Sample NDSR Data Analysis Plan

This data analysis plan was developed by and shared with you courtesy of Lisa Chow, MD, MS at the University of Minnesota Medical School. Results from the study were published in this article:

Oldenburg, Niki, et al. "Time-restricted eating, caloric reduction, and unrestricted eating effects on weight and metabolism: a randomized trial." *Obesity* (2025).

SFS2 Research Questions and Statistical Analysis Plan related to the 24-hour dietary recall data
DRAFT 09/21/2022

RESEARCH HYPOTHESES

Research Hypothesis 1 (part of Aim 2 grant proposal): Those in TRE and CR groups will reduce their energy intake (kcal/day) between baseline and follow up to a similar extent, and more than those in the MCC group.

Research Hypothesis 2 (exploratory outcome): Those in TRE and CR groups will improve their diet quality (total HEI 2015 score and scores for each of the 13 index components) between baseline and follow to a similar extent, and more than those in the MCC group.

Research Hypothesis 3 (exploratory outcome): Those in the TRE and CR groups will decrease sugar sweetened beverage intake to a similar extent, and more than those in the MCC group.

Research Hypothesis 4 (exploratory outcome): Those in the TRE and CR groups will decrease alcoholic beverage intake to a similar extent, and more than those in the MCC group.

Research Hypothesis 5 (exploratory outcome): At follow up those in the TRE group will generally eat over a shorter time period each day in comparison to those in the CR and MCC groups.

INTERVENTION COMPLIANCE RELATED ANALYSES

TRE group intervention compliance related questions:

To what extent was the eating window reduced between baseline and follow up among those in the TRE group?

To what extent did those in the TRE group comply with the prescribed eating window: $\leq$ 8 hour ($\leq$4,800 minute)?

CR group intervention compliance related questions:

To what extent was calorie intake reduced between baseline and follow up among those in the CR group?

To what extent did those in the CR group comply with the targeted energy reduction level ($\geq$15% reduction)?

DIETARY DATA COLLECTED

Three 24-hour dietary recalls were to be collected from each participant at baseline and another set of three recalls were collected during the final two weeks of the intervention periods (approximately 10 weeks after the first set of recalls). Three recalls were collected as a measure of usual eating patterns during the time period they were collected (because of high day-to-day variation in dietary habits a single day of reporting is an insufficient measure of usual diet).

The recalls were collected over the telephone by staff at the University of Minnesota Nutrition Coordinating Center (NCC) using Nutrition Data System for Research (NDSR), a dietary analysis software program designed for the collection and nutrient analysis of dietary intake information. As part of each dietary recall participants are asked to report all of the foods and beverages they ate over a day (24-hour period). The time and name of each eating occasion is entered into an NDSR dietary recall record (e.g. 8 am breakfast) along with detailed information about each food eaten at the occasion (e.g. 8 fluid ounces black coffee; 1 medium banana; 1 cup Honey Nut Cheerios; 3 fluid ounces 2% milk).

NDSR OUTPUT FILES NEEDED

NDSR generates a series of output files (n=24) that provide a variety of data for each 24-hour dietary recall record. Details regarding variables available in each output files are available in the NDSR User Manual . Data from the output files listed below will be needed for analyses.

File 02 (Food File)
File 03 (Meal File)
File 04 (Daily Intake Totals File)
File 09 (Serving Count Totals File)

CREATE SAS DATASETS

Create datasets that include all of the data (variables) from the aforementioned output files. SAS program files are provided by NCC for loading NDSR Output Files into the SAS Program, assigning formats and labels to the SAS variables, and defining the relationships within a set of Output Files. They may be used as templates and modified according to the needs of each study

DATA ANALYSIS PLAN

Step 1: Create following variables based on the variables available for the baseline (BL) and follow up (FU) dietary recalls collected for participants

Variable	Notes
Energy intake (kcal/day) BL	average across BL dietary recalls
Energy intake (kcal/day) FU	average across FU dietary recalls
Energy intake (kcal/day) change between BL and FU	FU –BL
Energy intake change as a percent of BL energy intake	(FU-BL)/BL * 100
Energy intake decrease between BL and FU $\geq$15%	
HEI 2015 Total Score BL	Sum of 13 BL component scores+
HEI 2015 Total Score FU	Sum of 13 FU component scores++
HEI 2015 Total Score change between BL and FU	FU –BL
HEI 2015 Total Fruits BL	*
HEI 2015 Total Fruits FU	*
HEI 2015 Total Fruits change between BL and FU	FU-BL
HEI 2015 Whole Fruits BL	*
HEI 2015 Whole Fruits FU	*
HEI 2015 Whole Fruits change between BL and FU	FU-BL

HEI 2015 Total Vegetables BL	*
HEI 2015 Total Vegetables FU	*
HEI 2015 Total Vegetables change between BL and FU	FU-BL
HEI 2015 Greens and Beans BL	*
HEI 2015 Greens and Beans FU	*
HEI 2015 Total Greens and Beans change between BL and FU	FU-BL
HEI 2015 Whole Grains BL	*
HEI 2015 Whole Grains FU	*
HEI 2015 Whole Grains change between BL and FU	FU-BL
HEI 2015 Dairy BL	*
HEI 2015 Dairy FU	*
HEI 2015 Dairy change between BL and FU	FU-BL
HEI 2015 Total Protein Foods BL	*
HEI 2015 Total Protein Foods FU	*
HEI 2015 Total Protein Foods change between BL and FU	FU-BL
HEI 2015 Seafood and Plant Protein Foods BL	*
HEI 2015 Seafood and Plant Protein Foods FU	*
HEI 2015 Seafood and Plant Protein Foods change between BL and FU	FU-BL
HEI 2015 Fatty Acids BL	*
HEI 2015 Fatty Acids FU	*
HEI 2015 Fatty Acids change between BL and FU	FU-BL
HEI 2015 Refined Grains BL	*
HEI 2015 Refined Grains FU	*
HEI 2015 Sodium BL	*
HEI 2015 Sodium FU	*
HEI 2015 Sodium change between BL and FU	FU-BL
HEI 2015 Added Sugars BL	*
HEI 2015 Added Sugars FU	*
HEI 2015 Added Sugars change between BL and FU	FU-BL
HEI 2015 Saturated Fats BL	*
HEI 2015 Saturated Fats FU	*
HEI 2015 Saturated Fats change between BL and FU	FU-BL
Eating window (minutes/day) BL	average across BL dietary recalls**
Eating window (minutes/day) FU	average across FU dietary recalls**
Eating window change between BL and FU (minutes/day)	FU-BL
Eating window ≤ 8 hours (≤4,800 minutes) BL	
Eating window ≤ 8 hours (≤4,800 minutes) FU	
SSB intake*** (servings/day) BL	
SSB intake*** (servings/day) FU	
SSB intake (servings/day) change between BL and FU	FU-BL
Alcoholic beverage intake**** (servings/day) BL	
Alcoholic beverage intake**** (servings/day) FU	
Alcoholic beverage intake**** (servings/day) change between BL and FU	FU-BL

* Index component scores across multiple 24-hour dietary recalls should **NOT** be determined by calculating the average of the daily scores provided. Instead, the 'Simple method for multiple days' approach will be used.

NCC SAS code available to support calculating component and total scores using the 'Simple method for multiple days' ([Approach 2](#)) will be used.

**the eating window in a 24-hour dietary recall is defined as the minutes between the time recorded for the first eating occasion and the last eating occasion in which a food other than water has been consumed. Foods with the following food IDs in output file 02 are to be considered 'water': 257 (bottled mineral water), 24218 (bottled spring water), 3187 (tap water).

*** total SSB intake is the sum of the following variables found in File 09 (Serving Count Totals File): BVS0400, BVS0300, BVS0500, BVS0100, BVS0200, BVS0600

**** total alcoholic beverage intake is the sum of the following variables found in File 09 (Serving Count Totals File): BVE0100, BVE0400, BVE0300, BVE0200

Step 2: Apply exclusion criteria

Exclude from all subsequent analyses those who meet any of the following criteria:
1) Less than 2 24-hour dietary recalls at baseline
2) Less than 2 24-hour dietary recalls at follow up
3) Mean energy intake of less than 500 kcals/day or more than 7,000 kcal/day at baseline
4) Mean energy intake of less than 500 kcals/day or more than 7,000 kcal/day at follow up

Step 3: Conduct PROC UNIVARIATE for each of the variables created in Step 1

Review results of this analysis as data integrity check; look for outliers; assess distribution of data including level of skewness

Step 4: Carryout analyses to populate the 'participant characteristics' table (see table 1 mock up)

Step 5: Carryout following multivariate regression models to test research hypotheses

Research Hypothesis 1
Dependent variable**:** energy intake (kcal/day) FU
Independent variables**:** experimental group, energy intake (kcal/day) BL, [additional covariates such as age, sex, to be determined]

Research Hypothesis 2

Dependent variable**:** HEI 2015 Total Score FU
Independent variables**:** experimental group, HEI Total Score BL, [additional covariates such as age, sex, to be determined]

RUN MODEL FOR EACH OF THE 13 HEI 2015 INDEX COMPONENTS

Research Hypothesis 3

Dependent variable: SSB intake FU
Independent variables: experimental group, SSB BL, [additional covariates such as age, sex, to be determined]

Research Hypothesis 4

Dependent variable: Alcoholic beverage intake FU
Independent variables: experimental group, alcoholic beverage intake BL, [additional covariates such as age, sex, to be determined]

Research Hypothesis 5
Dependent variable: eating window at follow up (minutes/day)
Independent variables: experimental group, eating window at baseline (minutes/day), [additional covariates such as age, sex, to be determined]

DATA ANALYSIS PLAN FOR INTERVENTION COMPLIANCE RELATED ANALYSES

TRE Group
To what extent was the eating window reduced between baseline and follow up among those in the TRE group?

Calculate mean eating window (minutes/day) for those in the TRE group at baseline and follow up.

To what extent did those in the TRE group comply with the prescribed eating window: $\leq$ 8 hour (4,800 minutes)?

Calculate the percent of TRE group with a mean eating window $\leq$ 8 hours (4,800 minutes) at follow up.

CR Group

To what extent was calorie intake reduced between baseline and follow up among those in the CR group?

Calculate mean energy intake (kcal/day) at baseline and follow up.

To what extent did those in the CR group comply with the targeted energy reduction level (15% reduction)?

Calculate the mean percent energy change in the CR group.

Calculate the percent of the CR group participants with a calorie reduction between baseline and follow up of $\geq$15% kcal.