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Eight-Year Weight Losses with an Intensive Lifestyle Intervention: The Look AHEAD Study

The Look AHEAD Research Group

Author manuscript

Abstract

Objective—To evaluate 8-year weight losses achieved with intensive lifestyle intervention (ILI) in the Look AHEAD (Action for Health in Diabetes) study.

Design and Methods—Look AHEAD assessed the effects of intentional weight loss on cardiovascular morbidity and mortality in 5,145 overweight/obese adults with type 2 diabetes, randomly assigned to ILI or usual care (i.e., diabetes support and education [DSE]). The ILI provided comprehensive behavioral weight loss counseling over 8 years; DSE participants received periodic group education only.

Results—All participants had the opportunity to complete 8 years of intervention before Look AHEAD was halted in September 2012; 88% of both groups completed the 8-year outcomes assessment. ILI and DSE participants lost (mean \pm SE) 4.7 \pm 0.2% and 2.1 \pm 0.2% of initial weight, respectively (p<0.001) at year 8; 50.3% and 35.7%, respectively, lost 5% (p<0.001), and 26.9% and 17.2%, respectively, lost 10% (p<0.001). Across the 8 years ILI participants, compared with DSE, reported greater practice of several key weight-control behaviors. These behaviors also distinguished ILI participants who lost 10% and kept it off from those who lost but regained.

Conclusions—Look AHEAD's ILI produced clinically meaningful weight loss (5%) at year 8 in 50% of patients with type 2 diabetes and can be used to manage other obesity-related co-morbid conditions.

Trial Registration—clinicaltrials.gov Identifier: NCT00017953

The Look AHEAD (Action for Health in Diabetes) study was designed to assess the effects of an intensive lifestyle intervention (ILI) on clinically important health outcomes in overweight/obese individuals with type 2 diabetes.¹ The trial's primary outcome was cardiovascular morbidity and mortality, on which no significant differences were observed between participants assigned to ILI or a usual care group (i.e., diabetes support and

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education [DSE]) after a mean follow-up of 9.6 years.² Investigators currently are examining changes in secondary outcomes in Look AHEAD including mood,³ quality of life,⁴ sleep apnea,⁵ and physical function,⁶ all of which were improved by the ILI during the trial's initial years.

Look AHEAD provides the largest and longest randomized evaluation to date of an ILI for weight reduction. The trial offers invaluable information about the feasibility of inducing and maintaining clinically significant weight loss, defined as a 5% reduction in initial body weight.^{7–10} Weight loss of this size confers additional health benefits beyond those described above. These include prevention and resolution of type 2 diabetes,^{11,12} reduction in blood pressure and lipids,^{13–14} amelioration of non-alcoholic fatty liver disease,¹⁵ and improvements in urinary incontinence and sexual dysfunction.^{16,17}

The present report provides a detailed analysis of changes in body weight in ILI and DSE participants over the first 8 years of the intervention, which all participants had the opportunity to complete before the trial was halted. ILI participants were provided frequent treatment visits the first year to induce weight loss, followed by a comprehensive weight loss maintenance program in years 2-8.18 Our primary hypotheses were that the ILI group, as compared with DSE, would achieve significantly greater mean weight losses at all years and be more successful in achieving reductions 5% and 10% of initial weight. Consistent with these hypotheses, we predicted that ILI participants, compared with DSE, would report greater practice of numerous weight control behaviors (e.g., reducing energy intake, increasing physical activity) recommended by the intervention. The study's large sample size (N=5,145) allowed us to examine the effect on 8-year weight loss of age, gender, and race/ethnicity, as evaluated previously for years 1 and 4.19 The large sample also allowed us to examine, within the ILI group, the percentage of participants that lost 10% of initial weight the first year and sustained the loss at year 8. Behavioral characteristics of these weight-loss maintainers were compared with those of participants who initially lost 10% but regained it.

METHODS AND PROCEDURES

Participants

A total of 5,145 men and women were enrolled in Look AHEAD at 16 centers throughout the U.S.^{1,2} Eligible individuals had type 2 diabetes, were 45–76 years of age, and had a body mass index (BMI) 25 kg/m² (or 27 kg/m² if taking insulin). Additional eligibility criteria have been reported and included applicants' completing a graded exercise test and a test of behavioral adherence.^{1,2} Those who remained eligible were randomly assigned, with equal probability, to ILI or DSE. All participants signed a consent form approved by their center's institutional review board.

Interventions

The ILI and DSE interventions have been described previously and are only briefly summarized here.^{18,20} Participants in both groups received all usual medical care from their own primary care providers.

ILI—In year 1, ILI participants received a comprehensive lifestyle intervention designed to induce an average, study-wide loss 7% of initial weight (with an individual goal of losing 10%).^{1,19} The intervention was adapted from the Diabetes Prevention Program (DPP)^{11,21} and delivered to groups of approximately 10-20 persons by experienced interventionists. In months 1–6, participants attended group sessions (of 60–75 minutes) for the first 3 weeks of each month; the fourth week, they met individually with their interventionist (for 20-30 minutes), and group sessions were not held. In months 7-12, they continued to have a monthly individual meeting, but group sessions were reduced to two per month. Participants were prescribed 1200–1800 kcal/day (depending on initial body weight) with 30% of calories from fat (<10% from saturated fat) and 15% of calories from protein. Structured meal plans²² and meal replacements¹⁸ were provided (free of charge) for the first 4 months, with patients encouraged to replace two meals and one snack daily with liquid shakes and meal bars. From months 5-12, they were instructed to replace one meal and one snack daily. Participants were prescribed 175 minutes/week of moderate intensity physical activity, to be achieved by month 6, with a further increase to 200 minutes/week for those who met this goal. The activity program relied on unsupervised exercise that, for most, consisted of brisk walking.^{1,18} Participants were instructed to keep daily records of their food intake, physical activity, and other targeted behaviors.

In years 2–8, the intervention focused principally on maintaining the weight losses and duration of physical activity achieved during year 1, as well as helping unsuccessful individuals achieve the study goals.^{18,19} Lifestyle counseling was provided primarily in individual sessions to allow tailoring to participants' specific treatment needs. Each month, participants had an individual, on-site meeting (20–30 minutes), with a second individual contact by telephone or e-mail, approximately 2 weeks later. (This second contact was discontinued beginning in year 5.) Participants had individualized calorie goals, based on their desire to maintain their weight loss, lose more (if their BMI was >23 kg/m²), or reverse weight gain. All were encouraged to continue to use meal replacements (at no charge) to replace one meal or snack per day, to exercise 200 minutes/week, and to monitor weight weekly or more often.

During years 2–8, all sites offered a monthly group meeting at which members weighed-in, reviewed diet and activity records, and participated in a lifestyle modification session. Each year sites also offered at least one Refresher Group and one National Campaign, as used in the DPP.²¹ Refresher Groups typically lasted 6–8 weeks and were organized around a weight loss and/or physical activity theme.¹⁹ National Campaigns were similar in providing a group experience for 8–10 weeks but challenged participants to meet a specific goal (e.g., losing 5 lb), for which they received a small prize. Participants were strongly encouraged but not required to attend the various group offerings.

Interventionists included registered dietitians, psychologists, and exercise specialists, all of whom were certified annually. In addition to cognitive behavioral therapy, they incorporated elements of problem solving, motivational interviewing, and cultural tailoring in their counseling.^{23–25} They also could select more intensive interventions from a toolbox, described previously.^{18,19}

DSE—For the first 4 years, DSE participants were provided three 1-hour group meetings per year that discussed diet, physical activity, and social support, respectively.²⁰ These sessions offered information but not specific behavioral strategies for adhering to the diet and physical activity recommendations. Years 5 to 8 provided one such session per year. Persons who desired more help with weight loss were referred to their PCPs, who were free to recommend whatever interventions they considered appropriate.

Assessments

Weight was measured at baseline and annually thereafter with a digital scale (model BWB-800; Tanita, Willobrook, IL), by certified staff who were masked to intervention assignment. Physical activity was assessed at baseline and years 1, 4, and 8 by the Paffenbarger Activity Questionnaire (PAQ),²⁶ which provides an estimate of weekly energy expenditure from moderate intensity physical activity (e.g., climbing stairs, walking, and other fitness, sport, and recreational activities). At baseline and years 1 and 4, only participants at eight centers (i.e., the same each year) completed the questionnaire; in year 8, participants at all sites completed it. All participants also reported at baseline and years 1–4, as well as at year 8, the number of weeks in the prior year that they engaged in behaviors previously determined to be associated with long-term weight control: 1) increasing physical activity;^{27–29} 2) monitoring body weight;^{30,31} 3) reducing calorie and fat intake;^{32,33} and 4) using meal replacements.³³ These items were included in a questionnaire developed by study investigators (available upon request).

Statistical Analyses

The present analyses focused on the first 8 years of intervention, which all participants had the opportunity to complete before the trial was halted in September 2012. (Weight data reported in the primary endpoint paper included participants at different stages of intervention, ranging from 8.2 to 11 years.) Differences between the DSE and ILI groups in changes in weight over the 8 years were analyzed using a mixed effects analysis of covariance, which included baseline weight, clinical center, and treatment arm. The analyses followed the intention-to-treat principle in which participants were grouped according to intervention assignment, regardless of adherence, and all follow-up data were included. The percentage of participants in each group who met different categorical weight losses (e.g.,

5% or 10% loss) at years 1 and 8 were compared using generalized estimating equations (GEE). For behavioral outcomes (e.g., physical activity), differences between groups on continuous measures were analyzed using analysis of covariance (adjusting for clinical center and baseline value of the outcome) and using GEE for categorical measures. Within the two intervention groups, a mixed effects analysis of covariance was used to examine the relationship between weight loss (at years 1, 4, and 8) and gender, age, and race/ethnicity (controlling for baseline weight, clinical center, and interactions of each of the subgroup variables with year and intervention group). All statistical analyses were performed using SAS version 9.2 (SAS Institute, Cary, NC).

Body weight data for participants who died during the 8-year trial were included in the analyses until censored at the time of death. In addition, all analyses were conducted with and without censoring weights of participants (in both groups) who underwent bariatric

surgery. In year 1, 5 ILI and 10 DSE participants had surgery, which increased by year 8 to a total of 76 and 84, respectively (the latter values representing 3.0% and 3.3% of participants randomized to ILI and DSE, respectively). The two sets of analyses yielded the same statistical conclusions concerning differences between groups. Mean weight losses for both sets of analyses are reported; however, we focus primarily on weight changes in which bariatric surgery patients were censored (at the time of surgery) to provide the most accurate estimate of the efficacy of the lifestyle intervention.

For the ILI participants only, weight loss trajectories over the 8 years were determined for participants who at year 1 had lost 10% of initial weight, 5 to <10%, or <5%. Logistic regression was used to determine the odds of achieving a loss 10% or 5% at year 8, based upon having achieved these categorical losses at year 1. Data for the 8-year trajectories comprised a completers' sample as a result of not including participants who had been censored or had failed to provide a measured body weight at both years 1 and 8.

RESULTS

Participants' baseline characteristics

ILI and DSE participants did not differ significantly on baseline characteristics, as reported previously (see Table 1).^{2,33} Overall, average (\pm SD) age was 58.7 \pm 6.8 years, BMI was 36.0 \pm 5.9 kg/m², and duration of type 2 diabetes was 6.8 \pm 6.5 years. Figure 1 shows that 89.9% and 88.3% of ILI and DSE participants, respectively, completed the 8-year outcomes assessment (p=0.077). Year-8 retention was 94.0% (across the two groups) when deceased participants were removed from the denominator.

Weight loss

At year 1, ILI participants lost a mean (\pm SE) of 8.5 \pm 0.2% of initial weight, compared with 0.6 \pm 0.2% for DSE (p<0.001; see Figure 2). (Mean losses, not censored for bariatric surgery, were 8.6 \pm 0.2 and 0.6 \pm 0.2%, respectively.) As reported previously,³³ more ILI than DSE participants lost 5% of initial weight (68.0% vs. 13.3%, p <0.001), as well as 10% (37.7% vs. 2.9%, p<0.001). (The percentage of participants who lost 5% includes those who lost 10%.) Figure 3a shows that ILI was superior to DSE on other measures of categorical weight loss.

At year 8, ILI participants lost $4.7\pm0.2\%$ of initial weight, compared with $2.1\pm0.2\%$ for DSE (p<0.001). (Mean losses, including participants who had bariatric surgery, were 5.3 ± 0.2 and $2.7\pm0.2\%$, respectively.) More ILI than DSE participants met the 5% (50.3% vs. 35.7%; p<0.001) and 10% (26.9% vs. 17.2%; p<0.001) categorical losses. Fewer participants in ILI than DSE (26.4% vs. 39.2%; p<0.001) exceeded their baseline weight at year 8 (see Figure 3b). Figure 2 shows that ILI produced greater mean weight loss than DSE at all years and that weight regain in ILI, following maximum weight loss at year 1, plateaued between years 4–6.

Weight loss according to demographic characteristics

Table 2 presents weight loss according to gender, age, and race/ethnicity at years 1, 4, and 8. (Data not censored for bariatric surgery are presented in supplementary Table 1 on-line.) At all years, participants in ILI lost significantly more weight than their corresponding peers in DSE (see Table 2 for means and p values). Within the ILI group, men and women achieved comparable weight losses over the 8 years, with mean differences between them ranging from 0.3% (year 1) to 0.9% (year 8) (Table 2). By contrast, the oldest ILI individuals (65–76 years at baseline) consistently lost more weight than the youngest participants (45–54 years), with differences ranging from 0.9% (year 1) to 3.0% (year 8). Non-Hispanic white participants in ILI lost significantly more weight at year 1 than participants who self-identified as African American, Hispanic, and American Indian/Other. However, at years 4 and 8, mean weight losses were comparable among the four racial/ethnic groups, as they were among DSE participants at all years. Older DSE participants lost more weight than their younger counterparts, with the greatest difference (1.9%) between age groups occurring at year 8.

Physical activity and weight control behaviors

At baseline, participants in both groups reported expending approximately 860 kcal/week in moderate intensity physical activity, as determined by the PAQ. ILI participants, compared with DSE, achieved significantly greater increases on this measure at all subsequent assessments (see Table 3). Reported energy expenditure more than doubled in ILI participants the first year (1737.8±47.6 kcal/week) but declined in subsequent years. Table 3 also presents the number of weeks in the past year that participants reported engaging in selected weight control behaviors. Groups did not differ at baseline on any measures; however, at all subsequent assessments, ILI participants, compared with DSE, significantly increased the number of weeks in which they reported exercising, reducing their calorie and fat intake, and using meal replacements (see Table 3). Practice of all behaviors increased the most during the first year. At years 1, 4, and 8, significantly more ILI than DSE participants also reported measuring their body weight weekly or more often, as well as daily or more often.

Achievement of categorical weight losses in ILI over 8 years

Figure 4a presents the weight loss trajectories of 825 ILI participants who lost 10% of weight at year 1 and qualified for data analysis at year 8 (as described in the Methods). Of these 825 participants, 324 (39.3%) achieved a 10% loss at year 8, 213 (25.8%) a loss of 5 to <10%, 171 (20.7%) a loss of 0 to <5%, and 117 (14.2%) gained above their baseline weight. A comparison of participants who at year 8 maintained the 10% loss versus gained above baseline weight revealed that maintainers reported (at year 8) a higher activity-related energy expenditure (1471.9±121.1 vs. 799.9±100.9 kcal/week, p<0.001) and a greater number of weeks (in the prior year) reducing their calorie and fat intake (both p values <0.001; see Table 4). Weight maintainers also were more likely than full regainers to weigh themselves daily or more often (47.8% vs. 28.4%), as well as weekly or more (82.4% vs. 69.8%) (both ps<0.001).

Figure 4b presents weight loss trajectories of the 633 participants who at year 1 lost 5 to <10% of initial weight and shows that 303 (47.9%) had a loss 5% at year 8. Figure 4c presents similar results for the 656 participants who lost <5% at year 1, of whom 226 (34.5%) achieved a 5% loss at year 8. The odds of achieving a 10% weight loss at year 8 were 2.3 (95% CI: 1.83, 2.97) times greater for participants who at year 1 lost 10%, compared to those who lost 5 to <10%, and 3.9 (95% CI: 2.99, 5.15) times greater compared to those who lost <5% at year 1. The odds of achieving 5% loss at year 8 were 2.1 (95% CI: 1.70, 2.64) times greater for participants who at 1 year lost 10%, compared to those who lost 5 to <10%, and 3.9 (95% CI: 3.10, 4.92) times greater compared to participants who lost <5% at year 1.

DISCUSSION

Look AHEAD is the longest randomized controlled evaluation to date of an intensive lifestyle intervention for weight management. Overweight/obese individuals with type 2 diabetes lost 4.7% of initial body weight at year 8, compared with 2.1% for participants assigned to DSE (i.e., usual care). Fifty percent of ILI participants lost 5% of initial weight, a common criterion of clinically meaningful weight loss,^{7–9} and 26.9% lost 10%. The same statistical differences were observed between the ILI and DSE groups when including or censoring weight losses of participants who had bariatric surgery. The Diabetes Prevention Program Outcomes Study³⁴ reported 10 years of follow-up of a lifestyle weight-loss intervention, but both the lifestyle group and the comparison groups received weight loss counseling after a mean of 3.2 years since randomization.

Look AHEAD's lifestyle intervention was effective over 8 years in both men and women and across an ethnically and racially diverse population. Weight losses of African Americans were among the largest reported in the literature. Older participants also lost more weight than their younger counterparts (as also observed in the DPP³⁵). Some of their weight loss, however, probably was attributable to the combined effects of diabetes³⁶ and aging, since it also occurred in older participants in Look AHEAD's DSE group and in the original placebo-treated group of the Diabetes Prevention Program Outcomes Study.³⁴

Look AHEAD's long-term weight loss maintenance intervention, which included monthly or twice monthly individual contacts combined with periodic group meetings (i.e., refresher groups and national campaigns), was modeled on the DPP^{11,21} and similar protocols.^{30,37} Look AHEAD, however, has demonstrated that the extended provision of a weight loss maintenance intervention can facilitate clinically meaningful weight loss for up to 8 years – two to three times the duration examined in previous randomized trials.^{30,37,38} Sustaining weight loss for longer periods may further improve the prevention of type 2 diabetes in atrisk individuals,³⁴ as well as maintain improvements in sleep apnea,⁵ physical mobility,⁶ and other health conditions ameliorated by weight loss.^{7–9}

ILI participants achieved their maximum weight loss (of 8.5%) in the first year, when they received the most intensive intervention and reported their highest adherence to the prescribed weight control behaviors, compared with DSE. The ILI group, on average, regained weight from years 1 to 5, at which time body weight stabilized at approximately a

4.0–4.7% loss for the remainder of the trial (compared with 0.7–2.1% for DSE at this time). Look AHEAD's large sample size permitted examination of patterns of long-term weight change among subgroups of participants, rather than simply the mean change. This analysis revealed that of 825 individuals who lost 10% of initial weight at year 1, 39% maintained this degree of weight loss at year 8, and another 26% maintained a loss of 5.0 to <10%. Those who maintained the full 10% loss at year 8, compared with those who regained above baseline, reported greater practice of several weight-maintenance behaviors, including high levels of physical activity, reduced calorie intake, and frequent monitoring of body weight. These behaviors have been identified in prior studies of successful weight loss maintainers.^{28–32}

The lifestyle intervention's strengths are offset by findings that 32% of ILI participants did not lose at least 5% of initial weight in the first year, and only 34.5% of these individuals achieved this goal at year 8. Logistic regression analyses clearly revealed the importance of successful first-year weight loss for achieving a clinically meaningful loss at year 8. This finding highlights the need for research on methods of inducing weight loss in persons who do not have an early, favorable response to lifestyle modification.

Nearly 36% of DSE participants achieved a 5% weight loss at year 8, compared with 13.3% at year 1. Several factors may have contributed to more of these participants reaching this criterion over time. DSE participants were permitted, in consultation with their PCPs, to pursue whatever weight loss options they wished. Their weight loss also could have been unintentional³⁹ and reflect the effects of aging⁴⁰ or illness³⁹ (including diabetes³⁶), as discussed with weight loss in older ILI participants.

In summary, Look AHEAD advances the management of obesity by showing that a comprehensive, long-term lifestyle intervention produced 5% weight loss at 8 years in 50% of participants. While efforts clearly are needed to translate the current treatment approach into clinical practice, Look AHEAD provides new optimism for the long-term management of obesity and its many co-morbid conditions that are ameliorated by weight loss.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Appendix

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What is already known about this subject?

The intensive lifestyle intervention (ILI) used in the Look AHEAD study was designed to induce a mean loss of 7% or more of initial weight in overweight/obese individuals with type 2 diabetes and to maintain this loss for up to 11.5 years of follow-up.

As reported previously in *Obesity*, ILI participants achieved a mean loss of 8.6% of initial weight at year 1 and 4.7% at year 4, compared with losses for the usual care group, referred to as diabetes support and education (DSE), of 0.7% and 1.0%, respectively.

At year 4, 46% of ILI participants maintained a loss 5% of initial weight (considered a clinically significant reduction), compared with 25% for DSE.

What does this study add?

The present study reports weight loss at year 8 -- the longest period for a randomized controlled trial -- when ILI participants lost a mean of 4.7% of initial weight, compared with 2.1% for ILI.

At year 8, 50% of ILI and 37% of DSE participants achieved a mean loss 5% of initial weight.

Nearly 40% of ILI participants who lost 10% of initial weight at year 1 maintained this loss at year 8, revealing that long-term weight control is possible with continued practice of skills taught in intensive lifestyle interventions.

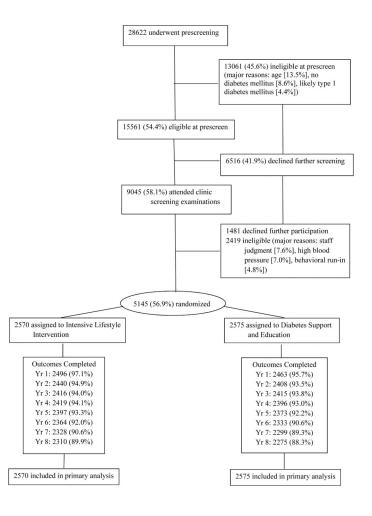


Figure 1.

Flowchart for screening, randomization, and follow-up of participants. Participants who did not complete outcome assessments in years 1 through 8 had either died, withdrawn from the study, or missed the assessment.

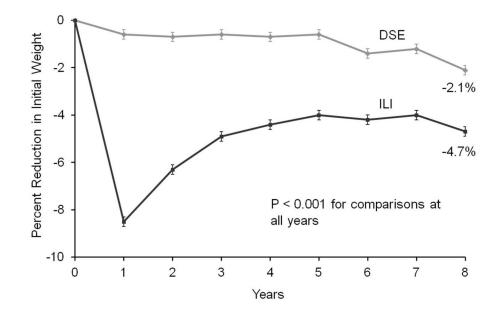
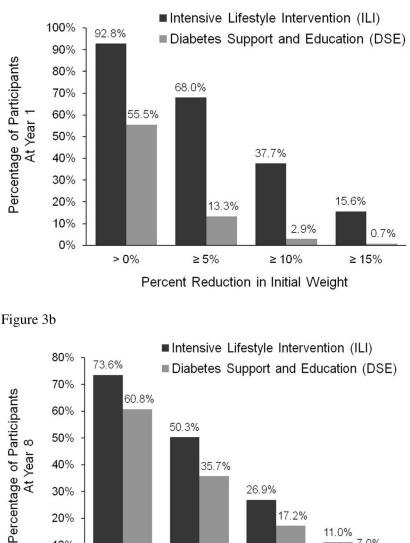
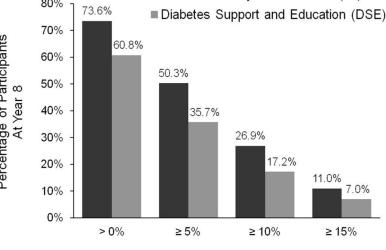


Figure 2.

Figure shows mean (\pm SE) weight losses over 8 years for participants randomly assigned to an intensive lifestyle intervention (ILI) or diabetes support and education (DSE; usual care group). Differences between groups were significant (p<0.001) at all years.







Percent Reduction in Initial Weight

Figure 3.

Figure 3(a). Percentage of participants in the ILI and DSE groups who achieved different categorical weight losses at year 1. The percentages are cumulative such that the 68% of ILI participants who lost 5% or more of initial weight includes those who also lost 10% and 15%. P<0.001 for all comparisons between treatment groups.

Figure 3(b). Percentage of participants in the ILI and DSE groups who achieved different categorical weight losses at year 8. The percentages are cumulative as described for Figure 1(A). P<0.001 for all comparisons between treatment groups.

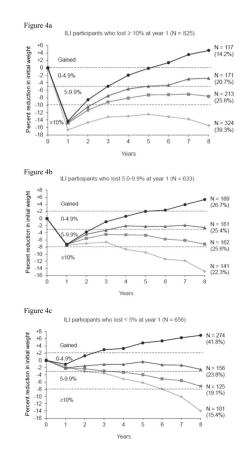


Figure 4.

Figure 4(a). Weight loss trajectories over 8 years in 825 participants in the intensive lifestyle intervention (ILI) who, at year 1, lost 10% of initial weight and, at year 8, provided a measured body weight. The figure shows the number of participants who, at year 8, maintained a loss of 10% or more of initial weight (N=324), of 5.0–9.9% (N=213), of 0– 4.9% (N=171), or who gained above their baseline weight (N=117). The percentages shown in parentheses are based on the sample size for the subgroup. Thus, the 324 of 825 participants who maintained a 10% loss at year 8 comprised 39.3% of this subgroup of participants.

Figure 4(b). Weight loss trajectories over 8 years in 633 ILI participants who, at year 1, lost 5.0–9.9% of initial weight and, at year 8, provided a measured body weight. The four categories of weight change that these participants achieved at year 8 are presented in the same manner as in Figure 4(A).

Figure 4(c). Weight loss trajectories over 8 years in 656 ILI participants who, at year 1, lost <5% of initial weight and, at year 8, provided a measured body weight. The four categories of weight change that these participants achieved at year 8 are presented in the same manner as in Figure 4(A).

Baseline characteristics of participants in the ILI and DSE groups.

Car (no of mhinate)	N = 2,570	N = 2,575	
Dev (IID. DI SUDJecis)			
Female	1526 (59.3)	1537 (59.6)	*200
Male	1044 (40.7)	1038 (40.4)	
Ethnicity			
African American	399 (15.5)	404 (15.7)	
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^{\dagger}
Weight (kg)			
Females	94.8 ± 17.9	95.4 ± 17.3	0.34^{\dagger}
Males	108.9 ± 19.0	109.0 ± 18.0	0.94^{\dagger}
Body mass index (kg/m ²)			
Females	36.3 ± 6.2	36.6 ± 6.0	0.15^{\ddagger}
Males	35.3 ± 5.7	35.1 ± 5.2	0.41^{\dagger}
Body mass index (kg/m ²)			
<30	403 (15.7)	362 (14.1)	0.13
30 to <35	918 (35.7)	899 (34.9)	
35 to <40	672 (26.1)	740 (28.7)	
40	577 (22.5)	574 (22.3)	

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

Table 2

Percent reduction in initial weight in the ILI and DSE groups at years 1, 4, and 8 according to gender, age, and race/ethnicity.

		Year 1			Year 4			Year 8	
Characteristic	III	DSE	p value	III	DSE	p value	ILI	DSE	p value
Total Sample	8.5 ± 0.2	0.6 ± 0.2	<.001	4.4 ± 0.2	0.7 ± 0.2	<.001	4.7 ± 0.2	2.1 ± 0.2	<.001
Gender									
Female	$8.4\pm0.2^{\rm a}$	$0.8\pm0.2^{\rm a}$	<.001	$4.3\pm0.2^{\rm a}$	$4.3\pm 0.2^{a} \qquad 1.1\pm 0.2^{a}$	<.001	$5.1\pm0.2^{\rm a}$	2.6 ± 0.2^{a}	<.001
Male	$8.7\pm0.3^{\rm a}$	$0.3\pm0.3^{\rm a}$	<.001	$4.6\pm0.3^{\rm a}$	$0.1\pm0.3^{\rm b}$	<.001	$4.2\pm0.3^{\rm b}$	$1.3\pm0.3^{\rm b}$	<.001
Age									
45–55 yr	$8.2\pm0.3^{\rm a}$	$0.3\pm0.3^{\rm a}$	<.001	$3.6\pm0.3^{\rm a}$	0.1 ± 0.3^{a}	<.001	$3.8\pm0.3^{\rm a}$	1.2 ± 0.3^{a}	<.001
56–65 yr	8.6 ± 0.2^{ab}	$0.6\pm0.2^{\rm a}$	<.001	$4.4\pm0.2^{\rm b}$	$0.7\pm0.2^{\rm b}$	<.001	4.7 ± 0.2^{b}	$2.2\pm0.2^{\rm b}$	<.001
66–76 yr	$9.1\pm0.4^{\rm b}$	$0.9\pm0.4^{\rm a}$	<.001	$6.0\pm0.4^{\rm c}$	$1.8\pm0.4^{\rm c}$	<.001	$6.8\pm0.4^{\rm c}$	$3.1\pm0.4^{\rm c}$	<.001
Race/Ethnicity									
Non-Hispanic White	$9.4\pm0.2^{\rm a}$	$0.8\pm0.2^{\rm a}$	<.001	4.6 ± 0.2^{a}	$0.8\pm0.2^{\rm a}$	<.001	$4.7\pm0.2^{\rm a}$	2.1 ± 0.2^{a}	<.001
Hispanic	$7.2\pm0.5^{\rm b}$	$-0.0\pm0.5^{\rm a}$	<.001	$4.6\pm0.5^{\rm a}$	0.4 ± 0.5^{a}	<.001	$4.8\pm0.5^{\rm a}$	2.1 ± 0.5^{a}	<.001
African American	6.4 ± 0.4^{bc}	$-0.0\pm0.4^{\rm a}$	<.001	3.8 ± 0.4^{a}	0.7 ± 0.4^{a}	<.001	$5.0\pm0.4^{\rm a}$	$1.8\pm0.4^{\rm a}$	<.001
American Indian/Other	$5.3\pm0.6^{ m c}$	0.2 ± 0.6^{a}	<.001	3.9 ± 0.6^{a}	$0.2\pm0.6^{\mathrm{a}}$	<.001	5.0 ± 0.6^{a}	1.9 ± 0.6^{a}	<.001

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values in DSE were 10, 45, and 84, respectively. Within columns and demographic groupings, values with different superscripts (i.e., a, b, c, etc.) differ significantly from each other. For example, at year 1, underwent bariatric surgery also were censored (at the time of surgery). In ILL, the cumulative numbers of participants who had surgery in years 1, 4, and 8 were 5, 30, and 76, respectively. Corresponding sharing a superscript "ab" with each group). At year 1, there were no significant differences between men and women in ILI, as shown by the shared superscript "a." All analyses were adjusted for clinical ILI participants 45–55 years of age lost significantly less weight than those 66–76 years ("a" vs. "b"), whereas weight loss of those 56–65 year did not differ significantly from either group (as shown by site and baseline weight. Each family of comparisons, at each assessment time, was conducted using the Bonferonni correction. This yielded p<0.05 for comparison of gender, p<0.017 for comparison of at the time of death. Data for participants who different age groups, and p<0.008 for comparison of racial/ethnic groups.

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Table 3

ILI and DSE participants' reports of their physical activity, calorie restriction, and other weight control behaviors.

		Baseline			Year 1			Year 4			Year 8	
Variable	ITI	DSE	p value	ITI	DSE	p value	ILI	DSE	p value	ITI	DSE	p value
Physical activity (kcal/wk)	859.5 ± 31.9	859.5 ± 31.9 862.4 ± 34.3	0.376	1737.8 ± 47.6	968.9 ± 40.9	<.001	1245.4 ± 43.2	974.7 ± 36.0	<.001	1040.2 ± 35.3	853.2 ± 27.3	0.001
Increased exercise (no. wk/yr)	10.3 ± 0.3	10.1 ± 0.3	0.696	35.6 ± 0.4	12.2 ± 0.4	<.001	13.8 ± 0.4	10.2 ± 0.4	<.001	10.9 ± 0.4	8.7 ± 0.4	<.001
Reduced kcal (no. wk/yr)	8.8 ± 0.3	9.3 ± 0.3	0.222	40.1 ± 0.4	12.6 ± 0.4	<.001	21.0 ± 0.4	12.1 ± 0.4	<.001	17.9 ± 0.4	11.0 ± 0.4	<.001
Reduced fat (no. wk/yr)	12.6 ± 0.4	12.8 ± 0.4	0.627	41.2 ± 0.4	16.4 ± 0.4	<.001	24.4 ± 0.5	16.2 ± 0.5	<.001	20.8 ± 0.5	14.1 ± 0.5	<.001
Meal replacements (no. wk/yr)	1.6 ± 0.1	1.6 ± 0.1	0.720	39.0 ± 0.3	3.5 ± 0.3	<.001	24.3 ± 0.4	2.0 ± 0.4	<.001	17.2 ± 0.4	1.8 ± 0.4	<.001
Monitored weight												
Weekly, N (%)	1041 (40.5)	1041 (40.5) 1052 (40.9)	0.798	2290 (91.1)	1085 (43.7)	<.001	1769 (73.1)	1045 (43.5)	<.001	1555 (67.2)	1027 (45.1)	<.001
Daily, N (%)	301 (11.7)	318 (12.3)	0.479	1162 (46.2)	318 (12.8)	<.001	822 (34.0)	315 (13.1)	<.001	754 (32.6)	319 (14.0)	<.001

Year 8 Behaviors Maintained 10% Los Gained Above Baseline Weight P Value Physical activity (kcal/wk) 1471.9 ± 121.2 799.9 ± 100.9 0.001 Reduced Kcal (no. wk/yr) 20.4 ± 1.4 11.9 ± 2.1 <0.01 Reduced fat (no. wk/yr) 20.4 ± 1.4 11.9 ± 2.1 <0.01 Increased exercise (no. wk/yr) 12.9 ± 1.3 8.2 ± 1.8 <0.01 Meal replacements (no. wk/yr) 12.9 ± 1.3 8.2 ± 1.8 0.013 Monitored weight 12.9 ± 1.3 8.2 ± 1.8 0.013 Monitored weight 12.9 ± 1.3 8.2 ± 1.8 0.013 Moekly, N (%) 22.8 ± 2.0 8.3 ± 1.8 0.072 Moekly, N (%) $262.(82.4)$ $81.(69.8)$ 0.01 Moekly, N (%) $152.(47.8)$ $33.(28.4)$ <0.01		Year 8 W	Year 8 Weight Change	
Physical activity (kcal/wk) 1471.9 ± 121.2 799.9 ± 100.9 0.001 Reduced Kcal (no. wk/yr) 20.4 ± 1.4 11.9 ± 2.1 <01 Reduced fat (no. wk/yr) 24.2 ± 1.5 15.6 ± 2.2 <01 Increased exercise (no. wk/yr) 12.9 ± 1.3 8.2 ± 1.8 0.013 Meal replacements (no. wk/yr) 22.8 ± 2.0 17.3 ± 2.9 0.072 Monitored weight $262 (82.4)$ $81 (69.8)$ 0.001 Weekly, N (%) $262 (82.4)$ $81 (69.8)$ 0.001 Values shown are LS means for Paffenbarger) \pm standard error or frequency count (percentage).	1		Gained Above Baseline Weight	P Value
Reduced Kcal (no. wk/yr) 20.4 ± 1.4 11.9 ± 2.1 <001 Reduced fat (no. wk/yr) 24.2 ± 1.5 15.6 ± 2.2 <011 Increased exercise (no. wk/yr) 12.9 ± 1.3 8.2 ± 1.8 0.013 Meal replacements (no. wk/yr) 22.8 ± 2.0 17.3 ± 2.9 0.072 Monitored weight $N(\%)$ 22.8 ± 2.0 $81.69.8$ 0.072 Monitored weight $262 (82.4)$ $81 (69.8)$ 0.001 Veckly, N (%) $152 (47.8)$ $33 (28.4)$ <001 Values shown are LS means for Paffenbarger) \pm standard error or frequency count (percentage). <001		71.9 ± 121.2	799.9 ± 100.9	0.001
Reduced fat (no. wk/yr) 24.2 ± 1.5 15.6 ± 2.2 <001 Increased exercise (no. wk/yr) 12.9 ± 1.3 8.2 ± 1.8 0.013 Meal replacements (no. wk/yr) 22.8 ± 2.0 17.3 ± 2.9 0.072 Monitored weight 17.3 ± 2.9 0.072 Weekly, N (%) $262 (82.4)$ $81 (69.8)$ 0.001 Daily, N (%) $152 (47.8)$ $33 (28.4)$ <001		20.4 ± 1.4	11.9 ± 2.1	<:001
Increased exercise (no. wk/yr) 12.9 ± 1.3 8.2 ± 1.8 0.013 Meal replacements (no. wk/yr) 22.8 ± 2.0 17.3 ± 2.9 0.072 Monitored weight 17.3 ± 2.9 0.072 Monitored weight 17.3 ± 2.9 0.072 Weekly, N (%) $262 (82.4)$ $81 (69.8)$ 0.001 Daily, N (%) $152 (47.8)$ $33 (28.4)$ <001		24.2 ± 1.5	15.6 ± 2.2	<.001
Meal replacements (no. wk/yr) 22.8 ± 2.0 17.3 ± 2.9 0.072 Monitored weightNo $262 (82.4)$ $81 (69.8)$ 0.001 Weekly, N (%) $262 (82.4)$ $81 (69.8)$ 0.001 Daily, N (%) $152 (47.8)$ $33 (28.4)$ $<.001$ Values shown are LS means for Paffenbarger) \pm standard error or frequency count (percentage).		12.9 ± 1.3	8.2 ± 1.8	0.013
Monitored weight $262 (82.4)$ $81 (69.8)$ 0.001 Weekly, N (%) $262 (82.4)$ $81 (69.8)$ 0.001 Daily, N (%) $152 (47.8)$ $33 (28.4)$ <01 Values shown are LS means for Paffenbarger) \pm standard error or frequency count (percentage).		22.8 ± 2.0	17.3 ± 2.9	0.072
Weekly, N (%)262 (82.4)81 (69.8)0.001Daily, N (%)152 (47.8)33 (28.4)<.001	Monitored weight			
Daily, N (%)152 (47.8)33 (28.4)<.001Values shown are LS means for Paffenbarger) \pm standard error or frequency count (percentage).		262 (82.4)	81 (69.8)	0.001
Values shown are LS means (raw means for Paffenbarger) \pm standard error or frequency count (percentage).		152 (47.8)	33 (28.4)	<.001
	Values shown are LS means (raw means fo	or Paffenbarger) ± staı	ndard error or frequency count (per	ccentage).
P values are adjusted for clinical site and baseline value.	P values are adjusted for clinical site and ba			

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