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 (HbA1c 7–11%; BMI 27–50 kg/m²) 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 HbA1c changes for WW and SC were −0.32 and +0.16, respectively; 24% of WW versus 14% of SC achieved HbA1c <7.0% (P = 0.004). Weight losses

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Author contributions: Authors from MUSC (PMO, PWT, LEB) and WW (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, WGT, DMR, RUM, 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 (Ps < 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.

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 A1c (HbA1c) <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/m²), and 85% of all cases occur among people with overweight or obesity (BMI >25 kg/m²) (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 HbA1c (<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; HbA1c = 7–11%; fasting blood glucose (FBG) <240 mg/dL (13.3 mmol/L); BMI 27 to 50 kg/m²; 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...
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 (~300 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.
Differences between groups in HbA1c 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 \( \chi^2 \) and Mann-Whitney tests, with post hoc comparisons between groups. To investigate treatment-associated variations in the relation of HbA1c change to weight loss, HLM models regressed HbA1c change on percent weight loss (%WL) across conditions.

To understand potential effects of missing data on study estimates of HbA1c 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 HbA1c, 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 (\( M_S = 55.6 \) and 52.2 respectively; \( P = 0.002 \)) but did not differ on baseline HbA1c, weight, BMI, systolic or diastolic blood pressure, FBG levels, gender, ethnicity, or self-reported income category.

#### Glycemic control

Estimated HbA1c 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 HbA1c, 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 HbA1c from baseline for WW participants was significantly greater than that of SC participants. For WW, but not SC participants, HbA1c was significantly lower at each visit than at baseline (\( P_S < 0.001 \)) 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 HbA1c 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).

### Data analysis plan

Detailed data analysis description is in Supporting Information.

Change in HbA1c 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.

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

<table>
<thead>
<tr>
<th>Measure</th>
<th>Treatment group</th>
<th>Baseline Mean ± SD</th>
<th>Month 3 Mean ± SD</th>
<th>Month 6 Mean ± SD</th>
<th>Month 9 Mean ± SD</th>
<th>Month 12 Mean ± SD</th>
<th>Group x time interaction&lt;sup&gt;a&lt;/sup&gt;, adjusted&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HbA1c (%)</strong></td>
<td>Standard care</td>
<td>8.28 ± 1.00</td>
<td>8.12 ± 1.22</td>
<td>8.30 ± 1.49</td>
<td>8.31 ± 1.45</td>
<td>8.40 ± 1.5</td>
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<td></td>
<td>Weight Watchers</td>
<td>8.36 ± 1.02</td>
<td>7.74 ± 1.26</td>
<td>7.73 ± 1.39</td>
<td>7.77 ± 1.33</td>
<td>8.01 ± 1.41</td>
<td>0.01</td>
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<tr>
<td><strong>HbA1c (mmol/mol)</strong></td>
<td>Standard care</td>
<td>67 ± 10.9</td>
<td>65 ± 13.3</td>
<td>67 ± 16.3</td>
<td>67 ± 15.8</td>
<td>68 ± 16.4</td>
<td>&lt;0.001</td>
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<tr>
<td></td>
<td>Weight Watchers</td>
<td>68 ± 11.01</td>
<td>61 ± 13.8</td>
<td>61 ± 15.2</td>
<td>61 ± 14.5</td>
<td>64 ± 15.44</td>
<td></td>
</tr>
<tr>
<td><strong>Weight (kg)</strong></td>
<td>Standard care</td>
<td>106.2 ± 19.9</td>
<td>104.6 ± 19.7</td>
<td>104.6 ± 19.7</td>
<td>103.7 ± 19.9</td>
<td>104.4 ± 20.1</td>
<td>&lt;0.001</td>
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<tr>
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<td>Weight Watchers</td>
<td>104.0 ± 19.4</td>
<td>99.9 ± 19.2</td>
<td>99.7 ± 20.1</td>
<td>99.8 ± 20.1</td>
<td>99.6 ± 19.3</td>
<td></td>
</tr>
<tr>
<td><strong>Percent weight loss (%)</strong></td>
<td>Standard care</td>
<td>0.00 na</td>
<td>1.43 ± 2.54</td>
<td>1.69 ± 3.34</td>
<td>1.85 ± 3.68</td>
<td>1.79 ± 4.01</td>
<td>&lt;0.001</td>
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<td></td>
<td>Weight Watchers</td>
<td>0.00 na</td>
<td>3.34 ± 3.26</td>
<td>4.07 ± 4.54</td>
<td>4.13 ± 5.33</td>
<td>3.99 ± 5.20</td>
<td></td>
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<tr>
<td><strong>Waist (cm)</strong></td>
<td>Standard care</td>
<td>116.56 ± 14.07</td>
<td>115.37 ± 14.36</td>
<td>115.22 ± 14.36</td>
<td>114.61 ± 14.36</td>
<td>115.23 ± 14.85</td>
<td>&lt;0.001</td>
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<tr>
<td></td>
<td>Weight Watchers</td>
<td>116.25 ± 14.27</td>
<td>113.11 ± 13.66</td>
<td>112.50 ± 14.34</td>
<td>112.59 ± 14.17</td>
<td>112.57 ± 14.51</td>
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<tr>
<td><strong>Fasting blood glucose (mg/dL)</strong></td>
<td>Standard care</td>
<td>165.2 ± 45.5</td>
<td>166.9 ± 54.4</td>
<td>171.3 ± 58.1</td>
<td>172.6 ± 55.9</td>
<td>173.4 ± 60.5</td>
<td>&lt;0.001</td>
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<tr>
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<td>Weight Watchers</td>
<td>166.1 ± 49.2</td>
<td>155.2 ± 53.5</td>
<td>151.5 ± 51.9</td>
<td>158.0 ± 53.2</td>
<td>150.0 ± 52.4</td>
<td></td>
</tr>
<tr>
<td><strong>C-reactive protein (mg/L)</strong></td>
<td>Standard care</td>
<td>6.08 ± 6.07</td>
<td>6.75 ± 10.3</td>
<td>6.33 ± 6.78</td>
<td>6.70 ± 8.73</td>
<td>6.61 ± 8.36</td>
<td>0.02</td>
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<td>Weight Watchers</td>
<td>7.33 ± 8.72</td>
<td>6.49 ± 6.82</td>
<td>6.31 ± 7.02</td>
<td>5.93 ± 6.40</td>
<td>6.30 ± 6.71</td>
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<tr>
<td><strong>HDL (mg/dL)</strong></td>
<td>Standard care</td>
<td>50.04 ± 12.6</td>
<td>49.10 ± 13.1</td>
<td>50.97 ± 13.4</td>
<td>51.04 ± 14.0</td>
<td>51.15 ± 13.3</td>
<td>0.29</td>
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<td>Weight Watchers</td>
<td>48.91 ± 12.5</td>
<td>47.68 ± 12.3</td>
<td>50.42 ± 13.1</td>
<td>50.06 ± 12.7</td>
<td>51.66 ± 13.6</td>
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<tr>
<td><strong>LDL (mg/dL)</strong></td>
<td>Standard care</td>
<td>103.8 ± 35.8</td>
<td>100.6 ± 31.6</td>
<td>100.9 ± 31.7</td>
<td>97.8 ± 31.9</td>
<td>97.45 ± 31.9</td>
<td>0.99</td>
</tr>
<tr>
<td></td>
<td>Weight Watchers</td>
<td>105.4 ± 38.4</td>
<td>99.22 ± 30.5</td>
<td>99.85 ± 32.9</td>
<td>97.90 ± 30.14</td>
<td>99.89 ± 31.3</td>
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</tr>
<tr>
<td><strong>Triglycerides (mg/dL)</strong></td>
<td>Standard care</td>
<td>149.7 ± 89.4</td>
<td>143.8 ± 79.5</td>
<td>146.9 ± 85.5</td>
<td>145.3 ± 85.3</td>
<td>148.2 ± 104.7</td>
<td>0.91</td>
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<td>Weight Watchers</td>
<td>158.6 ± 100.0</td>
<td>146.4 ± 79.1</td>
<td>143.5 ± 71.3</td>
<td>158.9 ± 91.7</td>
<td>163.7 ± 168.3</td>
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</tr>
</tbody>
</table>
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 ($P_S = 0.004$ 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 ($P_S < 0.001$). 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 HbA1c than did those with fewer than two ($P = 0.036$; month 12 $M_S = -0.428$ and $-0.018$, respectively).
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. 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
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 HbA1c 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, HbA1c 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 HbA1c 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 HbA1c 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.

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References


