

Select Data Analysis for a Randomized Control Trial to Reduce Post-Cessation Weight Gain

Sumaja Bandreddi, Brenna Peterman, Alex Rodriguez, Sebastian Ruiz, Jolisha Love

Background



Background

- Since smoking was discovered as a cause of various forms of cancer, there have been damage control efforts by public health professionals to try and convince current smokers to quit.
- The problem is that cigarettes are addictive and can be difficult to quit. To add on to that, there is research that shows that people who quit smoking tend to gain 2.8 to 3.8 kilograms¹, which is a common deterrent to quitting.
- This three-arm randomized control trial was designed to test the efficacy of a weight loss intervention or weight gain prevention against standard of care (self-guided bibliotherapy) weight gain after smoking cessation

¹ Driva, Stamatina et al.

Study Design

- Treatment groups
 - a. Weight gain prevention intervention
 - b. Weight loss intervention
 - c. Bibliotherapy (control)
- 400 participants who are willing to quit smoking are selected and randomized to each of the treatment groups
- All three treatment groups will receive an efficacious smoking cessation program and 6 months of varenicline pharmacotherapy (Chantix)
- Treatment groups a and b will receive monthly booster weight management sessions after completing the smoking cessation intervention
- Participants' weight will be measured before and after the study. They will also fill out surveys to measure variables like number of cigarettes smoked per day and nicotine dependence
- **Hypothesis**
 - a. Participants on the weight gain prevention and weight loss conditions will have significantly lower post-cessation weight gain at 12-month follow-up compared to bibliotherapy

Continuous Variables	Continuous Variables (cont)	Categorical Variables	Categorical Variables (cont)
Age (AGE)	Score for Fagerstrom Test for Nicotine Dependence (FTND_SCORE0)	Treatment Groups (TRT: A ,B, C) - A (Weight Maintenance) - B (Weight Loss) - C (control)	SECONDARY OUTCOME: Smoking point prevalence abstinence (POINTPREV at 12 months)
BMI (BMI)	Scores for “Why Smoke?” Survey (WHYSMOKESCORE)	Gender (GENDER: M, F)	Rural Location (RURALITY) - 0 (non rural) - 1 (rural)
Average Number of Cigarettes Smoked per Day (AVERAGECIGARETTESDAY)	Scores for “Weight Concerns” Survey (WEIGHTCONCERNSCORE)	Caucasian (WHITE) - 0 (non white) - 1 (white)	Education Level (EDUC) - 0 (high school or less) - 1 (college) - 2 (more than college)
Baseline Weight (BVWEIGHT)		Hispanic (ETHNICITY) - 0 (not hispanic) - 1 (hispanic)	Appearance of Missing Value in Weight after 12 Months (MISSINGWEIGHT12) - 0 (not missing data) - 1 (missing data)
PRIMARY OUTCOME: Weight Difference after 12 Months (WEIGHTDIFF_B12)		Married (MARRIED) - 0 (not married) - 1 (married)	Income (INC) - 0 (<30k) - 1 (30-50k) - 2 (50-100k) - 3 (100k+)

Exploratory Data Analysis



Table 1

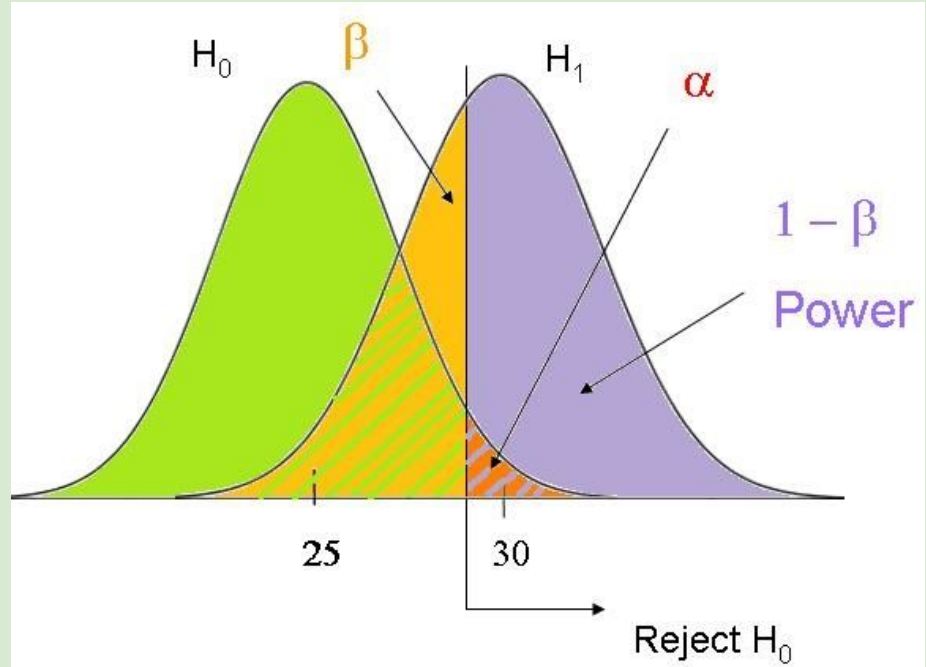
	Overall (N=305)	Weight Loss	Weight Maintenance	Bibliotherapy (control)	pvalue
age (years)	54.269(11.595)	53.413(11.398)	55.445(11.700)	53.849(11.718)	<.0001
BMI	31.754(6.608)	32.082(6.569)	31.182(6.516)	32.070(6.798)	<.0001
Average cigarettes per day	16.896(10.905)	16.787(11.425)	16.777(9.075)	17.186(12.405)	<.0001
gender (F)	207(67.870)	75(68.81)	72(65.45)	60(69.77)	0.787
Race (White)	159(52.130)	54(49.54)	60(54.55)	45(52.33)	0.759
Ethnicity (hispanic)	6(1.97)	2(1.83)	0(0)	4(4.65)	0.0662
married (yes)	131(42.950)	45(41.28)	52(47.27)	34(39.53)	0.5037
Education					0.9373
high school or less (0)	59(1.34)	23(21.1)	21(19.09)	15(17.44)	
college (1)	214(70.16)	74(67.89)	79(71.82)	61(70.93)	
more than college (2)	32(10.49)	12(11.01)	10(9.09)	10(11.63)	
Income					0.4514
<30K (0)	94(31.65)	31(28.97)	36(33.03)	27(33.33)	
30k-50k (1)	78(26.26)	33(30.84)	23(21.1)	22(27.16)	
50k-100k (2)	93(31.31)	29(27.1)	41(37.61)	23(28.4)	
100k+ (3)	32(10.77)	14(13.08)	9(8.28)	9(11.11)	
Data is presented as M(SD) or n(%)					

Age, BMI, and average cigarettes per day were normally distributed

Table 2

	complete at 12m	missing at 12m	pvalue
age(years)	54.710(11.200)	50.636(14.133)	0.0566
BMI	31.738(6.516)	31.882(7.434)	0.906
Average cigarettes per day	17.081(11.317)	15.379(6.543)	0.398
gender (F)	187(68.5)	20(60.61)	0.344
Race (White)	149(54.78)	10(30.3)	0.0079
Ethnicity(hispanic)	5(1.84)	1(3.03)	0.641
married(yes)	120(44.12)	11(33.33)	0.237
Education			0.2
education(hs or less)	49(18.01)	10(30.3)	
education(univeristy)	193(70.96)	21(63.64)	
more than college	30(11.03)	2(6.06)	
income			0.0023
income(<30K)	80(29.96)	14(44.67)	
income(30k-50k)	65(24.34)	13(43.33)	
income(50k-100k)	90(33.71)	3(10.00)	
100k+	32(11.99)	0(0)	
Data is presented as M(SD) or n(%)			

Testing



T test for Quantitative Variables

These p-values are all greater than 0.05, allowing us to conclude that there is no evidence of a significant difference between the treatment groups for Age, BMI, and number of cigarettes smoked per day at baseline.

AGE	BMI	AVERAGECIGARETTESDAY
B and C - (0.3446)	B and C - (0.3541)	B and C - (0.7903)
A and B - (0.1943)	A and B - (0.3100)	A and B - (0.9944)
A and C - (0.7936)	A and C - (0.9902)	A and C - (0.8163)

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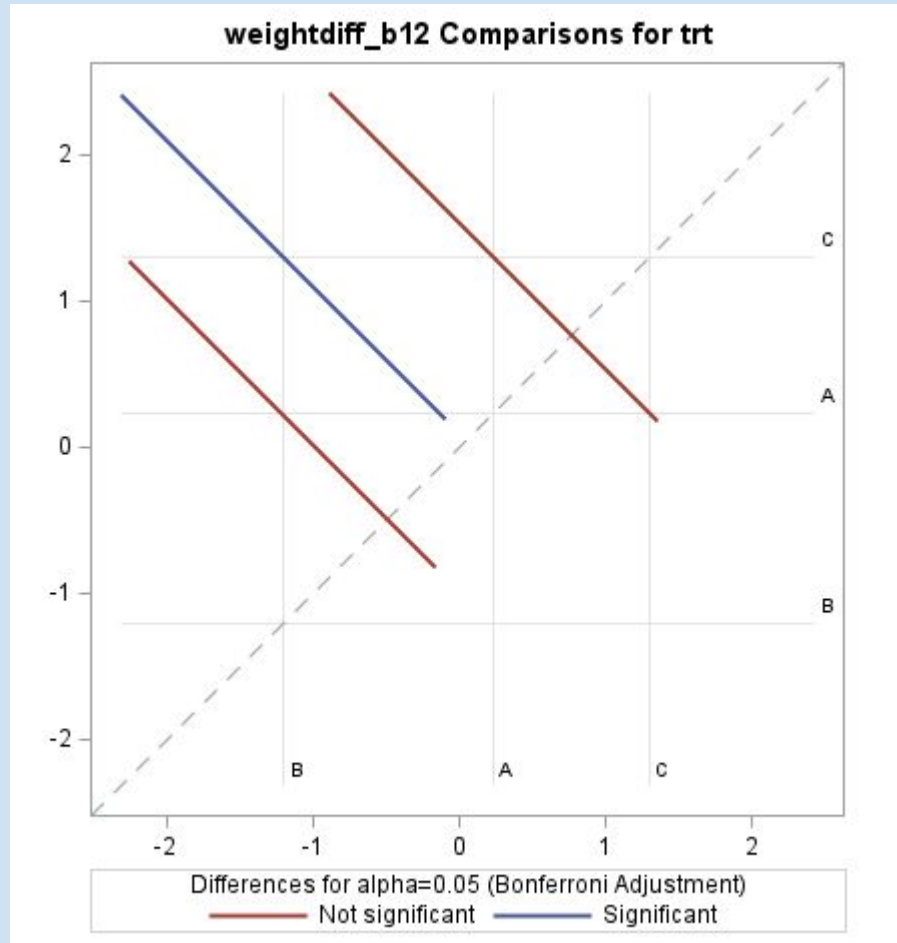
Based on the chi-square test, there are no baseline differences between the three treatment groups for the categorical data.

Is there a difference in weight change at 12 months by treatment arm while controlling for the other variables?

Solution for Fixed Effects														
Effect	trt	Gender	white	Ethnicity	married	educ	inc	Rurality	Estimate	Standard Error	DF	t Value	Pr > t	
Intercept									12.5076	3.5075	248	3.57	0.0004	
trt	A								-1.3980	0.9642	248	-1.45	0.1484	
trt	B								-3.0647	0.9560	248	-3.21	0.0015	
trt	C								0	-	-	-	-	
BVWeight									-0.02853	0.05287	248	-0.54	0.5899	
Age									-0.06601	0.03450	248	-1.91	0.0568	
Gender		F							-0.2177	1.1116	248	-0.20	0.8449	
Gender		M							0	-	-	-	-	
BMI									-0.09392	0.1588	248	-0.59	0.5548	
white			1						-0.3913	0.8276	248	-0.47	0.6367	
white			0						0	-	-	-	-	
Ethnicity				1					-0.8098	2.8887	248	-0.28	0.7795	
Ethnicity				0					0	-	-	-	-	
married					1				0.5973	0.8517	248	0.70	0.4838	
married					0				0	-	-	-	-	
educ						1			-0.4739	1.0450	248	-0.45	0.6506	
educ						2			-1.3247	1.5441	248	-0.86	0.3918	
educ						0			0	-	-	-	-	
inc							1		-1.3793	1.0390	248	-1.33	0.1856	
inc							2		-0.4354	1.0362	248	-0.42	0.6747	
inc							3		-2.2687	1.4447	248	-1.57	0.1176	
inc							0		0	-	-	-	-	
ftnd_score0									-0.03628	0.1908	248	-0.19	0.8494	
Rurality								1	-1.8816	1.2915	248	-1.46	0.1464	
Rurality								0	0	-	-	-	-	

Generalized Linear Model

Is there a
difference in
weight change
at 12 months
by treatment
arms?

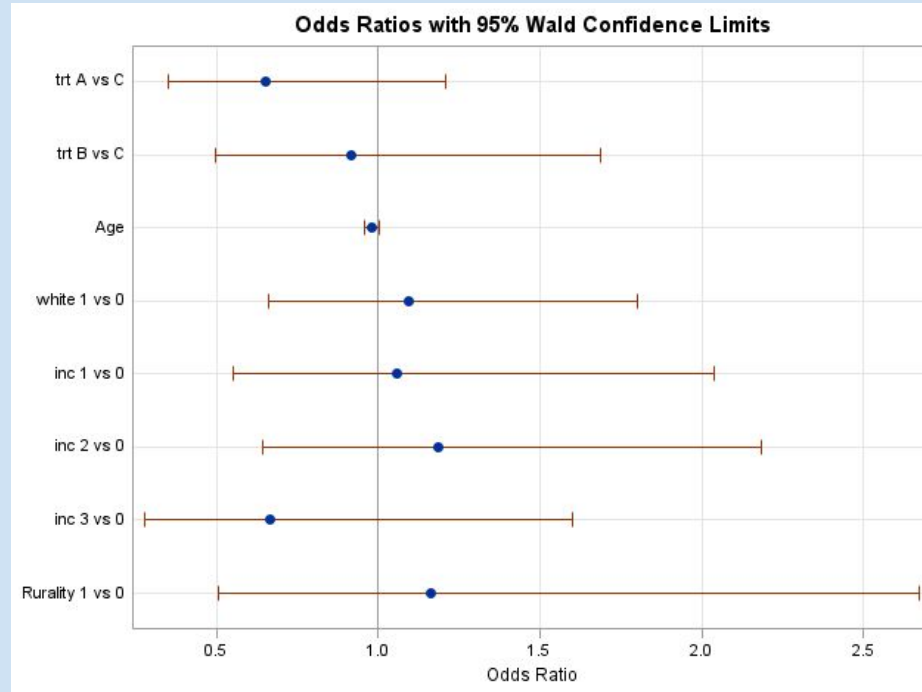


Is there an interaction between treatment arm and smoking point prevalence abstinence?

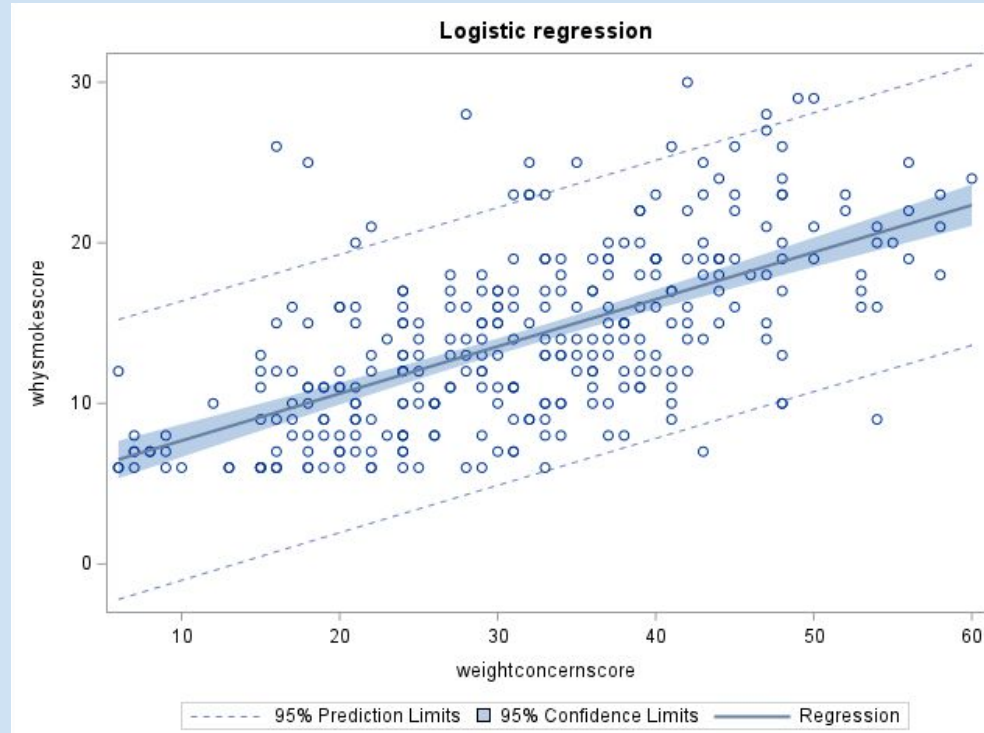
trt*pointprev	A	1								2.7801	1.9179	245	1.45	0.1485
trt*pointprev	A	0								0	-	-	-	-
trt*pointprev	B	1								-1.0826	1.8839	245	-0.57	0.5661
trt*pointprev	B	0								0	-	-	-	-
trt*pointprev	C	1								0	-	-	-	-
trt*pointprev	C	0								0	-	-	-	-

There is not an interaction between pointprev and any of the treatment groups.

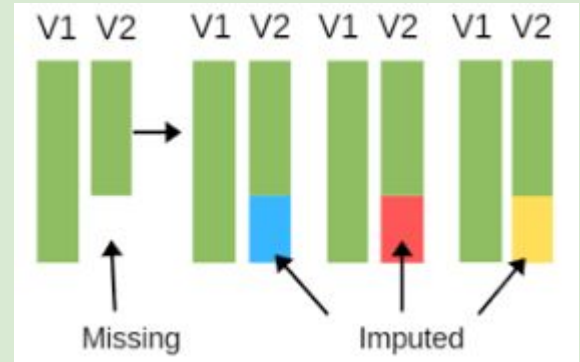
Does smoking abstinence at 12 months differ by treatment arm age, white, income and rurality?



Is there a correlation between why smoke score and weight gain concern score?



Multiple Imputation



Multiple Imputations

- Method used to impute data points for missing data
- The procedure 'proc mi' was used to create 25 complete data sets for the missing values in the 'Weight at 12 months' variable
- This method is useful for replacing missing data without creating bias, as with other methods (such as mean imputation)

Conclusion



Conclusions

- Out of the three treatment arms, only arm B (weight loss) had statistically significant weight loss
- Arm A and C (weight maintenance & standard of care) are still effective for stopping weight gain after quitting smoking 12 months later
- According to our regression model we can conclude that treatment B in reference to C is statistically significant and A in reference to C is not statistically significant
- There is no statistically significant interaction between any of the treatment arms and smoking point prevalence abstinence

Sources

- A Randomized Controlled Trial to Reduce Post-Cessation Weight Gain - Nature, www.nature.com/articles/s41366-023-01286-5.pdf. Accessed 27 June 2023.
- Driva, Stamatina et al. “The Effect of Smoking Cessation on Body Weight and Other Metabolic Parameters with Focus on People with Type 2 Diabetes Mellitus.” International journal of environmental research and public health vol. 19,20 13222. 14 Oct. 2022, doi:10.3390/ijerph192013222