Dataset Integrity Check for Physical Function Following a Long-Term Lifestyle Intervention Among Middle Aged and Older Adults with Type 2 Diabetes: The Look AHEAD Study Houston

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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

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 is a multicenter, randomized clinical trial that examines 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. Participants were followed for approximately 11.4 years.

The Look AHEAD intensive lifestyle intervention ended in September, 2012. Participants continued to be followed to determine the long-term effects of the intervention on health outcomes for an additional 1.6 years.

3 Archived Datasets

All the SAS data files, as provided by the Data Coordinating Center (DCC), are located in the following datasets:

1. Look_AHEAD/private_orig_data/LA.Mob.Disb.v2/pf_mobilitydisability_v2.sas7bdat

2. Look_AHEAD/private_orig_data/Post-INTERVENTION - NIDDK Release_2/Post-INTERVENTION - NIDDK Release/3-Key Data/3a-Key Data Sets/pi_key.sas7bdat
3. Look_AHEAD/private_orig_data/LA.INTERVENTION_v2/3-Key Data/3a-Key Data/la4_outcomes1.sas7bdat

4 Statistical Methods

Analyses were performed to duplicate results for the data published by Houston et al [1] in the journal Journals of Gerontology: Medical Science in 2018. To verify the integrity of the dataset, descriptive statistics were computed.

5 Results

For Table 2 in the publication [1], Unadjusted Means and Frequencies by Intervention Assignment and Adjusted Odds Ratios (95% CI) or Mean Differences (95% CI) for Physical Function by Treatment Group at 11 Year Follow-Up: The Look AHEAD Study, 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 published in Table 2.

The data package that was provided by the DCC excluded around 200 Native American participants due to consent limitations. As a result, 3,620 sets of measurements are included in the data package rather than the 3,783 that were included in the manuscript. Given this exclusion of subjects, the numbers below are not an exact match. However, the means and percentages for the data are in the expected range given the difference in subjects between the manuscript and the data package.

6 Conclusions

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

7 References

[1] Denise K Houston, PhD, Rebecca H Neiberg, MS, Michael E Miller, PhD, James O Hill, PhD, John M Jakicic, PhD, Karen C Johnson, MD, MPH, Edward W Gregg, PhD, Van S Hubbard, MD, PhD, Xavier Pi-Sunyer, MD, W Jack Rejeski, PhD, Rena R Wing, PhD, John P Bantle, MD, Elizabeth Beale, MD, Robert I Berkowitz, MD, Maria Cassidy-Begay, BS, Jeanne M Clark, MD, MPH, Mace Coday, PhD, Linda M Delahanty, MS, Gareth Dutton, PhD, Caitlin Egan, MS, John P Foreyt, PhD, Frank L Greenway, MD, Helen P Hazuda, PhD, Andrea Hergenroeder, PhD, Edward S Horton, MD, Robert W Jeffery, PhD, Steven E Kahn, MBChB, Anne Kure, BS, William C Knowler, MD, DrPH, Cora E Lewis, MD, MSPH, Corby K Martin, PhD, Sara Michaels, MD, Maria G Montez, MS, David M Nathan, MD, Jennifer Patricio, MS, Anne Peters, MD, Henry Pownall, PhD, Judith Regensteiner, PhD, Helmut Steinburg, MD, Thomas A Wadden, PhD, Karen White, MS, Susan Z Yanovski, MD, Ping Zhang, PhD, and Stephen B Kritchevsky, PhD. J Gerontol A Biol Sci Med Sci. 2018 Oct; 73(11): 1552–1559.

Table A: Variables used to replicate Table 2: Unadjusted Means and Frequencies by Intervention Assignment and Adjusted Odds Ratios (95% CI) or Mean Differences (95% CI) for Physical Function by Treatment Group at 11 Year Follow-Up: The Look AHEAD Study

Table Variable	**dataset.variable**
DSE, ILI	pf_mobilitydisability_v2.randarm
Mobility disability	pf_mobilitydisability_v2.mobdis_final
Gait impaired	pf_mobilitydisability_v2.gait_impaired
Impaired lower extremity function	pf_mobilitydisability_v2.sppb_impaired
Impaired Grip Strength	pf_mobilitydisability_v2.grip_impaired
Gait speed	pf_mobilitydisability_v2.gc_mpersec_4m
400m walk speed (m/sec, only for participants completing the 400m walk)	pf_mobilitydisability_v2.gs_mpersec_400m
SPPB score (range 0-12)	pf_mobilitydisability_v2.sppb_corrected
SPPB exp score (range 0-3)	pf_mobilitydisability_v2.exp_ppb
Grip Strength (kg)	pf_mobilitydisability_v2.avg_grip_strength

Table B: Comparison of values computed in integrity check to reference article Table 2 values. Unreproducible results are listed as n/a.

Variable	ILI Manuscript N	ILI Manuscript N (%) or Mean (STD)	ILI DSIC N	ILI DSIC N (%) or Mean (STD)	Diff N	Diff N (%) or Mean (STD)
Mobility Disability						
• Definite Mobility Disability	2,134	237 (11.1)	1,823	221 (12.1)	311	16 (1.0)
• Definite Mobility Disability or Death	2,134	487 (22.8)	n/a	n/a	n/a	n/a
• Definite/probable/possible mobility disability or death	2,134	607 (28.4)	n/a	n/a	n/a	n/a
Slow gait speed (<0.8 m/s)	1,832	386 (21.1)	1,734	368 (21.2)	311	18 (0.1)
Impaired lower extremity function (SPPB≤9)	1,781	742 (41.7)	1,682	692 (41.1)	99	50 (0.6)
Impaired Grip Strength (<26 kg men; <16 kg women)	1,761	252 (14.3)	1,669	232 (13.9)	92	20 (0.4)
Gait Speed						
• 4-m gait speed (m/s)	1,832	0.95 ± 0.21	1,734	0.95 ± 0.21	98	0 ± 0
• 400-m gait speed (m/s)	1,532	1.00 ± 0.19	1452	1.00 ± 0.19	0	0 ± 0
Lower extremity physical performance						
• SPPB score (range 0-12)	1,781	9.4 ± 2.4	1,682	9.4 ± 2.4	99	0 ± 0
• SPPB exp score (range 0-3)	1,855	1.50 ± 0.46	1,750	1.5 ± 0.46	105	0 ± 0
Grip strength (kg)	1,761	27.0 ± 9.9	1,669	27.2 ± 9.9	92	0.2 ± 0

Variable	DSE Manuscript N	DSE Manuscript N (%) or Mean (STD)	DSE DSIC N	DSE DSIC N (%) or Mean (STD)	Diff N	Diff N (%) or Mean (STD)
Mobility Disability						
• Definite Mobility Disability	2,137	260 (12.2)	1,797	247 (13.8)	340	13 (1.6)
• Definite Mobility Disability or Death	2,137	535 (25.0)	n/a	n/a	n/a	n/a
• Definite/probable/possible mobility disability or death	2,137	650 (30.4)	n/a	n/a	n/a	n/a
Slow gait speed (<0.8 m/s)	1,806	441 (24.4)	1,703	419 (24.6)	103	22 (0.2)
Impaired lower extremity function (SPPB≤9)	1,731	772 (41.7)	1,624	671 (41.3)	107	101 (0.4)
Impaired Grip Strength (<26 kg men; <16 kg women)	1,732	265 (15.3)	1,640	243 (14.8)	92	22 (0.5)
Gait Speed						
• 4-m gait speed (m/s)	1,806	0.93 ± 0.21	1,703	0.93 ± 0.21	103	0 ± 0
• 400-m gait speed (m/s)	1,494	0.97 ± 0.19	1407	0.97 ± 0.19	87	0 ± 0
Lower extremity physical performance						
• SPPB score (range 0-12)	1,731	9.3 ± 2.4	1,624	9.3 ± 2.4	107	0 ± 0
• SPPB exp score (range 0-3)	1,817	1.46 ± 0.46	1,705	1.46 ± 0.46	112	0 ± 0
Grip strength (kg)	1,732	26.5 ± 9.7	1,640	26.8 ± 9.7	92	0.3 ± 0

Attachment A: SAS Code

```
/*************************************************************************************************************************************************
  Program: /prj/niddk/ims_analysis/Look_AHEAD/prog_initial_analysis/Look_AHEAD.dsic.20191218.sas
*************************************************************************************************************************************************/
TITLE "%sysfunc(getoption(sysin))";

/************/
/* Formats */
/************/
PROC FORMAT;
  VALUE AGECAT
    44-54 = '44-54'
    55-64 = '55-64'
    65-76 = '65-76';
  VALUE $STUDY
    '0' = 'DSE'
    '1' = 'ILI';
RUN;

/*******************/
/* Import datasets */
/*******************/
LIBNAME SASDATA '/prj/niddk/dataset_files/Look_AHEAD_V5/Look_AHEAD_V5/Data/End_of_Intervention/Key_Data';
LIBNAME SASDATA3 '/prj/niddk/ims_analysis/Look_AHEAD/private_orig_data/Post-INTERVENTION - NIDDK Release_2/Post-INTERVENTION - NIDDK
Release/3-Key Data/3a-Key Data Sets/';
LIBNAME SASDATA5 '/prj/niddk/ims_analysis/Look_AHEAD/private_orig_data/Post-INTERVENTION - NIDDK Release_2/Post-INTERVENTION - NIDDK
Release/5-Measures/5a-Measures Data Sets/';
LIBNAME SASDATA6 '/prj/niddk/ims_analysis/Look_AHEAD/private_orig_data/Post-INTERVENTION - NIDDK Release_2/Post-INTERVENTION - NIDDK
Release/6-Physical Function/6a-Physical Function Data Sets/';
LIBNAME SASDATA7 '/prj/niddk/ims_analysis/Look_AHEAD/private_orig_data/Post-INTERVENTION - NIDDK Release_2/Post-INTERVENTION - NIDDK
Release/7-Questionnaires/7a-Questionnaire Data Sets/';
LIBNAME MOBDIS   '/prj/niddk/ims_analysis/Look_AHEAD/private_orig_data/LA.Mob.Disb.v2';

/*****************************************************/
/* Combine data from multiple sources to check table 2 */
/*****************************************************/
PROC SORT DATA=MOBDIS.PF_MOBILITYDISABILITY_v2 OUT=PF_MOBILITYDISABILITY NODUPKEY;
  BY MASKID;
RUN;

PROC SORT DATA=SASDATA.LA4_OUTCOMES1 OUT=LA4_OUTCOMES1;
  BY MASKID;
RUN;

PROC SORT DATA=SASDATA3.pi_key OUT=PI_KEY;
  BY MASKID;
RUN;

DATA COHORT;
```

```
  MERGE PF_MOBILITYDISABILITY      (IN=INMOBILE)
        PI_KEY                     (IN=INKEY)
       LA4_OUTCOMES1              (IN=INOUT KEEP=MASKID DEATH);
  BY MASKID;
  IF INMOBILE AND INKEY;
RUN;

/************************/
/* Check table 2 numbers */
/************************/
TITLE2 'Table 2 numbers';
PROC FREQ DATA=COHORT;
  TABLE (mobdis_final gait_impaired sppb_impaired grip_impaired) * randarm;
  format randarm $study.;
run;

PROC MEANS DATA=COHORT NOLABELS;
  VAR gc_mpersec_4m
      gs_mpersec_400m
      sppb_corrected
      EXP_PPB
      avg_grip_strength;
  CLASS RANDARM;
  format randarm $study.;
RUN;
```