



Published in final edited form as:

Obesity (Silver Spring). 2009 April ; 17(4): 713–722. doi:10.1038/oby.2008.637.

One-Year Weight Losses in the Look AHEAD Study: Factors Associated with Success

Thomas A. Wadden, PhD¹, Delia S. West, PhD², Rebecca Neiberg, MS³, Rena R. Wing, PhD⁴, Donna H. Ryan, MD⁵, Karen C. Johnson, MD, MPH⁶, John Foreyt, PhD⁷, James O. Hill, PhD⁸, Dace Trence, MD⁹, and Mara Vitolins, RD, PhD [on behalf of for The Look AHEAD Research Group]³

¹University of Pennsylvania

²University of Arkansas

³Wake Forest University

⁴Miriam Hospital/Brown Medical School

⁵Pennington Biomedical Research Center

⁶University of Tennessee Health Sciences Center

⁷Baylor College of Medicine

⁸University of Colorado Health Sciences Center

⁹University of Washington/VA Puget Sound Health Care System

Abstract

This report provides a further analysis of the first year weight losses in the Look AHEAD (Action for Health in Diabetes) study and identifies factors associated with success. Participants were a total of 5,145 men and women with type 2 diabetes who were recruited at 16 sites and randomly assigned to an intensive lifestyle intervention (ILI) or a control condition, Diabetes Support and Education (DSE). During year 1, participants in ILI received comprehensive diet and physical activity counseling in 42 group and individual sessions, compared with 3 educational sessions for DSE participants. As reported previously, at the end of the year, ILI participants lost 8.6% of initial weight, compared to 0.7% for DSE ($p < 0.001$). Within the ILI group, all racial/ethnic groups achieved clinically significant weight losses ($\geq 5.5\%$), although there were significant differences among groups. For the year, ILI participants attended an average of 35.4 treatment sessions and reported exercising a mean of 136.6 min/week and consuming a total of 360.9 meal replacement products. Greater self-reported physical activity was the strongest correlate of weight loss, followed by treatment attendance and consumption of meal replacements. The use of orlistat, during the second half of the year, increased weight loss only marginally in those ILI participants who had lost $< 5\%$ of initial weight during the first 6 months and chose to take the medication thereafter as a toolbox

All correspondence to: Thomas A. Wadden, Ph.D., University of Pennsylvania School of Medicine, 3535 Market Street, Suite 3029, Philadelphia, PA 19104. Tel.: 215-746-5046; Fax: 215-898-7316. E-mail: Wadden@mail.med.upenn.edu .

All other Look AHEAD staffs are listed alphabetically by site.

Disclosures

Thomas Wadden has received donations of meal replacement products (for two NIH-funded studies) from both Health Management Resources and SlimFast. John Foreyt has received grant support from SlimFast and serves on the company's Advisory Board. James Hill previously served on the SlimFast Advisory Board. None of the other authors has any potential conflicts of interest to declare.

option. The lifestyle intervention was clinically effective in all subsets of an ethnically and demographically diverse population.

The Look AHEAD (Action for Health and Diabetes) study is designed to assess the long-term health consequences of intentional weight loss in overweight and obese individuals with type 2 diabetes (1). More than 5100 participants have been randomly assigned to a usual care condition or to an intensive lifestyle intervention with a goal of inducing a loss of 7% or more of initial weight and increasing physical activity to 175 minutes or more per week. The study has statistical power to detect an 18% difference between the two groups in time to occurrence of myocardial infarction or stroke, as well as other cardiovascular outcomes. When completed, results of the trial should resolve (in diabetic patients) the conflicting findings from observational studies concerning the cardiovascular consequences of weight loss (2,3). Look AHEAD is the first randomized controlled trial to address this issue.

Results of the first year of treatment for Look AHEAD were recently reported (4) and revealed a loss of 8.6% of initial weight in the intensive lifestyle intervention (ILI), compared to a significantly smaller 0.7% for the usual care group, referred to as Diabetes Support and Education (DSE). As expected, participants in ILI also had significantly greater reductions in systolic and diastolic blood pressure, triglyceride levels, hemoglobin A_{1C}, and other cardiovascular risk factors than did those in DSE (4).

More than 2,500 individuals received the lifestyle intervention during the first year, making this by far the largest sample of individuals to receive the same program of behavioral weight control in a randomized controlled trial. The present study capitalized on this large sample to provide a detailed analysis of the influence of gender, age, education, ethnicity, and other factors on weight loss at 1 year. Based on previous investigations (5–7), we predicted that male gender, older age, and non-Hispanic white ethnicity would be associated with a greater percentage reduction in initial weight. We also predicted that measures of participants' treatment adherence, including attendance at intervention sessions, consumption of prescribed meals, and high levels of physical activity, would be associated with greater weight loss (8–9). Finally, we examined whether insulin use would attenuate weight loss, as suggested by prior reports (10–12).

Methods

Participants

Participants were a total of 5,145 men and women who were recruited at 16 centers across the U.S. As described previously (4,13), participation was open to persons with type 2 diabetes who were 45 to 74 years of age and had a body mass index (BMI) ≥ 25 kg/m² (or ≥ 27 kg/m² if taking insulin). (The lower age criterion was raised to 55 years in the second year of recruitment to increase the rate of anticipated cardiovascular events.) For safety, participants were required to have blood pressure $\leq 160/100$ mm Hg, hemoglobin A_{1C} $\leq 11\%$, and triglyceride levels < 600 mg/dl. These measures were obtained during a screening visit, after applicants gave their written informed consent to participate (following guidelines of the Helsinki Declaration and each site's institutional review board). In addition, applicants completed a graded exercise test, described previously (1,4,14), to ensure that they could safely adhere to the physical activity program prescribed in the ILI (15). All applicants also were required to have a primary care provider who would be responsible for providing their medical care (including for cardiovascular risk factors) during the 11.5 year trial.

In addition to these safety criteria, applicants were required to pass a test of behavioral adherence which consisted of recording their food intake and physical activity for two

consecutive weeks. Candidates who did not keep satisfactory records for at least 12 of 14 days were not eligible to participate. This adherence criterion was included to facilitate the selection of highly motivated individuals who could meet the study's weight and activity goals.

Participants reported their age, education, race/ethnicity, and other demographic characteristics. The study's recruitment goals were to enroll approximately equal numbers of men and women, with $\geq 33\%$ of participants from racial and ethnic minority groups.

Procedure

Prior to randomization, eligible participants received an initial session of diabetes education that included general recommendations for adopting healthy eating and activity habits and addressed the management of hypoglycemia and foot care. Participants who remained interested in the study were then randomly assigned with equal probability to the ILI and DSE conditions. Randomization was stratified by clinical center. Table 1 presents selected baseline characteristics of participants in the two conditions; a full description is provided elsewhere (13).

Treatment Conditions

Previous reports have described the interventions for the DSE and ILI groups for the full 11.5 years of the planned trial (1,15). The present description is limited to the first year.

DSE—During the first year, participants in DSE were invited to attend three 1-hour group meetings that addressed diet, physical activity, and social support, respectively. These sessions provided information, but not specific behavioral strategies, for adopting the diet and activity recommendations. Participants who wanted more help losing weight were told to speak with their own primary care providers (who were permitted to provide their usual recommendations).

ILI—These participants were provided a comprehensive intervention, expected to induce an average loss (across the 16 centers) $\geq 7\%$ of initial weight. Individual participants were given a goal of losing 10% or more of initial weight in order to increase the likelihood of their meeting the 7% study-wide goal. The weight control intervention was adapted from the Diabetes Prevention Program (DPP;16,17) and was delivered to participants in groups of approximately 10 to 20 persons. (Group sessions were led by lifestyle counselors who included registered dietitians, behavioral psychologists, and exercise specialists.) During the first 6 months, participants attended group sessions (of 60–75 min) for the first 3 weeks of each month. The fourth week each month, they had an individual meeting (of 20–30 minutes) with their lifestyle counselor, and group sessions were not held this week. These monthly individual meetings were used to tailor the intervention to participants' individual needs, including those related to dietary preferences (18,19). During months 7 to 12, participants continued to have a monthly individual meeting with their lifestyle counselor, but the number of group sessions was reduced from three to two per month.

During weeks 1–2, participants were instructed to eat a self-selected diet of conventional foods and to record their daily food and calorie intake in diaries provided. The energy goal for participants < 114 kg (250 lb) was 1200–1500 kcal/d and that for individuals ≥ 114 kg was 1500–1800 kcal/d (15). Participants were told to consume $< 30\%$ of calories from fat, with $< 10\%$ from saturated fat. During weeks 3–19, participants were prescribed a liquid-meal-replacement plan, given findings that this approach significantly increased weight loss compared to a self-selected diet of conventional foods with the same calorie goal (20,21). They were instructed to replace two meals (i.e., breakfast and lunch) with a liquid shake and one snack with a bar. They potentially could choose from four meal replacement products

(including Slim-Fast, Glucerna, OPTIFAST, and HMR) which were provided free of charge by their manufacturers. For dinner, participants were instructed to consume a meal of conventional foods, which included the option of prepared food entrees (22). They added fruits and vegetables to their diet until they met their daily calorie goal. Persons who declined the use of meal replacements were provided menu plans that specified conventional foods to be consumed (17,23). Meal plans were culturally tailored. During months 7 to 12, participants were instructed to replace one meal and one snack a day with shakes and bars to facilitate the maintenance of lost weight (24). The dietary intervention during this time also focused on eating more fruits and vegetables and other foods consistent with a low-energy-density diet (25). For the entire year, participants were instructed to record daily their food and calorie intake and to submit their records at each visit. Lifestyle counselors provided feedback on the records.

The ILI's physical activity goal was ≥ 175 minutes/week of moderately intense activity, to be achieved gradually by month 6. Persons who achieved this goal were encouraged to increase to ≥ 200 minutes/week from months 7 to 12. The activity program relied on unsupervised (at home) exercise which, for most participants, consisted of brisk walking. Participants recorded their weekly activity in their diaries; only bouts ≥ 10 minutes counted toward the weekly goal.

The ILI included a toolbox approach to help unsuccessful participants meet the study's diet and activity goals (17). In addition to problem solving (26) and motivational interviewing approaches (27,28), the toolbox included the weight loss medication, orlistat (29,30). The medication was used in three circumstances. First, participants who, after the first 6 months, had lost $< 5\%$ of initial weight were encouraged by their lifestyle counselors to try orlistat and were shown a videotape that explained it. Second, participants who had lost $\geq 5\%$ of initial weight but $< 10\%$ were informed that they were eligible for the medication but were not expressly encouraged to take it. Third, participants who had lost $\geq 10\%$ were not offered the medication because of its lack of efficacy in increasing weight loss beyond this amount (31). However, individuals in this category who, after month 6, regained 2% or more above their lowest weight (e.g., had lost 12.5% but regained to 10.5%) were allowed to take the medication to prevent further weight gain. Participants who took orlistat were monitored by a study physician (or nurse practitioner).

Dependent Measures

Weight—Weight was measured on all participants at randomization and 1 year later using a digital scale (Tanita, model BWB-800). These weights were obtained by study staff (masked to participants' treatment status) and comprised the study's formal outcome weights. (Height was measured on the same schedule using a wall-mounted stadiometer.) Individuals in ILI also were weighed at each treatment visit by (unmasked) intervention staff who informed participants of their weight change. These weights were entered in a tracking system that provided staff monthly reports of their participants' weight losses. These data were used in the present report to provide information about weight loss during different phases of treatment.

Behavioral adherence—Three measures were used to estimate adherence to the prescribed treatment regimen. First, participants' attendance at all group and individual meetings was recorded by study staff. Second, we summed the weekly number of minutes of brisk physical activity that participants reported in their diaries. Third, weekly use of meal replacement products (shakes and bars), as recorded in food diaries, also was tracked. In cases in which participants failed to submit records of their physical activity or meal replacement use, they were asked to bring the data to their next visit. If they did not, they received a value of 0 for data missing for the week in question.

Statistical Analyses

Differences between the DSE and ILI groups in changes in weight were examined using analysis of variance (ANOVA). The percentages of participants in the two groups who met different weight loss criteria (e.g., weight loss $\geq 7\%$) were compared using chi square tests. Randomization and 1-year weights, obtained by masked assessors, were used for all of these comparisons. Within the ILI condition, similar analyses were used to assess differences in weight loss among participants that were related to demographic factors. Data from the tracking system were used to compare differences between ILI participants that were related to session attendance, adherence to meal-replacement and physical-activity prescriptions, and the use of orlistat. For each family of comparisons, alpha was controlled using Bonferroni's method. As reported previously (4), the two groups did not differ significantly on any of the baseline characteristics shown in Table 1.

A total of 2496 (97.1%) ILI and 2463 (95.7%) DSE participants completed the 1-year assessment ($p = 0.004$). The 186 persons who did not complete the assessment were significantly ($p < 0.001$) more likely to be taking insulin than were completers (21.0% vs 15.1%, respectively). The non-completers included 101 individuals who missed the scheduled assessment and will be contacted for future follow-up visits. As described elsewhere (4), an additional 76 participants withdrew from the trial, and 9 individuals died during the first year.

Results

Weight Loss in ILI and DSE Groups

As reported previously (4), at the end of year 1, ILI participants lost $8.6 \pm 6.9\%$ of initial weight (8.6 ± 8.2 kg), compared to a significantly ($p < 0.001$) smaller $0.7 \pm 4.8\%$ (0.7 ± 5.0 kg) for individuals in DSE. As shown in Figure 1, 55.1% of ILI participants met the study-wide goal of losing $\geq 7\%$ of initial weight, compared with only 7.0% of individuals in DSE ($p < 0.001$). As expected, significantly ($p < 0.001$) more ILI than DSE participants also lost $\geq 10\%$ of initial weight (37.7% vs 3.3%, respectively). Nearly 45% of DSE participants gained weight during the year, compared with only 7.3% of individuals in ILI ($p < 0.001$).

Use of insulin and other diabetes medications was associated with smaller weight losses. In the DSE group, weight losses for participants who took insulin, other diabetes medications, or no medications were 0.4 ± 5.1 , 0.7 ± 4.7 , and $1.0 \pm 4.4\%$, respectively (with no significant differences among groups). Corresponding values in the ILI group were 7.4 ± 7.2 , 8.7 ± 6.9 , and $9.3 \pm 6.8\%$, respectively. Participants on insulin lost significantly ($p < 0.002$) less weight than those in the two other groups (which did not differ significantly).

Weight Loss Within the ILI Group

Participants in the ILI, taken together ($N = 2570$), lost an average of $8.2 \pm 5.7\%$ at week 26, which increased to $8.7 \pm 6.9\%$ at 1 year. This 1-year value, which was calculated from data in the tracking system, differed by only 0.1% from that obtained when weights from the outcome ascertainment visits were analyzed (4).

Influence of demographic characteristics—Examining all participants in ILI, men lost significantly ($p < 0.001$) more weight than women at 1 year (9.2 ± 7.1 vs. $8.1 \pm 6.8\%$). Among men, 58.5% met the study-wide criterion of a 7% weight loss, and 41.6% lost 10% or more. Comparable values for women were 52.9 and 35.2%, respectively. The study's oldest participants (65 to 74 years of age at baseline) lost a significantly ($p = 0.04$) greater percentage of initial weight than those in the middle group (55 to 64 years) or the youngest group (45 to 54 years), with 1-year losses of 9.4 ± 6.3 , 8.5 ± 7.0 and $7.9 \pm 7.2\%$, respectively. In each of these three age groups, 63.1, 54.6, and 50.0% met the 7% weight-loss criterion, respectively,

and 44.7, 37.5, and 32.7% met the 10% criterion, respectively. No consistent effect of education on weight loss was observed. Participants with 13 to 16 years of education lost significantly ($p < 0.001$) less weight than those with > 16 years, with participants with < 13 years of education falling in between these two groups.

A significant relationship was observed between race/ethnicity and weight loss, as shown in Figure 2. At 1 year, non-Hispanic white participants lost $9.5 \pm 7.3\%$ of initial weight, compared to losses of 8.0 ± 6.2 , 6.8 ± 5.4 , and $5.5 \pm 6.0\%$ for Hispanic, African American, and “other” participants, respectively. (Participants in the “other” category consisted principally of American Indians and are identified hereafter as American Indian/other.) Analysis of variance revealed that the four ethnic groups all differed significantly ($p < 0.001$) from each other, but there was not a statistically significant ethnicity-by-gender interaction. Additional analyses that controlled for age, education, income, and insulin use did not change the statistical differences among the four ethnic groups. Among the four groups, 60.5% of non-Hispanic whites, 53.3% of Hispanics, 45.5% of African Americans and 35.8% of American Indians/others met the 7% weight-loss criterion. In addition, 43.5, 38.1, 24.7, and 18.8% of participants in the four groups, respectively, lost 10% or more of initial weight.

Treatment Adherence and Weight Loss

During the first year, participants in ILI attended an average of 35.4 ± 7.3 of a possible 42 group and individual sessions. Correlation analysis revealed that the more sessions participants attended, the greater their weight loss at month 12 ($r = 0.31$, $p < 0.001$). Additional analyses, which divided participants into quartiles of attendance for year 1, showed that the odds (95% confidence interval) in favor of reaching the 7% and 10% weight loss goals for those in the highest quartile of attendance were 5.3 (4.0 – 7.0) and 8.1 (5.7 – 11.5) times the odds of the lowest quartile reaching the goals, respectively. Figure 4 presents the weight losses for each of the four quartiles, based on percentage of possible treatment sessions attended during the first year.

Physical activity—Participants reported engaging in brisk physical activity an average of 136.7 ± 110.4 minutes per week during the first year. Correlation analysis revealed that the greater the minutes of weekly physical activity, the greater participants’ weight loss at month 12 ($r = 0.41$, $p < 0.001$). The odds of reaching the 7% and 10% weight loss goals for participants in the highest quartile of physical activity were 7.5 (5.7 – 9.9) and 9.4 (6.8 – 13.0) times greater than the odds of participants in the lowest quartile, respectively. Figure 5 presents weight loss based on quartiles of weekly minutes of physical activity.

Meal replacements—ILI participants reported consuming an average total of 233.3 ± 113.3 meal replacement products during the first 6 months, equal to 9.7 ± 5.1 per week during weeks 3 to 26 (when meal replacements were recommended). They consumed an average total of 127.6 ± 100.8 meal replacements from months 7 to 12, equal to 4.6 ± 4.1 per week during this time. The self-reported total consumption for the year averaged 360.9 ± 193.5 . The number of meal replacements consumed in the first 6 months was significantly related to weight loss at week 26 ($r = 0.32$, $p < 0.001$), as was the total number consumed for the year to weight loss at week 52 ($r = 0.30$, $p < 0.001$). Participants in the highest quartile of meal replacement use had 4.0 (3.1 – 5.1) times greater odds of reaching the 7% weight loss goal and 4.1 (3.1 – 5.4) times greater odds of reaching the 10% goal than did participants in the lowest quartile. Figure 6 presents the relation between quartile of meal replacement use and weight loss.

Intercorrelation of measures—Additional analyses showed that the three measures of adherence were highly correlated. Attendance correlated with physical activity ($r = 0.47$, $p < 0.001$) and meal replacement use ($r = 0.56$, $p < 0.001$), and the two latter variables also were

positively related ($r = 0.51$, $p < 0.001$). Stepwise multiple regression, which allowed the model to enter the strongest variable first (i.e., Maximum R-squared procedure) revealed that minutes of physical activity accounted for 16.1% of the variance. This value increased to 19.0% with the addition of attendance and to 19.6% with the inclusion of meal replacements. All three variables contributed significantly ($p < 0.001$).

Adherence in Relation to Demographic Characteristics

Table 2 presents findings for treatment adherence according to gender, age, and ethnicity. Over the year, men reported more weekly minutes of physical activity ($p < 0.05$) and greater total consumption of meal replacements ($p < 0.05$) than women. The study's oldest participants (65 to 74 years) had significantly ($p < 0.05$) better treatment attendance than did participants in the two younger age categories and reported significantly ($p < 0.05$) greater minutes of physical activity and total consumption of meal replacements. Examining race/ethnicity, non-Hispanic white and African-American participants both attended approximately 36 treatment sessions during the year, which was significantly ($p < 0.001$) greater than the attendance observed in the American Indian/other group, with Hispanic participants falling in between these two groups. Self-reported physical activity was significantly ($p < 0.05$) greater in non-Hispanic white and Hispanic participants than in the African American and American Indian/other groups. Non-Hispanic white participants reported significantly ($p < 0.05$) greater consumption of meal replacements over the year than all other groups, with Hispanic and African American participants reporting significantly ($p < 0.05$) greater use than the American Indian/other group.

Weight loss controlling for treatment adherence—Differences in weight losses related to comparisons of gender, age, and race/ethnicity groups were re-analyzed (using analysis of covariance) to control for differences among these groups on the three measures of treatment adherence – attendance, physical activity, and meal replacements. Neither differences in weight loss between men and women, nor those among age groups, remained statistically significant after controlling for differences in treatment adherence. By contrast, weight losses of both non-Hispanic white and Hispanic participants remained significantly greater than those of African-American participants, as did differences among non-Hispanic whites and participants in the American Indian/other group. None of the remaining comparisons among the race/ethnicity groups remained statistically significant after controlling for the three measures of treatment adherence.

Use of Orlistat

Of the 722 participants who lost $< 5\%$ of initial weight in the first 6 months and were encouraged to take orlistat, 291 did so. Figure 6 shows that those who took the medication had lost $1.8 \pm 3.0\%$ at month 6, compared with $2.0 \pm 2.7\%$ for those who did not use orlistat. One-year weight losses of these two groups were 3.4 ± 7.3 and $2.2 \pm 4.0\%$, respectively ($p < 0.02$). Of the 780 participants who had lost 5.0 to 9.9% at month 6 and were eligible (but not encouraged) to take medication, only 201 chose to. Six-month weight losses of those who elected to use the medication were significantly ($p < 0.001$) smaller than those of participants who declined it (6.9 ± 1.2 vs $7.7 \pm 1.5\%$). One-year weight losses were 6.9 ± 3.3 vs. $7.5 \pm 3.4\%$, respectively ($p < 0.04$). Of the 838 participants who had lost $\geq 10\%$ in the first 6 months, 412 were eligible to take the medication from months 7 to 12 by virtue of regaining 2% or more of their lost weight. The 31 individuals who chose to use orlistat had a mean loss of $12.6 \pm 2.3\%$ at month 6, compared to $14.1 \pm 3.5\%$ for those who did not use it ($p < 0.03$). One-year weight losses for the two groups were 9.8 ± 4.1 and $14.8 \pm 6.0\%$, respectively ($p < 0.001$). The 523 total participants who took orlistat reported doing so for an average of 16.7 ± 8.8 weeks from months 7 to 12.

Further analyses showed that participants who were encouraged to take orlistat (i.e., < 5% loss) attended significantly ($p < 0.001$) fewer treatment sessions during the first 6 months than those who were eligible (but not expressly encouraged) to take the medication (i.e., < 10% loss) who, in turn, attended significantly ($p < 0.001$) fewer sessions than individuals who were ineligible to take the drug (i.e., $\geq 10\%$ loss) (attendance of 21.4 ± 4.5 , 23.3 ± 3.3 , and 24.3 ± 2.7 sessions, respectively). A similar set of significant ($p < 0.001$) differences was observed between these three groups in their average minutes of physical activity per week during the first 6 months (i.e., 101.5 ± 82.9 , 147.1 ± 98.6 , and 196.1 ± 116.9 minutes/week, respectively) and in their total consumption of meal replacements during this time (i.e., $195.1 + 112.3$, $237.9 + 105.8$, and $270.7 + 102.4$ meals, respectively).

Discussion

This study's principal finding was that an intensive lifestyle intervention induced a clinically significant weight loss in all subsets of a demographically and ethnically diverse population. While a statistically significant difference in weight loss was observed between men and women, as expected, the absolute difference was small, and both genders achieved clinically significant reductions. The study's oldest participants (65 to 74 years) achieved significantly greater weight losses than the two younger age groups, but all three groups were within 1.5% of each other (with mean losses ranging from 7.9% to 9.4%). Similarly, African-American and Hispanic participants lost significantly less weight than non-Hispanic whites, consistent with findings from other multi-site trials (5–7). However, weight losses achieved in this study are among the largest reported for either African-American or Hispanic participants, demonstrating the wide-scale acceptability of Look AHEAD's lifestyle intervention. American Indian/other participants achieved a mean loss of 5.5% which, while smaller than that of other ethnicities, is still sufficiently large to engender improvements in cardiovascular risk factors (2,16).

Participants' weight losses were related to their adherence to the study's treatment recommendations. Of the three measures of adherence, physical activity correlated most strongly with weight loss, accounting for 16.1% of the variance, as determined by multiple regression analysis. Participants in the highest quartile of self-reported physical activity lost 11.9% of initial weight, compared with only 4.4% for those in the lowest quartile. More frequent attendance at treatment sessions and greater consumption of meal replacements also were associated with greater weight loss, although to a lesser degree than physical activity (as determined by the regression analysis).

The design of the present study prevents us from concluding that adherence to any of the three treatment factors caused greater weight loss. For example, participants who achieved high levels of physical activity may have done so because they had lost more weight (and felt more comfortable exercising), rather than activity causing their weight loss. However, randomized trials (32,33), as well as observational studies (34), have reported a positive relationship between weight loss and high levels of physical activity. In addition to burning calories, increased physical activity may contribute to weight management by sparing the loss of fat-free mass, facilitating dietary adherence by controlling appetite, and improving mood (35). Randomized trials similarly have shown that meal replacements increase weight loss, compared with the consumption of a self-selected diet of conventional foods with the same calorie goal (20–22). Liquid meal replacements and other portion-controlled approaches appear to facilitate patients' adherence to their prescribed calorie targets (20–24). Controlled trials also have shown that the more treatment sessions participants are provided, the more weight they lose (35). Greater weight loss probably results from strengthening adherence to diet and activity recommendations, as suggested by the robust intercorrelations among the three measures in the present study.

Differences in weight loss among some of the study's demographic groups appeared to be explained by differences in treatment adherence. Thus, the significantly greater weight losses observed in men than women, and in the study's oldest participants (65 to 74 years), appeared to result from their greater treatment attendance, minutes of physical activity, and consumption of meal replacements. The analyses suggest that women would have lost as much weight as men, and younger participants as much as older ones, if they had adhered as closely to the study's treatment recommendations. By contrast, the significantly greater weight loss observed in non-Hispanic white participants, as compared with African Americans and Native Americans, was not eliminated by controlling for differences in physical activity, treatment attendance, and consumption of meal replacements. Smaller weight losses in these latter two groups could have been attributable to a variety of non-treatment related factors. African American women, for example, were found in previous studies to have a lower resting energy expenditure (REE) than age- and weight-matched non-Hispanic white women (36–37) and to have greater reductions in REE in response to weight loss (38–39), each of which could limit weight loss.

We note that the significantly lower treatment attendance of American Indian/other participants may have reflected significant economic barriers (e.g., lack of transportation) known at the study's outset. In addition, their lower reported minutes of physical activity and consumption of meal replacements are also likely a consequence of their attending fewer treatment sessions and, thus, having fewer opportunities to report their activity and food intake. Moreover, we believe that the data reported here underestimate physical activity and meal replacement use for all participants. If participants forgot to record these events in the diaries, or failed to submit a diary for a given week, they received a value of 0 for the number of minutes of physical activity for the week (as well as for number of meal replacements consumed).

In addition to underscoring the importance of treatment adherence, the results of this study offer two other practical findings. The first is that insulin users can achieve clinically significant weight loss by participating in a comprehensive weight loss intervention (10–12). Although insulin users lost approximately 2% less weight than participants who took no diabetes medications, the more important finding was that patients on insulin still lost an impressive 7.4% of initial weight. The second finding is that persons 65 to 74 years of age appear to be acceptable candidates for weight loss trials, from which they now are frequently excluded. The oldest participants in the present study were model citizens, in terms of their treatment adherence. Their achieving the largest weight losses of the three age groups confirms findings from the Diabetes Prevention Program (5). Older individuals may have more time and fewer barriers to participating than their younger counterparts. Analysis of body composition, however, is needed to ensure that the greater weight loss in older individuals was not attributable to a greater loss of lean tissue or bone (40).

Despite the lifestyle intervention's clear strengths, we note three limitations, the first of which is that the ILI participants were highly motivated and were provided intensive treatment, free of charge. Thus, the generalizability of the present findings to primary care practice is not known. Second, participants in ILI were weighed at each treatment visit by unmasked intervention staff, and these data were included in the present report. To fully understand the treatment effects, the reader should use these data in conjunction with weight data obtained by masked study staff (on all participants) at outcome visits. A third limitation is that nearly one-third of ILI participants did not achieve a 5% reduction initial weight, a benchmark of clinically significant weight loss (16). During the first 6 months, these participants had significantly poorer adherence to the study's treatment recommendations than did those who lost 5% or more of initial weight. The use of orlistat by 291 of the former participants, during the second 6 months of treatment, increased weight loss only marginally, in contrast to expected reductions (29). There has been little research in weight management on methods to assist sub-optimal or

non-responders. Over time, Look AHEAD will provide a rich data set with which to examine the effects of different “rescue” interventions for the induction or maintenance of weight loss.

In summary, an intensive group lifestyle intervention induced a mean loss of 8.6% of initial weight in overweight and obese participants with type 2 diabetes. The intervention was clinically effective in all subsets of an ethnically and demographically diverse population. Greater self-reported physical activity and consumption of meal replacements, as well as more frequent treatment attendance, were associated with greater weight loss. Study efforts are currently devoted to helping participants maintain their lost weight in order to have the best opportunity to determine whether intentional weight loss reduces cardiovascular mortality and morbidity.

References

1. The Look AHEAD Research Group. Look AHEAD (Action for Health in Diabetes): design and methods for a clinical trial of weight loss for the prevention of cardiovascular disease in type 2 diabetes. *Controlled Clinical Trials* 2003;24:610–628. [PubMed: 14500058]
2. Gregg, EW.; Williamson, DF. Relationship of intentional weight loss to disease incidence and mortality. In: Wadden, TA.; Stunkard, AJ., editors. *Handbook of obesity treatment*. New York: Guilford Press; 2002. p. 125-143.
3. Gregg EW, Gerzoff RB, Thompson TJ, Williamson DF. Intentional weight loss and death in overweight and obese U.S. adults 35 years of age and older. *Ann Intern Med* 2003;138:383–389. [PubMed: 12614090]
4. Look AHEAD Research Group. Reduction in weight and cardiovascular disease risk factors in individuals with type 2 diabetes. *Diabetes Care* 2007;30:1–10.
5. Wing RR, Hamman RF, Bray GA, Delahanty L, Edelstein SL, Hill JO, Horton ES, Hoskin MA, Kriska A, Lachin J, Mayer-Davis EJ, Pi-Sunyer X, Regensteiner JG, Venditti B, Wylie-Rosett J. Diabetes Prevention Program Research Group. Achieving weight and activity goals among diabetes prevention program lifestyle participants. *Obes Res* 2004;12:1426–1434. [PubMed: 15483207]
6. Wing RR, Anglin K. Effectiveness of a behavioral weight control program for blacks and whites with NIDDM. *Diabetes Care* 1996;19:409–413. [PubMed: 8732700]
7. Kumanyika SK, Espeland MA, Bahnson JL, Bottom JB, Charleston JB, Folmar S, Wilson AC, Whelton PK. TONE Cooperative Research Group. Ethnic comparison of weight loss in the Trial of Nonpharmacologic Interventions in the Elderly. *Obes Res* 2002;10:96–106. [PubMed: 11836455]
8. Wadden TA, Foster GD, Wang J, Pierson RN, Yang MU, Moreland K, Stunkard AJ, VanItallie TB. Clinical correlates of short- and long-term weight loss. *Am J Clin Nutr* 1992;56:271S–274S. [PubMed: 1615899]
9. Jeffery RW, Bjornson-Benson WM, Rosenthal BS, Lindquist RA, Kurth CL, Johnson SL. Correlates of weight loss and its maintenance over two years of follow-up among middle-aged men. *Prev Med* 1984;13:155–168. [PubMed: 6739444]
10. UK Prospective Diabetes Study (UKPDS) Group. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type II diabetes (UKPDS 34). *Lancet* 1998;352:854–865. [PubMed: 9742977]
11. Fritsche A, Haring H. At last a weight neutral insulin? *Int J Obes* 2004;28:S41–S46.
12. Carver C. Insulin treatment and the problem of weight gain in type 2 diabetes. *The Diabetes Educator* 2006;32:910–917. [PubMed: 17102158]
13. Bray G, Gregg E, Haffner S, Pi-Sunyer XF, Wagenknecht LE, Walkup M, Wing R. Look Ahead Research Group. Baseline characteristics of the randomised cohort from the Look AHEAD (Action for Health in Diabetes) study. *Diab Vasc Dis Res* 2006;3:202–215. [PubMed: 17160917]
14. Jakicic JM, Balasubramanyam A, Bancroft B, Curtis J, Jaramillo S, Mathews A, Pereira M, Regensteiner J, Ribsil P. for the Look AHEAD Research Group. Effect of a lifestyle intervention on change in cardiorespiratory fitness in adults with type 2 diabetes: Results from the Look AHEAD study. Submitted for publication.

15. Look AHEAD Research Group. The Look AHEAD study: a description of the lifestyle intervention and the evidence supporting it. *Obesity* 2006;14:737–752. [PubMed: 16855180]
16. The Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 2002;346:393–403. [PubMed: 11832527]
17. The Diabetes Prevention Program Research Group. The Diabetes Prevention Program (DPP). Description of lifestyle intervention. *Diabetes Care* 2002;25:2165–2171. [PubMed: 12453955]
18. Kumanyika, SK. Obesity treatment in minorities. In: Wadden, TA.; Stunkard, AJ., editors. *Handbook of obesity treatment*. New York: Guilford Press; 2002. p. 416-446.
19. Kumanyika SK, Espeland MA, Bahnson JL, Bottom JB, Charleston JB, Folmar S, Wilson AC, Whelton PK. TONE Cooperative Research Group. Ethnic comparison of weight loss in the trial of nonpharmacologic interventions in the elderly. *Obes Res* 2002;10:96–106. [PubMed: 11836455]
20. Ditschuneit HH, Flechtner-Mors M, Johnson TD, et al. Metabolic and weight loss effects of long-term dietary intervention in obese subjects. *Am J Clin Nutr* 1999;69:198–204. [PubMed: 9989680]
21. Heymsfeld SB, van Mierlo CA, van der Knaap HC, et al. Weight management using a meal replacement strategy: Meta and pooling analysis from six studies. *Int J Obes* 2003;27:537–549.
22. Metz J, Kris-Etherton P, Morris C, et al. Dietary compliance and cardiovascular risk reduction with a prepared meal plan compared with a self-selected diet. *Am J Clin Nutr* 1997;66:373–385. [PubMed: 9250117]
23. Wing RR, Jeffery RW, Burton LR, et al. Food provision vs. structured meal plans in the behavioral treatment of obesity. *Int J Obes* 1996;20:56–62.
24. Fletcher-Mors M, Ditschuneit H, Johnson T, Suchard M, Adler G. Metabolic and weight loss effects of long-term dietary intervention in obese patients. *Obes Res* 2000;8:399–402. [PubMed: 10968732]
25. Rolls, B.; Barnett, R. *Volumetrics: Feel full on fewer calories*. New York: Harper Collins Publishers; 2000.
26. Perri MG, McAllister D, Gange J, Jordan R, McAdoo W, Nezu A. Effects of four maintenance programs on the long-term management of obesity. *J Consult Clin Psychol* 1988;56:529–534. [PubMed: 2848874]
27. West DS, DiLillo V, Bursac Z, Gore SA, Greene PG. Motivational interviewing improves weight loss in women with type 2 diabetes. *Diabetes Care* 2007;30(5):1081–1087. [PubMed: 17337504] Epub 2007 Mar 2
28. Smith DE, Heckemeyer CM, Kratt PP, Mason DA. Motivational interviewing to improve adherence to a behavioral weight-control program for older obese women with NIDDM. A pilot study. *Diabetes Care* 1997;20:52–54. [PubMed: 9028693]
29. Sjostrom L, Rissanen A, Anderson T, et al. Randomized placebo-controlled trial of orlistat for weight loss and prevention of weight regain in obese patients. *Lancet* 1998;352:167–172. [PubMed: 9683204]
30. Hill J, Hauptman J, Anderson J, et al. Orlistat, a lipase inhibitor, for weight maintenance after conventional dieting: a 1-y study. *Am J Clin Nutr* 1999;69:1109–1116.
31. Wadden TA, Berkowitz RI, Womble L, Sarwer D, Arnold M, Steinberg C. Effects of sibutramine plus orlistat in obese women following 1 year treatment by sibutramine alone: a placebo-controlled trial. *Obes Res* 2000;8:431–437. [PubMed: 11011909]
32. Jeffrey RW, Wing RR, Sherwood NE, Tate DF. Physical activity and weight loss: does prescribing higher physical activity goals improve outcome? *Am J Clin Nutr* 2003;78(4):684–689. [PubMed: 14522725]
33. Jakicic JM, Marcus BH, Gallagher KI, Napolitano M, Lang W. Effect of exercise duration and intensity on weight loss in overweight, sedentary women: a randomized trial. *JAMA* 2003;290(10):1323–1330. [PubMed: 12966123]
34. Wadden TA, Vogt RA, Andersen RE, Bartlett SJ, Foster GD, Kuehnel RH, Wilk J, Weinstock R, Buckenmeyer P, Berkowitz RI, Steen SN. Exercise in the treatment of obesity: effects of four interventions on body composition, resting energy expenditure, appetite, and mood. *J Consult Clin Psychol* 1997;62:269–277. [PubMed: 9086690]
35. Perri MG, Nezu AM, Patti ET, McCann KL. Effect of length of treatment on weight loss. *J Consult Clin Psychol* 1989;57:450–452. [PubMed: 2500466]

36. Jones A, Shen W, St-Onge MP, et al. Body composition differences between African American and white women: relation to resting energy requirements. *AM J Clin Nutr* 2004;79:780–786. [PubMed: 15113715]
37. Weinsier RL, Hunter GR, Zuckerman PA, et al. Energy expenditure and free living physical activity in black and white women: comparison before and after weight loss. *Am J Clin Nur* 2000;71:1138–1146.
38. Jakicic JM, Wing RR. Differences in resting energy expenditure in African American vs Caucasian overweight females. *Int J Obes Relat Metab Disord* 1998;22:236–242. [PubMed: 9539192]
39. Foster GD, Wadden TA, Swain RM, et al. Changes in resting energy expenditure after weight loss in obese African American and white women. *Am J Clin Nutr* 1999;69:13–17. [PubMed: 9925117]
40. Villareal DT, Apovian CM, Kushner RF, Klein S. Obesity in older adults: Technical review and position statement of the American Society for Nutrition and NAASO, The Obesity Society. *Obes Res* 2005;13:1849–1863. [PubMed: 16339115]

Acknowledgements

This report represents a further analysis of the first year weight losses in the Look AHEAD study. It was prepared by the authors on behalf of the Look AHEAD Research Group. Members of the research group who participated in the recruitment, assessment, treatment, and retention of participants during the first year of the study are shown below:

Clinical Sites

The Johns Hopkins Medical Institutions Frederick L. Brancati, MD, MHS¹; Jeff Honas, MS²; Lawrence Cheskin, MD³; Jeanne M. Clark, MD, MPH³; Kerry Stewart, EdD³; Richard Rubin, PhD³; Jeanne Charleston, RN; Kathy Horak, RD

Pennington Biomedical Research Center George A. Bray, MD¹; Kristi Rau²; Allison Strate, RN²; Brandi Armand, LPN²; Frank L. Greenway, MD³; Donna H. Ryan, MD³; Donald Williamson, PhD³; Amy Bachand; Michelle Begnaud; Betsy Berhard; Elizabeth Caderette; Barbara Cerniauskas; David Creel; Diane Crow; Helen Guay; Nancy Kora; Kelly LaFleur; Kim Landry; Missy Lingle; Jennifer Perault; Mandy Shipp, RD; Marisa Smith; Elizabeth Tucker

The University of Alabama at Birmingham Cora E. Lewis, MD, MSPH¹; Sheikilya Thomas MPH²; Monika Safford, MD³; Vicki DiLillo, PhD; Charlotte Bragg, MS, RD, LD; Amy Dobelstein; Stacey Gilbert, MPH; Stephen Glasser, MD; Sara Hannum, MA; Anne Hubbell, MS; Jennifer Jones, MA; DeLavallade Lee; Ruth Luketic, MA, MBA, MPH; Karen Marshall; L. Christie Oden; Janet Raines, MS; Cathy Roche, RN, BSN; Janet Truman; Nita Webb, MA; Audrey Wrenn, MAEd

Harvard Center

Massachusetts General Hospital: David M. Nathan, MD¹; Heather Turgeon, RN, BS, CDE²; Kristina Schumann, BA²; Enrico Cagliero, MD³; Linda Delahanty, MS, RD³; Kathryn Hayward, MD³; Ellen Anderson, MS, RD³; Laurie Bissett, MS, RD; Richard Ginsburg, PhD; Valerie Goldman, MS, RD; Virginia Harlan, MSW; Charles McKittrick, RN, BSN, CDE; Alan McNamara, BS; Theresa Michel, DPT, DSc CCS; Alexi Poulos, BA; Barbara Steiner, EdM; Joclyn Tosch, BA

Joslin Diabetes Center: Edward S. Horton, MD¹; Sharon D. Jackson, MS, RD, CDE²; Osama Hamdy, MD, PhD³; A. Enrique Caballero, MD³; Sarah Bain, BS; Elizabeth Bovaird, BSN, RN; Ann Goebel-Fabbri, PhD; Lori Lambert, MS, RD; Sarah Ledbury, MEd, RD; Maureen Malloy, BS; Kerry Ovalle, MS, RCEP, CDE

Beth Israel Deaconess Medical Center: George Blackburn, MD, PhD¹; Christos Mantzoros, MD, DSc³; Kristinia Day, RD; Ann McNamara, RN

University of Colorado Health Sciences Center James O. Hill, PhD¹; Marsha Miller, MS, RD²; JoAnn Phillipp, MS²; Robert Schwartz, MD³; Brent Van Dorsten, PhD³; Judith Regensteiner, PhD³; Salma Bencheekroun MS; Ligia Coelho, BS; Paulette Cohrs, RN, BSN; Elizabeth Daeninck, MS, RD; Amy Fields, MPH; Susan Green; April Hamilton,

¹Principal Investigator

²Program Coordinator

³Co-Investigator

BS, CCRC; Jere Hamilton, BA; Eugene Leshchinskiy; Michael McDermott, MD; Lindsey Munkwitz, BS; Loretta Rome, TRS; Kristin Wallace, MPH; Terra Worley, BA

Baylor College of Medicine John P. Foreyt, PhD¹; Rebecca S. Reeves, DrPH, RD²; Henry Pownall, PhD³; Ashok Balasubramanyam, MBBS³; Peter Jones, MD³; Michele Burrington, RD; Chu-Huang Chen, MD, PhD; Allyson Clark, RD; Molly Gee, MEd, RD; Sharon Griggs; Michelle Hamilton; Veronica Holley; Jayne Joseph, RD; Patricia Pace, RD; Julieta Palencia, RN; Olga Satterwhite, RD;

Jennifer Schmidt; Devin Volding, LMSW; Carolyn White

University of California at Los Angeles School of Medicine Mohammed F. Saad, MD¹; Siran Ghazarian Sengardi, MD²; Ken C. Chiu, MD³; Medhat Botrous; Michelle Chan, BS; Kati Konersman, MA, RD, CDE; Magguri Perpetua, RD

The University of Tennessee Health Science Center

University of Tennessee East. Karen C. Johnson, MD, MPH¹; Carolyn Gresham, RN²; Stephanie Connelly, MD, MPH²; Amy Brewer, RD, MS; Mace Coday, PhD; Lisa Jones, RN; Lynne Lichtermann, RN, BSN; Shirley Vosburg, RD, MPH; and J. Lee Taylor, MEd, MBA

University of Tennessee Downtown. Abbas E. Kitabchi, PhD, MD¹; Helen Lambeth, RN, BSN²; Debra Clark, LPN; Andrea Crisler, MT; Gracie Cunningham; Donna Green, RN; Debra Force, MS, RD, LDN; Robert Kores, PhD; Renate Rosenthal PhD; Elizabeth Smith, MS, RD, LDN; and Maria Sun, MS, RD, LDN; and Judith Soberman, MD³

University of Minnesota Robert W. Jeffery, PhD¹; Carolyn Thorson, CCRP²; John P. Bantle, MD³; J. Bruce Redmon, MD³; Richard S. Crow, MD³; Scott Crow, MD³; Susan K Raatz, PhD, RD³; Kerrin Brelje, MPH, RD; Carlyne Campbell; Jeanne Carls, MEd; Tara Carmean-Mihm, BA; Emily Finch, MA; Anna Fox, MA; Elizabeth Hoelscher, MPH, RD, CHES; La Donna James; Vicki A. Maddy, BS, RD; Therese Ockenden, RN; Birgitta I. Rice, MS, RPh CHES; Tricia Skarphol, BS; Ann D. Tucker, BA; Mary Susan Voeller, BA; Cara Walcheck, BS, RD

St. Luke's Roosevelt Hospital Center Xavier Pi-Sunyer, MD¹; Jennifer Patricio, MS²; Stanley Heshka, PhD³; Carmen Pal, MD³; Lynn Allen, MD; Diane Hirsch, RNC, MS, CDE; Mary Anne Holowaty, MS, CN

University of Pennsylvania Thomas A. Wadden, PhD¹; Barbara J. Maschak-Carey, MSN, CDE²; Stanley Schwartz, MD³; Gary D. Foster, PhD³; Robert I. Berkowitz, MD³; Henry Glick, PhD³; Shiriki K. Kumanyika, PhD, RD, MPH³; Johanna Brock; Helen Chomentowski; Vicki Clark; Canice Crerand, PhD; Renee Davenport; Andrea Diamond, MS, RD; Anthony Fabricatore, PhD; Louise Hesson, MSN; Stephanie Krauthamer-Ewing, MPH; Robert Kuehnel, PhD; Patricia Lipschutz, MSN; Monica Mullen, MS, RD; Leslie Womble, PhD, MS; Nayyar Iqbal, MD

University of Pittsburgh David E. Kelley, MD¹; Jacqueline Wesche-Thobaben, RN, BSN, CDE²; Lewis Kuller, MD, DrPH³; Andrea Kriska, PhD³; Janet Bonk, RN, MPH; Rebecca Danchenko, BS; Daniel Edmundowicz, MD³; Mary L. Klem, PhD, MLIS³; Monica E. Yamamoto, DrPH, RD, FADA³; Barb Elnyczky, MA; George A. Grove, MS; Pat Harper, MS, RD, LDN; Janet Krulia, RN, BSN, CDE; Juliet Mancino, MS, RD, CDE, LDN; Anne Mathews, MS, RD, LDN; Tracey Y. Murray, BS; Joan R. Ritchea; Jennifer Rush, MPH; Karen Vujevich, RN-BC, MSN, CRNP; Donna Wolf, MS

The Miriam Hospital/Brown Medical School Rena R. Wing, PhD¹; Renee Bright, MS²; Vincent Pera, MD³; John Jakicic, PhD³; Deborah Tate, PhD³; Amy Gorin, PhD³; Kara Gallagher, PhD³; Amy Bach, PhD; Barbara Bancroft, RN, MS; Anna Bertorelli, MBA, RD; Richard Carey, BS; Tatum Charron, BS; Heather Chenot, MS; Kimberley Chula-Maguire, MS; Pamela Coward, MS, RD; Lisa Cronkite, BS; Julie Currin, MD; Maureen Daly, RN; Caitlin Egan, MS; Erica Ferguson, BS, RD; Linda Foss, MPH; Jennifer Gauvin, BS; Don Kieffer, PhD; Lauren Lessard, BS; Deborah Maier, MS; JP Massaro, BS; Tammy Monk, MS; Rob Nicholson, PhD; Erin Patterson, BS; Suzanne Phelan, PhD; Hollie Raynor, PhD, RD; Douglas Raynor, PhD; Natalie Robinson, MS, RD; Deborah Robles; Jane Tavares, BS

The University of Texas Health Science Center at San Antonio Steven M. Haffner, MD¹; Maria G. Montez, RN, MSHP, CDE²; Carlos Lorenzo, MD³

University of Washington / VA Puget Sound Health Care System Steven Kahn MB, ChB¹; Brenda Montgomery, RN, MS, CDE²; Robert Knopp, MD³; Edward Lipkin, MD³; Matthew L. Maciejewski, PhD³; Dace Trence, MD³; Terry Barrett, BS; Joli Bartell, BA; Diane Greenberg, PhD; Anne Murillo, BS; Betty Ann Richmond, MEd; April Thomas, MPH, RD

Southwestern American Indian Center, Phoenix, Arizona and Shiprock, New Mexico William C. Knowler, MD, DrPH¹; Paula Bolin, RN, MC²; Tina Killean, BS²; Cathy Manus, LPN³; Jonathan Krakoff, MD³; Jeffrey M. Curtis, MD, MPH³; Justin Glass, MD³; Sara Michaels, MD³; Peter H. Bennett, MB, FRCP³; Tina Morgan³; Shandiin Begay, MPH; Bernadita Fallis RN, RHIT, CCS; Jeanette Hermes, MS, RD; Diane F. Hollowbreast; Ruby Johnson; Maria Meacham, BSN, RN, CDE; Julie Nelson, RD; Carol Percy, RN; Patricia Poorthunder; Sandra Sangster; Nancy Scurlock, MSN, ANP-C, CDE; Leigh A. Shovestull, RD, CDE; Janelia Smiley; Katie Toledo, MS, LPC; Christina Tomchee, BA; Darryl Tonemah PhD

University of Southern California Anne Peters, MD¹; Valerie Ruelas, MSW, LCSW²; Siran Ghazarian Sengardi, MD²; Kathryn Graves, MPH, RD, CDE; Kati Konersman, MA, RD, CDE; Sara Serafin-Dokhan

Coordinating Center

Wake Forest University Mark A. Espeland, PhD¹; Judy L. Bahnson, BA²; Lynne Wagenknecht, DrPH³; David Reboussin, PhD³; W. Jack Rejeski, PhD³; Alain Bertoni, MD, MPH³; Wei Lang, PhD³; Gary Miller, PhD³; David Lefkowitz, MD³; Patrick S. Reynolds, MD³; Paul Ribisl, PhD³; Mara Vitolins, DrPH³; Michael Booth, MBA²; Kathy M. Dotson, BA²; Amelia Hodges, BS²; Carrie C. Williams, BS²; Jerry M. Barnes, MA; Patricia A. Feeney, MS; Jason Griffin, BS; Lea Harvin, BS; William Herman, MD, MPH; Patricia Hogan, MS; Sarah Jaramillo, MS; Mark King, BS; Kathy Lane, BS; Rebecca Neiberg, MS; Andrea Ruggiero, MS; Christian Speas, BS; Michael P. Walkup, MS; Karen Wall, AAS; Michelle Ward; Delia S. West, PhD; Terri Windham

Central Resources Centers

DXA Reading Center, University of California at San Francisco Michael Nevitt, PhD¹; Susan Ewing, MS; Cynthia Hayashi; Jason Maeda, MPH; Lisa Palermo, MS, MA; Michaela Rahorst; Ann Schwartz, PhD; John Shepherd, PhD

Central Laboratory, Northwest Lipid Research Laboratories Santica M. Marcovina, PhD, ScD¹; Greg Strylewicz, MS

ECG Reading Center, EPICARE, Wake Forest University School of Medicine Ronald J. Prineas, MD, PhD¹; Teresa Alexander; Lisa Billings; Charles Campbell, AAS, BS; Sharon Hall; Susan Hensley; Yabing Li, MD; Zhu-Ming Zhang, MD

Diet Assessment Center, University of South Carolina, Arnold School of Public Health, Center for Research in Nutrition and Health Disparities Elizabeth J Mayer-Davis, PhD¹; Robert Moran, PhD

Hall-Foushee Communications, Inc.

Richard Foushee, PhD; Nancy J. Hall, MA

Federal Sponsors

National Institute of Diabetes and Digestive and Kidney Diseases: Barbara Harrison, MS; Van S. Hubbard, MD PhD; Susan Z. Yanovski, MD

National Heart, Lung, and Blood Institute: Lawton S. Cooper, MD, MPH; Jeffrey Cutler, MD, MPH; Eva Obarzanek, PhD, MPH, RD

Centers for Disease Control and Prevention: Edward W. Gregg, PhD; David F. Williamson, PhD; Ping Zhang, PhD

Funding and Support

This study is supported by the Department of Health and Human Services through the following cooperative agreements from the National Institutes of Health: DK57136, DK57149, DK56990, DK57177, DK57171, DK57151, DK57182, DK57131, DK57002, DK57078, DK57154, DK57178, DK57219, DK57008, DK57135, and DK56992. The following federal agencies have contributed support: National Institute of Diabetes and Digestive and Kidney Diseases; National Heart, Lung, and Blood Institute; National Institute of Nursing Research; National Center on Minority Health and Health Disparities; Office of Research on Women's Health; and the Centers for Disease Control and Prevention. This research was supported in part by the Intramural Research Program of the National Institute of Diabetes and Digestive and Kidney Diseases.

Additional support was received from The Johns Hopkins Medical Institutions Bayview General Clinical Research Center (M01RR02719); the Massachusetts General Hospital Mallinckrodt General Clinical Research Center (M01RR01066); the University of Colorado Health Sciences Center General Clinical Research Center (M01RR00051) and Clinical Nutrition Research Unit (P30 DK48520); the University of Tennessee at Memphis General Clinical

Research Center (M01RR0021140); the University of Pittsburgh General Clinical Research Center (M01RR000056 44) and NIH grant (DK 046204); and the University of Washington / VA Puget Sound Health Care System Medical Research Service, Department of Veterans Affairs; Frederic C. Bartter General Clinical Research Center (M01RR01346)

The following organizations have committed to make major contributions to Look AHEAD: Federal Express; Health Management Resources; Johnson & Johnson, LifeScan Inc.; Optifast-Novartis Nutrition; Roche Pharmaceuticals; Ross Product Division of Abbott Laboratories; Slim-Fast Foods Company; and Unilever.

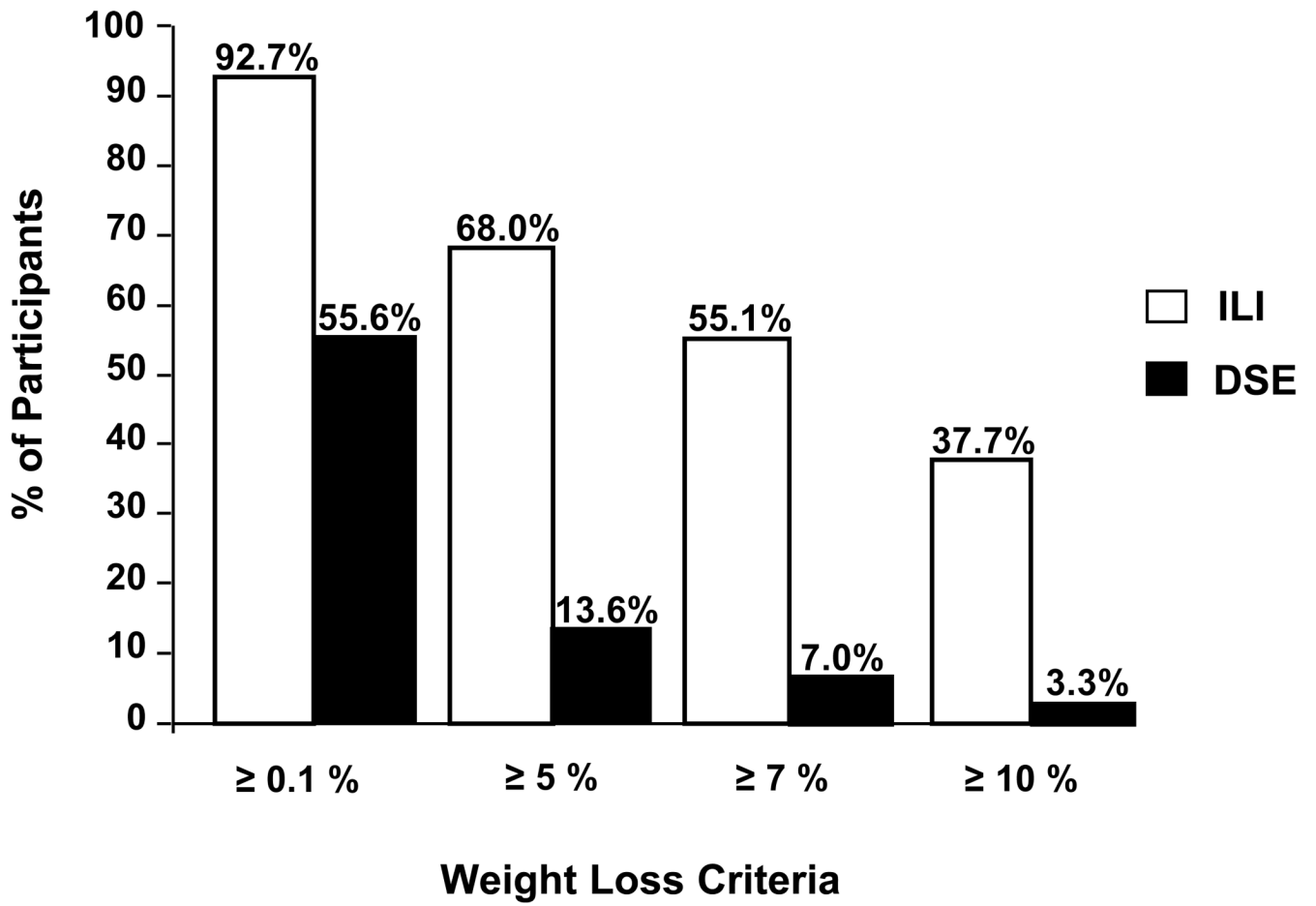


Figure 1. Percentage of participants in the intensive lifestyle intervention (ILI) and Diabetes Support and Education (DSE) groups that met different weight loss criteria.

Weight Loss by Gender & Ethnicity

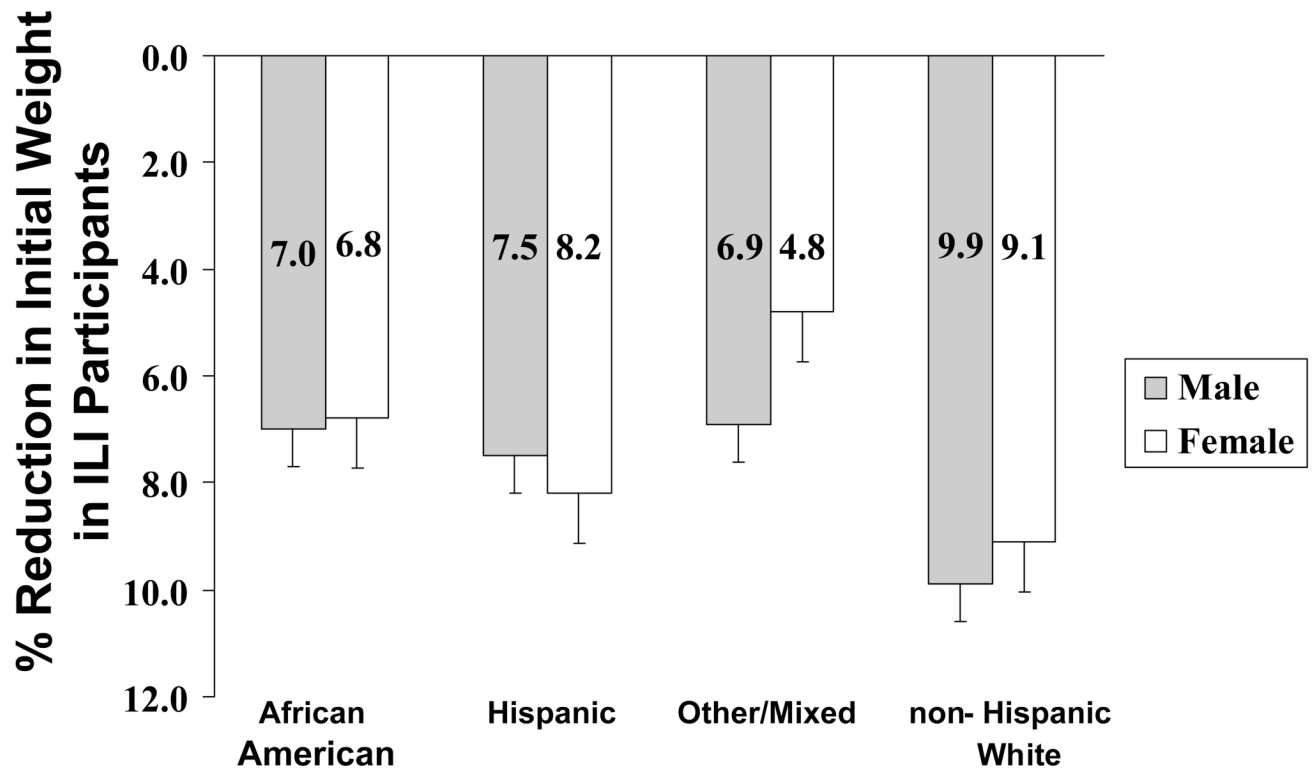


Figure 2. Percentage reduction in initial weight (in the ILI group) based on ethnicity and gender.

Quartile of Percentage of Possible Visits Attended

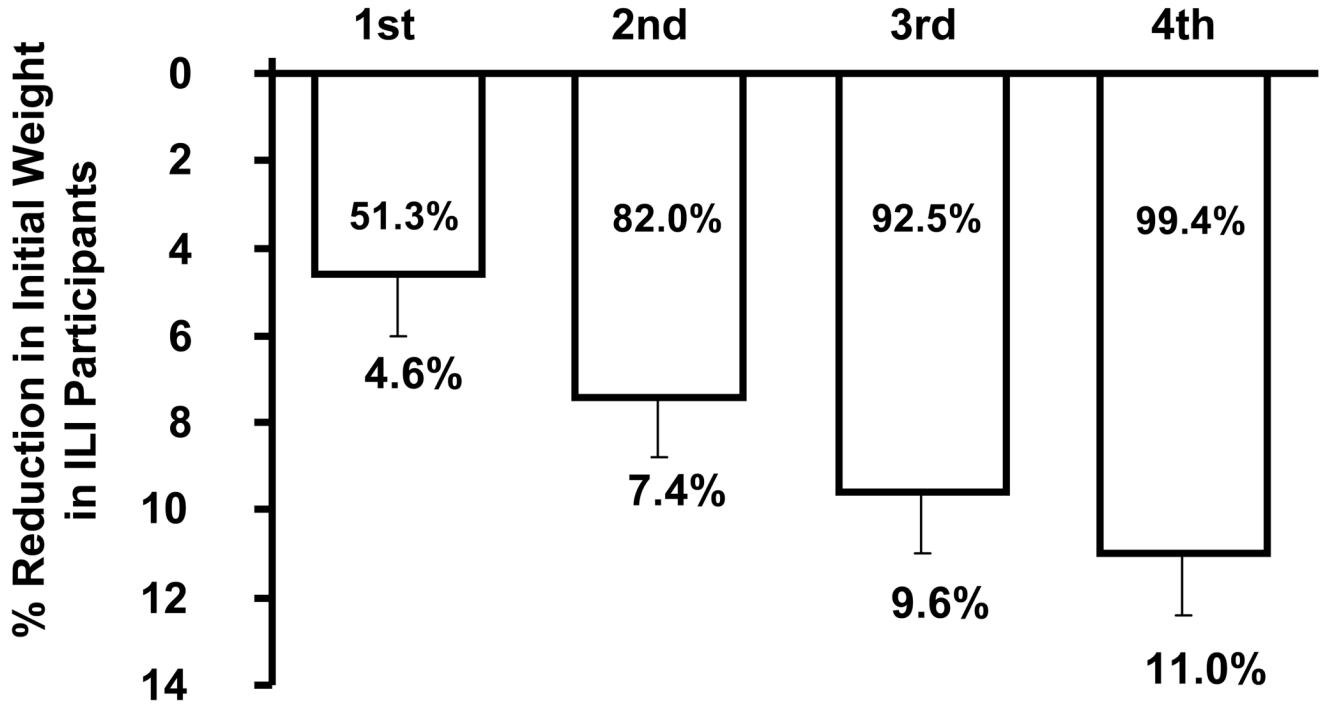


Figure 3. Percentage reduction in initial weight at 1 year based on quartile of percentage of possible visits attended. The number within each bar shows the mean percentage of visits attended for that quartile.

Quartile of Minutes of Weekly Physical Activity

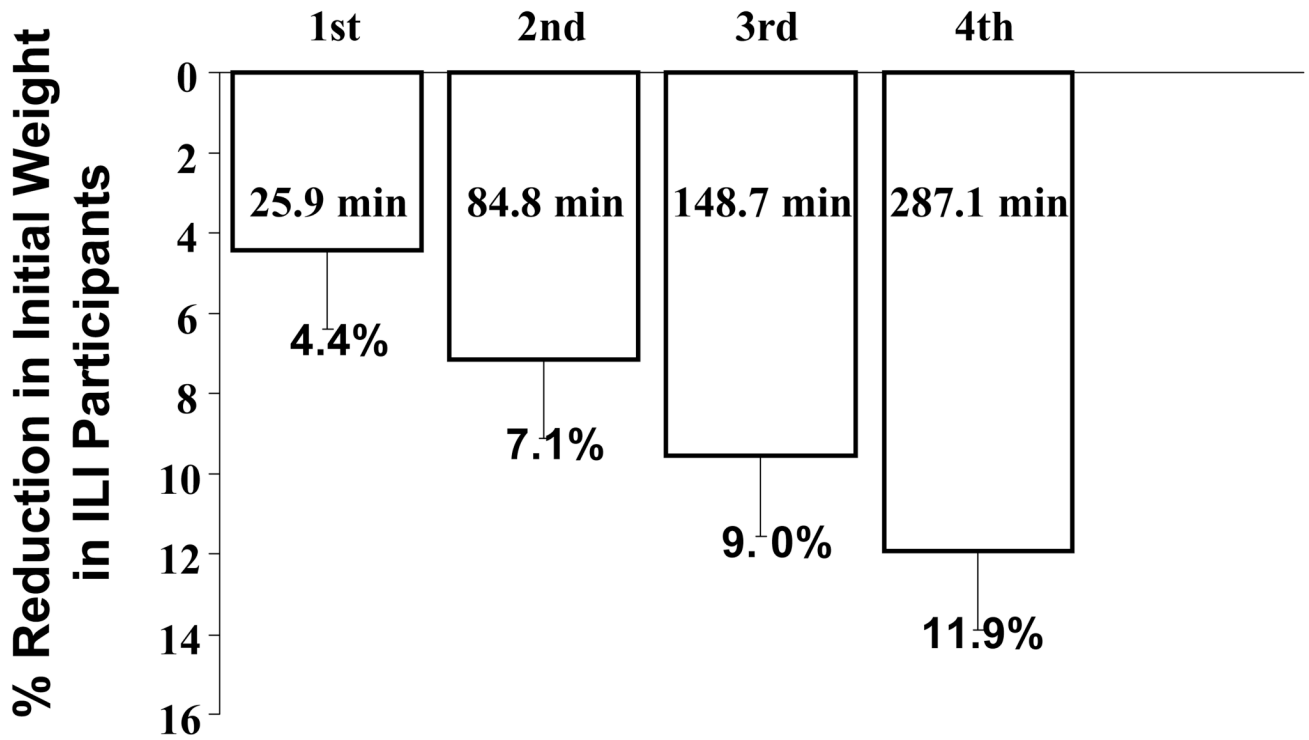


Figure 4.

Percentage reduction in initial weight at 1 year based on quartile of average weekly minutes of self-reported physical activity. The number within each bar shows the mean number of weekly minutes of physical activity.

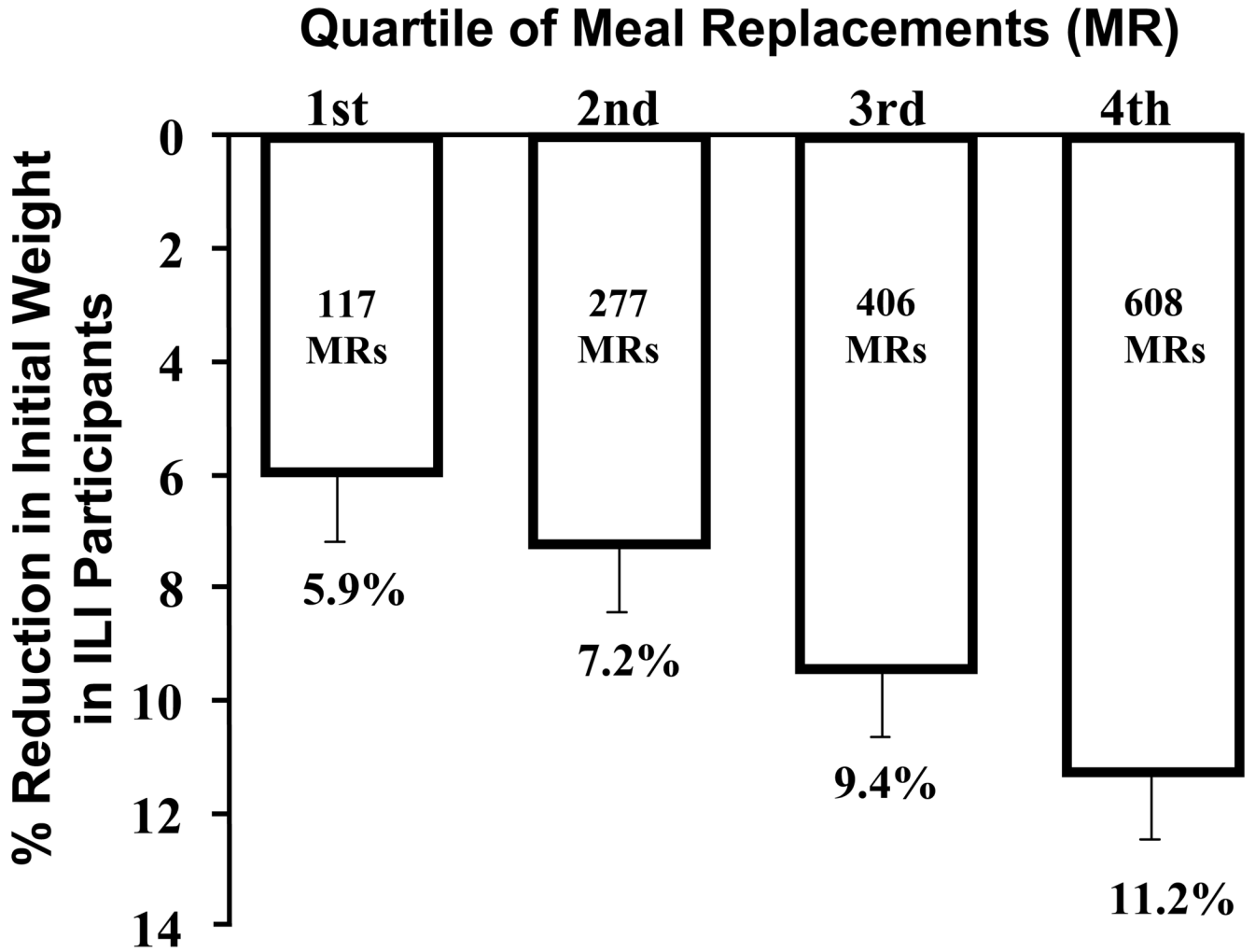


Figure 5. Percentage reduction in initial weight at 1 year based on quartile of meal replacement products (MR) used. The number within each bar shows the mean number of products used in that quartile.

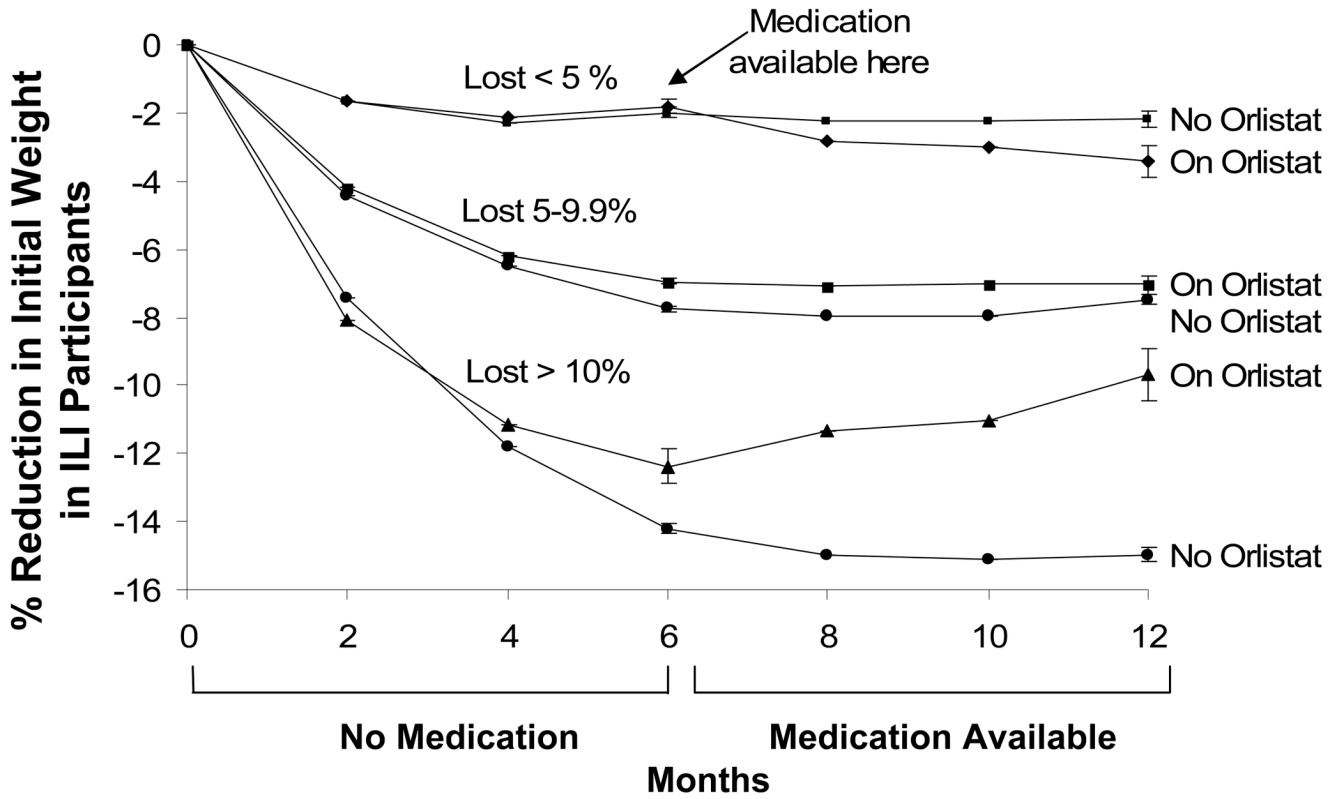


Figure 6. Percentage reduction in initial weight (in the ILI group) for individuals who did and did not receive orlistat after month 6. Individuals who had lost < 5% of initial weight at month 6 were encouraged to use the medication. Those who had lost 5.0 to 9.9% were allowed to use orlistat upon request. For participants who had lost $\geq 10\%$ at month 6, only those who had regained 2 percentage points or more above their lowest weight were allowed to use medication. (Participants were not randomized to treatment conditions.)

Table 1
Baseline characteristics of participants in the ILI and DSE groups.

Characteristic	ILI N = 2,570	DSE N = 2,575	p-value
Sex (no. of subjects)			
Female	1526 (59.3)	1537 (59.6)	0.85 [*]
Male	1044 (40.7)	1038 (40.4)	
Ethnicity			
African American	399 (15.5)	404 (15.7)	0.28 [*]
American Indian/Alaskan Native	130 (5.1)	128 (5.0)	
Asian/Pacific Islander	29 (1.1)	21 (0.8)	
Hispanic/Latino	339 (13.2)	338 (13.2)	
Non-Hispanic White	1618 (63.1)	1628 (63.3)	
Other/multiple	48 (1.9)	50 (1.9)	
Use of insulin	381 (14.8)	408 (15.8)	0.31 [*]
Age (yr)	58.6 ± 6.8	58.9 ± 6.9	0.12 [†]
Body mass index, (kg/m ²)			
Females	36.3 ± 6.2	36.6 ± 6.0	0.15 [†]
Males	35.3 ± 5.7	35.1 ± 5.2	0.41 [†]
Weight (kg)			
Females	94.8 ± 17.9	95.4 ± 17.3	0.34 [†]
Males	108.9 ± 19.0	109.0 ± 18.0	0.94 [†]

Values shown are means ± SDs or frequency counts (with percentages).

^{*} Chi square test

[†] Analysis of covariance, adjusted for clinical center

Table 2

Participants' attendance at treatment sessions and self-reported physical activity and consumption of meal replacements.

Characteristic	Number of Treatment Sessions Attended	Average Minutes of Weekly Physical Activity During Year 1	Total Number of Meal Replacements Used	
			6 months	12 months
Gender				
Male	35.8 ± 7.4 ^a	173.7 ± 124.4 ^a	239.4 ± 117.1 ^a	374.2 ± 201.8 ^a
Female	35.2 ± 7.2 ^a	129.4 ± 96.2 ^b	229.2 ± 110.5 ^b	351.7 ± 187.0 ^b
Age				
45–54 yr	34.9 ± 7.3 ^a	129.9 ± 97.5 ^a	236.3 ± 113.0 ^{ab}	353.2 ± 197.3 ^a
55–64 yr	35.3 ± 7.5 ^a	143.3 ± 109.7 ^a	227.5 ± 111.8 ^a	352.7 ± 189.3 ^a
65–74 yr	36.8 ± 6.4 ^b	179.0 ± 121.5 ^b	245.5 ± 116.8 ^b	391.8 ± 197.4 ^b
Ethnicity				
Non-Hispanic White	35.9 ± 6.9 ^a	155.6 ± 115.5 ^a	243.4 ± 115.8 ^a	378.3 ± 199.8 ^a
African American	35.6 ± 7.1 ^{ab}	125.8 ± 99.6 ^b	228.2 ± 110.2 ^{ab}	343.1 ± 184.5 ^b
Hispanic	34.5 ± 7.8 ^b	151.2 ± 94.9 ^a	215.2 ± 93.2 ^{bc}	340.0 ± 160.3 ^b
American Indian/Other	32.2 ± 8.8 ^c	113.8 ± 104.5 ^b	186.4 ± 115.2 ^c	280.5 ± 182.8 ^c

Within columns and demographic groupings, values with different superscripts (i.e., a, b, and c) differ significantly from each other ($p < 0.05$). Thus, for example, examining minutes of physical activity, men reported exercising significantly more minutes than women (a vs b). By contrast, there was no significant difference between men and women in attendance, as shown by the shared superscript a.