

Look AHEAD (Action for Health in Diabetes) Baseline, Year 4, and End-of-Intervention Data Archive

The Look AHEAD study is a multicenter randomized clinical trial in overweight and obese individuals with type 2 diabetes to evaluate the long-term effects of an intensive weight loss intervention on major cardiovascular events. Eligibility requirements are diagnosis of type 2 diabetes (determined by self-report and verification) in individuals age 45–76 years, BMI >25 kg/m² (>27 kg/m² if currently taking insulin). A total of 5,145 participants from 16 clinical centers were randomized between 2001 and 2004. The published manuscript by the Look AHEAD Research Group provides baseline and follow-up characteristics of this randomized cohort. Follow-up of the Look AHEAD cohort is ongoing. The Look AHEAD Data Archive contains related descriptive documentation, data collection forms, study data, and a data integrity check for the Baseline, Year 4 follow-up, and for the End-of-Intervention for this study.

The files in the archive are organized into the following directories, for the Baseline, Year 4, and End-of-Intervention data:

1. Documentation
2. Forms
3. Data
4. Dataset Integrity Checks (DSICs)

The Data and Forms directories are further organized into the following subdirectories for the Baseline, Year 4, and End-of-Intervention data:

1. Baseline
2. Year4
3. End_of_Intervention

Documentation

The Documentation directory contains:

- Introduction.pdf – Provides an overview of the study and the data package
- Bibliography.pdf – Bibliography of all study publications
- Examination & Follow-up Timeline.pdf – Provides the collection schedule for measurements and forms.
- Protocol.pdf – Protocol for Look AHEAD
- Protocol_Summary_of_all_changes – thru 2012.pdf – provides a summary of the changes with each revision of the Protocol.pdf document.

The Documentation\MOP\ directory contains 32 .pdf files for the 26 chapters of the Manual of Procedures. Each file is named in the format “Chapter_xx_...”.

Forms

The Forms directory contains the following subdirectories: Baseline, Year4, and End_of_Intervention. Each of these subdirectories contains the annotated versions of the study forms used during that phase of the study.

- Forms\Baseline

File (.pdf)	Form Name and Content
aabpV1	Ankle/arm blood pressures and waist meas., Baseline: Version 1
aabpV2	Ankle/arm blood pressures and waist meas., Baseline: Version 2
aabpV3	Ankle/arm blood pressures and waist meas., Baseline and Follow- up: Version 3
abilities	Abilities (e.g., vision, hearing, comprehension, movement, self- care, emotions, memory, pain)
alcohol	Alcohol use
beck	Moods
Bloodspec	Blood specimen collection: Baseline Version
BloodUrine	Blood and urine collection
boneDensity	Bone density and fat (DXA) Scan Substudy Form: Version 2
bpweight	Blood pressure and weight, Baseline Version 2
EatingHabits	Eating habits (e.g., consumption, use of diet pills)
eatingpatterns	Eating patterns (daily)
ecg	Electrocardiogram: Version 3
eligforma	Eligibility Screening Form A, Staff Completed: Version 6 (incl diabetes confirmation, blood pressure, body size, lab tests, age)
eligformb	Eligibility Screening Form B, Staff Completed: Version 3 (incl cardiovascular assessment, ECG and stress test eligibility)
exHabits	Exercise habits
famhistory	Family medical history, Baseline
feeltherm	Thoughts and feelings (self assessment of current health)
qxt	Maximal graded exercise test, Baseline Version 6
Knees	My Health: Part B, self-assessment of knee pain
medhistory	Medical History, Baseline
medinventory	Medication inventory
prescreening	Pre-screening, Interviewer Administered: Version 5
race	Respondent race
resource	Participant Resource Use (for exercise, food preparation, etc)
sf36	My Health, Part A: Health Utilities
sociodemographics	Sociodemographic characteristics: myself and my family
symptom	My Health: Part B, symptoms in past month, past 3 months
tobacco	Behaviors: Baseline, tobacco use
urinary	My Health: Part B, urinary habits
urineSpec	Urine Specimen Collection
weightcontrol	Weight Control Practices: Baseline
wgthistory	My Health: Part B, weight history
womenshealth	Women's Health: Baseline (pregnancy, medications, menopause)

- Forms\Year 4

File (.pdf)	Form Name and Content
AnnualBPWgt	Blood pressure and weight, annual follow-up
AnnualSocioDemg	Sociodemographic characteristics: myself and my family
AnnualTobacco	Tobacco behaviors, annual follow-up
AnnualWmnHealth	Women's health, annual follow-up
SubmaxGXT	Submaximal graded exercise test, version 2
Yr4SubmaxGXT	4 year submaximal graded exercise test

- Forms\End of Intervention

File (.pdf)	Form Name and Content
Costs_ResourceUse	Participant Resource Use
DXA_Questionnaire	Bone Density and Fat (DXA) Scan Substudy
HealthBehaviors_Alcohol	Alcohol Use
HealthBehaviors_DietRaw	Nutrition Questionnaire
HealthBehaviors_EatingPatterns	Eating Patterns
HealthBehaviors_ExerciseHabits	Exercise Habits
HealthBehaviors_Tobacco	Behaviors – Tobacco Use
HealthBehaviors_WeightControl	Weight Control Practices
HealthOutcomes_Falls	Falls in the past year
HealthOutcomes_Knees	Knee pain in the past month
HealthOutcomes_MedsInventory	Medication Inventory Follow-up
HealthOutcomes_ReproductiveHx	Women's Health, includes reproductive history, contraception
HealthOutcomes_Symptoms	My Health – Part B, includes complaints during past 4 weeks
HealthOutcomes_UrnryIncontinence	Urinary history
HealthOutcomes_WeightHistory	Weight history
MedicalHistory_Family	Family Medical History
MedicalHistory_Personal	Medical History
PhysicalMeasures_ABI_Waist	Ankle/Arm Blood Pressures and Waist circumference
PhysicalMeasures_BP_BMI	Blood Pressure, Weight, Waist, and Height
Psychosocial_Depression	Moods Annual BD-I
Psychosocial_EatingDisorders	Eating Habits
QALY_FeelThermometer	Thoughts and Feelings
QALY_HUI	Thoughts and Feelings, Self-Administered version
QOL_SF36	My Health, SF-36
Screening_EligibilityA	Eligibility Screening Form A, Staff Completed, version 6
Screening_EligibilityB	Eligibility Screening Form B, Staff Completed version 3
Screening_Prescreening	Pre-screening, Interviewer Administered, version 5
Sociodemographics	Myself and My Family, Baseline version 3
TechnologyUse	Technology Use, Version 2

Data

The Data directory contains the following subdirectories to organize the data files for each phase of the study: Baseline, Year4, and End_of_Intervention. Each of these subdirectories is further organized into analysis data, forms data, contents, or summary statistics.

- [LA Data Preparation Notes.pdf](#) – contains a description as well as variable and editing notes for each Key, Measures, and Questionnaire data set.
- [Data Availability.pdf](#) – contains information on that data that is available and the timing of data collection
- **Data\Baseline\Analysis Data**
 - [baseline_combined.sas7bdat](#) - dataset of derived and common sociodemographic and clinical variables (e.g., age, gender, race, BMI, lipids, Beck Depression score) in SAS format.
 - [baseline_combined.xlsx](#) - dataset of derived and common sociodemographic and clinical variables (e.g., age, gender, race, BMI, lipids, Beck Depression score) in Microsoft Excel format.
 - [diet_baseline.sas7bdat](#) - data derived from the Food Frequency Questionnaires (completed on the first half of randomized participants at each site) in SAS format.
 - [diet_baseline.xlsx](#) - data derived from the Food Frequency Questionnaires (completed on the first half of randomized participants at each site) in Microsoft Excel format.
 - [diet_baseline_raw.sas7bdat](#) - the raw data derived from the Food Frequency Questionnaire in SAS format.
 - [dxa_baseline.sas7bdat](#) - DEXA scan data (completed on all participants at sites 2, 4, 7, 8, and 17 in SAS format.
 - [dxa_baseline.xlsx](#) - DEXA scan data (completed on all participants at sites 2, 4, 7, 8, and 17 in Microsoft Excel format.
- **Data\Baseline\Contents\Analysis**
 - [Contents.baseline_combined.pdf](#) – provides output from SAS *proc contents* for the [baseline_combined.sas7bdat](#) file.
 - [Contents.diet_baseline.pdf](#) – provides output from SAS *proc contents* for the [diet_baseline.sas7bdat](#) file.
 - [Contents.diet_baseline_raw.pdf](#) - provides output from SAS *proc contents* for the [diet_baseline_raw.sas7bdat](#) file.
 - [Contents.dxa_baseline.pdf](#) - provides output from SAS *proc contents* for the [dxa_baseline.sas7bdat](#) file.
 - [LookAhead.baseline_combined.dictionary.xlsx](#) – the data dictionary for the [baseline_combined](#) file.

- **Data\Baseline\Contents\Forms**
 - 33 .pdf files, one for each baseline form, that contain the SAS *proc contents* for the named form dataset.

- **Data\Baseline\Form Data**
 - 33 SAS data sets that correspond to a form with the same name as the data set.
 - aabpv1.sas7bdat – Ankle/arm blood pressures and waist measures, version 1.
 - aabpv2.sas7bdat – Ankle/arm blood pressures and waist measures, version 2.
 - alcohol.sas7bdat – Alcohol use.
 - anklearmbloodprswaist.sas7bdat – Ankle/arm blood pressures and waist measures, version 4.
 - babloodspec.sas7bdat – Blood specimen collection, baseline.
 - baeatinghabits.sas7bdat – Eating habits (e.g. consumption, use of diet pills).
 - baeatingpatterns.sas7bdat - Eating patterns (daily).
 - bawgtcontrol.sas7bdat – Weight control practices, baseline.
 - beck.sas7bdat – Moods.
 - bloodpressureweightbaseline.sas7bdat – Blood pressure and weight, baseline.
 - bloodurine.sas7bdat – Blood and urine collection.
 - bonedensity.sas7bdat – Bone density and fat (DXA) Scan substudy, version 2.
 - ecg.sas7bdat – Electrocardiogram, version 3.
 - eligibility.sas7bdat - Eligibility Screening Form B, Staff Completed: Version 3 (incl cardiovascular assessment, ECG and stress test eligibility)
 - eligscreen.sas7bdat - Eligibility Screening Form A, Staff Completed: Version 6 (incl diabetes confirmation, blood pressure, body size, lab tests, age)
 - exhabits.sas7bdat – Exercise habits.
 - famhistory.sas7bdat – Family medical history, baseline.
 - feeltherm.sas7bdat – Thoughts and feelings (self-assessment of current health).
 - gradedexercise.sas7bdat - Maximal graded exercise test, Baseline Version 6.
 - hui.sas7bdat – Abilities (e.g., vision, hearing, comprehension, movement, self- care, emotions, memory, pain).
 - knees.sas7bdat - My Health: Part B, self-assessment of knee pain.
 - medhistorybaseline.sas7bdat - Medical History, Baseline.
 - medinventory.sas7bdat – Medication Inventory.
 - prescreening.sas7bdat - Pre-screening, Interviewer Administered: Version 5.
 - resource.sas7bdat - Participant Resource Use (for exercise, food preparation, etc).
 - sf36.sas7bdat - My Health, Part A: Health Utilities Index (SF-36).
 - sociodemographicbaseline.sas7bdat - Sociodemographic characteristics: myself and my family.
 - symptom.sas7bdat - My Health: Part B, symptoms in past month, past 3 months.

- tobaccobaseline.sas7bdat - Behaviors: Baseline, tobacco use.
 - urinary.sas7bdat - My Health: Part B, urinary habits.
 - urinespec.sas7bdat - Urine Specimen Collection.
 - wgthistory.sas7bdat - My Health: Part B, weight history.
 - womenshealthbaseline.sas7bdat - Women's Health: Baseline (pregnancy, medications, menopause).
- **Data\Baseline\Summary Statistics\Analysis**
 - Summary Statistics.baseline_combined.pdf – contains summary statistics for the baseline_combined file.
 - Summary Statistics.diet_baseline.pdf – contains summary statistics for the diet_baseline file.
 - Summary Statistics.diet_baseline_raw.pdf – contains summary statistics for the diet_baseline_raw file.
 - Summary Statistics.dxa_baseline.pdf – contains summary statistics for the dxa_baseline file.
- **Data\Baseline\Summary Statistics\Forms**
 - 33 .pdf files, one for each baseline form, that contain the summary statistics for the named form dataset.
- **Data\Year4\Analysis Data**
 - diet_year4.sas7bdat – data derived from the Food Frequency Questionnaires (completed on the first half of randomized participants at each site).
 - diet_year4_raw.sas7bdat – the raw data derived from the Food Frequency Questionnaire.
 - dxa_year4.sas7bdata – DEXA scan data (completed on all participants at sites 2, 4, 7, 8, and 17).
 - year4.combined.sas7bdat - dataset of derived and common sociodemographic and clinical variables (e.g., age, gender, race, BMI, lipids, Beck Depression score).
- **Data\Year4\Contents**
 - Contents.year4_combined.pdf – provides output from SAS *proc contents* for the year4_combined.sas7bdat file.
 - Contents.diet_year4.pdf – provides output from SAS *proc contents* for the diet_year4.sas7bdat file.
 - Contents.diet_year4_raw.pdf - provides output from SAS *proc contents* for the diet_year4_raw.sas7bdat file.
 - Contents.dxa_year4.pdf - provides output from SAS *proc contents* for the

dxa_year4.sas7bdat file.

- LookAHEAD.year4_combined.dictionary.xlsx – the data dictionary for the year4_combined file.

- **Data\Year4\Summary_Statistics**
 - Summary_Statistics.year4_combined.pdf – contains summary statistics for the year4_combined file.
 - Summary_Statistics.diet_year4.pdf – contains summary statistics for the diet_year4 file.
 - Summary_Statistics.diet_year4_raw.pdf – contains summary statistics for the diet_year4_raw file.
 - Summary_Statistics.dxa_year4.pdf – contains summary statistics for the dxa_year4 file.

- **Data\End_of_Intervention\Contents\Forms_Data**
 - 29 .pdf files (one for each End-of-Intervention phase form) that contain the SAS *proc contents* for the named form dataset.

- **Data\End_of_Intervention\Contents\Key_Data**
 - Contents.LA_Key.pdf – contains the SAS *proc contents* for the LA_Key dataset.
 - Contents.LA2_BaselineVariables.pdf – contains the SAS *proc contents* for the LA2_BaselineVariables dataset.
 - Contents.LA3_ActivityStatus.pdf – contains the SAS *proc contents* for the LA3_ActivityStatus dataset.
 - Contents.LA4_Outcomes1.pdf – contains the SAS *proc contents* for the LA4_Outcomes1 dataset.

- **Data\End_of_Intervention\Contents\Measures_Data**
 - Contents.Accelerometry0.pdf – contains the SAS *proc contents* for the accelerometry0.sas7bdat data file.
 - Contents.Accelerometry1.pdf – contains the SAS *proc contents* for the accelerometry1.sas7bdat data file.
 - Contents.DXA.pdf – contains the SAS *proc contents* for the dxa.sas7bdat data file.
 - Contents.DXA_Questionnaire.pdf – contains the SAS *proc contents* for the dxa_questionnaire.sas7bdat data file.
 - Contents.EducationAssessment.pdf – contains the SAS *proc contents* for the educationassessment.sas7bdat data file.
 - Contents.InterventionAssessment.pdf – contains the SAS *proc contents* for the interventionassessment.sas7bdat data file.

- [Contents.LaboratoryMeasures.pdf](#) – contains the SAS *proc contents* for the laboratorymeasures.sas7bdat data file.
 - [Contents.PhysicalMeasures_ABI_Waist.pdf](#) – contains the SAS *proc contents* for the physicalmeasures_abi_waist.sas7bdat data file.
 - [Contents.PhysicalMeasures_BP_BMI.pdf](#) – contains the SAS *proc contents* for the physicalmeasures_bp_bmi.sas7bdat data file.
 - [Contents.StressTest_MaximalGXT.pdf](#) – contains the SAS *proc contents* for the stresstest_maximalgxt.sas7bdat data file.
 - [Contents.StressTest_SubmaxGXT.pdf](#) – contains the SAS *proc contents* for the stresstest_submaxgxt.sas7bdat data file.
- **Data\End of Intervention\Forms Data**
 - costs_resourceuse.sas7bdat
 - healthbehaviors_alcohol.sas7bdat
 - healthbehaviors_diet.sas7bdat
 - healthbehaviors_dietraw.sas7bdat
 - healthbehaviors_eatingpatterns.sas7bdat
 - healthbehaviors_exercisehabits.sas7bdat
 - healthbehaviors_tobacco.sas7bdat
 - healthbehaviors_weightcontrol.sas7bdat
 - healthoutcomes_falls.sas7bdat
 - healthoutcomes_knees.sas7bdat
 - healthoutcomes_medsinventory.sas7bdat
 - healthoutcomes_meduse.sas7bdat
 - healthoutcomes_reproductivehx.sas7bdat
 - healthoutcomes_symptoms.sas7bdat
 - healthoutcomes_urnryincontinence.sas7bdat
 - healthoutcomes_weighthistory.sas7bdat
 - medicalhistory_family.sas7bdat
 - medicalhistory_personal.sas7bdat
 - psychosocial_depression.sas7bdat
 - psychosocial_eatingdisorders.sas7bdat
 - qaly_feelthermometer.sas7bdat
 - qaly_hui.sas7bdat
 - qol_sf36.sas7bdat
 - screening_eligibilitya.sas7bdat
 - screening_eligibilityb.sas7bdat
 - screening_prescreening.sas7bdat
 - sociodemographics.sas7bdat
 - technologyuse.sas7bdat

- **Data\End of Intervention\Key Data**
 - la_key.sas7bdat
 - la2_baselinevariables.sas7bdat
 - la3_activitystatus.sas7bdat
 - la4_outcomes1.sas7bdat

- **Data\End of Intervention\Measures Data**
 - accelerometry0.sas7bdat
 - accelerometry1.sas7bdata
 - dxa.sas7bdat
 - dxa_questionnaire.sas7bdat
 - educationassessment.sas7bdat
 - interventionassessment.sas7bdat
 - laboratorymeasures.sas7bdat
 - physicalmeasures_abi_waist.sas7bdat
 - physicalmeasures_bp_bmi.sas7bdat
 - stresstest_maximalgxt.sas7bdat
 - stresstest_submaxgxt.sas7bdat

- **Data\End of Intervention\Summary Statistics\Forms Data**
 - 28 .pdf files with summary statistics that correspond to each of the 28 SAS data sets in the Forms_Data data directory.

- **Data\End of Intervention\Summary Statistics\Key Data**
 - 4 .pdf files with summary statistics that correspond to each of the 4 SAS data sets in the Key_Data data directory.

- **Data\End of Intervention\Summary Statistics\Measures Data**
 - 11 .pdf files with summary statistics that correspond to each of the 11 SAS data sets in the Measures_Data data directory.

DSICs

The DSICs directory contains the following Dataset Integrity Check (DSIC) documents:

- [Baseline_DSIC.pdf](#) – a report based on an examination of the data in the repository by statisticians and quality control specialists at the Repository. The baseline data published by the Look AHEAD Research Group (in *Diab Vasc Dis Res*, 2006) were compared to values recalculated from the Look AHEAD Baseline data in the NIDDK repository. Data were checked for completeness, consistency, and usability.
- [Year4_DSIC.pdf](#) – a report based on an examination of the data in the repository by statisticians and quality control specialists at the Repository. The data published by the Look AHEAD Research Group (in *Obesity*, 2011) providing baseline and follow-up characteristics of this randomized cohort were compared to values recalculated from the Look AHEAD Year 4 data in the NIDDK repository. Data were checked for completeness, consistency, and usability.
- [End_of_Intervention_DSIC.pdf](#) - a report based on an examination of the data in the repository by statisticians and quality control specialists at the Repository. The data published by the Look AHEAD Research Group (in *New England Journal of Medicine*, 2013) providing follow-up data of this randomized cohort were compared to values recalculated from the Look AHEAD End of Intervention data in the NIDDK repository. Data were checked for completeness, consistency, and usability.