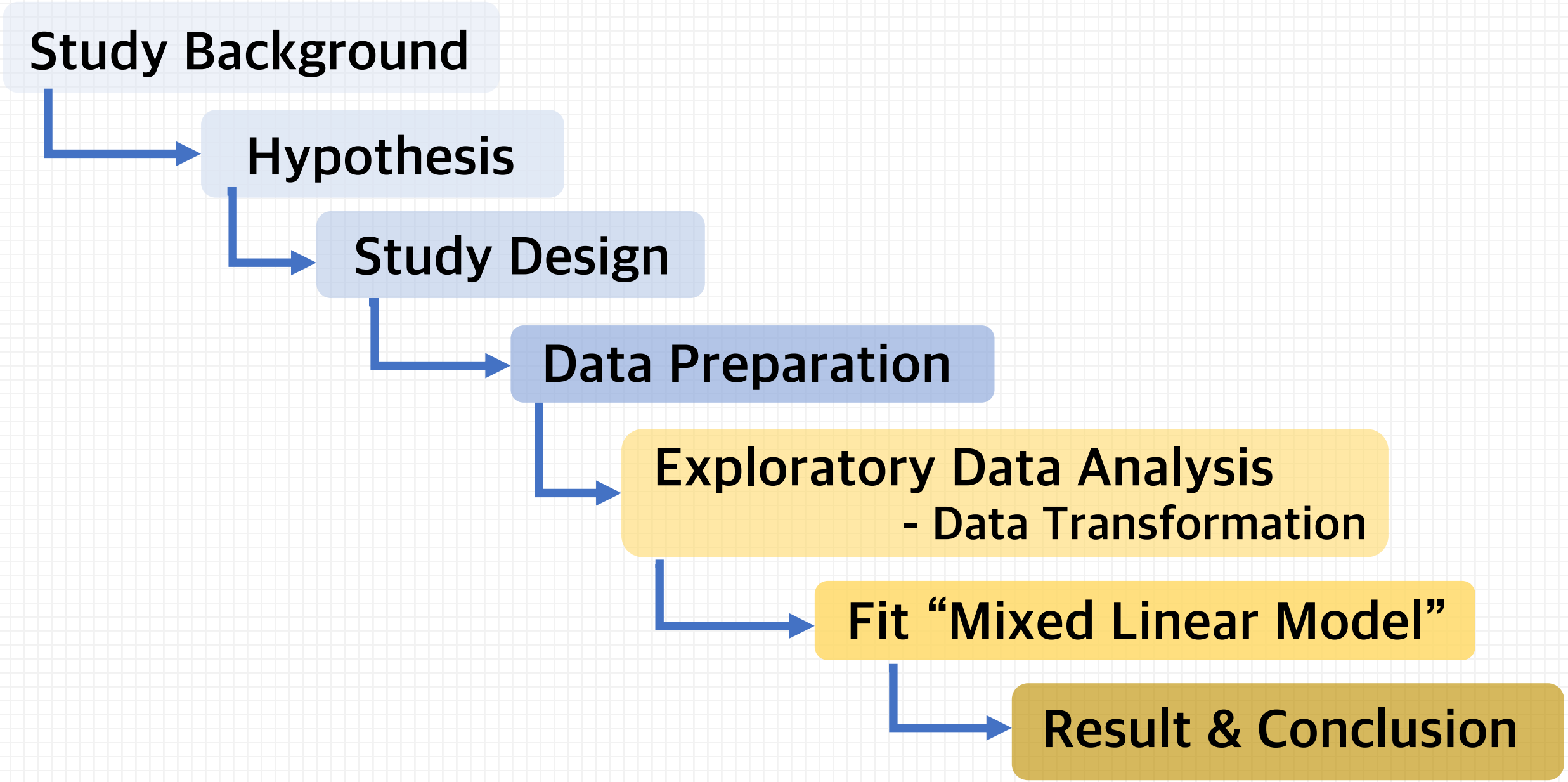
Effectiveness of a Novel Diet for Weight Loss in Women

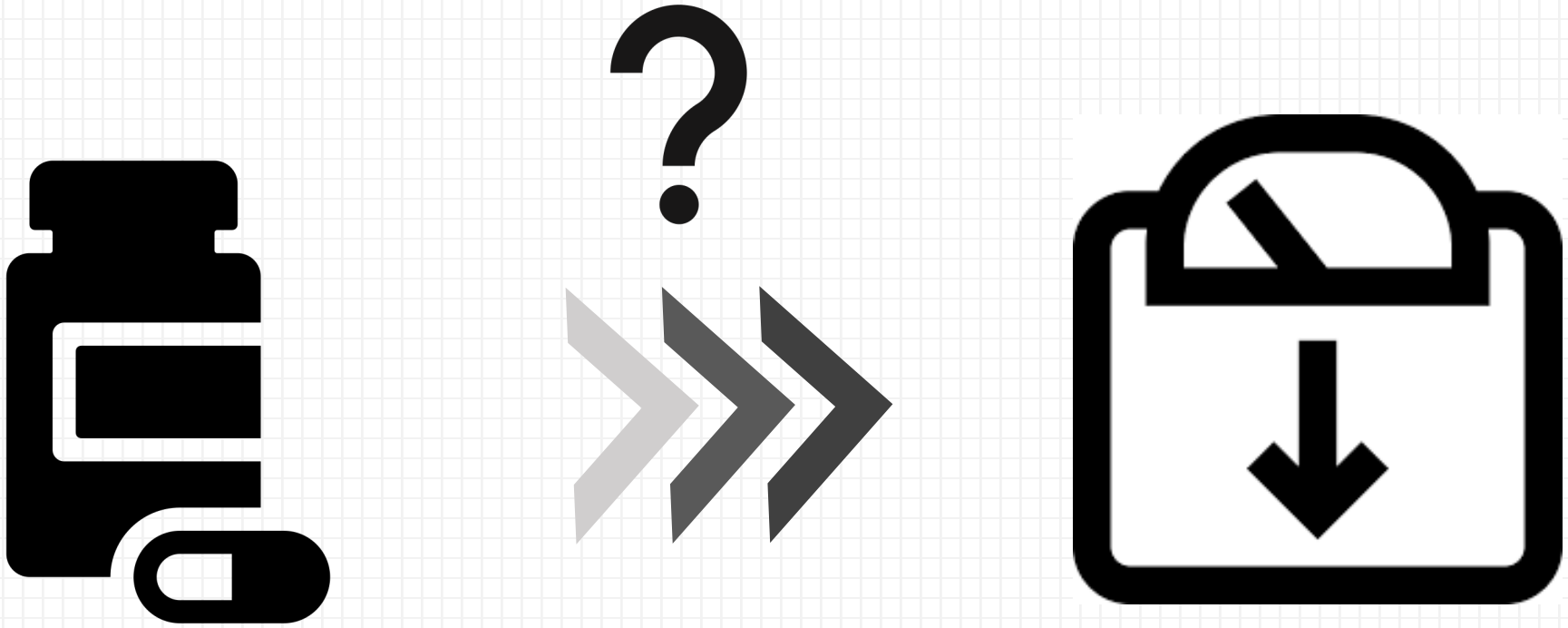
A Randomized Clinical Trial with Varying Treatment Effects Over Time

Candidate: Hyunseo Joelle Cho

Stanford Quantitative Sciences Unit Test


Study Background
Hypothesis
Study Design
Data Preparation
Exploratory Data Analysis
- Data Transformation
Fit “Mixed Linear Model”
Result & Conclusion

BACKGROUND



Novel Diet

Weight Loss in Women

Can novel diet help women lose weight ?

HYPOTHESIS

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

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

- 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.

Null Hypothesis :
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.

Alternative Hypothesis:
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.

STUDY DESIGN

Visit Number

Measure Weight

Treatment Group

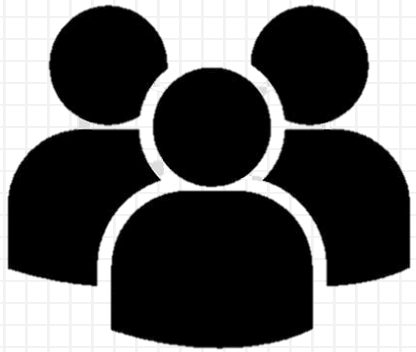
500 women

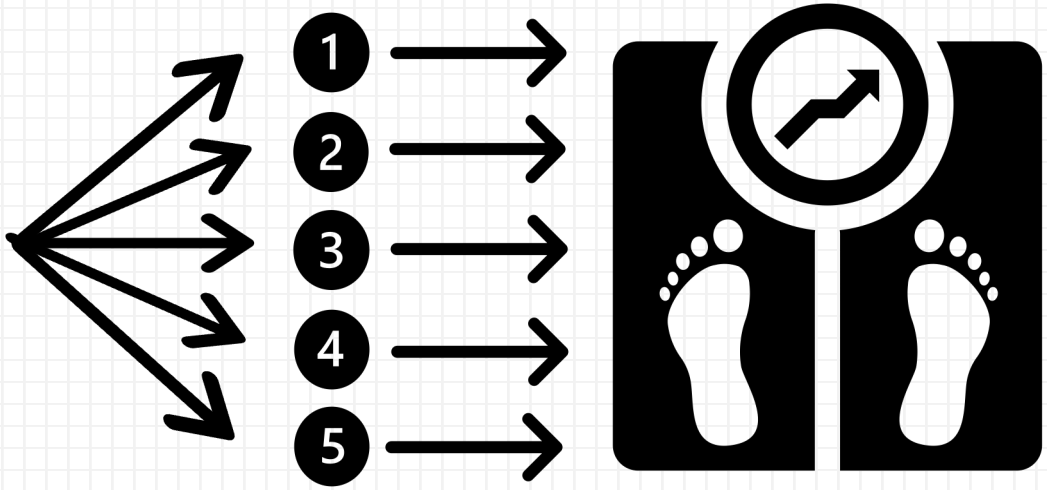
With Treatment

Control Group

500 women

No treatment





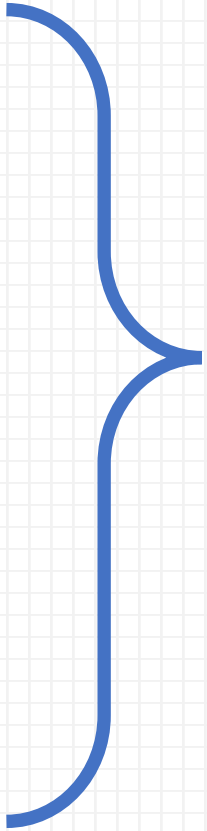
DATA PREPARATION

dataset.csv

id	treatment	age
1	1	61.899478
2	1	62.813407
3	1	65.009085
4	1	60.259313
5	1	66.229078

dataobserved.csv

id	outcome	visitnumber
1	149.125460	1
1	137.229366	4
1	133.096258	5
2	160.854708	1
2	155.566215	2



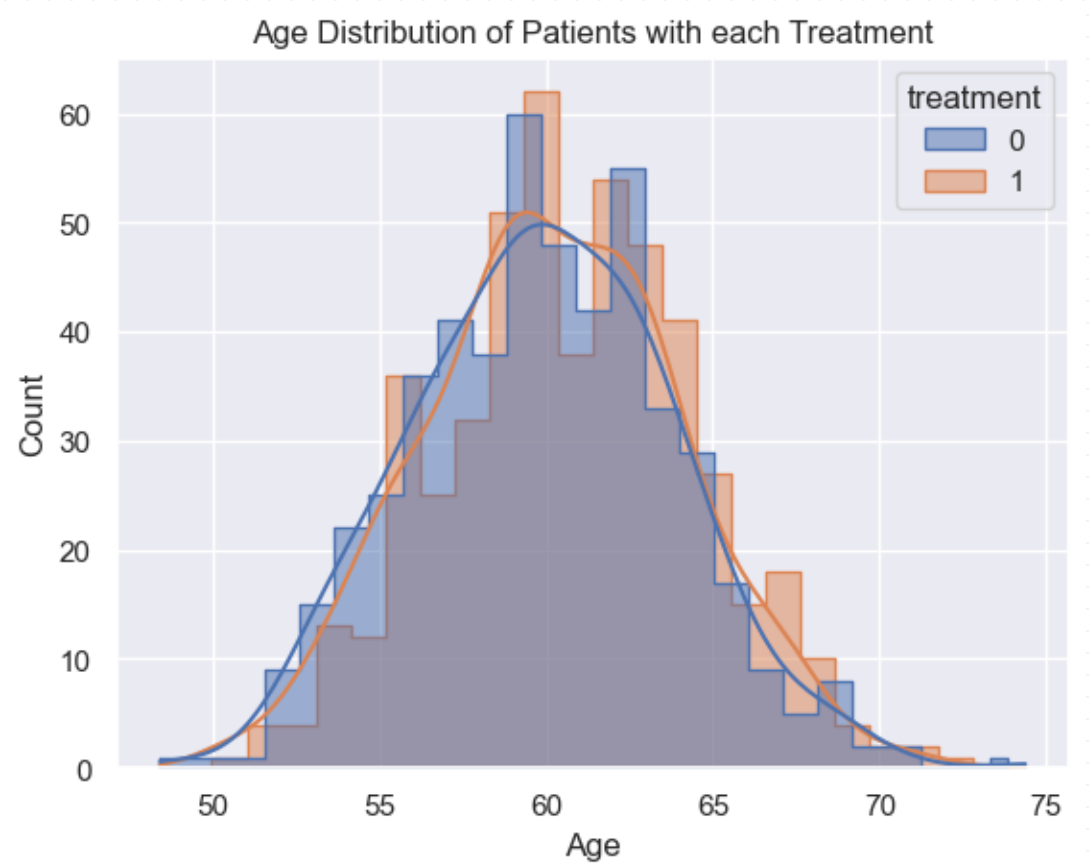
analytic_data

id	outcome	visitnumber	treatment	age
1	149.125460	1	1	61.899478
1	137.229366	4	1	61.899478
1	133.096258	5	1	61.899478
2	160.854708	1	1	62.813407
2	155.566215	2	1	62.813407
2	151.740785	3	1	62.813407
2	146.467257	4	1	62.813407
2	143.062480	5	1	62.813407
3	161.082812	1	1	65.009085
3	157.287549	2	1	65.009085

Used primary key ‘id’ to merge two data

Exploratory Data Analysis

1) ‘age’ variable



Shapiro-Wilk Test Result

- **Test Statistics = 0.998**
- **P- value = 0.533**

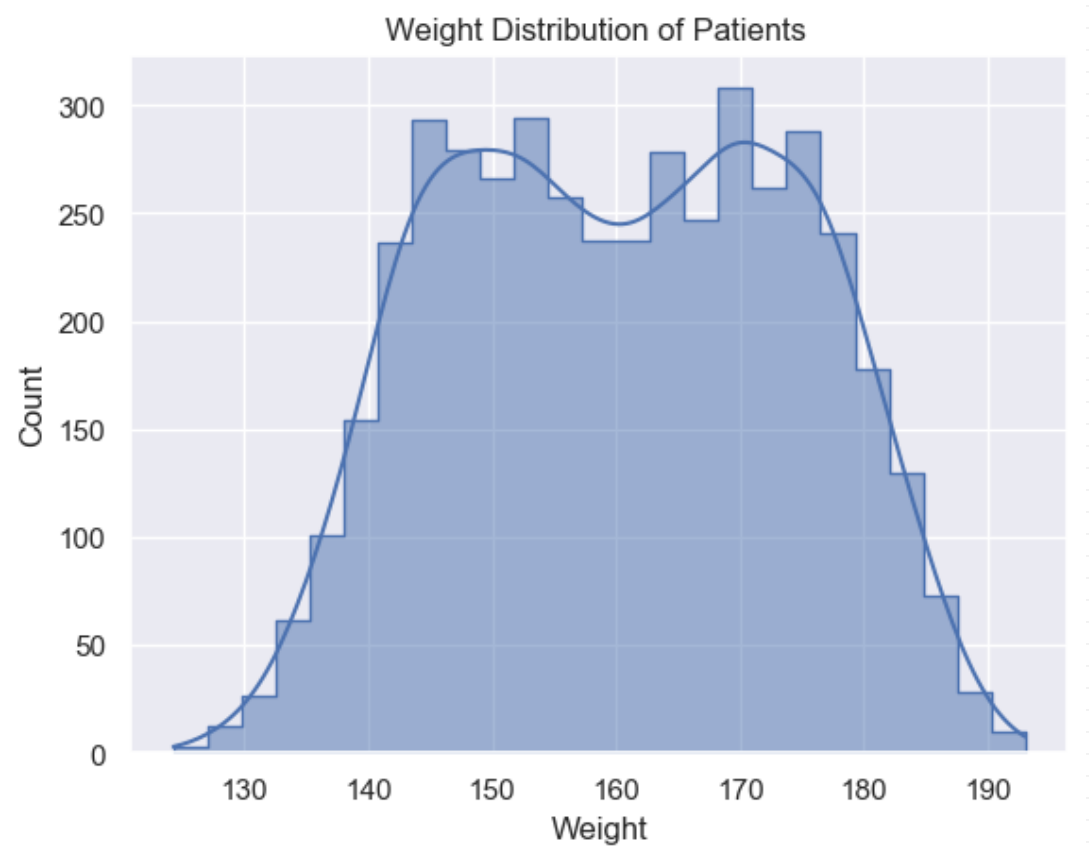
P-value > 0.05

‘age’ is Normally Distributed

```
By Shapiro test, Test Statistics is 0.998 and the p-value is 0.533.
So I could confirm that the data is Normally Distributed
```

Exploratory Data Analysis

2) ‘outcome’(weight) variable



Shapiro-Wilk Test Result

- **Test Statistics = 0.977**
- **P- value = 0.000**

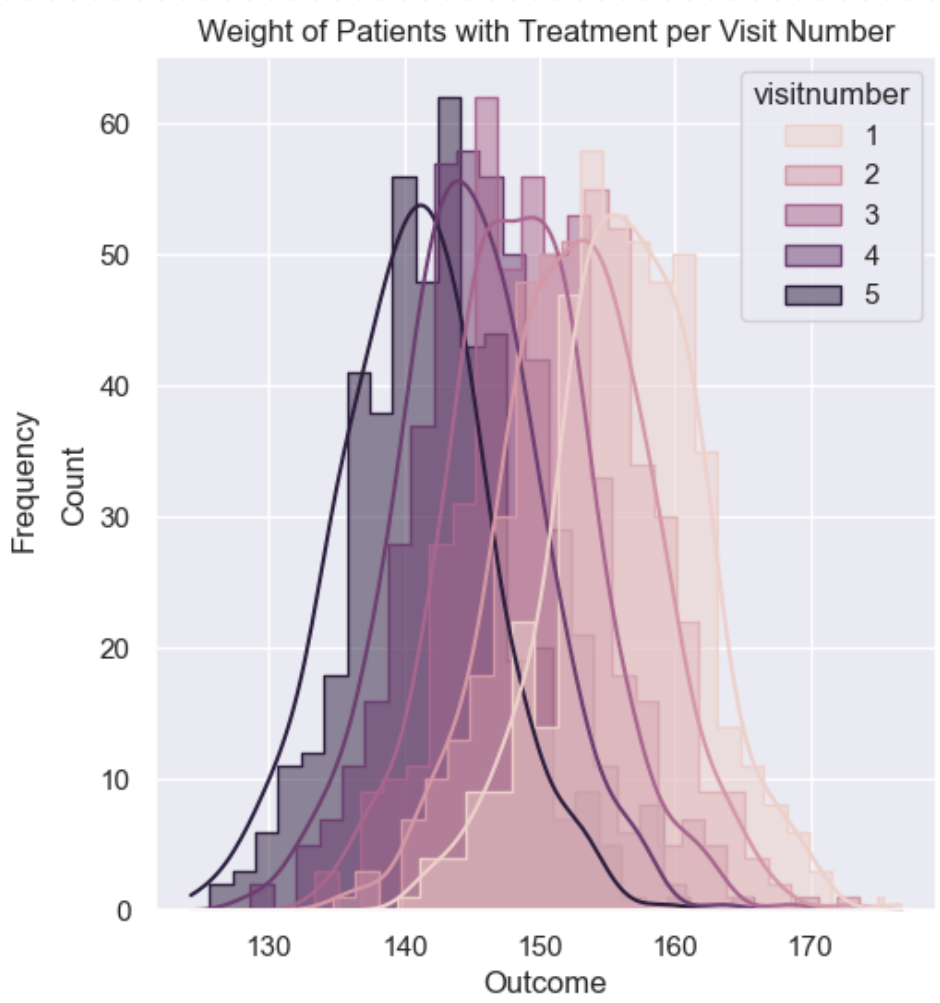
P-value < 0.05

‘outcome’ is NOT Normally Distributed

```
By Shapiro test, Test Statistics is 0.977 and the p-value is 0.000.
So I could confirm that the data is NOT normally distributed
```

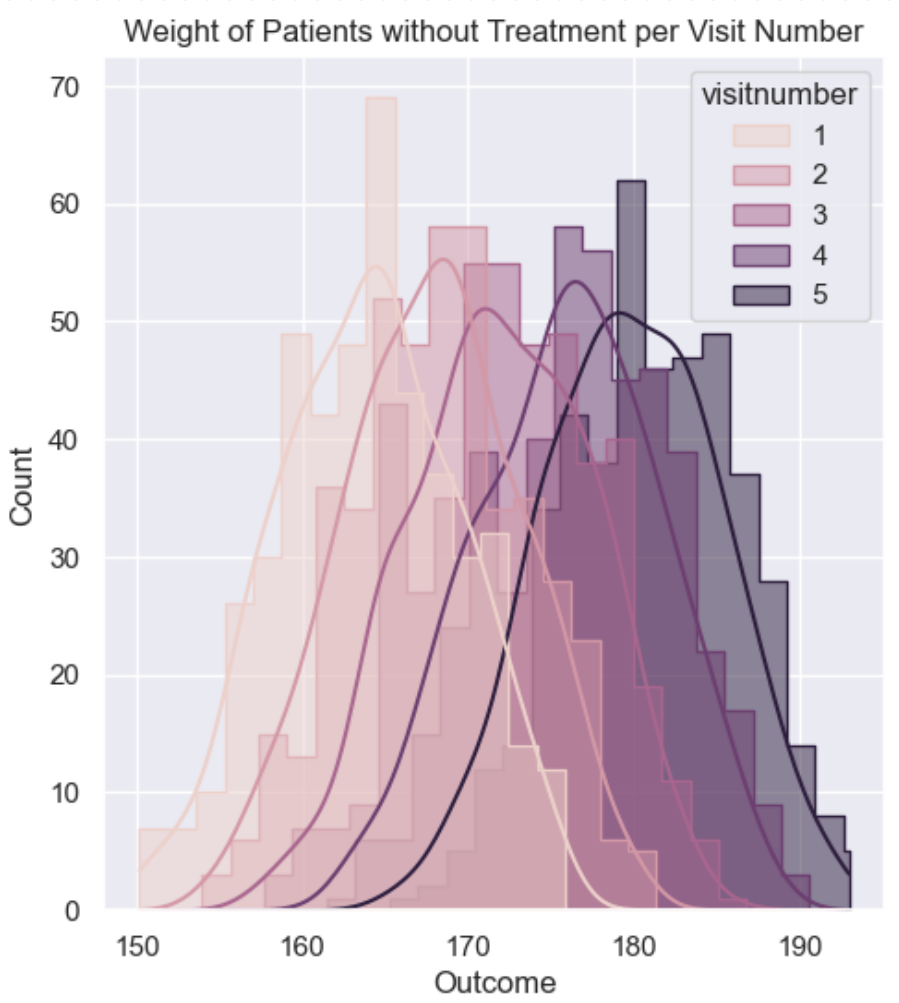
2) ‘outcome’(weight) distribution per group

Treatment Group



Average of weight
decreases per visit

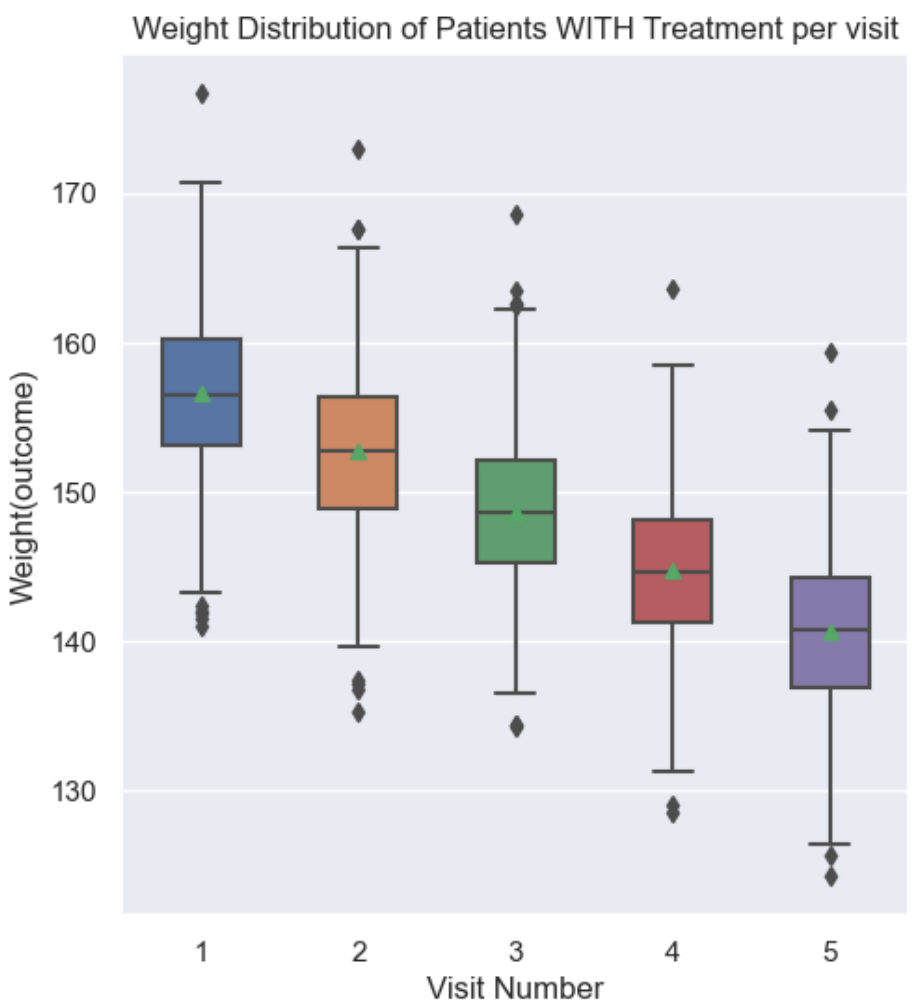
Control Group



Average of weight
increases per visit

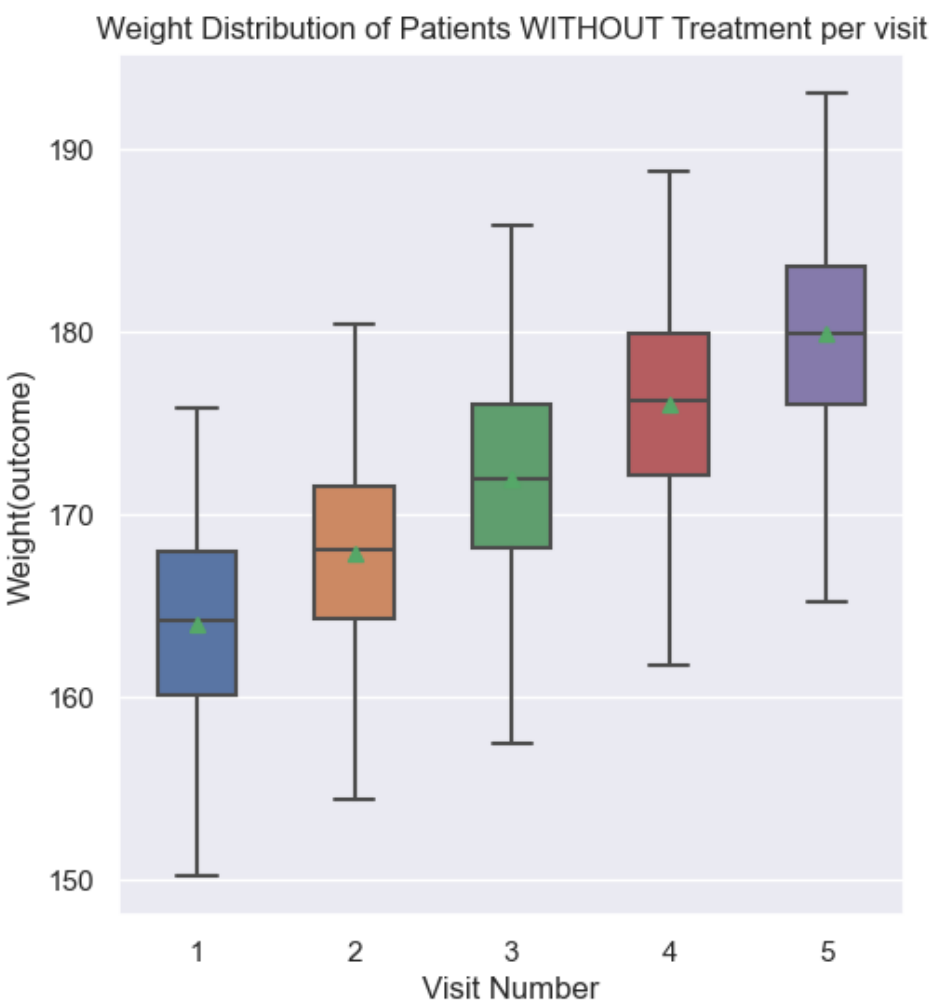
2) ‘outcome’(weight) distribution per group

Treatment Group



Average of weight
decreases per visit

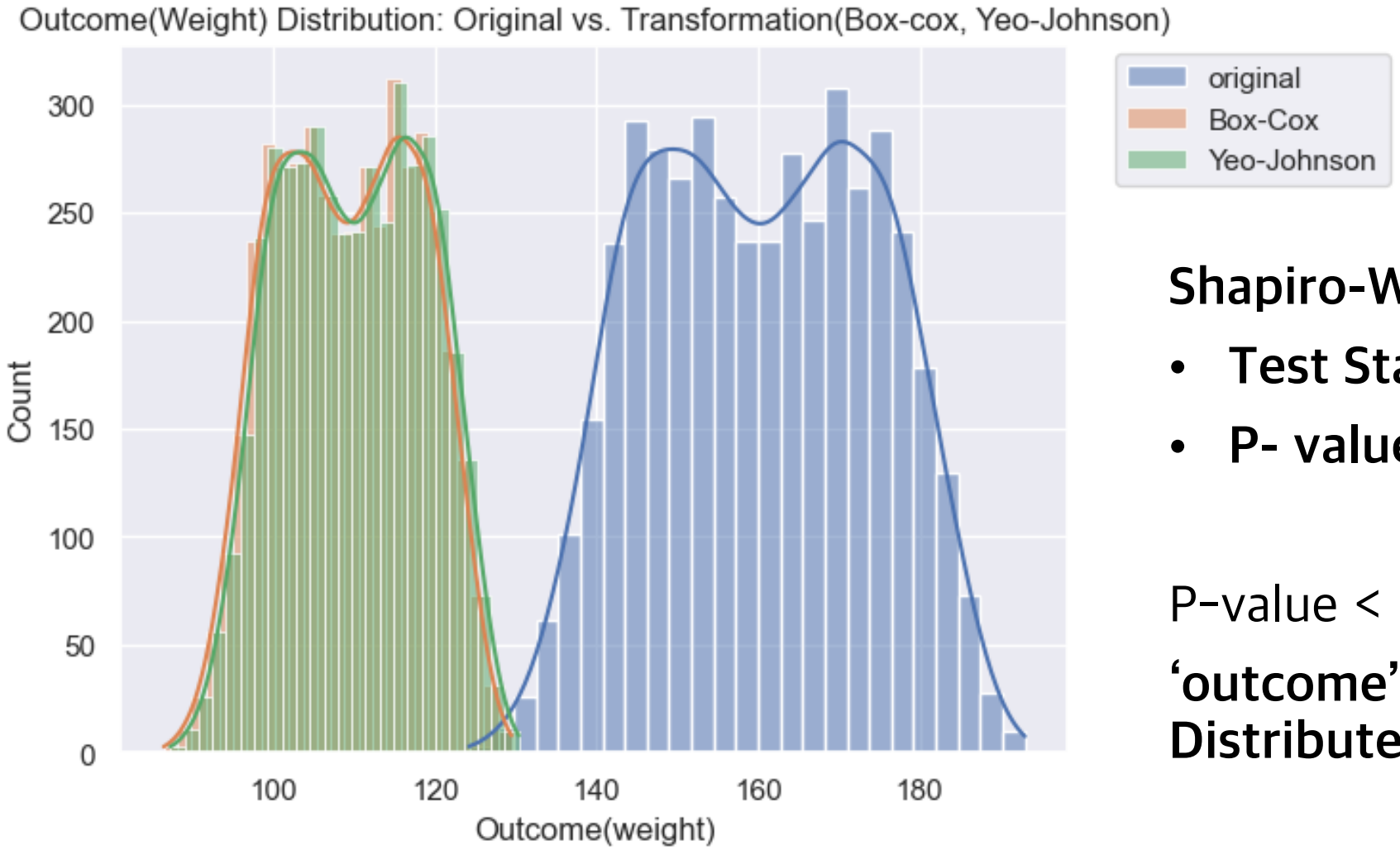
Control Group



Average of weight
increases per visit

3) Data Transformation

(❶ Box-Cox Method, ❷ Yeo-Johnson Method)



Shapiro-Wilk Test Result

- **Test Statistics = 0.977**
- **P- value = 0.000**

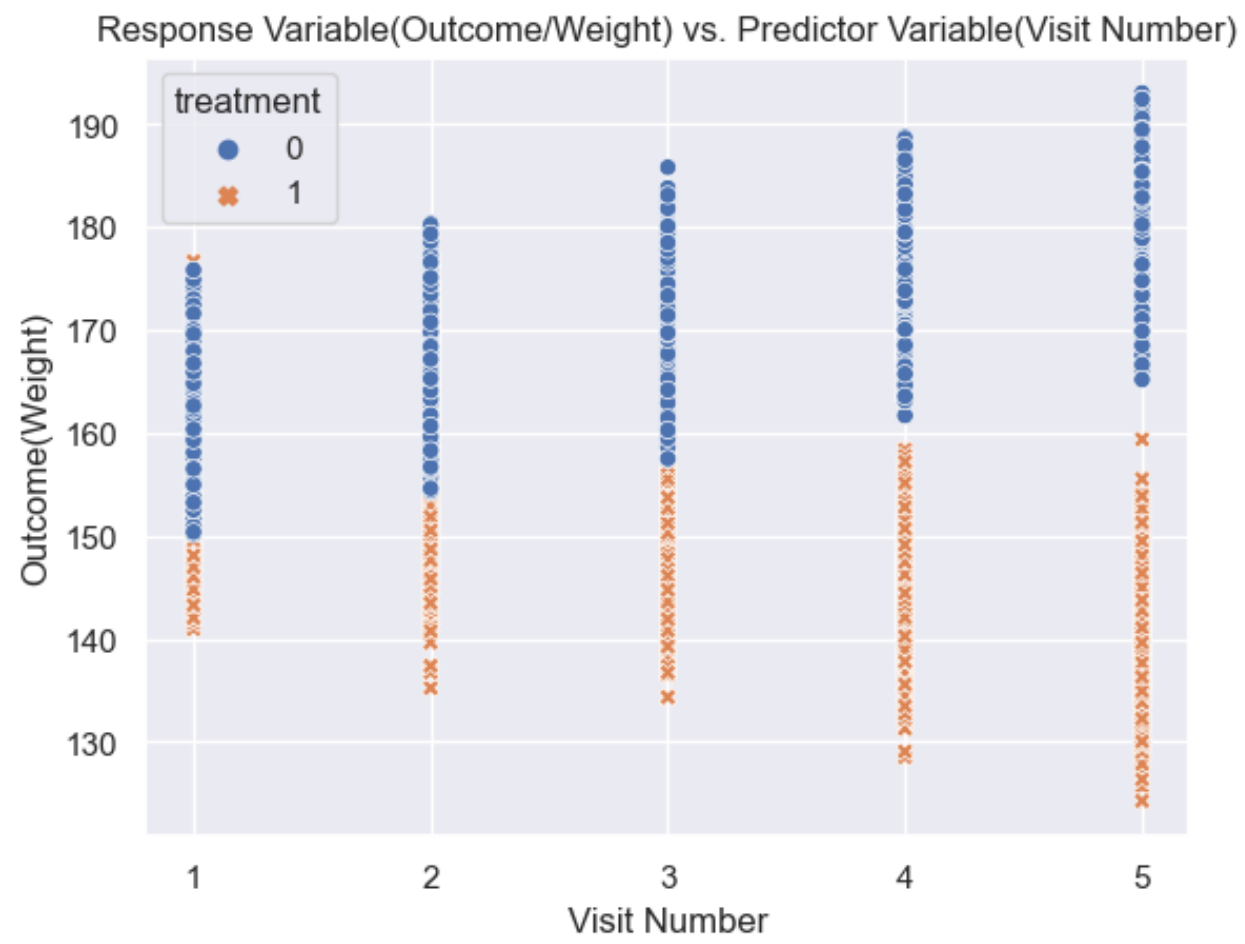
P-value < 0.05

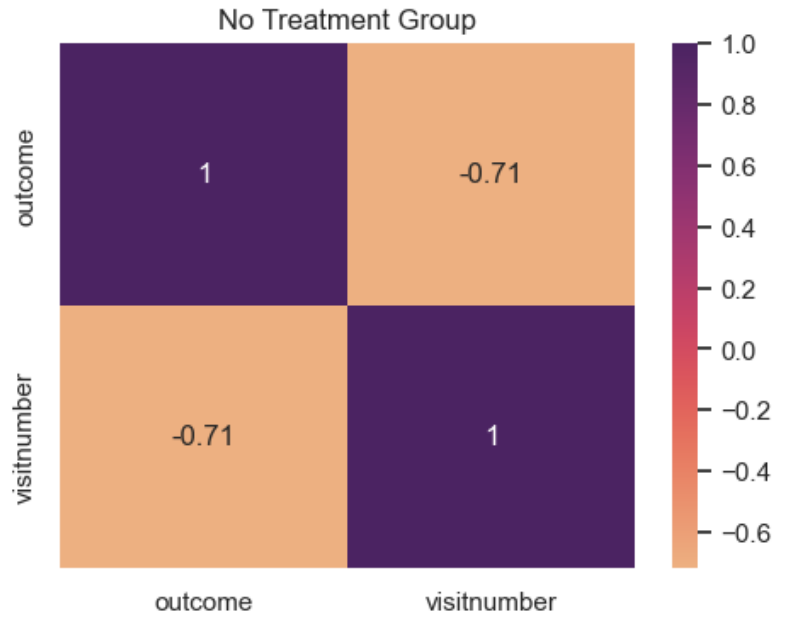
'outcome' is NOT Normally Distributed

After Transformation, 'outcome' data was still not normally distributed

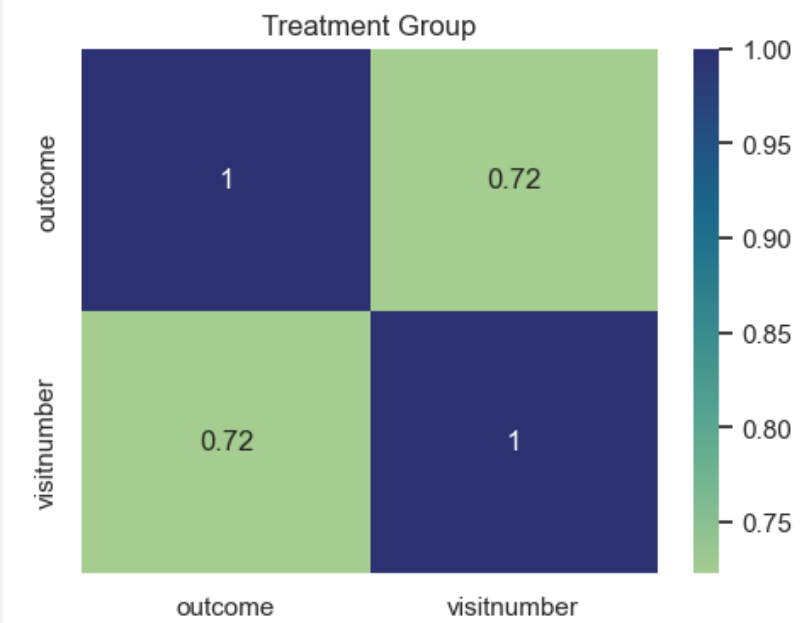
4) Relationship between Predict Variable vs. Response Variable

- Correlation Coefficient : 0.7, -0.7





Control Group



Treatment Group

Strong correlation between variables was observed

LINEAR MIXED 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

LMM Formula

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

where β_0, β_1, β_2, β_3, and β_4 are the fixed effects coefficients, u_{0i} is the random effect of the i-th group, and e_{ij} is the residual error of the j-th observation in the i-th group.

- β_0: the intercept, or the expected outcome when all predictor variables are zero.
- 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.

LMM Result Interpretation

Mixed Linear Model Regression Results

Model:	MixedLM	Dependent Variable:	outcome
No. Observations:	4499	Method:	REML
No. Groups:	1000	Scale:	1.0036
Min. group size:	2	Log-Likelihood:	-8831.5719
Max. group size:	5	Converged:	Yes
Mean group size:	4.5		

p-value - two tailed

	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
visitnumber	3.998	0.015	264.647	0.000	3.969	4.028
treatment:visitnumber	-8.043	0.021	-375.195	0.000	-8.085	-8.001
Group Var	29.070	1.485				

If p-value < alpha, Reject the Null

- Variable significantly Affects the Dependent Variable(Outcome)

<<< 95% Confidence Interval

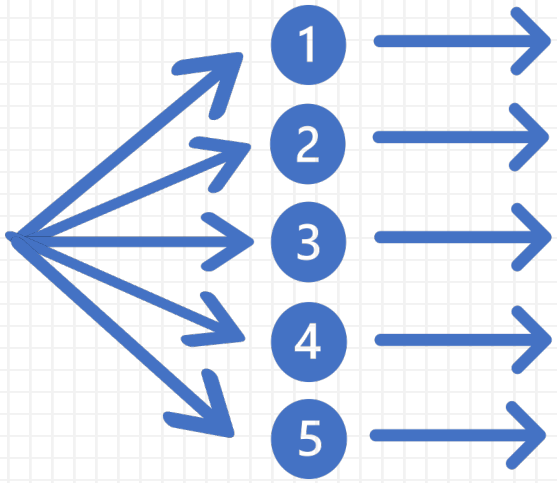
alpha = 0.05

1. Treatment significantly affect the outcome(weight) loss and its effect increased over time.
2. Age did not have significant effect on the outcome(weight).
3. Visit number had a significant positive effect on the outcome variable, while the treatment effect was more pronounced over time.

RESULT

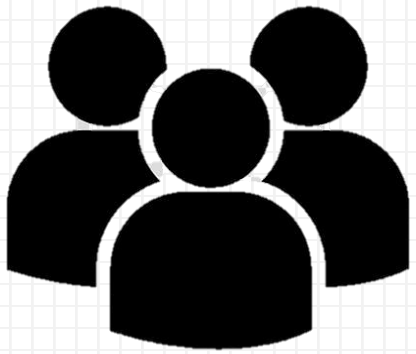
Treatment Group

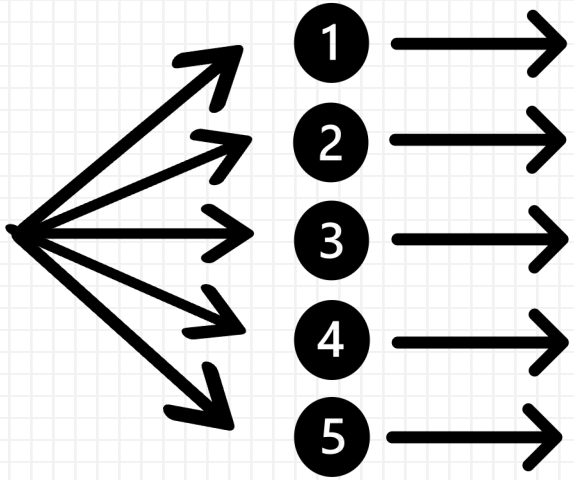
Visit Number

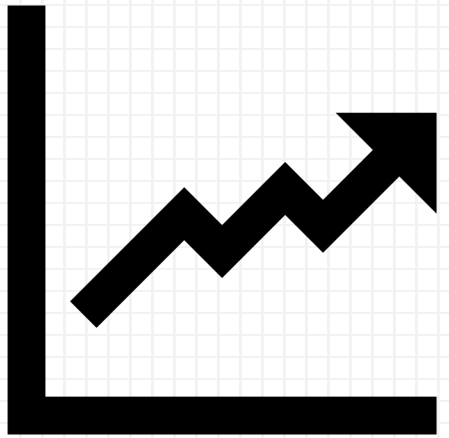


Measure Weight

Control Group

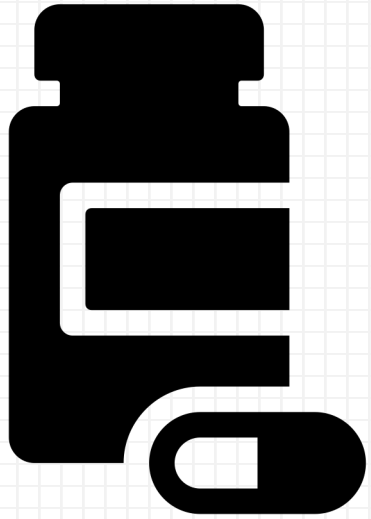






CONCLUSION

Novel Diet has a significant effect on weight loss



Novel Diet

Treatment Group

Weight Loss in Women