

Data Analytic Summary

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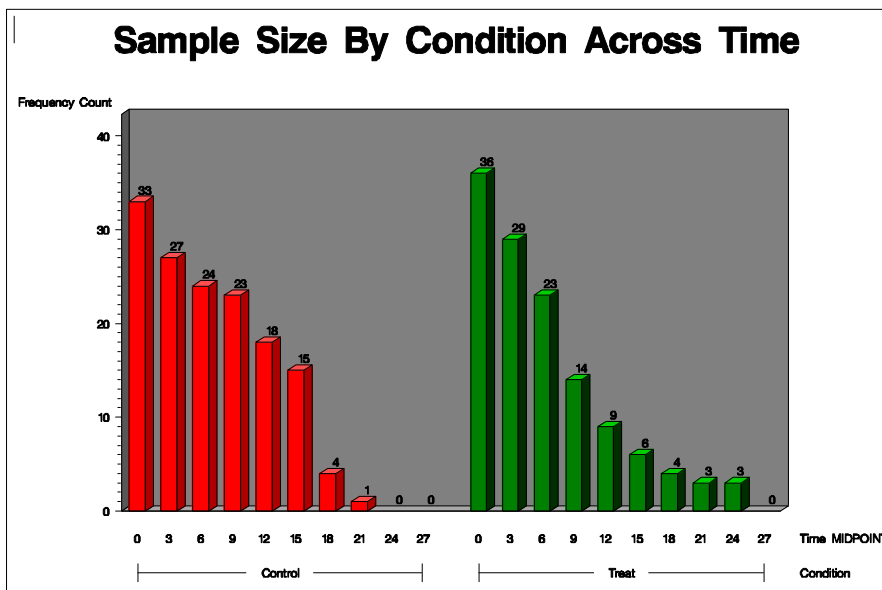
Relative to the standard care group, the intervention condition demonstrated decreases in psychiatric distress (*BSI-53*): there was evidence for differential change over time as a function of treatment. In terms of the amelioration of psychiatric distress these changes appear to be quite clinically meaningful. Similar changes were not observed in the *BDI-II*. In the *MULTNOMAH*, functioning appeared to suffer a decrement in the treatment group. Differences found in the *MULTNOMAH* total score could be due to systematic measurement error. These findings are robust in the sense that they are in evidence even with a relatively small sample size.

Four measures of outcome provided indices of the effectiveness of the intervention: 1) the SF-36, 2) the Brief Symptom Inventory-53 (*BSI-53*), 3) the Beck Depression Inventory-II (*BDI-II*), and 4) the *MULTNOMAH*. Introduction of the measures at different points during the intervention process reflects adjustments to the clinical needs of the sample, but also necessitates individual statistical models for each measure in order to maximize the sample sizes on which inferences are based: each outcome measure is addressed independently. Given the smaller cell sizes beyond the 6 month measurement point, initial analyses included the baseline, three month and six month measures in order to maximize the use of available client data. Subsequent analyses were conducted to include data up to the 12 month assessment time point.

SF-36

Inspection of missing data patterns revealed that missingness was a function of drop-out; there were no intermittent missing data points. The assumption that drop-outs occurred

completely at random was evaluated by conducting a logistic regression of missingness at one time point onto the SF-36 scores at the previous time point. Conducting this procedure for each of the two treatment groups produced no evidence for a predictive relation between drop-out and SF-36 scores at the preceding time point. This suggests that drop-out, when it occurred, was completely at random. Given the small cell sizes following the six month measurement point, analysis included only the baseline, three month and six month measures, however sample sizes at all time points are depicted in **Figure 1.** SF-36 Sample Size by condition across time.



While, doubly-multivariate MANOVA's conducted on the sub-scales of the SF-36 did not find differential change in distinct profiles over time (Wilks' Lambda = 0.609, $F(16,30) = 1.21, n.s.$), as a function of treatment, a main effect for treatment emerged ($F(1, 45) = 25.06, p \leq .0001$) as well as, a subscale by treatment interaction (Wilks' Lambda = 0.446, $F(8, 38) = 5.91, p \leq .0001$). Profiles of the SF-36 sub-scales are depicted in Figures 2, 3 and 4.

Figure 2.

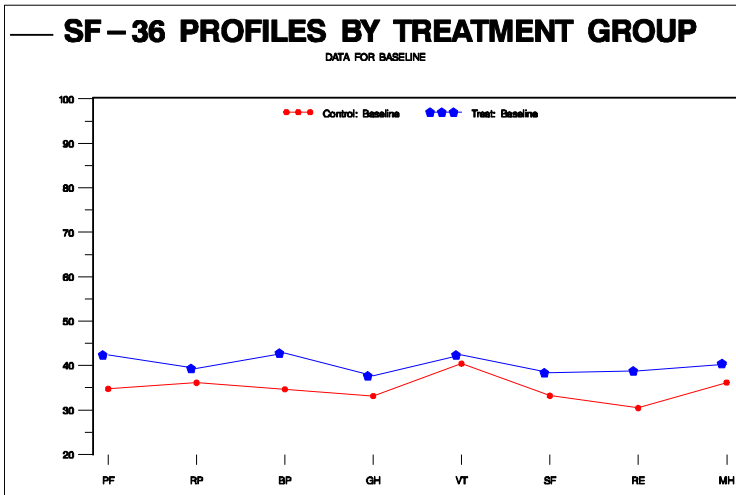


Figure 3.

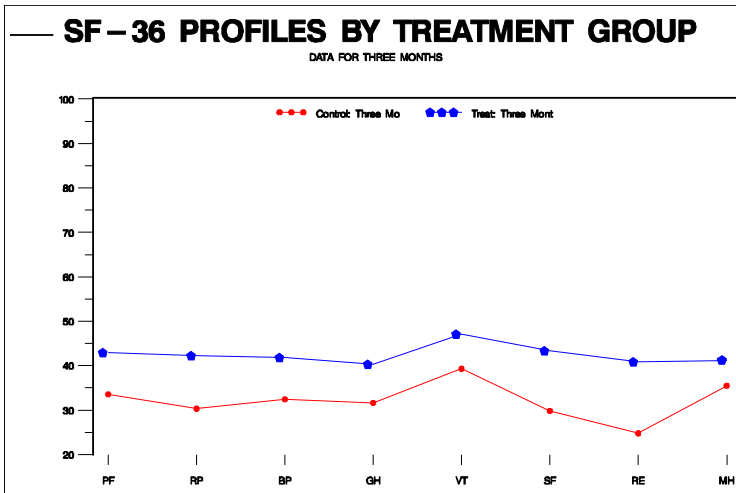
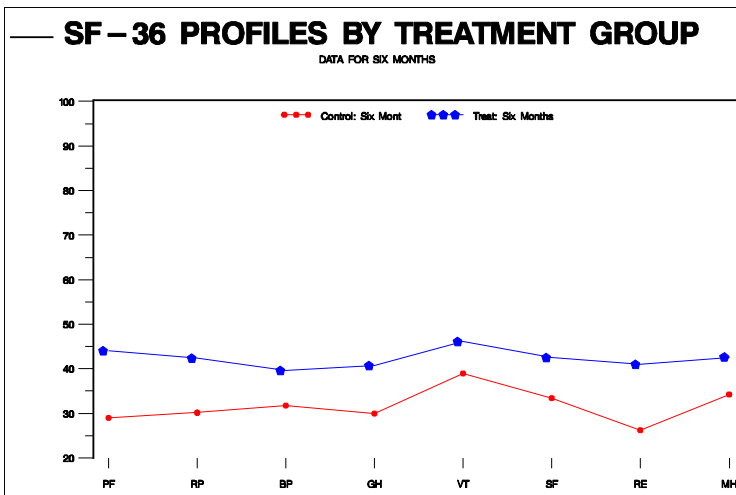


Figure 4.



The interpretation of the treatment by sub-scale interaction is that averaged across time the treatment and comparison groups demonstrated differential profiles on the SF-36 subscales. Disentangling the interaction, three cross-sectional profile analyses examined SF-36 subscales at each time point. Profile analysis of the baseline data found a main effect for treatment ($F(1,67) = 8.75, p \leq .0043$) and distinct profiles as a function of treatment (Wilks' Lambda = 0.793 $F(7,61) = 2.27, p \leq .0403$). Follow-up univariate analyses examined the effect of treatment on each sub-scale indicating that at baseline the treatment group reported better functioning on Physical Functioning, Bodily Pain, General Health and Role Emotional (Table 1).

Table 1. Main effect of treatment on the SF-36 subscales at baseline.

Subscale	F	Df	p-value
Physical Functioning	9.45	(1,67)	0.0031
Role-Physical	1.78	(1,67)	0.1870
Bodily Pain	11.83	(1,67)	0.0010
General Health	4.32	(1,67)	0.0416
Vitality	0.73	(1,67)	0.3945
Social Functioning	3.57	(1,67)	0.0630
Role Emotional	8.64	(1,67)	0.0045
Mental Health	2.37	(1,67)	0.1283

Profile analysis at three months revealed a main effect of treatment ($F(1,54) = 23.55, p \leq .0001$) and differential profiles on the subscales (Wilks' Lambda = 0.692, $F(7,48) = 3.05, p \leq .0097$). Examination of the univariate differences between treatment groups shows that the treatment group reports better functioning on all indices with marginal significance on Mental Health ($p \leq .0505$).

Table 2. Main effect of treatment on the SF-36 subscales at three months.

Subscale	F	df	p-value
Physical Functioning	10.71	(1,54)	0.0019
Role-Physical	24.79	(1,54)	0.0001
Bodily Pain	11.84	(1,54)	0.0011
General Health	11.38	(1,54)	0.0014
Vitality	9.20	(1,54)	0.0037
Social Functioning	26.50	(1,54)	0.0001
Role Emotional	25.41	(1,54)	0.0001
Mental Health	4.00	(1,54)	0.0505

Profile analysis at six months demonstrated a main effect of treatment ($F(1,45) = 21.78$, $p \leq .0001$) but there was no evidence for differential profiles on the subscales (Wilks' Lambda = 0.748, $F(7,39) = 1.88$, $p \leq .0992$). Examination of the univariate differences between treatment groups shows that the treatment group reports better functioning on all SF-36 indices.

Table 3. Main effect of treatment on the SF-36 subscales at six months.

Subscale	F	Df	p-value
Physical Functioning	29.78	(1,45)	0.0001
Role-Physical	23.99	(1,45)	0.0001
Bodily Pain	7.17	(1,45)	0.0103
General Health	15.68	(1,45)	0.0003
Vitality	6.14	(1,45)	0.0170
Social Functioning	9.34	(1,45)	0.0038
Role Emotional	22.34	(1,45)	0.0001
Mental Health	5.55	(1,45)	0.0229

Inspection of repeated measures MANOVA's for each treatment condition (Tables 4 & 5) indicate no temporal trends in the cases with data at all time points, with the exception of Social Functioning in the comparison group. The presence of only three time points precludes testing for anything beyond a linear trend.

Table 4. Time effect within the treatment group.

Subscale	Wilks' Lambda	F	df	p-value
Physical Functioning	0.821	2.29	(2,21)	0.1257
Role-Physical	0.898	1.19	(2,21)	0.3238
Bodily Pain	0.918	0.94	(2,21)	0.4072
General Health	0.780	1.84	(2,21)	0.2138
Vitality	0.966	2.37	(2,21)	0.6939
Social Functioning	0.926	0.84	(2,21)	0.4475
Role Emotional	0.971	0.31	(2,21)	0.7366
Mental Health	0.979	0.23	(2,21)	0.7984

Table 5. Time effect within the comparison group.

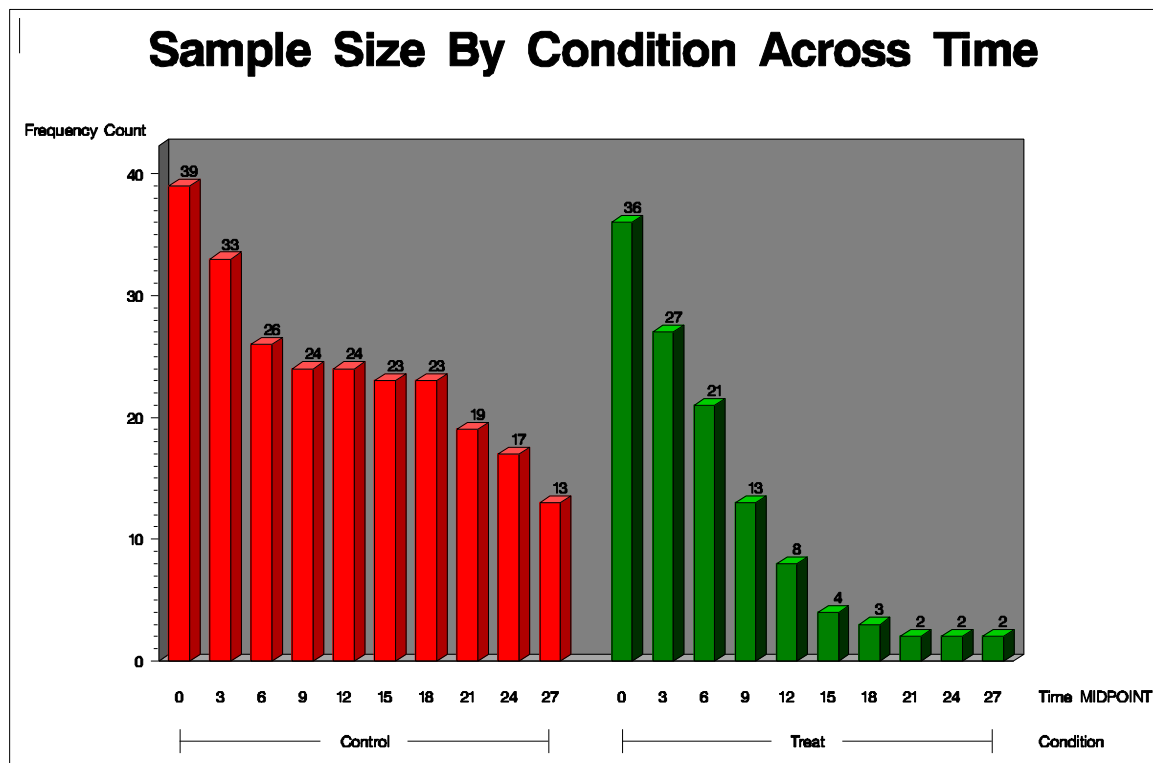
Subscale	Wilks' Lambda	F	df	p-value
Physical Functioning	0.925	0.90	(2,22)	0.4225
Role-Physical	0.778	3.14	(2,22)	0.0631
Bodily Pain	0.968	0.36	(2,22)	0.6987
General Health	0.975	0.29	(2,22)	0.7530
Vitality	0.997	0.04	(2,22)	0.9646
Social Functioning	0.667	5.49	(2,22)	0.0117
Role Emotional	0.825	2.34	(2,22)	0.1200
Mental Health	0.991	0.10	(2,22)	0.9083

In order to take advantage of the extended time frame available in the data, the same analyses were run including the nine month data. While this reduced the overall sample size, it provided an additional time point. Measurement times beyond this were not included because there were insufficient degrees of freedom to conduct the doubly-multivariate analysis. The addition of the nine month time point indicated that the findings were preserved on the whole. The more global main effect of treatment remained robust, even with diminished sample size.

BSI-53

Inspection of missing data patterns revealed that missingness was a function of drop-out; there were no intermittent missing data points. The assumption that drop-outs occurred completely at random was evaluated by conducting a logistic regression of missingness at one time point onto the BSI-53 scores at the previous time point. Conducting this procedure for each of the two treatment groups produced no evidence for a predictive relation between drop-out and BSI-53 scores at the preceding time point. This suggests that drop-out, when it occurred, was completely at random. Examination of the frequencies indicated that as substantial decline in cell size for the treatment group. Given the small cell sizes following the six month measurement point, analysis included only the baseline, three month and six month measures, however sample sizes at all time points are depicted in Figure 5.

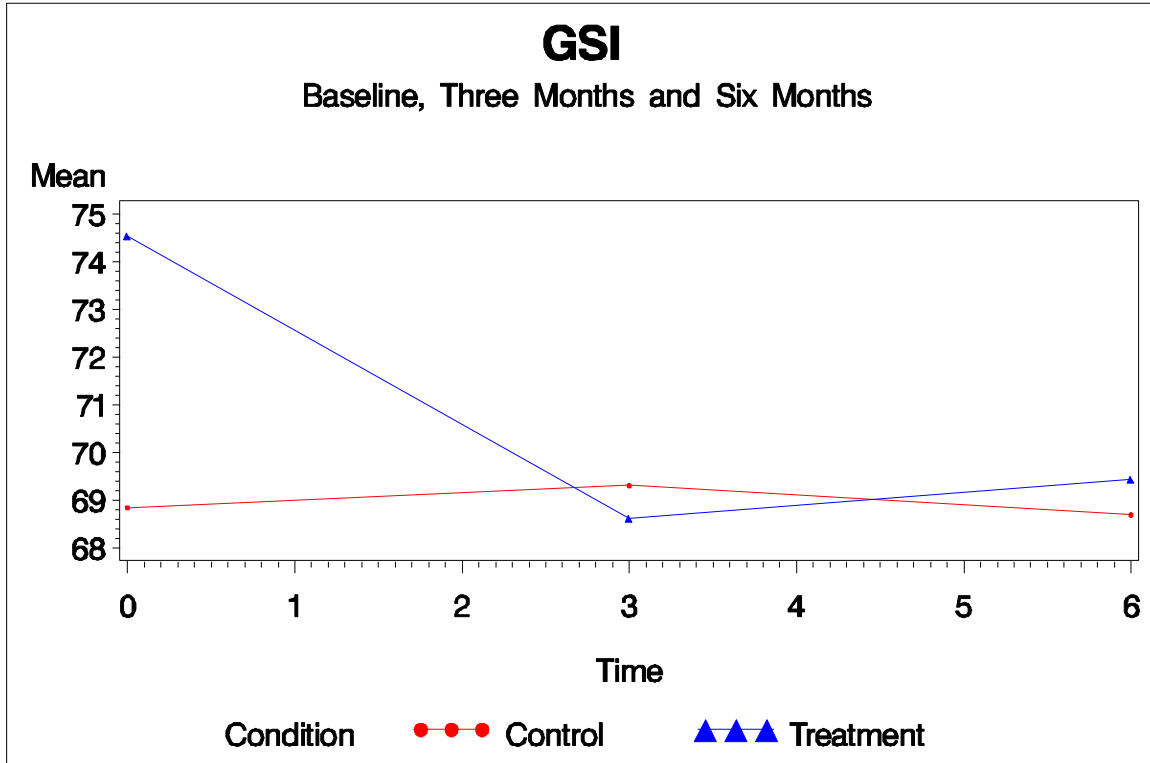
Figure 5. Sample sizes for the BSI-53.



A repeated measures MANOVA on the Global Severity Index (GSI), the summary index of the BSI-53, indicated an interaction between time and treatment condition (Wilks' Lambda = .762, $F(2,44) = 6.85, p \leq .0026$). The relation is graphically depicted in Figure 6.

Disentangling the interaction by examining simple effects indicated that while the GSI was higher for the treatment group at baseline ($F(1,46) = 6.09, p \leq .018$), no difference existed between the two groups at three ($F(1,46) = 0.07, n.s.$) or six months ($F(1,46) = 0.08, n.s.$). Further inspection of change across time for each group showed that distress as measured by the GSI decreased in the treatment group (Wilks' Lambda = .504, $F(2,19) = 9.34, p \leq .0015$), there was no change in the state of the comparison group (Wilks' Lambda = .992, $F(2, 24) = 0.10, n.s.$). Extending the analysis to include the first twelve months yield the same interaction between treatment condition and time, however, analysis of the simple effect of time did not yield reliable results for either treatment condition, likely due to insufficient sample size. However, given the interaction of treatment and time for the GSI, further examination of the sub-scales of the BSI-53 was warranted.

Figure 6. GSI Scores.



A doubly-multivariate MANOVA modeled the change in BSI-53 sub-scale profiles across time for each treatment group. There was no evidence for a three-way interaction between treatment, BSI-53 profile and time (Wilks' Lambda = .399, $F(22,24) = 1.64, p \leq .1188$). Profiles at the two time points are depicted in Figures 7, 8 and 9.

Figure 7. BSI-53 Profiles at Baseline.

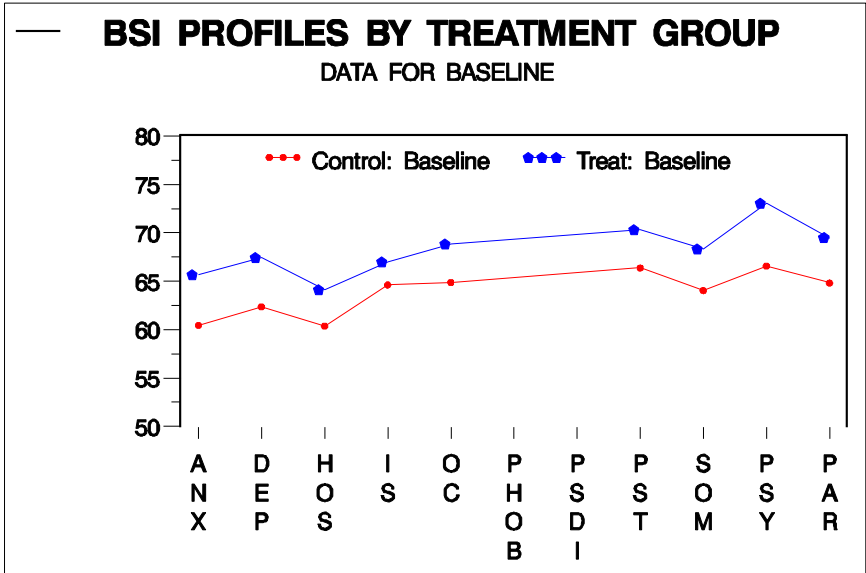


Figure 8. BSI-53 Profiles at Three Months.

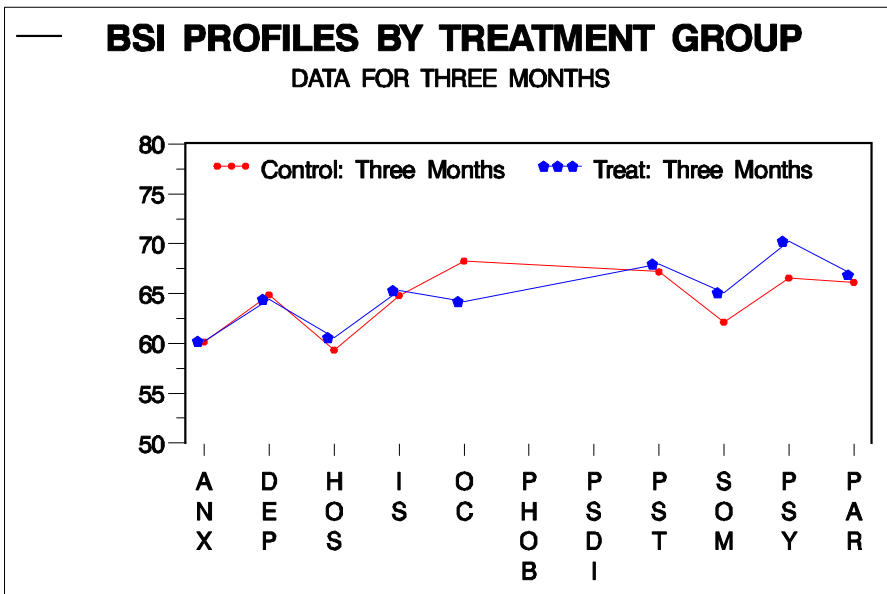
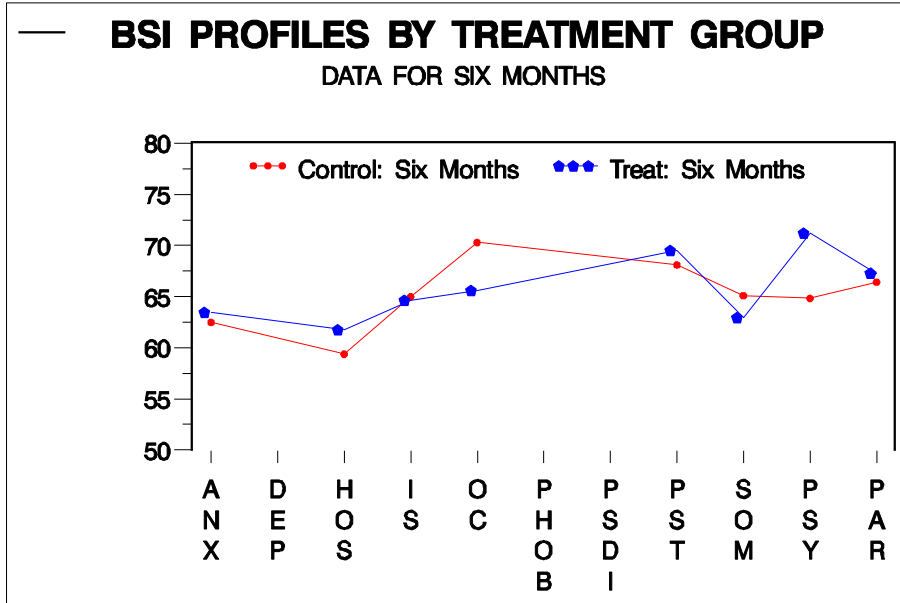


Figure 9. BSI-53 Profiles at Six Months.

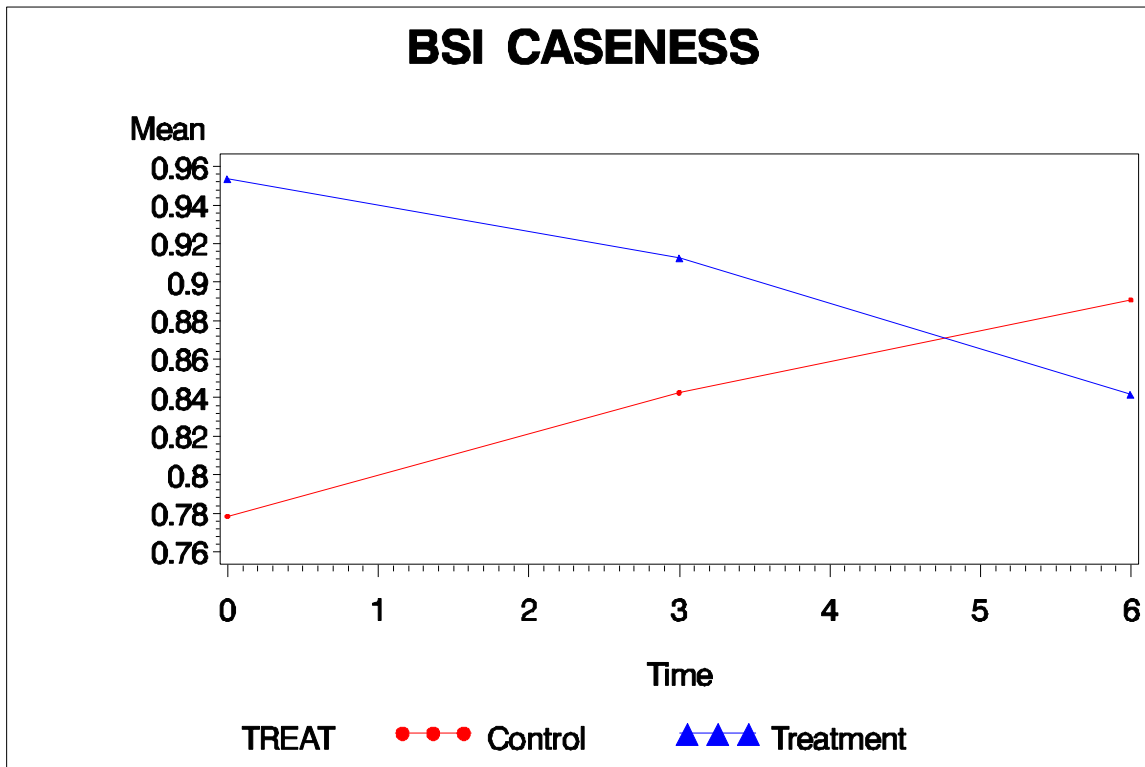


This failed to provide evidence that the profiles were changing differentially across time as function of treatment group. There was no evidence for a main effect of condition ($F(1,45) = 0.61, n.s.$) or for differential profiles for condition averaged across time (Wilks' Lambda = .606, $F(11,35) = 2.07, n.s.$). There was some evidence that in averaging across conditions these scales changed differentially over time (Wilks' Lambda = .322, $F(22,24) = 2.30, p \leq .025$), but this did not differ as function of group. Extension of the analysis to the twelve month measurement point yielded similar results.

Further analyses investigated the clinical meaningfulness of the changes in psychiatric distress over time, as a function of treatment. Each individual was characterized in terms of their "caseness" on the BSI-53. Caseness is defined as the elevation of any two sub-scales over a t-score of sixty-three or the elevation of the GSI over a t-score of sixty-three. Individuals positive for caseness may be regarded as demonstrating severe psychiatric distress. Repeated logistic regression utilizing a generalized estimating equation approach yielded an interaction between treatment and

time in the prediction of caseness (Wald $\chi^2(1) = 5.57, p \leq .0182$) (Figure 10). Further, there was evidence for a reliable main effect of treatment (Wald $\chi^2(1) = 5.17, p \leq .0229$), but not for time (Wald $\chi^2(1) = 0.30, p \leq .5833$).

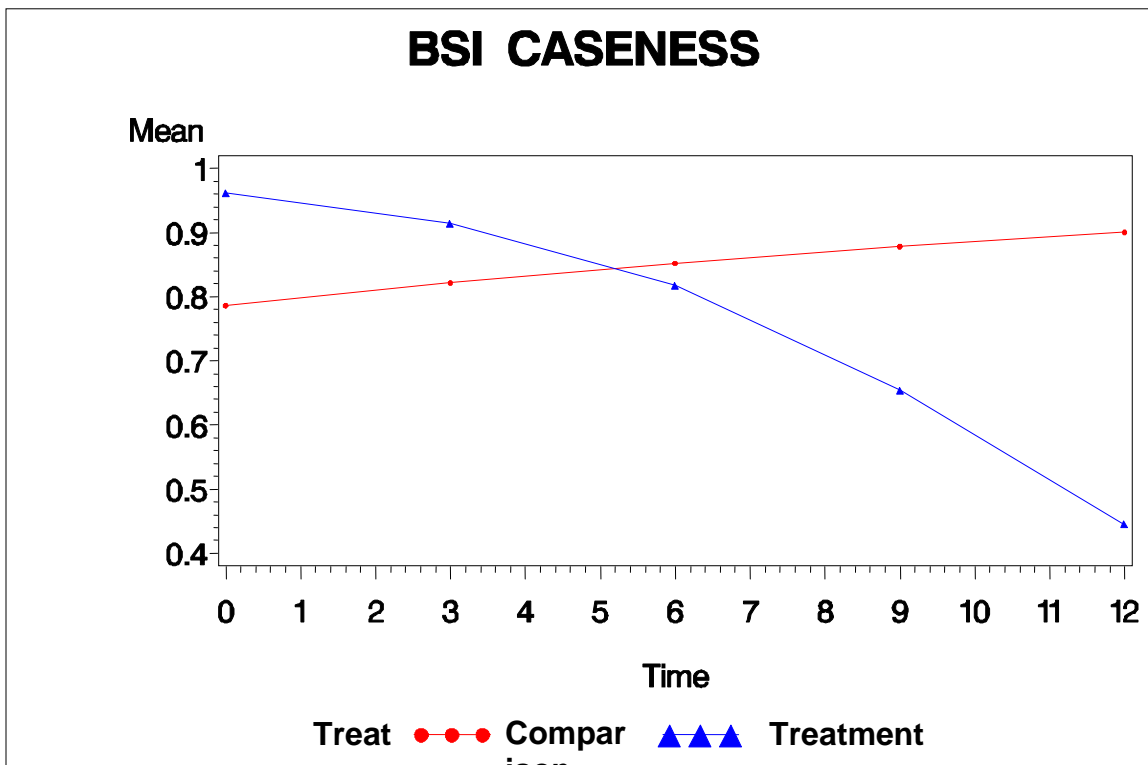
Figure 10. Probability of caseness over six months as a function of treatment.



Cross-sectional logistic regression indicated that at baseline the treatment group was associated with higher odds of being a case (O.R. 10.498, 95% C.I. 1.257-87.686). At three months there was no difference, between the two treatments, in the odds of being a case (O.R. 0.793, 95% C.I. 0.179-3.519). Finally, at six months there continued to be no evidence for a difference between the two groups (O.R. 1.239, 95% C.I. 0.187-8.198). Examination of change for each treatment across time demonstrated that between baseline and three months the odds of being a case decreased for the treatment group by a factor of 0.17 (95% C.I. 0.0282-0.9564), while between months three and six there was no evidence of change (O.R. 0.61, 95% C.I. 0.093-3.917). A similar temporal trend did

not occur in the comparison group for the time period from baseline to three months (O.R. 2.18, 95% C.I. 0.7003-6.7547) or during the three to six month time period (O.R. 0.95, 95% C.I. 0.3194-2.7999). This indicates that relative to the comparison group caseness decreased for participants in the treatment group during the first three months of the intervention. The conclusions remained substantively the same when the measurement times were extended to twelve months (Figure 11).

Figure 11. Probability BSI-53 defined “caseness” over twelve months as a function of treatment.

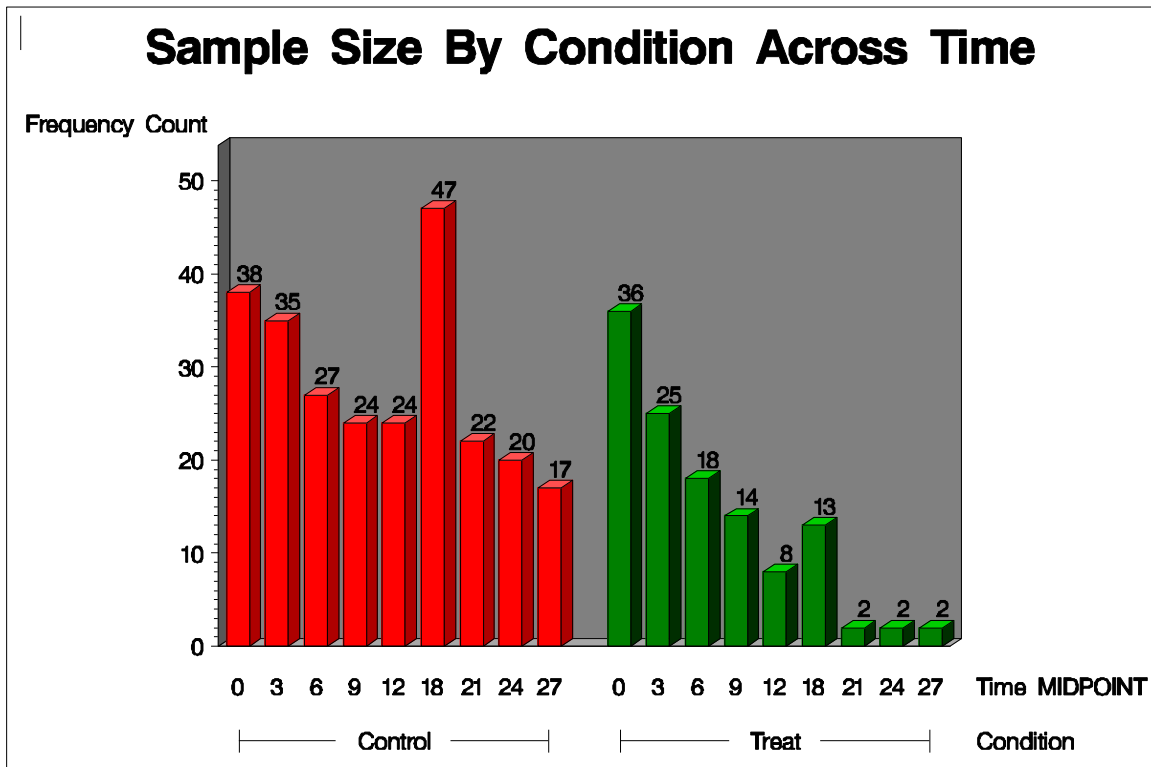


BDI

Inspection of missing data patterns indicates that all missingness was a function of drop-out. Conducting a series of logistic regressions, within each treatment condition, in which drop-out at each time point is predicted from the BDI scores at the preceding time point suggests that drop-out was completely at random. Sample sizes for data at each

assessment point is charted in Figure 12. Taking into consideration the available cell sizes at each time point, the initial analyses were conducted for baseline through six months.

Figure 12. Sample sizes for the BDI.



Repeated measures MANOVA revealed no reliable between group ($F(1,43) = 3.89, n.s.$) or time by treatment group interaction (Wilks' Lambda = .924, $F(2, 42) = 1.71, n.s.$).

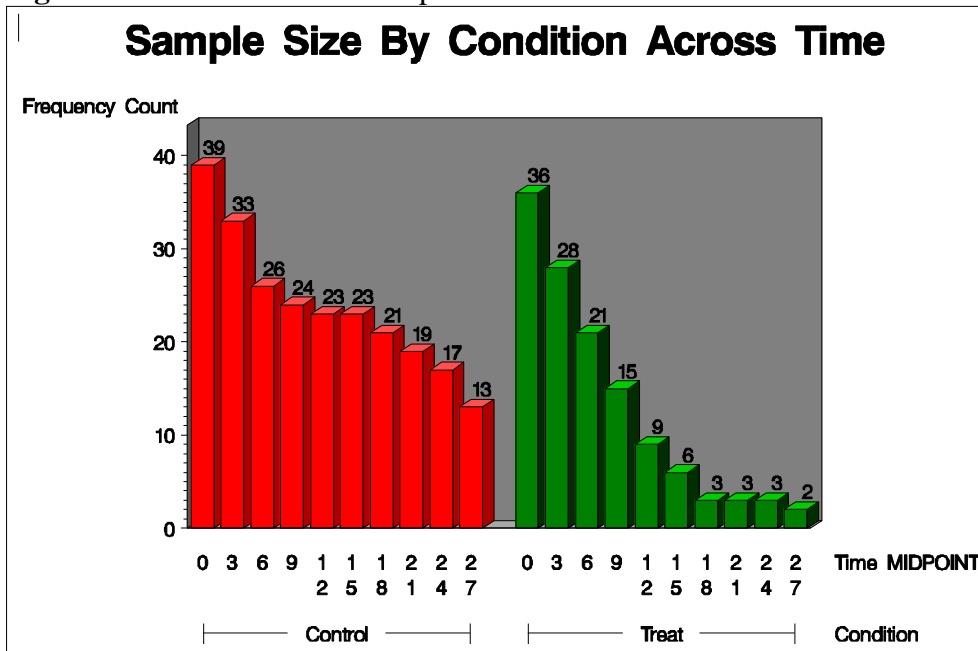
MULTNOMAH

Inspection of missing data patterns indicates that missingness is a function of drop-out.

Using logistic regression it was determined data is missing completely at random (Wald $\chi^2(1) = 3.95, p \leq .0469$). As such the results suggest that the data is missing completely at random. Sample size as a function of treatment condition and time is presented in Figure

13.

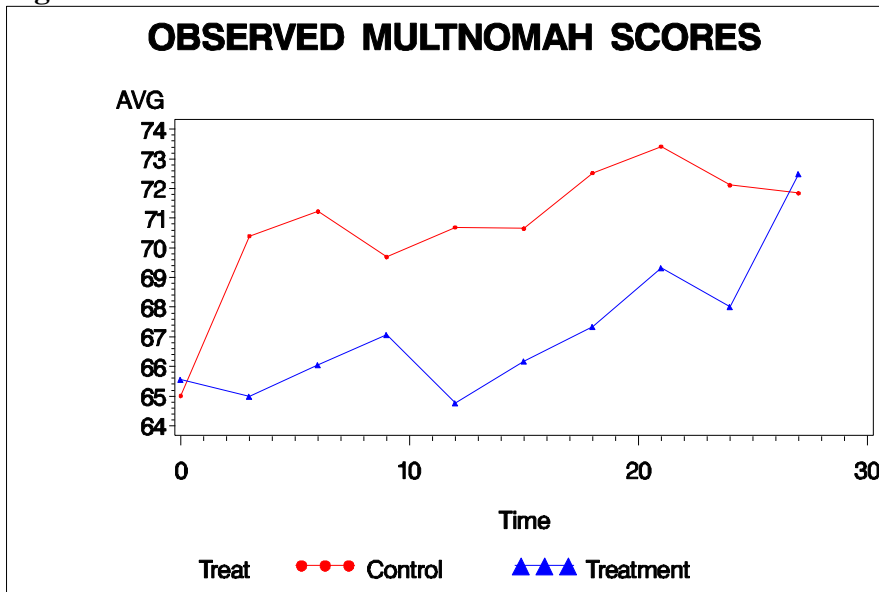
Figure 13. *MULTNOMAH* sample size as a function of treatment condition and time.



Given the respective cell sizes for each treatment condition across time, the first six months were selected for analysis.

The observed means at all six time points are depicted in Figure 14. Repeated measures MANOVA on the total scores for the first three measurement points demonstrates an interaction between treatment condition and time (Wilks' Lambda = 0.83, $F(2, 44) = 4.53$, $p \leq .0162$). Post-hoc inspection of univariate differences at each time point revealed that the comparison condition demonstrated higher total *MULTNOMAH* scores at six months. Examination of simple effects indicates that while there is no evidence for change over time in the treatment condition (Wilks' Lambda = 0.92, $F(2, 19) = 0.87$, $p \leq .4350$), there is a reliable time effect for the comparison condition (Wilks' Lambda = 0.73, $F(2, 24) = 4.48$, $p \leq .0222$) groups experienced change over time.

Figure 14. *MULTNOMAH* total score across time.

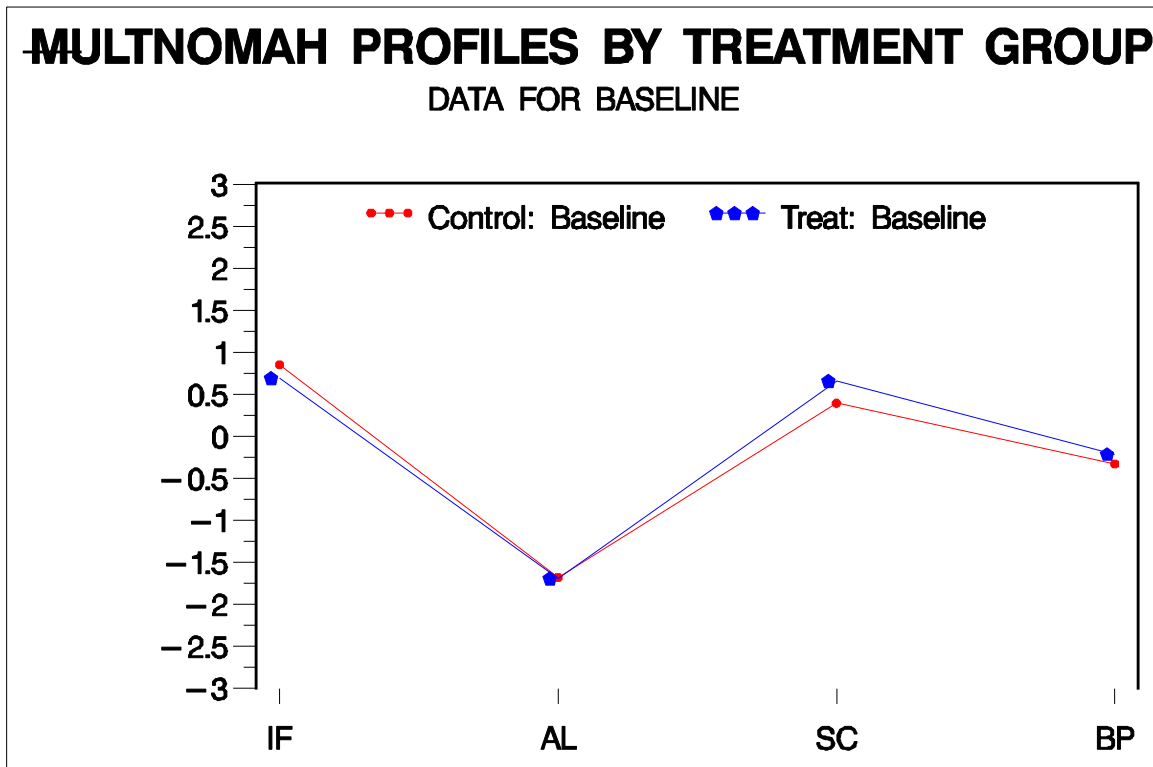


A series of contrasts for the comparison group indicated that baseline differs from both three ($F(1, 32) = 11.01, p \leq .0023$) and six months ($F(1, 32) = 7.97, p \leq .0092$), but that three and six months do not differ from each other ($F(1, 25) = 0.75, p \leq .3959$). This indicates that the comparison group, alone, showed change over time, with an increase during the first three months of the intervention. Extension of the analyses to twelve months results in a failure to find the interaction that was present at six months. This may be a function of the available power.

Doubly multivariate analyses of the *MUTNOMAH* sub-scales dissected the temporal trends in the total scores. These sub-scales include: Interference with Function (IF), Adjustment to Living (AL), Social Competence (SC), and Behavioral Problems (BP). While there was no evidence of distinct profiles changing differentially over time as a function of treatment (Wilks' Lambda = 0.69, $F(8,38) = 2.13, n.s.$), reliable sub-scale by treatment interaction emerged (Wilks' Lambda = 0.71, $F(4,42) = 4.10, p \leq .0068$) indicating that averaged across time the two treatment condition demonstrated differential

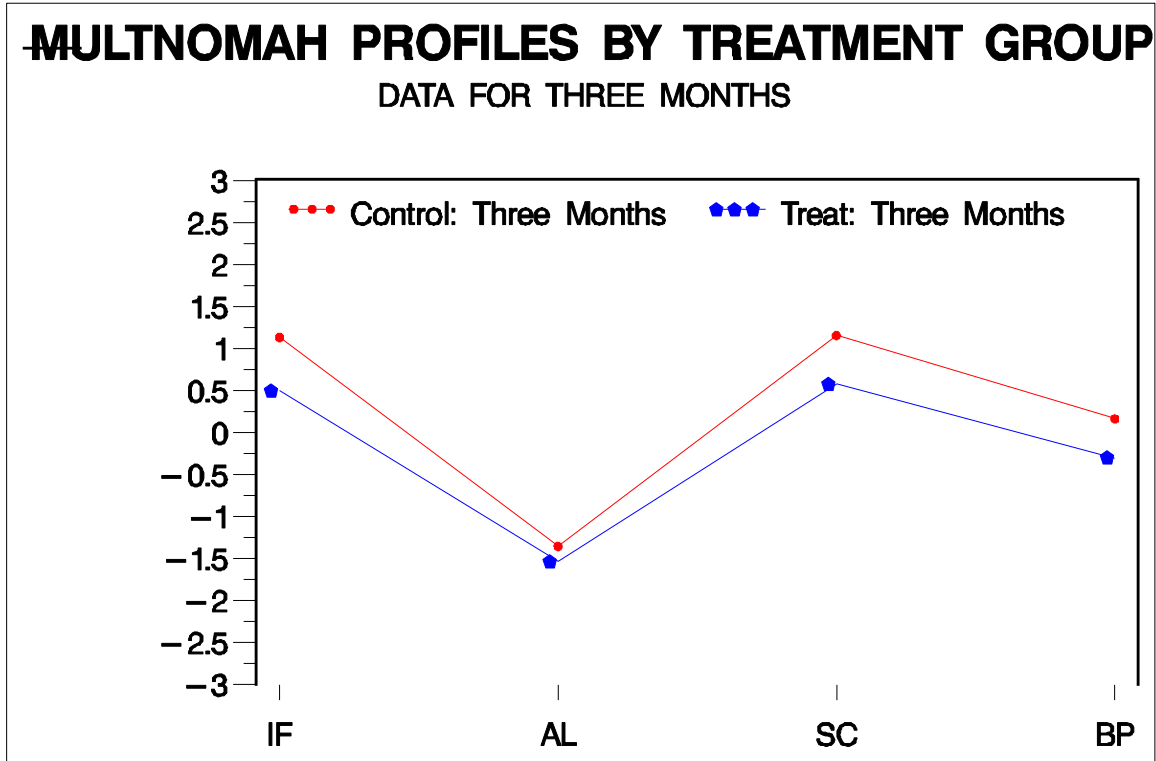
profiles. No differential profiles (Wilks' Lambda = 0.96, $F(3,71) = 0.92$, *n.s.*) or group differences ($F(1,73) = 0.06$, *n.s.*) existed at baseline. Baseline profiles are depicted in Figure 15. Extension of the analysis to twelve months yield the same substantive results.

Figure 15.



While there was no evidence for differential profiles at three months (Wilks' Lambda = 0.91, $F(3, 57) = 1.78$, *n.s.*), A reliable main effect for condition emerged ($F(1, 59) = 9.67$, $p \leq .0029$). Post-hoc univariate analyses revealed a reliable difference on the IF ($F(1, 59) = 8.80$, $p \leq .0043$), SC ($F(1, 59) = 9.31$, $p \leq .0034$) and BP ($F(1, 59) = 4.49$, $p \leq .0382$) subscales on all of which the comparison group exceeded the treatment group. Profiles at three months or presented in Figure 16.

Figure 16.

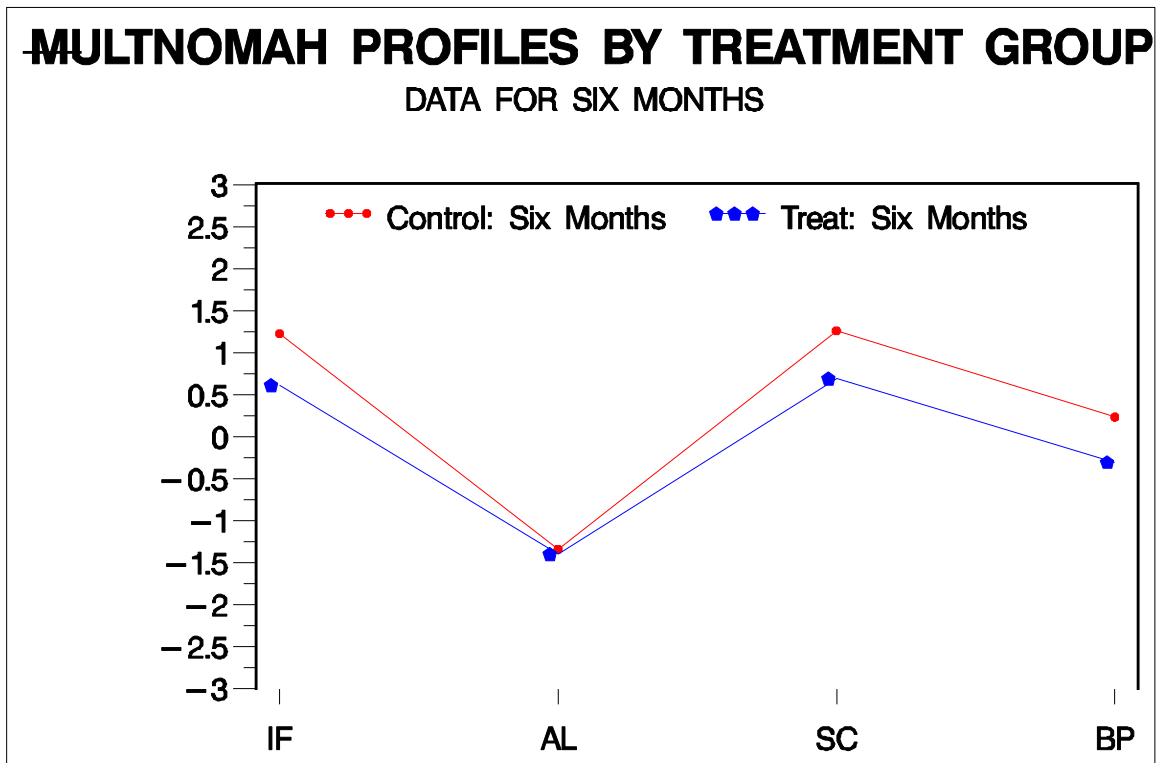


Examination of the cross sectional profiles for month six measures did not suggest differential profiles (Wilks' Lambda = 0.85, $F(3,43) = 2.55$, *n.s.*), but did provide evidence for an effect due to treatment ($F(1, 45) = 5.40$, $p \leq .0247$). Post-hoc comparisons were conducted between groups on each of the measures. Reliable differences emerged for the IF ($F(1, 45) = 6.00$, $p \leq .0182$), SC ($F(1, 45) = 4.35$, $p \leq .0426$) and BP ($F(1, 45) = 5.42$, $p \leq .0245$) sub-scales, for all of which the comparison group exceeded the treatment group. Six month profiles are displayed in Figure 17.

Inspection of the simple effects for each condition revealed a reliable effect of time for IF in the treatment group (Wilks' Lambda = 0.64, $F(2, 19) = 5.38$, $p \leq .0141$). Inspection of Helmert contrasts indicated that three and six months showed a decrease from baseline, while the three and six month time points do not differ from each other.

Examination of the simple effects for AL did not reveal a reliable effect of time for the treatment group (Wilks' Lambda = 0.91, $F(2, 19) = 0.90$, *n.s.*). Evaluation of the simple effects for SC revealed a reliable effect of time for the treatment group (Wilks' Lambda = 0.70, $F(2, 19) = 4.04$, $p \leq .0345$). Inspection of Helmert contrasts indicated that measures of SC at three and six months declined from baseline, while three and six month time points do not differ from each other. Finally, inspection of the temporal trend for the treatment group on the BP scale did not reveal a reliable effect. Similar inspection of the simple effects for the comparison condition demonstrated no such decrements across time.

Figure 17.



In extending the doubly multivariate findings to the twelve month time point, the main effect of treatment remains. Profile analysis does not exhibit any reliable effects. Profile

analysis at twelve months yielded a reliable main effect for treatment, with the treatment condition showing lower levels of function on Behavioral Problems.