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Further Validation of an Individualized Migraine Treatment Satisfaction Measure

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ABSTRACT

Objective: To assess individualized satisfaction with migraine treatment, patient expectations, importance rankings, treatment outcomes, and overall satisfaction were combined using a four-part conceptual model. This article describes the measurement properties of the Migraine Treatment Satisfaction Measure (MTSM) using participants from a randomized controlled trial evaluating a Headache Management Program (HMP).

Methods: Participants completed the first two parts of the MTSM upon enrollment and the final two parts at 6 months. Internal consistency reliability was computed within each of the four modules. Discriminant validity was ascertained using Migraine Disability Assessment Survey (MIDAS), Patient Health Questionnaire-9, and MSFB scores. Convergent validity was established by hypothesized positive correlations between MTSM scores, Medical Outcomes Study Short-Form (SF-36), MIDAS, and Migraine Symptom Frequency Bother (MSFB).

Results: In total, 124 participants (mean age 45.4 years, 75% women, 59.7% Caucasian) enrolled. Internal consistency for expectations, importance rankings, outcomes, and satisfaction measures was 0.83, 0.95, 0.86, and 0.95, respectively. As the severity of depression increased, MTSM scores decreased significantly. ANOVA between MTSM scores and symptom bothersomeness and symptom frequency tertiles showed a significant decrease in satisfaction in the moderate-to-severe groups. MTSM scores showed expected associations with MSFB scores (–0.301; $P < 0.01$), MIDAS (–0.267; $P < 0.01$), general health (0.253; $P < 0.05$), mental health (0.217; $P < 0.05$), and vitality subscales of SF-36 (0.214; $P < 0.05$). Patients in the HMP reported significantly higher MTSM scores (43.2 vs. 31.4; $P < 0.001$). Patients on triptans reported a significantly higher satisfaction compared to patients on analgesics (39.5 vs. 32.9; $P < 0.05$).

Conclusion: The MTSM is a valid and reliable patient-reported outcome that can be used to evaluate differences in treatment satisfaction associated with migraine therapies.

Keywords: migraine headaches, satisfaction with treatment.

Introduction

The Migraine Treatment Satisfaction Measure (MTSM) was developed to address the need for a standardized and individualized approach to the assessment of satisfaction with migraine treatment. An earlier conceptual model [1] proposed the measurement of patient satisfaction as an indicator of healthcare quality. Research supports the relationship between patient satisfaction and treatment-related behaviors, such as greater satisfaction with care leading to better adherence to treatment [2–6].

Patients, families, providers, insurers, and administrators all have an interest in promoting interventions and medications that are effective, safe, and convenient. Several tools have been developed and tested for use in measuring patient satisfaction with drug therapy [7–9] and multidimensional measures have been developed to measure aspects of care that are important to people with migraines [10–14].

Qualitative work shows, however, that persons with migraine headaches consistently express a variety of expectations about the attributes of migraine medications they are prescribed: effective pain relief (complete or rapid), duration of pain relief, low rate of migraine recurrence, route of administration (how easy the drug is to take), the number of doses needed to achieve pain relief, few side effects, how fast the medication allows return to normal activities, and effectiveness of relief of associated symptoms [10,11,14,15]. Existing measures fail to detail the specific aspects of a treatment that may be associated with satisfaction or dissatisfaction and therefore generally have lower reliability and validity compared with multidimensional measures [9]. Furthermore, distributions of satisfaction ratings are commonly positively skewed with a majority of patients expressing high satisfaction.

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Patient satisfaction is an affective response incorporating the cognitive evaluation of a treatment's performance. Expectations of performance or outcome are a key variable in determining satisfaction measurement in psychology and in business. Business customers are seen as having different expectations for a service or product and there is a zone of tolerance or gap between the adequate and desired aspects of the product. The service quality gap [16] is the gap between the expected ("what I want") and the perceived ("what I get").

Previous qualitative development [17] resulted in an approach for measuring individual patient satisfaction with treatment for migraine headaches in a way that puts a value on drivers of satisfaction. This approach identified patient expectations as modified by patient values and experience as key influences on perceived satisfaction with treatment. Underlying patient preferences (driven by multiple concepts such as cost, previous treatment experience, lifestyle, etc.) were represented in the model as an important generator of a patient's expectations about their treatment.

Nine attributes of treatment were identified and included in the measurement model (Patrick et al. 2003) [17]. These attributes, identified by patients in qualitative research, were as follows: 1) to have total relief from my migraine pain; 2) to have my migraine relieved quickly; 3) during a migraine, to be free from pain for a long time; 4) other than pain, to have no additional migraine symptoms that bother me; 5) to have confidence this treatment will work; 6) to have migraines cause less disruption in my life; 7) to have my migraine relieved with just one dose of medication; 8) as the medication wears off, to have freedom from migraine pain returning; and 9) to have a treatment that is easy to use. The measurement model for this four-part assessment contains four distinct measures: 1) expectations about the nine attributes of treatment; 2) importance rankings of the nine attributes; 3) patient-reported outcome for each attribute after the experience of a new treatment; and 4) an overall evaluation of satisfaction with treatment [17]. This earlier project produced the initial multistep approach to evaluating treatment satisfaction as an outcome and early evaluation results suggested the need for further application in a clinical trial to complete its testing.

The Duke Center for Clinical Health Policy Research conducted a randomized controlled trial of Headache Management Programs (HMP) at three clinical sites, with a grant from the Agency for Health Care Research and Quality (AHRQ). The trials were aimed at reducing headache-related disability, improving process of care, and reducing management costs for patients with chronic headache. The MTSM was included in the measurement package for this community headache management intervention to obtain the data needed to evaluate its measurement properties.

Objectives

The primary aim of this article is to report the further psychometric performance of the multicomponent MTSM using data generated from a subset of participants in a larger, randomized controlled trial of HMP at Duke University.

Methods

In conjunction with their participation in the larger, multisite study, at least 100 patients with migraine headaches were targeted for recruitment into this additional validation study. Once the patients met the eligibility criteria established in the larger AHRQ grant study and were enrolled in the larger trial, they were asked whether they were willing to complete an additional survey at baseline and at 6 months.

The option of participating in this additional validation study was presented to both intervention and control group patients. For intervention group patients, this occurred when they attended the initial group educational session that preceded individual treatment of the HMP program. For control group patients, this was concurrent with their baseline measures for the study. Patients who were willing to participate were asked to sign a consent form and were given the baseline MTSM (by mail) to self-administer, complete and return. Upon completion of the baseline measure, they received $25 from the study site for their participation. At 6 months, patients were mailed the follow-up MTSM measure. Upon receipt of this completed form, they received another $25.

Patients were included in the AHRQ study if they were 21 years of age or older, had chronic headache thought to be of tension-type, migraine, or mixed etiology, intended to continue general medical care at their current location for the following 12 months; had a Migraine Disability Assessment Survey (MIDAS) score greater than 5, and were referred by their primary care physician as having frequent and/or difficult-to-manage headaches. Patients were excluded from enrollment if they were not currently receiving treatment from a neurologist, and/or not currently receiving treatment from a headache clinic.

Measures

The MTSM is a four-part assessment [17]:

(Part 1) The Expectations of Treatment for Migraines (TE-M). The nine items in the TE-M correspond to nine main attributes of treatment satisfaction for migraine, and are worded to express the attribute as an expectation. Each item has a 5-point response scale unique to what one would expect in a treatment with 1 being the worst case scenario (i.e., "not relieve my pain at all") and 5 being the best situation (i.e.,

"totally relieve my pain"). This part of the MTSM addresses "ideal expectations."

(Part 2) The Importance Ranking for Migraine Treatment (IR-M). The IR-M uses a set of nine main attributes for participants to rank from most important to least important. A line is drawn from the attribute to a place on a 10-cm rating scale with "As important as can be" at the top to "Not important at all" at the bottom. The intersection of their drawn line and the 10-cm line gets scored on a 0- to 100-point scale. This part of the MTSM addresses "desired expectations" expressed as importance ratings.

(Part 3) The Outcomes of Treatment for Migraines (TO-M). The nine items in the TO-M correspond to the nine main attributes of treatment satisfaction for migraine, and are worded to express the patient's view of their treatment outcome. Each item has a 5-point response scale indicating the actual outcome of the treatment with 1 being the worst-case scenario (i.e., "did not relieve my pain at all") and 5 being the best situation (i.e., "totally relieved my pain"). This part of the MTSM elicits a self-report of treatment outcomes.

(Part 4) The Satisfaction with Migraine Treatment (PST-M). The PST-M contains a set of nine items worded to express the patient's degree of treatment satisfaction that correspond to each of the nine main attributes. Each item has a 0- to 10-point visual analog response scale with 0 being "The most dissatisfied I could be" and 10 being "The most satisfied I could be." This part of the MTSM addresses satisfaction of the actual treatment experience.

The following measures were also included in the study. The Medical Outcomes Study Short-Form (SF-36) [18] is a generic measure of functional status using eight domain scores (physical functioning, physical role limitations, emotional role limitations, social functioning, bodily pain, general mental health, vitality, and general health perceptions). Each domain is scored from 0 "poor health" to 100 "optimal health" [18]. A migraine symptom list was included which was comprised of 15 symptoms known to be associated with migraine headaches. These symptoms (nausea, vomiting, auras, tiredness, dizziness, palpitations, problems concentrating, difficulty communicating, weakness in limbs, tingling in limbs, and increased sensitivity to light, sound, heat, cold, and smell) were suggested by previous qualitative interviews with migraine patients and confirmed by clinician input. Each symptom has seven response options (along with an option of not having the symptom) ranging from 1 "Not at all bothered" to 7 "A very great deal bothered." The final score is the sum of each symptom's bothersomeness response ranging from 0 (not having any symptoms) to 105 (being a very great deal bothered by all 15 symptoms).

The MIDAS. The MIDAS is a seven-item questionnaire used to determine the level of pain and disability caused by headaches and to help health-care professionals find the best treatment [19]. The Patient Health Questionnaire-9 (PHQ-9) is a set of nine symptoms addressing depression and anxiety. Each symptom (based on a recall of 2 weeks) has four response options ranging from 0 "Not at all" to 3 "Nearly every day." The final score is the sum of each symptom's bothersomeness response ranging from 0 (not having any symptoms) to 27 (being a very great deal bothered by all nine symptoms). If respondents score a 5 or greater, they may have symptoms consistent with a depressive condition [20].

Statistical Methods

Patient evaluations were conducted at baseline (using the first two parts of the measure) and at 6 months (for the final two parts of the measure). Once collected by the Duke Center, the validation study data forms were copied and sent to Health Research Associates (Seattle, WA) where they were entered along with accompanying demographic data, various clinical variables, and comorbid conditions. All analyses were performed using SPSS for Windows, Version 10.1 (SPSS, Chicago, IL) [21]. Demographic variables were descriptively analyzed for both the intervention and control arms using *t*-tests for continuous variables and chi-square tests for categorical variables. Psychometric testing of the MTSM was conducted using the scoring procedures developed in the earlier pilot study, and the instrument review criteria developed by the Scientific Advisory Committee of the Medical Outcomes Trust [22]. Standard population and measurement descriptive tables were generated and missing data were evaluated.

Convergent validity involved comparing the measures to other logically related scales or items. If predictions of association are accurate (demonstrate significant correlations), then convergent validity is achieved. To assess convergent validity, a Spearman correlation was used to measure the association between satisfaction with migraine treatment and general health status (SF-36). Because of the primary impact of migraine on life disruption, we hypothesized that the total derived MTSM score will have a strong association (>0.30) with the MIDAS disability scale.

Guttman-Cronbach's alpha was calculated to assess internal consistency reliability for each of the measures. Alpha statistics were used to analyze additive scales to determine whether the items within the scale are highly associated [23]. A minimum correlation of 0.70 is necessary to claim the instrument is internally consistent and it is preferred to have alpha values between 0.80 and 0.90 [24].

Assessing known group's validity involved testing various hypotheses about how we intuitively believe

the MTSM scales should work. For the "known groups" analyses, we looked at treatment satisfaction by levels of symptom severity, frequency and bothersomeness. ANOVAs with Student-Newman-Keuls (SNK) comparisons were performed to assess discriminant validity. Regression analysis was used to identify a proportionate contribution of the difference between outcomes/expectations and the importance rank on the final patient reported level of satisfaction. Sensitivity to change was assessed by examining satisfaction scores by intervention group (HMP vs. control) using *t*-tests to assess group differences.

Scoring Methods

In the previous pilot study, several approaches to scoring were considered. Most options had inherent drawbacks in terms of usability and the numbers required in the data set to develop standardized weights. The most practical approach was defined as one that could build a scoring formula to express the conceptual model, but could be developed on a small set of sample data. The adopted scoring method was driven primarily by the conceptual model and involved a number of weighting assumptions. A regression analysis was used to identify the relative contribution of the differences between expectations and treatment outcomes and between the importance ranking and the final patient-reported level of satisfaction.

Separate regressions were run for each of the nine main attributes. For each attribute, the patient-reported (raw) satisfaction item was entered as the dependent variable and the independent variables were outcomes/expectation item differences and the item responses for importance ranking.

This produced nine pairs of regression coefficients (one for the difference in outcome/expectation and one for the importance rank for each attribute). The final value used for weighting the outcomes/expectation score was derived from averaging the regression coefficients (all of the difference in outcome/expectation for each attribute) and then all the values for the importance rank for each attribute. Therefore, the overall final weighting for the importance ranking came from the process of identifying and averaging these two sets of regression coefficients. Adjusted weight values derived from the regression analysis in this sample were 0.80 and 0.20 for outcomes/expectation difference and importance, respectively.

An exploratory factor analysis with varimax rotation was performed with the nine attribute scores to evaluate the validity of a single overall score for treatment satisfaction. The sensitivity of the scoring method was assessed by comparing the distributions of the global and the derived MTSM satisfaction scores against normal curves.

Scoring Steps

Step 1. A score was calculated using the two self-report parts of the measure for expectations and outcomes. Using the Bland and Altman theory that two measures of the same or highly related theme should be subtracted from one another, expectation (with a 1–5-response option) was subtracted from outcome (also a 1–5-response scale). This number was then transformed to a 0- to 100-point scale with higher scores representing expectations met and lowers scores indicating expectations not met. The resulting variable represented the difference between what a patient thought would happen and what actually happened (expectation modified by treatment experience/outcome). This step operationalizes treatment satisfaction as dependent upon expectations.

Step 2. The adjusted treatment expectations variable (from step 1) and the raw values given by patients for importance ranking were each multiplied by the regression weights. These two values were then summed to represent "modified expectations, adjusted further for importance."

Step 3. The value derived in step 2 was then divided by 10 to create a variable on a 0 to 10 scale that could be used as the final value for modifying the raw satisfaction scores.

Step 4. The derived treatment satisfaction values were generated by multiplying the raw individual satisfaction scores from the fourth part of the measure (Satisfaction items) with the variable created in step 3 (both on 0–10-response scales).

Scoring formula:

$$\text{Attribute Score} = (((\text{out} - \text{exp}) + 4)/(8) * (100) * 0.80 + (0.20 * \text{Imp}))/10 * \text{Satisfaction}$$

Step 5. The final overall MTSM treatment satisfaction score was generated by summing the nine different derived attribute scores generated in step 4. The MTSM score represents patient expectations about their treatment, modified by the treatment experience, weighted by their adjusted importance values, and used as to modify raw satisfaction values and yield a more sensitive expression of overall treatment satisfaction.

Sensitivity to Change

The measurement model calls for a study design where the first two parts of the measure are administered before the onset of a new treatment and the remaining two parts at a later point in time. This allows the MTSM score to reflect a change related to a new treatment. Sensitivity was evaluated by comparing MTSM scores for those receiving and not receiving the management

Table 1 MTSM by MIDAS

Migraine Disability Assessment Survey (MIDAS)	n	Migraine Treatment Satisfaction Score (MTSM) Mean (SD)
Little or no disability	34	39.4 (17.0)
Mild disability	26	40.8 (16.5)
Moderate disability	21	36.1 (13.8)
Severe disability	29	31.7 (14.8)
		F-stat (Sig.) = 1.901 (0.134)

MTSM, Migraine Treatment Satisfaction Measure.

Table 2 MTSM by PHQ-9

Patient Health Questionnaire-9 (PHQ-9)	n	Migraine Treatment Satisfaction Score (MTSM) Mean (SD)
Threshold depression	16	43.2 (16.9)
Mild depression	80	37.9 (15.0)
High depression	16	27.1 (15.7)
		F-stat (Sig.) = 4.728 (0.011)*

*$P < 0.05$.
MTSM, Migraine Treatment Satisfaction Measure.

program. Significant differences were also evaluated across the groups in the management program who were receiving different types of medications.

Results

Population Description

The mean age of the overall sample ($n = 124$) at baseline was 45.4 years (SD ± 11.6); 75% were female and 59.7% were Caucasian. In the intervention arm (HMP), the mean age of the participants was 45.3 (SD ± 11.6) years, 93.3% were women, and 65% of the participants were Caucasian. In the control arm (no HMP), the mean age of the participants was 45.4 (SD ± 11.1) years, 85.9% were women, and 64.1% were Caucasian. The participants in the intervention and control arms did not differ statistically in terms of age, gender, and race, F = 0.041 (0.840), $\chi^2 = 0.773$ (0.379), and $\chi^2 = 1.901$ (0.387), respectively.

Scale Results

The correlation between raw satisfaction scores and the MTSM adjusted satisfaction scores using Spearman methods was 0.96. Internal consistency results for the expectations, outcomes, and satisfaction parts of the measure were $\alpha = 0.83$, 0.86, and 0.95, respectively. The relatively high alpha values are consistent with the earlier development work and were expected due to the structure and design of the measure, the scoring, and the use of one variable to create the other. Results of the exploratory factor analysis indicated a single factor, with 68.5% of the variance explained.

Known Groups Validity

Migraine Treatment Satisfaction Measure scores were analyzed by groups of known levels of disability, as defined by the MIDAS score. The results of this analysis are shown below in Table 1. Though the results are not statistically significant, it is seen that as the level of disability due to migraine pain increases, the mean MTSM score decreases.

Migraine Treatment Satisfaction Measure scores were analyzed by severity of depression, based on the number of depressive symptoms experienced, as defined by the PHQ-9 score. The results of this analysis are shown below in Table 2. The results show that as the intensity of depressive symptoms experienced increases, the mean MTSM score decreases significantly. SNK comparisons of the ANOVA results showed that the MTSM scores for patients with highest depressive symptoms were significantly different from MTSM scores for patients with threshold and mild depressive symptoms.

Migraine Treatment Satisfaction Measure scores were assessed by the severity of bothersome symptoms experienced, as defined by the Migraine Symptom Frequency Bother (MSFB) score. The results shown in Table 3 indicated that as the intensity/severity of bothersome symptoms experienced increases, the mean MTSM score decreased significantly. SNK comparisons of the ANOVA results showed that the MTSM scores for patients with mild symptom-bothersomeness were significantly different from MTSM scores for patients with moderate and severe bothersomeness.

Migraine Treatment Satisfaction Measure scores were also analyzed by the frequency of bothersome symptoms experienced, as defined by the MSFB score. The results of this analysis are shown below in Table 4. The results show that as the frequency of bothersome symptoms experienced increases, the mean MTSM score decreases significantly, that is patients with mild symptom frequency were significantly different from MTSM scores for patients with moderate and severe symptom frequency.

Convergent Validity

The MTSM was expected to be more highly correlated with both the bodily pain and role-emotional subscales of the SF-36 than the other subscales. The strongest

Table 3 MTSM by MSFB (bothersomeness)

MSFB (bothersomeness)	n	Migraine Treatment Satisfaction Score (MTSM) Mean (SD)
Low symptom bother	57	42.3 (16.4)
Moderate symptom bother	37	32.6 (13.4)
Severe symptom bother	26	31.5 (13.9)
		F-stat (Sig.) = 6.888 (0.001)*

*$P < 0.05$.
MSFB, Migraine Symptom Frequency Bother; MTSM, Migraine Treatment Satisfaction Measure.

Table 4 MTSM by MSFB (symptom frequency)

MSFB (symptom frequency)	n	Migraine Treatment Satisfaction Score (MTSM) Mean (SD)
Mild	30	45.1 (14.3)
Moderate	27	31.6 (16.2)
Severe	63	35.4 (15.7)
		F-stat (Signif) = 6.442 (0.002)*

*$P < 0.05$.
MSFB, Migraine Symptom Frequency Bother; MTSM, Migraine Treatment Satisfaction Measure.

MTSM correlations were with the vitality (0.214), mental health (0.217), general health (0.253), and bodily pain (0.189) subscales. These relationships are lower than expected, but significant. Other correlations with SF-36 subscales were not significant.

The strongest association was seen between the derived MTSM score and the symptom score (0.301; $P < 0.01$). Of the individual items, the strongest correlations were seen with Item C (pain-free for long time) (0.371; $P < 0.01$), and Item F (less disruption) (0.325; $P < 0.01$). Significant associations were seen with Item A (total relief) (0.22; $P < 0.05$). Item D (derived symptom satisfaction) (0.218; $P < 0.05$), Item E (confidence in treatment) (0.087; $P < 0.01$), Item G (relief with one dose) (0.094; $P < 0.05$), Item H (freedom from pain return) (0.28; $P < 0.01$).

Another strong association was between the derived MTSM score and the MIDAS disability score (0.267; $P < 0.01$). Of the individual items, significant correlations were seen with Item A (total relief) (0.265; $P < 0.01$), Item C (pain-free for long time) (0.198; $P < 0.05$), and Item F (less disruption) (0.218; $P < 0.05$).

The relationship between SF-36 subscales and the item scores from the Satisfaction part of the measure are indicated in the following paragraphs. The derived Migraine Treatment Satisfaction Measure (MTSM) score showed significant correlations with Vitality (0.214; $P < 0.05$), Mental health (0.217; $P < 0.05$), Bodily pain (0.189; $P < 0.05$), and General health (0.253; $P < 0.01$) subscales of SF-36. Item F (less disruption) (0.22; $P < 0.05$) showed significant association with the Role-emotional subscale of SF-36.

Among the Social-functioning subscale, Item F (less disruption) (0.22; $P < 0.05$) and Item I (easy to use) (0.222; $P < 005$) showed significant correlations. In the Vitality subscale, Item E (confidence in treatment) (0.201; $P < 0.05$), Item F (less disruption) (0.256; $P < 0.01$), Item G (relief with one dose) (0.225; $P < 0.05$), Item H (freedom from pain return) (0.204; $P < 0.01$), and Item I (easy to use) (0.215; $P < 0.05$) showed significant associations.

Item E (confidence in treatment) (0.185; $P < 0.05$), Item F (less disruption) (0.286; $P < 0.01$), Item G (relief with one dose) (0.184; $P < 0.05$), and Item H (freedom from pain return) (0.198; $P < 0.05$) showed significant associations with the mental health subscale. Item F (less disruption) (0.193; $P < 0.05$), Item G (relief with one dose) (0.188; $P < 0.05$), and Item H (freedom from pain return) (0.192; $P < 0.05$) showed significant association with the SF-36 Bodily pain subscale.

Item A (total relief) (0.195; $P < 0.05$), Item C (pain-free for long time) (0.191; $P < 0.05$), Item D (derived symptom satisfaction) (0.208; $P < 0.05$), Item E (confidence in treatment) (0.186; $P < 0.05$), Item F (less disruption) (0.275; $P < 0.01$), and Item G (relief with one dose) (0.239; $P < 0.05$) showed significant association with the SF-36 general health subscale.

Sensitivity of the Scoring Algorithm

The sensitivity of the scoring method can be seen in Figures 1 and 2. Figure 1 shows the frequency of the global satisfaction item. The distribution is skewed to the right, with most of the participants reporting higher levels of satisfaction. Figure 2 shows the frequency of the derived MTSM satisfaction score in the same population, which approximates a normal distribution. The scoring algorithm incorporates the patients' responses from all the components (expectations, importance ratings, and treatment outcomes) to enhance or disenhance the raw satisfaction score. Table 5 lists the actual ranges of the derived MTSM score for each global satisfaction item score.

Sensitivity to Change

We hypothesized that patients in the HMP would have higher satisfaction than those not participating in the program. The results showed that patients in the HMP experienced significantly higher satisfaction (mean MTSM 43.2) when compared to those not in the HMP (mean MTS 31.4) (t-stat = –4.376; $P < 0.001$). Table 6 shows that for all nine items of the MTSM, patients in the HMP reported higher satisfaction compared to those not in the HMP. We also found that patients on triptans reported a significantly higher satisfaction compared to patients on analgesics (39.5 vs. 32.9; $P < 0.05$).

Discussion

This study built on our previously published work to refine the conceptual and measurement model of a standardized and individualized MTSM. In this article, we utilized data generated in a randomized controlled trial of HMP to assess and refine current scoring methods and to reevaluate the psychometric performance of the multicomponent MTSM.

In this, we reapplied the previous scoring to the current clinical trial data set to generate revised weights (0.80 for outcomes/expectations difference and 0.20 for importance). Once the MTSM was scored, it was found that all scores decreased with

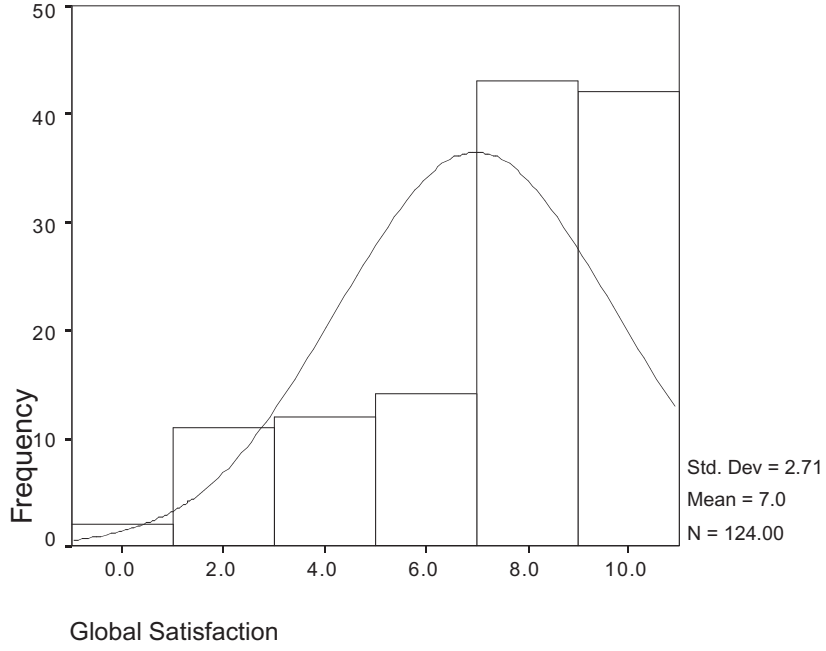

Figure 1 Frequency of global satisfaction scores.

increased depressive symptoms, migraine symptom frequency and bothersomeness.

Convergent associations were low between the MTSM and the SF-36 subscales. This is most likely related to the nature of the SF-36 being a global measure and the MTSM content being specific to the migraines. MTSM correlations were higher with the two migraine-specific measures (MIDAS and the migraine symptom) but were still relatively low. This might be related to the difference in constructs measured (quality of life, symptoms, and satisfaction).

The test of known groups validity showed that there was a significant difference in MTSM score between groups of patients according to the number of depressive symptoms experienced. There was a significant difference in MTSM scores between groups of patients according to the frequency and bothersomeness of migraine symptoms experienced. These results

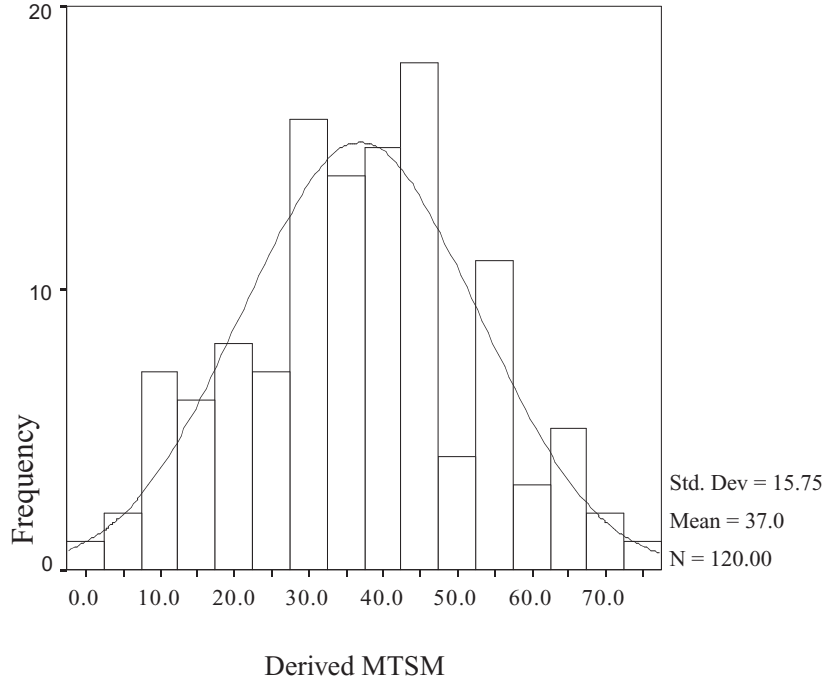

Figure 2 Frequency of derived MTSM scores. MTSM, Migraine Treatment Satisfaction Measure.

Table 5 Summary of global satisfaction and derived MTSM

Global satisfaction item	Derived MTSM score range
0 "The most dissatisfied I could be."	2.30–10.87
1	8.08–19.46
2	7.04–17.40
3	8.77–26.09
4	7.00–29.90
5	16.38–33.84
6	17.25–35.33
7	24.57–44.39
8	26.29–56.69
9	36.49–58.34
10 "The most satisfied I could be."	37.75–75.11

MTSM, Migraine Treatment Satisfaction Measure.

show that the MTSM is able to discriminate between patients with different symptom burden and bothersomeness. It also confirms the findings published earlier from the pilot work, suggesting the measure can perform reliably in reflecting treatment satisfaction for changes in migraine treatment.

Single-item satisfaction ratings are generally positively skewed, and can therefore be limited in the usefulness of their interpretation for clinical trial data (refer to Fig. 1). The incorporation of patient-based expectations into the equation provides a wider distribution of results and an increase in the sensitivity of satisfaction scores, which improves the distribution (refer to Figs. 1 and 2). Data from this study show that using the four-part individualized measure and scoring algorithm results in an augmenting of the raw satisfaction with expectations, importance, and outcomes and minimizes the amount of positive skew of the raw satisfaction ratings and maximizes the sensitivity of the scores (refer to Fig. 2 and Table 5).

Although both global satisfaction and raw satisfaction scores are highly correlated with the derived satisfaction score (MTSM), the scoring algorithms and weights introduce a different treatment-relevant construct into the MTSM score. Therefore, the pattern suggested is that the movement toward the more differentiated scores is measuring something different than addressed by the global and raw scores alone. This is a positive finding in support of the conceptual model and earlier findings [17], indicating the value of measuring treatment satisfaction as affected by individual expectations and importance.

An additional benefit of the structure of the MTSM is the ability to look at individual attributes of interest. Because the attributes are designed to be used as individual items, and are scored separately, one could, for example, examine the characteristics of Item 9 on its own to assess whether or not a given treatment was easy to use. If this was an attribute that a company expected greater patient preference for, it could be selected as an individual end point and stand on its own rather than having its effects masked as part of a larger scale with an aggregated score. Although this could present an advantage in measurement strategy, the application of the individual items in this manner would require further validation.

The design of the Duke Study excluded patients who were not currently receiving treatment from a neurologist, and those not currently receiving treatment from a headache clinic. This effectively focused the data set on a more severe headache population, which limits the generalizability of the validation results presented.

The study population was sufficiently large to test the validity and sensitivity of the measure to changes in treatment; the treatment itself (being a community-based HMP). Some characteristics of the study population provided a large amount of variability, such as the inclusion of patients having a variety of prescribed medications. We believe this may have diluted the statistical performance results. Therefore, this measurement design still needs to be tested inside a randomized controlled trial where a greater homogeneity and control of both patients and treatment can provide a less diffuse test of the responsiveness of the measure to changes in medication.

To conclude, the MTSM model appears to be a good solution to the problem we tasked ourselves with in developing a scoring system to reflect the premise

Table 6 Sensitivity of the MTSM

	Mean raw sat (SD)			Mean MTSM (SD)		
MTSM items	HMP	No HMP	*P*	HMP	No HMP	*P*
Attribute score: total relief	7.8 (1.9)	6.5 (2.4)	0.001	39.3 (17.7)	31.0 (16.2)	0.007
Attribute score: quick relief	7.1 (2.6)	5.6 (2.2)	0.001	34.1 (17.1)	27.1 (17.9)	0.027
Attribute score: pain free for long time	7.4 (2.4)	5.8 (2.8)	0.001	32.0 (16.9)	20.7 (16.2)	0.000
Attribute score: additional symptoms relief	7.3 (2.4)	5.8 (2.6)	0.003	29.7 (16.0)	21.3 (18.3)	0.008
Attribute score: confidence in TX	7.1 (2.5)	5.5 (2.9)	0.002	32.1 (16.9)	22.9 (16.7)	0.003
Attribute score: less disruption	7.5 (2.4)	5.8 (2.4)	0.000	33.0 (16.4)	22.9 (15.2)	0.001
Attribute score: relief with one dose	6.6 (2.8)	4.8 (2.8)	0.001	26.3 (17.8)	17.1 (15.0)	0.002
Attribute score: freedom from pain return	6.9 (2.5)	5.1 (2.7)	0.000	28.2 (16.7)	19.4 (14.7)	0.002
Attribute score: easy to use	8.6 (1.8)	8.3 (2.0)	0.439	34.3 (17.1)	26.2 (14.1)	0.005
Migraine Treatment Satisfaction Score	7.9 (2.3)	6.1 (2.8)	0.000	43.2 (14.4)	31.4 (14.9)	0.000

HMP, Headache Management Program; MTSM, Migraine Treatment Satisfaction Measure; TX, treatment.

of the conceptual model to generate a more sensitive and meaningful indicator of patient satisfaction with migraine treatment. This new application provides for the inclusion of both expectations and importance in the assessment of satisfaction with treatment. Figuring these two traits into the satisfaction scores provides for a truer picture of the patient's overall treatment experience.

The Duke Center for Clinical Health Policy Research received limited funding from the U.S. Agency for HealthCare Research and Policy to conduct a randomized controlled trial of HMP at three clinical sites. The trials were aimed at reducing headache-related disability, improving process of care, and reducing management costs for patients with chronic headache. Additional funds were provided to the Duke Center by AstraZeneca to support the inclusion of the MTSM in this community headache management intervention and support the data collection and analytic activities required to evaluate and validate the performance of the MTSM. AstraZeneca also provided funds to HRA to support the analysis of the validation data collected. For further information about the MTSM, contact: Kim Gilchrist, AstraZeneca.

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