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Intensive Weight Loss Intervention in Individuals Ages 65 Years or Older: Results from the Look AHEAD Type 2 Diabetes Trial

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Abstract

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OBJECTIVES—To compare the relative effects of four years of intensive lifestyle intervention on weight, fitness, and cardiovascular disease risk factors among older versus younger individuals

DESIGN—A randomized controlled clinical trial

SETTING—16 US clinical sites

PARTICIPANTS—Individuals with type 2 diabetes: 1,053 aged 65–76 years and 4,092 aged 45–64 years

INTERVENTIONS—An intensive behavioral intervention designed to promote and maintain weight loss through caloric restriction and increased physical activity compared to a condition of diabetes support and education.

MEASUREMENTS—Standardized assessments of weight, fitness (based on graded exercise testing), and cardiovascular disease risk factors

RESULTS—Across four years, older individuals had greater intervention-related mean weight losses than younger participants, 6.2% versus 5.1% (interaction $p=0.006$) and comparable relative mean increases in fitness, 0.56 versus 0.53 metabolic equivalents (interaction $p=0.72$). These benefits were seen consistently across subgroups of older adults formed by many demographic and health factors. Among a panel of age-related health conditions, only self-reported worsening vision was associated with poorer intervention-related weight loss in older individuals. The intensive lifestyle intervention produced mean increases in high density lipoprotein cholesterol (2.03 mg/dl; $p<0.001$) and decreases in glycated hemoglobin (0.21%; $p<0.001$) and waist girth (3.52 cc; $p<0.001$) across 4 years that were at least as large in older compared to younger individuals.

CONCLUSION—Intensive lifestyle intervention targeting weight loss and increased physical activity is effective in overweight and obese older individuals to produce sustained weight loss and improvements in fitness and cardiovascular risk factors.

Keywords

Behavioral intervention; Weight loss; Physical activity; Type 2 diabetes mellitus; Cardiovascular disease risk factors

INTRODUCTION

The prevalence of US seniors who are overweight or obese and who have type 2 diabetes mellitus (T2DM) has increased rapidly.^{1,2} Several successful trials that have included large numbers of seniors have shown that behavioral interventions benefit blood pressure control,³ physical function,^{4,5} diabetes prevention,⁶ cardiovascular risk factors,^{7–9} and health related quality of life.¹⁰ The Action for Health in Diabetes (Look AHEAD) recently reported that its intensive lifestyle intervention achieved mean weight losses at one and four years of 8.6% and 4.7%, respectively.^{11,12} Because it enrolled a larger cohort of individuals aged 65 years or older than featured in other influential clinical trials of weight loss interventions, its results among this important subgroup warrant focused description because there are many reasons why age may moderate the ability of individuals with type 2 diabetes to be successful with an intensive lifestyle intervention. Aging brings about biologic and

behavioral challenges for successful weight management. Health conditions that may be barriers to increased physical activity, such as musculoskeletal complications, become more prevalent.^{13,14} Older adults may face more frequent relapse due to acute illnesses and chronic disease complications that make it difficult to attend intervention sessions, including decreased visual acuity, declining functional status, and impaired or restricted driving.¹⁵

This manuscript describes secondary analyses of the first four years of the Look AHEAD clinical trial for individuals who were ages 65–76 years at enrollment. Their levels and patterns of weight loss and increased fitness are contrasted with those of younger participants, aged 45–64 years, as are the relative effects of the intervention versus diabetes support and education on cardiovascular risk factors (lipid-lipoprotein levels, blood pressure, glycated hemoglobin (HbA1c), and waist circumference), and medication use. Among the older participants in the intensive lifestyle intervention, we examine whether baseline age-related factors (e.g. physical and mental function, physical conditions, and cardiovascular complaints) influenced the amount of weight loss and degree of improvement in physical fitness.

METHODS

The design and methods of the Look AHEAD trial have been published previously.¹⁶ In brief, Look AHEAD recruited individuals who were 45–76 years of age and had a body mass index ≥ 25 kg/m² (≥ 27 kg/m² in participants on insulin), HbA1c $<11\%$, systolic blood pressure <160 mmHg, diastolic blood pressure <100 mmHg, and triglycerides <600 mg/dl. These individuals underwent a maximal graded exercise test to ensure that exercise could be safely prescribed, completed two weeks of self-monitoring, and attended a diabetes education session prior to randomization. All consent forms were approved by local Institutional Review Boards prior to use.

Interventions

Participants were randomly assigned by center, with equal probability, to an Intensive Lifestyle Intervention (ILI) or a Diabetes Support and Education (DSE) control condition. The ILI included diet modification and physical activity and was designed to induce at least an average 7% weight loss at year 1 and to maintain this weight loss in subsequent years.¹⁷ ILI participants were assigned a calorie goal (1200–1800 based on initial weight), with $<30\%$ of total calories from fat ($<10\%$ from saturated fat) and a minimum of 15% of total calories from protein. The physical activity goal was ≥ 175 minutes of physical activity per week through activities similar in intensity to brisk walking.

Participants in ILI were seen weekly for the first 6 months and 3 times per month for the next 6 months, with a combination of group and individual contacts. During years 2–4, participants were seen individually at least once a month, contacted another time each month by phone or e-mail, and offered a variety of centrally-approved group classes. Although the intervention was not tailored specifically for older adults, a toolbox approach that guided individualized problem solving for all participants who experienced difficulty in achieving study goals was incorporated in the treatment protocol that allowed adjustments to be made for age-related issues.

DSE participants were invited to three group sessions each year.¹⁸ These used standardized protocols with focus on diet, physical activity, or social support. Information on behavioral strategies was not presented and participants were not weighed.

Participants' personal physicians provided all medical care and made changes in medications, with the exception of temporary changes in diabetes medication during periods of intensive weight loss in ILI to avoid and treat hypoglycemia.

Assessments

Annual measurements were obtained by certified staff and self-reported characteristics and conditions were assessed using standardized questionnaires and interviews by staff members who were masked to participants' intervention assignments. Participants brought current prescription medications to update medication records. The Short Form-36 Health Survey (SF-36) was used as a measure of health status.¹⁹ The scales for physical and mental health and the subscales for bodily pain, general health, vitality, and social functioning were dichotomized at their normative means of 50, with scores below 50 indicating relatively worse self-reported health related quality of life. Weight and height were measured in duplicate using a digital scale and stadiometer. Waist girth was measured horizontally at midpoint between highest point of the iliac crest and lowest part of the costal margin. Blood pressure was measured in duplicate using a Dinamap Monitor Pro 100 automated device. Blood specimens were collected after at least a 12-hour fast and were analyzed by the Central Biochemistry Laboratory (Northwest Lipid Research Laboratories, University of Washington, Seattle, WA) using standardized laboratory procedures for measuring HbA_{1c} and high density lipoprotein cholesterol (HDL-C). A maximal graded exercise test was administered at baseline and a submaximal exercise test at years 1 and 4, and on a subset of participants at year 2.²⁰ Changes in fitness were computed as the difference between estimated metabolic equivalents (METs) when the participants achieved or exceeded 80% of age-predicted maximal heart rate (or Borg Rating of Perceived Exertion of 16 if the participant was using beta blocking medication) at baseline and at the subsequent assessment.²¹ One MET is approximately resting metabolism; 4 METs approximates walking on flat ground at just under 4 miles per hour.

Statistical analysis

Our analyses were secondary to the main trial findings of weight losses at Year 4 for the entire cohort.¹² We described baseline characteristics of participants aged 65 years or older by intervention assignment and the distribution of selected health conditions, and contrasted these with younger participants with chi-square and t-tests. We compared the relative intervention effects on weight and physical fitness between older and younger participants using tests of interaction, without and with covariate-adjustment for selected baseline characteristics, based on general linear models for the longitudinal assessments.²² We similarly assessed the impact of interventions on cardiovascular risk factors between older and younger participants and examined relationships that baseline age-related symptoms and health conditions had with relative intervention effects in older versus younger participants. Generalized estimating equations were used to contrast annual prevalence of medication use

over time between intervention conditions and comparisons in the magnitudes of interventions effects between age groups were based on tests of interactions.

RESULTS

Characteristics of participants at the time of enrollment, by age and intervention assignment, are presented in Table 1. Although randomization was not stratified by age, it produced good overall balance between intervention assignments for both age groups in this large cohort. Only two characteristics appeared moderately unbalanced. The ILI arm included slightly more younger individuals with a BMI between 30–34 kg/m² and slightly fewer younger individuals with a BMI between 35–39 kg/m² as compared to DSE. The baseline prevalence of hypertension among older participants differed slightly between intervention groups: 94.0% among DSE participants compared to 89.0% in ILI.

There were much more pronounced differences between younger and older participants (Table 1). Older participants were more likely to be men, to be white, to have hypertension or a history of cardiovascular disease, and to take greater numbers of prescription medications. They also had lower mean body weight and waist girth. Older participants were less likely to have the highest levels of BMI and HbA1c. They had higher mean SF-36 scores on the domains of general health, mental health, social function and vitality than younger participants, but lower mean scores for physical function.

Figure 1a portrays mean weight changes of the older and younger cohorts by intervention assignment over time from general linear models. The ILI produced marked one-year mean weight loss in both age cohorts. Overall, the patterns of weight changes differed over time between age groups (interaction $p < 0.001$). As can be seen qualitatively from the means and standard error bars, there was some regain in both age cohorts over time, however less among the older than younger group. There was little mean weight change among participants assigned to DSE in either age cohort. Overall, the relative intervention effect on weight loss within ILI was slightly greater among older participants: their mean [95% confidence interval] weight loss across the four years was 6.2% [5.5%, 6.9%] compared to 5.1% [4.7%, 5.5%] for younger participants (interaction $p = 0.006$). These translate to average differences of 6.2 [5.4, 7.0] versus 5.1 [4.7, 5.5] kilograms of relative weight loss. This pattern was apparent in each individual year.

Figure 1b portrays the mean changes in fitness over time based on graded exercise testing. Within both age groups, individuals assigned to the ILI had better relative fitness than those assigned to DSE (both $p < 0.001$). Averaged across the four years, these mean [95% confidence interval] differences were 0.56 [0.41, 0.71] METS for older participants compared to 0.53 [0.45, 0.61] METS for younger, however the magnitudes of these differences were similar between age groups (interaction $p = 0.72$). Qualitatively, older individuals assigned to the ILI had marked gains in fitness at Year 1 that were largely maintained at Year 2, but were essentially lost by Year 4. Younger participants assigned to the ILI had larger Year 1 gains in fitness than older ILI participants, and younger participants had not returned to baseline levels by Year 4. In weight and fitness were correlated within each age cohort. At four years, these correlations were $r = -0.36$ for older

individuals and $r = -0.34$ for younger individuals (both $p < 0.001$) and did not differ between the age groups ($p = 0.56$).

Table 2 describes the consistency of relative intervention effects on weight and fitness, averaged over four years, among subgroups of older participants. Intervention effects were similar for most subgroups, with a few notable exceptions. There was a strong graded relationship for greater weight loss among older participants assigned to ILI who had lower HbA1c levels at baseline ($p < 0.001$). There was also some evidence that mean weight loss was greater among non-Hispanic white and Hispanic participants compared to other race/ethnicity groups (overall differences among race/ethnic groups $p = 0.04$) and that fitness improvements were greater among men and among individuals with poorer general health and greater social function at baseline ($p = 0.05$).

At baseline, participants were queried on the prevalence of physical, cardio/respiratory, and other age-related health conditions. In this generally healthy cohort of volunteers with diabetes who had passed a maximal GXT, severe conditions at baseline were rare. The most prevalent symptoms of any level of severity were shortness of breath with exercise (42.5%), swelling of feet or ankles (38.9%), and leg or arm pain after exercise (30.9%). The relative intervention effects on weight and fitness were not significantly associated with any of the self-reported conditions, except for worsening eyesight, which was reported by 24.2% of the cohort. The relative intervention effect on weight for older participants who had reported worsening eyesight was smaller than for participants who had reported no worsening vision, averaging 1.35% (standard error = 0.60%) less across follow-up ($p = 0.001$). This association was independent of baseline HbA1c and remained fairly stable across all four years ($p = 0.42$).

Table 3 reports the mean relative intervention effects (averaged across Years 1–4) on HDL-C, systolic blood pressure, HbA1c, and waist circumference for the two age cohorts. For HDL-C ($p = 0.002$) and waist circumference ($p = 0.01$) there appeared to be greater intervention-related benefits among older participants. For systolic blood pressure, the mean benefits were slightly greater among younger participants; however, the interaction between intervention and age was not statistically significant ($p = 0.29$). There was a trend for greater benefit on HbA1c among older participants ($p = 0.08$).

Use of lipid lowering medications rose substantially over the four years in both age cohorts and both study arms. ILI was associated with less lipid medication use among younger ($p = 0.003$) but not older ($p = 0.52$) participants; however, the relative magnitudes of these intervention effects did not vary significantly (interaction, $p = 0.50$). Covariate adjustment for changes in the prevalence of lipid lowering medication use over time did not account for the differential intervention effect on HDL-cholesterol.

Use of antihypertensive medication increased slightly over the four years in both age cohorts and both intervention arms. ILI was associated with relatively less antihypertensive use among older ($p = 0.03$) but not younger ($p = 0.78$) participants (test for interaction $p = 0.04$). Covariate adjustment for changes in the prevalence of antihypertensive medications over time did not materially affect interventions effects on systolic blood pressure in Table 3.

Use of insulin rose among older DSE participants, from 17% at baseline to 23% at Year 4, and dropped slightly among older ILI participants from 14% at baseline to 13% at Year 4 (differences between intervention groups at Year 4 between groups after controlling for baseline use, $p<0.001$). Use of insulin rose among younger DSE participants, from 16% at baseline to 23% at Year 4, and among younger ILI participants from 15% at baseline to 18% at Year 4 ($p<0.001$). Across the four years and compared to DSE, ILI was associated with relatively less insulin use among both the older ($p=0.002$) and younger ($p<0.001$) participants; these intervention effects were similar ($p=0.43$). Use of diabetes medications in DSE and ILI rose in both groups. Across the four years, ILI was associated with relatively less total diabetes medications use among both the older ($p<0.001$) and younger ($p<0.001$) participants, with a slightly more pronounced intervention effect among the older participants ($p=0.05$). Covariate adjustment for changes in the prevalence of insulin and oral diabetes medications use over time did not materially affect intervention effects on HbA1c in Table 3.

DISCUSSION

In this large and diverse cohort of individuals with type 2 diabetes mellitus, the intensive lifestyle intervention was successful in producing sustained relative reductions in weight and increases in fitness across four years among older adults. These were comparable to or slightly larger than effects observed in younger participants across clinically important subgroups with little variation in magnitude. These changes occurred in spite of the age-related health conditions that were prevalent among the older Look AHEAD participants. The only exception was relatively less intervention-related weight loss among individuals who reported worsening vision at baseline. The Look AHEAD intervention was effective in inducing larger relative improvements in HDL-C and waist circumference among older compared to younger participants with similar reductions in HbA1c and systolic blood pressure in the two groups.

Intervention-related changes in weight and fitness

Lifestyle interventions have repeatedly been shown to be effective in promoting weight loss among older individuals. A meta-analysis of nine clinical trials found an average intervention effect of 3.0 kg at 12 months, with increasing weight losses achieved when physical activity and dietary advice were combined with evidence for maintenance through 3 years.²³ More recent studies have achieved greater mean weight losses through enhanced physical activity interventions,²⁴ dietary control,²⁵ or combined diet and physical activity intervention,⁵ and weight loss interventions have been successfully translated to community settings.²⁶ The Look AHEAD intervention achieved a weight loss at one-year that was comparable or superior to these prior trials. Look AHEAD's demonstration that substantive differences in weight and fitness can be sustained through four years in older individuals with type 2 diabetes is unprecedented.

The response of older individuals to the Look AHEAD intervention is consistent with the Diabetes Prevention Program, which found greater weight losses and self-reported hours of physical activity among older compared to younger individuals.⁶ Older Look AHEAD

participants improved their fitness at a level comparable to younger participants, even though they may not have exercised as vigorously as those who are younger. This echoes findings by Blumenthal and colleagues, who reported that older adults with cardiovascular disease made comparable improvements in fitness regardless of whether they exercised at low or high intensity.²⁷

We can only speculate why older adults in Look AHEAD were so successful in response to the lifestyle intervention. One possibility is that they have more time to dedicate to lifestyle change and found involvement in these types of interventions to be stimulating. A second possibility may be that older adults are more attuned to declining health status and are more motivated to engage in self-management behavior. Whatever the cause, it is encouraging to find that older adults are responsive to and successful in making behavior change for important health behaviors.

Of the age-related complications we considered, only worsening eyesight was found to be related to reduced intervention effectiveness. Others have reported that vision loss is associated with obesity, reduced mobility, and lower physical activity.^{28–30} Compromised vision is associated with poorer adherence to prescribed medications, as well,³¹ which may reflect barriers in following written instructions and guidelines.

Changes in cardiovascular risk factors

Lifestyle interventions have repeatedly been shown to be effective in improving individual cardiovascular risk factors in trials that were limited to or included large numbers of younger individuals.^{7,8,32,33} However, a recent meta-analysis concluded that there was not consistent evidence to support weight loss programs in older obese individuals.²³ Across the nine trials the authors selected, no significant overall benefits for HDL-C or HbA1c were found. Only one of two studies found a significant benefit for blood pressure: in the large Trial of Nonpharmacologic Intervention in the Elderly, mean blood pressure was significantly reduced (4.0/1.1 mmHg versus 0.8/0.8 mmHg) and the ability to control hypertension without medications over 30 months was enhanced (odds ratio=0.70) among participants assigned to weight loss intervention (all $p<0.001$).³

Importantly, the Look AHEAD intervention was found to produce sustained benefits in HDL-cholesterol, HbA1c, and waist circumference that were as large or larger among older, compared to younger, individuals. Benefits in systolic blood pressure did not reach statistical significance in the older cohort; however, the intervention was associated with significantly greater reductions in the use of antihypertensive medications among older compared to younger individuals. In addition, older individuals had greater reductions in the use of diabetes medications and comparable benefits on lipid lowering medications and insulin. The large sample size, sustained weight losses, and increased levels of physical activity achieved by the Look AHEAD trial may be important for establishing these benefits.³⁴ Whether these translate to reduced risks for major cardiovascular events in older individuals will be reported at the trial's conclusion.

Limitations

Look AHEAD participants were volunteers with type 2 diabetes and were selected to be good candidates for a randomized clinical trial. They had successfully completed a maximal graded exercise test and had a source of medical care. Thus, the results we report may not generalize to other cohorts or interventions. Look AHEAD did not enroll participants over 76 years of age.

Summary

Behavioral weight loss interventions can produce sustained meaningful differences in weight and fitness that remain through 4 years of intervention in overweight and obese individuals aged 65–76 years who have type 2 diabetes. Their effectiveness can be robust across many characteristics and health-related conditions among individuals. Sustained differences in HDL-C, waist girth, HbA1c, and medication use across 4 years can be produced that are comparable to or exceed those seen in younger individuals.

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CLINICAL SITES

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Figure 1a:

Figure 1b:

Figure 1.

Figure 1a. Mean ($\pm$ standard error) percent weight change from baseline for participants grouped by intervention assignment and age cohort. Included are results from a test of averaged differences between intervention groups for each age cohort and a comparison of the averaged relative intervention effect between age cohorts. Annual exam times have been offset to avoid overlap.

Figure 1b. Mean ($\pm$ standard error) change in fitness as measured by metabolic equivalents (METS) from baseline for participants grouped by intervention assignment and age cohort. Included are results from a test of averaged differences between intervention groups for each

age cohort and a comparison of the averaged relative intervention effect between age cohorts. Annual exam times have been offset to avoid overlap. One metabolic equivalent MET is the amount of energy consumed during rest. When individuals such as those in Look AHEAD walk for exercise, the metabolic requirement is between 3 and 4 METS (or 3 to 4 times what they use when at rest).

Table 1

Characteristics of Look AHEAD (Action for Health in Diabetes) participants aged 65 years or over at baseline included in analysis: by intervention assignment.

Baseline characteristic	Ages 45–64 At Enrollment			Ages 65–76 at Enrollment			Difference Between Age Cohorts p-value
	Diabetes Support and Education N=2022	Intensive Lifestyle Intervention N=2072	Difference Between Intervention Groups p-value	Diabetes Support and Education N=553	Intensive Lifestyle Intervention N=500	Difference Between Intervention Groups p-value	
Sex, %							
Female	62.4	62.2	0.93	49.9	47.6	0.45	<0.001
Race/Ethnicity, %							
African-American	16.4	16.2		13.0	12.8		
Asian/Pacific Islander	0.8	1.2		0.7	0.8		
Hispanic	14.2	14.7	0.90	9.4	7.0	0.75	<0.001
Native American	5.5	5.5		3.1	3.4		
Non-Hispanic White	61.1	60.4		71.6	74.4		
Other / Multiple	1.9	2.0		2.2	1.6		
Body mass index (kg/m ²), %							
25–29	12.5	14.2		19.7	21.8		
30–34	32.8	34.6	0.02	42.5	40.8	0.14	<0.001
35–39	30.6	26.3		21.9	25.6		
40	24.0	25.0		15.9	11.8		
Weight (kg), Mean (SD)	101.9 (19.1)	101.6 (20.3)	0.62	96.9 (17.4)	96.2 (16.3)	0.47	<0.001
Waist girth (cm), Mean (SD)	114.5 (13.7)	114.1 (14.8)	0.46	112.6 (13.0)	112.4 (12.4)	0.77	<0.001
HbA1c ^a (%), %							
<7.0	43.6	46.2		50.4	47.8		
7.0–8.9	30.7	29.4	0.24	32.2	34.0	0.69	<0.001
9.0–11.0	25.7	24.4		17.4	18.2		

Baseline characteristic	Ages 45–64 At Enrollment			Ages 65–76 at Enrollment			Difference Between Age Cohorts p-value
	Diabetes Support and Education N=2022	Intensive Lifestyle Intervention N=2072	Difference Between Intervention Groups p-value	Diabetes Support and Education N=553	Intensive Lifestyle Intervention N=500	Difference Between Intervention Groups p-value	
Insulin Use							
Yes	15.6	15.0	0.62	16.8	13.8	0.18	0.94
Hypertension							
Yes	80.8	83.1	0.05	94.0	89.0	0.003	<0.001
Prior cardiovascular disease							
Yes	10.5	11.0	0.66	24.4	27.8	0.21	<0.001
Depression							
Beck > 4	49.0	49.1	0.94	47.8	45.9	0.53	0.22
SF-36 ^a , Mean (SD)							
General Health	46.5 (8.9)	46.5 (9.2)	0.85	49.7 (7.6)	49.4 (7.9)	0.54	<0.001
Mental	53.3 (8.0)	53.0 (8.3)	0.22	55.6 (7.0)	55.2 (7.0)	0.47	<0.001
Pain	50.9 (8.7)	50.5 (8.6)	0.12	50.4 (8.8)	50.5 (9.3)	0.85	0.43
Physical	49.3 (7.6)	49.2 (7.7)	0.62	47.6 (8.3)	48.2 (7.5)	0.22	<0.001
Social Function	52.0 (7.6)	51.7 (8.1)	0.23	53.4 (6.6)	53.0 (6.7)	0.39	<0.001
Vitality	52.9 (9.0)	52.6 (9.3)	0.09	54.2 (8.0)	53.9 (8.7)	0.52	<0.001
Prescription drugs							
0–2	31.8	31.3		22.1	22.0		
3–4	38.2	38.2	0.94	40.1	39.4	0.96	<0.001
5	30.1	30.5		37.8	38.6		

^a Glycated hemoglobin

^b Short Form-36 Health Survey

Table 2

Relative effectiveness of intensive lifestyle interventions on weight and fitness changes among individuals aged 65 years for subgroups based on characteristics at the time of enrollment.

	Relative Differences In Mean Percent Weight Losses Over Time: ILI ^a minus DSE ^a		Relative Differences In Mean Fitness (METS ^c) Gains Over Time: ILI minus DSE	
	Mean (SE)	p-value	Mean (SE)	p-value
Sex				
Female	6.03 (0.48)	0.30	0.48 (0.10)	0.05
Male	6.70 (0.46)		0.74 (0.10)	
Race/Ethnicity				
African-American	4.42 (0.90)	0.04	0.26 (0.18)	0.05
Asian/Pacific Islander	4.42 (3.82)		1.70 (0.73)	
Hispanic	6.03 (1.14)		0.39 (0.24)	
Native American	3.29 (1.78)		0.26 (0.36)	
Non-Hispanic White	6.92 (0.39)		0.70 (0.09)	
Other / Multiple	4.31 (2.29)		0.03 (0.24)	
Body mass index, (kg/m ²)				
25–29	4.98 (0.71)	0.07	0.40 (0.15)	0.32
30–34	6.40 (0.51)		0.68 (0.11)	
35–39	7.97 (0.83)		0.73 (0.14)	
40	7.61 (0.97)		0.60 (0.19)	
HbA1c ^d (%)				
<7.0	7.77 (0.47)	<0.001	0.67 (0.10)	0.74
7.0–8.9	4.98 (0.56)		0.59 (0.12)	
9.0–11.0	5.35 (0.78)		0.54 (0.17)	
Insulin Use				
No	6.54 (0.37)	0.12	0.62 (0.08)	0.69
Yes	5.15 (0.84)		0.55 (0.18)	
Hypertension				
No	6.12 (1.16)	0.79	0.43 (0.23)	0.40
Yes	6.45 (0.36)		0.63 (0.08)	
Prior cardiovascular disease				
No	6.44 (0.39)	0.85	0.63 (0.09)	0.94
Yes	6.31 (0.64)		0.61 (0.14)	
Depression				
Beck >4	6.77 (0.46)	0.21	0.60 (0.10)	0.74
Beck ≤ 4	5.96 (0.49)		0.64 (0.11)	

	Relative Differences In Mean Percent Weight Losses Over Time: ILI ^a minus DSE ^a		Relative Differences In Mean Fitness (METS ^c) Gains Over Time: ILI minus DSE	
	Mean (SE)	p-value	Mean (SE)	p-value
SF-36 ^e General Health				
<50	6.42 (0.51)	0.93	0.77 (0.11)	0.05
50	6.36 (0.44)		0.51 (0.10)	
SF-36 Mental				
<50	5.02 (0.83)	0.07	0.54 (0.17)	0.62
50	6.64 (0.37)		0.63 (0.08)	
SF-36 Pain				
<50	6.98 (0.52)	0.12	0.60 (0.11)	0.82
50	5.96 (0.43)		0.63 (0.09)	
SF-36 Physical				
<50	7.01 (0.49)	0.08	0.62 (0.11)	0.99
50	5.89 (0.45)		0.62 (0.10)	
SF-36 Social Function				
<50	5.88 (0.77)	0.46	0.35 (0.16)	0.05
50	6.50 (0.38)		0.68 (0.08)	
SF-36 Vitality				
<50	6.51 (0.60)	0.79	0.68 (0.13)	0.55
50	6.33 (0.41)		0.59 (0.09)	
Prescription drugs				
0–2	6.38 (0.70)		0.51 (0.14)	
3–4	5.84 (0.52)	0.33	0.57 (0.11)	0.39
5	6.99 (0.53)		0.73 (0.12)	

^a Intensive Lifestyle Intervention

^b Diabetes Support and Education Intervention

^c Metabolic equivalents

^d Glycated hemoglobin

^e Short Form-36 Health Survey

Table 3

Mean relative effect of the intensive lifestyle intervention, compared to diabetes support and education, on HDL-cholesterol, systolic blood pressure, hemoglobin A1c, and waist circumference over time by age cohort.

Cardiovascular Disease Risk Factor	Relative Intervention Effect (ILI ^d minus DSE ^e) Mean (Standard Error)	p-value for Intervention Effect	Consistency of Intervention Effects Across Age p-value for Interaction
High density lipoprotein cholesterol, mg/dl			
45–64 yrs	0.94 (0.16)	0.007	0.002
65–76 yrs	2.03 (0.31)	<0.001	
High density lipoprotein cholesterol, mg/dl ^a			
45–64 yrs	0.94 (0.16)	<0.001	0.002
65–76 yrs	2.01 (0.31)	<0.001	
Systolic blood pressure, mmHg			
45–64 yrs	–1.97 (0.45)	<0.001	0.29
65–76 yrs	–0.93 (0.71)	0.30	
Systolic blood pressure, mmHg ^b			
45–64 yrs	–1.33 (0.70)	0.06	0.25
65–76 yrs	–0.19 (0.72)	0.79	
Glycated hemoglobin (HbA1c), %			
45–64 yrs	–0.12 (0.03)	<0.001	0.08
65–76 yrs	–0.21 (0.05)	<0.001	
Glycated hemoglobin (HbA1c), % ^c			
45–64 yrs	–0.29 (0.04)	<0.001	0.13
65–76 yrs	–0.17 (0.04)	<0.001	
Waist girth, cc			
45–64 yrs	–2.46 (0.19)	<0.001	0.01
65–76 yrs	–3.52 (0.37)	<0.001	

^aWith covariate adjustment for changes in use of lipid-lowering medications over time

^bWith covariate adjustment for changes in use of antihypertensive medications over time

^cWith covariate adjustment for changes in use of insulin and oral diabetes medications over time

^dIntensive Lifestyle Intervention

^eDiabetes Support and Education Intervention