SMART Weight Loss: Analytics for February 2021 Submission

February 10, 2021

1 Simply using a training set and a validation set

1.1 How many individuals did we consider and what percentage had missing data?

Table 1: First Column: Total number of individuals in APP ONLY arm (excluding one individual with data issue); Remaining Columns: Percent with no weights

Total No. Individuals	Day 1	Day 4	Day 7	Day 1, 4, or 7
184	3.804	11.413	16.304	25.543

1.2 Can we identify APP ONLY arm non-responders during the first week of treatment? ('non-response' as defined in previous SMART study at weeks 2, 4, 8)

Table 2: CART Only

	Sensitivity	Specificity
Training	0.773	0.737
Validation	0.875	0.800

Table 3: Overall Decision Rule, Option 1: Non-responder if 'day 1, 4, or 7' is missing

	Sensitivity	Specificity
Training	0.844	0.575
Validation	0.917	0.696

Table 4: Overall Decision Rule, Option 2: Non-responder if 'day 1' is missing

	Sensitivity	Specificity
Training	0.578	0.767
Validation	0.625	0.783

Table 5: Overall Decision Rule, Option 3: Non-responder if 'day 4 or 7' is missing

	Sensitivity	Specificity
Training	0.828	0.589
Validation	0.917	0.696

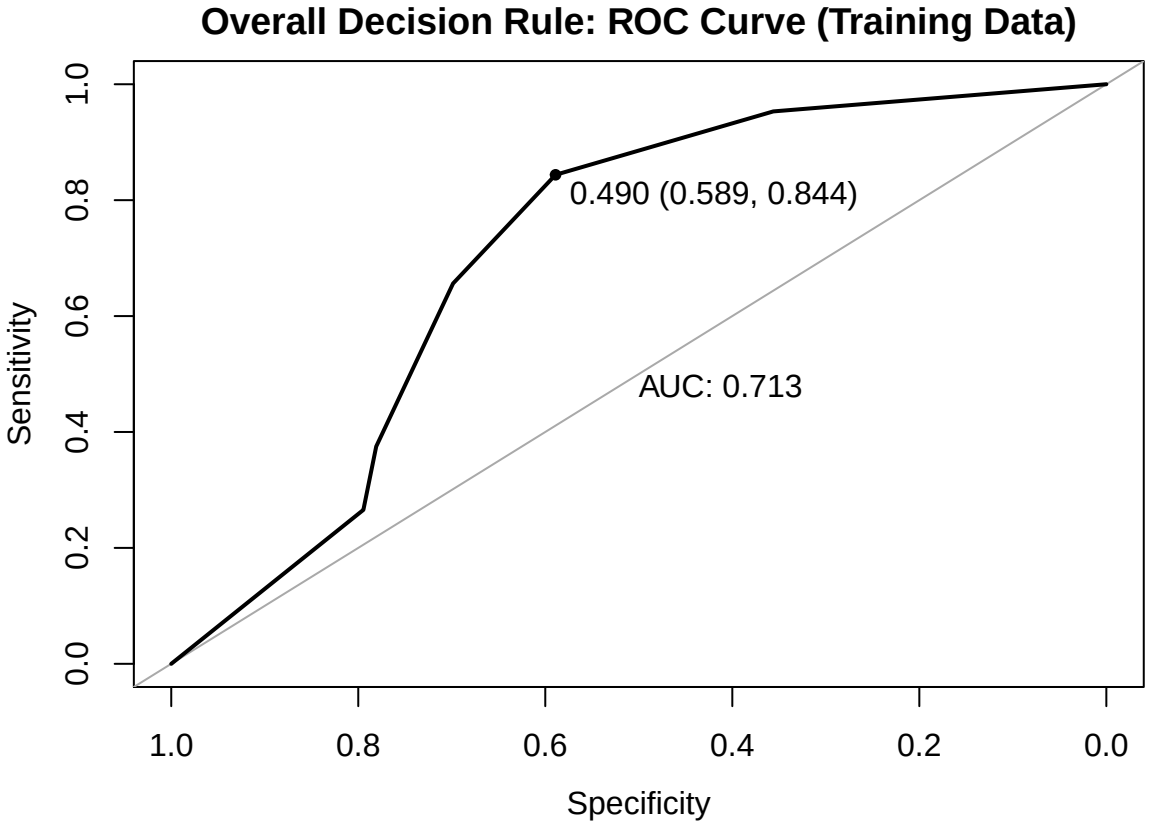
Table 6: Overall Decision Rule, Option 4: Non-responder if either 'day 1 and day 4' or 'day 7' is missing

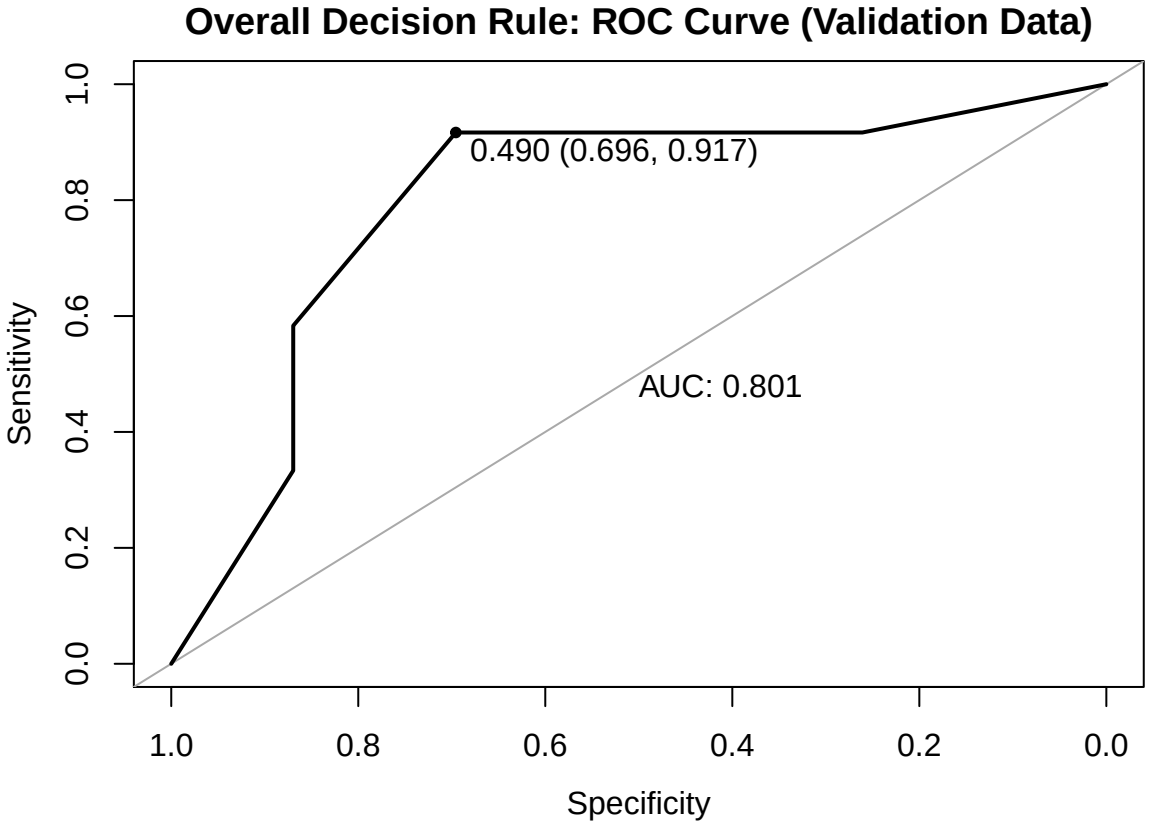
	Sensitivity	Specificity
Training	0.797	0.712
Validation	0.875	0.696

Table 7: Overall Decision Rule, Option 5: Non-responder if at least 2 days (any day) out of the first 7 days is missing

	Sensitivity	Specificity
Training	0.734	0.726
Validation	0.792	0.696

1.3 ROC Curve for Option 1





1.4 Among individuals in the APP ONLY arm, does non-response status based on overall decision rule (Option 1) predict weight loss success at Month X?

Table 8: Weight loss success at Month 3: Estimates of Parameters in a Logistic Regression Model (N=182 participants were used to estimate logistic regression model; 2 participants had missing weight at 3-mo)

	Estimate	Std. Error	z value	Pr(>|z|)
beta0	-0.288	0.242	-1.191	0.234
beta1	-1.065	0.336	-3.169	0.002

Table 9: Weight loss success at Month 6: Estimates of Parameters in a Logistic Regression Model (N=169 participants were used to estimate logistic regression model; 15 participants had missing weight at 6-mo)

	Estimate	Std. Error	z value	Pr(>|z|)
beta0	-0.305	0.249	-1.226	0.220
beta1	-1.057	0.349	-3.028	0.002

Odds ratio with respect to these two models is 0.345 and 0.348, respectively.

1.5 Among individuals in the APP ONLY arm, does non-response status based on overall decision rule (Option 5) predict weight loss success at Month X?

Table 10: Weight loss success at Month 3: Estimates of Parameters in a Logistic Regression Model (N=182 participants were used to estimate logistic regression model; 2 participants had missing weight at 3-mo)

	Estimate	Std. Error	z value	Pr(>|z|)
beta0	-0.424	0.214	-1.977	0.048
beta1	-1.047	0.344	-3.044	0.002

Table 11: Weight loss success at Month 6: Estimates of Parameters in a Logistic Regression Model (N=169 participants were used to estimate logistic regression model; 15 participants had missing weight at 6-mo)

	Estimate	Std. Error	z value	Pr(>|z|)
beta0	-0.329	0.219	-1.503	0.133
beta1	-1.355	0.373	-3.635	0.000

Odds ratio with respect to these two models is 0.351 and 0.258, respectively.

2 Use five-fold cross validation

Table 12: Total Number of paticipants in each fold

1st Fold	2nd Fold	3rd Fold	4th Fold	5th Fold
34	35	35	36	44

Table 13: 1st training set-validation set split: Overall Decision Rule, Option 1: Non-responder if 'day 1, 4, or 7' is missing

	Sensitivity	Specificity
Training	0.861	0.615
Validation	0.875	0.556

Table 14: 2nd training set-validation set split: Overall Decision Rule, Option 1: Non-responder if 'day 1, 4, or 7' is missing

	Sensitivity	Specificity
Training	0.853	0.642
Validation	0.900	0.400

Table 15: 3rd training set-validation set split: Overall Decision Rule, Option 1: Non-responder if 'day 1, 4, or 7' is missing

	Sensitivity	Specificity
Training	0.882	0.593
Validation	0.800	0.667

Table 16: 4th training set-validation set split: Overall Decision Rule, Option 1: Non-responder if 'day 1, 4, or 7' is missing

	Sensitivity	Specificity
Training	0.870	0.606
Validation	0.818	0.600

Table 17: 5th training set-validation set split: Overall Decision Rule, Option 1: Non-responder if 'day 1, 4, or 7' is missing

	Sensitivity	Specificity
Training	0.851	0.562
Validation	0.905	0.739

Table 18: Average across five splits: Overall Decision Rule, Option 1: Non-responder if 'day 1, 4, or 7' is missing

	Sensitivity	Specificity
Training	0.8634	0.6036
Validation	0.8596	0.5924

3 Is the overall decision rule (Option 1), more stringent than the rule for determining non-response utilized during the actual conduct of the SMART?

3.1 Using all 184 individuals: Among those who were not re-randomized at Week 2 (i.e., responders at Week 2), how many individuals were classified as non-responders by the overall decision rule (Option 1)?

Table 19: Cross-Tabulation of Truth Aginst Predicted Non-Response

	Predicted: Not Re-randomized	Predicted: Re-randomized
Truth (Week 2): Not Re-randomized	68	70
Truth (Week 2): Re-randomized	2	44

3.2 Using all 184 individuals: Among those who were not re-randomized at Week 2, 4, or 8 (i.e., responders at Week 2), how many individuals were classified as non-responders by the overall decision rule (Option 1)?

Table 20: Cross-Tabulation of Truth Aginst Predicted Non-Response

	Predicted: Not Re-randomized	Predicted: Re-randomized
Truth (Week 2, 4, or 8): Not Re-randomized	58	38
Truth (Week 2, 4, or 8): Re-randomized	12	76