Effectiveness of Lifestyle Interventions for Individuals With Severe Obesity and Type 2 Diabetes

Results from the Look AHEAD trial

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FOR THE LOOK AHEAD RESEARCH GROUP*

OBJECTIVE—Rates of severe obesity (BMI ≥40 kg/m²) are on the rise, and effective treatment options are needed. We examined the effect of an intensive lifestyle intervention (ILI) on weight loss, cardiovascular disease (CVD) risk, and program adherence in participants with type 2 diabetes who were severely obese compared with overweight (BMI 25 to <30 kg/m²), class I (BMI 30 to <35 kg/m²), and class II obese (BMI 35 to <40 kg/m²) obese participants.

RESEARCH DESIGN AND METHODS—Participants in the Look AHEAD trial were randomly assigned to ILI or diabetes support and education (DSE). DSE participants received a less intense educational intervention, whereas ILI participants received an intensive behavioral treatment to increase physical activity and reduce caloric intake. This article focuses on the 2,503 ILI participants (age 58.6 ± 6.8 years).

RESULTS—At 1 year, severely obese participants in the ILI group lost −9.04 ± 7.6% of initial body weight, which was significantly greater (P < 0.05) than ILI participants who were overweight (−7.43 ± 5.6%) and comparable to class I (−8.72 ± 6.4%) and class II obese (−8.64 ± 7.4%) participants. All BMI groups had comparable improvements in fitness, physical activity, LDL cholesterol, triglycerides, blood pressure, fasting glucose, and HbA1c at 1 year. ILI treatment session attendance was excellent and did not differ among weight categories (severe obese 80% vs. others 83%; P = 0.43).

CONCLUSIONS—Severely obese participants in the ILI group had similar adherence, percentage of weight loss, and improvement in CVD risk compared with less obese participants. Behavioral weight loss programs should be considered an effective option for this population.

Although the prevalence of overweight and mild obesity has begun to stabilize in recent years (1), rates of severe obesity (BMI ≥40 kg/m²) continue to rise (1,2). Recent estimates suggest that the prevalence of severe obesity rose by 52% in 5 years (2). The extreme categories of obesity represent the fastest growing segment of the overweight population, posing a significant public health concern (2). Severe obesity is associated with a significantly higher prevalence of comorbid conditions, including diabetes, and also results in higher mortality rates compared with overweight or moderate obesity (i.e., BMI <40 kg/m²) (3). For these reasons, it is critical that effective treatment options for this population be identified and implemented.

In the past, severely obese individuals have been excluded from the majority of clinical weight loss trials because of upper BMI exclusionary criteria and/or other comorbid conditions (4). Moreover, despite a lack of empirical evidence, it was suggested that this population cannot be effectively treated with lifestyle interventions (5). Currently, bariatric surgery is the recommended treatment approach for individuals with severe obesity “when less invasive methods of weight loss have failed” (5). Although surgical procedures are an effective strategy for reducing body weight and improving cardiovascular disease (CVD) risk factors, particularly diabetes (6), they may not be an ideal treatment approach for a large percentage of severely obese individuals (7,8). In addition, surgery is limited in reach, with only ~1% of the severely obese population undergoing surgical procedures each year (1,9). Thus, investigators have recently called for a re-examination of the effectiveness of lifestyle interventions for treating severe obesity (10).

A recent study by Goodpaster et al. (11) was the first to examine the effectiveness of an intensive lifestyle intervention on weight loss, abdominal fat, hepatic steatosis, and other CVD risk factors in a severely obese population. Study participants with a BMI >40 kg/m² lost ~10% of their initial body weight at 1 year and experienced favorable changes in CVD risk factors. In addition, severely obese participants lost significantly more weight than class II obese participants (BMI 35 to <40 kg/m²); however, the sample size was small (class II: n = 17; severely obese: n = 50) and individuals with diabetes were excluded. Given that diabetes may make it more difficult for individuals to lose weight compared with individuals without

* A complete list of the Look AHEAD Research Group at 1 year can be found in the Supplementary Data online. 

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Lifestyle interventions for the severely obese
diabetes (12), it is important to assess the
effects of intensive lifestyle interventions in
individuals with diabetes.

The current study used the 1-year re-
results from the Look AHEAD trial to com-
pare initial weight losses, changes in CVD
risk factors, and compliance to dietary and
exercise recommendations between
the severely obese (BMI ≥ 40 kg/m²) and
overweight (25 to <30 kg/m²), class I obese
(30 to <35 kg/m²), and class II obese (35 to
<40 kg/m²) participants.

RESEARCH DESIGN AND
METHODS—The Look AHEAD trial en-
rrolled 5,145 participants from 16 centers
across the U.S. Subject characteristics and
inclusion/exclusion criteria were previ-
ously described (13). In short, participants
had type 2 diabetes, were aged 45–76
years, had a BMI ≥25 kg/m² (or ≥27
kg/m² if taking insulin) and body weight
≤400 lb, HbA₁c ≤11%, triglycerides <600
mg/dL, and systolic and diastolic blood
pressure ≤160 and ≤100 mmHg, respec-
tively. Participants completed a maximal
graded exercise test, as previously de-
scribed (13), to ensure that exercise could
be tolerated. A 2-week behavioral run-in
period was used to determine participants’
adherence to recording their physical ac-
(ment) and food intake. All participants
provided written informed consent, and
study procedures were approved by each
center’s institutional review board.

**Treatment conditions**

Participants were randomized to either
an intensive lifestyle intervention (ILI) or
a diabetes support and education (DSE)
intervention. Participants randomized to
the DSE group attended four meetings
during year 1 and received general rec-
ommendations related to healthy eating
and PA (13). Initial analyses revealed that
the difference in weight loss between
the ILI group and DSE group at 1 year, as pre-
viously reported (13), was similar across
BMI categories; thus, all subsequent analy-
ses focus solely on ILI participants and the
comparison across BMI groups.

Details regarding the ILI used in the
Look AHEAD trial have been published
elsewhere (13,14). Briefly, this interven-
tion was designed to induce an average
1-year weight loss of at least 7% across
the 16 centers, whereas individual partic-
ips were given a goal of losing ≥10%
of initial weight. Modeled after the Di-
abetes Prevention Program (15), participants
were taught various behavioral strategies to
modify their eating and exercise behaviors
previously described (13). Serum measures
were analyzed by the Central Biochemistry
Laboratory (Northwest Lipid Research
Laboratories, University of Washington,
Seattle, WA). Frozen specimens were
shipped for the analysis of HbA₁c, f a s-
ting serum glucose, total triglycerides, HDL,
and LDL using methods described else-
where (13). Use of insulin, lipid-lowering
medications, and blood pressure medi-
cations was determined via standardized
interviewer-administered questionnaires.

PA (expressed in kcal/week) was only
assessed on a subsample of subjects (ap-
proximately half) using the Paffenbarger
Physical Activity Questionnaire (17). Par-
icipants reported the number of city blocks
walked, stair flights climbed, and the dura-
tion and frequency of sports and recreational
activities performed during the past week,
which was used to quantify activity-related
energy expenditure.

Cardiorespiratory fitness was assessed
using a maximal graded exercise treadmill
test at baseline and a submaximal test at
1 year. The maximal exercise test at base-
line was terminated at the point of voli-
tional fatigue or when the American
College of Sports Medicine (18) test termi-
nation criteria were observed. At 1 year, the
submaximal exercise test was terminated
when 80% of maximal heart rate was ac-
rued or, for patients taking β-blockers,
when a 16 on the rating of perceived exer-
sion scale was attained. Cardiorespiratory
fitness was defined as the estimated meta-
olic equivalent (MET) level, determined
by the speed and grade of the treadmill
(18), when 80% of maximal heart rate
r a rating of perceived exertion of 16 was
attained. Thus, the change in fitness was
calculated as the difference in MET levels
between baseline and 1 year (13).

**Behavioral adherence**

Using procedures similar to those of
Wadden et al. (14), adherence to the pre-
scribed treatment regimen was assessed
by attendance at treatment sessions and
self-reported use of meal replacements
(shakes and bars) from weekly diaries. If
participants failed to turn in their weekly
diary, they were asked to do so at a sub-
sequent visit. If a diary was never sub-
mitted, a 0 was assumed for each missing
variable.

**Statistical analysis**

All statistical analyses were performed us-
ing an assumed type I error rate of 0.05.
Baseline measures are presented as rela-
tive frequencies for discrete responses
and means and SDs for continuous responses. Frequency comparisons for discrete responses were performed using the Cochran-Mantel-Haenszel test for general association. Pairwise comparisons were performed by creating simultaneous Wald CIs of odds ratios in a logistic regression framework to conserve family-wise error rates. Comparisons of group means were performed using one-way ANOVA. Bonferroni method for controlling family-wise error rate was used for post hoc comparisons between BMI groups. If the initial ANOVA was not significant, no further pairwise comparisons were performed. Statistical analyses were performed using SAS version 9.3 (SAS Institute, Cary, NC).

**RESULTS**—The baseline characteristics of ILI study participants are presented in Table 1. Compared with participants with a BMI <40 kg/m², the severely obese were younger and had lower PA and fitness, and a larger proportion were female. Baseline values for CVD factors were similar between the severely obese and participants with a BMI <40 kg/m², except for systolic blood pressure, which was significantly higher among individuals with severe obesity.

**Changes in body weight, fitness, PA, and CVD risk factors**

Baseline to 1-year changes in body weight, fitness, PA, and CVD risk factors for ILI participants are displayed in Table 2. Presented below and in the tables are the unadjusted means and adjusted P values (controlling for age, sex, ethnicity, and baseline values and medication usage when appropriate). All analyses were repeated, excluding the very small number of individuals who underwent bariatric surgery during that year and also adjusting for and excluding orlistat users; the results were not altered.

**Body weight.** As shown in Table 2, the percentage of weight change achieved by ILI participants who were severely obese was -9.04%, which was comparable to class I (-8.72%) and class II obese (-8.64%) and significantly greater than overweight participants (-7.43%; P < 0.05). The percentage of severely obese individuals achieving a ≥5% weight loss at 1 year was 67.0%, which was similar to overweight (66.3%), class I (70.2%), and class II (68%) obese participants (P = 0.45). However, the proportion of severely obese participants achieving a ≥10% weight loss at 1 year was 39.2%, which was similar to class I (41.4%) and class II (38.8%) participants but significantly greater than overweight (30.1%) participants (P < 0.05).

**Fitness and PA.** All BMI groups experienced similar improvements in absolute fitness and PA at year 1 (Table 2). However, since the severely obese had lower fitness and PA levels at baseline, their fitness (5.4 ± 1.6 METs) was significantly lower than that of overweight (6.6 ± 2.0 METs), class I (6.5 ± 2.1 METs), and class II (6.0 ± 1.8 METs) obese participants at 1 year (P < 0.01). Similarly, severely overweight (41.4%) and signiﬁcantly different from one another (P < 0.05). These comparisons were only performed when the group comparison P value was < 0.05.

<table>
<thead>
<tr>
<th>Table 1—Baseline characteristics of ILI participants</th>
<th>P value for mean/proportional equivalence across groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>Overall</td>
</tr>
<tr>
<td>---</td>
<td>---------</td>
</tr>
<tr>
<td>n</td>
<td>2,503</td>
</tr>
<tr>
<td>Age</td>
<td>58.6 (6.8)</td>
</tr>
<tr>
<td>Sex (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>40.6</td>
</tr>
<tr>
<td>Female</td>
<td>59.4</td>
</tr>
<tr>
<td>Ethnicity (%)</td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>15.6</td>
</tr>
<tr>
<td>American Indian/Alaskan Native</td>
<td>5.1</td>
</tr>
<tr>
<td>Asian/Paciﬁc Islander</td>
<td>1.2</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>12.8</td>
</tr>
<tr>
<td>Non-Hispanic white</td>
<td>63.3</td>
</tr>
<tr>
<td>Other/multiple</td>
<td>1.9</td>
</tr>
<tr>
<td>Obesity measures</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>35.8 (6.0)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>100.6 (19.7)</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>113.8 (14.4)</td>
</tr>
<tr>
<td>CVD risk factors</td>
<td></td>
</tr>
<tr>
<td>HDL (mg/dL)</td>
<td>43.5 (11.8)</td>
</tr>
<tr>
<td>LDL (mg/dL)</td>
<td>112 (32.2)</td>
</tr>
<tr>
<td>Triglycerides (mg/dL)</td>
<td>183 (116)</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>128 (17.3)</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td>69.9 (9.5)</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>7.25 (1.1)</td>
</tr>
<tr>
<td>Fasting glucose (mg/dL)</td>
<td>152 (44.5)</td>
</tr>
<tr>
<td>Exercise variables</td>
<td></td>
</tr>
<tr>
<td>PA (kcal/week)</td>
<td>863.87 (1,107)</td>
</tr>
<tr>
<td>Fitness (80% maximal METs)</td>
<td>5.18 (1.5)</td>
</tr>
</tbody>
</table>

Data are means (SD) or percent, unless otherwise designated. Values with different superscript letters across columns are significantly different from one another (P < 0.05). These comparisons were only performed when the group comparison P value was < 0.05.
Lifestyle interventions for the severely obese

Table 2—Change in body weight, fitness, PA, and CVD risk factors from baseline to 1 year

<table>
<thead>
<tr>
<th>BMI groups</th>
<th>n</th>
<th>Overall</th>
<th>Overweight</th>
<th>Class I</th>
<th>Class II</th>
<th>Severely obese</th>
<th>P value for means across groups*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obesity measures</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>2,475</td>
<td>-8.71 (7.6)</td>
<td>-5.97 (4.7)a</td>
<td>-8.10 (6.2)b</td>
<td>-9.09 (8.0)b</td>
<td>-11.2 (9.7)c</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>2,475</td>
<td>-3.08 (2.6)</td>
<td>-2.10 (1.6)a</td>
<td>-2.84 (2.08)b</td>
<td>-3.23 (2.8)c</td>
<td>-4.01 (3.4)d</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Weight change (%)</td>
<td>2,475</td>
<td>-8.56 (6.9)</td>
<td>-7.43 (5.6)a</td>
<td>-8.72 (6.4)b</td>
<td>-8.64 (7.4)b</td>
<td>-9.04 (7.6)b</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>2,453</td>
<td>-7.61 (8.7)</td>
<td>-6.67 (7.4)</td>
<td>-7.72 (7.9)</td>
<td>-7.85 (10.1)</td>
<td>-7.84 (8.8)</td>
<td>0.06</td>
</tr>
<tr>
<td>Exercise variables</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fitness (%)</td>
<td>2,256</td>
<td>0.957 (1.4)</td>
<td>0.881 (0.97)</td>
<td>0.974 (1.4)</td>
<td>0.961 (1.3)</td>
<td>0.979 (1.2)</td>
<td>0.92</td>
</tr>
<tr>
<td>% Change in fitness</td>
<td>2,256</td>
<td>20.9 (29.1)</td>
<td>18.3 (19.6)a</td>
<td>19.6 (28.1)a,b</td>
<td>21.3 (29.4)b</td>
<td>24.4 (30.1)b</td>
<td>0.03</td>
</tr>
<tr>
<td>PA (kcal/week)</td>
<td>1,120</td>
<td>881 (1.617)</td>
<td>825 (1.662)</td>
<td>878 (1.574)</td>
<td>1,027 (1618)</td>
<td>761 (1.645)</td>
<td>0.25</td>
</tr>
<tr>
<td>CVD risk factors†</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HDL (mg/dL)</td>
<td>2,310</td>
<td>3.10 (7.2)</td>
<td>4.49 (8.2)a</td>
<td>3.99 (7.29)a,b</td>
<td>3.34 (7.16)b</td>
<td>1.83 (6.02)c</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>LDL (mg/dL)</td>
<td>2,309</td>
<td>5.21 (28.0)</td>
<td>-6.97 (28.4)</td>
<td>-3.93 (27.9)</td>
<td>-5.42 (29.3)</td>
<td>-5.68 (26.3)</td>
<td>0.52</td>
</tr>
<tr>
<td>Triglycerides (mg/dL)</td>
<td>2,379</td>
<td>-30.3 (102)</td>
<td>-25.4 (97.9)</td>
<td>-32.9 (107)</td>
<td>-32.4 (107)</td>
<td>-27.2 (88.9)</td>
<td>0.88</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>2,445</td>
<td>-6.77 (17.2)</td>
<td>-4.77 (15.4)</td>
<td>-6.39 (17.4)</td>
<td>-7.96 (18.4)</td>
<td>-7.74 (18.5)</td>
<td>0.49</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td>2,445</td>
<td>-3.00 (8.5)</td>
<td>-2.43 (7.9)</td>
<td>-3.12 (8.4)</td>
<td>-3.13 (8.4)</td>
<td>-3.08 (9.38)</td>
<td>0.19</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>2,378</td>
<td>-0.643 (0.99)</td>
<td>-0.617 (1.0)</td>
<td>-0.589 (0.97)</td>
<td>-0.662 (0.95)</td>
<td>-0.723 (1.02)</td>
<td>0.20</td>
</tr>
</tbody>
</table>

Data are unadjusted means (SD). Values with different superscript letters across columns are significantly different from one another (P < 0.05). *All P values adjusted for age, sex, and ethnicity. †P values for all CVD risk factors are also adjusted for baseline values and baseline medication usage (HDL, LDL, and triglyceride adjusted for lipid-lowering medication at baseline; systolic and diastolic blood pressure adjusted for hypertension medications; HbA1c and fasting glucose adjusted for insulin usage at baseline).

Obese participants had significantly lower (P < 0.01) absolute physical levels at 1 year (1,450 ± 1,584 kcal/week) compared with class I (1,857 ± 617 kcal/week) and class II (1,810 ± 1,645 kcal/week) obese and similar to overweight (1,841 ± 1,479 kcal/week) participants (P = 0.08).

CVD risk factors. Favorable improvements in lipids, blood pressure, and glycemic control were seen across all BMI categories from baseline to 1 year (Table 2). Controlling for baseline values and medication usage, severely obese participants experienced similar improvements in LDL cholesterol, triglycerides, systolic and diastolic blood pressure, HbA1c, and fasting glucose compared with their less obese peers (P > 0.05). However, the severely obese had smaller improvements in HDL cholesterol compared with individuals with a lesser degree of obesity (P < 0.01). The percentage of participants using insulin, lipid-lowering, and hypertension medication at baseline and who discontinued usage at 1 year was similar across weight categories. Similarly, the percentage of participants not using these medications at baseline but who initiated usage at 1 year did not differ between BMI groups (Supplementary Table A1).

Participants in each of the BMI categories who met the American Diabetes Association goals for LDL cholesterol (<100 mg/dL), blood pressure (<130/80 mmHg), and HbA1c (<7%) were compared at baseline and 1 year. The percentage of severely obese participants meeting the American Diabetes Association goal for LDL cholesterol (41.9%), HbA1c (71.3%), and blood pressure (65.7%) at 1 year was significantly greater than the percentage meeting these goals at baseline (34.1, 45.0, and 44.5%, respectively; P < 0.05). In addition, the proportion of participants meeting each of these goals at 1 year was similar across BMI categories (P > 0.05). For example, at 1 year, 71.3% of severely obese participants met the HbA1c goal, which was similar to the percentage of overweight (75.4%), class I (74.5%), and class II (70.1%) obese participants meeting this goal (Supplementary Table A2).

Program adherence

Severely obese individuals attended 80% of the treatment sessions over year 1, which was similar to all other BMI categories (P = 0.43). Similarly, meal replacement usage did not differ by BMI categories (P = 0.58).

CONCLUSIONS—The large number of participants with severe obesity (n = 562; 22% of the participants) treated in the intensive lifestyle group in Look AHEAD provides an unusual opportunity to consider whether severely obese individuals with type 2 diabetes can achieve significant initial weight losses and improvements in CVD risk factors when treated in a 1-year standard behavioral intervention. Nearly 40% of severely obese ILI participants lost ≥10% of initial body weight at 1 year. Additionally, 42% achieved the American Diabetes Association goal for LDL cholesterol, 66% for blood pressure, and 71% for HbA1c, all significantly greater than at baseline and comparable to individuals with a BMI <40 kg/m². These promising findings suggest that severely obese individuals with type 2 diabetes can be successfully treated through behavioral weight loss programs.

Previous studies have reported favorable weight loss outcomes among severely obese participants (11,19–22). For example, the Louisiana Obese Subjects Study examined nonsurgical weight loss for the severely obese within the primary care setting (21). Despite low retention rates (51%), completers’ analyses revealed that the average weight loss at 2 years was 9.7%. Similar weight loss outcomes (10.9%) and significantly better retention rates (78%) were also reported by Goodpaster et al. (11) after a 1-year ILI for severely obese individuals. However,
we are the first group to examine the effectiveness of a lifestyle intervention for severely obese individuals with type 2 diabetes, and our results are equally impressive. After 1 year, the average retention rate was 98.4%, and the mean weight loss was 11.2 kg, or 9% of initial body weight. In addition, this magnitude of weight loss resulted in a 9 and 10% improvement in fasting glucose and HbA1c, respectively. Additionally, 17% of severely obese participants using insulin at baseline were no longer using insulin after 1 year of treatment.

Another novel finding from this study was that after a 1-year ILI, severely obese participants achieved weight losses and improvements in fitness, PA, blood pressure, LDL cholesterol, triglycerides, fasting glucose, and HbA1c that were comparable to individuals with lesser degrees of obesity. This was the first study to examine whether there were differences in these outcome variables across various BMI categories. In a previous Look AHEAD publication (23), it was determined that the relationship between weight loss and CVD risk did not depend on baseline weight for all risk factors except HDL. Thus, the current article expands on the finding that severely obese individuals often do not benefit from more conservative treatments for weight loss and weight maintenance,” as stated in the current National Heart, Lung, and Blood Institute obesity guidelines (5). We do not suggest that the weight losses achieved through lifestyle interventions are comparable or superior to bariatric surgery, or do we suggest that remission in diabetes that is often seen in the majority of bariatric surgery patients after surgery is similar when lifestyle interventions are used. Rather we propose that lifestyle interventions be considered as one possible strategy to treat individuals with severe obesity. Given that a large percentage of severely obese individuals report that they would not choose surgical procedures as a method of weight reduction (8) and that the number of bariatric surgery procedures capable of being performed yearly is small in comparison with the number of individuals with severe obesity (1), it is critical that nonsurgical treatment approaches be developed and used.

Although the majority of severely obese participants in this study did not reach an ideal body weight, and many remained severely obese, marked improvements in their CVD risk factors were observed. As previously reported by Wing et al. (23), modest weight losses (5–10%) result in clinically significant improvements in CVD risk factors at 1 year after a lifestyle intervention. Other studies in severely obese individuals have also reported significant reductions in CVD risk factors (19–21). For example, Anderson et al. (19) reported a 17% reduction in LDL cholesterol, 14% reduction in triglycerides, and an ~9% improvement in blood pressure after an average weight loss of 35.3 kg. Furthermore, in a study that compared bariatric surgery to commercial weight loss camps and intermittent residential treatment programs, the surgery group lost significantly more weight than the lifestyle intervention groups (31 vs. 13 and 15%, respectively), yet all groups experienced similar improvements in risk factors and resolution of weight-related comorbidities (20). Look AHEAD will continue to follow participants to assess the long-term impact of these CVD risk factor improvements and determine whether a lifestyle intervention can reduce morbidity and mortality and also lower the costs associated with obesity among severely obese individuals.

One risk factor in which severely obese participants did not experience the same magnitude of improvement as their less obese peers was in HDL cholesterol. Explanations for this attenuated response are unclear; however, it is possible that, overall, lower levels of PA and fitness among the severely obese at 1 year may have contributed to this response (24). Although severely obese participants had similar improvements in fitness and PA after the 1-year intervention, their lower PA and fitness at baseline resulted in PA and fitness levels that were lower than the majority of their less obese peers at 1 year. These results are not surprising given previous research, which has indicated that severely obese individuals perform little moderate-to-vigorous PA (25). Thus, strategies to enhance PA within the context of behavioral weight loss treatment programs should be developed, targeting the special needs of this population.

There are several limitations to this study. First, participants were older (45–76 years of age) individuals with type 2 diabetes, at the lower end of the severe obesity range (95% of participants had a BMI between 40 and <52.5 kg/m²). They also were highly motivated individuals who completed a behavioral run-in and passed an exercise test; thus, the generalizability of these findings to other populations is uncertain. In addition, the measurement of meal replacements, medication usage, and PA were self-reported. Finally, severely obese individuals participated in group sessions along with those with lesser degrees of obesity; thus, it is unclear how they would respond when treated solely in groups with individuals with a similar BMI.

To summarize, an intensive behavioral weight loss program for older individuals with type 2 diabetes resulted in significant initial weight losses and improvements in CVD risk factors among the severely obese, both of which were comparable to those changes seen in participants with a lesser degree of obesity. Based on the current findings, behavioral therapy should be considered a viable treatment option for this population. All patients should be provided with a strong behavioral weight loss program, as described here, before undergoing bariatric surgery. In the future, strategies to enhance weight loss outcomes and PA compliance for individuals with severe obesity should be explored. Additionally, future efforts should examine whether weight losses achieved through lifestyle approaches can be sustained long-term.

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References