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RESEARCH SUBMISSION

A patient-centered conceptual model and measurement framework for migraine experience developed by the Migraine Clinical Outcome Assessment System

Rikki Mangrum MLS[1] | Alexandra L. Bryant BS[1] | Carrie R. Houts PhD[1] | James S. McGinley PhD[1] | Dawn C. Buse PhD[1,2] | Richard B. Lipton MD[2] | R. J. Wirth PhD[1]

[1]Vector Psychometric Group, Chapel Hill, North Carolina, USA

[2]Neurology, Albert Einstein College of Medicine, Bronx, New York, USA

Correspondence
Rikki Mangrum, Vector Psychometric Group, 847 Emily Lane, Chapel Hill, NC 27516, USA.
Email: rikki.mangrum@vpgcentral.com

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Abstract

Objective: To develop a comprehensive, evidence-based, patient-centered conceptual model of migraine and to derive a measurement framework for the development or selection of clinical outcome assessments used in clinical trials of treatments for migraine.

Background: Improving ways of assessing the outcomes that matter to people who live with migraine is an important goal for treatment development and evaluation. The Migraine Clinical Outcome Assessment System (MiCOAS) project aimed to gather qualitative data directly from people with migraine and develop a patient-centered core set of outcomes and endpoints for migraine clinical trials. Data gathered by the MiCOAS research team was used to develop a patient-centered conceptual model of migraine and a measurement framework designed to capture outcomes that matter to patients.

Methods: A post hoc, pooled secondary interpretive analysis of the results from two MiCOAS qualitative studies (executed in 2020 and 2021 with 71 US adults with migraine) was conducted to develop the conceptual model using iterative diagramming methods to create a visualization. Supporting information exhibits for the visualization were created to record concept definitions and describe their interrelationships. The conceptual model was used to guide development of a measurement framework intended to support the selection or development of patient-reported outcome assessments suitable for regulated clinical trials of both acute and preventive migraine therapies. Input from people with migraine, patient advocates, clinical researchers, and subject matter experts was integrated into the model and the measurement framework.

Results: The comprehensive conceptual model diagram organizes patient-reported experiences into domains for symptoms and impacts of migraine and depicts commonly occurring mediating contextual factors (e.g., perceived pain tolerance) that can affect patients' self-reported disease experiences. The measurement framework

Abbreviations: CHAMP, Coalition for Headache and Migraine Patients; COA, clinical outcome assessment; FDA, US Food and Drug Administration; IHS, International Headache Society; MiCOAS, Migraine Clinical Outcome Assessment System; PFDD, patient-focused drug development.

identifies concepts that are widely experienced or highly disabling to patients with episodic or chronic migraine but also meet the needs of clinical trial endpoint design (e.g., are cross-culturally relevant and amenable to treatment effect within a 3-month trial period) and are capable of capturing experiences during all phases of migraine, including interictal periods.

Conclusions: The patient-centered conceptual model of migraine provides a concise but comprehensive framework for describing and measuring patient experiences of migraine disease and its treatment, including symptoms, daily functioning, and distal outcomes that result from the aggregation of migraine experiences over time. The measurement framework was developed to support comprehensive endpoint design for migraine clinical trials and has been used to guide the development of the MiCOAS measurement instruments.

Plain Language Summary

Historically, migraine researchers and clinicians have not had a comprehensive, patient-focused way to understand migraine as a disease. In this study, we looked at the results of interviews from 71 US adults with migraine and worked with patient and clinician advisors to create a visualization of migraine experiences (often referred to as a conceptual model) that reflects what patients with migraine experience in their daily lives. We also built a framework for measuring those experiences in clinical trials of new treatments, and we believe these tools will help identify new pathways for treatment and improve our ability to see how well treatments work for people living with migraine.

KEYWORDS
conceptual modeling, functioning, measurement, patient-focused drug development, quality of life, symptoms

INTRODUCTION

Migraine is a chronic neurologic disease that affects hundreds of millions of people globally and results in significant disability, particularly among those in their prime childbearing and working years of life.[1–3] Although typically associated with severe headache, migraine causes episodic attacks comprised of several phases characterized by a range of symptoms that can vary across individuals as well as from attack to attack.[4,5]

The development of treatments that prevent attacks and/or relieve migraine symptoms results from more than a century of scientific efforts to understand the disease and its impacts.[6] Existing therapies benefit many patients, but research has also shown that many patients may not achieve the relief they want, need, or expect.[7,8] Recent studies have indicated, for example, that preventive treatments may be effective in reducing headache days by at least 30% for about one-third of patients[7] and that a range of factors may affect individual response to treatment.[9] Systematic reviews conducted for the Migraine Clinical Outcome Assessment System (MiCOAS) found that many migraine outcomes have not consistently been assessed in clinical trials, which limits understanding of treatment benefits. The review of acute therapy trials found that most assessed headache pain, but only about 40% included an endpoint for disability or functional impairment and two-thirds of these used a single broad question.[10] The review of preventive treatment trials showed that the number of migraine attacks/days or headache days are typically assessed, and only half of trials included a disability outcome measure.[11] Additionally, studies in both adults and children with migraine have highlighted patient preferences and priorities for treatment that are not consistently evaluated in clinical trials.[12,13] These findings highlight missed opportunities to better understand the benefits and limitations of existing therapies and identify new treatment pathways. Because they are profoundly distressing and disabling, headache, nausea, photophobia, and phonophobia are crucial symptoms for diagnosing migraine and evaluating treatments, but the MiCOAS project and other studies have robustly demonstrated that these are not the only distressing symptoms imposed by the disease and, by themselves, do not explain the full burden of migraine.[3,5,14,15]

Improving ways of assessing the outcomes that matter to people who live with migraine is an important goal for treatment

development and evaluation. This was the impetus for the multistage MiCOAS project, which was funded in 2019 by the US Food and Drug Administration (FDA). MiCOAS's aims included gathering qualitative data from people with migraine and developing a patient-centered core set of outcomes and endpoints for migraine clinical trials. As part of this effort, data gathered by the MiCOAS research team was used to develop a patient-centered conceptual model of migraine as a disease. This model was then used to support the development of a measurement framework designed to capture outcomes that matter to patients in alignment with FDA guidance on patient-focused drug development (PFDD).[16–18]

BACKGROUND

PFDD guidance, as well as guidance from International Society for Pharmacoeconomics and Outcomes Research–The Professional Society for Health Economics and Outcomes Research, directs that conceptual modeling grounded in qualitative data collected directly from patients should be completed as the first step toward selection or development of clinical outcome assessments (COAs) and trial endpoints.[16,17,19–21] Conceptual disease models are essential because they drive improved understanding of health conditions,[22] identify gaps in knowledge and potential pathways for treatment or healthcare delivery,[23] and help healthcare providers understand how to communicate with and support patients in health-related decision-making.[24] However, migraine clinicians and researchers have lacked a comprehensive, evidence-based, patient-centered conceptual model of the disease. Most published models are selective in representing the experiences of people living with migraine or are framed primarily with clinical considerations rather than patient-centered ones. Existing models address factors related to patient decision-making about migraine preventive treatment[25]; changes resulting from aerobic exercise in migraine[26]; concepts related to treatment, such as adverse events and features of self-injection devices[15]; or narrowly focus on specific research questions and reflect a clinical interpretive framework.[27–29] When qualitative inquiry or literature review has been broad, the resulting publications provide lists of concepts and themes but do not synthesize results into a conceptual model of migraine.[14,30] The most comprehensive model appears to be the one used in developing the Migraine Functional Impact Questionnaire.[31,32] This model was based on a literature review and clinician input, refined through concept elicitation interviews with patients, and then further adapted through consultation with clinicians and measurement experts. It organizes selected patient-centered data within a clinical framework that includes clinical diagnostic criteria established by the International Headache Society (IHS). Consequently, the model misses the opportunity to first capture the patients' own framework as suggested in PFDD guidance.

In approaching conceptual model development for MiCOAS, we decided that the blending of two interpretive frameworks—patient-centered and clinical—in prior attempts to develop a conceptual model was a significant problem. This practice hindered the full description of patients' experience in favor of expressing selected elements that were relevant to specific clinical aims and obstructed each model's capacity to identify gaps in knowledge or identify novel pathways for treatment. To address these limitations, MiCOAS data[3,5,33,34] was synthesized to produce a comprehensive, patient-centered conceptual model of migraine. This model was then used alongside the compiled qualitative data to develop a measurement framework to guide the development of the MiCOAS instruments. In this paper, we describe the methods used to develop the conceptual model, explain the content and aims of the model, and describe the use of the model to guide the development of a hypothesized measurement framework for MiCOAS.

METHODS

Secondary use of data from people living with migraine

The MiCOAS project included two concept elicitation studies that gathered in-depth interview data during 2020 and 2021 from 71 adults with migraine in the US. Previous publications by the MiCOAS research team have described the studies' methods and results of content and thematic analysis of interview data, which identified numerous concepts related to migraine experience and a variety of perspectives related to treatment, healthcare experiences, and management of, or adaptation to, life with migraine.[3,5,33–35] Study protocols and full study reports are also publicly available on the MiCOAS website (https://vpghealth.com/micoas/) to enhance data transparency. Both studies underwent ethical review by the WCG™ institutional review board (IRB), an independent IRB. Participants in both studies were recruited via outreach by The Coalition for Headache and Migraine Patients (CHAMP), a patient advocacy organization engaged in the MiCOAS project; Table 1 provides a summary of participants' demographic characteristics. A post hoc, pooled secondary interpretive analysis of the qualitative study results was used to synthesize findings and create the conceptual model and to support the selection and organization of outcomes for the measurement framework. Pooling of results was feasible and appropriate because both studies followed the same methods for recruitment and enrollment of participants, interviewing, and data analysis; and each study focused on different aspects of life with migraine: The first study focused on experiences with symptoms across migraine phases as well as treatment priorities, the second on experiences with the impacts of migraine on functioning.

Conceptual and measurement modeling methodology

Conceptual modeling provides a condensed representation of reality and requires two stages, each with its own interpretive principles, as

TABLE 1 Study participant characteristics.

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

Abbreviation: OTC, over the counter.

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

described succinctly by Roberts et al.[24]: "the problem conceptualization, which converts knowledge … into a representation of the problem, followed by model conceptualization, in which the components of the problem are represented using a particular analytic method" (p. 805). Interpretation and simplification also leave conceptual models open to various limitations or forms of bias. A migraine disease model developed to support clinical diagnosis, for example, may omit numerous aspects of patient experience that are crucial in other contexts, including assessing treatment efficacy. Conceptual models typically involve a diagram because visualization provides a concise means for displaying condensed data, representing known or theorized relationships among model elements, and conveying complex information in ways that are instructive, memorable, or thought-provoking.[36] However, visualization has the potential to mislead readers and bias interpretation, for example, by intentionally or unintentionally prioritizing certain perspectives or attitudes[37] or by distorting the underlying data.[36] Visualizations are also difficult to interpret when the relationship between the model and the data being modeled is unexplained.[36] To address this potential for misinterpretation, this paper presents both the model diagram and narratives to explain the elements of the model and how they are related to each other.

Measurement models apply a new interpretive framework to a conceptual model of a disease by identifying one or more concepts to be assessed and representing the ways an assessment tool is "intended to work to generate a score(s) that can be interpreted as a measure of the concept of interest in the context of use."[17(p17)] A measurement model may focus on a single symptom, for instance, headache pain, and demonstrate the intended means of measurement (e.g., by assessing pain intensity, frequency, location, or other features). Used as a precursor to a measurement model for a specific context of use, a measurement framework may be used to lay out the hypothesized concepts of interest and articulate the observed relationships between them.

Modeling the MiCOAS study results to develop a patient-centered disease model

In developing the patient-centered conceptual model diagram, we aimed to concisely convey how people with migraine describe their experiences in their entirety, based on the pooled results of the prior qualitative data analysis. This entailed depicting all areas of disease experience and burden, as well as the contextual or environmental factors that may affect them, without regard to the interests or aims of any other stakeholders, including clinicians or regulators. The model was developed through iterative diagramming, a process in which different approaches to organization and visualization were tried and reviewed one after the other by the research team and its patient and clinical advisors (as described further below). First, diagrams were created (see examples in Figure 1 and Exhibit S1) by one analyst (R.M.) who transferred concepts listed in study reports into Miro (www.miro.com), an online collaborative design platform, using

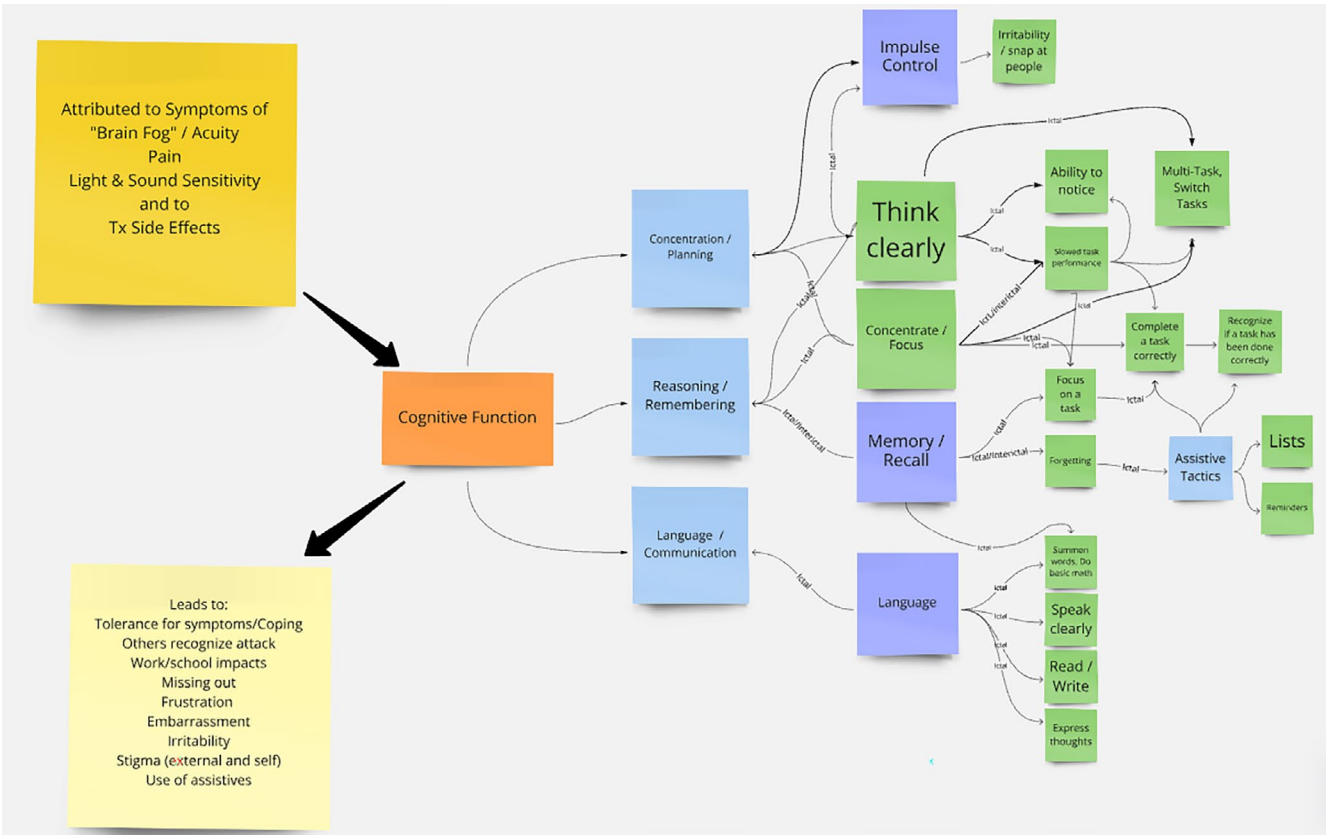

FIGURE 1 Example of initial concept mapping of interview data. Green boxes indicate concepts drawn directly from interview data; blue boxes indicate a layer of analytic organization or synthesis (e.g., "assistive tactics" provides a thematic clarification of how study participants used lists and reminders to support memory functions); orange boxes indicate domain level name; yellow boxes indicate related concepts; and arrows indicate conceptual interconnections.

mind-mapping tools to depict logical groupings and links among concepts. Two analysts (R.M., A.L.B.) then met multiple times to identify strengths and weaknesses of each approach, discuss concept organization and positioning options, and obtain feedback on interim diagrams from a clinician on the research team (D.C.B.). As concepts were placed in the model (or later, in the framework), we reviewed reports and revisited coding and transcripts to test assumptions and look for disconfirming evidence. For example, review of coding and raw transcripts was needed in addressing the concept of dizziness/vertigo. Transcript review affirmed that some interview participants used these terms interchangeably; MiCOAS's clinical advisors also noted that these two experiences can be challenging to differentiate.

Because the resulting initial diagrams were large and detailed, subsequent attempts focused on simplifying the model. These attempts also followed the common practices of mind-mapping and flow-charting but resulted in complex diagrams, did not successfully illustrate relationships found among the concepts in the interview data, or did not permit representation of sufficient detail (see examples in Figure 2 and Exhibits S2–S4). Chief among the weaknesses of the modeling approach shown in Figure 2 was the difficulty of placing symptom concepts, including the crucial factors of symptom frequency, severity, and duration, into a logical position that would effectively indicate their foundational centrality to all migraine experiences but also depict their differential impacts on functioning across groups of people with migraine. The diagram included numerous arrows and color coding to depict relationships among concepts, which resulted in problematic inconsistencies in visualization. In Figure 2, for example, the notion of "functions that depend on other functions" was shown in a blue box to highlight its connection to psychosocial outcomes, but its links to cognitive and physical functioning outcomes were conveyed by its position in the diagram. These difficulties prompted us to take a cue from models reviewed by Krieger[37] and focus the visualization principally on relationships among major components of experience found in the data while limiting the details to selected examples that illustrated what the components were. This approach permitted the development of a concise, holistic diagram that represents all types of experiences described by people with migraine and depicts the way these experiences depend on each other, although the diagram also reflects a high degree of synthesis and simplification (Figure 3).

While drafting the model diagram, the research team received stakeholder input from the MiCOAS External Technical Advisory Committee and CHAMP affiliates on multiple occasions. The Advisory Committee included clinicians, patients, and subject matter experts who were engaged throughout the entire MiCOAS project. CHAMP hosted multiple meetings with patients and patient

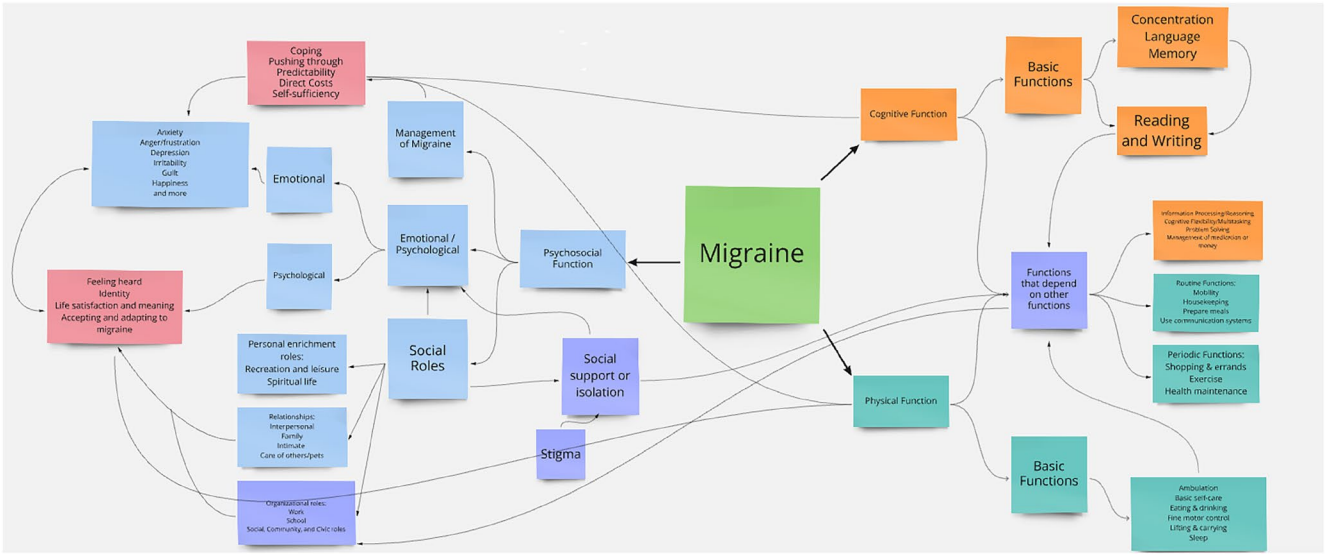

FIGURE 2 Example of interim patient-centered model. Light-blue, orange, and green boxes indicate domain assignments for concepts; pink and dark-blue boxes indicate crosscutting concepts, arrows indicate relationships among concepts.

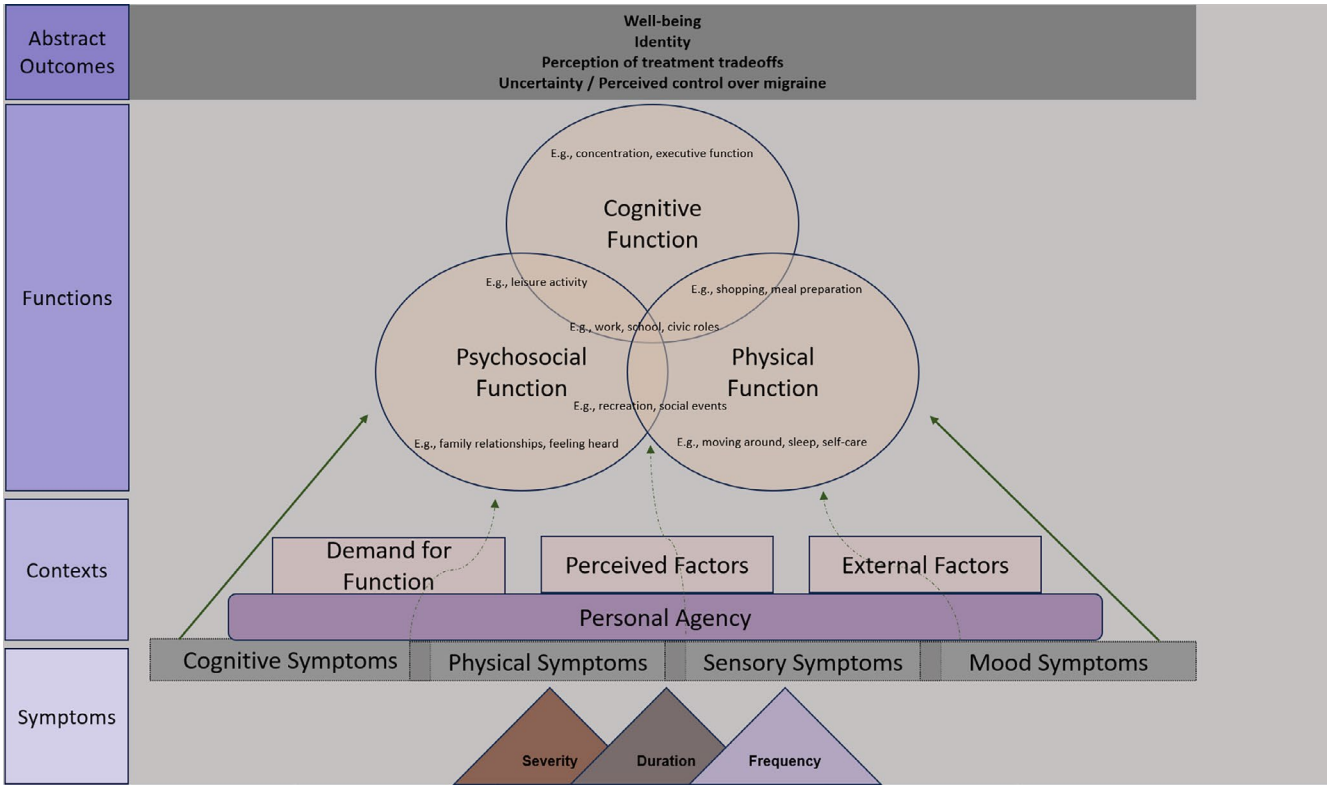

FIGURE 3 The MiCOAS conceptual model. MiCOAS, Migraine Clinical Outcome Assessment System.

advocates to review study findings and provide input on the model content and visualization. These stakeholders suggested several changes, including the use of a "migraine-friendly" color palette and adjustments to the diagram layout, such as the level of detail depicted and the positioning of objects. The initial draft, for example, used bright colors that people with migraine found bothersome and did not include the categorical labels for symptoms, contexts, functions, and abstract outcomes. Feedback also addressed terminology, although individual stakeholder views on terminology sometimes varied substantially, as illustrated by an iterative debate about terms like cognitive versus mental versus "brain fog" as a descriptor for symptoms. Some stakeholders advocated for "brain fog" because many patients use it, whereas others noted that the phrase was often used as a catch-all term for both ictal symptoms and postdrome or

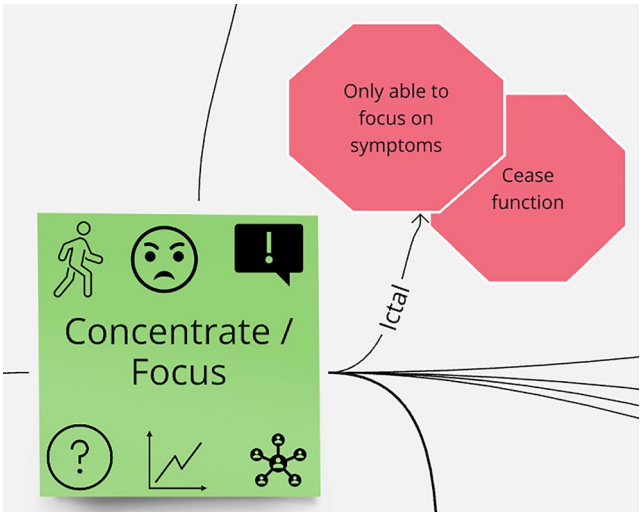

FIGURE 4 Example concepts mapping detail with graphical annotations. Icons used to annotate concept read from top left as follows: affects functioning, bothersome, important for treatment to address this experience, contributes to uncertainty, experiences are variable within/across participants, affects psychosocial well-being.

interictal impacts on cognitive functioning. Some thought the word "cognitive" seemed like jargon, whereas others associated the word "mental" with negative past experiences of stigma. Finally, all stakeholders recommended the research team increase the accessibility of the model by creating a plain-language explanatory video to include on the MiCOAS website.[38]

Developing a measurement framework

To develop a measurement framework, initial models were iteratively expanded (see example in Figure 4) to depict a range of other content in the study results relevant to selecting concepts that are suitable candidates for evaluating treatment effects, including whether participants:

- Said they experienced it during or between attacks, which would permit measurement to include outcomes that reflect interictal burden
- Attributed an impact to specific symptoms or to other impacts from migraine, which could support streamlining of measurement to reduce respondent burden
- Referenced adaptive or avoidance behaviors relevant to the concept, which are indicative of burden and could have important consequences for phrasing of questions and responses
- Described important impacts on functioning or psychosocial well-being (e.g., emotional state, social relations) that have been underutilized as outcomes in migraine clinical trials
- Described experiences as bothersome, variable or unpredictable, or important for treatment to address, which are indicators of concepts that matter to patients

Based on the refined diagrams and with systematic reference to accumulated data from interviews and to the patient-centered model itself, we developed a measurement framework (Figure 5) to delineate the domains and concepts that appeared most relevant for clinical trials using the criteria shown in Table 2. The entire MiCOAS research team, including qualitative researchers, psychometricians, and clinicians, met repeatedly to review available information, reach decisions on the applicability of criteria to concepts, and determine the content and organization of the framework. The MiCOAS Advisory Committee and CHAMP were also engaged to ensure the inclusion of multiple perspectives and expertise in developing the framework. Resources used to support decision-making included the conceptual model; original study reports, which include tables of concepts with definitions and frequencies of report by study participants; and interview transcripts. Additionally, the research team compiled an Excel version 2408 spreadsheet of item-level concepts found in 20 existing migraine or headache patient-reported outcome measures (PROMs), permitting evaluation of their degree of correspondence to the MiCOAS conceptualization of migraine experience (see Exhibits S5 and S6). During decision-making, tables were used to track concepts considered for measurement and record summaries of discussion points, stakeholder perspectives, links between symptoms and impacts of migraine, and sources of variability or unpredictability that could affect measurement (see example in Exhibit S7). Additional tables for the selected concepts provided a concise definition and recorded assumptions, possible endpoints, and notes describing specific relationships found in the qualitative data that might be pertinent to understanding sources of variability in measurement (example shown in Table 3).

RESULTS

The MiCOAS holistic, patient-centered model of migraine (Figure 3) is intended to be read starting from the bottom to the top and presents four broad, interconnected aspects of migraine experience that were described by interview participants: symptoms experienced, contexts applying to migraine experiences, functions affected by migraine, and abstract outcomes resulting from the cumulative experience of life with migraine and its treatment. Table 4 describes each part of the model in detail. Visual design elements in the model are intended to convey important aspects of migraine experience. Triangles used to depict symptom severity, frequency, and duration, for example, are intended to illustrate that these foundational factors affect the stability of relationships among the other elements. If one triangle increased substantially in size, other elements of the model would be pushed aside or overwritten, echoing how people with migraine describe their symptoms as overwhelming or profoundly disabling (see Exhibit S8 for an example diagram). The same is true for other elements in the model. A person who has a great deal of personal agency (making this rectangle larger) may experience migraine differently from a person who has less agency, and a person who reports many physical impacts (making this circle bigger) may have different experiences than someone who reports many cognitive impacts.

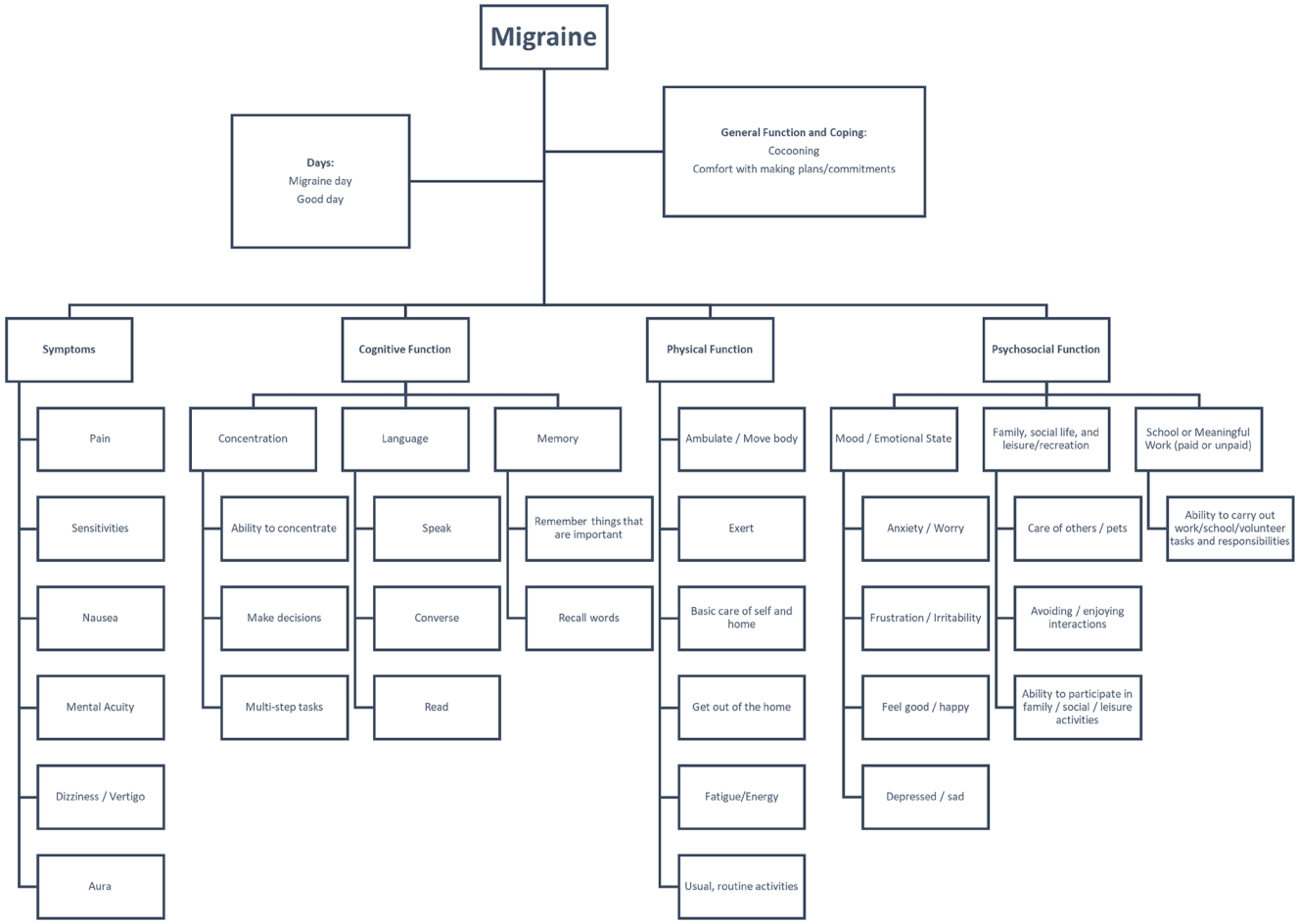

FIGURE 5 The draft MiCOAS measurement framework. MiCOAS, Migraine Clinical Outcome Assessment System.

TABLE 2 Criteria for selecting concepts for the MiCOAS measurement framework.

Criterion	Explanation
Broadly applicable to all people with migraine	Addresses the full range of overall migraine frequency and severity without embedding assumptions based on diagnostic criteria or past research practices
Include representation of all symptoms and impact outcomes reported or desired by patients	Addresses both symptoms and impacts and delineates them systematically based on patient perspectives, addresses symptoms/impacts experienced interictally, and includes assessment of overarching "positive" outcomes (e.g., good day, feel happy, enjoy activities)
Amenable to direct modification by treatment	Likely to be directly affected by pharmacological treatments; for example, concepts like drug costs or stigma are crucially important to people with migraine but are not directly modifiable by treatment
Broadly applicable to all treatment modalities	Relevant to both acute and preventive treatment priorities
Amenable to short-term change due to treatment	Likely to show change within a relatively short period of time (3 months)
Commonly experienced and/or associated with meaningful burden to patients	Found with sufficient prevalence and/or associated with meaningful burden (suffering or impairment of functioning)
Articulable	Conceptually precise and articulable in a brief assessment tool; social and recreational life are examples of complex, varied areas of human experience that are difficult to articulate clearly and precisely in a questionnaire
Cross-culturally relevant	Unlikely to be culturally or geographically specific in ways that are not amenable to translation or adaptation; doing laundry and grocery shopping are example concepts that may encompass a very wide range of experiences depending on culture or geography

Abbreviations: MiCOAS, Migraine Clinical Outcome Assessment System.

TABLE 3 Example of measure concept detail table.

Concept	Definition	Assumptions	Possible endpoints	Notes
Concentration	Ability to concentrate on whatever you are doing	Ability to concentrate can be indicative of altered mental acuity as a symptom but can also be negatively impacted by other symptoms (e.g., pain, dizziness), meaning it reflects both potential symptomology and disability impact.	Level of difficulty with concentration on headache days; frequency of difficulties with concentration over time; interictal incidence of difficulty with concentration (e.g., due to post-attack fatigue)	Related to thinking clearly. Also related to short-term memory experiences, which were often linked to ability to concentrate; COA items about ability to remember what are doing may thus reflect concentration in addition to/instead of memory.
Think clearly	Ability to think clearly, make decisions	Thinking clearly is related to but distinct from concentration. Individuals may be able to think clearly but not concentrate; however, concentration does seem to require thinking clearly.	Level of difficulty with thinking clearly on headache days; frequency of difficulty with thinking clearly over time; impact of difficulty with thinking clearly on daily functioning	Appears to overlap, or be most similar to, the symptom of feeling mentally slow/foggy (altered mental acuity), but other symptoms can affect ability to think clearly (e.g., irritability, fatigue).

Abbreviations: COA, clinical outcome assessment.

The model also depicts the interconnectedness of different types of migraine experiences. Overlapping diagram elements indicate how people with migraine talk about their experiences in ways that would be obscured by a rigid hierarchy or taxonomy. Symptoms are often interlinked: They overlap each other across phases of an attack, and the experience of one can exacerbate the experience of another. For example, among MiCOAS interview participants, irritability often preceded and was overlapped by the physical and sensory symptoms of the headache phase,[5] whereas cognitive problems were described variously as a distinct symptom, an impact of headache pain, and a consequence of post-attack fatigue.[3,39] Similarly, the three major domains of functioning overlap because migraine symptoms and people's individual contextual factors may affect one or more of these domains simultaneously, and specific functions often fit into more than one domain. Shopping provides an excellent illustration of this latter point. MiCOAS interview participants referenced significant physical challenges with shopping but also highlighted cognitive aspects, such as the need to remember where things are, read labels, or estimate costs. Several participants also referenced social aspects, such as recreational shopping with friends as an important social activity that could be affected by migraine. One MiCOAS participant who had experienced frequent, severe attacks prior to starting preventive treatment joyfully reported being able to go to a loud, brightly lit store. This experience was emblematic of a return to normalcy and restoration of their ability to participate in a central family responsibility. Interview participants also highlighted the general adaptability of most shopping tasks, an observation that has important implications for using shopping ability as an outcome when evaluating treatment efficacy. Many MiCOAS interview participants noted that shopping was something they could easily do in between attacks when they felt well. Thus, simply asking about 'how often you had difficulty going shopping' might be less informative than asking how often shopping trips must be arranged around migraine attacks.

The draft MiCOAS measurement framework (Figure 5) depicts the elements selected for inclusion as core outcomes for clinical trials. These selections are largely aligned with the prior models used to support clinical outcome assessment development but also reflect several novel approaches. First, in alignment with the interview data[39] and input from patient and clinical advisors, mental acuity problems (an umbrella concept comprising experiences of "brain fog", slowed thinking, confusion, and feeling that one is "not as sharp" as usual) is included as a core symptom, and functions associated with cognitive capacity are included. Second, several positive outcomes are included, such as the concepts of a good day and feeling good or happy, providing a means to assess whether improvements in these outcomes are associated with reduction in symptoms or to understand how often positive outcomes co-occur with symptoms and burdens, thus providing a more detailed picture of migraine experience. Third, cross-cutting concepts related to general function (comfort with making plans, self-isolation) are included but treated as distinct because they are reflective of contextual factors (e.g., personal agency, demand for function) that may be inconsistently applicable to patients as well as more resistant to treatment effect. Finally, for both physical and social domains, broad concepts were selected because these may be more flexibly interpreted, potentially resulting in less unintended variability in measurement due to restrictive phrasing. For example, 'care of others or pets' is a broader conceptualization for caregiving compared with one that only references caring for family members. Similarly, a concept like "ability to carry out usual, routine activities" permits each individual to determine the relevant scope of activity to consider rather than being constrained by examples of specific activities that are not equally applicable to all people who have migraine (e.g., doing laundry, driving, shopping). This latter feature of the measurement framework is consistent with some existing measures of migraine that include broadly phrased items (e.g., the

TABLE 4 Description of concept model components.

Explanation	Limitations, bias, gaps in knowledge
Symptoms occurrence: The severity, frequency, and duration of migraine attacks, or of specific symptoms that occur before, during, after, or between attacks	
These concepts comprise the foundation for the model because they profoundly influence the way people experience the symptoms and impacts of migraine. The overlapping triangles convey two important features. First, these are distinct but interrelated factors such that considering only one of them provides an incomplete basis for understanding a patient's experience (e.g., frequent, long-lasting attacks may result in different experiences than frequent, brief ones). Second, triangles are used to illustrate the variability in experience that can result from differences in the frequency, severity, or duration of attacks. Making any one triangle bigger or smaller to represent these changes would alter the balance of all the elements of migraine experience that rest upon them within the diagram.	Speed of onset of symptoms was a key factor for some MiCOAS interview participants. Attacks that escalate quickly can create specific burdens (e.g., when driving a car, a sudden migraine attack can be dangerous). When attacks develop gradually, symptoms are harder to notice and people may miss the window of opportunity for achieving acute treatment efficacy. Speed of resolution of symptoms could also be important because many participants highly valued rapid relief. Differences in symptom speed might be useful in explaining differences in impact on function among people with otherwise similar frequency, severity, and duration of migraine attacks.
Four types of symptoms: Physical (e.g., pain, nausea, vomiting, muscle stiffness, dizziness, fatigue); *Sensory* (e.g., photo- and phonophobia, visual disturbances, tinnitus, numbness, tingling); *Cognitive* (e.g., altered mental acuity ["brain fog"], slurred or jumbled words, memory problems); and *Mood* (e.g., irritability, anxiety, sadness, euphoria)	
The categories overlap to represent the varied links people with migraine made between the symptoms they experience, such as perceiving that sensitivity to sound is related to pain level. Not depicted are the ways symptoms can vary within a single attack (i.e., the symptoms a person has often varies over the phases of an attack), across attacks experienced typically (i.e., some attacks are like this and others are like that), or across the individual person's history of migraine (i.e., attacks used to be like that, but now they are like this). This variability in symptom experience contributed significantly to people's perception of the burden imposed by migraine and their ability to manage migraine but is difficult to convey in a simple diagram.	It is not always clear to people with migraine what is a symptom and what is an impact; nor is it always clear when the distinction is meaningful. For example, is anxiety a direct symptom of migraine, or is it the result of having migraine that is distressing and disruptive? Shedding more light on this issue could be a key benefit of increased precision and scope in migraine measurement. Better measurement could illuminate whether symptoms like anxiety can be meaningfully addressed independently of symptoms like nausea or pain.
Personal agency: Personal agency encompasses a person's strategies for managing migraine, including all the decisions they make in response to migraine, either for a particular attack or over the course of a lifetime.	
In MiCOAS interviews, personal agency affected participants' direct experience of migraine; thus, this model element is shown as slightly overlapping the symptom elements. Agency included treatment decision-making; migraine attack management practices, including the ability to "push through" an attack or to "cocoon" (i.e., self-isolate during an attack); and lifestyle strategies such as avoiding triggers. Components of agency are not available to everyone or at all times: A person may be unable to access effective treatment (e.g., due to cost) or be out of medication when an attack occurs.	How much personal agency could affect assessment of treatment effect in a clinical trial is unclear. Trial design and implementation typically control for some aspects of agency (e.g., by specifying when treatment is used) but not others (e.g., decisions to push through or cocoon during attacks).
Contextual factors: Three types of contextual factors influence people's migraine experience—the level of demand for function people face each day (e.g., at work or at home), the way people are perceived by others (e.g., experiences of understanding or stigma) or perceive themselves in relation to their symptoms (e.g., pain tolerant/intolerant), and external factors (e.g., physical environment, insurance coverage).	
Personal context affects symptom experience and people's ability to exercise personal agency, with consequences for functioning and well-being. The model positions contextual factors so they touch the personal agency box but do not touch each other to illustrate that contextual factors can influence agency but may operate independently of each other.	These concepts condense an array of detail not depicted in the model. The physical environment includes uncontrollable factors like weather, as well as lighting, noise, and smells, which may or may not be controllable depending on circumstances. Treatment access includes factors such as whether people have found a medication that works for them or can obtain sufficient doses to meet their needs.
Some contextual factors lie outside a person's control (e.g., inclement weather, work duties that preclude the use of certain medications for an attack).	Further inquiry is needed to understand how these concepts may be relevant for treatment development, outcome assessment, or healthcare delivery.

TABLE 4 (Continued)

Explanation	Limitations, bias, gaps in knowledge
Domains of functioning: Migraine impacts a wide range of human functioning, including physical, cognitive, and psychosocial activities.	
The domains are depicted as overlapping, and the position of exemplar concepts within domains illustrates that these delineations are somewhat arbitrary and may not reflect all possible patient perspectives (e.g., shopping may variously be regarded as physical, cognitive, or social in nature). Although many MiCOAS interview participants reported interictal periods characterized by a return to normal functioning, many others did not. This included participants with chronic migraine and participants who experienced long-lasting or very severe attacks (i.e., requiring time for recovery before resuming normal activity).	The MiCOAS studies showed that symptoms have differing impacts on individuals. For example, one person with migraine may long regret the impacts of irritability on their children, whereas experiencing negligible impacts from periodic slurring of their words. Someone else whose occupation requires clear communication may experience significant impacts from slurred words. MiCOAS participants reported impacts on functioning linked to avoidance practices (e.g., avoiding activities that might trigger an attack) and uncertainty (e.g., limiting future plans or commitments).
Solid and dotted lines: These lines depict the direct and indirect relationships between symptoms and the domains of functioning.	
Solid lines illustrate the direct impact of symptoms on functioning (e.g., dizziness may lead directly to impairment of cognitive functioning by obstructing a person's ability to read). Dotted lines illustrate that symptoms also have indirect or aggregate effects that result from the interaction of symptom experiences with other factors (e.g., repeated absences can affect performance at work or school but could be mitigated by personal agency or contextual factors).	Although direct and indirect relationships could be observed, the MiCOAS data did not support a clear delineation between them or a precise understanding of which symptoms produce which impacts (or produce more/less direct or indirect impact). Indirect relationships constitute an important knowledge gap because they may result in unexpected or atypical links between symptoms and impacts of migraine. For example, a person who considers it important to honor their commitments may routinely "push through" their attacks and report little impact on functioning despite having significant symptoms.
Abstract outcomes: Abstract outcomes include people's general well-being, their sense of identity, their perspectives on the tradeoffs between treatment benefits and burdens, and their overall experience of uncertainty or sense of whether they have control over migraine's impact on their life.	
These personal outcomes result from the totality of migraine experiences over time and thus vary widely: A person who has just started having weekly migraine attacks may keenly feel that they have lost control of their life, whereas someone who has lived with migraine for years may have developed management strategies that restore a sense of control.	Not depicted are the varied, individualistic ways in which people experience these outcomes, which affects the utility of these concepts in health research. For some MiCOAS participants, migraine's impact on their sense of identity was entirely negative and unwelcome. For others, living with migraine became an important part of their identity, and they valued their engagement in the migraine patient community or roles in building knowledge and awareness in their community or workplace.

Abbreviations: MiCOAS, Migraine Clinical Outcome Assessment System.

Migraine Physical Function Impact Diary[31] includes questions asking about daily routine and usual activities).

DISCUSSION

Statistician George Box once wrote, "Models, of course, are never true, but fortunately it is only necessary that they be useful."[40(p2)] This aphorism underscores that models are invariably limited because they are simplifications but can nevertheless aid in understanding or support decision-making. It serves as a reminder that models are subject to refinement or change over time as knowledge of the modeled phenomenon evolves.

Prior models of migraine share a great many characteristics with the MiCOAS model but also exhibit significant differences or limitations in scope in relation to the understanding of migraine experiences derived from the MiCOAS interviews. Seng et al.[41] present an adaptation of the social ecological framework for migraine and thus does not depict the specific types of impacts migraine has on functioning or quality of life. The model developed by Mannix et al.[32] and updated in Hareendran et al.[31] limits its depiction of symptoms to those defined by IHS criteria and conflates cognitive effects (i.e., difficulties with concentrating or thinking clearly) with physical functioning. The Mannix–Hareendran model places content on a continuum of proximal to distal to a migraine attack (which suggests a more orderly, linear relationship between migraine attacks and migraine impacts than was found in the experiences of MiCOAS interview participants) but does not specify the intended time frame for proximal/distal. Some of these placements did not allow room for important findings from the MiCOAS project. For example, the Mannix–Hareendran model depicts "impact on plans/schedules" as proximal to migraine attacks, but MiCOAS participants also reported limitations on plans/schedules between attacks due to uncertainty about when attacks will occur.

The history of selective modeling of migraine patient experiences and the practice of filtering patients' own perspectives through a clinical practice or trial lens may have contributed to gaps in understanding and consequently to limitations in migraine research and healthcare delivery practices. First, some key symptoms and impacts that comprise migraine burden have been overlooked or underrepresented in clinical research. Diminished mental acuity, often referred to as "brain fog" by patients, received relatively little

attention in research until the past decade, and its relationship to other symptoms and contribution to overall migraine experience is not fully understood.[42] Second, the focus on pain and cardinal migraine symptoms like nausea or photophobia makes sense in the context of clinical diagnosis but may have resulted in therapy trials that did not fully address patients' disease burden, leaving clinicians and patients without information relevant to treatment planning. Even if an acute medication worked consistently to resolve headache within 2 hours, for example, each migraine attack may still have resulted in a significant disruption of a person's life in ways that impair their overall well-being or jeopardize their employment and family relationships. When acute medications work inconsistently, patients are burdened with added uncertainty about how to treat their symptoms and plan their lives. Third, limited modeling of patients' experiences and perspectives may have contributed to a correspondingly limited understanding of migraine phenotypes. What might a detailed understanding of migraine symptoms, and the ways that combinations of symptoms may vary over the course of individual attacks or a lifetime with migraine, tell us about migraine as a disease? How might an improved understanding of the relationships among symptoms, treatment effects, and functioning or abstract outcomes help us develop better treatments or better healthcare delivery practices for migraine?

LIMITATIONS

There are important limitations to this work. First, the model was driven by studies of English-speaking study participants in the US, a majority of whom were female, well-educated, and self-reported prior use of migraine preventive treatment. Results from a more varied sample might have altered the conceptualization of migraine or prompted a different visualization approach. Second, the scope of interviews may have limited findings that underlie the model and measurement framework. Interviews were long (90 min), covered a wide range of topics, and endeavored to provide participants with ample opportunities to raise topics on their own. However, the underlying aim of COA development may have influenced interview conversations to focus on specific topics (e.g., symptoms and disabilities), resulting in underdeveloped data on other topics. Third, conceptualization and visualization were conducted by a single research team and its advisors and thus inevitably reflect their expertise, interpretations, and assumptions. Continued interrogation and testing of both model and measurement framework are necessary to affirm, refine, or expand them.

CONCLUSION

The MiCOAS holistic conceptual model represents the ways patients themselves report and interpret their migraine experiences. It provides a comprehensive picture but will likely require expansion and refinement to reflect continued evolution of knowledge of migraine and its treatment. The model provides a patient-centered foundation for a range of practical efforts to improve outcomes for people with migraine, including clinical research, healthcare delivery, measure development, patient advocacy, and patient education. The model may also support new ways of thinking about treatment effects (and perhaps pathways for treatment) and inform broader policies that may affect people with migraine, such as workplace or school policies or policies related to disability assessment. The draft MiCOAS measurement framework presents a distillation of content from the conceptual model designed to support a robust approach to assessing response to treatment in a migraine clinical trial. This measurement framework was used to prepare COA items for MiCOAS but can also be used to evaluate the conceptual coverage of other available COAs and to support endpoint design for future migraine trials.

AUTHOR CONTRIBUTIONS

Rikki Mangrum: Conceptualization; methodology; investigation; formal analysis; visualization; writing – original draft; data curation. **Alexandra L. Bryant:** Investigation; formal analysis; writing – review and editing; data curation. **Carrie R. Houts:** Conceptualization; writing – review and editing; formal analysis. **James S. McGinley:** Conceptualization; formal analysis; writing – review and editing. **Dawn C. Buse:** Conceptualization; supervision; funding acquisition; writing – review and editing. **Richard B. Lipton:** Conceptualization; methodology; funding acquisition; project administration. **R. J. Wirth:** Conceptualization; methodology; supervision; funding acquisition; project administration; writing – review and editing.

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CONFLICT OF INTEREST STATEMENT

Rikki Mangrum, **Carrie R. Houts**, and **James S. McGinley** are full-time employees of Vector Psychometric Group, which in turn received funds from the FDA to conduct the research detailed in the manuscript. James S. McGinley has received honoraria/payment/reimbursement

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ORCID

Rikki Mangrum https://orcid.org/0000-0001-6231-5890
Carrie R. Houts https://orcid.org/0000-0003-1233-9389

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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