

## SUPPLEMENTARY DATA

### Look AHEAD Research Group at End of Intervention

Updated 08/11/2015

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SUPPLEMENTARY DATA

**Supplementary Table S1.** Frequency of Component Events in the Composite Primary and Secondary Outcomes by Sex

| Total Outcome and Outcome Components | Primary Outcome Events |     | Secondary Outcome 1 Events |     | Secondary Outcome 2 Events |     | Secondary Outcome 3 Events |     |
|--------------------------------------|------------------------|-----|----------------------------|-----|----------------------------|-----|----------------------------|-----|
|                                      | M                      | F   | M                          | F   | M                          | F   | M                          | F   |
| Total Composite Outcome              | 482                    | 355 | 320                        | 242 | 600                        | 477 | 689                        | 539 |
| Any Death                            |                        |     |                            |     | 244                        | 190 | 244                        | 190 |
| CVD Death                            | 78                     | 33  | 78                         | 33  |                            |     |                            |     |
| Nonfatal MI                          | 208                    | 144 | 208                        | 144 | 208                        | 144 | 208                        | 144 |
| Nonfatal Stroke                      | 72                     | 83  | 72                         | 83  | 72                         | 83  | 72                         | 83  |
| Hospitalized Angina                  | 240                    | 154 |                            |     | 240                        | 154 | 240                        | 154 |
| CABG                                 |                        |     |                            |     |                            |     | 347                        | 185 |
| CHF                                  |                        |     |                            |     |                            |     | 133                        | 87  |
| CEA                                  |                        |     |                            |     |                            |     | 32                         | 25  |
| PVD                                  |                        |     |                            |     |                            |     | 52                         | 35  |

Abbreviations: CVD = cardiovascular disease, MI = myocardial infarction, CABG = coronary artery bypass graft, CHF = congestive heart failure, CEA = carotid endarterectomy. PVD = peripheral vascular disease. The sum of component CVD events exceeds the number of events in the composite outcomes because a single individual could have a first occurrence of more than one component event during the same hospital admission, but only one event counted toward the composite outcome. Eleven participants had multiple Primary Outcome events, 4 participants had multiple Secondary Outcome 1 events, 11 participants had multiple Secondary Outcome 2 events, and 418 participants had multiple Secondary Outcome 3 events. In men, 268 of 689 (38.9%) Secondary Outcome 3 events involved multiple co-occurring component events; in women, 161 of 539 (29.8%) Secondary Outcome 3 events involved multiple co-occurring component events. The most frequently occurring combinations of events were Angina + CABG (men: 155, women: 83) and MI + CABG (men: 86, women: 41).

SUPPLEMENTARY DATA

**Supplementary Table S2.** Association of Baseline BDI Score with Incidence of Look AHEAD Primary and Secondary Outcomes Stepping in Covariates in Three Sequential Models

|                 |        | Baseline BDI Score    |         |                      |         |                      |         |                      |         |
|-----------------|--------|-----------------------|---------|----------------------|---------|----------------------|---------|----------------------|---------|
|                 |        | Primary               |         | Secondary 1          |         | Secondary 2          |         | Secondary 3          |         |
|                 |        | HR (95% CI)           | P-value | HR (95% CI)          | P-value | HR (95% CI)          | P-value | HR (95% CI)          | P-value |
| Model 1         | Male   | 1.030 (1.011, 1.050)  | 0.0024  | 1.017 (0.992, 1.041) | 0.1807  | 1.031 (1.013, 1.049) | 0.0005  | 1.033 (1.017, 1.049) | <0.0001 |
|                 | Female | 1.001 (0.981, 1.022)  | 0.9246  | 0.993 (0.968, 1.019) | 0.6125  | 0.999 (0.982, 1.017) | 0.9444  | 1.001 (0.984, 1.018) | 0.9340  |
| Model 2         | Male   | 1.026 (1.006, 1.047)  | 0.0103  | 1.011 (0.986, 1.037) | 0.3937  | 1.028 (1.010, 1.047) | 0.0023  | 1.032 (1.015, 1.050) | 0.0002  |
|                 | Female | 0.994 (0.973, 1.015)  | 0.5673  | 0.988 (0.962, 1.014) | 0.3582  | 0.994 (0.976, 1.012) | 0.5043  | 0.994 (0.977, 1.011) | 0.4909  |
| Model 2 +       | Male   | 1.028 (1.008, 1.049)  | 0.0069  | 1.011 (0.986, 1.037) | 0.3896  | 1.029 (1.010, 1.047) | 0.0020  | 1.032 (1.051, 1.049) | 0.0002  |
| A1c and insulin | Female | 0.992 (0.9741, 1.013) | 0.4610  | 0.985 (0.959, 1.012) | 0.2807  | 0.992 (0.974, 1.011) | 0.3964  | 0.992 (0.975, 1.010) | 0.3762  |
| Model 2 +       | Male   | 1.025 (1.005, 1.046)  | 0.0129  | 1.010 (0.985, 1.036) | 0.4274  | 1.027 (1.009, 1.046) | 0.0031  | 1.032 (1.015, 1.049) | 0.0002  |
| BP, BP meds     | Female | 0.993 (0.972, 1.015)  | 0.5381  | 0.987 (0.961, 1.013) | 0.3187  | 0.993 (0.975, 1.012) | 0.4867  | 0.993 (0.976, 1.011) | 0.4548  |
| Model 2 +       | Male   | 1.022 (1.001, 1.043)  | 0.0367  | 1.005 (0.797, 1.032) | 0.7065  | 1.026 (1.007, 1.045) | 0.0066  | 1.030 (1.013, 1.047) | 0.0006  |
| lipids and meds | Female | 0.994 (0.972, 1.016)  | 0.5784  | 0.989 (0.962, 1.016) | 0.4062  | 0.996 (0.977, 1.015) | 0.6456  | 0.996 (0.978, 1.013) | 0.6339  |
| Model 2 +       | Male   | 1.026 (1.006, 1.047)  | 0.0108  | 1.011 (0.986, 1.037) | 0.3907  | 1.029 (1.011, 1.048) | 0.0018  | N/A                  |         |
| ABI             | Female | 0.994 (0.973, 1.015)  | 0.5696  | 0.988 (0.962, 1.014) | 0.3650  | 0.994 (0.975, 1.012) | 0.4994  | N/A                  |         |
| Model 2 +       | Male   | 1.026 (1.006, 1.047)  | 0.0114  | 1.010 (0.984, 1.036) | 0.4628  | 1.028 (1.009, 1.046) | 0.0028  | 1.032 (1.015, 1.049) | 0.0002  |
| Smoking         | Female | 0.994 (0.973, 1.015)  | 0.5669  | 0.988 (0.962, 1.014) | 0.3622  | 0.994 (0.976, 1.012) | 0.5072  | 0.994 (0.976, 1.011) | 0.4606  |
| Model 2 +       | Male   | 1.022 (1.002, 1.043)  | 0.0316  | 1.005 (0.980, 1.031) | 0.6910  | 1.024 (1.006, 1.043) | 0.0103  | 1.028 (1.011, 1.046) | 0.0011  |
| METs            | Female | 0.989 (0.968, 1.011)  | 0.3308  | 0.983 (0.957, 1.010) | 0.2102  | 0.990 (0.971, 1.009) | 0.2849  | 0.990 (0.972, 1.007) | 0.2443  |
| Model 2 +       | Male   | N/A                   |         | N/A                  |         | N/A                  |         | N/A                  |         |
| HRT meds        | Female | 0.994 (0.973, 1.015)  | 0.5744  | 0.988 (0.962, 1.014) | 0.3642  | 0.994 (0.976, 1.012) | 0.5109  | 0.994 (0.977, 1.011) | 0.4932  |
| Model 3         | Male   | 1.020 (0.999, 1.041)  | 0.0679  | 0.998 (0.972, 1.025) | 0.9011  | 1.023 (1.004, 1.042) | 0.0178  | 1.026 (1.009, 1.044) | 0.0030  |
|                 | Female | 0.988 (0.966, 1.010)  | 0.2802  | 0.982 (0.956, 1.010) | 0.2019  | 0.991 (0.972, 1.010) | 0.3389  | 0.990 (0.973, 1.008) | 0.2908  |

Model 1: Gender specific model stratified by clinic and including treatment assignment

Model 2: Gender specific model stratified by clinic and including treatment assignment, age (continuous), race/ethnicity, prior CVD, BMI, waist circumference

Model 3: Model 3 + A1c, insulin use, SBP, DBP, antihypertensive use, LDL, HDL, Total Cholesterol, Triglycerides, lipid lowering medication use, ABI outside normal range (<0.9, >1.3) except in Secondary 3, smoking, maximal METs achieved, HRT (females only)

SUPPLEMENTARY DATA

**Supplementary Table S3.** Association of Baseline ADM Use with Incidence of Look AHEAD Primary and Secondary Outcomes Stepping in Baseline Covariates in Three Sequential Models

|                 |        | Baseline ADM use     |         |                      |         |                      |         |                      |         |
|-----------------|--------|----------------------|---------|----------------------|---------|----------------------|---------|----------------------|---------|
|                 |        | Primary              |         | Secondary 1          |         | Secondary 2          |         | Secondary 3          |         |
|                 |        | HR (95% CI)          | P-value | HR (95% CI)          | P-value | HR (95% CI)          | P-value | HR (95% CI)          | P-value |
| Model 1         | Male   | 0.986 (0.746, 1.304) | 0.9222  | 0.836 (0.586, 1.194) | 0.3256  | 1.046 (0.818, 1.337) | 0.7227  | 1.103 (0.880, 1.382) | 0.3945  |
|                 | Female | 0.796 (0.601, 1.055) | 0.1128  | 0.919 (0.662, 1.278) | 0.6165  | 0.796 (0.623, 1.016) | 0.0668  | 0.804 (0.639, 1.011) | 0.0619  |
| Model 2         | Male   | 0.989 (0.745, 1.314) | 0.9401  | 0.804 (0.560, 1.156) | 0.2389  | 1.063 (0.826, 1.367) | 0.6356  | 1.121 (0.890, 1.412) | 0.334   |
|                 | Female | 0.793 (0.596, 1.057) | 0.1135  | 0.932 (0.667, 1.303) | 0.6808  | 0.779 (0.607, 0.998) | 0.0482  | 0.807 (0.640, 1.019) | 0.0721  |
| Model 2 +       | Male   | 0.797 (0.737, 1.301) | 0.8850  | 0.782 (0.544, 1.124) | 0.1840  | 1.050 (0.816, 1.351) | 0.7019  | 1.109 (0.881, 1.397) | 0.3785  |
| A1c and insulin | Female | 0.770 (0.577, 1.027) | 0.0755  | 0.906 (0.647, 1.269) | 0.5650  | 0.764 (0.596, 0.980) | 0.0340  | 0.798 (0.631, 1.008) | 0.0578  |
| Model 2 +       | Male   | 0.963 (0.724, 1.280) | 0.7955  | 0.781 (0.543, 1.124) | 0.1836  | 1.038 (0.807, 1.337) | 0.7708  | 1.086 (0.861, 1.369) | 0.4882  |
| BP, BP meds     | Female | 0.781 (0.586, 1.041) | 0.0916  | 0.910 (0.651, 1.273) | 0.5830  | 0.773 (0.603, 0.991) | 0.0420  | 0.801 (0.634, 1.011) | 0.0618  |
| Model 2 +       | Male   | 1.049 (0.788, 1.398) | 0.7422  | 0.850 (0.590, 1.224) | 0.3820  | 1.134 (0.879, 1.462) | 0.3324  | 1.182 (0.936, 1.491) | 0.1594  |
| lipids and meds | Female | 0.774 (0.577, 1.040) | 0.0889  | 0.930 (0.662, 1.306) | 0.6735  | 0.773 (0.600, 0.996) | 0.0468  | 0.806 (0.635, 1.022) | 0.0753  |
| Model 2 +       | Male   | 0.987 (0.743, 1.311) | 0.9275  | 0.802 (0.558, 1.153) | 0.2330  | 1.065 (0.828, 1.370) | 0.6245  | N/A                  |         |
| ABI             | Female | 0.794 (0.596, 1.057) | 0.1138  | 0.931 (0.666, 1.302) | 0.6774  | 0.779 (0.608, 0.999) | 0.0490  | N/A                  |         |
| Model 2 +       | Male   | 0.971 (0.729, 1.293) | 0.8387  | 0.775 (0.537, 1.118) | 0.1732  | 1.044 (0.810, 1.346) | 0.7370  | 1.108 (0.878, 1.398) | 0.3871  |
| Smoking         | Female | 0.791 (0.594, 1.054) | 0.1090  | 0.928 (0.664, 1.297) | 0.6606  | 0.776 (0.605, 0.995) | 0.0452  | 0.804 (0.637, 1.015) | 0.0666  |
| Model 2 +       | Male   | 0.940 (0.707, 1.250) | 0.6715  | 0.755 (0.525, 1.086) | 0.1297  | 1.013 (0.787, 1.304) | 0.9212  | 1.069 (0.848, 1.347) | 0.5748  |
| METs            | Female | 0.742 (0.556, 0.990) | 0.0422  | 0.873 (0.623, 1.221) | 0.4269  | 0.738 (0.575, 0.947) | 0.0168  | 0.761 (0.603, 0.962) | 0.0225  |
| Model 2 +       | Male   | N/A                  |         | N/A                  |         | N/A                  |         | N/A                  |         |
| HRT meds        | Female | 0.794 (0.596, 1.058) | 0.1153  | 0.936 (0.670, 1.309) | 0.6989  | 0.779 (0.608, 0.999) | 0.0489  | 0.806 (0.639, 1.018) | 0.0707  |
| Model 3         | Male   | 0.949 (0.709, 1.270) | 0.7233  | 0.720 (0.495, 1.046) | 0.0846  | 1.033 (0.798, 1.337) | 0.8061  | 1.072 (0.847, 1.357) | 0.3350  |
|                 | Female | 0.708 (0.526, 0.954) | 0.0234  | 0.858 (0.608, 1.210) | 0.3829  | 0.723 (0.559, 0.935) | 0.0133  | 0.755 (0.594, 0.960) | 0.0217  |

Model 1: Gender specific model stratified by clinic and including treatment assignment

Model 2: Gender specific model stratified by clinic and including treatment assignment, age (continuous), race/ethnicity, prior CVD, BMI, waist circumference

Model 3: Model 3 + A1c, insulin use, SBP, DBP, antihypertensive use, LDL, HDL, Total Cholesterol, Triglycerides, lipid lowering medication use, ABI outside normal range (<0.9, >1.3) except in Secondary 3, smoking, maximal METs achieved, HRT (females only)

SUPPLEMENTARY DATA

**Supplementary Table S4.** Association of Baseline BDI $\geq$ 10 with Incidence of Look AHEAD Primary and Secondary Outcomes Stepping in Baseline Covariates in Three Sequential Models

|                 |        | Baseline BDI $\geq$ 10 |         |                      |         |                      |         |                      |         |
|-----------------|--------|------------------------|---------|----------------------|---------|----------------------|---------|----------------------|---------|
|                 |        | Primary                |         | Secondary 1          |         | Secondary 2          |         | Secondary 3          |         |
|                 |        | HR (95% CI)            | P-value | HR (95% CI)          | P-value | HR (95% CI)          | P-value | HR (95% CI) in       | P-value |
| Model 1         | Male   | 1.243 (0.963, 1.605)   | 0.0945  | 1.209 (0.886, 1.650) | 0.2304  | 1.227 (0.977, 1.542) | 0.0785  | 1.308 (1.061, 1.612) | 0.0120  |
|                 | Female | 0.901 (0.689, 1.177)   | 0.4451  | 0.780 (0.556, 1.093) | 0.1491  | 0.899 (0.714, 1.133) | 0.3676  | 0.874 (0.702, 1.087) | 0.2255  |
| Model 2         | Male   | 1.233 (0.952, 1.595)   | 0.1119  | 1.142 (0.835, 1.561) | 0.4071  | 1.220 (0.968, 1.538) | 0.0920  | 1.351 (1.093, 1.671) | 0.0054  |
|                 | Female | 0.868 (0.663, 1.136)   | 0.3031  | 0.756 (0.538, 1.062) | 0.1068  | 0.873 (0.692, 1.101) | 0.2520  | 0.837 (0.671, 1.043) | 0.1122  |
| Model 2 +       | Male   | 1.253 (0.965, 1.626)   | 0.0901  | 1.218 (0.887, 1.672) | 0.2236  | 1.220 (0.966, 1.542) | 0.0953  | 1.330 (1.074, 1.649) | 0.0091  |
| A1c and insulin | Female | 0.840 (0.641, 1.100)   | 0.2044  | 0.732 (0.520, 1.029) | 0.0726  | 0.846 (0.670, 1.068) | 0.1589  | 0.812 (0.651, 1.012) | 0.0642  |
| Model 2 +       | Male   | 1.224 (0.946, 1.584)   | 0.1241  | 1.209 (0.883, 1.656) | 0.2360  | 1.213 (0.962, 1.528) | 0.1019  | 1.348 (1.090, 1.667) | 0.0058  |
| BP, BP meds     | Female | 0.865 (0.660, 1.133)   | 0.2911  | 0.749 (0.533, 1.054) | 0.0972  | 0.872 (0.691, 1.100) | 0.2480  | 0.835 (0.670, 1.041) | 0.1088  |
| Model 2 +       | Male   | 1.178 (0.906, 1.533)   | 0.2220  | 1.150 (0.833, 1.587) | 0.3957  | 1.190 (0.940, 1.506) | 0.1475  | 1.327 (1.070, 1.646) | 0.0099  |
| lipids and meds | Female | 0.840 (0.638, 1.107)   | 0.2165  | 0.774 (0.549, 1.089) | 0.1416  | 0.857 (0.675, 1.087) | 0.2033  | 0.827 (0.660, 1.035) | 0.0974  |
| Model 2 +       | Male   | 1.234 (0.953, 1.598)   | 0.1104  | 1.223 (0.893, 1.675) | 0.2097  | 1.224 (0.971, 1.543) | 0.0871  | N/A                  |         |
| ABI             | Female | 0.867 (0.662, 1.135)   | 0.2982  | 0.758 (0.539, 1.065) | 0.1101  | 0.870 (0.689, 1.098) | 0.2405  | N/A                  |         |
| Model 2 +       | Male   | 1.220 (0.941, 1.582)   | 0.1338  | 1.180 (0.859, 1.620) | 0.3075  | 1.205 (0.955, 1.522) | 0.1158  | 1.338 (1.081, 1.656) | 0.0075  |
| Smoking         | Female | 0.867 (0.663, 1.136)   | 0.3005  | 0.756 (0.538, 1.062) | 0.1066  | 0.873 (0.692, 1.101) | 0.2504  | 0.837 (0.672, 1.043) | 0.1137  |
| Model 2 +       | Male   | 1.199 (0.926, 1.552)   | 0.1687  | 1.168 (0.853, 1.600) | 0.3321  | 1.183 (0.938, 1.491) | 0.1557  | 1.315 (1.064, 1.627) | 0.0114  |
| METs            | Female | 0.834 (0.637, 1.093)   | 0.1877  | 0.727 (0.517, 1.022) | 0.0666  | 0.842 (0.667, 1.064) | 0.1495  | 0.804 (0.645, 1.003) | 0.0531  |
| Model 2 +       | Male   | N/A                    |         | N/A                  |         | N/A                  |         | N/A                  |         |
| HRT meds        | Female | 0.869 (0.664, 1.137)   | 0.3063  | 0.756 (0.538, 1.062) | 0.1069  | 0.874 (0.692, 1.102) | 0.2547  | 0.837 (0.672, 1.043) | 0.1127  |
| Model 3         | Male   | 1.147 (0.875, 1.503)   | 0.3199  | 1.048 (0.754, 1.459) | 0.7787  | 1.143 (0.898, 1.455) | 0.2782  | 1.261 (1.012, 1.571) | 0.0387  |
|                 | Female | 0.784 (0.594, 1.035)   | 0.0860  | 0.729 (0.517, 1.029) | 0.0726  | 0.808 (0.636, 1.027) | 0.0815  | 0.781 (0.623, 0.980) | 0.0325  |

Model 1: Gender specific model stratified by clinic and including treatment assignment

Model 2: Gender specific model stratified by clinic and including treatment assignment, age (continuous), race/ethnicity, gender, prior CVD, BMI, waist circumference

Model 3: Model 3 + A1c, insulin use, SBP, DBP, antihypertensive use, LDL, HDL, Total Cholesterol, Triglycerides, lipid lowering medication use, ABI outside normal range (<0.9, >1.3) except in Secondary 3, smoking, maximal METs achieved, HRT (females only)