments at 3, 6, 9, and 12 months post-randomization. Those who missed any follow-ups were encouraged to attend all later ones, and there was no minimum treatment adherence requirement in either condition. Weight, waist circumference, and blood pressure were measured; fasting blood samples were obtained and shipped to a central laboratory for blinded analyses (laboratory procedures are in the online Supporting Information). Screening and follow-up laboratory results were sent to participants' physicians. Participants were queried about any medication changes and hypoglycemic symptoms. WW participants reported on their use of the online program and tools and turned in meeting logs documenting meeting attendance.

Data analysis plan

Detailed data analysis description is in Supporting Information.

Change in HbA_{1c} at 12 months was the primary outcome, with an expected difference between groups on this value of 0.3% based on projected weight losses. For 90% power to detect this difference with a two-tailed 0.05 significance level, a between-pairs correlation of $\rho = 0.8$, 25% attrition, and an uncertainty allowance of 10%, a sample of 560 (280/group) was required.

Differences between groups in HbA_{1c} were investigated using a mixed model/hierarchical linear modeling (HLM) approach, using the intention-to-treat sample. Treatment condition was entered as a fixed effect and the interaction between treatment condition and time was used for hypothesis testing. Analyses of secondary continuous outcomes used the above HLM methods but employed Bonferroni-type corrections of *P* values based on 11 separate inquiries. Proportional outcomes were investigated with χ^2 and Mann-Whitney tests, with *post hoc* comparisons between groups. To investigate treatment-associated variations in the relation of HbA_{1c} change to weight loss, HLM models regressed HbA_{1c} change on percent weight loss (%WL) across conditions.

To understand potential effects of missing data on study estimates of HbA_{1c} and weight change, we conducted (a) HLM analyses separately for the subsample of participants who had every point of measurement and (b) last-observation-carried-forward (LOCF) analyses for all randomized participants.

Results

Detailed results are in Supporting Information.

Participants and baseline data

Of 904 participants consented and screened, 563 were randomized (284 SC, 279 WW; see Figure 1). Treatment conditions did not differ significantly on HbA_{1c}, BMI, gender distribution, ethnicity, or other baseline characteristics (Tables 1 and 2). Nearly all (95.0%) participants were on one or more diabetes medications; 38.2% were on insulin (Table 1).

The 12-month follow-up was attended by 254 (89.4%) SC participants and 230 (82.4%) WW participants ($P = 0.015$; Figure 1). Attendees were older than nonattendees ($Ms = 55.6$ and 52.2 respectively; $P = 0.002$) but did not differ on baseline HbA_{1c}, weight, BMI, systolic or diastolic blood pressure, FBG levels, gender, ethnicity, or self-reported income category.

Glycemic control

Estimated HbA_{1c} of WW subjects decreased by 0.32% (95% CI 0.16–0.49%) over the trial ($P < 0.001$), compared with an increase among SC subjects of 0.16% (95% CI 0.03–0.36%; $P = 0.020$). Time of assessment alone was not a statistically significant predictor of HbA_{1c}, but the time by treatment interaction was significant ($P < 0.001$). The treatment effect did not differ as a function of gender ($P = 0.45$) or ethnicity ($P = 0.84$).

At each follow-up visit, the reduction in HbA_{1c} from baseline for WW participants was significantly greater than that of SC participants. For WW, but not SC participants, HbA_{1c} was significantly lower at each visit than at baseline ($Ps < 0.001$) despite a significant increase by WW participants from 9 to 12 months ($P < 0.001$) (Figure 2A and Table 2). More WW participants than SC participants achieved HbA_{1c} below 7.0% at 12 months [WW = 23.8% (95% CI 18.2–29.4%); SC = 13.6% (95% CI 9.4–17.8%); $P = 0.004$] and at all earlier follow-up visits (Supporting Information Table S2).

TABLE 2 Observed means, standard deviations (SD), and cell numbers for clinical outcomes at each observation point

Measure	Treatment group		Baseline	Month 3	Month 6	Month 9	Month 12	Group × time interaction[a], adjusted P[b]
HbA_{1c} (%)	Standard care	Mean ± SD	8.28 ± 1.00	8.12 ± 1.22	8.30 ± 1.49	8.31 ± 1.45	8.40 ± 1.5	<0.001
		N	284	257	247	241	250	
	Weight Watchers	Mean ± SD	8.36 ± 1.02	7.74 ± 1.26	7.73 ± 1.39	7.77 ± 1.33	8.01 ± 1.41	
		N	279	251	235	215	223	
HbA_{1c} (mmol/mol)	Standard care	Mean ± SD	67 ± 10.9	65 ± 13.3	67 ± 16.3	67 ± 15.8	68 ± 16.4	<0.001
		N	284	257	247	241	250	
	Weight Watchers	Mean ± SD	68 ± 11.01	61 ± 13.8	61 ± 15.2	61 ± 14.5	64 ± 15.44	
		N	279	251	235	215	223	
Weight (kg)	Standard care	Mean ± SD	106.2 ± 19.9	104.6 ± 19.7	104.6 ± 19.7	103.7 ± 19.9	104.4 ± 20.1	<0.001
		N	284	255	248	243	254	
	Weight Watchers	Mean ± SD	104.0 ± 19.4	99.9 ± 19.2	99.7 ± 20.1	99.8 ± 20.1	99.6 ± 19.3	
		N	279	250	237	214	230	
Percent weight loss (%)	Standard care	Mean ± SD	0.00 na	1.43 ± 2.54	1.69 ± 3.34	1.85 ± 3.68	1.79 ± 4.01	<0.001
		N	284	255	248	243	254	
	Weight Watchers	Mean ± SD	0.00 na	3.34 ± 3.26	4.07 ± 4.54	4.13 ± 5.33	3.99 ± 5.20	
		N	279	250	237	214	230	
Waist (cm)	Standard care	Mean ± SD	116.56 ± 14.07	115.37 ± 14.36	115.22 ± 14.36	114.61 ± 14.36	115.23 ± 14.85	<0.001
		N	284	256	250	244	255	
	Weight Watchers	Mean ± SD	116.25 ± 14.27	113.11 ± 13.66	112.50 ± 14.34	112.59 ± 14.17	112.57 ± 14.51	
		N	278	250	237	215	228	
Fasting blood glucose (mg/dL)	Standard care	Mean ± SD	165.2 ± 45.5	166.9 ± 54.4	171.3 ± 58.1	172.6 ± 55.9	173.4 ± 60.5	<0.001
		N	284	256	250	243	248	
	Weight Watchers	Mean ± SD	166.1 ± 49.2	155.2 ± 53.5	151.5 ± 51.9	158.0 ± 53.2	159.0 ± 52.4	
		N	279	248	233	214	224	
C-reactive protein (mg/L)	Standard care	Mean ± SD	6.08 ± 6.07	6.75 ± 10.3	6.33 ± 6.78	6.70 ± 8.73	6.61 ± 8.36	0.02
		N	284	270	255	249	221	
	Weight Watchers	Mean ± SD	7.33 ± 8.72	6.49 ± 6.82	6.31 ± 7.02	5.93 ± 6.40	6.30 ± 6.71	
		N	279	259	242	222	201	
HDL (mg/dL)	Standard care	Mean ± SD	50.04 ± 12.6	49.10 ± 13.1	50.97 ± 13.4	51.04 ± 14.0	51.15 ± 13.3	0.29
		N	284	258	247	243	250	
	Weight Watchers	Mean ± SD	48.91 ± 12.5	47.68 ± 12.3	50.42 ± 13.1	50.06 ±12.7	51.66 ± 13.6	
		N	277	249	234	214	224	
LDL (mg/dL)	Standard care	Mean ± SD	103.8 ±35.8	100.6 ± 31.6	100.9 ± 31.7	97.8 ± 31.9	97.45 ± 31.9	0.99
		N	278	254	243	237	240	
	Weight Watchers	Mean ± SD	105.4 ± 38.4	99.22 ± 30.5	99.85 ±32.9	97.90 ±30.14	99.89 ± 31.3	
		N	267	245	232	209	219	
Triglycerides (mg/dL)	Standard care	Mean ± SD	149.7 ± 89.4	143.8 ± 79.5	146.9 ± 85.5	145.3 ± 85.3	148.2 ± 104.7	0.91
		N	284	258	247	243	250	
	Weight Watchers	Mean ± SD	158.6 ±100.0	146.4 ± 79.1	143.5 ± 71.3	158.9 ± 91.7	163.7 ± 168.3	
		N	277	249	235	214	224	

TABLE 2. (continued).

Measure	Treatment group		Baseline	Month 3	Month 6	Month 9	Month 12	Group × time interaction[a], adjusted P[b]
Total cholesterol (mg/dL)	Standard care	Mean ± SD	183.2 ± 41.3	178.3 ± 37.9	181.4 ± 38.9	177.4 ± 38.6	177.0 ± 37.0	0.49
		N	284	258	247	243	250	
	Weight Watchers	Mean ± SD	184.6 ± 45.5	175.8 ± 37.5	178.9 ± 39.0	180.2 ± 37.8	182.9 ± 40.3	
		N	277	249	235	213	224	
Diastolic blood pressure (mm Hg)	Standard care	Mean ± SD	79.3 ± 9.4	78.3 ± 9.7	77.6 ± 9.6	77.7 ± 10.0	77.7 ± 9.8	0.99
		N	283	255	249	243	254	
	Weight Watchers	Mean ± SD	77.7 ± 10.0	77.3 ± 10.6	76.0 ± 9.8	79.6 ± 51.2	75.7 ± 10.1	
		N	277	249	237	214	229	
Systolic blood pressure (mm Hg)	Standard care	Mean ± SD	129.3 ± 15.2	128.7 ± 16.5	129.2 ± 15.8	128.4 ± 16.6	128.5 ± 16.4	0.43
		N	283	255	249	243	254	
	Weight Watchers	Mean ± SD	128.8 ± 16.4	126.8 ± 16.5	125.1 ± 16.0	125.3 ± 16.0	125.9 ± 15.8	
		N	277	249	237	214	229	

[a]Models for outcomes: *P* values based on group by time interaction coefficient.
[b]Bonferroni-type adjustments for 11 multiple comparisons; HbA_{1c} was primary outcome and thus not adjusted.
International conversion units are: for C-reactive protein, use 9.524 for mmol/L; for glucose, use 0.055 for mmol/L; for HDL, LDL, and total cholesterol, use 0.0259 for mmol/L; for triglycerides, use 0.01129 for mmol/L.

FBG levels for WW participants were lower than those of SC participants at all follow-up visits ($P < 0.001$) and lower than baseline at all follow-up visits ($Ps = 0.004$ to < 0.001). FBG levels for SC participants were higher than baseline at months 9 ($P = 0.042$) and 12 ($P = 0.013$).

Weight change

Both groups lost weight over the trial, with the WW group losing more than the SC group at each follow-up ($Ps < 0.001$). Modeled 12-month %WL was 4.0% (95% CI 3.1–4.0%) for WW participants and 1.9% (95% CI 1.3–2.0%) for SC participants. Figure 2B and Table 2 show the observed means at each follow-up visit. At 12 months, 34.3% of WW participants lost ≥5%, compared with 18.1% of SC participants ($P < 0.001$).

Cardiovascular risk factors

WW participants had greater reductions than SC participants in waist circumference ($P < 0.001$) and high-sensitivity C-reactive protein (adjusted $P = 0.020$) (Table 2; Table S1 in Supporting Information). Groups did not differ on changes over the trial in lipids or blood pressure. However, the total sample showed increases from baseline to 12-month follow-up in HDL cholesterol ($P < 0.001$) and reductions in total cholesterol ($P = 0.027$), LDL cholesterol ($P < 0.001$), systolic blood pressure ($P = 0.026$), and diastolic blood pressure ($P < 0.001$), but not in triglyceride levels ($P = 0.863$).

Diabetes medication changes

Participants' diabetes medications at baseline and at final observed visit were independently reviewed by two board-certified endocrinologists (KLH, NDS) blinded to treatment assignment, and coded as increased, decreased, or no net change compared with baseline (for details, see Supporting Information). Changes in diabetes medications were reported at one or more follow-up visits by 38% of all participants, but directions of change differed between groups ($P < 0.001$). More WW than SC participants reduced diabetes medication over the trial (26% vs. 12%; $P < 0.001$). Conversely, SC participants were more likely to not experience any net changes in medications (67% vs. 57%; $P = 0.017$); 21% and 17% of SC and WW participants, respectively, had increases in diabetes medications ($P = 0.181$). Of the 213 participants initially on insulin, 13 discontinued it by week 52 (9 WW, 4 SC; $P = 0.254$).

Safety measures

More WW participants than SC participants reported having had symptoms of hypoglycemia at 3 months (35% vs. 21%; $P < 0.001$) and 6 months (29% vs. 19%; $P = 0.014$), but not at 9 months (24% vs. 18%; $P = 0.169$) and 12 months (18% vs. 16%; $P = 0.63$). Over the trial, 21 serious adverse events were reported (10 SC, 11 WW). Only one involved hypoglycemia that required hospitalization (WW); it was the only serious adverse event considered possibly study-related.

Weight Watchers program utilization

Of the 279 WW subjects, 253 (90.2%) had at least one CDE telephone consultation, and 215 (77.1%) had two or more. Over the trial, those who had two or more CDE consultations had significantly greater improvement in HbA_{1c} than did those with fewer than two ($P = 0.036$; month 12 $Ms = -0.428$ and -0.018, respectively).

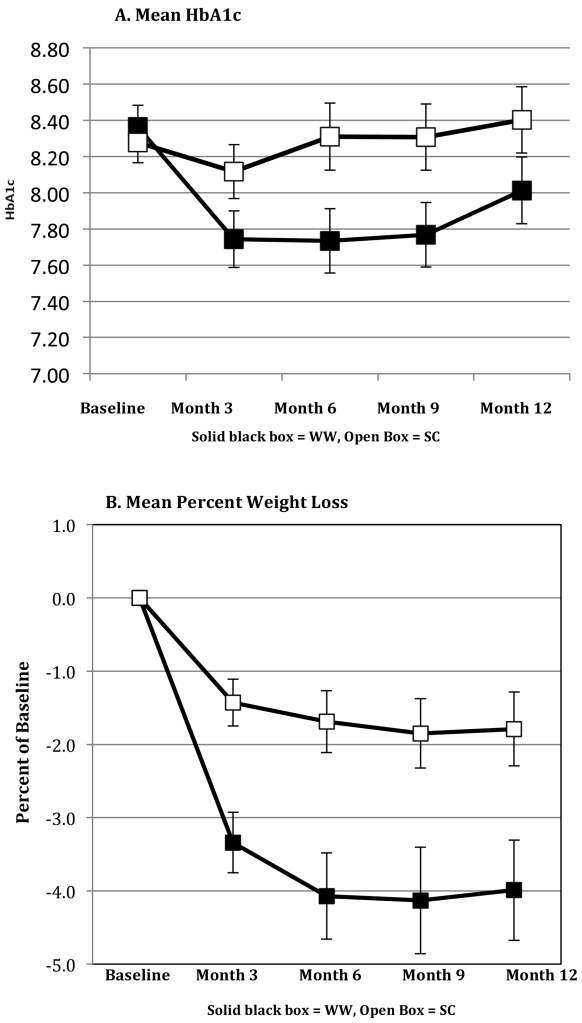

Figure 2 Mean percent weight loss and HbA_{1c} (observed means) at baseline and at months 3, 6, 9, and 12 by groups. (**A**) Mean HbA_{1c} over time by group. (**B**) Mean percent weight loss over time by group. Error bars indicate 95% confidence interval. WW, Weight Watchers group; SC, standard care group.

Average meeting attendance shown by participants' meeting logs was 8.5 meetings (range = 0–16) during the first 3-month period and declined somewhat during the second, third, and fourth follow-up periods (*M*s = 6.9, 6.5, and 6.2, respectively; ranges = 0–18, 0–15, 0–16). During the first follow-up period, 71.8% of participants reported using the online tools at least weekly; rates were 60.1%, 52.6%, and 42.4%, respectively, during the next three periods. The percentage of subjects who reported using the smartphone app at least weekly during the first period was 36.3%, dropping to 33.2%, 28.5%, and 28.7% in subsequent periods.

Sensitivity analyses

Repeated main analyses for HbA_{1c} and percent weight change restricted to participants with data from all four follow-ups yielded results similar to the main (HLM) intention-to-treat analyses (*P*s < 0.001). To determine whether differences in 12-month follow-up attendance may have influenced findings, we examined changes in HbA_{1c} and %WL for all randomized participants using LOCF to impute missing values. Results showed group differences nearly identical to those of the respective HLM analyses. To assess whether LOCF analyses might have been affected by the differing month 12 follow-up rates, additional analyses were restricted to participants with no 12-month data but who had at least one post-baseline measurement (*N*s = 17 SC and 30 WW). Results showed no significant HbA_{1c} reduction as of their last obtained measurement ($P = 0.28$) with no treatment group differences ($P = 0.72$) and similar results on weight loss.

Relation of HbA_{1c} change to weight change

Correlations between %WL and HbA_{1c} change for the groups combined were significant ($P < 0.001$) at each follow-up ($rs = -0.32$ to -0.39; where weight loss is a positive number and HbA_{1c} reduction is a negative number). In HLM analyses, %WL predicted HbA_{1c} change ($P < 0.001$), accounting for 11% of variance. Further, the interaction of treatment condition and percent weight change accounted for an additional 2% of variance above weight change alone ($P = 0.01$). Every 1% weight change was associated with 0.11 HbA_{1c} change in the WW group and 0.065 HbA_{1c} change in the SC group. Restricting the analysis only to subjects with weight loss yielded similar findings.

Discussion

Participants with diabetes who received the commercially available Weight Watchers program combined with telephone and email CDE consultation showed greater improvements in glycemic control and in weight compared with participants receiving brief standard diabetes nutritional counseling. At 12 months, the estimated HbA_{1c} of WW participants had fallen by 0.32 whereas that of SC participants had risen by 0.16 despite receiving diabetic nutrition education and ongoing background medical diabetes management. At study end, although the majority of subjects in both groups had not reached the treatment target of HbA_{1c} levels below 7.0%, nearly twice as many WW subjects as SC subjects had achieved that criterion (23.8% vs. 13.6%), and more than twice as many WW subjects as SC subjects had decreased diabetes medications (26% vs. 12%). The superior improvement among WW participants did not appear to be solely attributable to their greater weight loss, as their drop in HbA_{1c} per unit weight loss was almost twice that of SC, suggesting that other treatment program impacts contributed to their HbA_{1c} reduction.

Context for these results may be provided by recent weight loss trials for T2DM participants utilizing obesity medications or other commercial weight loss programs. While the absolute average reduction in HbA_{1c} in the WW group was modest, their improvement in HbA_{1c} relative to the increase of the SC group is equivalent to the placebo-subtracted reduction in HbA_{1c} seen in two 1-year trials of obesity medications among patients with overweight or obesity and diabetes (7,13). The WW group's improvement in HbA_{1c} relative to SC was also comparable to that seen in trials of two other commercial weight loss programs modified for T2DM participants (22,23). Unlike the WW intervention, both of those programs used portion-controlled diets (PCDs) providing, at no cost, prepackaged foods constituting the majority of participants' recommended intake. In one study, two different (low fat and low carbohydrate) PCDs within the Jenny Craig program produced HbA_{1c} reductions of −0.3 and

−0.7, respectively, compared with an increase of 0.1 with limited weight loss and diabetes education (23). A 6-month study found that another diabetes-tailored PCD (Nutrisystem) plus study-specific group-based lifestyle change instruction produced an HbA_{1c} reduction of −0.7 versus −0.4 from a diabetes self-management program (22).

While the WW intervention was associated with greater reductions in waist circumference and C-reactive protein, it did not produce greater improvements on lipids or blood pressure. However, both groups showed small but statistically significant improvements on all lipid levels except triglycerides and on blood pressure.

At the final (month 12) assessment, the WW group showed an increase in HbA_{1c} from the prior visit while remaining significantly lower than the SC group at that visit and lower than its own baseline. There was no corresponding weight gain during the period. In the aforementioned 12-month PCD trial, HbA_{1c} in the two PCD conditions increased by 0.4 and 0.5 from month 6 to month 12 (23). Calorie restriction reduces glycemia independently of weight loss; caloric intake during weight maintenance is increased relative to that during weight loss, which may explain the partial HbA_{1c} rebound (24).

The present study has a number of strengths. The large sample was diverse in ethnicity (<50% Caucasian), geographic region, and gender. Participants' baseline severity of diabetes was varied and often chronic; all participants were under the care of a non-study physician for their diabetes and nearly all were on one or more diabetes medications. Furthermore, 38.2% of patients were treated with insulin and 33.7% with sulfonylureas, two diabetes medication classes associated with weight gain and resistance to weight loss (25).

The SC condition was meant to reflect the general level of diabetes education commonly received by people with diabetes. National survey data show that only 54.6% of respondents with diabetes reported receiving any diabetes education at diagnosis (26). In an urban public safety-net primary care system, only 13.4% of patients with diabetes had any diabetes or nutrition education (27). All SC subjects in this trial received an individual diabetes nutrition consultation with a registered dietitian, a hypocaloric diet, and additional written information at follow-up visits. Thus, while offering less treatment exposure than did the WW condition, this intervention provided an amount of education and counseling equal to or somewhat greater than that received on average in the general diabetic population, in addition to the prior and concurrent background diabetes management received by all participants through their physicians. Further, the level of intensity of the SC intervention was comparable to that of control groups in other trials of lifestyle change interventions for weight loss in diabetes (28-31).

Attrition rates were low for a weight loss trial of this duration. The somewhat greater month 12 completion rate among the SC group may have been attributable to the promised Weight Watchers membership and CDE consultation for SC participants who attended this visit. However, sensitivity analyses did not indicate an effect of differential attrition on the primary results.

Apart from the telephone and email CDE counseling, the underlying weight loss program is widely available and was used "off the shelf." WW participants were integrated in standard online offerings and in self-selected community meetings where their study status was generally not known, and study staff were uninvolved in their treatment.

At the same time, there were some limitations to this study. The purpose of the study was to assess the effects of the enhanced Weight Watchers program as a whole; the design did not permit ascertainment of the individual contributions of the CDE counseling and the Weight Watchers program. Doing so would have required including a WW group that did not receive any diabetes-specific nutrition counseling, which would be inconsistent with current guidelines (32,33). However, *post hoc* analyses showed that WW patients who did not receive the minimum expected number of CDE consultations showed significantly less improvement in HbA_{1c} than did those who did, suggesting a role for that counseling in the WW group's better glycemic control.

As with all long-term clinical trials in obesity, overall attrition, while limited, still may have impacted findings somewhat in ways that the sensitivity analyses did not detect. The necessarily unblinded nature of the trial may have contributed to differential patient expectations about the efficacy of their assigned intervention. Finally, given that participants were all under treatment for their diabetes, results may not generalize to individuals not receiving ongoing diabetes care.

The number of adults with diabetes is large and growing, and a variety of accessible treatment approaches is needed. The results of this and related trials suggest that adapted nationally available weight loss programs emphasizing lifestyle changes may represent accessible and effective adjunctive health management resources for people with overweight or obesity and T2DM. The approach studied here, which employed an existing, widely available community and online program combined with a scalable method of providing complementary diabetes education, may represent a useful model.

At the same time, results here and elsewhere demonstrate the challenges of diabetes management and the need for more effective treatment options. Comprehensive, multicomponent approaches and medical management are necessary but in many cases not sufficient. Development of additional treatments will be required for more widespread achievement of diabetes management goals. O

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