

Evaluation of a Letter Intervention Promoting a Plant-based Diet (NCT03880838)

Statistical Analysis Plan

March 11, 2021

Statistical Analysis Plan

Project Status

All interventions have been launched and data collection is ongoing. The time period for the primary outcomes (1 year pre-intervention, 1 year post-intervention) has already elapsed, and the analysis will focus on this time period. The data have not been examined as of the time this document has been posted.

Due to delays in pulling claims-level data from the Geisinger Health Plan, we currently do not have access to 3 of the 6 primary outcomes: (1) change in number of visits, (2) change in number of prescriptions, and (3) change in number of unique prescribed medications. The plans outlined below will still be followed for these outcomes if we are later able to acquire these data. The key primary outcome – change in medical cost – was collected, as were the other primary and secondary outcomes.

Planned Analyses

We currently have 7 primary and 6 secondary outcome variables, with timeframes for analysis relative to the intervention date outlined below.

Outcome	Desired Level	Primary Analysis	Secondary Analysis 1	Secondary Analysis 2
Medical Cost	Lower	1 year pre, 1 year post		5 years pre, 2 years post
Visits*	Lower			
Number of Prescriptions*	Lower			
Number of Unique Prescribed Medication*	Lower			
Body Mass Index	Between 18.5 to 25			
Systolic Blood Pressure	< 120 mmHG			
Diastolic Blood Pressure	< 80 mmHG			
Triglyceride Level	< 150 mg/dl		1 year pre, 1 year post	
Low-density Lipoprotein (LDL) Level	< 100mg/dl			
High-density Lipoprotein (HLD) Level	< 60 mg/dl			
LDL/HDL Ratio	< 3 for men, < 2 for women			
Hemoglobin A1c (hba1c)	< 5.7%			
Depressed Mood and Anhedonia (PHQ-2)	Lower			

* Data currently unavailable

For clarity in this plan, the different conditions (and planned sample sizes) of the study are presented below. Passive control participants who are missing all outcome data and all other participants who returned mail (e.g., wrong address; did not accept mail) will be excluded from the analysis.

Passive Control	Active Control (Letter with no Video)	Letter with Video			
		Link	DVD	DVD + Link	
2200	2200	550	550	550	Letter Only
		550	550	550	Commitment Nudge
		550	550	550	Prevention Nudge
		550	550	550	Commitment + Prevention
2200	2200	2200	2200	2200	

The overall hypothesis for this project is that the experimental conditions (e.g., participants who received Forks Over Knives materials; shaded yellow in the figure above) should have better outcomes compared with those in the control conditions, one year after the intervention. All outcomes are hypothesized to shift in the direction of the desired levels (i.e., lower costs, better health). Among the primary outcomes, cost is of greatest interest and importance, as it encompasses multiple other outcomes.

Primary Analysis and Secondary Analysis 1

As we are interested in the change in each outcome between 1 year pre-intervention and 1 year post-intervention, mixed-effects regression models will be used for continuous outcomes, using a log-link function and negative binomial distribution for outcomes involving highly positively skewed count or count-related data: costs, visits, number of prescriptions, and number of unique medications. A mixed-effects logistic regression will be used for binary outcomes.

Question 1: Does getting Forks Over Knives materials lead to improved outcomes over controls?

Passive Control	Active Control (Letter with no Video)	Letter with Video			
		Link	DVD	DVD + Link	
2200	2200	550	550	550	Letter Only
		550	550	550	Commitment Nudge
		550	550	550	Prevention Nudge
		550	550	550	Commitment + Prevention
2200	2200	2200	2200	2200	

Data for all participants who received Forks Over Knives materials (in yellow above) will be collapsed into one group.

Main analysis 1: Active Control, Passive Control vs. Forks Over Knives (reference group)

Exploratory analysis 1: Active Control vs. Passive Control (reference group)

Question 2: Do the behavioral science-informed components in the letter lead to improved outcomes over the controls?

Passive Control	Active Control (Letter with no Video)	Letter with Video			
		Link	DVD	DVD + Link	
2200	2200	550	550	550	Letter Only
		550	550	550	Commitment Nudge
		550	550	550	Prevention Nudge
		550	550	550	Commitment + Prevention
2200	2200	2200	2200	2200	

Data for all participants within each behavioral nudge condition (in yellow, green, grey, and white above) will be collapsed into one group.

Main analysis 2: Commitment Nudge, Prevention Nudge, Commitment + Prevention vs. Letter Only (reference group)

Main analysis 3: Commitment Nudge, Prevention Nudge, Commitment + Prevention, Letter Only vs. Active Control (reference group)

Main analysis 4: Commitment Nudge, Prevention Nudge, Commitment + Prevention, Letter Only vs. Passive Control (reference group)

Exploratory analysis 2: Commitment Nudge, Prevention Nudge vs. Commitment + Prevention (reference group)

Exploratory analysis 3: Commitment Nudge vs. Prevention Nudge (reference group)

Question 3: Does medium (DVD, Link, DVD + Link) influence outcomes?

Passive Control	Active Control (Letter with no Video)	Letter with Video			
		Link	DVD	DVD + Link	
2200	2200	550	550	550	Letter Only
		550	550	550	Commitment Nudge
		550	550	550	Prevention Nudge

Exploratory analysis 5: DVD, Link, DVD + Link vs. Passive Control (reference group)

Exploratory analysis 6: DVD, Link vs. DVD + Link (reference group)

Exploratory analysis 7: DVD vs. Link (reference group)