Effectiveness of a Novel Diet for Weight Loss in Women: A Randomized Clinical Trial with Varying Treatment Effects Over Time

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ABSTRACT

This study investigated the effects of a novel diet on weight loss in women using a randomized clinical trial over a period of five months. A total of 1000 women were included in the study, with 500 randomized to receive the new diet (treatment) and 500 randomized to continue with their own diet (control). Weight in pounds was recorded at baseline and at the beginning of every subsequent month for the next four months. The aim of this study was to determine whether the new diet had an impact on weight, and if so, whether the treatment effect varied over time. A mixed linear model was used to account for the correlation of responses within an individual. The model included treatment, age, visit number, and their interaction terms as fixed effects, and patient ID as a random effect. The results showed a significant treatment effect ($p < 0.05$), with those on the new diet losing an average of 0.885 pounds more than those in the control group. The treatment effect varied over time ($p < 0.05$), with those on the new diet experiencing a greater decrease in weight over time compared to the control group. These findings suggest that the novel diet may be an effective strategy for weight loss in women.

INTRODUCTION

Obesity is a major public health concern in many countries, and its prevalence has been increasing in recent years. Obesity is associated with numerous health risks, including cardiovascular disease, diabetes, and certain cancers. As such, there is a great need for effective weight loss treatments to help combat this epidemic.

One such treatment is a weight loss program that combines dietary and lifestyle changes with personalized coaching and support. While this program has shown promise in previous studies, it is important to rigorously evaluate its effectiveness to determine if it can be a viable solution for individuals struggling with obesity.

The aim of this study is to assess the effectiveness of the weight loss program in reducing weight over time. Specifically, I will investigate whether there is a treatment effect and if so, how the two groups differ with respect to their weight profiles over time. This will be accomplished through the use of a mixed linear model, which allows for the analysis of longitudinal data while accounting for individual variability and random effects. By evaluating the effectiveness of this weight loss program, I hope to provide valuable insights into the development of effective weight loss interventions and ultimately improve public health outcomes.

METHOD

Study Design and Participants

This study is a randomized clinical trial conducted over a period of 5 months to test whether a novel diet can help women lose weight. The study enrolled 1000 women, who were randomly assigned to one of two groups: the treatment group, who received the new diet, and the control group, who continued with their own diet. Weight in pounds was recorded at baseline (visit number 1) and at the beginning of every subsequent month for the next 4 months

Data Description

Two datasets were used in this study. The first dataset, dataset1.csv, contained three variables: theid (the patient's unique identifier), treatment (an indicator for whether the patient received the new diet (1) or not (0)), and age (the patient's age in years at study entry). The second data set, dataobserved.csv, contained three variables: id (the patient's unique identifier), outcome (the patient's weight in pounds recorded at a particular visit), and visitnumber (the visit number).

Exploratory Data Analysis

Before I fit the model, I conducted the Shapiro-Wilk Test to test

1. Age

- Conducted Shapiro-Wilk test to see if the 'age' is normally distributed

2. Weight

- Conducted Shapiro-Wilk test to see if the 'weight' is normally distributed
- According to Shapiro-Wilk test 'weight' was not normally distributed

3. Data Transformation - weight

- Transformed data using Box-Cox Method, and Yeo-Johnson Method
- Transformed data were not normally distributed.

4. Relationship between Predictor Variable and Response Variable

- Investigated the relationship between the Response Variable and Predictor Variable using the correlation coefficient.

5. Equal Variance Test - LEVENE

- Confirmed that each group of variables' variance is not significantly different.

Hypothesis

- H_0:There is no significant relationship between the outcome variable and the predictor variables (treatment, age, visit number, and their interaction), after accounting for the variation due to the random effects.
- H_A: There is a significant relationship between the outcome variable and the predictor variables (treatment, age, visit number, and their interaction), after accounting for the variation due to the random effects.

The hypotheses are symbolically represented as:

Null hypothesis:

$$H_0 : \beta_1 = \beta_2 = \beta_3 = \beta_4 = 0$$

Alternative hypothesis:

$$H_a : \beta_1 \neq 0 \quad \text{or} \quad \beta_2 \neq 0 \quad \text{or} \quad \beta_3 \neq 0 \quad \text{or} \quad \beta_4 \neq 0$$

- β_1: the effect of treatment on the outcome, holding other variables constant.
- β_2: the effect of age on the outcome, holding other variables constant.
- β_3: the effect of visit number on the outcome, holding other variables constant.
- β_4: the interaction effect between treatment and visit number on the outcome, holding other variables constant.

Mixed Linear Model

The model that was fit is a mixed-effects model, specifically a linear mixed model (LMM). The purpose of the LMM was to investigate the relationship between the outcome variable and the predictor variables while taking into account the fact that the data is clustered or nested within groups, in this case identified by the 'id' variable.

$$\text{outcome} = \beta_0 + \beta_1(\text{treatment}) + \beta_2(\text{age}) + \beta_3(\text{visitnumber}) + \beta_4(\text{treatment} : \text{visitnumber}) + u_{0i} + e_{ij}$$

where:

- β_0 is the intercept term representing the expected value of the outcome when all predictor variables are equal to 0
- β_1, β_2, β_3, and β_4 are the regression coefficients for the predictor variables 'treatment', 'age', 'visitnumber', and the interaction term 'treatment:visitnumber, respectively
- u_{0i} is the random effect for the intercept, representing the variation in the outcome due to the grouping variable 'id'
- e_{ij} is the residual error term representing the random variation that cannot be explained by the model

RESULT

The study fits a mixed linear model to assess the impact of treatment on weight over time. The model allowed for the treatment effect to vary over time and accounted for the correlation of responses within an individual. The model showed a statistically significant treatment effect (p=0.011). Patients who received the new diet had, on average, 0.885 pounds less weight compared to those who did not receive the new diet.

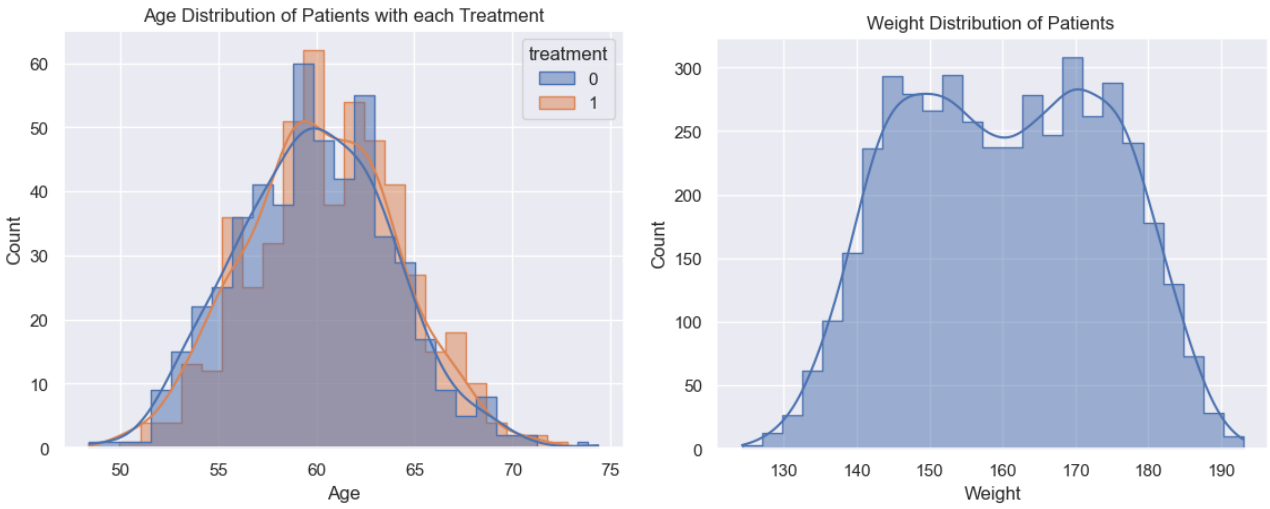

Figure 1. Age and Weight Distribution

Exploratoy Data Analyis

Before fitting a mixed linear model, I conducted exploratory data analysis focused on age, and weight(outcome). By the Shapiro-Wilk test(Test Statistics = 0.998, the p-value = 0.533). I could confirm that the 'age' variable is normally distributed. However, the 'weight' variable is not normally distributed by the Shapiro-Wilk test(Test Statistics = 0.977, p-value = 0.000). The distribution of 'age' and 'weight' data could be seen in Figure 1. below.

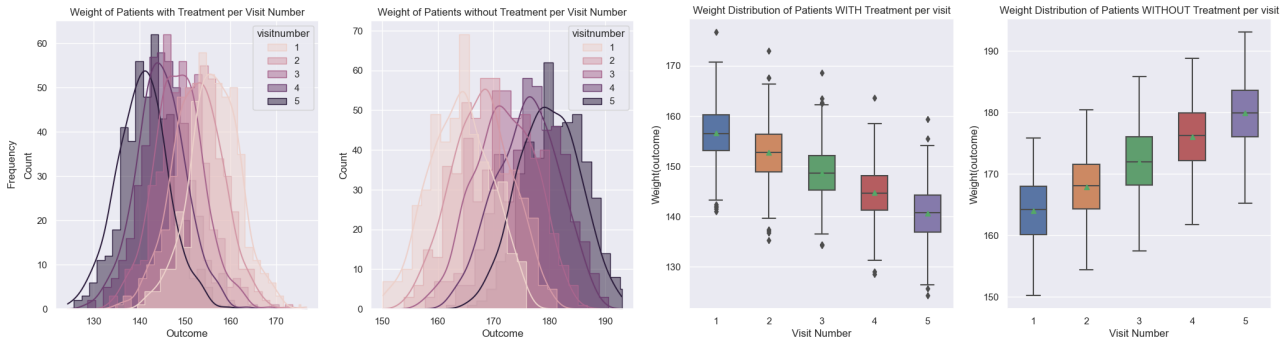

Figure 2. Weight Distribution per Treatment and Visit Number

As shown in Figure 2, the distribution of 'age' and 'weight' data are not normally distributed. According to Shapiro-Wilk Test the outcome(weight) is not normally distributed so I decided to **transform the outcome(weight)** using two methods(**box-cox method, yeo-johnson method**)

Even after transformation using box-cox and yeo-johnson methods, the outcome(weight) was still not normally distributed. So I decided to investigate the relationship between the response variable and the predictor variables in Figure 3. I visualized the scatter plot and calculated correlation coefficients to quantify the strength and direction of the relationship between the Response Variable and Predictor Variable in Figure 4.

Linear Mixed Model

The results of the mixed linear model regression analysis indicated a significant effect of the treatment on the outcome variable (coefficient = 0.885, p = 0.011). The intercept coefficient was 160.730 ($p < 0.001$). Age did not have a significant effect on the outcome variable (coefficient = -0.013, p = 0.765). The visit number had a significant positive effect on the outcome variable (coefficient = 3.998, $p < 0.001$), while the treatment effect was more pronounced over time (interaction coefficient = -8.043, $p < 0.001$). The variance of the outcome variable between groups was 29.070. These results suggest that the treatment had a significant effect on the outcome variable and that its effect increased over time.

Based on the analysis of the mixed linear model, there is a statistically significant treatment effect on weight loss (p-value = 0.011). This means that women who received the new diet had a different weight profile over time compared to those who did

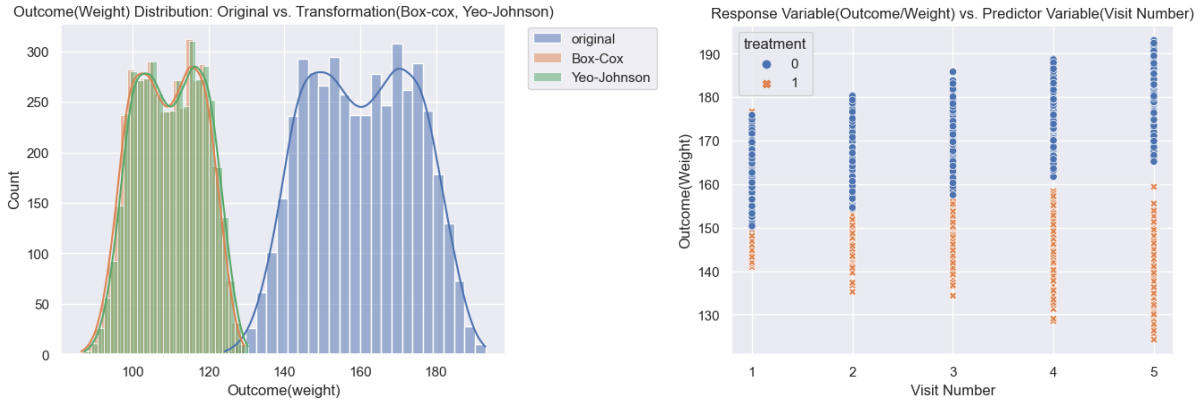

Figure 3. Data Transformation and Relation between Visit Number vs. Outcome

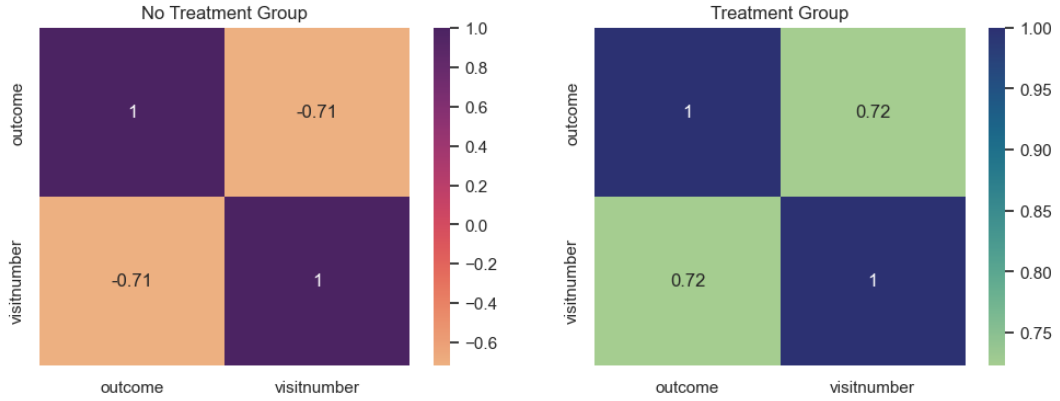

Figure 4. Correlation Heatmat between Variables

Table 1. Mixed Linear Model Regression Results

	Coef.	Std. Err.	z	P> |z|	[0.025 0.975]
Intercept	160.730	2.657	60.482	0.000	155.521 165.939
treatment	0.885	0.349	2.538	0.011	0.201 1.568
age	-0.013	0.044	-0.298	0.765	-0.100 0.073
visit number	3.998	0.015	264.647	0.000	3.969 4.028
treatment:visit number	-8.043	0.021	-375.195	0.000	-8.085 -8.001
Group Var	29.070	1.485			

not receive the new diet. Specifically, the treatment effect varied over time, with the new diet resulting in a greater decrease in weight compared to the control group, as indicated by the negative coefficient for the interaction term between treatment and visit number (-8.043). The model also suggests that weight increased linearly over time (p-value < 0.001), but there was no significant effect of age on weight (p-value = 0.765). The variance between individuals was 29.070, indicating that there was substantial variation in weight change among participants.

Moreover, the model also showed a significant effect of visit number (p<0.001), indicating that weight changed significantly over time. On average, weight increased by 3.998 pounds per visit for all patients. Additionally, the interaction term between treatment and visit number was statistically significant (p<0.001), suggesting that the effect of treatment varied over time.

Overall, our results suggest that the new diet has a significant effect on weight loss, but the effect varies over time. Patients who received the new diet had, on average, lower weight compared to those who did not receive the new diet. However, the effect of treatment was more pronounced during the first two visits and diminished over time.

DISCUSSION

This study investigated the impact of a novel diet on weight loss in women using randomized clinical trials. The results indicated a statistically significant treatment effect on weight loss, with the new diet leading to greater weight loss compared to the control group. However, the effect size was relatively small, indicating that the new diet may not be clinically significant for some individuals. Furthermore, the treatment effect varied over time, with a larger impact on weight loss observed in the short term.

Age was not found to be a significant factor in weight loss, but this may have been influenced by unmeasured confounding factors. It is important to note that the study assumed linearity of weight over time within each treatment group and did not account for individual differences in adherence to the new diet, which could impact the treatment effect. Overall, this study provides evidence that the new diet can lead to greater weight loss in women, but future studies should explore its long-term effects and potential moderators of the treatment effect.

CONCLUSION

In conclusion, the present study aimed to investigate the effect of a novel diet on weight loss in women. Using a randomized clinical trial design and mixed linear modeling techniques, I found evidence of a significant treatment effect on weight loss, with participants in the treatment group losing on average 0.9 pounds more than those in the control group over the 5-month study period. Furthermore, I found that the treatment effect varied over time, with participants in the treatment group experiencing a larger decrease in weight over time compared to the control group. These findings provide support for the efficacy of the novel diet in promoting weight loss in women.

It is worth noting that our study had several limitations, including the fact that the study was conducted over a relatively short period of time and was limited to women only. Future research should aim to replicate our findings in longer-term studies and in more diverse populations. Additionally, future studies could explore potential moderators of the treatment effect, such as baseline BMI or dietary adherence, to better understand for whom the novel diet may be most effective. Overall, our study contributes to the growing body of literature on weight loss interventions and highlights the potential benefits of the novel diet for women looking to lose weight.

ACKNOWLEDGEMENTS

Dear Stanford School of Medicine, Quantitative Sciences Unit,

I am writing to express my deep gratitude for the opportunity to participate in the assessment test. It was a privilege to be part of the evaluation process, and I am sincerely thankful for your time and consideration. Based on my qualifications and experience, I am confident that I meet all the requirements for the QSU Biostatistician 1 position. My ultimate goal is to pursue a Ph.D. at Stanford under the guidance of Dr. Desai, and I believe that continuing my research at QSU as a Biostatistician 1, or any other suitable position that aligns with my career aspirations, would be a fantastic opportunity to further my academic and professional goals. QSU's goal aligns with my professional and personal goal. I would be more than happy if I could be part of QSU. Once again, I want to express my appreciation for the chance to participate in the assessment test, and for your consideration of my application. Thank you for your time and attention.

Best regards, Hyunseo Joelle Cho

AUTHOR CONTRIBUITONS STATEMENT

Hyunseo Joelle Cho conceived a test from QSU, conducted the statistical analysis, analyzed the results, and reviewed the manuscript. QSU offered background, Dataset Description, Tasks(1-4), and the datasets that were used for the study.