Motivational Interviewing Improves Weight Loss in Women with Type 2 Diabetes

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Running Title: Motivational Interviewing and Obesity Treatment

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Abstract

Objective: To determine whether adding motivational interviewing (MI) to a behavioral weight control program improves weight loss outcomes and glycemic control for overweight women with type 2 diabetes.

Research Design and Methods: A randomized, controlled clinical trial in which participants all received an 18-month, group-based behavioral obesity treatment and were randomized to individual sessions of motivational interviewing (MI) or attention control (total of 5 sessions) as an adjunct to the weight control program. Overweight women with type 2 diabetes treated by oral medications who could walk for exercise were eligible. Primary outcomes were weight and HbA1c assessed at 0, 6, 12 and 18 months.

Results: 217 overweight women (38% African American) were randomized (93% retention). Women in MI lost significantly more weight at 6-months (p=0.01) and 18-months (p=0.04). Increased weight losses with MI were mediated by enhanced adherence to the behavioral weight control program. African-American women lost less weight than white women overall and appeared to have a diminished benefit from the addition of MI. Significantly greater HbA1c reductions were observed in MI at 6-months (p=0.02) but not at 18-months.

Conclusions: MI can be a beneficial adjunct to behavioral obesity treatment for women with type 2 diabetes, although the benefits may not be sustained among African-American women.
Individuals with type 2 diabetes frequently are overweight (1-3) and experience a range of obesity-related co-morbidities (4). With every unit increase in body mass index (BMI), direct medical costs associated with type 2 diabetes increase significantly (5). Weight loss has been shown to improve metabolic control and other health parameters among individuals with type 2 diabetes (6, 7), with greater weight losses producing greater improvements in metabolic functioning (8). However, sustained weight loss can be challenging (9), particularly for individuals with diabetes (10). African-American women experience particular difficulties in achieving weight loss (11, 12), concern given high rates of obesity (13) and diabetes (14) in this group. Therefore, improving obesity treatment outcomes for overweight individuals with co-morbid diabetes has been identified as a research priority (15).

Motivational interviewing (MI) (16) is a brief intervention approach demonstrated to promote better long-term outcomes for a range of health outcomes (17, 18), with preliminary support as an adjunct to behavioral obesity treatment. MI produced significantly better glycemic control and treatment adherence, as well as a trend towards greater short-term weight loss, in a pilot study of overweight diabetic women (19). Furthermore, MI interventions have been shown effective in promoting changes in diet and physical activity (20-22). Despite this promising foundation, there have been no controlled evaluations of the long-term efficacy of MI for obesity treatment. The purpose of the current study was to determine whether the addition of MI to a behavioral obesity treatment program for overweight women with type 2 diabetes enhances long-term weight loss and metabolic control.

Research Design and Methods

Participants

Volunteers were recruited from the Birmingham, AL area between 2000 and 2002, using social marketing channels, direct mail solicitation and physician referrals. Individuals were phone screened and then invited to a group orientation where the study was described and informed consent obtained. Baseline data were collected on subsequent visits.

Women were eligible if they had type 2 diabetes treated by oral diabetes medications but not insulin, were overweight (BMI of 27-50) but generally healthy otherwise and could walk for exercise. Women with uncontrolled diabetes (HbA1c > 12%) or hypertension (diastolic blood pressure > 90 or systolic blood pressure > 140) were referred to their physician for treatment and invited to re-screen. Exclusion criteria included pregnancy, recent significant weight loss (>10 lbs), or a severe debilitating disease that might interfere with study participation. Volunteers obtained physician’s consent for participation and successfully completed a 7-day diary monitoring dietary intake prior to randomization. A total of 561 women were screened and 217 (38% African-American) women were randomized using a sequentially-numbered, closed-envelope procedure.

All research procedures were approved by the University of Alabama at Birmingham Institutional Review Board for Human Use and the University of Arkansas for Medical Sciences Institutional Review Board.

Study Design Overview

Participants were randomized to receive individual sessions of either MI or an attention placebo control as an adjunct to a group-based behavioral weight control program. Participants were classified as white or African American based on self-identification and randomization was done within race to assure balanced representation across the experimental conditions. All participants received the same group-based weight control program delivered by
interventionists masked to experimental assignment. Baseline data were obtained across two clinic visits and 6-, 12- and 18-month follow-up data at a single clinic visit. Retention was encouraged by small incentives but participants were not compensated.

Group-based Behavioral Weight Control Program

All participants, regardless of experimental condition, received a 42-session weight management program, which met weekly for 6 months, biweekly for 6 months and monthly 6 months. Weight loss induction was emphasized in the first 6 months and weight maintenance in the subsequent 12 months. Group size averaged 14 and sessions were delivered by a multidisciplinary team (behaviorist, nutritionist, exercise physiologist and diabetes educator) blinded to experimental condition. Because the experimental treatment was delivered in adjunct individual sessions that were distinct from the group, it was possible to include participants from both experimental conditions within a given weight control group, increasing confidence that the group program was delivered comparably across the experimental conditions.

The behavioral group program focused on attainable and sustainable changes in dietary and physical activity habits, with a strong emphasis on goal setting and problem solving to achieve successful behavior change. Caloric restriction was prescribed (1200 – 1500 kcal/day) with a fat intake goal of 33 – 42 grams/day. Gradual increases in physical activity were promoted with an ultimate goal of at least 150 minutes/week.

Self-monitoring diaries were a cornerstone of the program and focused on recording dietary intake (including calorie and fat gram intake) and physical activity (minutes and type of exercise). Diaries were reviewed weekly and returned with feedback. Goal setting and problem solving were introduced early on and figured prominently in weekly sessions. Other behavioral topics included stimulus control, developing social support, cognitive restructuring and relapse prevention. Information about diabetes, obesity and weight loss, as well as recommendations specific to individuals with diabetes (e.g., identifying and treating hypoglycemia, proper foot care while exercising, etc) were also addressed.

Experimental Conditions

Motivational Interviewing (MI). MI is a client-centered approach to promoting behavior change by exploring ambivalence in a non-judgmental, supportive yet directive fashion (16, 23). Meta analyses establish the efficacy of MI as a brief intervention to facilitate health behavior changes across a range of domains (20, 21). Key elements of MI are the client-centered nature of eliciting change talk (the individual’s own reasons and arguments for change) and exploring ambivalence about behavior change while trying to develop discrepancies between the individual’s current behavior and core values or personal goals. Reflective listening is a critical component of MI, allowing clarification of goals and concerns and eliciting reasons for change in the individual’s own words. Objective feedback presented in a neutral fashion is used to anchor discussions about personal goals and develop discrepancy between current behavior and personal aspirations. Central to the spirit of MI are methods such as the strategic use of reflective listening to acknowledge both sides of ambivalence surrounding behavior change, using open-ended questions to amplify client-generated reasons for change and resolve ambivalence, emphasizing personal choice for action, affirming self-confidence in ability to change, and supporting perceived importance of behavior change. When resistance and defensiveness emerged, counselors used reflection to sidestep these responses because there is evidence that these reactions undermine progress toward behavior change (24). MI sessions explored personally-relevant factors motivating a participant to lose weight and how weight loss fit into future goals. Sessions did not introduce new
information about weight loss methods. When issues related to behavioral weight control strategies came up or participants made were requests for weight control content information (e.g., calories, exercise, etc), the MI counselor directed these questions back to the participant’s group for discussion. The focus of the MI session was on eliciting change talk and commitment language (24), engaging in discussions of what motivated change, the shifting landscape of ambivalence about changing eating and exercise habits, and how behavior changes might be congruent with the individual’s visions for the future and her personal values.

Ongoing clinical supervision of MI skills and intervention protocol fidelity monitoring were combined in weekly supervision sessions. Randomly-selected audiotapes were reviewed weekly by two clinical psychologists using a standardized coding format modeled on other studies of MI proficiency (25) that assessed overall “MI spirit”, the presence of specific behaviors that characterize MI, the absence of specific behaviors antithetical to MI, and the proportion of time the counselor spent talking (25).

Five individual MI sessions were offered, with the first session prior to starting group and then at 3, 6, 9 and 12-months. Sessions lasted approximately 45 min and were delivered by licensed clinical psychologists who had received structured training in MI. Each session followed a semi-structured interview format of MI adapted for weight management (26).

Attention Control Group. Individual health education sessions served as an attention placebo control, with session number and length matched to MI to control for any impact that individual attention from a health care professional might produce. Masters-level health educators delivered sessions, which focused on women’s health topics (e.g., breast self care, skin care, dental health, food safety, sleep habits, etc). Women were encouraged to pick topics of greatest personal interest from a menu to replicate the client-centered agenda setting of MI.

Measures

All assessments were conducted by trained interviewers blind to experimental condition. Measures were collected at baseline, 6, 12 and 18 months unless otherwise specified. Body weight was measured without shoes using a calibrated balance beam scale. Height was measured without shoes using a wall-mounted stadiometer. BMI was calculated as weight [kg] / height [m]². Glycemic control was indexed by glycosolated hemoglobin A₁C (HbA₁C) measured with a Bayer DCA 2000 Analyzer.® Demographic information was obtained by self report at baseline only.

Intervention process measures were also collected to determine engagement in the group weight loss program. Number of group sessions attended, number of self-monitoring diaries submitted and average group leader rating of self-monitoring diary quality (on a 3-point scale) were assessed.

Data Analysis

Baseline comparisons between experimental conditions and for study drop outs compared with completers were performed using two sample t-test and chi-square test for continuous and categorical measures respectively. Primary outcomes were weight, BMI and HbA₁C. Analyses of weight and BMI yielded comparable results; therefore only weight results are presented. Main effect of treatment on primary outcomes was analyzed using 2-factor analysis of variance (ANOVA) with repeated measures on visit. Main effect of race then was added, extending the analysis to 3-factor ANOVA with repeated measures on visit. Interactions were examined and when significant, the model was simplified by stratifying within treatment conditions. Changes in primary outcomes were further modeled using analysis of covariance (ANCOVA) with adjustments for baseline weight or HbA₁C as appropriate. To account for the relationship between glycemic control and weight loss, weight
change was added as covariate to the models where HbA1c change was the outcome. Multiple comparisons in ANOVA and ANCOVA were performed with Tukey-Kramer adjustments. For variables with unequal variances between conditions, Satterthwaite adjusted p-values are presented. All treatment outcome variables were also examined using random effects mixed models, which consider all available data. The pattern of results was similar to the ANCOVAs and therefore these are not reported here. Pearson correlation coefficients were used to assess the direction and magnitude of associations between weight loss and glycemic control, as well as between adherence measures and weight and metabolic control. Two sample t-tests were used to examine adherence between treatment conditions. Multivariable regression models were used to test the meditational effect of behavioral adherence measures on weight change at 6 and 18 months. Treatment and baseline weight were forced in the models while adherence covariates were reduced to the most parsimonious subset using purposeful selection approach.

All analyses were conducted using SAS Version 9 (SAS Institute Inc., Cary, NC). Alpha level of 0.05 was established as a level of significance for all tests.

Results

Participant Characteristics

Two hundred and seventeen women (38% African American) were randomized. The majority were obese (BMI ≥ 30), had good metabolic control (HbA1c ≤ 7%), were middle-aged and well-educated (Table 1). Experimental conditions did not differ significantly at baseline in sociodemographic characteristics or health parameters. Attrition in the sample was modest (93% retention at 18 months) and study dropouts did not differ on baseline demographic factors, initial weight or diabetes control compared to study completers. The majority of individual sessions were attended by most participants in both conditions, with no differences between conditions in number of individual sessions received (Table 1).

Weight Loss

Participants in both conditions lost weight during the group program and weighed significantly less at each follow-up compared to baseline (Table 1), indicating that the group-based behavioral obesity program was effective in promoting weight loss. A main effect for treatment condition was also apparent, such that women in MI had lost significantly more weight than controls at each visit. Repeated measures ANOVA indicated a significant interaction between experimental condition and visit (p<.02), which was further explored by examining weight loss at each visit within treatment condition using Tukey-Kramer adjustments for multiple comparisons. Weight losses within the conditions displayed different patterns. Both MI and controls lost weight during weight loss induction (0 to 6 months), although MI had significantly greater weight losses (-4.7 kg ± 5.4 for MI versus -3.1 kg± 3.9 for controls, p=0.003). Furthermore, average weight losses in the MI condition remained stable during the first 6 months of weight maintenance with no regain observed by Month 12. Regain occurred only after 12 months, when the maintenance-focused group meetings continued but the MI sessions had ceased (+1.2 kg between month 12 and 18). In contrast, the control group began to regain after 6-months despite ongoing weight maintenance group sessions (+0.3 kg between months 6 and 12) and weight regain continued with an additional gain of +0.9 kg between months 12 and 18. Total 18-month weight loss between conditions differed significantly, with a 3.5± 6.8 kg loss in MI and 1.7± 5.7 kg in controls, p = 0.04.

Weight Loss by Race/Ethnic Group

Treatment outcome differed significantly by race, with African-American women losing less weight than white women, regardless of treatment condition. At 6-months, African-American women lost 3.0± 3.9 kg compared with white women who lost 4.5± 5.1 kg.
A similar pattern was evident at both 12-months (2.3± 4.4 kg for African-American women vs 4.6±6.8 kg for whites, p=0.009) and 18-months (1.4± 4.7 vs 3.3± 7.1 kg, respectively, p=0.04). To further examine the impact of adding MI to the behavioral program, repeated measures analysis of weight was re-examined with race included as a factor in the model. The 2 (condition) x 2 (race) x 4 (time) repeated measures ANOVA produced several significant interactions: race x treatment condition (p<0.0001), treatment condition x visit (p=0.04) and race x visit (p=0.01). Therefore, the weight patterns over time by race were examined separately for each treatment condition using a 2-factor repeated measures ANOVA stratified by treatment condition. Among women in the control group, there was an effect for visit (p <0.0001) and for race (p =0.03), such that body weight at each follow-up was significantly lower than baseline and African Americans weighed more than whites at each assessment. Among African-American controls, weight was significantly lower at 6-months than baseline (p=0.002) indicating successful initial weight losses. However, weight did not differ significantly from study entry at 12-month or 18-month among African-American controls. Therefore, weight regain during maintenance had essentially returned African-American women to baseline. In contrast, weight among white controls was significantly lower than baseline at 6-months (p<0.0001), 12-months (p<0.0001) and 18-months (p=0.005), indicating some enduring impact of the behavioral weight control program alone.

Within MI a different pattern of weight change was observed, with a significant race x visit interaction in the treatment stratified 2-factor repeated measures ANOVA (p=0.02). African-American women receiving MI weighed less at 6-months (p=0.0007) and also weighed less at 12 months (p=0.008) but had regained such that by 18-months they no longer weighed significantly less than baseline. Thus, for African-American women with type 2 diabetes the addition of MI to the behavioral weight control program produced greater weight losses than seen in the control group, but this additional benefit was not sustained after 12 months, when MI sessions had been discontinued. However, white women receiving MI weighed significantly less than baseline at 6, 12 and 18 months (all p < 0.0001). Therefore, the impact of MI on weight control was more sustained for white women and was evident even after the MI sessions had ceased. This extended 18-month benefit among white women receiving MI contrasts with an apparent diminution of an MI effect among African-American women by 18-months.

Glycemic Control

Glycemic control significantly improved in both conditions during the weight loss program (p<0.0001) despite fairly good glycemic control at baseline. Women in both conditions had significantly lower HbA1c values at 6-months (p<0.0001) and 12-months (p<0.0001). However, by 18-months, both conditions experienced increases in HbA1c such that they were no longer significantly lower than baseline and on average were slightly above the 7% treatment target recommended by the American Diabetes Association (27).

Women in MI experienced significantly greater HbA1c decreases than controls (p=0.002). This difference was most pronounced at 6-months when MI had a mean reduction of 0.8±1.12% in HbA1c compared with -0.5 ±1.12% among controls. Further analyses added race to the model and demonstrated significant main effects for treatment (p=0.002), race (p<0.0001), and visit (p<0.0001), but no interactions. African-American women had higher HbA1c values at each time regardless of treatment assignment (Figure 1).

Greater reductions in HbA1c with MI, when these were apparent, reflected greater weight losses in MI. That is, improvements in glycemic control were strongly associated
with weight loss ($r=.44$, $p<0.0001$ for MI and $r=.28$, $p=0.004$ for controls) and when weight loss was added to the model examining changes in HbA1c by experimental condition, condition was no longer significant but weight loss was significant at each visit (all $p<0.0001$).

**Treatment Adherence**

Analyses next explored possible mechanisms that may account for the superior weight loss and glycemic outcomes in MI. Participants in MI had significantly better engagement in the behavioral weight management program on all adherence measures (Table 1). Better attendance at group sessions was apparent in MI during the initial 6-month weight loss induction phase ($p=0.006$) and in the first 6-months of weight maintenance ($p=0.02$). By the final phase of weight maintenance, after MI sessions had ceased, differences between conditions were no longer apparent and attendance between the groups was comparable. In addition to better group attendance, MI participants submitted significantly more self-monitoring diaries than controls during each phase. Further, the average rating of diary quality, an index of treatment engagement made by group leaders masked to experimental condition, indicated women in MI submitted more comprehensive diaries. In aggregate, these adherence data indicate that women receiving MI were more engaged in the behavioral weight loss program.

**MI Increased Weight Loss by Increasing Treatment Adherence**

Multivariate models examining weight loss which included both experimental condition and adherence measures indicated that condition was not a significant factor explaining weight loss at either 6- or 18-months when adherence measures were included. However, adherence variables remained significant in the multivariate model, with group session attendance ($p=0.03$) and diary rating ($p<0.0001$) predicting weight loss at 6-months. At 18-months, diary rating was the single significant predictor of weight loss ($p=0.007$). A mediational model can be demonstrated when associations disappear with the addition of the mediating factor(s) into the model (28), as was the case in these analyses. Therefore, it would appear that treatment adherence mediated or explained the impact of MI on weight loss. Specifically, attendance and quality of self-monitoring diaries emerged as the factors accounting for variation in weight loss.

**Conclusions**

Motivational interviewing as a brief adjunctive intervention significantly enhanced both weight loss and glycemic control among overweight women with type 2 diabetes enrolled in a behavioral obesity treatment program. The beneficial impact of MI was apparent after only 2 sessions, with significantly greater weight losses and improvements in metabolic control at 6-months. Continued superior weight losses were observed at 18-months. The additional long-term weight produced with the addition of MI was modest, 1.6 – 1.8 kg more than weight loss achieved with standard behavioral intervention. This incremental benefit is comparable to short-term weight loss improvements in other controlled studies (19, 29).

Increased weight loss and HbA1c reductions achieved with MI were mediated by enhanced adherence to treatment recommendations, replicating a pattern of greater treatment uptake among problem drinkers receiving two sessions of MI in addition to standard therapy (30). MI augmented weight loss by increasing attendance at group sessions and producing more frequent and more comprehensive self monitoring. Previous obesity treatment research has demonstrated a strong association between self monitoring and weight loss (12, 31), and attendance at treatment sessions is consistently associated with better weight losses. Therefore, it is not altogether surprising that superior weight loss outcomes observed with the addition of MI
were mediated by enhanced adherence to the behavioral program.

Weight losses in the control group were smaller than those reported by some investigators implementing a similar behavioral intervention approach among predominantly white populations with diabetes (32-33) and are substantially smaller than those produced with behavioral programs that provide meal replacements (34). However, weight losses among controls were comparable to those reported in meta-analyses of behavioral therapies for diabetic individuals (35) and long-term losses in other studies of diabetic individuals (10, 36), particularly studies including significant representation of African-American participants (37-38).

African-American women in both experimental conditions experienced significantly smaller weight losses than white women in the study, consistent with the results of other clinical trials of obesity treatment in diabetic populations (39) and in overweight individuals at risk for diabetes (12). The extended impact of MI also differed by race, with greater long-term enhancement of weight loss with MI for White women than for African-American women. Increased weight losses with the addition of MI were apparent among African-Americans only until month 12 and dissipated by 18-months, while improved outcomes were still apparent for White women at the end of the program. Resnicow has shown that the addition of MI to a culturally-tailored program designed to promote fruit and vegetable consumption increased intake among African Americans by approximately 1 serving/day above that with self-help materials alone (40,41). However, another study of African-American female smokers failed to find an effect for MI (42). The current study is the first to report the potential attenuated impact of MI among African-American women relative to White women. Project MATCH examined whether there was differential impact by ethnicity to three approaches to treating alcoholism, including an MI-derived therapy, in an ethnically-diverse sample of problem drinkers and found no differential response to motivational enhancement therapy for Hispanic and non-Hispanic men (43). Although outcomes for African Americans or minority women receiving the motivational modality are not presented separately, thus precluding direct comparisons, ethnicity was not associated with poorer alcohol-related outcomes in African Americans across treatment conditions (44). However, African Americans reported significantly lower satisfaction with treatment (44). Clearly further research is warranted to identify parameters which may be associated with or promote a positive response to MI for weight management in ethnically-diverse samples, as well as mechanisms responsible for facilitating behavior change. Further evaluation of MI for weight management among men and non-diabetic individuals is also necessary.

Acknowledgements
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References


Table 1. Sample Characteristics and Outcomes (Mean ± SD unless otherwise noted)

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<tr>
<th></th>
<th>Total Sample</th>
<th>Motivational Interviewing</th>
<th>Attention Control</th>
<th>Comparisons between conditions (p-value)</th>
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<tr>
<td>N</td>
<td>217</td>
<td>109</td>
<td>108</td>
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</tr>
<tr>
<td>African American (%)</td>
<td>39</td>
<td>39</td>
<td>38</td>
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</tr>
<tr>
<td>Married (%)</td>
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<td>Age (years)</td>
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<td>College Education or higher (%)</td>
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<td>Employed (%)</td>
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<tr>
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<td>97 ± 15</td>
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<td>89</td>
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<td>HbA1c</td>
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<td>Diabetes Duration (years)</td>
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**Retention Rates (N)**

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<th>12 months</th>
<th>18 months</th>
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<tr>
<td>N</td>
<td>210 (97%)</td>
<td>195 (90%)</td>
<td>202 (93%)</td>
</tr>
<tr>
<td>Total attended (%)</td>
<td>107 (98%)</td>
<td>103 (94%)</td>
<td>103 (94%)</td>
</tr>
<tr>
<td>Retained (%)</td>
<td>103 (95%)</td>
<td>92 (85%)</td>
<td>99 (92%)</td>
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**Attendance at Individual MI/AC Sessions**

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<th>12 months</th>
<th>18 months</th>
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<tbody>
<tr>
<td>Proportion attending ≥ 80% of sessions</td>
<td>81%</td>
<td>76%</td>
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</tr>
<tr>
<td>Group Sessions Attended</td>
<td>72%</td>
<td>79%</td>
<td>71%</td>
</tr>
<tr>
<td>Diaries Submitted (number)</td>
<td>15 ± 8</td>
<td>17 ± 8</td>
<td>13 ± 8</td>
</tr>
<tr>
<td>Average Diary Rating (0-2 range)</td>
<td>1.3 ± 0.6</td>
<td>1.4 ± 0.6</td>
<td>1.1 ± 0.6</td>
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**Behavioral Adherence Measures**

<table>
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<th>6 months</th>
<th>12 months</th>
<th>18 months</th>
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<td>1.1 ± 0.6</td>
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*ANCOVA adjusted for baseline value of variable, adjusted means and standard error (SE) presented*
Figure 1. Treatment Outcomes for Total Sample and by Ethnic Group

For Total Sample

By Ethnic Group