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Research Scenario:

For this set of problems, the research scenario represents a common set of data. A common set of data elements was obtained based on the primary endpoint of determining the efficacy of biofeedback training to reduce mild depression. This was an experimental model which was also intended to evaluate effect on depression scores associated with certain characteristics of the patients. There were 56 patients randomly sampled from a larger population, and divided randomly into the two experimental groups. Patient characteristics recorded included current Drug therapy, Fitness level, Gender, Belief in a god, Self Esteem, Locus of Control, Social Ability, Depression score, and Attitude scores before and after intervention.

General Assumptions:

This is a normal population

Patients are random selected
Samples are independent
There is equality of variance or homoscedasticity

General Considerations:

The measures of Self Esteem, Locus of Control, Social Ability, Depression and Attitude are not defined. As such an assumption is made that the higher the score, the more significant the event. Specifically – a higher Self Esteem score means better self esteem, a higher Social Ability score means greater social skills and capability, a higher depression score means more depression. Presumably a higher attitude score means a better attitude. Locus of control is more difficult to assume, but likely means more internal control rather than external. These definitions require clarification in order to further interpret the following results.

It was requested that some of the relationships between characteristics of the population be described statistically. These analysis do not specifically respond to the primary endpoint question of efficacy, but would provide context for understanding that result.

1. Is there a difference in depression as a function of group and drug?

Hypothesis:

Problem formulation: Group is the primary division for the experimental study, and Drug Therapy is a characteristic of the population. Depression is the final (dependent) outcome variable. This question asks for an evaluation of the mean of the Depression score for the treatment group compared to the mean of the Depression score for the control group. These groups represent two random samples of the larger study population.

Data Definitions/Comments:

Variables - Depression; Group; Drug

Dependent Variable - Depression

Data types - Dependent variable - continuous
 Independent variable(s) - both nominal

Relationship between independent variables – Independent

NOTES: Consider the word ‘and’ as it relates to Group and Drug. This would imply that the combination of characteristics is of particular concern, not each one individually.

Null Hypothesis: $H_0: A \square B$

There is no significant difference in the measure of depression based on group and drug.

Alternative Hypothesis: $H_1: A = B$

There is a significant difference in the measure of depression based on group and drug.

Statistical Procedure, Tests and Assumptions:

Test: Univariate General Linear Model

Level of Significance: $\alpha = 0.05$

Assumptions: This is a normal population

Patients are random selected

Samples are independent

There is equality of variance

Results:

Warnings

Post hoc tests are not performed for Group because there are fewer than three groups.

Between-Subjects Factors

		Value Label	N
Group	1.00	BioFeedback	28
		Training	
	2.00	Control Training	28
Drug Therapy	1.00	Drug A	18
		Drug B	20
		No Drug	18

Group	Drug Therapy	Mean	Std. Deviation	N
BioFeedback Training	Drug A	6.0000	2.92770	8
	Drug B	8.3333	2.67423	12
	No Drug	8.5000	2.20389	8
	Total	7.7143	2.76026	28
Control Training	Drug A	7.8000	2.04396	10
	Drug B	8.5000	2.20389	8
	No Drug	6.4000	1.07497	10
	Total	7.5000	1.95316	28
Total	Drug A	7.0000	2.56676	18
	Drug B	8.4000	2.43656	20
	No Drug	7.3333	1.94029	18
	Total	7.6071	2.37164	56

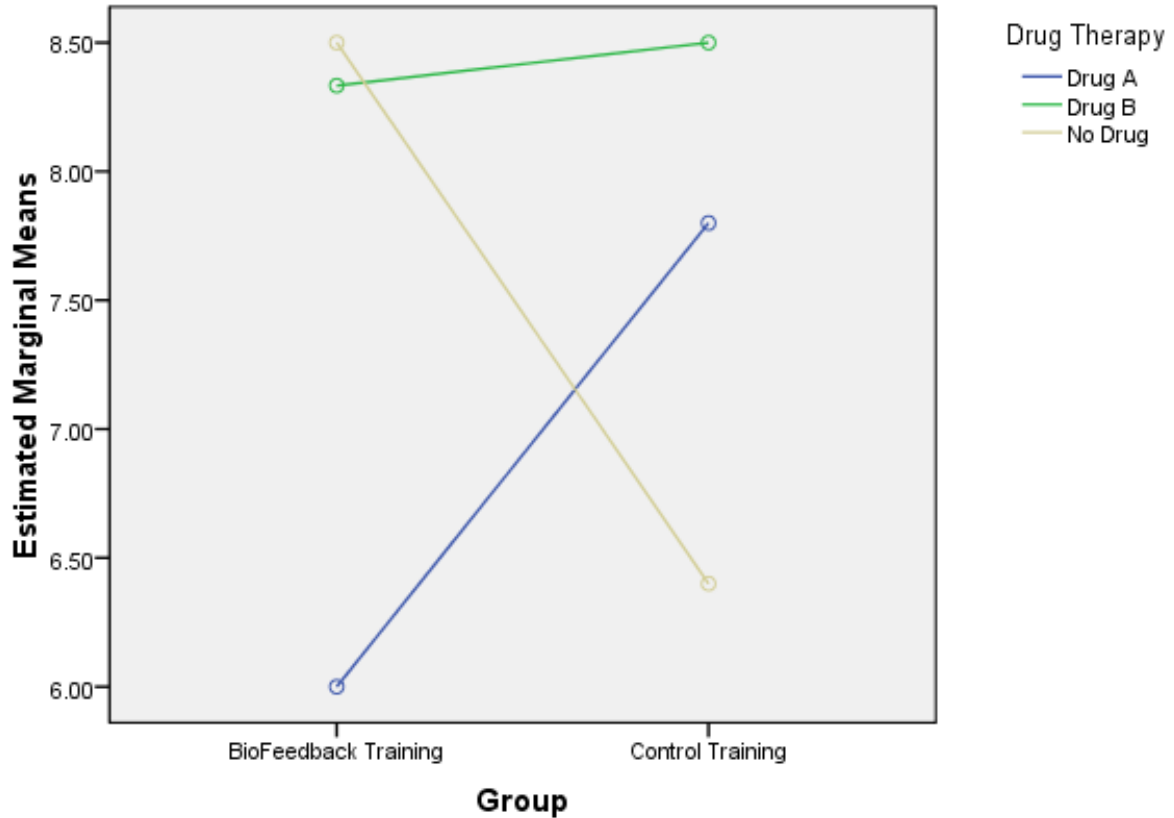
Tests of Between-Subjects Effects

Dependent Variable: Depression

Source	Type III Sum of Squares	Df	Mean Square	F	Sig.
Corrected Model	54.690 ^a	5	10.938	2.148	.075
Intercept	3149.293	1	3149.293	618.317	.000
Group	.027	1	.027	.005	.942
Drug	21.911	2	10.955	2.151	.127
Group * Drug	34.113	2	17.056	3.349	.043
Error	254.667	50	5.093		
Total	3550.000	56			
Corrected Total	309.357	55			

a. R Squared = .177 (Adjusted R Squared = .094)

Estimated Marginal Means of Depression



Inference:

The null hypothesis is rejected as $p=0.43$ (0.05) based on the Drug*Group interaction. The Drug*Group interaction is consistent with the graph of the Estimated Marginal Means of Drug Therapy, which demonstrates crossing of the lines. This result is consistent with the graph which shows higher depression scores with Biofeedback intervention in the patients with no drug therapy, but lower Depression scores with any drug therapy. $R^2 = .177$, indicating $\sim 18\%$ of the variation in the dependent variable is accounted for by this model. Neither Group nor Drug demonstrated significant changes in measure of depression in independent analysis.

2. Is there a significant change in attitude from the pretest to the posttest across all study subjects?

Hypothesis:

Problem formulation: Attitude is a continuous variable measured at two points in time. These samples can be compared by a standard T test to determine the average variation. The key word 'all' indicates that the evaluation should be done by comparing samples, not individuals within the sample.

Data Definitions/Comments:

Variables - PreAtt; PostAtt

Relationship between independent variables - paired based on individual

Data types - continuous

NOTES: 'all' => sample mean

Null Hypothesis: $H_0: A = B$

There is no significant change in attitude from the pretest to the posttest across all study subjects.

Alternative Hypothesis: $H_1: A \neq B$

There is a significant change in attitude from the pretest to the posttest across all study subjects.

Statistical Procedure, Tests and Assumptions:

Test: T-Test; Paired Samples

Level of Significance: $\alpha = 0.05$

Assumptions: This is a normal population
 Samples are independent

Patients are random selected
 There is equality of variance

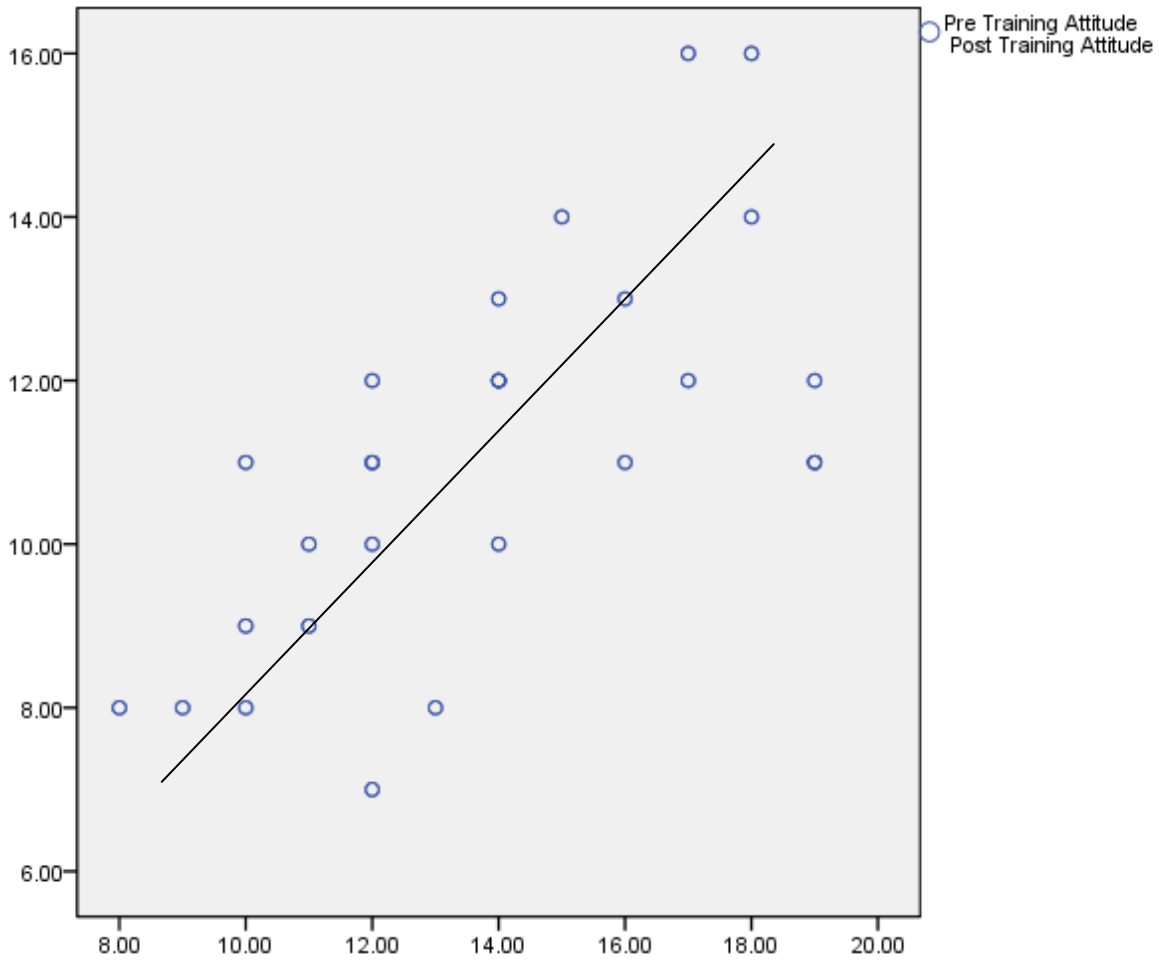
Results:

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Pre Training Attitude	11.1071	56	2.29370	.30651
	Post Training Attitude	13.7857	56	3.19496	.42694

Paired Samples Test

		t	df	Sig. (2-tailed)
Pair 1	Pre Training Attitude - Post Training Attitude	-8.467	55	.000



Inference:

The null hypothesis is rejected as $p=0.000 (<0.05)$. This is consistent with the visual evaluation of the scatter plot comparison of Pre and Post training Attitude measures, which creates a line with a distinctly positive slope. There is a significant change in attitude from the pretest to the posttest across all study subjects. This would potentially indicate that the overall effect of the study was to improve attitude regardless of the intervention. This may represent a confounding factor in the absence of a bimodal population (e.g. differences between the Groups).

3. Is the change in attitude from the pretest to the posttest the same for the BioFeedback and Control Group?

Hypothesis:

Problem formulation: DeltaAtt is a computed value based on the Attitude measures of the same patient at two different points in time. This represents a characteristic of the samples within the population. Group is the primary division for the experimental study and as such a nominal variable. The question is to determine the variance between the groups based on the characteristic measured.

Data Definitions/Comments:

Variables - Group, DeltaAtt

Dependent Variable – Change in Attitude

Data types - Dependent variable - Continuous

 Independent variable(s) - Nominal

Null Hypothesis: $H_0: A = B$

There is no significant difference in the change of attitude from the pretest to the posttest between the Bio-Feedback and Control groups.

Alternative Hypothesis: $H_1: A \neq B$

There is a significant difference in the change of attitude from the pretest to the posttest between the Bio-Feedback and Control groups.

Statistical Procedure, Tests and Assumptions:

Test: univariate General Linear model

Level of Significance: $\alpha = 0.05$

Assumptions: This is a normal population

Patients are random selected

Samples are independent

There is equality of variance

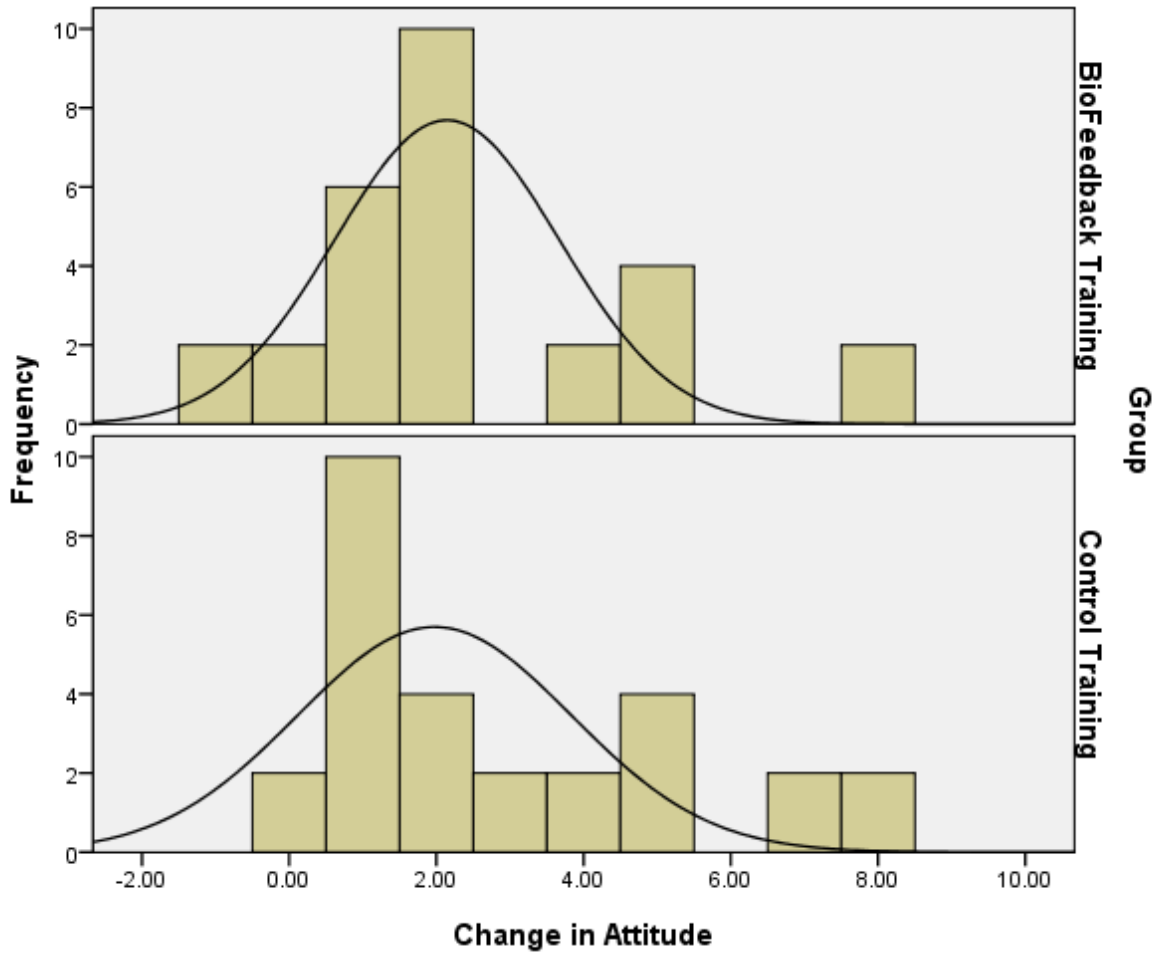
Results:

Group Statistics

Group	N	Mean	Std. Deviation	Std. Error Mean
BioFeedback Training	28	2.4286	2.30022	.43470
Control Training	28	2.9286	2.44841	.46271

Independent Samples Test

		t-test for Equality of Means		
		Sig. (2-tailed)	Mean Difference	Std. Error Difference
Change in Attitude	Equal variances assumed	.434	-.50000	.63487
	Equal variances not assumed	.434	-.50000	.63487



Inference:

The null hypothesis IS NOT rejected as $p=0.434$ (>0.05). As can be seen from the histograms with normal curve, the sample means are very similar, with a significant visual difference only see in the amplitude of the curves. There is no significant difference in the change of attitude from the pretest to the posttest between the BioFeedback and Control groups. This might indicate independence of the expression of Attitude compared to Depression if there is a determined effect that there is a significant effect of Biofeedback on the primary endpoint. This could be looked at as a future study if that is the case.

4. Is there a significant relationship between fitness and gender?

Hypothesis:

Problem formulation: Fitness and Gender are two characteristics of the population. They are both nominal as defined. As such they are nonparametric. The goal is to determine the level of independence between the samples.

Data Definitions/Comments:

Variables - Fitness, Gender

Column Variable - Fitness

Relationship between variables - independent

Data types - Row variable - nominal

Column variable(s) - nominal

Null Hypothesis: $H_0: A \square B$

There is no significant relationship between fitness and gender.

Alternative Hypothesis: $H_1: A = B$

There is a significant relationship between fitness and gender.

Statistical Procedure, Tests and Assumptions:

Test: Chi Square

Level of Significance: $\alpha = 0.05$

Assumptions: Randomness of data samples

Independence

Mutually exclusive (nominal) measurement classes

Average cell frequency is greater ≥ 5

Results:

Gender * Physically Fit Crosstabulation

	Physically Fit	
--	----------------	--

			Fail	Pass	Total
Gender	Male	Count	20	6	26
		% within Gender	76.9%	23.1%	100.0%
	Female	Count	12	18	30
		% within Gender	40.0%	60.0%	100.0%
Total		Count	32	24	56
		% within Gender	57.1%	42.9%	100.0%

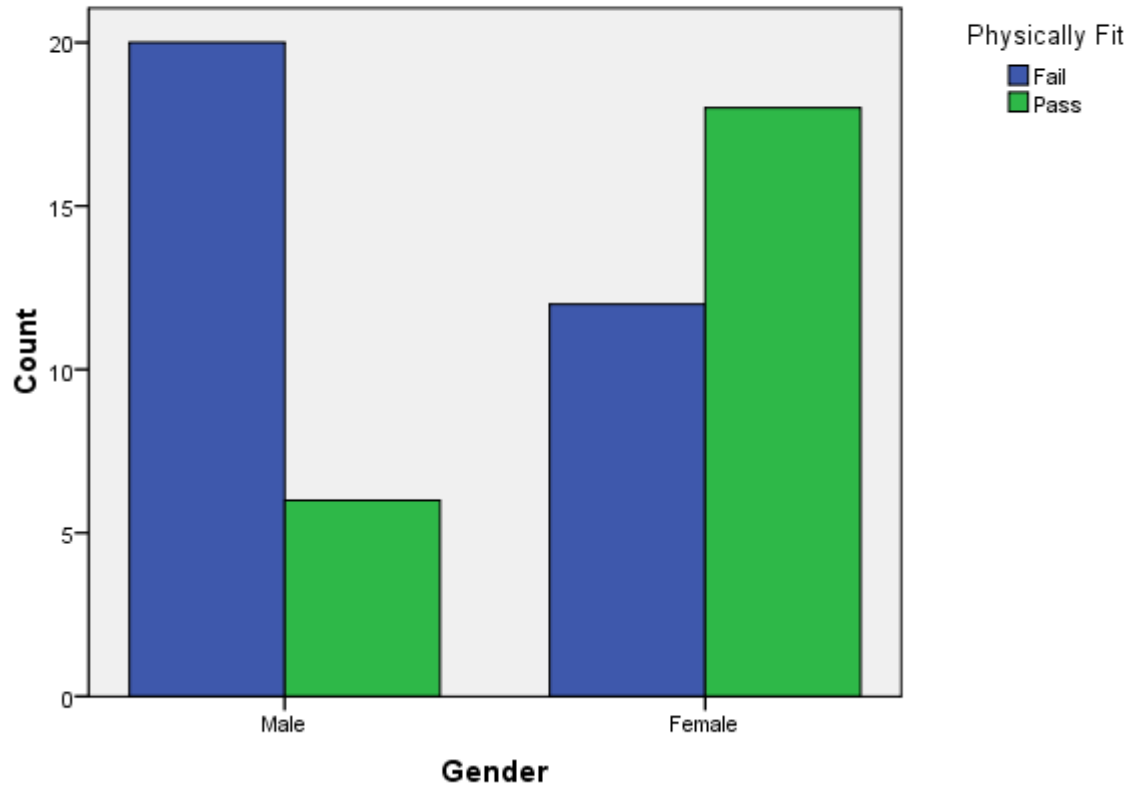
Chi-Square Tests

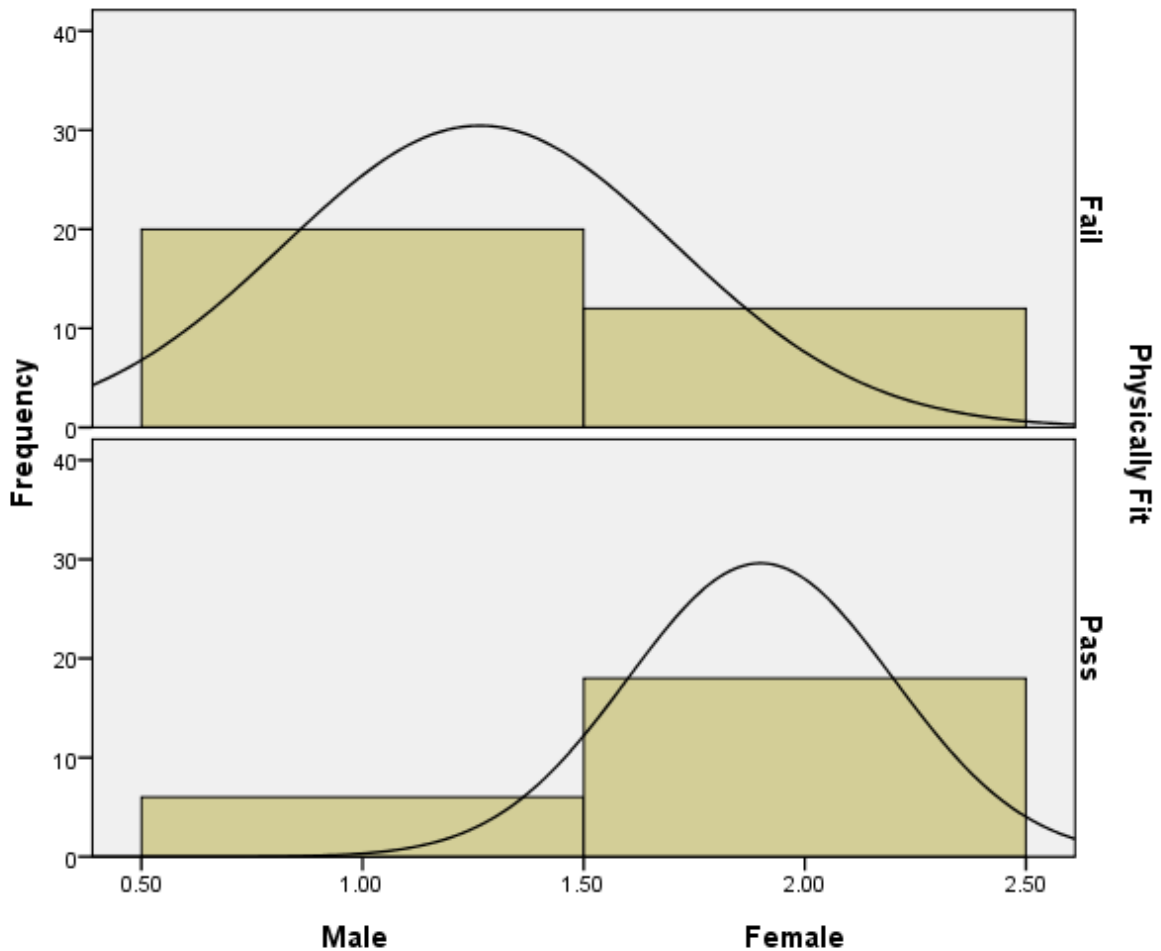
	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	7.754 ^a	1	.005		
Continuity Correction ^b	6.319	1	.012		
Likelihood Ratio	8.014	1	.005		
Fisher's Exact Test				.007	.006
Linear-by-Linear Association	7.615	1	.006		
N of Valid Cases	56				

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 11.14.

b. Computed only for a 2x2 table

Bar Chart





Inference:

The null hypothesis is rejected as $p=0.005$ (<0.05). This is consistent with the clear visual difference in means for the two sample populations noted in the graphs above. This would indicate that there is a significant relationship between fitness and gender. In particular, there is a tendency for women to pass the fitness test more often than men. Some consideration might need to be made as to whether the test is biased toward women in some way, or other measure may want to be considered to confirm or correlate with this fitness level (e.g. BMI, blood pressure).

5. Is a subject's pretest attitude related to the type of drug they are on?

Hypothesis:

Problem formulation: Pre-test attitude is measured on a continuous scale both before and after the intervention. In this case only the first of the two measures is considered and the question is whether it is correlated to the type of drug regimen being used. The Drug regimen is a nominal variable, having only 3 potential values that are independent of each other.

Data Definitions/Comments:

Variables – PreAtt, Drug

Dependent Variable - PreAtt

Data types - Dependent variable - Continuous

Independent variable(s) - Nominal

Null Hypothesis: $H_0: A \neq B$

There is no significant relationship between pre-test attitude and the type of drug taken.

Alternative Hypothesis: $H_1: A = B$

There is a significant relationship between pre-test attitude and the type of drug taken.

Statistical Procedure, Tests and Assumptions:

Test: One way ANOVA

Level of Significance: $\alpha = 0.05$

Assumptions: This is a normal population

Patients are randomly selected

Samples are independent

There is equality of variance

Results:

Descriptives

Change in Attitude

					95% Confidence Interval for Mean	
	N	Mean	Std. Deviation	Std. Error	Lower Bound	Upper Bound
Drug A	18	1.4444	1.19913	.28264	.8481	2.0408
Drug B	20	2.7000	2.00263	.44780	1.7627	3.6373
No Drug	18	3.8889	3.00762	.70890	2.3932	5.3845
Total	56	2.6786	2.36725	.31634	2.0446	3.3125

ANOVA

Change in Attitude

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	53.792	2	26.896	5.603	.006
Within Groups	254.422	53	4.800		
Total	308.214	55			

Post Hoc Tests

Multiple Comparisons

Change in Attitude

Tukey HSD

(I) Drug Therapy	(J) Drug Therapy	Mean Difference (I-J)	Std. Error	Sig.
Drug A	Drug B	-1.25556	.71184	.192

	No Drug	-2.44444*	.73033	.004
Drug B	Drug A	1.25556	.71184	.192
	No Drug	-1.18889	.71184	.226
No Drug	Drug A	2.44444*	.73033	.004
	Drug B	1.18889	.71184	.226

*. The mean difference is significant at the 0.05 level.

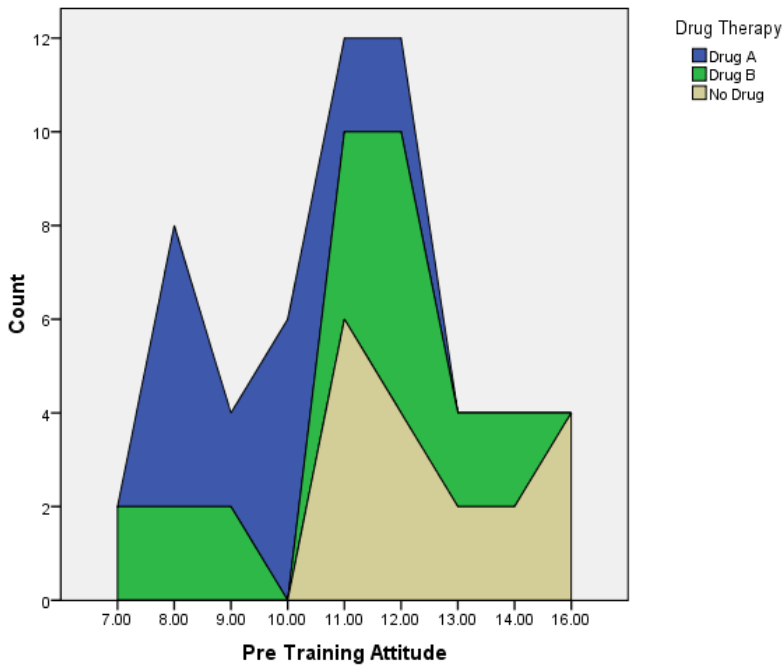
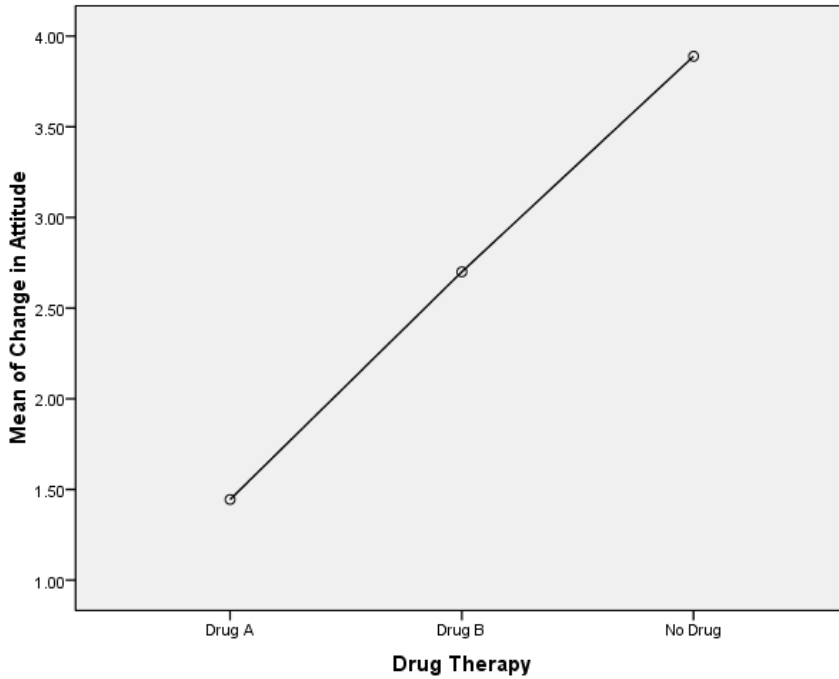
Homogeneous Subsets Change in Attitude

Tukey HSD^{a,b}

Drug Therapy	N	Subset for alpha = 0.05	
		1	2
Drug A	18	1.4444	
Drug B	20	2.7000	2.7000
No Drug	18		3.8889
Sig.		.197	.232

Means for groups in homogeneous subsets are displayed. a. Uses Harmonic Mean Sample Size = 18.621. b. The group sizes are unequal. The harmonic mean of the group sizes is used. Type I error levels are not guaranteed.

Means Plots



Inference:

The null hypothesis is rejected as $p=0.006$ (<0.05). This would indicate that there are differences in attitude prior to the intervention with Bio-Feedback, and the primary outcome results may need to be adjusted to account for this difference. The multiple comparisons are consistent with the graphic separation of the Drug A and No Drug

sample populations in particular. See also [Summary](#) for further comparison.

6. Is there a relationship between belief in god and depression?

Hypothesis:

Problem formulation: Belief in god is a characteristic of the population. Depression is the final (dependent) outcome variable. This question asks whether there is a correlation between the level of belief and the associated Depression score for the same patient.

Data Definitions/Comments:

Variables - Belief, Depression

Dependent Variable - Depression

Data types - Dependent variable - continuous

Independent variable(s) - continuous*

Null Hypothesis: $H_0: A \neq B$

There is no significant relationship between belief in god and depression.

Alternative Hypothesis: $H_1: A = B$

There is a significant relationship between belief in god and depression.

Statistical Procedure, Tests and Assumptions:

Test: Correlation

Level of Significance: $\alpha = 0.05$

Assumptions: Normal population

Random data

Independent data

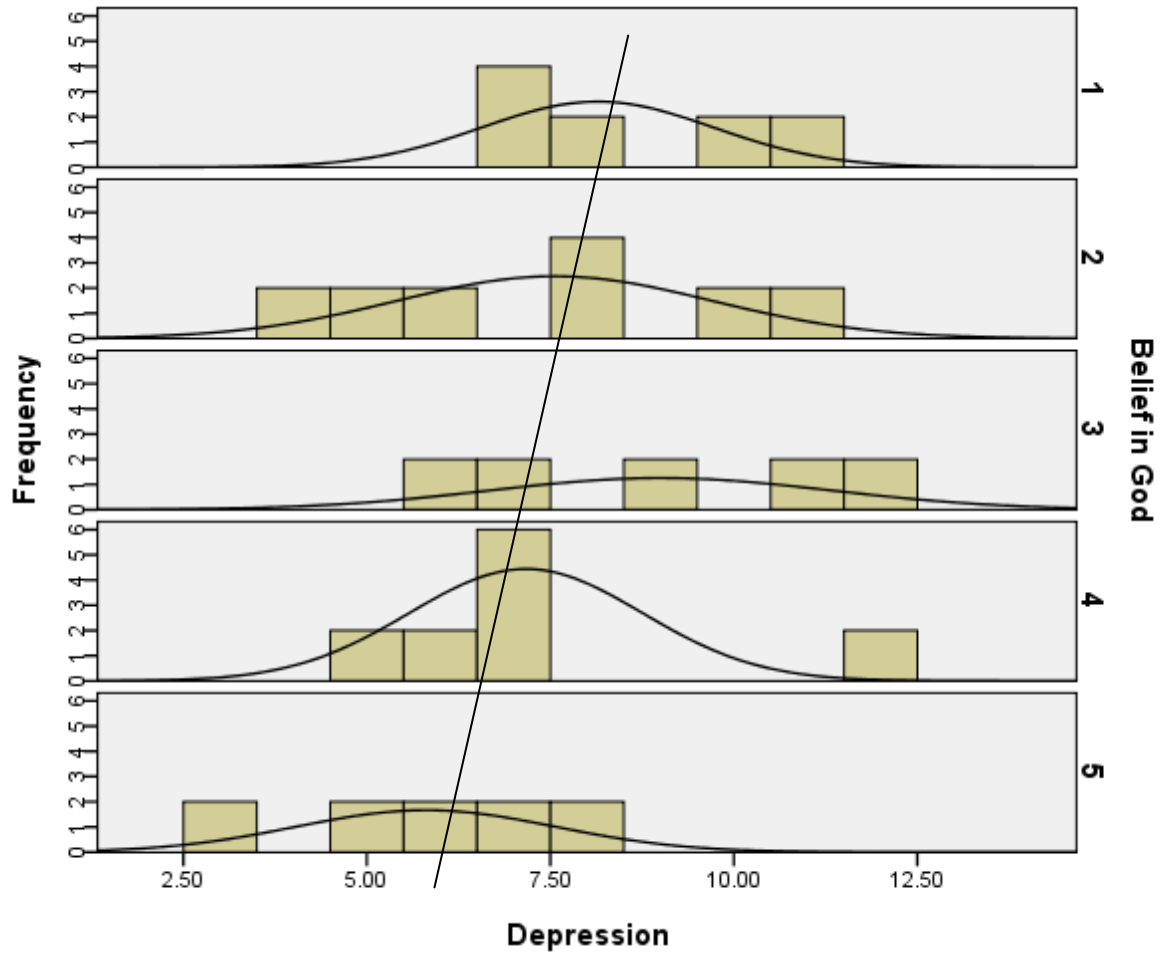
Homoscedasticity

Results:

Correlations

		Belief in God	Depression
Belief in God	Pearson Correlation	1	-.314 [*]
	Sig. (2-tailed)		.019
	N	56	56
Depression	Pearson Correlation	-.314 [*]	1
	Sig. (2-tailed)	.019	
	N	56	56

*. Correlation is significant at the 0.05 level (2-tailed).



Inference:

The null hypothesis IS rejected as $\rho=0.019$ (<0.05). As can be seen in the comparison of the 5 subpopulations based on levels of belief, there is a mild but discernable shift consistent with an increase in depression score associated with an increase in belief. This is roughly consistent with the line drawn across the graphs. The level of correlation is low ($-.314$). This is somewhat counter-intuitive, as one might expect that depression would be helped through faith, but this may represent a selection bias in that more depressed people seek out faith as a healing tool.

7. How well does locus of control, social ability and alienation predict self-esteem?

Hypothesis:

Problem formulation: The goal is to predict self esteem by evaluating a series of characteristic of the sample population. As noted under general considerations, the information provided by high and low scores on the measures used is not defined and will therefore need to be accounted for after determining if the scores themselves offer a significantly predictive equation.

Data Definitions/Comments:

Variables - SelfEsteem, LOC, SocialAbility, Alienation

Dependent Variable - SelfEsteem

Relationship between independent variables - independent measures

Data types - Dependent variable - continuous

Independent variable(s) - continuous

Null Hypothesis: $H_0: A \neq B$

Self Esteem is not predictable based on LOC, Social Ability or Alienation scores.

Alternative Hypothesis: $H_1: A = B$

Self Esteem is predictable based on at least one of the variables LOC, Social Ability or Alienation scores

Statistical Procedure, Tests and Assumptions:

Test: Regression

Level of Significance: $\alpha = 0.05$

Assumptions: This is a normal population
Samples are independent

Patients are random selected
There is homoscedasticity

Results:

Variables Entered/Removed

Model	Variables Entered	Variables Removed	Method
1	Alienation, Social Ability, Locus of Control ^a		Enter

a. All requested variables entered.

Correlations

		Self-Esteem	Locus of Control	Social Ability	Alienation
Pearson Correlation	Self-Esteem	1.000	-.516	.422	.701
	Locus of Control	-.516	1.000	-.651	-.553
	Social Ability	.422	-.651	1.000	.342
	Alienation	.701	-.553	.342	1.000

Sig. (1-tailed)	Self-Esteem	.	.000	.001	.000
	Locus of Control	.000	.	.000	.000
	Social Ability	.001	.000	.	.005
	Alienation	.000	.000	.005	.
N	Self-Esteem	56	56	56	56
	Locus of Control	56	56	56	56
	Social Ability	56	56	56	56
	Alienation	56	56	56	56

Model Summary^b

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.729 ^a	.531	.504	2.77751

a. Predictors: (Constant), Alienation, Social Ability, Locus of Control

b. Dependent Variable: Self-Esteem

ANOVA^b

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	455.057	3	151.686	19.662	.000 ^a
	Residual	401.157	52	7.715		
	Total	856.214	55			

a. Predictors: (Constant), Alienation, Social Ability, Locus of Control

b. Dependent Variable: Self-Esteem

Coefficients^a

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	8.649	6.201		1.395	.169
	Locus of Control	-.107	.208	-.073	-.517	.608

Social Ability	.087	.065	.169	1.349	.183
Alienation	5.368	1.015	.603	5.288	.000

a. Dependent Variable: Self-Esteem

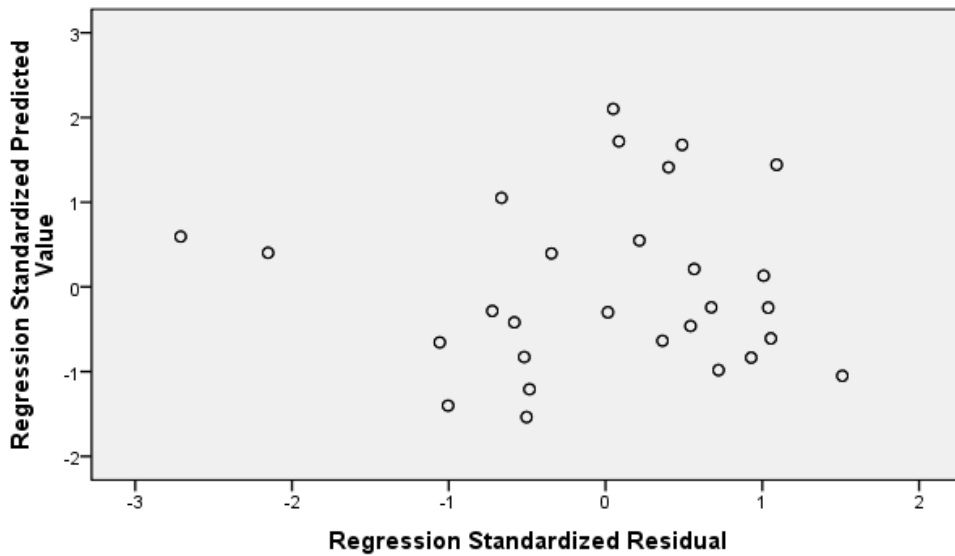
Residuals Statistics^a

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	20.4007	30.8651	24.8214	2.87642	56
Residual	-7.52831	4.19555	.00000	2.70070	56
Std. Predicted Value	-1.537	2.101	.000	1.000	56
Std. Residual	-2.710	1.511	.000	.972	56

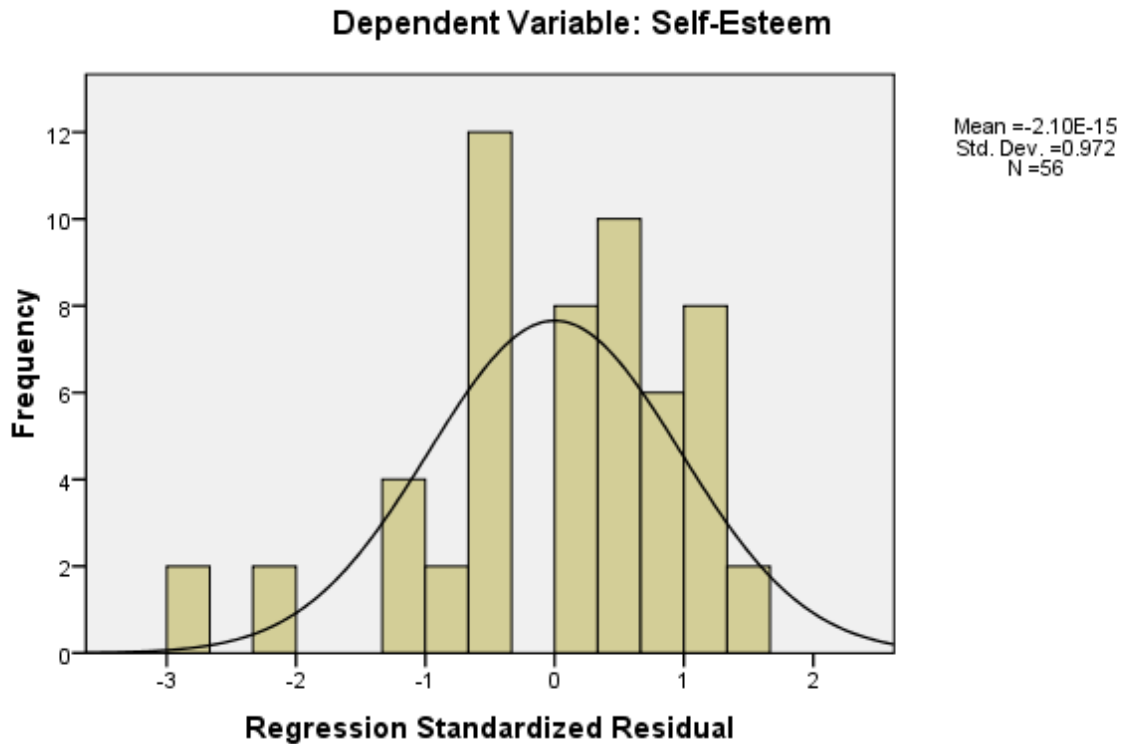
a. Dependent Variable: Self-Esteem

Scatterplot

Dependent Variable: Self-Esteem



Histogram



Inference:

The null hypothesis is rejected as $p=0.00$ (<0.05). The ANOVA model is significant as noted. The correlation coefficients indicate that:

$$\text{SelfEsteem} = 8.649 + (-.107) \text{LocusOfControl} + (.087) \text{SocialAbility} + (5.368) \text{Alienation}$$

The square of the regression coefficient (R^2) indicates that percentage of variation within the model is 53%. This indicates that 53% of the data does fit the model. ($R = .729$)

Based on the level of significance of the coefficients in the model, it would appear that Alienation is the most significant factor. Separating this out and recalculating the regression for Alienation alone yields $R = .701$ and $R^2 = .491$, a slightly worse fit. Repeating the regression with Alienation and Locus of Control (since Social Ability was the least correlated), yields $R = .718$ and $R^2 = .515$. The result of this comparison indicates that although the range of regression coefficients is small, the best fit is with all 3 variables being used.

The graph of standardized predicted residual against the regression standardized residual is widely dispersed consistent with this result.

Summary of Dataset questions:

Although the primary question of whether Depression is affected by Biofeedback is not answered specifically with these analysis, some interesting information is gained. There is a difference between the patient Pretest Attitude based on the Drug they are on, but the change in Attitude is not different based on the intervention (Biofeedback). On the other hand, the combination of groups shows a significant Change in Attitude. This would indicate an effect of the study that is not related to the intervention.

Possibly associated with the difference in Pretest Attitude being related to Drug regimen, there was a difference in Depression score as a function of the combination of Group and Drug regimen.

The relationship of Gender to Fitness, Belief in god and Depression, and the predictors of Self Esteem did not offer any obvious insight into the intended primary outcome. These analysis did not respond specifically to the question of whether Biofeedback affects Depression.