

Dataset Integrity Check for Action
for Health in Diabetes (Look AHEAD)
Study Data

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1 Standard Disclaimer

The intent of this DSIC is to provide confidence that the data distributed by the NIDDK repository is a true copy of the study data. Our intent is not to assess the integrity of the statistical analyses reported by study investigators. As with all statistical analyses of complex datasets, complete replication of a set of statistical results should not be expected in secondary analysis. This occurs for a number of reasons including differences in the handling of missing data, restrictions on cases included in samples for a particular analysis, software coding used to define complex variables, etc. Experience suggests that most discrepancies can ordinarily be resolved by consultation with the study data coordinating center (DCC), however this process is labor-intensive for both DCC and Repository staff. It is thus not our policy to resolve every discrepancy that is observed in an integrity check. Specifically, we do not attempt to resolve minor or inconsequential discrepancies with published results or discrepancies that involve complex analyses, unless NIDDK Repository staff suspect that the observed discrepancy suggests that the dataset may have been corrupted in storage, transmission, or processing by repository staff. We do, however, document in footnotes to the integrity check those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

2 Study Background

Short-term studies have shown numerous benefits of weight loss in overweight or obese patients, including improvements in glycemic control, risk factors for cardiovascular disease, quality of life, and other obesity-related coexisting illnesses. The Look AHEAD study was designed to test whether weight loss similarly improved cardiovascular morbidity and mortality in patients with type 2 diabetes. The study was a multicenter, randomized clinical trial that examined the long-term effects of an intensive lifestyle intervention program designed to achieve and maintain weight loss by decreased caloric intake and increased physical activity.

Eligible patients with type 2 diabetes and a body-mass index (BMI) of 25.0 or more were enrolled and randomly assigned either to participate in an intensive lifestyle intervention (intervention group) or to receive diabetes support and education (control group). The intensive lifestyle intervention, which included both group and individual counseling sessions, was aimed at achieving and maintaining weight loss of at least 7% by focusing on reduced caloric intake and increased physical activity. The diabetes support and education program featured sessions focusing on diet, exercise, and social support. Both the intervention and control programs occurred with decreasing frequency as the trial progressed. The primary outcome measure was the first occurrence of a composite cardiovascular outcome, which consisted of death from cardiovascular causes, nonfatal myocardial infarction, nonfatal stroke, and hospitalization for angina.

3 Archived Datasets

All data files, as provided by the Data Coordinating Center (DCC), are located in the Look AHEAD folder in the data package. For this replication, variables were taken from the “la_key.sas7bdat” and “mortality.sas7bdat” datasets.

4 Statistical Methods

Analyses were performed to replicate results for the data in the publication by Wing et al. [1]. To verify the integrity of the data, only descriptive statistics were computed.

5 Results

For Table 1 in the publication [1], Cause of death in the ILLI and DSE, Table A lists the variables that were used in the replication, and Table B compares the results calculated from the archived data files to the results in Table 1. The results of the replication are within expected variation of the published results given the recency of the publication compared to the when the data were submitted by the DCC.

6 Conclusions

The NIDDK Central Repository is confident that the Look AHEAD data files to be distributed are a true copy of the study data.

7 References

[1] Wing RR, Bray GA, Cassidy-Begay M, Clark JM, Coday M, Egan C, Evans M, Foreyt JP, Glasser S, Gregg EW, Hazuda HP, Hill JO, Horton ES, Isaac JC, Jakicic JM, Jeffery RW, Johnson KC, Kahn SE, Kritchevsky S, Lewis E, Maruthur NM, Maschak-Carey BJ, Nathan DM, Patricio J, Peters A, Pi-Sunyer X, Reboussin D, Ryan DH, Ruelas V, Steinburg H, Toledo K, Wadden TA, Wagenknecht LE, Wesche-Thobaben J, Wyatt H, Yanovski SZ, Zhang P. Effects of Intensive Lifestyle Intervention on All-Cause Mortality in Older Adults With Type 2 Diabetes and Overweight/Obesity: Results From the Look AHEAD Study. *Diabetes Care*, 45(5), 1252-1259, March 2022. doi: <https://doi.org/10.2337/dc21-1805>

Table A: Variables used to replicate Table 1 – Cause of death in the ILI and DSE

| Table Variable | dataset.variable |
|---------------------------|------------------------------------------------------------------------------------------------|
| Cancer | la_key.randarm mortality.deathprimcause |
| Cardiovascular | la_key.randarm mortality.deathprimcause |
| Other | la_key.randarm mortality.deathprimcause |
| Accidental | la_key.randarm mortality.primcause |
| Complications of diabetes | la_key.randarm mortality.otherknowncause |
| Gastrointestinal | la_key.randarm mortality.otherknowncause |
| Hepatobiliary/pancreas | la_key.randarm mortality.otherknowncause |
| Infectious | la_key.randarm mortality.otherknowncause |
| Neurological | la_key.randarm mortality.otherknowncause |
| Other known cause | la_key.randarm mortality.otherknowncause |
| Pulmonary | la_key.randarm mortality.otherknowncause |
| Renal failure | la_key.randarm mortality.otherknowncause |
| Unclassifiable | la_key.randarm mortality.otherknowncause |
| Unknown | la_key.randarm mortality.primcause |
| Total | la_key.randarm mortality.primcause mortality.otherknowncause mortality.deathprimcause |

Table B: Comparison of values computed in integrity check to reference article Table 1 values

| Causes of Death | DSE | DSE DSIC | Diff. | ILI | ILI DSIC | Diff. | Total | Total DSIC | Diff. |
|---------------------------|----------|----------|---------|----------|----------|--------|-------|------------|-------|
| Cancer | 177 (30) | 172 (30) | 5 (0) | 157 (29) | 155 (30) | 2 (1) | 334 | 327 | 7 |
| Cardiovascular | 149 (25) | 147 (26) | 2 (1) | 154 (28) | 152 (29) | 2 (1) | 303 | 299 | 4 |
| Other | 207 (35) | 200 (35) | 7 (0) | 172 (31) | 161 (31) | 11 (0) | 379 | 361 | 18 |
| Accidental | 21 | 21 | 0 | 20 | 19 | 1 | 41 | 40 | 1 |
| Complications of diabetes | 3 | 3 | 0 | 2 | 2 | 0 | 5 | 5 | 0 |
| Gastrointestinal | 7 | 7 | 0 | 2 | 2 | 0 | 9 | 9 | 0 |
| Hepatobiliary/pancreas | 22 | 21 | 1 | 9 | 8 | 1 | 31 | 29 | 2 |
| Infectious | 46 | 42 | 4 | 44 | 44 | 0 | 90 | 86 | 4 |
| Neurological | 30 | 29 | 1 | 29 | 27 | 2 | 59 | 56 | 3 |
| Other known cause | 4 | 4 | 0 | 7 | 7 | 0 | 11 | 11 | 0 |
| Pulmonary | 26 | 26 | 0 | 18 | 17 | 1 | 44 | 43 | 1 |
| Renal failure | 12 | 11 | 1 | 12 | 9 | 3 | 24 | 20 | 4 |
| Unclassifiable | 36 | 36 | 0 | 29 | 26 | 3 | 65 | 62 | 3 |
| Unknown | 56 (10) | 48 (8.5) | 8 (1.5) | 66 (12) | 57 (11) | 9 (1) | 122 | 105 | 17 |
| Total | 589 | 567 | 22 | 549 | 525 | 24 | 1,138 | 1,092 | 46 |

Note: DSE = Diabetes support and education; ILI = Intensive lifestyle intervention. Results are N (%) unless otherwise indicated.

Attachment A: SAS Code

```
libname la "X:\NIDDK\niddk-dr_studies2\Look_AHEAD\private_created_data\Look
AHEAD_V9\Data\Intervention\Data\Key Data";
libname la2 "X:\NIDDK\niddk-dr_studies2\Look_AHEAD\private_created_data\Look
AHEAD_V9\Data\Post_Intervention\Outcomes Data";

/*****/
/* Look AHEAD DSIC for Mortality */
/* Outcomes data -Wing et. al. */
/*****/

proc contents data=la.la_key;
run;
*use la_key dataset for the RandArm variable;
*use the Mortality outcomes dataset for Mortality by cause;

*create temp datasets;
data key; set la.la_key;
keep MaskID randArm;
run;

data mort; set la2.mortality;
run;

*sort data by MaskID;
proc sort data=key;
by MaskID;
run;

proc sort data=mort;
by MaskID;
run;

*merge datasets and keep only those in the Mortality dataset;
data one;
merge
key (in=a)
mort (in=b);
by maskid;
if b=1;
run;

*frequencies for causes of mortality in the Look AHEAD study;
proc freq data=one;
tables (DeathPrimCause OtherKnownCause PrimCause)*randArm/missing norow nopercnt;
run;
```