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RESEARCH SUBMISSIONS

The impacts of migraine on functioning: Results from two qualitative studies of people living with migraine

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Abstract

Objective: To describe the impact of migraine on functioning based on comprehensive data collection, analysis, and reporting of patients' experiences.

Background: Qualitative research conducted to understand patients' perspectives on living with migraine has often focused on narrow topics or specific groups of patients or has been selectively reported.

Methods: Qualitative interviews with 71 participants were conducted during two concept elicitation studies as part of the Migraine Clinical Outcome Assessment System (MiCOAS) project, an FDA grant-funded program designed to develop a core set of patient-centered outcome measures for migraine clinical trials. Participants self-reported being diagnosed with migraine by a healthcare professional and participated in semi-structured qualitative interviews about their experiences with the symptoms and impacts of migraine. Interview transcripts were coded to identify and define concepts, which were then grouped into broad domains based on conceptual similarities.

Results: A total of 66 concepts were identified: 12 for physical functioning, 16 for cognitive functioning, 10 for social role functioning, 19 for emotional and psychological functioning, and 9 related to migraine management. Participants described a complex and varied relationship between migraine attack symptoms and impacts on functioning. Impacts from migraine were further influenced by numerous contextual factors, such as people's individual social environments and the level of day-to-day demand for functioning they face.

Conclusion: Findings showed that migraine impacted individual functioning in multiple ways and the nature of these impacts was dependent on social-contextual factors. The results are being used in the development of core measures designed to improve our understanding of the burden of migraine and the efficacy of migraine therapies.

Abbreviations: CHAMP, Coalition for Headache and Migraine Patients; CM, chronic migraine; EM, episodic migraine; FDA, U.S. Food and Drug Administration; FIMQ, Functional Impact of Migraine Questionnaire; HDI, Headache Disability Index; HIT-6, Headache Impact Test-6; MFIQ, Migraine Functional Impact Questionnaire; MiCOAS, Migraine Clinical Outcome Assessment System; MIDAS, Migraine Disability Assessment; MSQ, Migraine-Specific Quality-of-Life Questionnaire; PROM, patient-reported outcome measure.

The results also offer new insights and raise new questions about migraine experience that can be used to guide future research.

KEYWORDS
cognitive function, migraine, physical function, psychosocial function, qualitative research, quality of life

BACKGROUND

Migraine is a prevalent disorder that is a top contributor to disability worldwide.[1–4] The variability and natural fluctuations in migraine create challenges for understanding disease burden and assessing treatment benefits.[5] Since the International Headache Society began classifying headache disorders in 1988, adjustments have been made to migraine subclassifications and diagnostic criteria.[6] In 2004, the Society published revised diagnostic criteria for chronic migraine (CM), defined as a per-month average of at least 15 days with headache over at least 3 months.[7] By convention, migraine that does not meet this criterion has since been called episodic migraine (EM) and this subdivision has been used as the basis for differing treatment guidelines or clinical trial designs.[8,9] Recent studies, however, have suggested that this classification is insufficient for understanding the burden of migraine and patients' treatment needs.[10–12]

Because migraine lacks biomarkers for disease assessment, data gathered directly from people living with migraine is the primary means for understanding the disease and the perceived benefits of treatment; however, existing qualitative studies of migraine have often focused on a narrow topic, such as treatment decision-making[13,14] or a patient subgroup, such as women.[15] Others have blended perspectives from patients with those of family members and healthcare professionals.[16] Differences in research aims and analytic methods across studies lead to differences in reported findings, making it difficult to compare or synthesize results.[17] Qualitative studies conducted for patient-reported outcome measure (PROM) development are often briefly summarized without providing full insight into people's experiences. Rather, results are presented to support measure validity and omit other potentially useful content. For example, when describing the initial qualitative study to develop the Migraine Functional Impact Questionnaire (MFIQ), the authors only reported concepts discussed by at least 50% of participants.[18] This threshold may be suitable for selecting concepts for a specific PROM but fails to document the full spectrum of patient experiences.

The lack of published studies that comprehensively report on the lives of people with migraine hampers understanding and creates barriers to the development of patient-centered disease models, conceptual frameworks, and measurement frameworks that could guide research and clinical practice. It may also contribute to a proliferation of migraine-related PROMs that focus on different domains and concepts (or define them differently), which creates challenges for selecting appropriate measures or comparing metrics reported in different studies. The Migraine Clinical Outcome Assessment System (MiCOAS) is a multi-stage project funded by the U.S. Food and Drug Administration (FDA) to develop a patient-centered core set of outcomes and endpoints for migraine clinical trials. As part of the project, the MiCOAS research team endeavored to address these obstacles by gathering and synthesizing data from people living with migraine through two sequential interview studies.

OBJECTIVE

The objective of the interview studies was to develop a comprehensive understanding of people's lived experiences with the symptoms and impacts of migraine, including experiences during interictal phases (the period between migraine attacks).

METHOD

Two concept elicitation studies were conducted. Study 1 collected data about people's symptom experiences across the phases of migraine (including all phases of an attack and the interictal period), and also examined patient priorities for treatment benefits. Study 2 collected data about the proximal and distal impacts of migraine on functioning and quality of life. The WCG IRB Institutional Review Board approved the protocols for both studies. This paper reports the primary analysis of data from both studies. Some findings from Study 1 related to cognition and perspectives on treatment benefits have been previously published.[19,20]

Recruitment and data collection

Participants with self-reported, medically diagnosed migraine were recruited through study announcements distributed by the Coalition for Headache and Migraine Patients (CHAMP, https://headachemigraine.org/), a coalition of patient advocacy organizations capable of reaching a large, geographically diverse population through newsletters and social media. Broad outreach also provided an efficient means to recruit from populations often underrepresented in migraine research (e.g., males), while still achieving an overall sample that was representative of clinical trial participants and people who seek medical care for migraine. Study announcements directed people to a website with information about each study and an electronic eligibility screening questionnaire. Participants who met eligibility criteria (see Table 1) were directed to an electronic informed consent form and those who provided consent were directed to a health and demographic questionnaire. From a total of 581 eligible individuals, 40 participants were interviewed for Study 1, and 31 were interviewed for Study 2. Participants were selected using iterative purposive sampling aimed at achieving a balanced representation of EM and CM and a diverse representation of characteristics such as sex, race, and ethnicity. Participants were enrolled in waves of 4–6 interviews and interview results were monitored for achievement of data saturation.[21] Demographic characteristics from completed waves were used to determine priority characteristics for subsequent waves to ensure diversity in the participant sample.

Semi-structured interview guides were piloted in the field with two volunteers with migraine prior to data collection. Interviewers were trained and observed by senior members of the research team (M.T.G., K.P.M., R.M.). Interviews were conducted via web-conferencing in 2020 for Study 1 and in 2021 for Study 2. Interviews were recorded with participant consent and transcribed verbatim for analysis. Qualitative data analysis was conducted in Atlas.ti for Study 1 and NVivo Windows for Study 2.

Analysis

Interview transcripts were read multiple times and coded by at least three analysts using content analysis and grounded theory methods appropriate for concept elicitation for measure development.[22–24] Content analysis codes were used to label discrete concepts (e.g., irritability) and terminology (e.g., short-tempered, snapping at people) used by participants when describing their experiences. Grounded theory coding was used to group content codes based on discernable patterns (e.g., anxiety and worry are similar) and to reflect theoretical notions (e.g., level of social support influences the perceived level of disability). The emergence of novel information across interviews was used to determine when data saturation (i.e., the point at which new content no longer appeared in the data) was achieved.[25] No new concepts or terms were identified after interview 27 in Study 1 and interview 24 in Study 2. Analytic memos were developed to condense the data in each code by quantifying and summarizing coded content, describing themes found in the data, and documenting disconfirming examples.[26] Descriptive statistics included the total number of interviews and the total number of references coded with each code.

RESULTS

Table 2 provides the participant demographic characteristics for both studies. Participants were 75% female ($n=53$), 63% White ($n=45$), 60% college-educated ($n=43$), and 59% employed ($n=42$). Hispanic participants were 21% ($n=15$) of the sample and included individuals who identified as White and Black. Slightly more than half of the participants ($n=38$, 53%) had EM.

Physical function in migraine

Participants described numerous ways that migraine affected their ability to carry out physical activities. These were grouped into 12 broad concepts (Table 3) ranging from basic ambulation to the ability to carry out health maintenance activities, such as keeping medical appointments. Unlike other concepts in Table 3, sleep does not require physical activity; however, participants uniformly discussed sleep in relation to physical function. For example, one participant said “between headaches, I get this period that I really want to sleep. Like, I don't want to do anything other than just sleeping.... I'm not able to fully wake up, to fully function.” Use of communications and information technology was grouped within physical functioning because it can require physical activity to use (e.g., getting up to answer a telephone, holding a device, typing). Participants noted that using smaller mobile devices created less physical burden, while also noting that lighted screens could trigger attacks or exacerbate symptoms.

TABLE 1 Eligibility criteria.

Inclusion criteria	Exclusion criteria
• U.S. resident • Ages 18–75 • Self-reported that they had been diagnosed with migraine by a healthcare provider • Screened positive for migraine on the ID-migraine screener[44] • Comfortable reading and speaking in English • Reported being able to distinguish a day with migraine and other types of headache days • Reported limiting activities due to migraine on at least 1 day in the prior 3 months	• Self-reported diagnosis of multiple sclerosis, schizophrenia, bipolar disorder, cognitive impairment, Alzheimer's disease or dementia, or epilepsy • Screened positive for substance use over the prior 3 months using the CAGE questionnaire[45] • Reported being an employee or family member of an employee of FDA or any of the organizations involved in conducting the study • For Study 1, which took place during the 2020 COVID-19 pandemic, self-reported diagnosis, symptoms, or hospitalization related to COVID-19 infection at time of screening • Participants from Study 1 were excluded from Study 2

Abbreviation: FDA, U.S. Food and Drug Administration.

TABLE 2 Study participant characteristics ($n = 71$).

Characteristic	Study 1 ($n = 40$)	Study 2 ($n = 31$)	Total ($n = 71$)
Age (years)			
18–24	5 (12%)	1 (3%)	6 (8%)
25–34	5 (12%)	4 (13%)	9 (13%)
35–44	12 (30%)	7 (23%)	19 (27%)
45–54	9 (23%)	6 (19%)	15 (21%)
55–64	4 (10%)	11 (35%)	15 (21%)
65–75	5 (13%)	2 (6%)	7 (10%)
Sex/gender			
Female woman	31 (77%)	22 (71%)	53 (75%)
Male man	7 (18%)	9 (29%)	16 (23%)
Genderqueer/nonbinary/transgender	2 (5%)	0	2 (1%)
Race[a]			
American Indian/Alaskan Native	4 (10%)	3 (10%)	7 (10%)
Asian	3 (7%)	1 (3%)	4 (6%)
Black or African American	9 (23%)	6 (19%)	15 (21%)
Native Hawaiian/Pacific Islander	1 (2%)	–	1 (1%)
White	27 (67%)	18 (58%)	45 (63%)
Other	1 (2%)	4 (13%)	5 (7%)
Prefer not to answer	1 (2%)	0	1 (1%)
Ethnicity			
Hispanic	9 (23%)	6 (19%)	15 (21%)
Migraine type			
Episodic	20 (50%)	18 (58%)	38 (53%)
Chronic	20 (50%)	13 (42%)	33 (47%)
Education			
Completed high school	3 (8%)	1 (3%)	4 (6%)
Some college/technical school	18 (45%)	6 (19%)	24 (34%)
Completed college	11 (27%)	12 (39%)	23 (32%)
More than college	8 (20%)	12 (39%)	20 (28%)
Employment[a]			
Paid employment	22 (55%)	20 (64%)	42 (59%)
Student	8 (20%)	2 (6%)	10 (14%)
Homemaker	3 (8%)	2 (6%)	5 (7%)
Retired	6 (15%)	3 (10%)	9 (13%)
Unemployed	2 (5%)	1 (3%)	3 (4%)
Disabled (or on disability or leave of absence)	10 (25%)	10 (32%)	20 (28%)
Other	1 (2%)	–	1 (1%)
Used any OTC or prescription acute treatments in prior year			
Yes	40 (100%)	30 (97%)	70 (98%)
No	–	1 (3%)	1 (1.5%)
Used any OTC or preventive treatments in prior year			
Yes	35 (87%)	28 (90%)	63 (89%)
No	5 (8%)	3 (10%)	8 (11%)
Use opioids/barbiturates			
Yes	3 (7%)	5 (16%)	8 (11%)
No	37 (9%)	26 (84%)	63 (89%)

Abbreviation: OTC, over the counter.

[a] Participants were able to select more than one race or employment status.

Capacity for physical function was related to the specific symptoms experienced and to symptom severity, speed of onset, frequency, duration, and timing. Participants reported that gradual onset premonitory symptoms were harder to notice and might not immediately impact function. One participant described this experience as: "like the frog in the pot, the hot water, it gradually builds up and by the time I notice, it's been building up for a bit." By contrast, rapid onset could lead to abrupt disruption of physical functioning. For example, several participants recounted experiences of being stranded by the sudden onset of symptoms while driving. Physical impairments were linked to a variety of symptoms and 64 participants (90%) noted a strong preference for retreating to a suitable place and suspending all functioning, a practice labeled in analysis as "cocooning." Pain, nausea, dizziness, or visual disturbances profoundly affected people's ability to move around, while cognitive symptoms interfered with physical functions that require thinking (e.g., cooking, driving). Frequent or long-lasting symptoms created greater impairments of daily physical functions (e.g., getting dressed, walking) but also impaired participants' ability to engage in intermittent activities, such as running errands or exercising.

The perceived links between specific symptoms and functional impairments varied. For example, difficulty walking could be related to pain, dizziness, or nausea. Individuals who experienced all these symptoms might attribute impairment during a given attack to one or more of them. The level of impairment also varied: Participants described being physically unable to move during an attack, being able to move around slowly or with support, or being able to move around but enduring considerable discomfort to do so (often called "pushing through"). Moreover, all these scenarios could occur during a single attack: A person might have one period when they avoided movement, one when they were unable to move, one when they could move about slowly or while holding onto furniture, and one when they pushed through their symptoms for imperative tasks like working or taking care of children or pets. Finally, the timing of migraine symptoms played a role. Attacks that occurred when a person had scheduled activities could result in different impairments compared with attacks at times they planned to stay home.

TABLE 3 Physical functioning concepts.

Concept	# Interviews coded	Definition	Example quotes
Ambulation	57	Ability to move one's body around, such as walking, moving head or limbs, making changes in posture, or sitting up or standing for a prolonged period of time	But it hurts to walk. It hurts to move your arms around. It hurts to do anything I cannot walk because I'm dizzy and I cannot walk around because I'll throw up because too much motion on my stomach will make me throw up There's no bending down to grab anything or too much turning because I just have to kind of keep my head very still
Mobility and transportation	57	Ability to move around in the community or to travel, such as by car (as a driver or a passenger), public transportation, or airplane	I'm no longer allowed to drive, because [attacks] hit fast and furious Because public transportation is really bad. Like, I've been stuck on public transportation in a bad attack, and that's the worst experience I used to love to travel, but again, the whole being overstimulated, at the airport, running through the airport, going through security, being around all those people. Those are all things that kind of made it difficult for me
Ability to exercise	40	Ability to engage in physical exercise	I do not do too much exercise because, if I do too strenuous exercise, then that creates a migraine I like to be active, work out, play sports, and the migraine definitely—sometimes I have to sit it out. Sometimes I'll go and try, because sometimes the adrenaline from exercise makes you feel better … sometimes it makes you feel worse
Household chores	39	Ability to carry out activities such as cleaning, laundry, gardening, taking out trash, or minor repairs	Even if that was the day that the trash needed to be taken out to get taken that week, it would not happen I'll push off just regular tasks like laundry or the dishes or organizing something. It's a lot harder to get those things done, and I would prefer not to do them while I have a headache
Ability to prepare meals and eat	22 (Study 2 only)	Ability to prepare food (for oneself or others) and to eat, including having to avoid food triggers	If I cannot cook, I have a bunch of microwavable food all the time that I can make if I'm not feeling well I am very careful about what I eat. I do not eat chocolate or cheese or no wine—really no alcohol—and no processed meats. I mean, the list just goes on.… I stick to the migraine diet
Health maintenance	21 (Study 2 only)	Ability to keep medical appointments, work towards health goals, or choose and use migraine treatments	Sometimes I actually have to cancel medical appointments because I have terrible migraine I mean, even taking my medicine—like, sometimes I do not even want to go down and take my medicine, because I have to face the light, so I'll just lay there in pain
Basic self-care	15 (Study 2 only)	Ability to carry out basic self-care activities such as bathing, grooming, or dressing	The shower is scary. It is not a happy place. The water that comes down on my scalp is painful … And then the noise of the water and the echoing of the bathroom in the shower, just all of that is just not a happy place I have like an Afro hair and I was just doing wash-and-go's for my natural hair, but I switched to locking my hair … And then I also started buying a lot of hats, so I just do not have to put as much effort into styling it
Shopping and running errands	13 (Study 2 only)	Ability to go shopping in a store or run errands, such as going to the post office	I've had to order groceries and have them delivered, which is very expensive, because I'd have three migraine days in a row and I just know that even if I do not have one that day, it's too much for me to grocery shopping physically
Sleep impacts	12 (Study 2 only)	Migraine impacts on sleep, such as awakening with pain, being unable to sleep, or sleeping more than usual	They [migraine attacks] make me want to sleep more The pain will wake me up at like two or three, and then continue to wake me up throughout the rest of the night. So, that has been probably one of the worst parts
Ability to use communications and information systems	10 (Study 2 only)	Ability to use telephones, smartphones, tablets, computers, or other information systems, at work, at home, or in the community	Too much time on the computer triggers a migraine, so I have to be really careful of that.… And sometimes I can type where I cannot talk, I find. Like, I can text a message, even though it hurts my eyes to be reading
Fine motor control	8 (Study 2 only)	Ability to execute movements like picking up small objects or opening medicine bottles	You know, they do not make those [medication] containers easy to open when you have a headache … I've got a pet peeve about that. Whoever designed the packaging so you cannot get into it when you cannot function has got to get their act [together]
Lifting and carrying	7 (Study 2 only)	Ability to lift and carry a weight, such as a heavy box or laundry bin	I cannot lift as much weight during a migraine. I have to be much more careful

Participants typically described the post-headache phase as a gradual return to normal daily living that could take hours or days. Post-headache physical limitations were primarily associated with lingering symptoms and feelings of fatigue. Participants also avoided activities they thought might cause renewed symptoms or delay recovery. Physical functioning limitations did not seem to play a significant role in interictal burden for many participants, who described returning to normal levels of physical activity; however, participants with known triggers or many attacks per month did report interictal limitations, such as systematically avoiding certain activities (e.g., strenuous activities, shopping in bright, noisy stores). When severely affected by migraine, some participants had to "live kind of like a hermit," spending large amounts of time at home unable to do much.

Cognitive functioning in migraine

Eleven cognitive aspects of migraine experience identified in Study 1 have been published previously.[16] Briefly, Study 1 identified feelings of mental fogginess and confusion (often referred to as brain fog) as well as impairments of concentration, speech (both speaking and comprehension of speech), short- and long-term memory, decision-making, learning, and information processing. Study 2 replicated these findings and identified five additional concepts related to cognitive functioning (Table 4), including impacts on people's ability to read and write, control their impulses, solve problems, and do math or handle monetary transactions. Participants linked impairments of cognitive function to brain fog and to interference from symptoms (e.g., pain or light sensitivity impairs reading). Burdens ranged from mild embarrassment to the inability to engage in any activity requiring cognitive functioning. Participants in Study 2 described managing cognitive impairments through a variety of strategies such as making lists and notes, slowing down and double-checking, or avoiding activities when errors might result in serious consequences (e.g., banking, work activities).

Psychosocial function in migraine

Psychosocial functioning concepts were organized into three broad categories: social role functioning, emotional and psychological experiences and functions, and migraine management.

Concepts related to social role functioning

Ten concepts captured the ways migraine affected participants' ability to engage in social roles (Table 5). Participants often described migraine's impact on their ability to "be present," a phrase that conveyed both physical presence and cognitive or emotional presence in social contexts. The level of impact depended largely on the severity and frequency of migraine symptoms. Participants with severe or frequent migraine described a wide range of constraining effects on their personal, social, and work/school lives.

TABLE 4 Additional cognitive functioning concepts identified in Study 2.

Concept	# Interviews coded	Definition	Example quotes
Ability to read	17	Ability to read, including the ability to comprehend what one is reading	If I'm reading from a book, usually it's okay, because it's not a screen. But after I read for a couple of minutes, I start seeing lines merging It takes me twice as long to read a sentence between the throbbing and the visual problems, and then I'm not able to process it because so much of my brain is focused on the pain itself
Math/money management	11	Ability to do math or conduct financial transactions	During an attack, I cannot do basic things like count money, so I always make sure I have a debit card
Ability to write	10	Ability to write by hand or using a keyboard	I just flat out write down the wrong words or wrong letters
Impulse and behavior management	9	Ability to control impulses and reactions	I'll just, out of the blue, my language turns bluer than ultraviolet. I mean, it's flaming blue. I'm dropping [curse words] and all kinds of other crazy language for no good reason. I'm not angry at anything, but all of a sudden, I'm dropping all kinds of ultraviolet, flaming blue language
Problem solving	6	Ability to identify/recognize problems and engage in problem solving behaviors	Well, if I'm having a migraine, I'm not able to really look at two or three moves ahead. I'm doing good to be looking at one move ahead ... And you go back and you look at it and you say, dumb. What'd you do? Why'd you do this? Why did not you catch that?

TABLE 5 Social role functioning concepts.

Concept	# Interviews coded	Definition	Example quotes
Work	58	Ability to work at a paying job	It wasn't till later that retrospectively I looked at all the jobs I had or the problems I've had with my jobs, and they were probably all caused by the fact that I was in pain I miss work all the time. And this feeling of like—I cannot miss work for anything else because I have to save any sick days that I have for a migraine
Social, community, and civic roles	55	Ability to participate in social gatherings with friends or family, participate in community life, or civic events	I'm a volunteer [specifics redacted] here in the area where I live. I write letters to the elderly who have no one to write to them. So, I'm trying to do the things that I can do that can work with the migraine. I'd love to be more active. I'd love to be more out and engage with the public on causes that matter to me, but I realize that I'm limited by what I can do I have missed functions, baby showers, weddings, due to migraines … Anything that's enjoyable, you cannot do when you have a migraine above a 4 or a 5 on a scale of 1 to 10. You just cannot do it … cannot go to a soccer game, watch your kids play sports or something
Interpersonal relations	38	Ability to form and maintain personal relations and engage in interpersonal interactions with non-family members or people outside the household	I've lost friendships because they do not want to hear me complain, or they do not want to be canceled on I want to be able to enjoy myself and hang out with friends and everything … I also want to be—make sure I'm there—like my cognitive ability is also there. I do not want to be there but then just taking up space, like I have nothing to contribute because I'm trying to get through a migraine
Recreation and leisure	31	Ability to engage in recreational or leisure activities	I actually went to music school and I'm no longer able to play my French horn due to the pressure and the head and neck pain Oh, activities, like if I wanted to go roller skating that day or I wanted to go exercise or ride my bike that day, get on the treadmill … Cannot go to the movies; you cannot go out to dinner
Family relations	43	Impacts of migraine on family relationships or on one's ability to participate in family relationships	You miss out on family time…. Those things you do not get—you do not get that time back I will not be able to be with my children, who are grown—wanting me to do things with my grandkids … it takes away from them. And that makes life very, very depressing to me because my grandkids are my life
Social support/isolation	22 (Study 2 only)	Ability to access social support—either from family, friends, community, colleagues, or a support group or organization; ability not to feel alone or isolated	It's like a family, another family, the whole migraine community. Everybody's accepting and warm and you can talk about anything … You can say anything to them and they are always there for you But the migraines really isolated me. And I do struggle from depression, and it just magnified that a bunch. It was really brutal
Intimate relations	17 (Study 2 only)	Ability to have intimate relationships, with or without sex	It has really destroyed relationships, both romantic sexual relationships as well as friendships, because it's hard for people to handle, you know, my being sick so much … For example, I've gone from being married to divorced bachelor … it has become clear to me that, you know, that it really is more suitable for me to remain single and celibate. You know … because of my health—I'm not really in a position to where I could date or, you know, anything like that. It's—it's too challenging
Care of other people or pets	28	Ability to provide care and fulfill any familial/household roles such as parenting, taking care of elders, taking care of pets, etc.	Fifty percent of the time, it's even so bad that I cannot take the dogs out for a walk … I cannot function at the level I need to do to carry out those responsibilities Like I said, I have six kids and my husband's a disabled vet, so they all need me. So mama just pushes on through, takes the medicine and just keeps going. So it's just kind of hard

TABLE 5 (Continued)

Concept	# Interviews coded	Definition	Example quotes
School	22	Ability to attend classes/days of school and complete required schoolwork, including full or part time and online or in person	I was trying to study engineering, and that was something that I absolutely loved. But my migraines did not like it because the heavy thinking and the math was so much all the time, it forced me to change my major into something liberal arts instead Through high school, I had to go on independent study because they [migraine attacks] were so bad.... [recently] I actually reenrolled back in school. So, now I'm trying to do school on the computer, which is another thing that migraines affect because it's hard to look at the screen for that long
Spiritual life	7	Ability to attend religious meetings or engage in routine religious activity at home (e.g., praying, fasting, preparing for holidays)	Well, one of my big things is going to church and helping out at church and stuff, and I have not been able to really go to church much or help out in the past several months, because I just—I cannot sit through a service for a whole hour

These included limited or no ability to work or take classes, loss of personal relationships and the inability to form new ones, and lifestyles hallmarked by limited capacity for social, recreational, or civic life. By contrast, those with less severe or less frequent migraine experienced challenges and disruptions, but were typically able to maintain substantial psychosocial functioning. Migraine's impact on social roles was also influenced by the level of support and understanding that participants received in their community. Those who described having supportive environments noted that this mitigated challenges, even when living with severe migraine. Those who described unsupportive social environments experienced social role impacts even when their attacks were infrequent or responded quickly to treatment.

Participants described indirect negative experiences associated with these impairments (e.g., stigma, guilt) and impacts on their sense of identity that were linked to their specific social contexts and preferences. For example, some participants indicated that social role impairments, such as inability to maintain friendships or engage in civic life, were among the most difficult aspects of living with migraine, but others described themselves as not very social and did not find all social impacts equally meaningful. For some participants, disengagement was not an option (e.g., children must be cared for despite an attack). Others described prioritizing social role functions because these were important to their sense of self and described pushing through attacks or adapting their lifestyles, such as finding alternative work, friends, or recreational outlets.

Concepts related to the emotional and psychological experiences of migraine

Interview participants described varied psychological impacts linked to migraine, including short- and long-term effects on their state of mind, sense of individual identity, and general sense of well-being (Table 6). Emotional and psychological aspects of migraine were captured in 19 codes, of which 13 were emotional and six were abstract concepts (e.g., life satisfaction). Interviews elicited information about feelings of anxiety, irritability, depression, and more, as well as insights into how migraine affected people's sense of self. Participants also commented on migraine's impact on their sense of being understood or respected by others and noted that life with migraine exposed them to a range of stigmatizing experiences. Because migraine could impact every aspect of life with unpredictable, distressing interruptions, the emotional and psychological impacts were pervasive and often negative. Many participants, including some of the most severely affected individuals, were nevertheless quick to note that they experienced joy and lived fulfilling lives, with plans for the future and hope for improvement in their condition. Several participants expressed concern about the narrow focus on symptoms and negative outcomes they encountered in healthcare, while acknowledging that these burdens are substantial and of profound concern to them. This narrow focus may, however, serve to overemphasize burden at the expense of understanding the broader nuances of life with migraine. One participant, who had frequent severe migraine attacks and described an active lifestyle, commented that "it would probably sound worse than I think it is to other people who don't have to deal with it … because the way that I have described it, thinking back on my own words, is that it's like there's a gun to my head all the time. I don't feel that way, but I understand the words that I have spoken and I understand that they can be interpreted that way."

Although all participants longed for a cure, many talked about learning to accept and adapt to life with migraine, which brought some participants a sense of peace or greater control over their lives—sometimes described as "making friends with" migraine. Adapting to life with migraine did little to lessen the concrete burdens of the disease. Rather, comments about acceptance suggest that the fight to control migraine, or to minimize its impact on life, may actually add to the burden of illness for some people. Accepting and adapting to migraine may minimize or eliminate this added burden.

TABLE 6 Emotional and psychological experiences.

Concept	# Interviews coded	Definition	Example quotes
Feeling heard	29 (Study 2 only)	Experiences with feeling dismissed or not taken seriously, or experiences with feeling heard and supported by people around you	Most of my friends are very understanding, and they are like, "Oh, yeah, whenever you can, and if you cancel, we totally understand. You can cancel last minute." … They know what's going on I went to 20 doctors in eight years, and they are basically like, "You're fine. It's all in your head. You're too young to be sick" … they dismissed everything. So, that was really frustrating
Well-being	27 (Study 2 only)	General ability to achieve a state of being comfortable, healthy, and happy	So mostly I'm just staying home all the time. It gets pretty boring … it's really hard on me, because, you know, like, I'm an adult, and I want to do stuff. I want to do stuff for my own as well, but I really cannot do stuff … it's being crippled in a lot of ways I just want to be normal. I'm not enjoying this, I'm not enjoying life like this. I just want to be normal, whatever normal is. Pain free. That's it. Migraine free
Identity	26 (Study 2 only)	Self-image, sense of individuality, and ability to be the person you want to be	I'm never as smart as I used to be, let us put it that way … I want to be smart again. I just want to be me. I want to be me again I think it triggers me to imagine the fact that I cannot have a life outside of work or a life that does not involve being sick … And so, I think those—when I am able to do those things like exercise and all these things, then I feel like, no, I have a life outside of this. I'm a person outside of my illness
Anxiety	49	Experiences of anxiety as a symptom or result of an attack, anxiety about having attacks, or anxiety about the impacts of migraine on one's life	You know, so I think I kind of live in fear. So, even when I do not have a migraine, I'm afraid that I'm going to have one or that I'm going to somehow trigger one Yeah, one of the other things too is I start to feel anxious. Anxiety plays a part, because I know it's coming … I start thinking about, OK, how bad is this migraine? What am I going to take for it? How long is it going to last? What do I have to tell people around me for the rest of the day or the night? All that anxiety, I guess, just makes it worse
Anger or frustration	38	Feelings of anger or frustration related to migraine	I also feel frustration and guilt sometimes, like if I shirked my duties for days or I have not gotten anything accomplished at work The frustrations that have come with not having health insurance, not having great answers, and really just, at this point, feeling like I have to live with this
Depression	39	Feelings of depression or sadness during an attack or because of the cumulative impact of migraine on one's life and well-being	I get super, super depressed and really quickly, almost like whiplash almost, where an hour ago, I was totally fine It just makes your life a living heck. But I'm depressed all the time with them. All the time … I'm very agitated. I'm very depressed all the time. Because I just cannot get my life together
Irritability	41	Feelings of irritability that occur like a symptom, often beginning in the pre-headache period and increasing during the headache phase, but occurring after the headache as well	I'm more irritable. I'm definitely irritable. Because I'm generally—I'm a people-person, so I like dealing with people. But during a migraine I'm just like, leave me alone I'm just more like—I would say like easily, easily agitated, like I get more aggressive with my kids, like just leave and just—I'm not patient at all or my normal self
Feelings of relief	42	Feelings of relief or invigoration that occur when an attack ends or during a migraine-free day, sometimes accompanied by a strong desire to catch up on missed activity	And when I have a good day, I'm excited. There's a relief when I have a good day, a tremendous relief … a migraine-free day is a gift, and I take them that way. I do not take them for granted Absolute relief, because it's like, oh my God, it does not hurt anymore. It's like thank God. It is the best euphoria.… So it's like the reward. It is just total excitement, like yes, it's gone. Now I can function
Feelings of increased or decreased energy or drive	16 (Study 2 only)	Impacts of migraine on energy, including reduced energy during or in between attacks, or experiences of increased energy during interictal phases	Between headaches, I get this period that I really want to sleep. Like, I do not want to do anything other than just sleeping Sometimes also, I have a little bit of energy, and I'm like, oh good, I'm finally going to come out of this.… But it's the energy level. It just really feels like somebody's sucked the life out of you and you are trying to get a little bit back

TABLE 6 (Continued)

Concept	# Interviews coded	Definition	Example quotes
Skepticism	15 (Study 2 only)	Feelings of skepticism during an attack about one's ability to gauge symptoms, or in between attacks regarding treatment efficacy or individual and healthcare provider ability to understand and manage migraine	I have doubts how well I can cope … I'm sure people do this, but sometimes I question my own sanity. Am I really feeling as bad as I think I'm feeling? Answer is probably yes. But I do question myself I said to a doctor, which I think offended him maybe a little, because he told me how bad he feels, and I said, "I feel worse for you guys." And he says, "Why do you say that?" I said, "Think about it. You went to medical school. You do fellowships. You're double-, triple-board certified. And you still do not seem to know anything about this"
Guilt	24	Feelings of guilt related to impairments during an attack, inability to keep commitments, or burden placed on others	I feel bad because I feel like everyone's always having to adjust how they are for me … I've always felt like I've been an imposition on my family because they have to change how they are I could probably take the time off, but I just always felt so guilty because you do not want to be the person that's unreliable, especially at work, especially if you have big due dates coming up
Happiness or euphoria	25	Feelings of joy experienced when an abortive medication works, an attack ends, or when experiencing migraine-free days	I have joy in my life, and I definitely—there is sometimes when it's like—you feel the med work suddenly, and that's rare. Usually, it's just kind of a gradual—the pain dulls, and you are like, oh, it stopped. But sometimes, boom, ah, I feel it, and there's definitely a smile on my face
Embarrassment	10 (Study 2 only)	Experiences of embarrassment during and in between attacks related to impaired ability to speak or having to cancel plans	It's very embarrassing, especially in business. You're talking to a new client and your words come out all jumbled up or you just stop talking, and they do not know what's going on
Grief	3 (Study 2 only)	Feelings of grief over lost opportunities and time due to migraine	I lost my career to migraine … I grieved a lot for my career, because I'm a single woman … my image of myself was a lot tied to my career, and so when that was gone, it was like, ugh, what am I going to do?
Other positive feelings	5	Included feelings of hope for the future and a deliberate, positive attitude	Migraines are debilitating…. But they are coming out with new medications, so it's hope for us migraine sufferers, and we just hope they get them on the market…. You've just got to look at it, like, you know, with some positivity that they are working on it behind the scenes. We might not see it every day, but they are working on it
Other negative feelings	17	Included a negative outlook on the future and thoughts of feeling like a failure	When the headache pain is going on, there's that feeling of, this is forever, it's not going to go away this time, this is it. During the after-pain, that feels so temporary and so fleeting, like any minute it's going to come raging back So, it's the result of not being able to do something, feeling like a failure, feeling lazy
Accepting or adapting to life with migraine	23 (Study 2 only)	Accepting life with migraine as a "new normal," developing a sense of tolerance about one's experiences, or embracing a positive attitude by focusing on what one can do rather than on what one cannot	I've tried to adopt, let me call it, more of a can-do attitude … I try to keep a positive kind of spin. Like, I ask myself, instead of "what cannot I do," "what can I do?" I think that the biggest thing is just respecting it and kind of maybe treating it—basically to stop resisting. To treat it more like a friend and try to understand it rather than this uninvited intruder because that just makes it worse. I need to work with it and not against it
Stigma	26	Experiences of stigma from interpersonal relationships or broader society (e.g., healthcare system, workplace environment)	I had an emergency room visit [with severe migraine], and I felt like the doctor was treating me as if I was a drug seeker and did not really want to listen to what I was having to say There's an awful stigma about migraines. The whole "just a headache" thing
Life satisfaction and meaning	16 (Study 2 only)	Perspectives on how migraine affects overall satisfaction with life or the sense that one's life has meaning	It's not the pain. It's what I'm missing out of because I have migraine. It's what I cannot do or what I would like to do that does not happen because of my lack of functioning, whether that's taking care of my kids, holding a job, feeling fulfilled I think my quality of life is pretty low…. I live kind of like a hermit

Concepts related to management of migraine

The concept of accepting and adapting to migraine exemplifies how migraine burden is linked not only to its symptoms and impacts on functioning, but also to personal circumstances and choices about how to manage illness. Nine codes captured concepts related to experiences with managing migraine (Table 7).

Participants made varying decisions about whether to use treatments that were effective for them (at all or for a specific attack), when to push through or cocoon during an attack, and how to adjust

TABLE 7 Migraine management.

Concept	# Interviews coded	Definition	Example quotes
Predictability/control of migraine	63	Ability to feel that you have control over your life and circumstances, to predict how you will feel and function over a given period of time so that you can plan ahead	I make a lot of my decisions on an as-needed or morning basis, because there's no way I've found to be able to predict what tomorrow's going to bring I've just had random ones that just come on, and I do not know what even triggered it … I could be driving down the road and, boom, one hits me and I get to where I cannot even see. So I have to stop. I have to pull over I already know that before my [menstrual] period, I should just plan to be sick … it's almost like I feel in control, that I know when I'm going to be sick. So, when I'm surprised and I'm sick when I'm not supposed to be, then that feels like it impacts my life a lot more
Cocooning	64	Practices of withdrawal and self-isolation during an attack	And for me what migraine looks like is kind of a dark room with no sounds and just being in bed for a long time During a migraine, it all stops … I just have to retreat. I have to come back and close the curtains in my room, turn off all the lights
Avoiding selected activities	21	Choosing to avoid activities because of the risk of triggering a migraine, withdrawing from participation during attacks	Sometimes you mentally remove yourself because it almost hurts to try and keep up with everything … I do not talk. There are times when I just will not participate in the conversation because I know I'm going to have problems I avoid definitely long-term tablet or computer use … I love music, but I find myself listening to much less than I used to or even at lower volumes … I very much avoid stressful situations, confrontation of any sort, maybe avoid driving, because that's sort of a stress
Avoiding triggers	26	Avoiding specific known triggers, such as foods or environmental factors	I'll try to not eat sugary things, especially in the morning, and then I'll try to not stay out in the heat or humidity for too long and I'll just try to de-stress as much as possible
Lifestyle changes	11 (Study 2 only)	Choosing to adopt a lifestyle that minimizes risk of migraine attacks, builds health and well-being, or prioritizes one's own health and welfare needs	For me, what's important is all the preventative stuff, right? Sleep, number one. Making sure I do not do anything to disrupt my sleep, which is really easy to do. And I really hate—the doctors were right on this one—but exercise. So, regular exercise, which is really hard to do when you have an attack going
Use of non-pharmaceutical therapies	12 (Study 2 only)	Use of therapies other than medication to manage migraine symptoms or to prevent attacks	I use peppermint aromatherapy cooling sticks—like, it just goes on my wrists—for the nausea … I have a whole bunch of different weighted masks and that kind of thing just to be more comfortable, you know I have the ice hat. I do that. I meditate. I do stretches
Pushing through	42	Choosing to continue functioning during a migraine attack despite symptoms or impairments	You know, every time you have an attack, you cannot just shut down. If it's a milder one, you have to do things. And you do not feel good doing them, but that's life. Sorry, bad luck I will push through because that's my responsibility as a mom

TABLE 7 (Continued)

Concept	# Interviews coded	Definition	Example quotes
Direct costs	21 (Study 2 only)	Comments about the direct costs of migraine, such as out-of-pocket medical costs or time spent obtaining medical care or dealing with insurance companies	At the beginning of the year, it cost, like, $400 for eight pills, and you are like, "Oh. Great. Is this attack bad enough to take a pill?" You know? So it's, like, rationing and figuring out, how bad is this attack? … I had a really forward-thinking doctor who wanted to try all these different procedures, but every time there was a procedure it was, like, a day off of work and then a day to recover, so this is two days I was taking off
Self-sufficiency	21 (Study 2 only)	Ability to feel self-sufficient, have the sense that one can manage one's health condition	I have not found the magical solution or the cure—that does not really exist for migraine—but have learned by being very proactive and advocating for myself and my own management of migraine to find things that have allowed me to live a pretty controlled and pretty normal life around migraine I actually built like a migraine emergency kit to deal with especially the depression because it's kind of sudden and I would not know what to do, so I have a kit to help me with that … I have an anxiety workbook that has coloring and jokes in it … A cute little teddy bear thingy in there. And all the extra medicine stuff. Like portable heating pads and icy things. Like the medical stuff but also things to just make me happy

their lifestyle or their specific plans for a day in response to migraine. These decisions had emotional and psychological components and consequences. For example, one participant described a certain treatment as "a lifesaver" but then continued, "but it's not what I use every day. I only use it on days I have to function more than taking a different drug. I get anxiety, actually, about functioning and how much I've got to function during a particular day."

Participants also described other aspects of migraine, such as its unpredictability and the direct costs it imposes, that presented challenges for managing attacks and contributed to the psychosocial burdens associated with migraine. Unpredictability, for example, resulted in diverse burdens. One participant noted being unable to "make many plans, because I don't know one minute to the next or one day to the next, you know, what's going to be, how miserable I'm going to be." Another observed that they could "have something scheduled and boom, a migraine attack could happen and I couldn't be present." Participants also noted that unpredictability led to uncertainty about whether, when, and how to treat an attack and contributed to feelings of frustration and isolation.

DISCUSSION

These two qualitative studies collected a robust amount of information about people's lived experiences with migraine and analysis resulted in a catalog of 66 concepts describing ways in which migraine impacts daily life and individual well-being. These findings are aligned with, but add detail and specificity to, existing published qualitative research on patient experiences with migraine.[27] Some of these concepts have already been used in PROMs for headache or migraine, which often include questions about physical and emotional functioning;[28,29] however, findings suggest that measurement of some concepts could be improved and that other concepts may be missing from many existing measures. For instance, the MFIQ v. 2[18] includes a question about taking care of family which could result in a missed opportunity to capture impacts on people who have responsibilities for caring for friends, neighbors, or pets. The Migraine-Specific Quality-of-Life Questionnaire (MSQ) v. 2.1[30] and Migraine Disability Assessment (MIDAS)[31] integrate the concept of family care into broad questions that also reference concepts like household chores, home repairs, and shopping, an approach that can prevent determining when treatment helps people feel well enough to care for other people or pets (a priority for many study participants), but not go shopping (typically not a priority). Similarly, the Functional Impact of Migraine Questionnaire (FIMQ; previously called the Assessment of Chronic Migraine Impacts),[32] Headache Disability Index (HDI),[33] and Headache Impact Test-6 (HIT-6)[34] include questions that ask about irritability, but many other measures do not include this important, commonplace experience. Similarly, the HIT-6, MFIQ v.2, MSQ v. 2.1, and the Migraine Physical Function Impact Diary[35] include questions about concentration, but not about other concepts related to cognition. By contrast, the FIMQ and HDI include questions about concepts like memory, reading, and speech. The Mig-SCog,[36] a self-reported measure of subjective cognition for migraine, appears unique in addressing cognitive functioning alone, but asks about a limited number of concepts. Notably, the centrally important concept of "brain fog" does not seem to be clearly addressed, although the measure does include a question about difficulty "performing at your normal speed."

One of the challenges of accurately classifying, synthesizing, and conveying people's lived experience with migraine is navigating the differentiation between symptoms and functions, and between physical function and other types of function. For example, headache pain is so prevalent and severe pain is so disabling that it is tempting to attribute all functioning limitations to pain. Interview participants strongly prioritized pain but noted that the absence of pain was no guarantee of feeling well or being able to function. A few participants who had taken a monoclonal antibody for prevention reported having attacks without pain, but experienced impairments from other symptoms. Participants also described impacts—ranging from anxiety to avoidance of activities—that were distally related to symptoms but closely tied to the unpredictability of attacks and the uncertainty that acute medication will be effective for every attack. Available PROMs often frame questions with "when you had a migraine" or "because of your headaches"; thus, these measures may prevent desirable, nuanced assessment, such as capturing when treatment helps people function better during interictal periods but not during attacks, or improve functioning because symptoms that precede or follow the headache phase are reduced.

Study participants also described complex relationships between migraine attack symptoms and impacts on functioning that were influenced by numerous contextual factors, such as the timing and location of attacks, the level of planned activities or responsibilities people have, and the perceived necessity or importance of completing activities. These results showed that migraine-related disability can vary both between individuals and within individuals across attacks and over time. These findings underscore the importance of recognizing that, while impairments of functioning are most common and most severe during the headache phase, they may occur at other times and are linked to an array of migraine symptoms (including those that are not cardinal, such as dizziness) or may result from individual choices or strategies undertaken to manage migraine (e.g., cocooning, pushing through). These findings enhance our understanding of life with migraine and offer additional constructs that could be used in assessing the efficacy of individual treatments or treatment regimens, comparing treatments to each other, and tailoring health care for individual patients. For example, a range of behavioral treatment options like cognitive behavioral therapy,[37,38] acceptance and commitment therapy,[39] and mindfulness-based therapies[39,40] have been shown to improve symptom experience or functioning and reduce disability in the same ways as pharmacological treatments. These treatments also demonstrate capacity to improve self-efficacy, acceptance, and other important outcomes that may not be affected by medication alone. Indeed, the plethora of pharmacological and non-pharmacological treatments raises questions about which therapies are best suited to specific groups of patients or best combined with each other when outcomes could be affected not only by migraine features (e.g., frequency, specific symptoms present, interictal burden) but also individualized, contextual factors. For example, existing research often references the concept of work as though it were relatively uniform in nature, but work can vary in terms of demand characteristics, autonomy, and flexibility.[41] Some jobs are physically demanding while others are cognitively demanding, some allow employees flexibility to manage their attacks while others do not, and workplaces vary considerably in their capacity to make accommodations. These variations directly influence how much impact migraine has on an individual patient's work life and thus may influence the desirable benefits of all forms of migraine therapy. Precisely measuring these interrelated aspects of migraine could permit better tailoring of treatment to the clinical and contextual factors that affect each patient's migraine experience; however, variation in the conceptual scope of available PROMs hampers efforts to achieve this type of measurement. When a comprehensive assessment of patient experience is desired, multiple instruments could be used, but it is unclear how the resulting scores should be synthesized and interpreted since they could reflect both unique and redundant concepts. Findings from these two MiCOAS studies can inform refinements of existing measures as well as the development of new instruments that are designed to capture concepts in specific domains that may be important to measure for specific patient populations or research aims.

This study has some limitations. Participants in the study were purposively selected to achieve representation of certain characteristics resulting in a sample with a higher percentage of people with CM compared with the overall prevalence of CM in the population. All recruitment and sampling strategies are subject to bias and a different strategy may have resulted in elicitation of additional or different information about migraine experience. To mitigate this potential for bias, a substantial number of additional interviews were conducted after data saturation was achieved in both studies. In qualitative inquiry, the results may be biased by the interpretation of the researchers who conduct coding and analysis. To mitigate this bias in both studies, multiple analysts coded the data and conducted analysis. Strengths of this study include the qualitative format, large sample for a qualitive study, and the diverse and representative nature of the sample.

The MiCOAS project is currently using the study findings to develop core measures that can be used in future clinical trials and recommendations for endpoint selection aimed at improving assessments of outcomes that are important to people with migraine. These findings may also open new pathways for patients and clinicians to approach migraine management, including identifying important experiences to be discussed and monitored. Including a broader assessment of the true impact and disability associated with migraine has been shown to help in more accurate diagnosis, more comprehensive treatment plans, and improved patient outcomes.[42,43] The study findings may also serve as a starting point for other types of inquiry because, as is often the case in qualitative research, they raise perhaps as many questions as they answer. For example, a person's level of social support is an important mediator of migraine experience, but the results do not provide a clear understanding of which specific supports are most beneficial or how treatment (or healthcare more broadly) might affect these experiences. Future research should focus on developing knowledge about these complex areas of migraine experience as well as examining intra- and interindividual variability, understanding the full range of migraine symptoms, and detailing how impacts on functioning vary across phases of migraine or in relation to specific symptoms. Refined insights into these elements of migraine experiences could support enhanced drug development as well as the tailoring of treatment regimens for specific groups of patients based on the symptoms and impacts that affect them.

AUTHOR CONTRIBUTIONS

Rikki Mangrum: Conceptualization; data curation; formal analysis; methodology; writing – original draft. **Alexandra L. Bryant:** Conceptualization; data curation; formal analysis; methodology; writing – original draft. **Maya T. Gerstein:** Conceptualization; data curation; formal analysis; methodology; writing – review and editing. **Kelly P. McCarrier:** Conceptualization; methodology; supervision; writing – review and editing. **Carrie R. Houts:** Conceptualization; writing – review and editing. **James S. McGinley:** Conceptualization; writing – review and editing. **Dawn C. Buse:** Conceptualization; writing – review and editing. **Richard B. Lipton:** Conceptualization; funding acquisition; methodology; supervision; writing – review and editing. **R. J. Wirth:** Conceptualization; funding acquisition; methodology; supervision; writing – review and editing.

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Rikki Mangrum and **Alexandra L. Bryant** are full-time employees of Vector Psychometric Group, LLC, which in turn received funds from the FDA to conduct the research detailed in the manuscript. **Maya T. Gerstein** was a full-time employee of Pharmerit/OPEN Health, which in turn received funds from Vector Psychometric Group LLC and the FDA to conduct the research detailed in the manuscript. **Kelly P. McCarrier** is a full-time employee of Pharmerit/OPEN Health, which in turn received funds from Vector Psychometric Group LLC and the FDA to conduct the research detailed in the manuscript. **Carrie R. Houts** is a full-time employee of Vector Psychometric Group LLC, which in turn received funds from the FDA to conduct the research detailed in the manuscript. **James S. McGinley** is a full-time employee of Vector Psychometric Group LLC, which in turn received funds from the FDA to conduct the research detailed in the manuscript. J.S.M. has received honoraria/payment/reimbursement from the journal *Cephalalgia* (biostatistics editor). J.S.M. has also received research grants/support from Amgen, Inc., and the National Headache Foundation. **Dawn C. Buse** is a part-time employee of Vector Psychometric Group LLC, which in turn received funds from the FDA to conduct the research detailed in the manuscript. In addition, she has been a consultant to Allergan/AbbVie, Amgen, Collegium, Lilly, Lundbeck, Theranica, and Teva Pharmaceuticals. **Richard B. Lipton** received research support from the FDA on the MiCOAS project. In addition, he receives research funding from the NIH, the National Headache Foundation, and the Marx Foundation. He also receives research support from Allergan/AbbVie, Amgen, Biohaven, Eli Lilly, and electroCore. He receives personal fees as a consultant or advisor from Allergan/AbbVie, Amgen, Biohaven Holdings, Dr. Reddy's, GSK, Grifols, Eli Lilly, Lundbeck, Merck, Novartis, and Teva Pharmaceuticals. He holds stock or options in Biohaven Holdings and Ctrl M Health. In addition, he receives royalties for Wolff's Headache, 7th and 8th editions. **R. J. Wirth** is a full-time employee of Vector Psychometric Group LLC, which in turn received funds from the FDA to conduct the research detailed in the manuscript.

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