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Long-term sustained effects of the Look AHEAD lifestyle intervention on body composition among adults with type 2 diabetes

Maxine Ashby-Thompson, EdD^{1,2}, Stanley Heshka, PhD¹, Andrea Anderson, MS³, Henry Pownall, PhD⁴, Blandine Laferrière, MD, PhD^{1,5}, Ashok Balasubramanyam, MD⁶, Steven B. Heymsfield, MD⁷, Thomas Wadden, PhD⁸, Dymrna Gallagher, EdD^{1,5,9}, Look AHEAD Research Group*

¹New York Nutrition Obesity Research Center, Columbia University

²Dept. Of Pediatrics, Molecular Genetics, College of Physicians and Surgeons, Columbia University

³Dept. of Biostatistics and Data Science, Wake Forest University School of Medicine

⁴The Methodist Hospital Research Institute, Houston, Texas

⁵Division of Endocrinology, Dept. of Medicine, Columbia University Irving Medical Center

⁶Dept. of Medicine, Endocrinology, Diabetes and Metabolism, Baylor College of Medicine

⁷Pennington Biomedical Research Center, Baton Rouge, LA

⁸Dept. of Psychiatry, Perelman School of Medicine, University of Pennsylvania

⁹Institute of Human Nutrition, Columbia University

Abstract

Objective: To test whether there are sustained effects of the Look AHEAD intensive lifestyle intervention (ILI), vs diabetes support and education (DSE), on weight and body composition 12–16 years after randomization.

Research Design and Methods: Participants were a subset of enrollees in the Look AHEAD DXA substudy that completed the final visit, comprised of men (DSE=99; ILI=94) and women (DSE=134; ILI=135) with type 2 diabetes, mean (\pm SD) age 57.2 \pm 6.4 years and BMI 34.9 \pm 5.1 kg/m² at randomization. Dual energy x-ray absorptiometry measured total and regional fat and lean masses at randomization, Years 1, 4, 8 and final visit. Linear mixed-effects regressions were applied with adjustment for group, clinic, sex, age, race/ethnicity, and baseline body composition.

Address correspondence to: Dr. Dymrna Gallagher, Body Composition Unit-New York Nutrition Obesity Research Center, Columbia University, 21 Audubon Ave, Suite SB-0133, New York, New York 10032. dg108@columbia.edu.

*See online Supporting Information Appendix for full list of Look AHEAD Research Group.

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Results: Weight and most body compartments were reduced by 2–8% (and BMI 4%) in ILI versus DSE, in men but not women. ILI-induced loss of lean tissue did not show a lower percent lean mass versus DSE at 16 years post randomization.

Conclusion: ILI-related changes in weight, fat, and lean mass were detectable 12–16 years after randomization in men but, for unknown reasons, not in women. There was no evidence that the intervention led to a disproportionate loss of lean mass by end of study.

Keywords

obesity; body composition; weight loss maintenance

INTRODUCTION

The prevalence of obesity in the US adult population is around 42%.¹ Lifestyle modification, a first-line intervention to induce weight loss, improves metabolic markers,^{2,3} but maintenance of reduced weight continues to be a challenge.^{4–8} Important clinical questions include how the distribution of excess adiposity, and the effects of weight loss interventions differentially influence body composition compartments; specifically, how do interventions change the amount of total and regional fat and lean mass, known to be related to indicators of health status. Long-term randomized studies of changes in body composition and metabolic health markers can address these questions.

The Look AHEAD trial provided an opportunity for such an investigation. The randomized trial design and protocol have been described elsewhere.⁹ In year 1, Look AHEAD provided an intensive lifestyle intervention (ILI) designed for weight loss and increased physical activity, compared to diabetes support and education (DSE) control. ILI participants received additional weight-loss maintenance therapy for up to 10 years. The protocol, which provided for repeated dual-energy X-ray absorptiometry (DXA) body composition measurements at four sites on a subset of 1,200 participants (out of 5,145), has been described.^{9,10}

Previous publications have reported weight and body composition changes at intervals of 1, 2, 4, and 8 years following randomization^{2,11–16} and weight changes at up to 6 years after termination of the intervention phase.^{17–19} At year 8, fat mass (FM) was smaller in women in the ILI group than in the DSE group, while men in ILI had less lean mass (LM, body weight minus fat mass and bone mineral) than men in DSE.¹⁵ A weight difference of 3.3 kg remained between the ILI and DSE groups.¹⁶ Regional analyses revealed less fat in all regions (arms, trunk, legs) for women in ILI versus DSE but only in legs for men in ILI vs DSE; there was less trunk LM in women in ILI but no significant regional LM differences in men. One study investigated the relationship of adipose tissue changes with metabolic markers after year 1 of Look AHEAD and reported significant associations for 8 of the 9 markers studied.²

After the ILI and randomized trial were terminated (for statistical futility for its primary CVD outcome) in September 2012, Look AHEAD continued data collection as an observational study for approximately 8 years, or ~12–16 years after randomization (see

detailed timeline¹⁸). We use data from this extended observational period to investigate body composition changes at the final visit, 12–16 years after randomization.

This study's aim was to test the hypothesis that there would be sustained effects of the ILI on weight and DXA-measured total and regional FM and LM, compared to DSE, at 12–16 years after randomization (a median of 6 years after termination of the weight-loss intervention).

METHODS

Study design and participants

The study design and enrollment criteria of the Look AHEAD trial have been published.⁹ Briefly, Look AHEAD was a 16-center, randomized controlled trial designed to test the effects on cardiovascular morbidity and mortality of an intensive lifestyle intervention intended in Year 1 to produce 5–10% weight loss and increased physical activity versus DSE among 5,145 adults ages 45 to 76 years with type 2 diabetes, and a body mass index (BMI) of ≥ 25 kg/m² (or ≥ 27 kg/m² if receiving insulin). In Years 2–8, the ILI focused on maintaining weight loss and high levels of physical activity (175 minutes/week of moderate intensity activity and 10,000 steps/day). Protocol and consent forms were approved by institutional review boards and participants provided informed consent. General medical and diabetes care were provided by participant's non-study health care providers. All Look AHEAD participants alive at the end of the trial when the intervention was stopped, were invited to join a follow-up observational study to determine the longer-term effects of the intervention on several outcomes. A total of 1,201 participants received DXA scans at baseline at the 4 sites (Baton Rouge, Boston, Houston, and Seattle) and 1,020 had a baseline and at least one follow-up DXA scan. The consort diagram for the DXA substudy is presented in Supplemental Figure 1. After removing 46 (5%) participants who underwent bariatric surgery, 974 (492 DSE; 482 ILI) remained. Of these, 462 (DSE: 233; ILI: 229) had body composition measured at a final visit, through June 2020, when the median follow-up was 6 years after termination of the weight-loss intervention phase (or after 12–16 years of follow-up after randomization). This paper reports on the 462 participants with body composition measures at baseline and final visit.

Measures

Body Composition: Body composition was measured by DXA at four Look AHEAD sites, using Hologic (QDR-4500A) fan beam densitometers at baseline, years 1, 4, 8 and final visit. The principles of the DXA methodology provide a 2-compartment measurement of FM and fat free mass (FFM) at the molecular level, and the FFM component can be subdivided into bone mineral and lean soft tissue. LM is calculated as the difference between FFM and bone mineral content. The coefficient of variation (CV) for FM is 1.5% in persons with and without obesity; CV for LM is 0.45% in lean and 0.80% in participants with obesity.²⁰ Software upgrades during the study were approved and monitored by a central DXA reading center (Prevention Sciences Group, University of California at San Francisco). Participant scans were centrally monitored for quality of acquisition and analysis. A set of traveling cross calibration phantoms (spine, hip, linearity, and whole-body) was regularly

scanned on all densitometers to assess differences across machines. Longitudinal corrections were applied to body composition results based on the whole-body phantom. Whole body results were corrected for underestimation of FM using Hologic software.²¹ Regions of interest (leg, trunk, arm) set by the Hologic software were adjusted by the DXA operator if the software failed to achieve the standard demarcations. The arm boundary is a line bisecting the shoulder joint, and the leg boundary is a line bisecting the femoral neck.¹⁶ Participants weighing >300 pounds and those with soft tissue that extended beyond the scan field-of-view were excluded.

Anthropometrics: Height (cm) was measured at study entry only using a stadiometer.²² Weight (kg) was measured at baseline and during annual follow-up using a digital scale. Height and weight were each measured in duplicate, and the average value was used for analysis.

Other measures: At baseline, 78% of the women in our sample had gone through menopause. Descriptions of diet and physical activity in subsamples of the Look AHEAD participants, which provide some context for this study, have been published.^{23,24}

Statistical Analysis

Changes in weight, FM and LM totals, and regions (arm, leg, trunk) expressed as absolute values (kg) were calculated for sex and treatment groups. Such tabulations include variability due to study center, which was addressed with longitudinal general linear models that provided least squares estimates of the changes in body composition totals and regions adjusted for study center and missed visits at the time points of interest. Analyses were stratified by sex following previous reporting practice in Look AHEAD body composition reports. Treatment differences in totals and regions were tested with contrasts. In other models, when appropriate, age, baseline characteristics, ethnicity, and sex were investigated as covariates.

Analyses were conducted with SAS 9.4 (SAS Institute, Cary, NC), and $p < 0.05$, two-tailed significance level. These post-hoc exploratory analyses were not adjusted for multiple testing.

RESULTS

Demographic and body composition baseline characteristics of participants in the DXA subgroup who completed the final visit (BL-C) and those who did not complete (BL-NC) are presented in Table 1. Comparison of BL-C vs BL-NC in women found age related to attrition, with completers ~3 years younger than non-completers. The male groups showed a similar bias for younger participants to remain in the study. However, there were also reliable differences in total fat mass ($p < 0.05$) resulting from differences in arm and trunk regions ($p < 0.05$) and similar trends in leg fat, but no significant differences in total or regional lean mass. These results, along with comparisons on waist circumference and BMI, indicate that men with greater body weight/BMI were more likely to leave the trial before the year 12–16 follow-up.

Table 1 also presents body composition measures at baseline and final visit (Final) for those cases where both measures are available. Significant differences over time were found for both sexes and treatment arms. The magnitude of the changes within each group and comparison of the changes between groups are discussed in the results of the longitudinal regression models.

Changes in weight, total and regional fat mass, and lean mass from baseline to Year 12–16

The trajectories of changes in total body fat mass (FM) and soft tissue lean mass (LM) throughout the entire study period for participants who made baseline, year 8, and a final visit are shown in Figures 1A and 1B. These figures extend the trajectories beyond year 8 to the final visit at 12–16 years. They show trends for decreasing body fat and, with the exception of women in ILI, decreasing lean mass in all groups from year 8 to final visit.

Results of linear regression models estimating body composition and weight changes from baseline to final visit by treatment group and sex are shown in Table 2. Among men, the ILI group lost an average of 3.63 kg more weight than DSE, with significantly greater losses of both FM and LM. Compared to DSE, men in the ILI group lost more FM in arms and legs and lost more LM in legs and trunk. Expressed as percentages of the mass at final visit, the ILI/DSE differences were ~4% of weight, 7–8% of total and regional fat, and 2–3% of total and regional lean mass, except for trunk fat and arm lean where changes were not significantly different. Women in ILI and DSE groups did not differ in amounts of lost weight, FM or LM. Both groups of women had less fat and lean mass compared to baseline; men had similar losses except that FM change in DSE was not significant.

Since changes in both fat and lean compartments were observed, and loss of lean mass is an issue with intentional weight loss, the proportion of body weight as lean mass at final visit for DSE and ILI was calculated using values of lean mass and weight in Table 1. The unadjusted proportions of lean mass were 0.525 (i.e., 47.5/90.5) for women in DSE and 0.534 for women in ILI, and 0.622 for men in DSE and 0.627 for men in ILI. Next, changes in percent total body fat (percent final minus percent baseline) adjusting for baseline percent fat, age, ethnicity and clinical site for men and women were calculated. Model estimates indicated small decreases in percent fat in women in ILI (LS mean (se): ILI -0.86 (0.4)%, $p < 0.05$; DSE -0.54 (0.4)%, $p = 0.2$), and small increases in men in DSE (ILI 0.51 (0.5)%, $p = 0.35$; DSE 1.18 (0.5)%, $p = 0.02$). The differences in changes between treatment groups were not significant ($p = 0.48$, women, $p = 0.17$, men). Models indicated that baseline percent fat influenced amount of change in both sexes (coefficients -0.16 for men, -0.28 for women, both $p < 0.01$) with higher baseline percent fat associated with smaller increases or larger decreases in percent fat.

To investigate further how percent lean mass was related to weight change during the trial we selected the 10% ($N = 46$) of our sample with the largest weight loss (> 19 kg) between randomization and final visit and compared their change in body composition with that of the remaining 90%. The large weight losers increased in percent lean mass compared to the remainder of the sample (men $5.0 \pm 3.9\%$ vs $-0.7 \pm 3.8\%$, $N = 13$ vs 178; $p < 0.001$; women $6.8 \pm 3.1\%$ vs $0.6 \pm 3.9\%$, $N = 33$ vs 236; $p < 0.001$ by t-test). This was the case in both ILI and DSE groups.

DISCUSSION

The sustained effects of ILI on body mass at 12–16 years after randomization (a median of 6 years after termination of the intervention phase) were accompanied by parallel changes in most body composition compartments in men but not in women (Table 2). In men the intervention resulted in 2.08 kg less fat mass and 1.07 kg less lean mass than in DSE, about 6% and 2% respectively of mass at the final visit. In women, the weight difference between groups was only 0.45 kg without any difference in any of the body composition compartments. The reason for the small difference in women is unknown but it may be a consequence of an unexpectedly large weight loss in DSE, consisting of 3.29 kg fat loss and a 1.93 kg lean mass loss. A possible explanation lies in the trajectories of weight change with aging observed in the American population²⁵ where the rate of weight loss in women with BMI >30 kg/m², ages 60 to 70 was twice that of men. The earlier losses by men and women in the ILI groups resulting from the intervention (~7–9 kg) were, by the time of the final visit, matched in women in DSE by the expected rapid age-related weight loss for women with BMI >30.

Another notable feature of Table 2 is the large number of body compartments in ILI and DSE that show significant declines in mass (>2 standard errors) from randomization to final visit. While in ILI this could be viewed as a consequence of weight loss treatment, it is also apparent in DSE. These declines may be attributed to age-related loss²⁵ given the mean ages of ~57 years at randomization and ~72 years at final visit. Some losses may result from the progression of participants' diabetes but that cannot be evaluated in the absence of an appropriate control group. Several studies, including Health ABC, have reported on body composition changes in aging patients with and without type 2 diabetes (T2DM).^{26–29}

A weight loss intervention such as the ILI designed to reduce fat mass in persons with obesity should be beneficial.²² However, as previously noted elsewhere,^{16,30} the ILI produced significant lean mass loss which could contribute to subsequent reduced energy expenditure, loss of mobility, frailty, etc. Our analysis of change in fat and lean compartments found that changes in percent fat or lean from baseline were small, not different between groups, and insofar as the direction of the means indicates, were more favorable (lower percent fat, higher percent lean) in the ILI groups.

A recent Look AHEAD analysis¹⁹ identified a subgroup of participants (~10%) that experienced elevated rates of mortality during a follow-up period. Steep post-intervention weight loss was associated with increased risk of mortality. Could those large weight losses have resulted in disproportionate loss of lean mass that could be contributing to the adverse outcomes? In our sample of cases, those with larger weight losses tended to increase the proportion of weight as lean mass. In general, when the composition of weight lost (fat:lean ratio) is higher than the individual's existing body composition ratio, additional weight loss will increase the proportion of weight as lean mass. Nevertheless, aside from any possible role of body composition in the outcomes, Wing et al¹⁹ reported significant associations of baseline older age, higher BMI, longer duration of illness, and multi-morbidities with deaths during the follow-up period. This suggests that some effort might profitably be put into the

development of guidelines for expected benefits or risks for ILI candidates with different characteristics presenting to clinicians.

Strengths and Limitations

This study benefits from a many-faceted multi-center randomized trial that followed a cohort of well-characterized participants for a long period of time collecting specialized body composition data. Our findings and conclusions should be limited to men and women in the fifth through seventh decade of life with T2DM who constituted the study sample. Among the limitations of this study is the fact that only 47% of the original DXA sample had a repeat DXA scan at 12–16 years after randomization. Participants who had bariatric surgery were excluded from the current analyses. Data on dietary intake and physical activity were measured in separate subgroups of the Look AHEAD cohort, and the overlap with the DXA subgroup was not adequate for analysis. Finally, medication usage was not controlled as part of the intervention.

Conclusions

Changes in almost all total and regional body composition compartments induced by the ILI treatment were detectable 12–16 years after randomization in men but, for unknown reasons, not in women. ILI-induced loss of lean tissue did not result in a lower percent lean mass compared to DSE at 16 years post randomization.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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What is already known about this subject?

- In persons with overweight and obesity, lifestyle modification induces weight loss and improves metabolic markers.
- Maintenance of reduced weight following weight loss is difficult.

What are the new findings in your manuscript?

- Sustained effects of the Look AHEAD intensive lifestyle intervention (ILI) treatment were observed at 12–16 years after randomization (a median of 6 years after termination of intervention) on measures of weight, body mass index (BMI) and most body composition compartments in men but not in women.
- ILI-induced loss of lean mass (LM, body weight minus fat mass and bone mineral) did not result in a lower percent lean body mass in the ILI group compared to DSE in participants who were measured at 12–16 years after randomization.

How might your results change the direction of research or the focus of clinical practice?

- This study could help mitigate concerns about loss of lean mass in intensive lifestyle interventions.

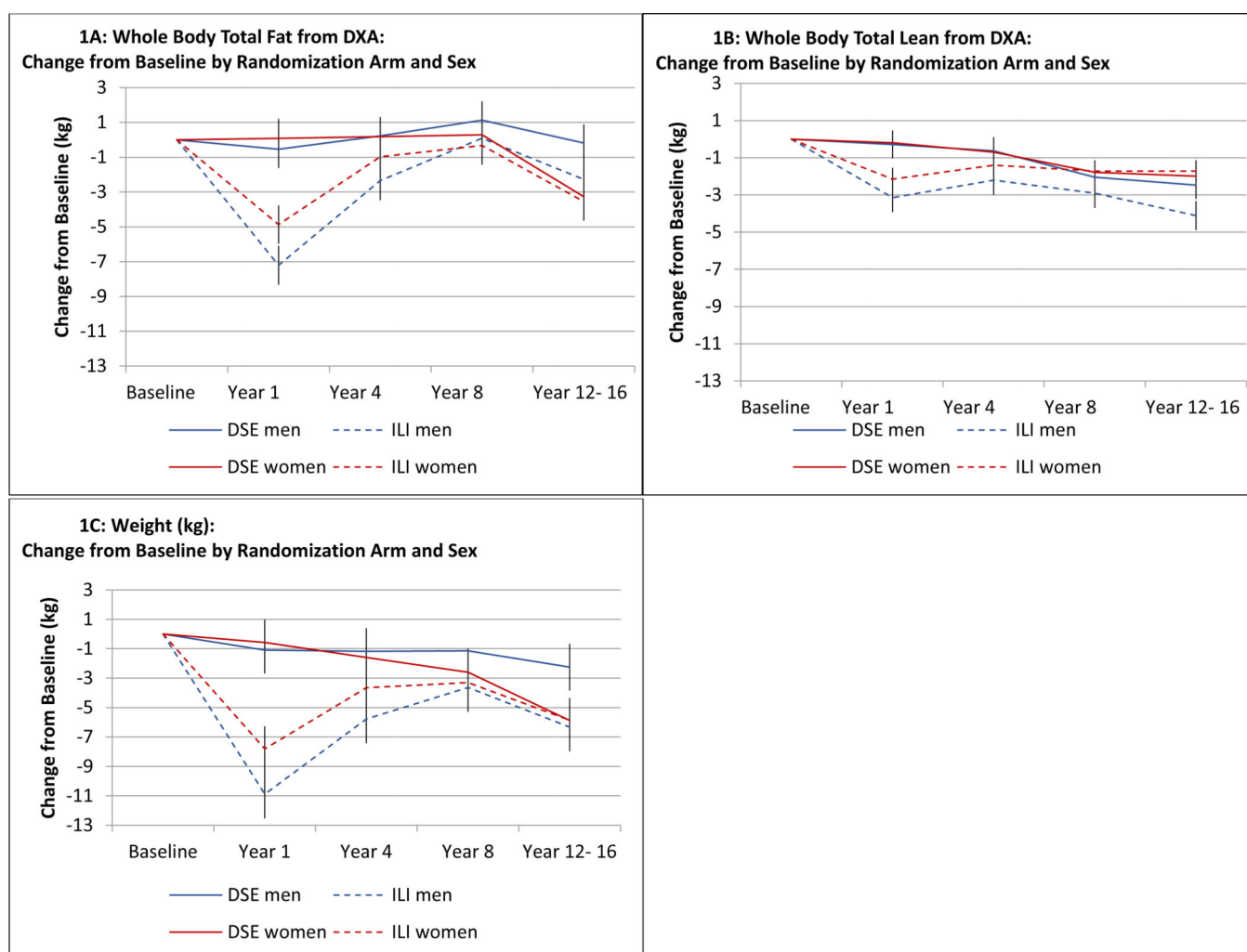


Figure 1.

Changes in body composition assessed by DXA from baseline to end of study in participants who completed baseline, year 8 and final visits: Total fat mass (Figure 1A), Total lean mass (Figure 1B) and Body Weight (Figure 1C).

Error bars shown are 95% Confidence Intervals. Sample sizes are Baseline: DSE=227, ILI=222; Year 1: DSE=223, ILI=221; Year 4: DSE=225, ILI=219; Year 8: DSE=227, ILI=222; Year 12-16: DSE=227, ILI=222.

Table 1.

Demographic and body composition measures of DXA subsample at baseline (BL) for completers (C) who reached final (Final) visit and non-completers (NC) who did not reach final visit, by sex and randomization arm [Mean (SD)].

Men	DSE					ILI				
	BL-C (N=99)	BL-NC (N=117)	p-value*	Final (N=99)	p-value [†]	BL-C (N=94)	BL-NC (N=103)	p-value*	Final (N=94)	p-value [†]
Age (Years)	58.2 (5.7)	62.2 (6.4)	<.0001	73.4 (5.6)	<.0001	59.4 (6.8)	61.9 (6.5)	0.0072	74.6 (6.6)	<.0001
Diabetes duration (years)	7.4 (6.3)	6.9 (5.7)	0.6218	22.6 (6.3)	<.0001	7.3 (6.5)	7.3 (6.5)	0.9303	22.4 (6.5)	<.0001
Baseline History of CVD [N (%)]	10 (10.1)	31 (26.5)	0.0022	-----	-----	14 (14.9)	31 (29.8)	0.0124	-----	-----
Race/Ethnicity [N (%)] [‡]										
African American/Black	7 (7.1)	10 (8.6)	0.7913	-----	-----	5 (5.3)	5 (4.8)	0.7381	-----	-----
	81 (81.8)	96 (82.1)				80 (85.1)	84 (80.8)			
	5 (5.1)	7 (6.0)				4 (4.3)	8 (7.7)			
	6 (6.1)	4 (3.4)				5 (5.3)	7 (6.7)			
Fat Mass (kg)	35.2 (7.3)	38.1 (9.3)	0.0109	34.9 (9.5)	0.7185	35.4 (8.6)	38.5 (10.7)	0.0262	33.2 (9.5)	0.0018
	9.6 (2.3)	10.3 (2.9)	0.0600	9.6 (3.0)	0.8889	9.5 (3.0)	10.3 (3.6)	0.0928	8.9 (3.1)	0.0010
	3.9 (0.9)	4.3 (1.1)	0.0038	4.2 (1.3)	0.0018	3.9 (1.0)	4.3 (1.1)	0.0090	3.8 (1.2)	0.4556
	20.3 (4.6)	22.2 (5.8)	0.0094	19.6 (5.7)	0.0799	20.7 (5.4)	22.6 (6.6)	0.0280	19.2 (5.6)	0.0008
Lean Mass (kg)	65.4 (6.9)	65.0 (7.2)	0.6998	62.8 (8.9)	0.0001	65.0 (6.3)	64.1 (7.1)	0.3702	61.2 (8.0)	0.0001
	20.9 (2.7)	20.7 (2.7)	0.5570	19.5 (3.3)	0.0001	20.9 (2.6)	20.5 (2.9)	0.2627	18.8 (2.9)	0.0001
	7.9 (1.1)	7.7 (1.1)	0.1663	7.3 (1.2)	0.0001	7.8 (1.0)	7.7 (1.0)	0.7447	7.0 (1.2)	0.0001
	32.9 (3.4)	33.0 (3.7)	0.7654	32.9 (4.5)	0.7493	32.8 (3.3)	32.5 (3.7)	0.5136	31.9 (4.1)	0.0037
Anthropometrics	176 (6.5)	176 (6.4)	0.8657	-----	-----	177 (6.3)	174 (6.4)	0.0064	-----	-----
	103 (12.0)	107 (15.3)	0.0135	101.0 (15.8)	0.2706	104 (14.3)	106 (15.8)	0.2562	97.6 (16.3)	0.0001
	33.3 (4.0)	34.4 (4.5)	0.0726	33.5 (6.1)	0.7362	33.2 (4.4)	35.0 (5.0)	0.0103	31.9 (5.2)	0.0003
	113.5 (11.4)	116.8 (11.1)	0.0312	114.9 (14.1)	0.4615	113.9 (10.5)	117.8 (12.2)	0.0174	113.5 (12.2)	0.8455
Women										
DSE					ILI					p-value [†]
	BL-C (N=134)	BL-NC (N=142)	p-value*	Final (N=134)	p-value [†]	BL-C (N=135)	BL-NC (N=149)	p-value*	Final (N=135)	
Age (Years)	56.4 (6.0)	59.6 (7.1)	<.0001	71.8 (5.9)	<.0001	55.8 (6.3)	58.6 (7.1)	0.0005	71.2 (6.0)	<.0001

Diabetes duration (years)		6.1 (5.7)	6.3 (6.4)	0.7882	21.6 (5.8)	<.0001	5.4 (5.5)	5.6 (5.5)	0.7365	20.8 (5.5)	<.0001
Baseline History of CVD [N (%)]		8 (6.0)	25 (17.6)	0.0029	-----	-----	13 (9.6)	19 (12.8)	0.4060	-----	-----
Race/Ethnicity [N (%)] [¶]											
Fat Mass (kg)	African American/Black	31 (23.1)	24 (16.9)	0.0405	-----	-----	19 (14.1)	33 (22.2)	0.2434	-----	-----
	White	88 (65.7)	90 (63.4)				94 (69.6)	98 (65.8)			
	Hispanic	6 (4.5)	20 (14.1)				12 (8.9)	12 (8.1)			
	Other	9 (6.7)	8 (5.6)				10 (7.4)	6 (4.0)			
Lean Mass (kg)	Whole Body	44.0 (10.5)	45.4 (9.8)	0.2424	40.9 (12.0)	0.0001	42.9 (9.9)	43.2 (10.9)	0.8380	39.4 (10.7)	0.0001
	Legs	14.1 (4.6)	14.6 (4.6)	0.4246	13.2 (5.0)	0.0001	13.4 (4.3)	13.9 (4.5)	0.3898	12.3 (4.6)	0.0001
	Arms	5.5 (1.3)	5.7 (1.5)	0.1171	5.4 (1.6)	0.5314	5.3 (1.4)	5.4 (1.7)	0.3745	5.4 (1.8)	0.4007
	Trunk	23.2 (5.9)	24.0 (5.5)	0.2883	21.2 (6.3)	0.0001	23.0 (5.7)	22.7 (6.1)	0.6487	20.6 (5.7)	0.0001
Anthropometrics	Whole Body	49.4 (6.5)	48.9 (5.9)	0.4547	47.5 (8.3)	0.0001	49.2 (5.9)	48.4 (6.5)	0.2787	47.5 (7.5)	0.0001
	Legs	16.0 (2.7)	15.6 (2.6)	0.1792	14.8 (3.3)	0.0001	15.8 (2.4)	15.5 (2.7)	0.3136	14.6(2.6)	0.0001
	Arms	5.0 (0.8)	4.9 (0.8)	0.6483	4.6 (1.0)	0.0001	4.9 (0.7)	4.9 (0.9)	0.7724	4.6 (0.8)	0.0001
	Trunk	25.5 (3.3)	25.4 (3.0)	0.7944	25.1 (4.4)	0.1280	25.5 (3.1)	25.0 (3.4)	0.2065	25.3 (4.0)	0.4149
Anthropometrics	Height (cm) [#]	162 (6.2)	163 (6.4)	0.1998	-----	-----	163 (6.2)	161 (5.7)	0.0200	-----	-----
	Weight (kg)	96.1 (16.1)	96.9 (15.1)	0.6681	90.5 (19.1)	0.0001	94.7 (14.7)	94.0 (16.9)	0.7188	88.9 (16.6)	0.0001
	BMI (kg/m ²)	36.3 (5.5)	37.1 (5.6)	0.2242	34.9 (6.7)	0.0007	35.8 (5.3)	36.3 (6.2)	0.5113	34.4 (6.3)	0.0003
	Waist Circumference (cm)	108.7 (13.2)	110.8 (11.4)	0.1601	108.9 (14.7)	0.9143	108.4 (12.2)	109.2 (13.6)	0.6093	109.6 (13.9)	0.4600

ILI, intensive lifestyle intervention; DSE, diabetes support and education.

[‡] Participants self-reported race at baseline from the following options: African American/Black, American Indian/Alaska Native, Asian, Native Hawaiian/Pacific Islander, White, and other; participants self-reported ethnicity from the following options: Latino, Hispanic, or Spanish origin or not. We provide data on the three largest racial/ethnic categories (African American/Black, Hispanic, and White) and a fourth category (other) that combines the smaller groups and those who selected multiple race categories.

p-values:

^{*}, independent groups t-test comparing BL-C and BL-NC;

^f, paired t-test comparing BL and Final on cases with both measures; ILI, intensive lifestyle intervention; DSE, diabetes support and education; BL-NC, baseline value for cases that did not complete final visit; BL-C, baseline values for cases that completed final visit.

[#] Participants had height measured at the start of the study only.

Table 2.

Longitudinal linear regression comparing changes in fat mass, lean mass, and weight (kg) by randomization arm adjusted for baseline value of the outcome, stratified by sex ^{*} [Mean difference (SE)].

Outcome		Baseline to Year 12–16		
		DSE	ILI	p-value
Men				
Fat Mass (kg)	Whole Body	−0.26 (0.48)	−2.34 (0.50)	0.0026
	Legs	−0.01 (0.13)	−0.63 (0.13)	0.0007
	Arms	0.25 (0.06)	−0.08 (0.06)	<.0001
	Trunk	−0.77 (0.32)	−1.64 (0.33)	0.0566
Lean Mass (kg)	Whole Body	−2.69 (0.31)	−3.76 (0.32)	0.0172
	Legs	−1.50 (0.13)	−2.07 (0.13)	0.0023
	Arms	−0.70 (0.06)	−0.77 (0.06)	0.3913
	Trunk	0.07 (0.17)	−0.81 (0.17)	0.0003
Weight (kg)		−2.69 (0.70)	−6.32 (0.72)	0.0003
Women				
Fat Mass (kg)	Whole Body	−3.29 (0.46)	−3.86 (0.45)	0.3760
	Legs	−1.01 (0.15)	−1.20 (0.15)	0.4013
	Arms	−0.11 (0.07)	0.03 (0.07)	0.1388
	Trunk	−2.14 (0.27)	−2.63 (0.26)	0.1952
Lean Mass (kg)	Whole Body	−1.93 (0.24)	−1.86 (0.24)	0.8434
	Legs	−1.22 (0.10)	−1.25 (0.10)	0.8134
	Arms	−0.33 (0.04)	−0.27 (0.04)	0.3345
	Trunk	−0.33 (0.13)	−0.24 (0.13)	0.6331
Weight (kg)		−5.83 (0.63)	−6.28 (0.63)	0.6130

^{*} Models are adjusted for clinical site. ILI, intensive lifestyle intervention; DSE, diabetes support and education.