Psychosocial Correlates of Medication Adherence in African American and Caucasian Headache Patients: An Exploratory Study

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ABSTRACT

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Psychosocial Correlates of Medication Adherence in African American and Caucasian Headache Patients: An Exploratory Study (65 pp.)

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Study Objectives To examine predictors of medication non-adherence in a racially diverse sample of patients receiving specialty treatment for headache disorders.

Methods: Using a longitudinal naturalistic study design, data from 33 African American and 79 Caucasian headache patients were collected to characterize patterns and predictors of non-adherence to daily headache preventive medication. Patients completed 30-day headache diaries that assessed daily preventive medication use, headache frequency, and headache severity during the 30-days following their six month follow-up medical visit with their physician at headache specialty clinics in four major cities in Ohio. At pre-treatment and 6-month follow-up, patients provided data on headache-specific quality of life and headache disability.

Results: African Americans (73%) and Caucasians (83%) were equally adherent to their preventive headache medication. A within-group examination of predictors of non-adherence to preventive medication revealed that greater headache severity and poorer quality of life at baseline predicted lower levels of non-adherence at 6-month follow-up for African Americans. Among Caucasians, the presence of a comorbid psychiatric disorder at baseline predicted greater non-adherence at 6-month follow-up.

Conclusions: Adherence to preventive medications in headache patients in specialty care clinics appears to be good. Poorer quality of life and greater headache severity predicted non-adherence in African Americans while psychiatric comorbidity predicted non-adherence in Caucasians. Racial differences in predictors of adherence suggest that adherence-improvement interventions in this clinical population should consider racial- and culturally-specific factors.

Approved: _____

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INTRODUCTION

Approximately 30 to 60% of patients living with chronic health conditions report "poor adherence" to medication regimens (typically defined as less than 80% adherence; Vermeire, Hearnshaw, Van Royen, & Denekens, 2001). Inconsistent adherence to medical treatment regimens is associated with many adverse consequences, including increased disease-related mortality (Saran et al., 2003), disease progression (Adler et al., 2006; Paterson et al., 2000), more frequent hospitalizations (Weiden, Kozma, Grogg, & Locklear, 2004), and poorer clinical heart-related outcomes (Ghali, Kadakia, Cooper & Ferliz, 1988). Moreover, in the United States alone, the economic impact of non-adherence with respect to healthcare related costs is estimated to exceed "$100 billion dollars annually" (Dunbar-Jacob & Mortimer-Stephens, 2001).

While adherence has been studied extensively across a variety of health conditions, such as HIV/AIDS (Levine et al., 2005; Schneider, Kaplan, greenfield, & Wilson, 2004; Chesney, 2003; Fogart, Roter, Larson, Burke, Gillespie, & Levy, 2001), cardiovascular diseases (Dunbar-Jacob, Bohachick, Murtimer, Sereika & Foley, 2003), and asthma (Apter et al., 2003), relatively very few studies have examined adherence to treatments in patients with headache disorders. Headache disorders are highly debilitating and are related to high rates of employee absenteeism, increased physical impairment, and reduced quality of life (Lipton, Bigal, Diamond, Freitag, Reed, Stewart, 2007; Silberstein, Diamond, Reed, Bigal, Lipton, 2007; Steiner, Scher, Stewart, Kolodner, Liberman, Lipton, 2003). Abortive and preventive medications can significantly reduce the frequency and disability associated with headache disorders

(Brandes, *et al.,* 2005). More importantly, studies show that preventive medications, which include antidepressants (e.g., TCA and SSRIs), anticonvulsants, and β-blockers (Silberstein & Goadsby, 2002), are particularly effective in reducing patients' number of days with headaches, increasing daily physical activities, and improving patients' overall quality of life (Zissis, *et al,* 2007; D'Amico, Solari, Usai, Santoro, & Bernardoni, 2006; Ozyalcin, Talu, Kiziltan, Yucel, Ertas & Disci, 2005; Bendtsen, Rigmore & Jensen, 2004). These benefits are dependent on the patient adhering to medication guidelines. Packard and colleagues (1988) however, reported high levels of non-adherence to preventive and acute medications (53%) among patients with headache disorders suggesting that the benefits associated with compliance to headache medications may not outweigh the barriers to adherence.

Only two studies have examined adherence to preventive medication in headache patients. In a pilot study that examined the daily medication adherence in migraine patients seeking treatment at an headache specialty clinic, Steiner and colleagues (1994) found that rates of daily adherence to pizotifen (serotonin antagonist) over an eight week period ranged from 21% to 91% depending on how adherence was assessed. Specifically, rates ranged from 62 to 91% when assessed by returned-pill count and 21 to 47% when measured by electronic event recorders that tracked the number of doses taken on schedule (Steiner, Catarci, Hering, Whirmarsh, & Couturier 1994). Mullerners and colleagues (1997) examined adherence to preventive medication among migraine patients at a London headache specialty clinic. When assessed via pill-count, patients' mean two month adherence rate was 91%. However, electronic event recorders reported a mean

adherence rate of only 66% over the same period of time. When regimen complexity was taken into account, patients who were required to take their preventive medications once a day reported an adherence rate of 79%, patients who were prescribed twice-daily preventive medications reported a 60% adherence rate, and patients prescribed a three-times daily preventive medication reported an adherence rate of 54%. It is important to note, however, that these studies were based on very small samples (e.g., n=4 and n=29, respectively) and none of these studies examined behavioral, psychosocial, or demographic factors that might explain adherence behaviors related to preventive medication among patients with headache disorders.

Racial differences in adherence to headache medications have not been studied, in spite of the fact that : (a) 3.3 % of African Americans are diagnosed with a headache disorder (Scher, Stewart, Liberman & Lipton, 1998); (b) African Americans living with a variety of chronic health conditions (e.g., HIV/AIDS and hypertension) tend to report poorer adherence to daily pharmaceutical treatments than their Caucasian counterparts (Weng, Israni, Marshall, Hoy, Gaughan & Newman, 2005; Golin, et al.,2002; Gifford, Bormann, Shively, Wright, Richman, Bazzette, 2002; Monane, Bohn, Gurwitz, Glynn, Levin, & Avorn, 1996); and (c) African American and Caucasian patients appear to respond equally well to contemporary headache treatments (Heckman, 2007), underscoring the importance of consistent adherence to preventive headache treatments in African American headache patients.

Only one study has addressed racial differences in adherence behaviors in headache patients. Heckman and colleagues (2007) found that African Americans in

headache specialty clinics were significantly more likely than Caucasians to miss one or more headache treatment appointments (Heckman et al., 2007). In fact, even when controlling for factors such as gender, age, education, and SES, African Americans were 2.1 times more likely than Caucasians to miss one or more treatment appointments.

It remains unclear, however, if African American and Caucasian patients with headache disorders differ in rates of adherence to preventive headache medications. The present study was a secondary analysis of data provided by African American and Caucasian headache patients receiving treatment in headache specialty clinics throughout Ohio. The study was guided by Social Cognitive Theory (Bandura, 1989), which states that human behaviors--including important health behaviors such as adherence--can be explained by a group of inter-dependent factors that include the individual's behaviors, environmental influences, cognitions (attitudes and beliefs), and other psychosocial factors. The current study tested the following hypotheses: (1)African Americans would report more medication non-adherence than Caucasians; (2) variables that predicted medication adherence in African Americans would be different than those that predicted adherence in Caucasians; and (3) that African American and Caucasian patients who reported poorer medication adherence would also report poorer treatment outcomes. Findings from the current study can identify headache patients at elevated risk for non-adherence to preventive medication regimens and inform the development of culturally-contextualized interventions to improve rates of medication adherence in African American and Caucasian headache patients

METHODS

Participants

This research is a secondary analysis of data provided by 33 African American and 79 Caucasian headache patients who received treatment in outpatient specialty treatment clinics throughout Ohio. Participants were recruited from four outpatient headache treatment clinics in four large urban cities in Ohio: Cincinnati, Cleveland, Columbus, and Toledo. Study inclusion criteria were: (1) 18 years of age or older; (2) self-identifying as African American or Caucasian American; (3) meeting IHS criteria for either episodic migraine, chronic migraine, episodic tension-type headache, chronic tension-type headache, and substance abuse headache, (4) the participant's physician believed that he or she would benefit from a new preventive therapy medication; (5) proficiency in the English language; and (6) the participant was willing to delay the initiation of a new preventive treatment for one month.

Procedure

Study participants were recruited by their neurologist during their initial visit of their 6-month course of routine treatment. Participants were recruited using print materials (i.e., brochures) that described the study and that were distributed to potential participants as they waited for treatment in the waiting rooms or reception areas of participating clinics. Eligible patients who expressed interest in the study provided written informed consent in the treatment clinic.

The study used a prospective, longitudinal design and assessed participants at pre-treatment and 1-, 2, and 6-month follow-up. These follow-up time periods were used in

the current study because they represent the timing of participants' normally scheduled follow-up visits to participating clinics. Participants were provided abortive medication at their initial visit if they were not already taking them. Physicians also made modifications to the abortive regimen for patients who were already receiving abortive treatments. Patients were then assessed at the second visit that occurred 1-month after the initial visit. During this visit, physicians used headache activity data obtained over the past month to determine if the need existed for new preventive medications and, if necessary, one or more preventive medications were prescribed as clinically indicated. Patients were then scheduled to participate in two follow-up visits at two and six months after the initial visit.

Assessment Methodologies

Headache Diagnosis. During the initial patient-physician interaction, the physician diagnosed the patient's current headache disorder(s) using International Headache Society criteria (International Headache Society, 2003). The physician also recorded data on each patient's past and current pharmacological and behavioral headache treatments.

Psychiatric Diagnosis. Psychiatric disorders were diagnosed using the Primary Care Evaluation of Mental Disorders *(PRIME MD; Spitzer et al., 1990)*. The PRIME-MD was administered to participants by trained research staff during a telephone interview conducted within two days of the baseline visit. The Prime-MD yields a subset of diagnoses included in the Diagnostic and Statistical Manual of Mental Disorders (DSM

IV; Spitzer et al., 1990), including mood and anxiety disorders, as well as alcohol (abuse/ dependence), eating disorders, and somatoform disorders.

30-Day Daily Headache Diary. At the conclusion of the initial visit, research staff provided each participant with a self-administered, paper-and-pencil daily diary that patients used to rate the frequency, severity, and disability of each headache they experienced during the next 30 days. This 30-day period was the interval between the patient's initial visit and his or her second visit. Patients received their new preventive therapy at the second visit. *Headache frequency* was operationally defined as the "number of days over the 30-day period during which patients experienced a 'moderate' or 'severe' headache. *Headache severity* was assessed daily for each headache using a 4-point scale (1="No pain," 2="Mild," 3="Moderate," or 4="Severe"). Headache severity scores were calculated by averaging headache severity over the 30-day period.

Preventive Medication Adherence. Patients' medication adherence was obtained using the 30-day headache diary described above. Adherence was assessed only at the 6-month follow-up assessment. It was computed as the number of days that patients took their preventive medication as prescribed over the 30-day period.

Headache Disability. Headache disability was assessed using the Headache Disability Inventory *(HDI; Jacobson et al., 1994).* The HDI assessed the burden of chronic headaches and used 25 items that inquired into the perceived impact of headaches on emotional functioning and daily activities (α=.88; Chin & Ramadan, in press). The measure evidenced good internal consistency (α=.92).

Headache Specific Locus of Control *(HSLC; Martin, Holroyd, & Penzien, 1990; VandeCreek & O'Donnell, 1992)*. The HSLC scale is a 33-item self-report instrument that measured patients' beliefs regarding factors that control their headaches. The HSLC scale contained three locus-of-control subscales that assessed the extent to which individuals believed that their headaches were controlled by their own efforts (Internal subscale), chance circumstances (Chance subscale), and health care professionals (Health Care Professional subscale). Respondents rated the extent to which they agreed with each locus-of-control item (e.g., "It's a matter of fate whether I have a headache.") using a five-point rating scale (1= "Strongly disagree" to 5="Strongly agree"). The HSLC scale has demonstrated good psychometric properties, with coefficients alpha ranging from .84 to .88. Coefficient alpha in the current study was .87.

Headache Management Self-Efficacy *HMSE; French et al., 2000).* The HMSE scale is a 25-item self-report inventory that assessed an individual's perceived ability to prevent and manage headache activity. Respondents rated the extent to which they agreed with each item (sample item: "There are things I can do to reduce headache pain") using a seven-point rating scale (1="Strongly disagree" to 7="Strongly agree"). The HMSE evinced good internal consistency in the present study (α=.90).

Perceived Social Support *(MSPSS; Zimet, Dahlem, Zimet, & Farley, 1988).* The 12-item MSPSS scale measures perceived social support from three sources: family; friends; and significant other(s). In past research, the MSPSS scale has demonstrated excellent psychometric characteristics (α=.91, test-rest reliability=.93). Each item of the MSPSS scale (e.g., "My friends really try to help me") used a seven-point Likert scale to

assess level of agreement with each item (1="Very strongly disagree" to 7="Very strongly agree"). Higher scores indicated higher perceptions of social support. The MSPSS showed excellent internal consistency in the current study (α=96).

Headache Specific Quality of Life (*MSQ; Jhingran, Osterhouse, Miller, Lee, & Kirchdoerfer, 1998)*. A modified version of the MSQ assessed the long-term impact of headache disorders on patients' quality of life. The original version of the MSQ is a 14-item scale that assesses quality of life in patients diagnosed only with migraine disorders. In the current study, the MSQ was modified by replacing the term "migraine" with "headache" in each relevant item. For example, the original MSQ item "In the past 4 week, how often have migraines interfered with how well you dealt with family, friends and others close to you" was changed to "In the past 4 week, how often have your *headaches* interfered with how well you dealt with family, friends and others close to you." The revised MSQ was scored so that higher scores indicate *poorer* quality of life. Coefficient alpha for the current study was .95.

Demographic characteristics. Patients completed a survey that indicated the racial group with which they most identified, their age, gender, number of years of education completed, employment status, health insurance status (HMO, PPO, private, SSI), and annual income.

Data Analytic Procedures

The current study utilized four main data analytic strategies. Data screening analyses evaluated the distribution of study variables (e.g., skew, kurtosis) and identified potential univariate and bivariate outliers. One-way analyses of variance and chi-square

tests of association characterized associations among patients' race, sociodemographic characteristics, headache diagnoses, and psychosocial variables. Separate bivariate correlations for both African Americans and Caucasians were conducted to determine variables to enter in regression models (See appendix 1). For the bivariate correlations, the following rule of thumb was applied: independent variables with correlation coefficients of less than .80 and p-values of less than .20 were entered in our regression models. Finally, a series of regression analyses examined associations among adherence, psychosocial variables, and demographic variables and determined if relationships among adherence and the sets of predictors variables differed by race.

RESULTS

Data Screening Analyses

Data screening analyses examined each variable's skewness and kurtosis, checked for data entry errors, and assessed amounts and patterns of missing data. Bivariate scatterplots examined variables' linearity and homoscedasticity. "Adherence" was significantly and negatively skewed, (Skew = -1.61, SE Skew=0.22; see figure 2); accordingly, this variable was reflected and a log10(x+1) transformation was applied to the reflected variable. After this transformation, higher values on this variable indicated greater rates of *non-adherence*.

Race, Demographics, and Headache Diagnoses

Chi-square tests of association and one-way ANOVA characterized associations among race, sociodemographic variables, headache diagnoses, and headache characteristics. Table 1 shows the demographic characteristics of the 112 patients taking preventive medications during the 30-day follow-up period. Of the 114 African Americans initially enrolled in the study, 30% (n= 33) had been prescribed preventive medication and, of the 173 Caucasians initially enrolled into the study, 46% (n=79) had been prescribed preventive medication. The average patient was female (88%), 38.0 years of age (SD=10.8, Min=18, Max=66), had completed 14.0 years of education, reported an annual income less than $60,000 (87%), and had some form of health insurance (99%). Episodic migraine without aura was the most prevalent headache disorder (38%). On average, participants experienced one or more headaches on 12.7 days during the past month (Min=1, Max=30, SD=7.7). Table 1 shows that African

American patients were slightly older, had fewer years of education, were more likely to be diagnosed with depression, and reported significantly lower levels of social support compared to Caucasians (all $p_s < .05$). Caucasians and African Americans were equally likely to be diagnosed with a migraine disorder , $X^2(1) = 1.645$, $p > .05$; however, African Americans were more likely than Caucasian Americans to be diagnosed with an episodic tension-type headache disorder, $X^2(1) = 7.6$, $p < .05$. Both Caucasian Americans and African American patients were equally likely to be diagnosed with chronic $X^2(1) = .371$, $p > .05$ and episodic headache disorders, $X^2(1) = .110$, $p > .05$

Objective 1: Racial Differences in Rates of Non-adherence among Headache Patients

A one-way ANCOVA was conducted to determine if Caucasian and African Americans differed in self-reported rates of non-adherence 6 months after the initiation of preventive treatments. Participants' age, education, depressive disorder diagnosis, and social support at pre-treatment were entered as covariates in the model. Results from this analysis indicated that Caucasians (M = 0.41) and African Americans (M = 0.58) reported comparable levels of non-adherence as assessed by the Log10 of reflected adherence scores, $F(1,103)=2.64$, $p = .11$. In order to determine if the transformation of adherence accounted for the aforementioned findings, analyses were re-conducted using raw scores of the original adherence measure (i.e., number of days of adherence during the past 30 days). This analysis showed that Caucasian patients (M=25.0 days, 83% daily adherence) and African American patients (M=22.0 days, 73% daily adherence) reported a comparable number of days of adherence $F(1,111) = 2.46$, $p = .120$.

Objective 2: Predictors of Non-adherence in African American and caucasian headache patients

Predictors of non-adherence in African American patients. To identify variables that predicted non-adherence in African American patients, a multiple regression analysis was conducted. The multiple regression analysis used hierarchical entry method and variables were entered in three blocks. Block One consisted of headache type: the presence of tension-type headache and migraine headache. Block Two consisted of headache severity. Block Three consisted of social support. As shown in Table 2, all headache type variables in Block one significantly predicted non-adherence in African American patients , R^2= .374, F (2, 27)=8.052, p = .002. Inspection of the individual headache types shows that being diagnosed with tension-type headaches was associated with greater non-adherence to preventive medication. In Block Two, headache severity significantly predicted non-adherence and added 10.2% to the explained variance, ΔR^2 = .102, F(1, 26)=5.035, p = .034. In Block Three, social support did not significantly contribute to the explanation of preventive medication non-adherence, ΔR^2 = .007, F(1, 25) = .322, p= .575. When Block Three was entered, only two variables significantly predicted non-adherence. Specifically, African American patients who reported greater headache severity at baseline had lower levels of non-adherence at the 6-month follow-up, beta=-.342, p = .031, and African Americans with tension-type headaches had higher levels of non-adherence, beta = .591, p= .017; R^2= .48, F(4, 29)=5.814, p = .002.

Predictors of non-adherence in Caucasian patients. A multiple regression analysis identified predictors of non-adherence in Caucasian patients. Results from

bivariate correlations indicated that only psychiatric comorbidity (e.g., being diagnosed with one or more psychiatric conditions) was related to non-adherence to preventive medication. This variable was entered as Block One. As shown in Table 2, medication non-adherence in Caucasians was marginally related to psychiatric comorbidity. Specifically, patients who were diagnosed with one or more psychiatric disorders reported more non-adherence to their preventive medication, beta = .200, p =.07, R^2= .04, F(1,77)=3.18, p = .07.

Bivariate correlations between predictor variables and the criterion variable are shown in Appendix 1 to identify associations between predictor variables and to demonstrate why the predictor variables entered into the model in the manner that they did.

Objective 3: Associations among Non-adherence and Changes in Headache Frequency, Disability, and Quality of Life

A series of regression analyses was conducted to determine how non-adherence was associated with changes in the outcome measures of headache frequency, headache disability, and quality of life across treatment. In these regression analyses, conducted separately for Whites and African Americans, the outcome measure of interest (i.e., headache frequency at 6-month follow-up, headache disability at 6-month follow-up, and headache-specific QOL at 6-month follow-up) served as the criterion variable, non-adherence served as the predictor variable, and the pre-treatment value of the criterion measures served as covariates.

Non-adherence and Changes in Headache Frequency. In Caucasian patients, pre-treatment values of headache frequency significantly predicted 6-month values of headache frequency, beta=.581, $p < .001$, but non-adherence was unrelated to headache frequency at 6-month follow-up, beta=.009, $p = .92$. In African Americans, pre-treatment values of headache frequency were marginally associated with 6-month headache frequency values, beta=.337, $p < .08$, but non-adherence was unrelated to headache frequency at 6-month follow-up, beta=.170, $p = .35$.

Non-adherence and Changes in Headache Disability. In Caucasian patients, pre-treatment values of headache disability were related to headache disability at 6-month follow-up, beta=.395, $p < .001$ but non-adherence was unrelated to headache disability at 6-month follow-up, beta=-.004, $p = .97$. In African Americans, pre-treatment values of headache disability were significantly associated with headache disability at 6-month follow-up, beta=.548, $p < .04$, but non-adherence was unrelated to headache disability at 6-month follow-up, beta=.104, $p = .55$.

Non-adherence and Changes in Headache Quality of Life. In Caucasian patients, pre-treatment values of quality of life were unrelated to quality of life at 6-month follow-up, beta=.173, $p = .139$ and non-adherence was unrelated to quality of life at 6-month follow-up, beta= -.038. In African Americans, pre-treatment values of quality of life was significantly associated with quality of life at 6-month follow-up, beta=.682, $p < .01$ and non-adherence was marginally related to quality of life at 6-month follow-up, beta=.284, $p < .07$; African Americans who reported more non-adherence also reported poorer headache specific quality of life at 6-month follow-up.

DISCUSSION

This study is one of the firt, if not the first, to characterize patterns and predictors of adherence to preventive headache treatment medications and to consider the role of race in these relationships. Major findings from this study include the following: (1)African Americans and Caucasians did not differ in levels of adherence to preventive headache treatment medications; (2) increases in headache severity was related to greater non-adherence in African Americans; (3) being diagnosed with tension-type headache predicted non-adherence in African Americans and (4) being diagnosed with a psychiatric comorbid disorder predicted non-adherence in Caucasians; and (5) in general, non-adherence did not predict change in study outcome measures from pre-treatment through 6-month follow-up; the lone exception to this pattern was that non-adherence was related to quality of life at 6-month follow-up in African Americans.

The current study found that, after adjusting for age, years of education, diagnosis of depression, and levels of social support, race was unrelated to adherence to preventive medications in headache patients. This finding is not consistent with results from previous research showing that race is related to adherence practices in persons living with other chronic health conditions (e.g., HIV/AIDS, asthma, diabetes; Monane, Bohn, Gurwitz, Glynn, Levin, & Avorn, 1996; Weng et al., 2005; Golin, et al., 2002; Gifford, Bormann, Shively, Wright, Richman, Bazzette, 2000). The inconsistencies between the current study's findings and those reported in past research may be explained by differences between headache disorders and other chronic health conditions (e.g., symptom presentation and disease-related disability). Indeed, some studies show that

people living with chronic headache disorders experience significantly more impairment with respect to physical role and social functioning than patients suffering from other chronic illnesses such as hypertension, diabetes, and osteoarthritis (Osterhaus, Townsend, Gandek, & Ware, 1994; Stewart, Greenfield et al., 1989). Therefore, it is not unreasonable to assume that the aforementioned negative influences may increase motivation among headache patients to properly adhere to their medication

While several studies have reported an association between race and medication adherence behaviors, other research suggests that race and other demographic factors are poor predictors of adherence. In a meta-analysis of 569 studies of medication adherence across numerous health conditions, DiMatteo (2004) found that the associations among adherence and sociodemographic factors (e.g., race, SES, and gender) were "small" and tended to be moderated by sample characteristics, type of medication regimen, and assessment methodologies. The use of different operational definitions of "adherence" and dissimilar assessment methodologies in adherence studies makes cross-study comparisons very difficult. Finally, it is important to note that over one-half of the study's sample prematurely terminated treatment prior to the 6-month follow-up. Therefore, the African American and Caucasian patients who remained in and completed the study may have been highly adherent by nature, rendering race-related differences in medication adherence less likely.

A major goal of this study was to identify differences in predictor variables of adherence behaviors in Caucasian and African American patients. Results indicated that, for African Americans, having a tension-type headache disorder was associated with

higher rates of non-adherence. There are no studies, to date, that have reported on the impact of differential headache diagnoses on adherence behaviors. However, epidemiologic data indicate that tension-type headaches are highly prevalent, but may not be as severe as other forms of headaches including migraines. For example, although physical activities may aggravate pain associated with tension-type headaches, they usually do not cause the pain to worsen; thus, limiting the impact of the headache on patients' lives. On the other hand, pain associated with migraines is usually aggravated by physical activities, resulting in more disabling headaches. Because of the limited impact of tension-type headaches relative to migraines, African American patients may feel less of a need to properly adhere to their preventive medication and may resign to taking their medications only when their headaches become severely disabling. In contrast, migraines are usually extremely disabling, which may lead African American patients to exercise more prudence with respect to their medication taking habits. Interestingly, some studies show that African Americans with migraine headache disorders report more frequent headaches and greater headache-related severity than do Caucasian headache patients (Stewart, Lipton, Liberman, 1996).

Results also show that headache severity at baseline was found to be negatively associated with non-adherence among African Americans headache patients at 6-month follow-up. Specifically, African Americans who reported greater headache severity had significantly lower rates of non-adherence with their preventive medication. Both clinical and experimental studies show that African Americans report lower levels of pain tolerance (Sheffield, Biles, Maixner, & Sheps, 2000), higher levels of pain

unpleasantness, and have greater emotional response to pain (Riley, Wade, Meyers, Sheffield, Papas & Price, 2002) relative to their Caucasian counterparts. In light of these findings, it is not unreasonable to assume that because of their heightened reaction to pain relative to Caucasians, African Americans who experience more severe headaches may have increased adherence to preventive therapy to mitigate the adverse influence of their disorder.

This study found that Caucasian patients who were diagnosed with psychiatric comorbid disorders also reported greater non-adherence to preventive headache medications. This finding is in accord with past research showing that elevated psychiatric symptoms and the presence of one or more psychiatric disorders are associated with poorer adherence in patients suffering from hypertension (Wang, Bohn, Knight, Glynn, Mogun and Avorn, 2002), diabetes (Lustman & Clouse, 2005), and coronary artery disease (Gehi, Haas, Pipkin & Whooley, 2005). This finding is troubling given that both epidemiologic and clinic-based research has found high prevalence rates of psychiatric disorders in headache patients, including depression, anxiety (Mitsikostas, & Thomas, 1999) and bipolar disorders (Fasmer, 2001). Patients with psychiatric disorders experience heightened sensitivity to unpleasant side effects from medication (Waxman, McCreary, Weinrit, & Carner, 1987). It may be that headache patients with psychiatric disorders experience heightened sensitivity to unpleasant side effects from their medications which may, in turn, increase their likelihood of non-adherence.

Although non-adherence was greater in Caucasians with psychiatric conditions, no such relationship was observed in African Americans. Approximately 60% of African

American headache patients were diagnosed with one or more psychiatric disorders. It could be that African Americans had qualitatively different types of psychiatric disorders than Caucasians and this may explain, in part, the lack of a relationship between psychiatric comorbidity and non-adherence. Future research should examine why psychiatric comorbidity is related to non-adherence in Caucasians but not African Americans.

In addition to examining race-related differences in predictors of non-adherence, the current study explored possible racial differences in the associations among preventive medication non-adherence and changes across headache treatment outcomes. Higher rates of non-adherence in African Americans were associated with poorer quality of life at the end of the study's follow-up period. One explanation for this finding is that African American patients who reported poorer quality of life at the 6-month follow-up period may have discontinued proper adherence behaviors during the treatment period. Turk and Rudy (1991) report that patients with chronic pain disorders were frequently discouraged with extended treatments that did not produce clinically significant therapeutic results and, consequently, some became more non-adherent over time. Conversely, the association between poor quality of life and higher levels of non-adherence may be a direct consequence of improper adherence to medication. That is, as a result of not taking their preventive therapies optimally, some African American patients may not have experienced improvements in their quality of life or may even have seen reductions in their quality of life. As noted previously, no significant associations were found among non-adherence and other study outcome measures, such as headache

frequency, severity, and disability. These null findings may be due, at least partially, to the study's relatively small sample size, which limited the study's ability to detect small and medium effects that may characterize the relationship between non-adherence and the other outcome variables.

The present study had a number of limitations. All participating headache treatment facilities were located in large urban areas in Ohio. The extent to which these findings generalize to other geographic regions is unclear. Many measures used in the current study were not designed specifically to assess behaviors and beliefs specifically related to adherence. For example, the headache self-efficacy measure did not assess the degree to which headache patients believed in their own agency to adhere to preventive medication; instead, the measure assessed patients' ability to manage their headache disorders. Consequently, results obtain from this and similar measures may not accurately target the variable(s) of interest in the present study. The current study utilized a self-report measure of adherence; no objective measures of adherence were used (e.g., electronic medication event monitoring devices). Self-report measures are known to over-report rates of medication adherence (Grymopre, Didurc, Montgmery, & Sitar, 1998). Finally, the sample was a non-probability sample and relatively small. The extent to which this sample is representative of the population of person seeking treatment in headache specialty clinics throughout the United States is uncertain. Moreover, this relatively small sample may have resulted in the current study's inability to detect small or medium effects. An additional limitation is that adherence was assessed only once near the end of the follow-up period. Patients who dropped out of the study may have

evidenced different rates of adherence than patients who remained in the study, further limiting the generalizability of study findings.

In spite of the above limitations, the current study is the first to investigate racial differences in rates of non-adherence to preventive medications in headache patients and also the first to examine racial differences in predictors of adherence behaviors in a clinic-based headache population. Considering the debilitating effects of headaches, clinicians should attempt to ensure that all patients enjoy the full benefits of preventive medications by identifying patients who may be at increased risk of medication non-adherence. Interventions should be developed for patients who have difficulty adhering to preventive medication regimens so that these treatments can yield significant and sustained reductions in headache frequency and severity and, hopefully, produce greater quality of life for persons living with severe headache disorders.

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APPENDIX A: TABLES

Table 1 : Sociodemographic Characteristics & Headache Diagnoses of Caucasian and African American Patients

Characteristic	Overall Sample (n=112)	Caucasians (n=79)	African Americans (n=33)	χ^2 or t	p-value
Age	38.0 ± 10.8	36.5 ± 10.5	40.8 ± 11.2	1.7	0.09
Years of Education	9.2 ± 2.1	9.4 ± 2.1	8.6 ± 2.0	2.8	0.06
Income Below $60,000	87%	81.3%	100%	6.7	.01
Adherence	24.21 ± 9.6	25.0 ± 8.7	22.0 ± 11.1	1.57	0.12
Social Support	70.3± 15.9	72.8 ± 13.1	64.3±20.3	2.6	0.01
Diagnosed with Psychiatric Comorbid Condition	51.3%	47.4%	60.6%	1.6	0.20
Diagnosed with Depression	33.3%	26.9%	48.5%	4.8	0.02
Headache Frequency	12.7±7.7	11.9±7.6	14.3±7.7	1.5	.13
Headache Severity	.969± .523	.894± .453	1.15± .634	2.40	0.01
Diagnosed with Chronic Migraine (with or without aura)	28.0%	29.0%	25.0%	0.1	0.66
Diagnosed with Episodic Migraine (with or without aura)	48.6%	53.2%	37.5%	2.24	0.13
Diagnosed with Migraine (Episodic or Chronic/ with or without aura)	90.0%	92.4%	84.3%	1.64	0.20
Diagnosed with Chronic Tension-Type Headache	10.8%	8.8%	15.6%	1.1	0.29
Diagnosed with Episodic Tension-Type Headache	2.7%	0.00%	9.4%	7.6	0.006
Tension-Type Headache (Epi Chronic)	13.4%	8.8%	25.0%	5.07	0.24
Diagnosed with MOH	3.6%	2.5%	6.2%	0.9	0.34
Diagnosed with Chronic Headache	42.3%	40.5%	46.8%	0.38	0.54
Diagnosed with Episodic Headache	64.8%	65.8%	62.5%	0.11	0.74

Table 2: Associations Among Demographics, Headache Characteristics, Psychosocial Variables, Headache Diagnoses, Psychiatric
Comorbidity, and Medication Non-adherence.

Predictors	**African American (N=33)**			**Caucasian American (N=79)**		
	beta	**R^2**	**ΔR^2**	**beta**	**R^2**	**ΔR^2**
Block 1: (Headache Diagnosis)		.374 *	.374		.04	.04
Tension-Type	.591*					
Migraine	-.067					
Having Psych Comorbidity (CA)				.200**		
Block 2: HA Characteristics		**.475***	**.102***			
HA Severity	**-342***					
Block 3: Psychosocial Measures		.482*	.007			
Social Support	-.092					

*p < .05 **p < .08

Table 3: Demographic and Behavioral Differences Between Treatment Completers and Dropouts

Characteristic	*Overall Sample (n=257)*	*Completers (n=112)*	*Drops (n=145)*	*χ^2 or t*	*p-value*
Age	36.6 ±10.4	37.9 ± 10.9	35.0 ± 9.6	2.1	0.03
Years of Education	8.9 ± 2.2	9.2 ± 2.2	8.6 ± 2.1	2.1	0.04
Diagnosed w/Psychiatric Disorder	*67.0%*	*66.9%*	*67.1%*	*.002*	*0.96*
Headache Frequency (Headaches Days/Month)	17.4 ± 7.8	17.7 ± 7.7	16.8 ± 8.0	0.67	0.50
Headache Severity	.98 ± 0.54	0.98 ± 0.55	0.96 ± 0.53	0.17	0.86
Headache Disability Inventory	26.1 ±11.9	26.4 ± 10.9	25.8 ± 13.1	0.41	0.68
Headache Specific Quality of Life	31. ± 15.7	31.7 ± 14.5	32.0 ± 17.1	0.15	0.88
Being Caucasian	60.2%	57.2%	42.8%	10.46	0.001
Diagnosed with Chronic Migraine (with or without aura)	24.4%	28.68%	27.6%	1.6	0.20
Diagnosed with Episodic Migraine (with or without aura)	45.2%	50.3%	40.1%	2.9	0.08
Diagnosed with Chronic Tension-Type Headache	17.3%	10.6%	23.9%	8.7	0.003
Diagnosed with Episodic Tension-Type Headache	2.12%	2.21%	2.11%	0.0	0.99
Diagnosed with Medication Overuse Headache	6.3%	2.8%	9.8%	5.8	0.02

Table 4: Preventive Medications Prescribed to Patients by Race

Treatment	Overall Sample (n=223)	Caucasians (n=79)	African Americans (n=33)	χ^2	p-value
Preventive medication					
Antidepressant	34.8%	31.6%	42.4%	1.54	0.21
Anticonvulsant	42.4%	40.5%	42.4%	0.12	0.73
Beta Blocker	7.2%	7.6%	6.6%	0.05	0.81
Calcium Blocker	3.6%	2.5%	6.1%	0.92	0.33
Other (B12, MAO, NSAs)	25.0%	26.6%	21.2%	0.25	0.65

Figure 1: Study Design

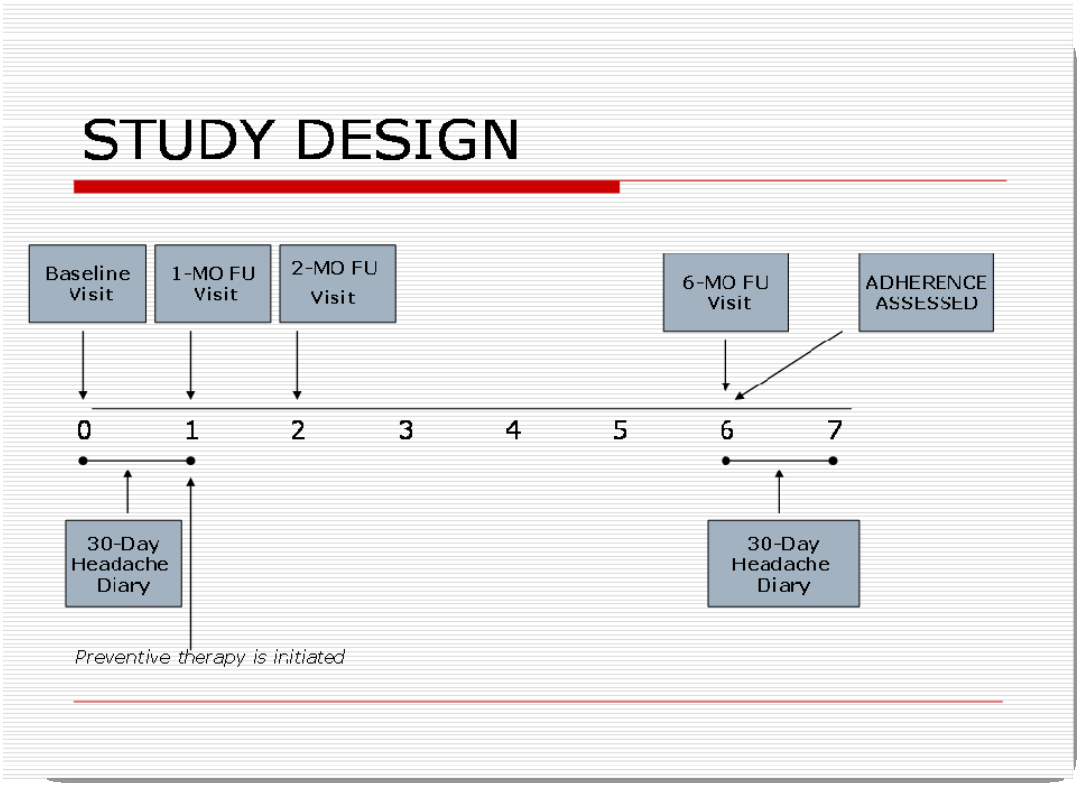
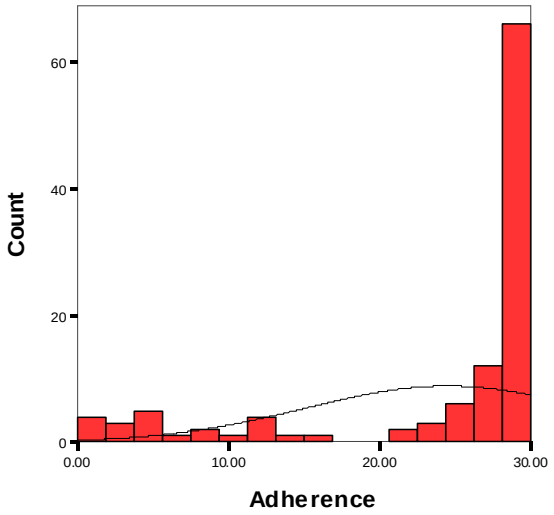
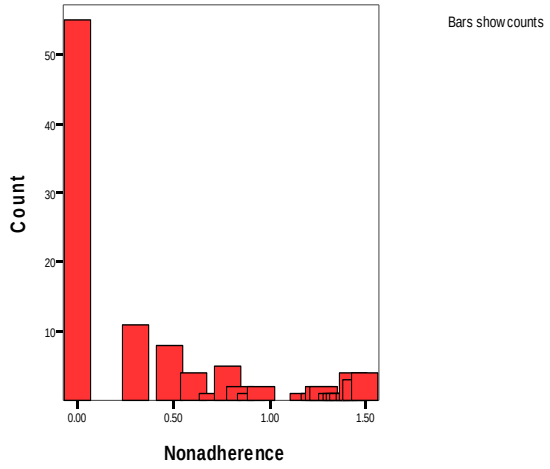


Figure 2: Transformation of Adherence Variable

Descriptive Statistics

	N	Mean	Std. Deviation	Skewness		Kurtosis	
	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
Adherence	111	24.4234	9.37361	-1.609	.229	1.041	.455
Nonadherence	111	.4411	.54157	.854	.229	-.808	.455
Valid N (listwise)	111						





APPENDIX B: BIVARIATE CORRELATION FOR AFRICAN AMERICAN AND CAUCASIAN PATIENTS

Correlation: African American and Caucasians * p < .20, #p <.05

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)
(1) Nonadherence	1	.008	-.069	.002	.595*	-.479*	-.244*	-.330*	.051	.267*	-.007	.052	-.107	-.140
(2) Age	.041	1	-.377#	-.150	.164	.026	.406#	.467#	.434	-.097	-.060	.074	-.057	.058
(3) Education	.102	-.132	1	.403#	-.348	.258	-.228	-.269	-.035	.193	-.093	.030	.214	-.451#
(4) Income	.084	.364#	.327#	1	.221	.199	-.117	-.225	.127	.016	-.013	.036	.249	-.097
(5) Tension-Type	-.038	-.151	.022	-.143	1	-.745#	-.016	-.042	-.025	.325	-.024	.253	-.066	-.149
(6) Migraine	.100	.022	.032	.154	-.672#	1	-.136	.055	.174	-.108	.148	.280	.108	.067
(7) Frequency	.121	.012	-.080	.043	.327#	-.374#	1	.837#	.064	-.241	.362#	.134	-.140	.290
(8) Severity	.113	-.058	-.122	-.116	.263#	-.357#	.909#	1	-.105	-.193	.224	.014	-.347	.276
(9) Self-Efficacy	-.020	.115	.078	.094	-.071	.191	-.087	-.108	1	-.147	.049	.030	.507#	-.033
(10) Social-Support	.061	-.139	.190	.125	-.352#	.246#	-.137	-.096	.217	1	-.350#	.360#	.189	-.078
(11) LOC-Chance	-.045	.135	-.236#	-.161	-.174	.200	.052	.106	-.133	-.099	1	.086	-.099	.208
(12) LOC-Health	-.065	.256#	-.104	.075	-.181	.235#	-.258#	-.244#	.215	-.086	.239#	1	.294	-.053
(13) LOC-Internal	-.057	-.014	.093	.069	-.010	.087	.148	.169	.363#	-.080	.036	.389#	1	.071
(14) Psychiatric Co	.200*	-.068	-.045	-.085	.061	-.024	.124	.162	.000	-.193	.178	.038	.150	1

APPENDIX C: BINARY LOGISTIC REGRESSION ANALYSIS (SUPPLEMENTAL)

Summary of Binary Logistic Regression Analysis for Variables Predicting Non-adherence to Preventive Headache Medication for African American (n=33) and Caucasian (n = 79) Headache Patients.

Predictors			
Caucasians	**B**	**SE B**	**E^B**
Psychiatric	-.629	.585	.533
Constant	-1.13	.383	.321
X^2 = 1.18			
df = 1			
Predictors			
African Americans	**B**	**SE B**	**E^B**
Tension-Type	3.52	1.95	.030
Migraine	-1.11	1.52	3.04
Severity	-3.47*	1.73	.031
Social Support	-.030	.031	.970
Constant	6.58	4.15	723.89
X^2 = 14.99**			
df = 4			

*p = .045, ** p = .005

APPENDIX D: PRIME MD

1. Within each module, proceed sequentially from question to question unless instructed either to skip to another question or to EXIT from the module. Remember: Always proceed to the next question unless you are instructed to go elsewhere.
2. Diagnoses are boxed.
3. EXIT means to exit from the module you are in. Then proceed either to the next module that needs to be evaluated or to the Summary Sheet on the last page.

INTRODUCTION TO PATIENT:

Now, I'll be asking you some question to help me understand any other symptoms you might be having. I'll be making some notes as we go along.

PSYCHIATRIC HISTORY:

A. Have you ever seen your doctor about difficulty with nerves, tensions, or depression?

☐ If yes, what, when, how long, treatment? _____

_____

_____

☐ No

B. Do you currently have any difficulties with nerves, tension, or depression?

☐ Yes, what? _____ (ask below questions 1,2, and 3)

☐ No

If participant responded *yes* to question *B,* query for the following:

1. Has your doctor ever prescribed you tablets for this difficulty?

☐ Yes, what_____ ☐ No

If answer yes to question 1, ask following question. If not, go to question 3.

2. Are you still currently taking medication for this problem?

☐ Yes, what_____ ☐ No

3. Are you currently seeing a counselor/therapist for this difficulty?

☐ Yes ☐ No

MOOD MODULE

For the last 2 weeks, have you had any of the following problems nearly every day?

1. Trouble falling or staying asleep, or sleeping too much? Yes No

2. Feeling tired or having little energy? Yes No

3. Poor appetite or overeating? Yes No

4. Little interest or pleasure in doing things? Yes No

5. Feeling down, depressed, or hopeless? Yes No

6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down? Yes No

7. Trouble concentrating on things, such as reading the newspaper or watching television? Yes No

8. Being so fidgety or restless that you were moving around a lot more than usual?
If no*:* What about the opposite – moving or speaking so slowly that other people could have noticed? Yes No
Count as Yes *if Yes to either question, or if psychomotor agitation or retardation observed during the interview.*

9. In the last 2 weeks, have you had thoughts that you would be better off dead or of hurting yourself in some way? ***If yes****:* Tell me about it. \Yes No

10. Are answers to five or more of #1 to #9 Yes (one of which is #4 or #5)? Major Depressive Disorder **Go to #12** *No*

MOOD MODULE cont.

11. Have you ever had a time when you were either much more down or depressed, or had even less interest or pleasure in doing things?
If yes*:* At that time, did you have many of the problems that I just asked you about, like trouble sleeping, concentrating, feeling tired, poor appetite, little interest in things? Yes- Partial Remission of Major Depressive Disorder No
Count as Yes only *if, in the past, patient probably had Five of symptoms #1 to #9 and acknowledges some Current depressed mood or little interest or pleasure.*

12. Over the last 2 years, have you often felt down or depressed, or had little interest or pleasure in doing things?
Count Yes only if Yes to: Was that on more than half the days over the last 2 years? Yes Go to #14 No-

13. In the last 2 years, has that often made it hard for you Yes- Dysthymia N0
14. to do your work, take care of things at home, or get along with other people?

15. Was major depression (including partial remission) Diagnosed at #10 or #11? Yes- Go to # 16 No

16. Are answers to two or more of #1 to #9 Yes (one of which is #4 or #5)? Yes Minor No- Exit

17. Did a doctor ever say you were manic-depressive or give you Lithium or Depakote? Yes Add No
If yes*:* When was that? Do you know why?

_____

_____

18. Are current depressed symptoms probably due to the biological effects of a physical disorder, medication, or other drug? Yes → Add R/O Depressive → Exit; No → Exit

ANXIETY MODULE

18. During the PAST MONTH have you had an anxiety attack (suddenly feeling fear or panic)? Yes No → Go to #34a

19.You indicated that you had an anxiety attack this month. Has this ever happened before? Yes No → Go to #34a

20.Does the attack sometimes come <u>suddenly out of the blue?</u> **If unclear**: In situations where you don't expect to be nervous or uncomfortable? Yes No → Go to #34a

21.Have you worried a lot about having another attack or worried that there was something wrong with you? Yes No → Go to #34a
Count as Yes if ever present.

Think about your last really bad attack.

Go to #33 as soon as you have checked four symptoms that occurred during the patient's last bad attack.

22. ↑ Were you short of breath?

23. ↑ Did your heart race, pound, or skip?

24. ↑ Did you have chest pain or pressure?

25. ↑ Did you sweat?

26. ↑ Did you feel as if you were choking?

27. ↑ Did you have hot flashes, or chills?

28. ↑ Did you have nausea, or an upset stomach, or the feeling that you were going to have diarrhea?

29. ↑ Did you feel dizzy, unsteady, or faint?

30. ↑ Did you have tingling or numbness in parts of your body?

31. ↑ Did you tremble or shake?

32. ↑ Were you afraid you were dying?

33. *Are four or more of #22 to #32 checked* Yes- Panic Disorder No- Anxiety Disorder NOS

34a. Have you felt nervous, anxious, or on edge <u>on more than half the days in the last month?</u> Yes No

34b. Have you been worrying about a lot of different things <u>on more than half the days in the last month?</u> Yes- No- **Exit**

In the last month, have you <u>often</u> been bothered by any of these problems?

35. ☐ Feeling restless so that it is hard to sit still?

36. ☐ Getting tired very easily?

37. ☐ Muscle tension, aches, or soreness?

38. ☐ Trouble falling asleep or staying asleep?

39. ☐ Trouble concentrating on things, such as reading or watching TV?

40. ☐ Becoming easily annoyed or irritated?

41. *Are three or more of #35 to #40 checked?* Yes No- **Go to #44**

42. In the last month, have these problems made it hard for you to do your work, take care of things at home, or get along with other people? Yes No- Anxiety Disorder NOS **Go to #45**

43. In the last 6 months, have you been worrying <u>a great deal</u> about different things?
Count as Yes only if also Yes to: *Has this been on more than half the days in the last 6 months?* Yes No- Anxiety Disorder NOS **Go to #45**

44. When you are worrying this way, do you find that you can't stop? Yes- Generalized Anxiety Disorder **Go to #45** No- Anxiety Disorder NOS **Go to #45**

45. *Has Panic Disorder or Anxiety Disorder NOS been Diagnosed?* Yes No- **Exit**

46. *Are current anxiety symptoms probably due to biological effects of a physical disorder, medication, or other drug?* Yes- Add R/O Anxiety Disorder Due to Physical Disorder, Medication or Other Drug **Exit** No- **Exit**

Alcohol Module

47. Do you drink alcohol? Yes No- **Exit**

During the PAST MONTH…

48. Have you thought you should cut down on your your drinking of alcohol? Yes No

49. Has anyone complained about your drinking? Yes No

50. Have you felt guilty or upset about your drinking? Yes No

51. Was there ever a single day in which you had more drinks of beer, wine or liquor? Yes No

52. Has a doctor <u>ever</u> suggested that you stop drinking because of a problem with your health? Yes No

Count as Yes if has continued to drink in the last 6 months after doctor suggested stopping.

Have any of the following happened to you <u>more than one time</u> in the last 6 months?

53. Were you drinking, high from alcohol, or hung over while you were working, going to school, or taking care of other responsibilities? Yes No

54. What about missing or being late for work, school, or other responsibilities because you were drinking or hung over? Yes No

Alcohol Module cont.

55. What about having a problem getting along with other people while you were drinking? Yes No

56. What about driving a car after having several drinks or after drinking too much? Yes No

57. *Is at least one of #48 to #52 Yes- OR- do responses for questions #53 to #56 indicate patient has probably had a significant problem with alcohol within the past 6 months?*

Yes- Probable Alcohol Abuse or Dependence **Exit**

No- **Exit**

EATING DISORDER MODULE

58. During the PAST MONTH, have you been bothered by your eating being out of control? Yes No- **Exit**

59. Did you often eat, within any 2-hour period, what most people would regard as an unusually large amount of food? Yes No- **Exit**

60. When you eat this way, do you often feel that you Can't control what or how much you eat? Yes No- **Exit**

61. Has this been as often, on average, as twice a week for the last 3 months? Yes No- **Exit**

62. Do you often make yourself vomit, or take more than twice the recommended dosage of laxatives, to avoid gaining weight after eating this way? Yes No- **Exit**

63. Has this been as often, on average, as twice a week for for the last 3 months? Yes- Bulimia Nervosa, Purging Type **Exit** No

64. Do you often fast- no eat anything at all for at least 24 hours- or exercise for more than an hour specifically in order to avoid gaining weight after eating this way? Yes No- Binge Eating Disorder **Exit**

65. Has this been as often, on average, as twice a week for the last 3 months? Yes- Bulimia Nervosa, nonpurging Type **Exit** No- Binge Eating Disorder **Exit**

Summary Sheet

Patient ID#_____

Summary Diagnosis
Check all the diagnoses made in the modules.
¡ No diagnosis made in any modules

Mood

¡ Major Depressive Disorder (296.20)
¡ Partial Remission of Major Depressive Disorder (296.25)
¡ Dysthymia (300.4)
¡ Minor Depressive Disorder (311)
¡ R/O Bipolar Disorder (if confirmed: 296.50)
¡ R/O Depressive Disorder Due to Physical Disorder, Medication, or Other Drug
(If confirmed and due to physical disorder: 293.83)
(If confirmed and due to medication or other drug: 295.84)

Anxiety

¡ Panic Disorder (300.01)
¡ Generalized Anxiety Disorder (300.02)
¡ Anxiety Disorder NOS (300.00)
¡ R/O Anxiety Disorder Due to Physical Disorder, Medication, or other Drug
(If confirmed and due to physical disorder: 293.89)
(If confirmed and due to medication or other drug: 292.89)

Alcohol

¡ Probable Alcohol Abuse/Dependence
(If confirmed Alcohol Abuse: 305.00)
(If confirmed Alcohol Dependence: 303.9)

Eating Disorder

¡ Binge Eating Disorder (307.50)
¡ Bulimia Nervosa, Purging Type (307.51)
¡ Bulimia Nervosa, Nonpurging Type (307.51)

APPENDIX E: DAILY HEADACHE DIARY

Baseline and 6 month Follow-up ID#_____

Project Insight:Headache Diary

Day 1_____ (mo/dy/yr)

Headache severity is: (Check one ☐)	**Ability to perform activities: (Check one ☐)**	**Associated symptoms: (Check all that apply ☐)**
No headache……☐	Normal……☐	Sensitivity to light……☐
Mild pain……☐	Mildly impaired……☐	Sensitivity to sound……☐
Moderate pain……☐	Severely impaired……☐	Nausea……☐
Severe pain……☐	Unable to do activities, requires bed rest..☐	Vomiting……☐
Did you take your preventive medication today?	☐**yes** ☐ **no**	☐ **not part of my TX regimen**

Day 2_____ (mo/dy/yr)

Headache severity is: (Check one ☐)	**Ability to perform activities: (Check one ☐)**	**Associated symptoms: (Check all that apply ☐)**
No headache……☐	Normal……☐	Sensitivity to light……☐
Mild pain……☐	Mildly impaired……☐	Sensitivity to sound……☐
Moderate pain……☐	Severely impaired……☐	Nausea……☐
Severe pain……☐	Unable to do activities, requires bed rest..☐	Vomiting……☐
Did you take your preventive medication today?	☐**yes** ☐ **no**	☐ **not part of my TX regimen**

Day 3_____ (mo/dy/yr)

Headache severity is: (Check one ☐)	**Ability to perform activities: (Check one ☐)**	**Associated symptoms: (Check all that apply ☐)**
No headache……☐	Normal……☐	Sensitivity to light……☐
Mild pain……☐	Mildly impaired……☐	Sensitivity to sound……☐
Moderate pain……☐	Severely impaired……☐	Nausea……☐
Severe pain……☐	Unable to do activities, requires bed rest..☐	Vomiting……☐
Did you take your preventive medication today?	☐**yes** ☐ **no**	☐ **not part of my TX regimen**

Day 4_____ (mo/dy/yr)

Headache severity is: (Check one ☐)	**Ability to perform activities: (Check one ☐)**	**Associated symptoms: (Check all that apply ☐)**
No headache……☐	Normal……☐	Sensitivity to light……☐
Mild pain……☐	Mildly impaired……☐	Sensitivity to sound……☐
Moderate pain……☐	Severely impaired……☐	Nausea……☐
Severe pain……☐	Unable to do activities, requires bed rest..☐	Vomiting……☐
Did you take your preventive medication today?	☐**yes** ☐ **no**	☐ **not part of my TX regimen**

APPENDIX F: LOCUS OF CONTROL SCALE

The HSLC is a 33 item questionnaire that has responses ranging from 1 (strongly disagree) to 5 (strongly agree). The HSLC consists of 3 subscales: Health Care Professionals Locus of Control, Internal Locus of Control, and Chance Locus of Control

Note that to create a total I/E score items on either the Internal subscale or on the two External subscales (Health Care Professionals & Chance) need to be reverse scored. In previous reports using this scales items on the Internal subscale have been reverse scored so that higher scores indicate a more external LOC.

1.Scoring the Health Care Professionals subscale: calculate the sum for items **6, 8, 10, 12, 14, 15, 16, 22, 24, 27, 30.**	2. Scoring the Internal subscale: calculate the sum for items **2, 4, 5, 7, 11, 17, 19, 21, 26, 28, 32.**	3. Scoring the Chance subscale: calculate the sum for items: **1,3,9,13,18,20, 23,25,29,31,33.**

Instructions: This is a questionnaire designed to determine the way in which people view certain important headache-related issues. Each item is a belief statement with which you may agree or disagree. Beside each statement are numbers which correspond to a scale on which you may rate the extent to which you agree or disagree with each item. The values range from "Strongly Disagree" = 1 to "Strongly Agree" = 5. Circle the number that represents the extent to which you disagree or agree with the statement. Please make sure that you answer every item and that you circle only one number per item. This is a measure of your personal beliefs; there is no right or wrong answers.

1 = Strongly Disagree
2 = Moderatley Disagree
3 = Neutral
4 = Moderately Agree
5 = Strongly Agree

1.When I have a headache, there is nothing I can do to affect its course 1 2 3 4 5

2. I can prevent some of my headaches by avoiding certain stressful situations 1 2 3 4 5

3.I am completely at the mercy of my headaches… 1 2 3 4 5

4. I can prevent some of my headaches by not getting emotionally upset 1 2 3 4 5

5.If I remember to relax, I can avoid some of my headaches 1 2 3 4 5

6.Only my doctor can give me ways to prevent my headaches 1 2 3 4 5

7.My headaches are sometimes worse because I am overactive 1 2 3 4 5

8.My headaches can be less severe if medical professionals (doctors, nurses, etc.) take proper care of me 1 2 3 4 5

9.My headaches are beyond all control 1 2 3 4 5

10.My doctor's treatment can help my headaches 1 2 3 4 5

11.When I worry or ruminate about things, I am more likely to get headaches 1 2 3 4 5

12.Just seeing my doctor helps my headaches 1 2 3 4 5

13.No matter what I do, if I am going to get a headache, I will get a headache 1 2 3 4 5

14.Having regular contact with my physician is the best way for me to control my headaches 1 2 3 4 5

15.When I have headaches, I should consult a medically trained professional 1 2 3 4 5

16.Following the doctor's medication regimen is the best way for me not to be laid-up with a headache 1 2 3 4 5

17.When I drive myself too hard, I get headaches 1 2 3 4 5

18.Luck plays a big part in determining how soon I will recover from a headache 1 2 3 4 5

19.By not becoming agitated or overactive, I can prevent many headaches 1 2 3 4 5

20.My not getting headaches is largely a matter of good fortune 1 2 3 4 5

21.My actions influence whether I have headaches 1 2 3 4 5

22.I usually recover from a headache when I get proper medical help 1 2 3 4 5

23.I'm likely to get headaches no matter what I do 1 2 3 4 5

24.If I don't have the right medication, my headaches will be a problem 1 2 3 4 5

25.Often I feel that no matter what I do, I will still have headaches 1 2 3 4 5

26.I am directly responsible for getting some of my headaches 1 2 3 4 5

27.When my doctor makes a mistake, I am the one to suffer with headaches 1 2 3 4 5

28.My headaches are worse when I'm coping with stress 1 2 3 4 5

29.When I get headaches, I just have to let nature run its course 1 2 3 4 5

30.Health professionals keep me from getting headaches 1 2 3 4 5

31.I'm just plain lucky for a month when I don't get headaches 1 2 3 4 5

32.When I have not been taking proper care of myself, I am likely to experience headaches 1 2 3 4 5

33.It's a matter of fate whether I have a headache . 1 2 3 4 5

APPENDIX G: SELF-EFFICACY SCALE

Headache Management Self-Efficacy Scale

Instructions: You will find below a number of statements related to headaches. Please read each statement carefully and indicate how much you agree or disagree with the statement by circling a number next to it. Use the following scale as a guide.

Strongly Disagree	Moderately Disagree	Slightly Disagree	Neither Agree nor Disagree	Slightly Agree	Moderately Agree	Strongly Agree
1	2	3	4	5	6	7

(1) I can keep even a bad headache from disrupting my day
By changing the way I respond to the pain……1 2 3 4 5 6 7
(2) When I'm in some situations, nothing I do will
Prevent headaches……...1 2 3 4 5 6 7
(3) I can reduce the intensity of a headache by relaxing…....1 2 3 4 5 6 7
(4) There are things I can do to reduce headache pain…..…..1 2 3 4 5 6 7
(5) I can prevent headaches by recognizing headache
triggers……1 2 3 4 5 6 7
(6) Once I have a headache, there is nothing I can do to control
it……..1 2 3 4 5 6 7
(7) When I'm tense, I can prevent headaches by controlling
(8) my tension…….1 2 3 4 5 6 7
(9) Nothing I do reduces the pain of a headache……...1 2 3 4 5 6 7
If I do certain things every day, I can reduce the number of
Headaches I will have……..1 2 3 4 5 6 7
(10) If I can catch a headache before it begins, I can stop
it……...1 2 3 4 5 6 7
(11) Nothing I do will keep a mild headache from turning
into a bad headache…….1 2 3 4 5 6 7
(12) I can prevent headaches by changing how I respond to
stress……...1 2 3 4 5 6 7
(13) I can do things to control how much my headaches
interferes with my life……1 2 3 4 5 6 7
(14) I cannot control the tension that causes my
headaches……..……..1 2 3 4 5 6 7
(15) I can do things that will control how long a headache
lasts……..……...1 2 3 4 5 6 7

(16) Nothing I do will keep a bad headache from disrupting my day……1 2 3 4 5 6 7
(17) When I'm not under a lot of stress, I can prevent many headaches……1 2 3 4 5 6 7
(18) When I sense a headache is coming, there is nothing I can do to stop it……..…….1 2 3 4 5 6 7
(19) I can keep a mild headache from disrupting my day by Changing the way I respond to the pain…….……..1 2 3 4 5 6 7
(20) If I am under a lot of stress, there is nothing I can do to Prevent headaches…..……1 2 3 4 5 6 7
(21) I can do things that make a headache seem not so bad…….1 2 3 4 5 6 7
(22) There are things I can do to prevent headaches…..……1 2 3 4 5 6 7
(23) If I am upset, there is nothing I an do to control the pain of a headache……...1 2 3 4 5 6 7
(24) I can control the intensity of headache pain…….…...1 2 3 4 5 6 7
(25) I can do things to cope with my headaches…….....1 2 3 4 5 6 7

APPENDIX H: SOCIAL SUPPORT SCALE

Multidimensional Scale of Perceived Social Support

Instructions: Read each statement carefully. Indicate how you feel about each statement by circling the appropriate number suing the following scale:

1 = Very strongly disagree
2 = Strongly disagree
3 = Mildly disagree
4 = Neurtral
5 = Mildly agree
6 = strongly agree
7 = very strongly agree

(1) There is a special person who is around when I am in need….1 2 3 4 5 6 7
(2) There is a special person with whom I can share joys and sorrows……....1 2 3 4 5 6 7
(3) My family really tries to help me……..1 2 3 4 5 6 7
(4) I get the emotional help and support I need from my family…1 2 3 4 5 6 7
(5) I have a special person who is a real source of comfort to me.1 2 3 4 5 6 7
(6) My friends really try to help me……1 2 3 4 5 6 7
(7) I can count on my friends when things go wrong……1 2 3 4 5 6 7
(8) I can talk about my problems with my family……..1 2 3 4 5 6 7
(9) I have friends with whom I can share my joys and sorrows….1 2 3 4 5 6 7
(10) There is a special person in my life who cares about my feelings……....1 2 3 4 5 6 7
(11) My family is willing to help me make decisions……1 2 3 4 5 6 7
(12) I can talk about my problems with my friends……....1 2 3 4 5 6 7

APPENDIX I: DEMOGRAPHIC SURVEY

ID#_____

Demographics.

(1) What is your gender?
- o Male What is your DOB__/__/__Age___
- o Female

(2) What ethnic background or race do you consider yourself?
- o White/Non-Hispanic
- o Hispanic/Latino
- o African American/Non-Hispanic
- o African American-Hispanic
- o Asian or Pacific Islander
- o Native American
- o Other_____(Specify)

(3) What is the highest grade or year of school that you have completed?

6 7 8 9 10 11 12 13 14 15 16 17 18 19 20+
Elementary High School Trade/College Graduate School

(4) What is your current employment status? (Mark all that apply)
- o Working full-time (35 or more hours per week)
- o Working part-time (fewer than 35 hours per week)
- o Unemployed
- o Student (either full or part-time
- o Social Security Disability
- o Applying for Social Security
- o Other (Please explain:_____)

(5) What figure is closest to your current annual income?
- o $0-$20,000
- o $20,001-$40,000
- o $40,001-$60,000
- o $60,001-$80,000
- o $80,001-$100,000
- o Over $100,000

(6) Do you have insurance? (Please select all that apply)
- o HMO
- o PPO
- o Private
- o SSI/SSD
- o Out of pocket
- o Other_____

APPENDIX J: QUALITY OF LIFE SCALE

Modified Migraine Specific Quality of Life

The purpose of this scale is to identify difficulties that you may be experiencing because of your headaches. Please circle **yes**, **sometimes**, or **no** to each item. Answer each item as it pertains to your headache only.

1. Because of my headaches, I feel handicapped	No	Sometimes	Yes
2. Because of my headaches, I feel restricted in performing my routine daily activities	No	Sometimes	Yes
3. No one understands the effect that my headaches have on my life	No	Sometimes	Yes
4. I restrict my recreational activities (e.g., sports, hobbies) because of my headaches	No	Sometimes	Yes
5. My headaches make me angry	No	Sometimes	Yes
6. Sometimes I feel that I am going to lose control because of my headaches	No	Sometimes	Yes
7. Because of my headaches, I am less likely to socialize	No	Sometimes	Yes
8. My spouse (significant other), or family and friends, have no idea what I am going through because of my headaches	No	Sometimes	Yes
9. My headaches are so bad that I feel I am going to go insane	No	Sometimes	Yes
10. My outlook on the world is affected by my headaches	No	Sometimes	Yes
11. I am afraid to go outside when I feel that a headache is starting	No	Sometimes	Yes
12. I feel desperate because of my headaches	No	Sometimes	Yes
13. I am concerned that I am paying penalties at work or at home because of my headaches	No	Sometimes	Yes
14. My headaches place stress on my relationships with family or friends	No	Sometimes	Yes
15. I avoid being around people when I have a headache	No	Sometimes	Yes
16. I believe my headaches are making it difficult for me to achieve my goals in life	No	Sometimes	Yes
17. I am unable to think clearly because of my headaches	No	Sometimes	Yes
18. I get tense (e.g. muscle tension) because of my headaches	No	Sometimes	Yes

19. I do not enjoy social gatherings because of my headaches	No	Sometimes	Yes
20. I feel irritable because of my headaches	No	Sometimes	Yes
21. I avoid traveling because of my headaches	No	Sometimes	Yes
22. My headaches make me feel confused	No	Sometimes	Yes
23. My headaches make me feel frustrated	No	Sometimes	Yes
24. I find it difficult to read because of my headaches	No	Sometimes	Yes
25. I find it difficult to focus my attention away from my headaches and on other things	No	Sometimes	Yes