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## Factors influencing enrollment of African Americans in the Look AHEAD trial

David L Mount<sup>a</sup>, Cralen Davis<sup>a</sup>, Betty Kennedy<sup>b</sup>, Susan Rantz<sup>c</sup>, Kathy Dotson<sup>a</sup>, Tiffany L Gary-Webb<sup>d</sup>, Sheikilya Thomas<sup>e</sup>, Karen C Johnson<sup>f</sup>, Mark A Espeland<sup>a</sup>, and the Look AHEAD Research Group

<sup>a</sup>Department of Internal Medicine, Wake Forest University School of Medicine, Winston-Salem, NC 27157, USA

<sup>b</sup>School Wellness Coordinator, Louisiana School Boards Association, Baton Rouge, LA 70809, USA

<sup>c</sup>University of Minnesota, Minneapolis, MN 55455, USA

<sup>d</sup>Columbia University Mailman School of Public Health, New York 10032, NY, USA

<sup>e</sup>University of Alabama at Birmingham, Birmingham, AL 35205, USA

<sup>f</sup>Department of Preventive Medicine, The University of Tennessee Health Science Center, Memphis, TN 38163, USA

### Abstract

**Background**—Many factors have been identified that influence the recruitment of African Americans into clinical trials; however, the influence of eligibility criteria may not be widely appreciated. We used the experience from the Look AHEAD (Action for Health in Diabetes) trial screening process to examine the differential impact eligibility criteria had on the enrollment of African Americans compared to other volunteers.

**Methods**—Look AHEAD is a large randomized clinical trial to examine whether assignment to an intensive lifestyle intervention designed to produce and maintain weight loss reduces the long-term risk of major cardiovascular events in adults with type 2 diabetes. Differences in the screening, eligibility, and enrollment rates between African Americans and members of other racial/ethnic groups were examined to identify possible reasons.

**Results**—Look AHEAD screened 28,735 individuals for enrollment, including 6226 (21.7%) who were self-identified African Americans. Of these volunteers, 12.9% of the African Americans compared to 19.3% of all other screenees ultimately enrolled ( $p < 0.001$ ). African Americans no more often than others were lost to follow-up or refused to attend clinic visits to establish eligibility. Furthermore, the enrollment rates of individuals with histories of cardiovascular disease and diabetes therapy did not markedly differ between the ethnic groups. Higher prevalence of adverse levels of blood pressure, heart rate, HbA1c, and serum creatinine among African American screenees accounted for the greater proportions excluded (all  $p < 0.001$ ).

**Conclusions**—Compared to non-African Americans, African American were more often ineligible for the Look AHEAD trial due to comorbid conditions. Monitoring trial eligibility

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Author for correspondence: David L Mount, Department of Internal Medicine, Section on General Internal Medicine and the Director of Community Outreach, Partnerships, and Advocacy, Maya Angelou Center for Health Equity, Wake Forest University Health Sciences, Medical Center Boulevard, Winston-Salem, NC 27157, USA. Dmount@wfubmc.edu.

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criteria for differential impact, and modifying them when appropriate, may ensure greater enrollment yields.

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## Introduction

As the largest racial minority group 40 years of age and older, African Americans carry a disproportionately high burden of type 2 diabetes mellitus (T2DM) and have excessive risk for diabetes health-related complications [1–4]. Much attention has been focused on identifying factors that may impede the recruitment of African Americans to clinical trials. Factors implicated have included distrust of the medical/scientific community, power-difference barriers (e.g., unequal authority, inequitable collaboration), poorer access to primary medical care, alienation of minority health professionals, lack of knowledge about clinical trials, and language and cultural barriers [5–8]. Low rates of African American enrollment can hinder scientific investigations and restrict the generalizability of clinical trial findings [9–12].

Trials often require individuals to meet health-related benchmarks for inclusion. The influence of health disparities, particularly in diseases such as diabetes, that differentially affect African Americans, and differential exclusion of greater numbers of African Americans due to eligibility criteria may be underappreciated.

The motivation for the current investigation was our hypothesis that eligibility criteria related to health status may be important factors that limit enrollment of African Americans in clinical trials. We used data from a large multicenter clinical trial of individuals with T2DM, the Look Action for Health in Diabetes (AHEAD) trial, with the expectation that the Look AHEAD experience would help to inform the design of future trials that target enrollment of individuals from this minority group. Recruitment for Look AHEAD was conducted between July 2001 and April 2004, with the goal of enrolling 5000 volunteers, with approximately equal numbers of men and women, of whom at least 33% would self-identify as being from racial/ethnic minority groups, that is, not non-Hispanic White. More than 27,000 individuals were screened for Look AHEAD at 16 clinical centers. Volunteers were identified through a variety of methods including informational mailings, open screenings, advertisements, and referrals from health care professionals.

## Methods

### Design and status of Look AHEAD

The Look AHEAD trial was designed to test whether assignment to an intensive lifestyle intervention featuring weight loss through diet and exercise would reduce the risk of major cardiovascular events in overweight or obese individuals with T2DM. The Look AHEAD trial design and intervention are reported in several documents [13–16]. The comparison (control) condition is usual care, which includes a diabetes support and education component. Up to 13.5 years of follow-up of participants is planned. The Look AHEAD trial protocol, including the consent forms, was approved by the local institutional review board of each participating site. Informed consent was obtained before individuals participated in any screening procedure.

Eligibility criteria included a diagnosis of T2DM (determined by self-report and verification) in individuals aged 45–76 years who had a body mass index (BMI)  $> 25\text{kg/m}^2$  ( $>27\text{kg/m}^2$  if currently taking insulin).

## Screening of volunteers

Each site had a full-time recruitment coordinator and an assistant who were trained and certified centrally. The first training session was held in March 2001, prior to launching recruitment in June 2001. Follow-up central training was provided in September 2002 and September 2004. Each training session included curricula on minority recruitment, and an additional material was provided in the Look AHEAD manual of operations.

Clinic personnel used a variety of methods to identify volunteers, including direct mail from purchased targeted mailing lists, radio and television advertisements, websites, referrals, and health fairs. Prescreening, most often by telephone, established preliminary eligibility on self-reported criteria such as age and diabetes status. Individuals deemed eligible during prescreening were scheduled for a series of clinic-based screening visits. Funds were provided to cover travel expenses to clinic visits. The initial clinic screening visits were used to obtain informed consent, medical histories, specimens for laboratory tests, anthropometric measurements, and data on sociodemographic and behavioral characteristics. All candidates were required to complete a 2-week self-monitoring run-in to confirm their ability to record daily information about diet and physical activity. Clinics had flexibility in the sequence and number of examinations required to complete screening procedures. Additional clinic visits typically were used to obtain ankle-brachial index measurements, electrocardiograms, and maximal graded exercise treadmill tests. A behavioral assessment interview was also conducted as part of the screening process. A maximum of 4 months was allowed to complete all aspects of screening for each volunteer. Once a candidate was determined to be eligible for participation, a randomization visit was scheduled.

## Analysis

We examined the Look AHEAD exclusion factors for those that accounted for greater rates of ineligibility among African American relative to other volunteers, compared the rates of attrition during the screening process between African American and other volunteers, and described how exclusion criteria and attrition altered the characteristics of individuals screened versus the final enrolled cohort. We computed frequencies and proportions to portray the distribution of African American and other volunteers by enrollment status, overall, and by selected characteristics. Statistical comparisons between groups and among proportions were performed using chi-square tests. Logistic regression models, that included clinic site as a covariate and interaction terms, were used to assess whether the rates of ineligible volunteers between African Americans and others varied among subgroups. We defined  $p$  values less than 0.05 to denote statistically significance differences used as the basis of inferences. Analyses were performed using SAS version 9.1 (SAS Institute Inc., Cary, NC).

## Results

We examined the differences among racial and ethnic groups with attention to study status rates stratified by enrollment status: screened, excluded because ineligible, missed or refused examinations to ascertain eligibility (lost/refused), and randomized. As shown in Table 1, a total of 28,735 volunteers of all racial and ethnic groups were screened. African Americans were the largest minority group screened among those persons who provided racial/ethnicity data. However, compared to Hispanic/Latino, Native American, and Asian, as well as White, enrollment yields, the percentage of African Americans randomized was markedly lower. Thus, we combined all other racial/ethnic groups (non-African Americans) in order to identify the factors that adversely affected African American enrollment.

Table 2 gives the reasons for ineligibility of African Americans and other volunteers screened. At the initial prescreening contact, the only difference was for age outside the eligible range. However, during screening clinic visits, health-related criteria were primarily responsible for higher rates of ineligible African Americans. Reasons for differential exclusion of African Americans included poor control of blood pressure, abnormal heart rate, elevated levels of HbA1c or serum creatinine, and history of other heart disease (defined as history of uncomplicated myocardial infarction, coronary artery bypass surgery, percutaneous coronary angiography, atherectomy or stent placement, chronic stable angina pectoris, no resting or exercise induced complex arrhythmias, and stable New York Heart Association (NYHA) Class I or Class II congestive heart failure if they are beyond three months) ( $p < 0.001$ , all tests). In addition, more African Americans were eliminated because of unconfirmed T2DM, for failure to complete behavioral tasks (filling out self-monitoring diaries and questionnaires), and study team assessment as unsuitable candidates, a subjective criterion. African Americans less often were eliminated for elevated levels of triglycerides.

Table 3 identifies the subgroups of African Americans who were differentially excluded at higher rates than other participants, based on tests of interaction, and shows odds ratios for the relationship between ineligibility and racial/ethnic group within each subgroup. African American men were excluded 1.5 times as often as non-African American men, but African American women were excluded only 1.2 times as often as non-African American women. The tests of interaction of African American race/ethnicity with covariates revealed statistically significant interactions for gender, use of insulin, and use of other diabetes medication.

Table 4 compares participant characteristics by racial/ethnic group for those actually enrolled and randomized in Look AHEAD. As a group, African Americans who enrolled in the trial differed from other Look AHEAD participants with respect to many characteristics; for example, as a group they were slightly younger; more often women, less often had a history of, angioplasty, had higher body mass indices; and more often had hypertension.

## Discussion

African Americans had differentially lower enrollment rates in the Look AHEAD trial compared to all other volunteers screened. The reasons for this lower enrollment were not attributable to losses to follow-up or attrition during the screening process; the percent of African American screenees who were lost to follow-up or refused to continue screening procedures did not differ from other screenees. The differential rates of enrollment were due primarily to failure of eligibility criteria, including criteria related to poor control of chronic disease, to conditions that were thought to limit the lifespan of participants and to interfere with ability to participate safely in the trial, and characteristics and behaviors that were judged to predict poor adherence procedures if enrolled.

The Look AHEAD trial did not provide direct medical care and required participants to identify their source of care. Individuals with poorly controlled hypertension or diabetes were excluded from the trial. In addition, participants had to have verification of T2DM (e.g., by medical records, current treatment, verification from personal health care provider, or test result). These health-related eligibility criteria differentially excluded African Americans, who as a group in the United States have higher rates of uncontrolled hypertension and diabetes and lower rates of access to health care [17–22]. Look AHEAD allowed volunteers who initially did not meet these criteria to be rescreened at later dates, and assistance was provided, when needed, to find sources of medical care. However, the trial funding and design did not provide for direct intervention. Some of the reasoning behind this was to separate the source of medical care from the investigators administering

the trial's unmasked behavioral intervention, thereby reducing the potential for confounding. However, had there existed separate avenues and funding for administering the health care needed to bring hypertension and diabetes into control, it is possible that greater numbers of African Americans would have been eligible and would have enrolled.

Our findings raise the issue of whether the Look AHEAD criteria for exclusion were justified. Abnormal heart rates, chronic heart conditions, and evidence of renal disease were adopted as exclusion criteria because the behavioral interventions in Look AHEAD may not have been safe for individuals with these conditions and because such conditions may have interfered with their ability to complete the trial. These criteria differentially excluded African Americans who have greater burdens of renal and heart diseases than non-African Americans [22–25].

Look AHEAD used a behavioral run-in task as part of screening for participants who were likely to adhere to trial procedures; in the run-in, candidates were required to record information about diet and physical activity daily during a 2-week period. The use of behavioral run-ins and reliance on staff judgment are important components of trial enrollment. Look AHEAD clinic staffs were centrally trained to promote cultural awareness both in providing instructions regarding run-in tasks and in evaluating participants. Prior to randomization, the local study team met to review each volunteer's screening data to determine whether there was consensus that the individual was an appropriate candidate for the trial. Consideration was given to safety, whether there were inconsistencies between entries on forms and self-reports, and concerns about adherence. However, unlike most reasons for exclusion, this one could be challenged as subjective, despite the training in cultural sensitivity.

The requirements related to diabetes control and access to a regular health care provider may have acted to account for the higher rates of exclusions related to diabetes treatment. However, for most subgroups of screenees we examined, the differential rates of exclusion of African Americans were consistent.

The lower enrollment rates for African Americans had a relatively larger effect on the enrollment of male patients and those whose diabetes was either untreated or required insulin treatment (Table 3). Many trials have reported difficulties in enrolling African American male patients [26–30]. Speculations concerning low participation rates of African American male patients are multipronged, ranging from prior history of biomedical research mistreatment, racial concordance, awareness about research studies, clinical trial literacy, and factors that are more socioeconomically driven: job flexibility, transportation, housing, and neighborhood factors, which could adversely affect participation continuity [31–33].

The African American enrollees in the Look AHEAD trial tended to differ from others with respect to many demographic, health, and behavioral characteristics, thus stressing the importance of including these individuals in clinical trials to ensure generalizability of findings regarding the effects of interventions. Because losses to follow-up and refusal were reported as a single category, we cannot comment on the approximately 41% of volunteers who were possibly eligible but then did not continue with screening or enroll in the trial. Although Look AHEAD included clinical sites located throughout the United States, recruitment areas necessarily were limited geographically and may not reflect the general populations. Furthermore, this analysis was conceived post hoc; more information could have been collected, for example, in an ancillary study, if it had been planned 'up front'.

## Conclusions

Improving enrollment requires more attention to the influences of, and knowledge about, clinical trial design strategies and policies. Although recent research has focused on the modifying effects of personal knowledge and perceived benefits [34,35], factors within the trial design warrant continuing attention. For the largest minority group recruited to the Look AHEAD trial, that is, African Americans, eligibility criteria differentially limited enrollment yields compared to other volunteers. Similarly, restrictive criteria may contribute greatly to difficulties in meeting enrollment objectives in other trials unless efforts are made as part of the enrollment process to improve risk factor profiles. Both blood pressure and HbA1c can be modified in ‘real time’; trialists interested in enrolling African Americans should plan to facilitate referrals to primary care providers to improve eligibility rates as well as health overall.

To inform the successful planning of future trials of interventions for health problems that differentially affect certain racial/ethnic groups, we recommend careful consideration and periodic reconsideration of eligibility and exclusion criteria. Adjustment could be made to criteria overall or modification could be made that depend upon patient characteristics. In some trials, close monitoring of reasons for ineligibility and failure to enroll among early screenees has prompted careful reevaluation and modification of eligibility criteria [36–38]. Safety concerns may restrict full participation in some aspects of an intervention, for example, the physical exercise component of Look AHEAD. But less demanding physical exercise could be formulated for subgroups who may not tolerate the desired regimen. These possibilities that should be considered for future trials, given the desire for greater participation by members of minority populations in trials of conditions that affect them differentially.

Overall, our findings have alerted us to the need to evaluate the effects of eligibility criteria as a source of disparate enrollment in diabetes trials. Although our experience in Look AHEAD, a single trial, may not be representative of experiences in other trials, it is possible that fewer African Americans are eligible for clinical trials because they have greater burdens of adverse risk factors than non-African Americans and greater than trial designers anticipate. Successful strategies to recruit and enroll African Americans must take into account the differential impact of health-related eligibility criteria.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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For full details of the Look AHEAD Clinical sites, coordinating center, central resource centres and federal sponsors please refer to the online supplementary material.

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**Table 1**

Enrollment status of Look AHEAD volunteers by self-identified race/ethnicity

Race/ethnicity	Screened <sup>a</sup>	Nonenrollment status frequency/percent		Enrollment status phase frequency/ percent
		Ineligible <sup>b</sup>	Lost/refused <sup>b</sup>	Randomized <sup>b</sup>
Missing	1171	690	480	1
	4.08	58.92	40.99	0.09
African American/Black (not Hispanic)	6226	2994	2428	804
	21.67	48.09	39.00	12.91
American Indian/Native	1235	280	697	258
American/Alaskan Native	4.30	22.67	56.44	20.89
Asian/Pacific Islander	278	148	80	50
	0.97	53.24	28.78	17.99
White	16,739	6736	6751	3252
	58.25	40.24	40.33	19.43
Hispanic	2465	957	828	680
	8.58	38.82	33.59	27.59
Other/mixed	621	277	244	100
	2.16	44.61	39.29	16.10
Total	28,735	12,082	11,508	5145

<sup>a</sup>Percents in the column add to 100%.<sup>b</sup>Percents in the rows add to 100%.

**Table 2**

Reasons for ineligibility among African American and non-African American screenees at prescreening contacts and prerandomization screening examinations for the Look AHEAD trial

Reason ineligibility	African Americans screenees, <sup>a</sup> n = 6226	All other screenees, <sup>a</sup> n = 22,509	p value, <sup>2</sup>
Initial contact			
Age outside eligible range, <45 or >75 years	380 (6.1)	1173 (5.3)	0.01
Not diabetic	378 (6.1)	1307 (5.9)	0.52
Diabetes diagnosed before age 25 years and requires insulin	21 (1.3)	47 (1.1)	0.52
Self-reported BMI too low (<25 kg/m <sup>2</sup> or <27 kg/m <sup>2</sup> when using insulin)	99 (2.6)	371 (2.9)	0.25
Weight too high (>350lbs)	82 (2.1)	241 (1.9)	0.38
Total number excluded at initial contact			
Clinic visits			
Diabetes not confirmed	51 (0.8)	91 (0.4)	<0.001
Blood pressure > 160/100 mmHg	135 (6.9)	229 (2.7)	<0.001
Heart rate outside eligible range, <45 or >100 bpm	51 (2.6)	121 (1.4)	<0.001
Measured BMI too low, <25 kg/m <sup>2</sup> or <27 kg/m <sup>2</sup> when using insulin	3 (0.2)	12 (0.2)	0.89
HbA1c too high, >11%	59 (3.4)	89 (1.1)	<0.001
Serum creatinine too high, >1.5 mg/dL for men or >1.4 mg/dL for women	103 (5.9)	175 (2.2)	<0.001
Triglycerides too high, >600mg/dL	2 (0.1)	76 (1.0)	<0.001
Behavioral tasks incomplete	53 (4.5)	158 (2.6)	<0.001
Team assessment <sup>b</sup>	107 (9.3)	438 (7.3)	0.02
Heart disease	8 (0.8)	12 (0.2)	0.003
Resting ECG abnormalities	2 (0.2)	21 (0.4)	0.35
Other excluding medical conditions	37 (3.6)	190 (3.4)	0.75
Maximal graded exercise test	134 (14.4)	777 (15.9)	0.23
Procedures not completed within 4-month enrollment window	78 (1.3)	328 (1.5)	0.23

BMI, body mass index.

<sup>a</sup>Denominators were all individuals for whom data were collected and may vary among criteria.

<sup>b</sup>The assessment team were multidisciplinary including a registered dietitian, behavioral psychologist (or other mental health professional), and an exercise specialist.

Table 3

Comparison of ineligibility rates of African American and other screenees within subgroups and between race ethnicity groups based on logistic regression analyses with covariate adjustment for a clinical site

Subgroup	Race	Number screened	Percent ineligible	Odds ratio (95% CI)	Interaction <i>p</i> value
Age (years)					
45–59	African Americans	3405	44.7	1.2 (1.2, 1.4)	0.80
	Others	11,180	36.8	Reference	
60–74	African Americans	2420	46.0	1.3 (1.2, 1.4)	Reference
	Others	9775	38.7	Reference	
Gender					
Women	African Americans	4562	47.5	1.2 (1.1, 1.3)	0.01
	Others	12,375	40.1	Reference	
Men	African Americans	1654	49.3	1.5 (1.3, 1.6)	Reference
	Others	9568	38.8	Reference	
Prior MI					
No	African Americans	3090	51.7	1.4 (1.3, 1.5)	0.27
	Others	9761	40.9	Reference	
Yes	African Americans	227	58.2	1.6 (1.1, 2.2)	Reference
	Others	953	43.3	Reference	
Prior stroke					
No	African Americans	3094	51.8	1.4 (1.3, 1.5)	0.62
	Others	10,119	40.7	Reference	
Yes	African Americans	223	56.5	1.2 (0.8, 1.7)	Reference
	Others	575	48.4	Reference	
Prior CABG					
No	African Americans	3220	51.9	1.4 (1.3, 1.5)	0.39
	Others	9993	41.0	Reference	
Yes	African Americans	94	57.5	1.6 (1.0, 2.5)	Reference
	Others	707	43.4	Reference	
Prior angioplasty					
No	African Americans	3149	51.9	1.4 (1.3, 1.5)	0.69
	Others	9802	41.1	Reference	

Subgroup	Race	Number screened	Percent ineligible	Odds ratio (95% CI)	Interaction <i>p</i> value
Yes	African Americans	167	54.5	1.3 (0.9, 1.8)	
	Others	899	41.8	Reference	
Prior cardiac rehabilitation					
No	African Americans	3211	51.9	1.4 (1.3, 1.5)	0.13
	Others	10,038	41.1	Reference	
Yes	African Americans	102	57.8	1.9 (1.2, 3.0)	
	Others	649	40.7	Reference	
Insulin use					
No	African Americans	4468	45.6	1.2 (1.1, 1.3)	0.02
	Others	17,969	39.4	Reference	
Yes	African Americans	1758	54.4	1.4 (1.2, 1.5)	
	Others	4540	44.2	Reference	
Other diabetes medications					
No	African Americans	1872	61.2	1.3 (1.2, 1.5)	0.02
	Others	6272	51.4	Reference	
Yes	African Americans	4354	42.5	1.2 (1.1, 1.3)	
	Others	16,237	36.1	Reference	
BMI (kg/m <sup>2</sup> ) <sup>a</sup>					
25–29	African Americans	887	42.8	1.3 (1.1, 1.5)	0.70
	Others	4121	35.6	Reference	
30–34	African Americans	1767	39.9	1.2 (1.1, 1.4)	
	Others	6650	32.9	Reference	
35–39	African Americans	2360	45.5	1.3 (1.2, 1.5)	
	Others	7863	37.1	Reference	
40	African Americans	873	59.1	1.1 (1.0, 1.3)	
	Others	2299	52.3	Reference	
Alcohol use					
No	African Americans	3935	37.3	1.2 (1.1, 1.3)	0.39
	Others	13,493	32.2	Reference	
Yes	African Americans	953	35.2	1.2 (1.1, 1.4)	
	Others	5099	30.2	Reference	

Mount et al.

Page 14

MI, myocardial infarction; CABG, coronary artery bypass graft; BMI, body mass index.

Percentages are in parentheses; denominators may vary by subgroups.

<sup>a</sup>Limited to individuals with BMI  $\geq 25\text{kg/m}^2$  (i.e., within the BMI range studied by Look AHEAD).

**Table 4**

Baseline characteristics of African American and other enrollees randomized in the Look AHEAD trial

Baseline characteristic	Number (%) of randomized participants		p value
	African Americans	Others	
Age (years)			
45–59	491 (61.2)	2443 (56.7)	0.02
60–74	311 (38.8)	1868 (43.3)	
Gender			
Women	615 (76.5)	2448 (56.4)	<0.001
Men	189 (23.5)	1893 (43.6)	
Prior MI			
No	396 (96.6)	2076 (93.4)	0.01
Yes	14 (3.4)	146 (6.6)	
Prior stroke			
No	402 (98.0)	2155 (97.0)	0.23
Yes	8 (2.0)	67 (3.0)	
Prior CABG			
No	405 (98.8)	2104 (94.7)	<0.001
Yes	5 (1.2)	118 (5.3)	
Prior angioplasty			
No	399 (97.3)	2057 (92.6)	<0.001
Yes	11 (2.7)	165 (7.4)	
Prior cardiac rehabilitation			
No	402 (98.0)	2091 (94.1)	0.001
Yes	8 (2.0)	131 (5.9)	
Insulin use			
No	657 (2.0)	3695 (2.3)	0.84
Yes	147 (98.0)	646 (97.7)	
Other diabetes medications			
No	152 (18.9)	847 (19.5)	0.69
Yes	652 (81.1)	3494 (80.5)	
BMI (kg/m <sup>2</sup> ) <sup>a</sup>			
25–29	119 (14.8)	824 (19.0)	<0.001
30–34	280 (34.8)	1588 (36.6)	
35–39	331 (41.2)	1656 (38.1)	
40	74 (9.2)	273 (6.3)	
Alcohol use			
No	603 (75.0)	2973 (68.5)	<0.001
Yes	201 (25.0)	1368 (31.5)	
Hypertension <sup>b</sup>			
No	92 (11.4)	734 (16.9)	<0.001
Yes	712 (88.6)	3107 (83.1)	

MI: myocardial infarction, CABG: coronary artery bypass graft, BMI: body mass index.

Percentages are in parentheses; denominators may vary by subgroups.

<sup>a</sup>Limited to individuals with BMI  $\geq 25\text{kg/m}^2$  (i.e., within the BMI range studied by Look AHEAD).

<sup>b</sup>Defined as history of diagnosis, current treatment, or measured blood pressure  $>140/90\text{mmHg}$ .