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## Changes in Body Composition over Eight Years in a Randomized Trial of a Lifestyle Intervention: The Look AHEAD Study

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### Abstract

**Objective**—To determine the effects of an intensive lifestyle intervention vs. a comparison group on body composition in obese or overweight persons with type 2 diabetes at baseline and at 1, 4, and 8 years.

**Design and Methods**—Body composition was measured by dual energy X-ray absorptiometry in a subset of 1019 Look Ahead study volunteers randomized to intervention or comparison groups. The intervention was designed to achieve and maintain 7% weight loss through increased physical activity and reduced caloric intake. The comparison group received social support and diabetes education.

**Results**—At 1 year, the intervention group lost fat ( $5.6 \pm 0.2$  kg) and lean mass ( $2.3 \pm 0.1$  kg) but regained fat (~100%), and lost lean mass between years 1 and 8. Between baseline and year-8, weight-loss was greater in intervention vs. comparison groups ( $4.0 \pm 0.4$  vs.  $2.3 \pm 0.4$  kg); comparison group weight-loss was mostly lean mass ( $2.1 \pm 0.17$  kg). Fat mass in the intervention group was lower than that of the comparison group at all post-baseline time points.

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All other Look AHEAD staffs are listed alphabetically by site.

Author Contributions: Drs. Pownall, Wagenknecht, and Johnson had full access to all data in the study and take responsibility for the integrity of the data and the accuracy of its analysis. All authors provided input to the conceptualization of the study design and data interpretation.

**Conclusions**—Reduced FM may place the intervention group at a lower risk of obesity-linked sequelae, a hypothesis that can be tested by future studies of this cohort.

**Trial Registration**—ClinicalTrials.gov Identifier: *NCT00017953*

## Keywords

Obesity; diabetes; body composition; weight loss

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## Introduction

Intentional weight loss, which is associated with loss of lean (LM) and fat mass (FM), is a function of diet, (1) physical exercise,(2, 3) age, gender, ethnicity,(4, 5, 6, 7) and initial body composition.(8, 9, 10, 11) Diet and various diseases, especially diabetes, also affect LM loss, particularly in older individuals.(12, 13, 14, 15, 16, 17, 18, 19, 20) Look AHEAD is a randomized trial in which 5,145 overweight or obese individuals with type 2 diabetes were assigned to either intensive lifestyle intervention or to diabetes support and education (comparison) groups to test whether intervention reduces cardiovascular morbidity and mortality.(21, 22, 23, 24) The Look AHEAD population is an ideal model for testing the effects of an intensive lifestyle intervention, and thus, intentional weight loss, on body composition (FM and LM) by dual-energy x-ray absorptiometry (DXA) in obese and overweight persons with type 2 diabetes. Body composition at baseline has been reported. (25) Here we compare the body composition at baseline and at 1, 4 and 8 years post entry within a subgroup of 1,019 participants in the intervention and comparison groups at Look AHEAD sites in Baton Rouge, Houston, Boston, and Seattle.

## Methods

### Participants

A total of 5,145 men and women were randomized to intervention or comparison groups at 16 Look AHEAD study sites using a web-based data management system that verifies eligibility. Randomization is stratified by clinical center and blocked with random block sizes of four and six. At entry, participants were 45 to 76 years of age, presented with type 2 diabetes, and had a body mass index (BMI)  $\geq 25$  kg/m<sup>2</sup> (or  $\geq 27$  kg/m<sup>2</sup> if receiving insulin). The complete enrollment criteria have been reported.(21) Participants completed a maximal exercise tolerance test prior to enrollment.(26) Protocol and consent forms were approved by institutional review boards at each site.

### Interventions

Participants in each site were randomly assigned to intervention or comparison groups with equal probability. The intervention was designed to achieve and maintain weight loss of 7% through reduced caloric intake and increased physical activity.(27, 28) Participants were assigned a caloric intake goal of 1200–1500 or 1500–1800 kcal/day depending on initial weight and advised to increase the duration of physical activity to 175 minutes per week. In years 2–8, the intervention focused on maintaining the weight loss and the duration of physical activity achieved during year 1, as well as helping unsuccessful individuals reach

the study goals. Participants randomized to the comparison group received general information related to healthy eating and physical activity but did not receive the comprehensive components of the intervention nor specific strategies for weight loss.(29) General medical care and diabetes care were provided to all participants by their non-study health care providers.

### Study Measures

Participants visited clinics annually. Height was measured in duplicate using a wall-mounted stadiometer at baseline. Waist circumference was measured at the midpoint between highest point of the iliac crest and lowest part of the costal margin in the mid-axillary line with a non-distensible tape measure.

Body Composition was measured by DXA at four Look AHEAD sites, using Hologic (QDR-4500A) fan beam densitometers. DXA uses 2-compartment models to distinguish FM and fat-free mass and to distinguish bone, measured as bone mineral content, and soft tissue. LM is calculated as the difference between fat-free mass and bone mineral content. Precision, expressed as coefficient of variation (CV), for fat mass is 1.5% in lean and obese subjects; CV for lean mass is 0.45% in lean and 0.80% in obese subjects.(30) Software upgrades during the study were approved by a DXA quality assurance center (University of California San Francisco). At baseline, a set of cross calibration phantoms were circulated to assess differences across scanners. Longitudinal performance was monitored with regular scanning of a spine phantom and a whole body phantom on each densitometer, and longitudinal corrections were applied to participant body composition results based on the whole body phantom. Whole body scan results were corrected for underestimation of fat mass using Hologic software.(31) Scans were centrally monitored for quality of acquisition and analysis. Participants weighing more than 300 pounds were not scanned due to DXA scanner weight limits.

### Statistical Analysis

A total of 1161 participants received a DXA scan at baseline. This analysis includes 1019 (88%) participants (513 comparison group; 506 intervention group) who had at least one follow-up measure. Participants receiving an anti-resorptive medication such as bisphosphonates at baseline were included in these analyses (n=70). The primary analysis goal was to compare body composition measures between the intervention and comparison groups across an 8-year time interval. Changes in weight, FM, and LM in the intervention group—expressed as absolute values (kg) and percent [e.g., %LM = 100 x LM/(LM + FM)]—were compared with those of the comparison group. Interaction terms for randomization group with gender and for randomization group with age were included in the mixed models. The only significant interaction term was for randomization group with gender for the FM outcome (P=0.03) thus, all further models were stratified by gender. No interactions with age were observed. General estimating equations were used to model the longitudinal data with adjustment for randomization group, clinic, gender, age, race/ethnicity, hemoglobin A1c, and baseline body composition measure. P-values were calculated for each of the 4 time points (baseline, years 1, 4, and 8) and for the average effect across the entire follow-up period. Sensitivity analyses were conducted in those who participated in all time

points (N= 805) [completers] and compared to the entire cohort as presented here. Analyses were performed using SAS v 9.2 (Cary, NC);  $P < 0.05$  was set as the significance level.

## Results

### Baseline Characteristics

At baseline, intervention (60% female) and comparison (57% female) groups did not differ with respect to age, gender, race, weight, BMI, waist circumference, FM, and LM (Table 1). Mean waist circumferences in both groups were similar and exceeded current guidelines (102 cm for men and >88 cm for women). Both groups were primarily White (~73%), African American (~13%), or Hispanic (8%). The respective percentages of the baseline DXA subgroup completing the 1, 4 and 8-year follow-up visits were similar across randomization groups as follows: Comparison group females, 96, 92, and 88%; comparison group males, 98, 91, 80%; intervention group females, 98, 90, 83%; intervention group males, 99, 92, 79%. A consort diagram of patient flow through the study is given in Figure 1.

**Overall Changes in Weight, FM, and LM by Randomized Group from Baseline to Year 8**—Weight loss was greater in the intervention vs. comparison groups at all 3 post-entry time points (Figure 2A), i.e., weight loss in intervention group (mean  $\pm$  SE):  $7.9 \pm 0.3$ ,  $3.7 \pm 0.4$ , and  $4.0 \pm 0.4$  kg; weight loss in comparison group:  $0.5 \pm 0.3$ ,  $1.2 \pm 0.4$ , and  $2.3 \pm 0.4$  kg, for years 1, 4, and 8, respectively. This observation was consistent for men and women (Figure 2B, C).

Comparison of the changes in FM and LM underlying weight changes within the comparison group (Figure 2D, G) revealed that from baseline to year 8, nearly all weight loss was due to LM loss ( $2.2 \pm 0.2$  kg;  $0.23$  kg/y) rather than FM loss ( $0.1 \pm 0.3$  kg). Within the intervention group, from baseline to year 1, both FM and LM decreased (Figure 2D, G) with FM loss > LM loss ( $5.6 \pm 0.2$  vs.  $2.3 \pm 0.2$  kg). From year 1 to 8, FM increased whereas LM decreased, both approaching the corresponding values of the comparison group but nevertheless significantly lower in the intervention group at year 8.

**Changes in Percent FM and LM by Randomized Group from Baseline to Year 8**—Percent LM within the intervention group increased from baseline to year 1 and then decreased to near comparison group values by year 8 (Figure 3A). Among comparison group males and females, LM declined nearly linearly between baseline and year 8 and was lower than baseline at years 4 and 8 ( $P < 0.0001$ ). Complementary changes in percent FM are shown in Figure 3D.

**Gender-Specific Changes in Body Composition by Randomized Group from Baseline to Year 8**—There were no significant gender-specific differences in the LM response to the intervention (Figure 2H–I). Mean LM in comparison vs. intervention groups was different at all post-entry time points except year 8 LM for females. The FM response within the intervention vs. comparison groups differed according to gender, with the FM response at year 4 being greater for males than for females. At year 8, FM for intervention and comparison group males was not different, whereas FM for females was significantly

lower for the intervention vs. comparison groups at all post entry time points. Gender differences in FM are reflected in baseline data showing a higher percentage of FM in females vs. males (Figure 3B, C, E, and F). With respect to mean percent LM and percent FM at baseline, the intervention and comparison groups were not different; for males these were respectively;  $65.3 \pm 0.4$  and  $64.5 \pm 0.5\%$ ;  $34.8 \pm 0.3$  and  $35.0 \pm 0.3\%$ . The respective values for females were  $49.4 \pm 0.4$  and  $49.2 \pm 0.4\%$ ;  $46.2 \pm 0.3$  and  $45.4 \pm 0.3\%$ . During year 1, percent LM among comparison group males and females did not change whereas percent LM within the intervention group increased (Figure 3B, C, E, and F). For comparison and intervention group males respectively, percent LM =  $62.5 \pm 0.3$  and  $65.8 \pm 0.3\%$ . For intervention and comparison group females, percent LM =  $51.4 \pm 0.3$  and  $54.1 \pm 0.3\%$  respectively. Changes in mean percent FM complemented those for percent LM in intervention and comparison groups, respectively. Percent FM =  $34.7 \pm 0.3$  vs.  $31.3 \pm 0.4\%$  for males and  $46.2 \pm 0.3$  vs.  $45.4 \pm 0.3\%$  for females. As with the other measures of obesity, percent LM for intervention group males and females declined from year 1 to years 4 and 8, while percent FM increased. Although small, percent LM differences between intervention and comparison group were significant at years 1, 4 and 8 for males, but only at years 1 and 4 for females.

The weight changes from baseline to years 1 and 8 were similar for males and females (Figure 2.). From baseline to year 1, FM and LM change among comparison group males and females was nil whereas intervention group males and females, respectively, lost 9.4 and 7.0 kg of total weight of which 6.6 kg (~70%) and 5.0 kg (~70%) was FM. From year 1 to 8 there was little change in the FM and LM of the comparison group and LM within the intervention group. In contrast, however, the year 1 to year 8 weight gain among males and females within the intervention group was ~100% FM. Overall, despite weight regain, the intervention group weighed less than the comparison group at years 1, 4, and 8 (Figure 2A).

An analysis of the subset who participated at all time points (completers) compared to the entire cohort did not alter the findings substantively. For example, at one year weight loss among female completers-only was  $-0.57 \pm 0.35$  (N = 246) and  $-7.75 \pm 0.36$  (N = 238) with  $P < 0.0001$  for comparison and intervention groups respectively; similarly the respective weight losses for females including completers and non-completers was  $-0.66 \pm 0.34$  (N = 282) and  $-7.60 \pm 0.33$  (N = 299)  $P < 0.0001$ . All other comparisons led to similar conclusions.

## Discussion

Using DXA, we compared the effects of an intensive lifestyle intervention with a comparison group receiving only diabetes support and education, on body composition changes over 8 years. From baseline to year 8, overall weight declined gradually for the comparison group almost entirely due to loss of LM. This resulted in parallel decreases of percent LM and increased percent FM. In contrast, weight within the intervention group decreased and was lower than that of the comparison group after year 1 of the intervention. Concurrently, LM, and to a much greater extent FM, declined. Thus, percent FM and LM, respectively, decreased and increased during year 1. These effects did not differ by age group, but there was a gender effect in that the FM changes differed for males and females,

with the intervention group having lower FM than the comparison group in men but not in women at year 8.

Weight regain had a major effect in the intervention group. Between years 1 and 8, regaining of weight, LM, and FM led to a convergence of the intervention and comparison groups. Despite this, at year 8, the intervention group maintained small but significantly lower FM and LM overall, and the mean effect over the entire eight-year period was highly significant ( $P < 0.0001$ ). In gender-specific models, differences in FM (males only) and LM (females only) were not significant at year 8. Gender differences in FM are well known(24, 25, 32, 33, 34) and the failure of LM differences in intervention vs. comparison groups in females and FM in males to reach significance may simply reflect differences in the LM and FM in males and females; females have more FM to lose than males and males have more LM to lose than females.

Hypothetically, the lower weight, FM and LM throughout the 8-year period in the intervention group would have a salutary, long-term effect, i.e., effects that persist beyond eight years. Thus, the occurrence of obesity-related morbidity and mortality within the comparison group could be predicted to be greater than that of the intervention group. Conversely, quality of life would be better and health care costs lower within the intervention group.(35) The hypothesis that years of poorer health habits will have latent effects has a well-known precedent; former smokers develop chronic obstructive pulmonary disease many years after smoking cessation.(36, 37) There was considerable loss of LM between baseline and eight years within both comparison and intervention groups, with the effect being greater for the intervention group. Longitudinal studies in older men and women show a decline in LM relative to fat,(32) and even though DXA measurements do not distinguish muscle from non-muscular sources of LM, it is often assumed that ~80% of LM loss is a loss of skeletal muscle. Given that the 4-year Look AHEAD data showed that weight-loss improved mobility,(38) examining whether mobility within the intervention group exceeds that of the comparison group, despite the loss of LM, warrants further investigation. Sarcopenia or the LM loss, with aging is a recognized concern,(14, 15, 16) especially considering that loss of mobility is a major determinant for entering a nursing home. Thus, identification of alternative interventions that suppress age-dependent LM loss remains an important public health priority.

## Conclusion

There are several strengths to this study. First, it is a large, randomized population of persons with diabetes who have been assessed for body composition with more than 80% follow-up at eight years. Second, Look AHEAD included an ethnically diverse population with a large number of participants from each of the major ethnic groups. A limitation of the study is that the DXA is not as precise as X-ray computed tomography or magnetic resonance imaging methods, which give better estimates of skeletal muscle and visceral fat. DXA measurements of fat and lean mass are limited by use of a two-compartment model that assumes a constant level of hydration.(39) In addition, not all participants attended all visits for various reasons including death. However, sensitivity analysis comparing results for the entire DXA subgroup with those providing data at each time point (completers) did



not alter the outcomes in a clinically meaningful way. Insulin treatment in patients with initial poor glucose control can increase LM hydration.(40) However, in Look AHEAD, the intervention group tended to have better glucose control and used less anti-diabetic medications(35) so that hydration effects are expected to be minimal. Nevertheless, the present eight-year follow-up in a subgroup of the Look AHEAD study subjects showed statistically significant effects of an intensive lifestyle intervention on the magnitude of the changes in body composition. Weight, FM and LM were lower in the intervention vs. comparison groups at all post-baseline time points. Follow-up is needed to determine the long-term consequences of these body composition changes on physical function and other clinical outcomes.

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## Appendix

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**What is already known**

Exercise and caloric restriction induce weight-loss.

Weight-loss alters body composition.

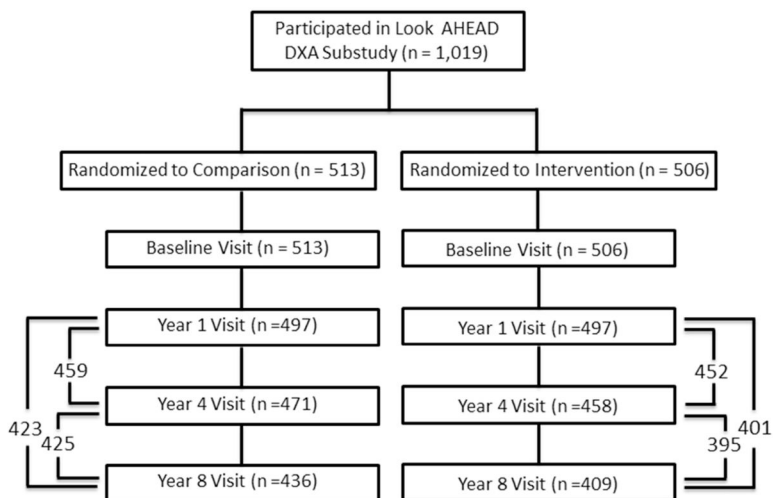
Body composition is a determinant of insulin resistance.

**What does this study add?**

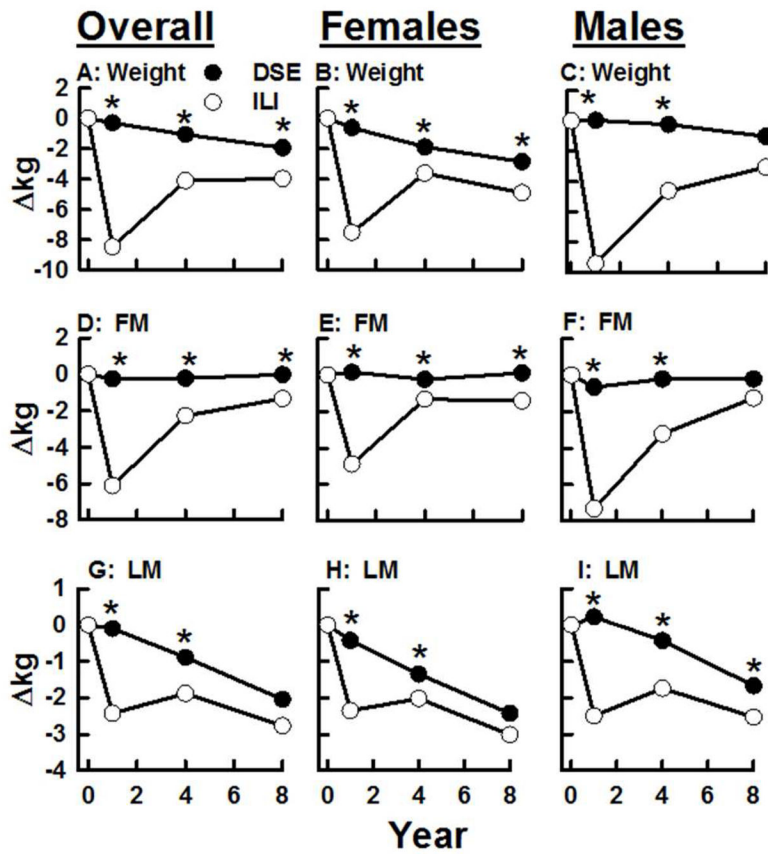
Approximately two-thirds of the weight-loss among obese or overweight diabetic persons via an intensive lifestyle intervention is fat.

Weight regain in the intervention group is nearly 100% fat mass.

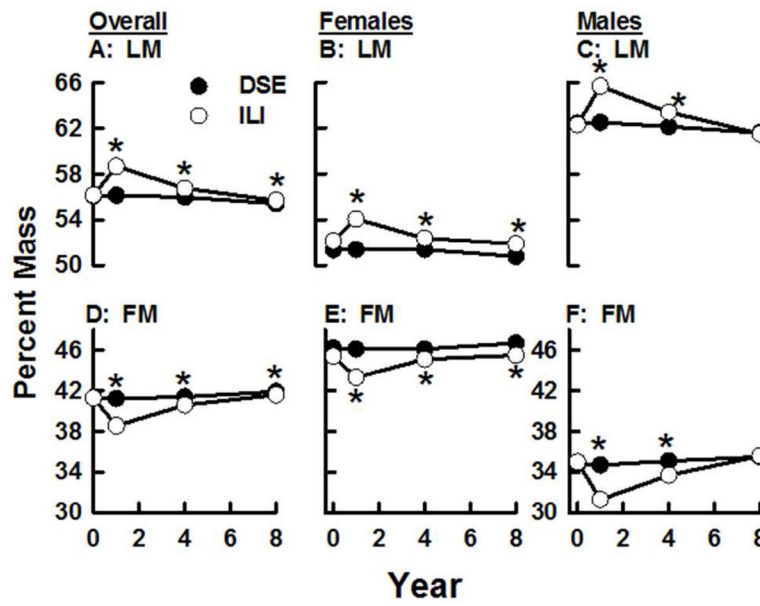
Over 8 years, both comparison and intervention groups lost lean body mass.



**Figure 1.** Flow chart for the DXA Body Composition Sub study. All participants received DXA scans at baseline and at least one follow-up scan. Numbers in rectangles indicate number of DXA scans at each visit. The number of patients who were scanned at a given pair of visits are connected by the brackets as shown.



**Figure 2.** Anthropometric changes as labeled, baseline to year eight. \* $P < 0.05$ , comparison and intervention groups are different. A – I,  $P < 0.0001$  for overall treatment effects.



**Figure 3.** Percent change in LM and FM from baseline to year eight, as labeled. \*P < 0.05, comparison and intervention groups are different. A – F, P < 0.0001 for overall treatment effects.

**Table 1**

## Baseline Characteristics by Randomization Group

	Comparison Group	Intervention Group	P-value
N	513	506	
Age (y)	58.9 ± 6.7	58.6 ± 7.0	0.48
Gender (Male)	42.9%	39.7%	0.31
Race/Ethnicity			
Non-Hispanic African American	72 (14%)	62 (12.3%)	
Native American or Alaskan Native	4 (0.8%)	1 (0.2%)	
Asian/Pacific Islander	9 (1.8%)	12 (2.4%)	
White	373 (72.7%)	378 (74.7%)	
Hispanic	40 (7.8%)	38 (7.5%)	
Other and mixed race/ethnicity	15 (2.9%)	15 (3.0%)	
Height (cm)	168.1 ± 9.4	167.4 ± 9.0	0.19
Weight, kg <sup>b</sup>	100.4 ± 15.1	98.8 ± 15.9	0.11
BMI (kg/m <sup>2</sup> )	35.6 ± 5.1	35.3 ± 5.4	0.44
Waist Circumference (cm)	112.5 ± 12.3	112.0 ± 12.8	0.53
Fat Mass (kg) <sup>b</sup>	41.7 ± 10.4	41.1 ± 10.9	0.40
Lean Body Mass (kg) <sup>b</sup>	56.2 ± 10.3	55.3 ± 9.9	0.14

<sup>a</sup> Values are mean ± SD;

<sup>b</sup> DXA measures.