

Regression-Discontinuity Designs in Medical Settings: An Alternative to Quasi-Experimental Designs in Testing Treatment Effectiveness

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The regression-discontinuity design (RD) is a powerful methodological alternative to an experimental design when one is not feasible. RD is frequently a better alternative than quasi-experimental design in minimizing threats to internal validity. The traditional approach in RD is to test for slope or intercept differences between the control and the treatment groups. However, an alternative approach in RD is presented that tests for slope differences, intercept differences, and permits examination of change in individuals. This alternative approach illustrates how RD can be used to enhance evidence-based practices and interventions in a clinical setting when analyzing a single group of subjects.

The regression-discontinuity design (RD) is a powerful methodological alternative to an experimental design when one is not feasible. RD is frequently a better alternative than quasi-experimental design in minimizing threats to internal validity. The traditional approach in RD is to test for slope or intercept differences between the control and the treatment groups. However, an alternative approach in RD is presented that tests for slope differences, intercept differences, and permits examination of change in individuals. This alternative approach illustrates how RD can be used to enhance evidence-based practices and interventions in a clinical setting when analyzing a single group of subjects. The heuristic data for this study is typical of data collected in pain management research.

Methods and Procedures

Data Source

The traditional approach would randomly assign subjects to experimental and control groups (i.e., experimental design), or, more often, utilize a comparison group with matching subject characteristics to a treatment group (i.e., quasi-experimental design). An example of a traditional data set with 10 subjects in the comparison group and 10 subjects in the treatment group is shown in Appendix A.

The alternative approach example has a single group of 25 people measured 6 times each, with 3 scores before and 3 scores after pain management treatment. The heuristic data include: ID, time, control (before intervention), TX (after intervention), pain (dependent variable), and 24 person vectors ($P_n - 1$) (see Appendix B). The medical pain treatment data include dummy coded person vectors in the alternative RD approach to obtain the correct statistical models with the appropriate error term and degrees of freedom (*df*).

Regression Discontinuity

The statistical analysis of data in the traditional RD design involves testing pre- and post- slope or intercept differences between the group regression lines at the intervention point for statistical significance. The basic RD equation can be expressed as:

$$Y_{Post} = b_0 + b_1Z + b_2X_{Pre} + e ; \quad (1)$$

where: Y_{Post} = post measures
 Z = group assignment (0 = control; 1 = treatment)
 X_{Pre} = pre measures,
 e = residual error, and
 b 's = estimated sample regression weights.

The regression weight for Z , the treatment variable, indicates the amount of gain or loss in the post assessment measure. That is, a positive sign indicates a group gain, while a negative sign indicates a group loss. The alternative approach illustrates another use of the RD design when testing pre- to post-change of a single group of individuals. This permits additional pre- and post-test measures, rather than a single assessment at each time point. Graphically, Figure 1 shows that either RD approach could be represented below with the alternative approach indicating multiple pre- and post-test measures.

Traditional RD Approach

The traditional RD approach tests for slope differences between the comparison and the treatment groups controlling for pre-test differences. The descriptive statistics in Figure 2 indicate that the pre-test means are close for the two groups, but the post-test means are different.

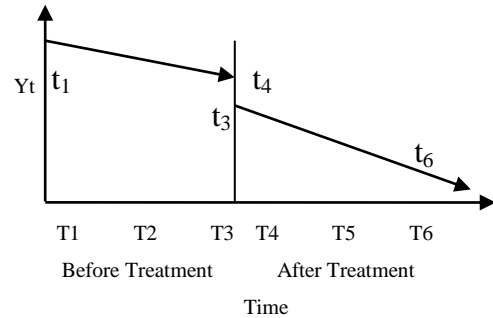


Figure 1. Alternative RD approach.

Traditional RD Analysis

The traditional RD approach follows five steps to test for slope or intercept differences between the comparison and the treatment groups. Interpretation of slope differences between the groups is based on creating an interaction variable (interact), while interpretation of intercept differences is based on the statistical significance of the regression weight for the group variable.

Step 1: Subtract the pre-test mean from each pre-test score, so that the mean cut value on the pre-test scores (pre-cut) will be equal to zero (see Figure 3). That is, pre - mean of pre.

```
COMPUTE precut = pre - 5.35.
```

Step 2: Create a new variable (interact) to represent an interaction term for group*precut.

```
COMPUTE interact=group * precut.
```

Step 3. As seen in Figure 4, evaluate the model: Post = intercept + group + interact + precut

```
UNIANOVA post WITH group interact precut
  /METHOD=SSTYPE(1)
  /INTERCEPT=INCLUDE
  /PRINT=PARAMETER
  /CRITERIA=ALPHA(.05)
  /DESIGN=precut group interact.
```

The interaction term is not statistically significant. If the interaction term were statistically significant, it would mean that the two groups differ with respect to the slope of their separate pre-test regression lines.

group	N	Mean (Slope)	Std. Deviation	Std. Error Mean
pre Control	10	5.00	1.491	.471
pre Treatment	10	5.70	1.252	.396
post Control	10	12.60	2.413	.763
post Treatment	10	19.30	2.830	.895

Figure 2. Descriptive Statistics

Step 4: As seen in Figure 5, evaluate the model: Post = intercept + group + precut

The groups have different intercepts as indicated by the statistically significant regression weight for the group variable ($t = 5.832$; $p = .0001$). The regression weight for group is also the estimate of the treatment effect, which is 7.05 points.

Step 5: As seen in Figure 6, compare separate group results

```
SORT CASES BY group.
SPLIT FILE SEPARATE BY group.
REGRESSION
  /MISSING LISTWISE
  /STATISTICS COEFF OUTS R ANOVA
  /CRITERIA=PIN(.05) POUT(.10)
  /NOORIGIN
  /DEPENDENT post
  /METHOD=ENTER precut.
```

	N	Min	Max	Mean	Std. Deviation
pre	20	3.00	8.00	5.35	1.387
precut	20	-2.35	2.65	.0000	1.38697

Figure 3. Traditional RD Results: Descriptives

Intercept and Slope Difference

In Figure 6, we also see that the slope difference is -0.15 (control) and -1.00 (treatment), which shows up for the variable interact (-0.85) and confirms that the slopes are not statistically different ($t = -0.932, p = 0.365$). The intercept difference is 12.548 (control) and 19.65 (treatment), which shows up for the variable group (7.102) in Figure 4 and confirms that the intercepts are statistically different ($t = 5.846, p < 0.001$).

Alternative RD Approach

Test of Hypotheses

In many medical research settings, it is not possible or ethical to have a control group or an equivalent comparison group. The RD design involves testing trends in baseline scores compared to trends in scores after implementation of a treatment (or intervention). Consequently, an alternative RD approach is presented that tests three separate hypotheses: Hypothesis 1: test of slope differences, Hypothesis 2: test of intercept differences, and Hypothesis 3: $(t_1 - t_3) \neq (t_4 - t_6)$, a test of gain score difference.

Hypothesis 1: Test of Slope Differences. The restricted model (Model 1) indicates a common intercept and slope (subscript c) with individuals dummy coded. The full model (Model 2) indicates different intercepts and slopes with individual dummy coded:

$$\text{Model 1: Restricted (R}^2_1\text{): } Y = a_c U_c + a_c S_c + Zb_1(P_1) + \dots Zb_n(P_n) + e_1$$

$$\text{Model 2: Full (R}^2_2\text{): } Y = a_{01} U_1 + a_1 S_1 + a_{02} U_2 + a_2 S_2 + Zb_1(P_1) + \dots Zb_n(P_n) + e_1$$

If the R^2 difference (change) is statistically significant, then the slope differences and intercept differences, together, account for a significant amount of variance. The full model allows for intercept and slope differences, while the restricted model has common slopes and common intercepts for the before and after groups. That is, if a common slope is supported (S_c), and common intercepts are supported (U_c), then there would be no significant difference between Model 1 and Model 2.

Hypothesis 2: Test of Intercept Differences. The restricted model (Model 1) indicates a common slope (subscript c), but different intercept terms. The full model (Model 2) indicates different intercepts and slopes with individuals dummy coded:

$$\text{Model 1: Restricted (R}^2_1\text{): } Y = a_{01} U_1 + a_{02} U_2 + a_c S_c + e_2$$

$$\text{Model 2: Full (R}^2_2\text{): } Y = a_{01} U_1 + a_1 S_1 + a_{02} U_2 + a_2 S_2 + Zb_1(P_1) + \dots Zb_n(P_n) + e_1$$

If the R^2 difference (change) is statistically significant, then the intercepts are different. This implies that the before treatment group intercept is different than the after treatment group intercept. When the intercepts are not statistically different, the R^2 difference is non-significant.

Dependent Variable:post		Parameter Estimates				
Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	5.445	1.914	2.845	.012	1.387	9.503
Precut	.700	1.364	.513	.615	-2.193	3.593
Group	7.102	1.215	5.846	.000	4.527	9.678
Interact	-.850	.912	-.932	.365	-2.782	1.082

Figure 4. Traditional RD results: Evaluation.

Dependent Variable:post		Parameter Estimates				
Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	5.373	1.905	2.820	.012	1.354	9.393
Precut	-.501	.447	-1.121	.278	-1.445	.442
Group	7.051	1.209	5.832	.000	4.500	9.602

Figure 5. Traditional RD results: Evaluation.

Group = Control

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
1 (Constant)	12.548	.830		15.115	.000
precut	-.150	.570	-.093	-.263	.799

Group = Treatment

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
1 (Constant)	19.650	.888		22.136	.000
precut	-1.000	.717	-.442	-1.395	.201

Figure 6. Traditional RD Results: Comparisons

Regression: Model 1 and Model 2

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.932 ^a	.869	.843	.880	.869	32.962	25	124	.000
2	.958 ^b	.918	.900	.704	.049	36.011	2	122	.000

ANOVA for Pain

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	638.484	25	25.539	32.962	.000 ^a
	Residual	96.076	124	.775		
	Total	734.560	149			
2	Regression	674.148	27	24.968	50.423	.000 ^b
	Residual	60.412	122	.495		
	Total	734.560	149			

Figure 7. Hypothesis 1.

Regression: Model 1 and Model 2

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.957 ^a	.915	.897	.712	.915	50.970	26	123	.000
2	.958 ^b	.918	.900	.704	.003	3.991	1	122	.048

ANOVA for Pain

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	672.172	26	25.853	50.970	.000 ^a
	Residual	62.388	123	.507		
	Total	734.560	149			
2	Regression	674.148	27	24.968	50.423	.000 ^b
	Residual	60.412	122	.495		
	Total	734.560	149			

Figure 8. Hypothesis 2.

Hypothesis 3: Test of Gain Score Differences. The restriction on the Full Model is $t_1 - t_3 \neq t_4 - t_6$. (i.e., $t_1 = a_{01}$ in Model 2 and $t_4 = a_{02}$ in Model 2). To obtain t_3 and t_6 , one can use the regression equation to calculate the predicted score:

$$t_3 = a_{01}U_1 + a_1S_1 + Zb_1(P_1) + \dots Zb_n(P_n)$$

$$t_6 = a_{02}U_2 + a_2S_2 + Zb_1(P_1) + \dots Zb_n(P_n);$$

where t_3 is the last time point on the X axis for Before Treatment (S_1) and t_6 is the last time point on the X axis for After Treatment (S_2).

F-test. The F-test is used to determine the statistical significance between the Model 1 and the Model 2 R^2 values in both hypotheses. If the F-test is statistically significant in Hypothesis 1, then the regression slopes of the two regression lines would be significantly different. If the F-test is statistically significant in Hypothesis 2, then the intercepts of the before and the after treatment groups would be different. The F-test for difference in R^2 values is given by:

$$F = \frac{(R_1^2 - R_2^2)/df_1}{(1 - R_1^2)/df_2}$$

where:

Y = score for dependent variable pain

a_{01} ; a_{02} ; a_1 ; a_2 ; a_c ; b_n ; Z_n = partial regression weights

S_1 = score for independent variable at time 1

S_2 = score for independent variable at time 2

S_c = scores for all independent variables (time 1 and time 2)

P_n = is 1 if the pain score came from person 1, 0

Otherwise ... P_n is 1 if the pain score came from person n , 0 otherwise.

The person vectors control for individual differences (see note)[†].

Results

The SPSS syntax used for testing the model differences in Hypothesis 1 and Hypothesis 2 is found in Appendix C. The general linear model results for each hypothesis are presented in Figures 7 and 8. The first hypothesis indicated that the two slopes were different (i.e., before and after treatment) because the R-square change was statistically significant ($R^2_{\text{change}} = 0.049$; $F = 36.01$, $df = 2, 122$, $p = .0001$). The second hypothesis tested whether the group intercepts were different (i.e., pre-measures for the control and the treatment groups). The full model had different slopes and different intercepts, while the restricted model set intercepts equal, but allowed slopes to be different. The intercepts were statistically different at the $p = .05$ level ($R^2 = 0.003$; $F = 3.99$, $df = 1, 122$, $p = .048$).

Hypothesis 3 compared the mean gain from the first observation to the last observation in the Before Treatment regression line to the mean gain from the first observation to the last observation in the After Treatment regression line, when controlling for individual differences. A simple way to examine this contrast, $t_1 - t_3 \neq t_4 - t_6$, is in a one-way analysis of variance with a post-hoc test or a dependent samples t -test (see Appendix C). Other intercept differences could also be hypothesized, for example, $t_3 \neq t_4$. The descriptive statistics for the Before Treatment time points and the After Treatment time points are given in Figures 9 and 10. Table 1 indicates the mean gain difference for the Before Treatment and the After Treatment.

Pain		Descriptives							
	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	
					Lower Bound	Upper Bound			
0	75	3.64	.895	.103	3.43	3.85	2	6	
T1	25	8.04	1.172	.234	7.56	8.52	6	10	
T2	25	7.72	.792	.158	7.39	8.05	6	9	
T3	25	7.16	.850	.170	6.81	7.51	5	9	
Total	150	5.64	2.220	.181	5.28	6.00	2	10	

Pain		ANOVA				
	Sum of Squares	df	Mean Square	F	Sig.	
Between Groups	609.920	3	203.307	238.148	.000	
Within Groups	124.640	146	.854			
Total	734.560	149				

Figure 9. Before Treatment.

Pain		Descriptives							
	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	
					Lower Bound	Upper Bound			
0	75	7.64	1.009	.116	7.41	7.87	5	10	
T4	25	4.40	.645	.129	4.13	4.67	3	6	
T5	25	3.60	.577	.115	3.36	3.84	3	5	
T6	25	2.92	.759	.152	2.61	3.23	2	5	
Total	150	5.64	2.220	.181	5.28	6.00	2	10	

Pain		ANOVA				
	Sum of Squares	df	Mean Square	F	Sig.	
Between Groups	627.440	3	209.147	285.058	.000	
Within Groups	107.120	146	.734			
Total	734.560	149				

Figure 10. After Treatment.

Individual Change

A potentially unique analysis of the Appendix D data identifies 6 individuals out of the 25, or 24%, (i.e., persons 5, 6, 8, 11, 20, 24) whose scores did not account for a significant amount of unique variance in the criterion variable. This is indicated by their non-statistically significant regression weights. Individuals with larger regression weights accounted for more variance in the criterion variable. The after treatment as a whole showed a statistically significant slope difference, but the individual change results indicated that group average can mask individual gains, losses, or no change in treatment. The ability to examine individual treatment gains is an important result obtained from the alternative RD approach, and is especially important in medical settings where the emphasis is on individual rather than group prediction. This type of analysis can be the first stage in a mixed methods approach (Newman & Benz, 1998; Newman, Newman & Newman, 2011; Ridenour & Newman, 2008) where the scores of the six individuals that show non-statistically significant results can be coded 1 if the treatment worked for them and 0 if it did not. Variables could then be selected from a theoretical or qualitative (such as focus groups, interviews, etc.) position to determine how the group of 6 are uniquely different from the other 19; thus, giving insight related to who is most likely to benefit from the treatment.

Table 1. Mean Gain Difference for Before After Treatment.

Regression Line	Mean Gain	SD Error	<i>t</i>	<i>p</i>
Before Treatment ($t_1 - t_3$)	0.88	0.261	3.37	.0120
After Treatment ($t_4 - t_6$)	1.48	0.242	6.12	.0001

Alternative hypothesis with mean gain difference is stated as:

$$\begin{aligned} H_A: (t_1 - t_3) &\neq (t_4 - t_6) \\ H_A: (8.04 - 7.16) &\neq (4.40 - 2.92) \\ H_A: 0.88 &\neq 1.48 \end{aligned}$$

The dependent samples *t*-test for the mean gain difference is statistically significant at the 0.05 level:

$$t = \frac{1.48 - 0.88}{(0.261 + 0.242)/2} = \frac{0.60}{0.252} = 2.38$$

Summary and Conclusions

The traditional RD approach tests for slope differences, but also includes in the regression model a group* precut interaction term that can be interpreted for any slope difference between the comparison and the treatment groups. This approach does require the creation of a centered interaction term. The alternatives RD approach tested slope differences, intercept differences, and provided an individual rate of change due to dummy coded vectors. The test of intercept differences is clearly a required test in traditional quasi-experimental designs if controlling for pre-test differences. The dummy coded vectors for each individual provided a test of each individual regression weight; thus, a measure of individual change. It clearly showed that although an after treatment slope was different, not all individuals had the same rate of change. This information is very important if diagnosing individual treatment effectiveness, which is common in medical settings, where identifying differences between “responders” and “non-responders” to a treatment may be more important than the overall treatment group effect.

Newman, Fraas, Newman, and Brown (2002) discuss the concept of a Type VI Error, which is the inconsistency between the research question and the statistical model developed to reflect the research question of interest. In this case, it is extremely important to have the person vectors reflected in the models so that the models accurately reflect the questions of interest. It is also necessary to include the person vectors to have the correct error terms, since subjects are repeated over time. As one can see from the three suggested hypotheses, the regression models are written to directly reflect the questions of interest; thus, decreasing the likelihood of making a Type VI Error.

Educational researchers should make increased use of the RD method in their data analysis from quasi-experimental research designs. Researchers can gain a better understanding of

treatment effectiveness from the intervention in their research design. The traditional approach provided a test of slope and intercept difference between a comparison and treatment group. The alternative method used a single group of subjects and tested two different hypotheses; one for testing slope differences and the other for testing intercept differences. The alternative approach tested for slope and intercept differences using an F-test of the R-square change value between full and restricted models. This approach further provided measures of individual rates of change due to dummy coding. The alternative approach to RD should be considered above and beyond a traditional RD method.

Footnote

† Dummy coded person vectors are required to obtain the correct df . The data analysis should contain $k - 1$ dummy coded vectors for persons.

References

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- Newman, I., Fraas, J., Newman, C., & Brown, R. (2002). Research practices that produce Type VI Errors. *Journal of Research in Education, 12*, 138-145.
- Newman, I., Newman, D., & Newman, C. (2011). Writing research articles using mixed methods: Methodological considerations to help you get published. In T. S. Rocco & T. Hatcher (Eds.), *The handbook of scholarly writing and publishing* (pp. 191-208). San Francisco: Jossey-Bass.
- Ridenour, C., & Newman, I. (2008). *Mixed methods research: Exploring the interactive continuum*. Carbondale, IL: Southern Illinois University Press.

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APPENDIX A

Data: Traditional Approach (Group: 0 = comparison; 1 = treatment)

Group	Pre	Post
0	5	10
0	6	11
0	7	12
0	3	14
0	5	16
0	4	17
0	6	12
0	7	13
0	3	10
0	4	11
1	6	15
1	6	16
1	8	18
1	6	20
1	5	21
1	4	19
1	7	17
1	6	22
1	5	24
1	4	21

APPENDIX C
SPSS Syntax for Testing Model Differences

Comment Hypothesis 1.

```
REGRESSION
  /MISSING LISTWISE
  /STATISTICS COEFF OUTS R ANOVA CHANGE
  /CRITERIA=PIN(.05) POUT(.10)
  /NOORIGIN
  /DEPENDENT Pain
  /METHOD=ENTER TX Person_1 Person_2 Person_3 Person_4 Person_5
Person_6 Person_7 Person_8 Person_9 Person_10 Person_11
Person_12 Person_13 Person_14 Person_15 Person_16 Person_17
Person_18 Person_19 Person_20 Person_21 Person_22 Person_23
Person_24
  /METHOD=ENTER Control_Time TX_Time.
```

Alternative Approach: R-squared change for intercept differences

Comment Hypothesis 2.

```
REGRESSION
  /MISSING LISTWISE
  /STATISTICS COEFF OUTS R ANOVA CHANGE
  /CRITERIA=PIN(.05) POUT(.10)
  /NOORIGIN
  /DEPENDENT Pain
  /METHOD=ENTER Person_1 Person_2 Person_3 Person_4 Person_5
Person_6 Person_7 Person_8 Person_9 Person_10
Person_11 Person_12 Person_13 Person_14 Person_15 Person_16
Person_17 Person_18 Person_19 Person_20
Person_21 Person_22 Person_23 Person_24 Control_Time TX_Time
/METHOD=ENTER TX.
```

Comment Hypothesis 3.

```
ONEWAY Pain BY Control_Time
  /STATISTICS DESCRIPTIVES
  /MISSING ANALYSIS
  /POSTHOC=SCHEFFE ALPHA(0.05).
```

```
ONEWAY Pain BY TX_Time
  /STATISTICS DESCRIPTIVES
  /PLOT MEANS
  /MISSING ANALYSIS
  /POSTHOC=SCHEFFE ALPHA(0.05).
```

APPENDIX D
Alternative Approach: Individual Change

Dependent Variable: Pain

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	
	B	Std. Error	Beta			
	2	(Constant)	9.464			.328
	Person_1	-1.491	.392	-.132	-3.805	.000
	Person_2	-1.824	.392	-.162	-4.655	.000
	Person_3	-1.657	.392	-.147	-4.230	.000
	Person_4	-1.324	.392	-.117	-3.379	.001
	Person_5	-.491	.392	-.043	-1.252	.213
	Person_6	-.157	.392	-.014	-.402	.689
	Person_7	-.991	.392	-.088	-2.528	.013
	Person_8	-.657	.392	-.058	-1.678	.096
	Person_9	-.824	.392	-.073	-2.103	.038
	Person_10	-.824	.392	-.073	-2.103	.038
	Person_11	-.157	.392	-.014	-.402	.689
	Person_12	-1.491	.392	-.132	-3.805	.000
	Person_14	-1.657	.392	-.147	-4.230	.000
	Person_15	-.991	.392	-.088	-2.528	.013
	Person_16	-1.324	.392	-.117	-3.379	.001
	Person_17	-1.324	.392	-.117	-3.379	.001
	Person_18	-1.578	.414	-.128	-3.812	.000
	Person_19	-1.157	.392	-.102	-2.954	.004
	Person_20	-.657	.392	-.058	-1.678	.096
	Person_21	-.824	.392	-.073	-2.103	.038
	Person_22	-1.491	.392	-.132	-3.805	.000
	Person_23	-.991	.392	-.088	-2.528	.013
	Person_24	-.657	.392	-.058	-1.678	.096
	Person_25	-1.157	.392	-.102	-2.954	.004
	Control_Time	-.408	.100	-.213	-4.090	.000
	TX_Time	-.740	.100	-.858	-7.436	.000
	TX	-1.096	.549	-.248	-1.998	.048