

RESEARCH SUBMISSION

Assessing attack-related fear in headache disorders—Structure and psychometric properties of the Fear of Attacks in Migraine Inventory

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Abstract

Objective: This study aimed to develop a self-report questionnaire for the assessment of attack-related fear in migraine, and to determine its factor structure as well as its psychometric properties by the primary analysis of a cross-sectional survey's data.

Background: High fear of attacks in migraine increases the burden of disease and is assumed to have a negative impact on the course of the disease. Little is known about the structure and dimensionality of attack-related fear, and a valid instrument for the comprehensive assessment is lacking.

Methods: Based on a literature search and interviews with persons with migraine as well as with experienced practitioners, a 46-item self-report questionnaire, the Fear of Attacks in Migraine Inventory (FAMI) was developed. A cross-sectional online survey comprising an assessment of diagnostic criteria of migraine and a battery of questionnaires including the FAMI was conducted ($N = 387$ persons with migraine, 364/387 [94.1%] women, $M = 40.9$ [$SD = 13.1$] years, migraine without aura: 153/387 [39.5%], migraine with aura: 85/387 [22.0%], and chronic migraine: 149/387 [38.5%]).

Results: Item selection led to 29 items for the FAMI. Exploratory factor analysis resulted in three clearly interpretable factors (fear of negative consequences; attention and anticipation; fear-avoidance); a confirmatory factor analysis yielded an acceptable to good model fit ($\chi^2(3) = 1328.84$, $p = 0.001$, $\chi^2/df = 3.55$, $RMSEA = 0.085$, $SRMR = 0.073$, $CFI = 0.98$, and $TLI = 0.97$). Reliability was good (fear-avoidance, $\omega = 0.85$; attention and anticipation, $\omega = 0.88$) to excellent (fear of negative consequences, $\omega = 0.91$). Correlational analyses confirmed the convergent validity of the FAMI.

Abbreviations: CFA, confirmatory factor analysis; CS-HD, Cogniphobia-Scale for Headache Disorders; DASS, Depression Anxiety Stress Scales; DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, version IV; EFA, exploratory factor analysis; FAMI, Fear of Attacks in Migraine Inventory; GAD-7, Generalized Anxiety Disorder Screener; HIT-6, Headache Impact Test; HMSE-G-SF, Headache Management Self-Efficacy Scale, Short Form; HTSAQ-SF, Headache Triggers Sensitivity and Avoidance Questionnaire, Short Form; ICHD-3, International Classification of Headache Disorders, 3rd edition; MIDAS, Migraine Disability Assessment Scale; NEO-FFI-30, NEO-Five-Factor Inventory, 30-Item Short Version; PASS-20, Pain Anxiety Symptom Scale 20; pMOH, probable medication-overuse headache; PVAQ, Pain Vigilance and Awareness Questionnaire.

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Conclusions: The FAMI appears suitable and promising for the assessment of attack-related fear in migraine research and clinical care.

KEYWORDS

anxiety, attacks, fear, migraine, questionnaire

INTRODUCTION

Migraine is a primary headache disorder with high prevalence and is one of the most disabling conditions worldwide.^{1,2} Because genetic, pathophysiological, and psychological factors contribute to the development and course of the disorder, migraine should be conceptualized within a biopsychosocial model.³⁻⁵ In addition to stress, anxiety is an important feature among the psychological factors in migraine. The relation between anxiety and migraine appears bidirectional, complex, and strong. Anxiety and migraine are substantially positively correlated in that persons with migraine are more likely to report anxiety, and higher headache frequency leads to increased risk of anxiety.⁶⁻⁸ Anxiety in persons with migraine (i) leads to higher disability and higher pain intensity,^{9,10} (ii) is an emotional burden itself,⁶ (iii) may lead to a higher medication intake and thus be a risk for the development of medication overuse headache,¹¹⁻¹³ (iv) can be a trigger of migraine attacks,¹⁴ and (v) has a negative impact on treatment effects.¹² Because higher headache activity can lead to increased anxiety, and increased anxiety may result in higher headache activity, anxiety presumably serves as an essential part of a vicious circle leading to the chronicity of migraine. Additionally, anxiety may lead to fear-motivated avoidance of potential triggers, which can foster sensitization and reduced tolerance to triggers, as described in the trigger avoidance model of headaches.¹⁵ Thus, anxiety or fear represent essential psychological factors contributing to the clinical course of migraine.

Fear of attacks is a very specific feature in persons who experience recurring attacks of headache (e.g., cluster headache and migraine). Peres and colleagues¹¹ conceptualized the fear of attacks in migraine as a specific phobia ("Cephalalgiphobia") according to the Diagnostic and Statistical Manual of Mental Disorders, version IV (DSM-IV).¹⁶ The fear of attacks has been assessed by Giannini and colleagues¹³ in using a nonvalidated structured interview. This interview comprises four items, with a focus on medication intake in three items. However, it can be assumed that attack-related fear is more complex and includes other facets. In a worldwide online survey of adult persons with migraine from 2018, 55% reported having fear of attacks,¹⁷ and, in a recent Delphi study, patient experts recommended assessing attack-associated fear.¹⁸ Because fear of attacks in migraine may be common and presumably has an impact on the course of the disorder, it should be considered explicitly in clinical research and practice. The construct "fear of attacks" is assumed to be multidimensional, including behavioral as well as cognitive dimensions. A valid instrument which provides a comprehensive

assessment of this construct in migraine is lacking. This study aimed to develop a self-report questionnaire for the assessment of attack-related fear in migraine and to determine its factor structure as well as its psychometric properties by the primary analysis of a cross-sectional survey's data.

METHODS

Study design and participants

This study is part of the project "Optimization of Diagnostic Instruments in migraine, (ODIN-migraine)," which aims to improve the behavioral medicine assessment in migraine. The study was designed as a cross-sectional online survey in Germany and was conducted at the Department of Psychology (University of Mainz, Germany). The study protocol was approved by the local ethics committee of the Department of Psychology, University of Mainz, Germany (2020-JGU-psychEK-009). The survey (as part of the ODIN-migraine project) was prospectively registered with the German Clinical Trials Register (DRKS-ID: DRKS00022812).

Participants were recruited via advertisement on the online portals of two umbrella associations of pain-related self-help groups (i.e., "MigräneLiga e.V.," www.migraeneliga.de, and "UVSD Schmerzlos e.V.," www.uvsd-schmerzlos.de), as well as via social media (Facebook, "Migräne Forum," www.facebook.com/groups/608605402602066/) and a university press release. The advertisement announced that the study was investigating the issues of anxiety and fear in persons with migraine. It was publicized that a project objective was to improve questionnaires for assessing migraine-specific anxiety and fear. To motivate potential candidates, it was pointed out that taking part in the survey can contribute to the improvement of migraine care in the future. There were no material incentives. However, the advertisement declared that the general results of the study would be presented in the respective portal or website. Each advertisement contained a link to the survey.

Inclusion criteria were: (i) meeting the International Classification of Headache Disorders criteria (3rd edition, ICHD-3)¹⁹ of migraine without aura, migraine with aura, or chronic migraine; (ii) disease duration of at least 1 year, and (iii) age of at least 18 years. Exclusion criteria were not defined. Because the study version of the developed questionnaire comprised 45 items, a sample size of at least $N = 225$ was targeted.²⁰

Procedure

The online survey was provided via the portal SoSci-Survey (www.sosicisurvey.de).²¹ Before the online survey was released to the participants, several staff members checked the usability and technical functionality with repeated pretests. After activating the link to the survey, participants were first informed about the aim of the study and other issues (including data protection). It was explained that the data would be collected anonymously and stored digitally for at least 10 years, and the contact information of the university's data protection officer was given. The participants were informed about the organization and persons carrying out the study. An email address was provided for questions about the study and the treatment of migraine. Participants were asked to contact a doctor in their area in the event of acute health problems or emergencies. Furthermore, the participants were informed that the survey was voluntary, was estimated to take about 45 min, and could be cancelled without any disadvantages. Subsequently, participants had to confirm their age, a medically diagnosed migraine disease, disease duration of at least 1 year, and their consent to participate in the study (each by ticking a checkbox). The survey consisted of two parts, (i) a query of sociodemographic and disease data, including a differentiated assessment of diagnostic criteria of migraine (according to the ICHD-3)¹⁹ as well as a medical history, and (ii) a battery of questionnaires on headache-related factors (including the developed Fear of Attacks in Migraine Inventory [FAMI]), as well as more generic instruments (such as the German version of the Depression Anxiety Stress Scales [DASS]).²² When switching to the next page of the online survey, the participants were reminded with a text warning if an item had not been filled out. By ticking a checkbox, the participants were able to confirm that they did not want to provide any further information on the current page and were thus able to continue with the survey. Additionally, the participants were able to navigate within the survey using the "Next" and "Back" buttons. The survey comprised 24 pages in total, including two optional pages (e.g., for the description of aura symptoms), and with an average of $M = 11.2$ items per page ($SD = 12.3$). At the end of the survey, the participants had to confirm that they had processed the survey conscientiously and that they consent to the use and storage of the data for scientific purposes.

In recording the medical history, participants were asked about other existing diseases (free text field). The stated diseases were classified subsequently into "physical illness" or "mental disorder." If only unspecific symptoms were given, this was classified as "unspecific." In recording the disease data, participants were also asked about their headache activity in the past 6 months. In doing so, the average number of headache days and the number of acute medication intake days (triptans or analgesics) per month were inquired. Participants who reported an average number of greater than or equal to 15 headache days and greater than or equal to 10 medication intake days per month were classified as persons with "probable

medication-overuse headache (pMOH)" according to the ICHD-3 (c.f. page 123).¹⁹

Construction of the questionnaire

To define the dimensions of the construct "fear of attacks" and to generate suitable items, a literature search as well as semistructured interviews with three experienced practitioners and four persons with migraine were carried out. The literature search was performed combining the terms "migraine," "fear of attack," and "cephalalgiphobia" in PubMed and Google Scholar, using comprehensive search strategies. Existing headache- and fear-related questionnaires were studied to get an impression of relevant factors or items. This was followed by the semistructured interviews with four persons with prediagnosed migraine (3 women, mean age 36.0 years, $SD = 17.7$). Main topics of the interviews related to disorder characteristics in general, specific behavior in the context of migraine attacks and potential triggers, and fear in the context of migraine attacks. In doing so, ideas on how to formulate items to assess fear of attacks were gathered. The semistructured interviews with three experienced practitioners (one neurology specialist and two licensed psychotherapists, each practicing in a pain center or a headache clinic) focused on potential dimensions of the construct "fear of attacks in migraine" as well as observed behavior patterns in this context. Formulation options for items to assess fear of attacks were gathered as well. Based on the information gained in these processes, a preliminary questionnaire with 46 items was drafted. The preliminary questionnaire was pretested with a sample of $N = 10$ persons with prediagnosed migraine (6 women, mean age 41.4 years, $SD = 13.1$, $n = 9$ with chronic migraine). The majority ($n = 7$) of participants was recruited via the Migraine and Headache Clinic Königstein, which explains the high proportion of chronic migraine in this sample. Participants were requested to answer each item on a 5-point scale (1 = strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, and 5 = strongly agree). Additionally, the participants had to assess the comprehensibility as well as the relevance of each item on a 4-point scale (1 = not at all, 2 = little, 3 = intermediate, and 4 = very). Further, the participants had the opportunity to write short informal feedback to each item. All participants of the semistructured interviews and the pretest had to give written informed consent. Both the comprehensibility and the relevance of all items were rated as satisfactory on average (mean 3.0 or higher). Afterward, all items of the preliminary version were finally discussed with a panel of experts. In doing so, the wording of some items was optimized again, and two items with similar content were grouped so that the final draft of the FAMI for the online survey comprised 45 items, each with a range of five possible answers on a Likert scale (1 = strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, and 5 = strongly agree). Seven underlying dimensions of fear of attacks in migraine were assumed in the FAMI, that is (i) general fear of attacks, (ii) performance-related fear of

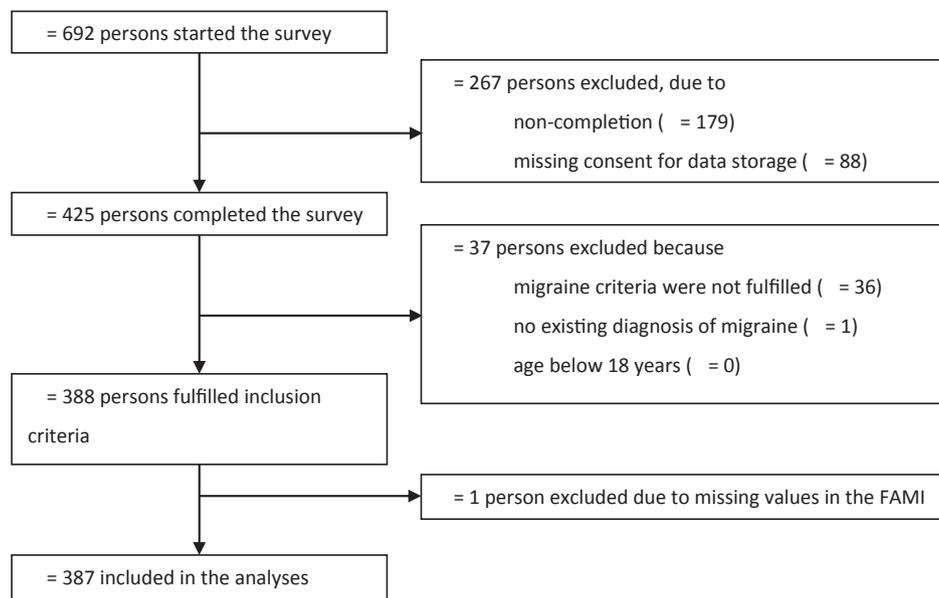


FIGURE 1 Flowchart of attrition. FAMI, Fear of Attacks in Migraine Inventory

attacks, (iii) social aspects of attack anxiety, (iv) fear-related medication intake, (v) trigger-related fear of attacks, (vi) fear-related avoidance behavior, and (vii) attentional aspects in fear of attacks. The FAMI was developed and evaluated in German. A translation into English was made only for the purpose of publication.

Measures

To assess the convergent validity of the FAMI, the following self-report instruments were used in the online survey (each in the German version): (i) Migraine Disability Assessment Scale (MIDAS),²³ (ii) Headache Disability Inventory (HDI),²⁴ (iii) Headache Impact Test (HIT-6),²⁵ (iv) Depression Anxiety Stress Scales (DASS),²² (v) Pain Anxiety Symptom Scale 20 (PASS-20),²⁶ (vi) Headache Triggers Sensitivity and Avoidance Questionnaire, Short-Form (HTSAQ-SF),²⁷ (vii) Generalized Anxiety Disorder Screener (GAD-7),²⁸ (viii) short form of the Headache Management Self-Efficacy Scale (HMSE-G-SF),²⁹ and (ix) Pain Vigilance and Awareness Questionnaire (PVAQ).³⁰ For the determination of discriminant validity, the German version of the NEO-Five-Factor Inventory (30-Item-Short-Version [NEO-FFI-30]) was applied.³¹ The NEO-FFI-30 was developed to measure the five basic personality factors (neuroticism, extraversion, openness, agreeableness, and conscientiousness) and comprises five subscales accordingly. Because neuroticism is assumed to correlate highly with anxiety,³² the subscale neuroticism was excluded in the assessment of discriminant validity. Another part of the ODIN-migraine project was the development of a German version of the Cogniphobia Scale for Headache Disorders (CS-HD).³³ Thus, the battery of the online survey contained a German translation of the 15 items of the CS-HD. The psychometric

properties of the CS-HD (German version) are intended to be reported elsewhere.

Statistical analyses

Descriptive statistics were calculated (mean, SD, frequency, and percentage) to describe sample characteristics. Because the software of the SoSci survey generates information on the processing time (after adjustment for interruptions), referring descriptive statistics (mean and SD) were calculated.

Items for the final version of the FAMI were selected based on item statistics. Items with skewness greater than two, kurtosis greater than seven, item difficulty less than 0.10 or greater than 0.90, and item intercorrelations greater than 0.7 were excluded. Suitability for factor analysis was determined with Kaiser-Meyer-Olkin (KMO) criterion and the Bartlett test. The number of factors for the factor analysis was determined with scree plot, Kaiser criterion, parallel analysis, Wayne Velicer's minimum average partial criterion, and comparison data.³⁴ To more rigorously psychometrically test the goodness of fit of the observed three-factor model, we specified a confirmatory factor analysis (CFA) model (containing only main loadings and correlated factors) using diagonally weighted least squares (DWLS) estimation due to ordinal data. Model fit was evaluated with χ^2 , root mean square error of approximation (RMSEA), standardized root mean square residual (SRMR), comparative fit index (CFI), and Tucker Lewis fit index (TFI) utilizing the recommendations of Schermelleh-Engel and colleagues.³⁵ Reliability was investigated with McDonald's ω (a reliability coefficient similar to Cronbach's Alpha with the main advantage of taking into account the strength of association between items and constructs as well as item-specific measurement errors).³⁶

Validity was tested using Spearman correlations of the subscales with questionnaire scores and clinical characteristics. Differences between the subgroups of the sample (e.g., participants with or without comorbid mental health disorder) in the FAMI scales were calculated using a t-test for independent samples with a two-tailed α of 0.05.

Analyses were calculated with JASP,³⁷ R version 4.0.3,³⁸ and SPSS statistics version 23.

RESULTS

Inclusion occurred between September 23, 2020, and November 30, 2020. In total, 692 persons started the survey. Because 179 persons did not complete the survey, 88 persons did not give their consent to data storage, and 38 persons had to be excluded subsequently (e.g., due to an unconfirmed migraine diagnosis), 387 persons were included in the final sample (Figure 1). The frequency of missing values in the questionnaires is shown in Table S1. The average processing time for the survey was $M = 34.6$ min ($SD = 12.0$, range 17.5 to 77.4), indicating careful answers.³⁹ Sample characteristics are presented in Table 1. Almost all participants (96.9%, $n = 375$) used acute medication. A majority (63.6%, $n = 246$) were on a migraine preventive medication (traditional medication, e.g., beta-blockers: 40.1%, $n = 155$; onabotulinumtoxinA injection: 8.8%, $n = 34$; and CGRP pathway monoclonal antibodies: 14.7%, $n = 57$).

Item selection

Due to skewness and kurtosis, four items, and due to high inter-item correlation, another 12 items had to be excluded. No item needed to be excluded based on item difficulty. The final questionnaire consisted of 29 items (c.f. Supporting Information).

Factorial structure and model fit

The KMO criterion indicated that the data were suited for factor analysis ($MSA = 0.92$; which corresponds to the highest possible level of suitability, described by Kaiser 1974 as "marvelous")⁴⁰ and the Bartlett test confirmed that the variables were not completely uncorrelated ($\chi^2(406) = 6013.51$, $p < 0.001$). To determine the number of factors, different approaches were utilized (inspection of the scree plot, Kaiser criterion, parallel analysis, Wayne Velicer's minimum average partial criterion, and comparison data), which all proposed the extraction of three factors.

Accordingly, in the exploratory factor analysis (EFA), three clearly interpretable factors were extracted using weighted least squared estimation and oblimin rotation (Table 2). Nine items loaded on a factor, which was interpreted as *fear of negative consequences* (item 11 with the highest loading: "I worry

TABLE 1 Sample characteristics

	N = 387
Age, years	40.9 (13.1)
Range	18 to 80
Female	94.1% ($n = 364$)
In stable partnership	80.1% ($n = 310$)
Advanced level or degree after high school	63.6% ($n = 246$)
Employed	72.9% ($n = 282$)
Headache diagnosis	
Migraine without aura	39.5% ($n = 153$)
Migraine with aura	22.0% ($n = 85$)
Chronic migraine	38.5% ($n = 149$)
Disease duration, years	23.4 (13.2)
Range	1.5 to 58
Current headache activity, past month	
Headache days	12.2 (8.3)
Range	0 to 31
Days with medication intake (analgesics or triptan)	6.1 (4.4)
Range	0 to 30
Sick leave days due to headache	4.0 (6.0)
Range	0 to 31
Comorbidity ^a	
No comorbid disorder/illness	39.0% (151)
Mental health disorder ^b	18.9% (73)
Physical illness ^c	50.1% (194)
Unspecific ^d	2.3% (9)
Mental health disorder as comorbidity ^a	
No comorbid mental health disorder	81.1% (314)
Anxiety disorder	5.7% (22)
Depressive disorder	13.4% (52)
Other mental health disorder	2.8% (11)
Several mental health disorders	4.7% (18)
Probable medication-overuse headache ^e	
No	77.3% (299)
Yes	21.7% (84)

Note: Data are percentage (n) or mean (SD) unless otherwise stated.

^aMultiple answers possible.

^bParticipant has at least one mental health disorder.

^cParticipant has at least one other physical illness (additional to the headache diagnosis).

^dOnly unspecific symptoms (such as "fatigue") are reported.

^eBased on the period of the last 6 months ($n = 4$ participants were excluded from this analysis due to missing or unclear information).

that my migraine attacks will keep me from meeting my social responsibilities satisfactorily"). Fourteen items loaded on factor 2, which was interpreted as *attention and anticipation* (item 27 with the highest loading: "I regularly watch myself for signs of

TABLE 2 Factor loadings (>0.3), uniqueness^a, item difficulty (p_i), and item discrimination (r_{it}) of the exploratory factor analysis

No.	Item	Factor			Uniqueness ^a	p_i	r_{it}
		1	2	3			
1	When I am not in pain, I fear that a migraine attack could occur soon		0.58		0.54	0.74	0.59
2	I am afraid of the next migraine attack		0.70		0.40	0.78	0.68
3	When I am not in pain, I clearly remember how I suffered during the last migraine attack		0.56		0.66	0.71	0.49
4	I try to predict migraine attacks (for example, based on regular intervals between migraine attacks)		0.62		0.65	0.65	0.48
5	Before important appointments, I worry about the way past migraine attacks interfered with my effectiveness	0.44 ^b	0.37		0.52	0.72	0.63
6	I am aware of the limitations caused by past migraine attacks, even when I am not currently in pain		0.39		0.72	0.81	0.49
7	I'm anxious about the pain of a coming migraine attack		0.61		0.49	0.76	0.64
8	I fear that my migraine attacks will have long-term health consequences		0.30		0.82	0.66	0.39
9	Before important events (career, family, or personal), I am afraid of a migraine attack	0.65			0.37	0.83	0.70
10	I fear that I will not be able to meet my obligations because of a migraine attack	0.73			0.40	0.84	0.64
11	I worry that my migraine attacks will keep me from meeting my social responsibilities satisfactorily	0.81			0.33	0.80	0.67
12	I fear that people will speak badly of me if I have to cancel appointments because of a migraine attack	0.60			0.55	0.74	0.59
13	I am afraid that my migraine attacks will cause me to miss the good things in life	0.70			0.44	0.81	0.64
14	I worry that my migraine attacks are preventing me from enjoying life	0.69			0.49	0.77	0.59
15	I'm worried that my migraine attacks will have a negative impact on my important relationships (partner, friends, or colleagues)	0.79			0.43	0.75	0.58
16	I fear that my migraine attacks will prevent me from realizing my goals in life (career, family, or leisure)	0.77			0.44	0.75	0.58
17	If I notice symptoms indicating an upcoming migraine attack (such as sensitivity to light), I take acute medication (analgesics and triptans) as a precaution		0.34		0.91	0.45	0.19
18	I fear that certain external stimuli (such as weather, light, crowds, or noise) will trigger a migraine attack			0.35	0.62	0.79	0.58
19	I'm afraid of getting a migraine attack when I'm experiencing certain internal states (such as strong emotions, stress, or fatigue)		0.36		0.52	0.82	0.66
20	I worry that certain behaviors (for example, overexertion, irregular sleep, or certain foods) will trigger a migraine attack			0.47	0.57	0.83	0.58

TABLE 2 (Continued)

No.	Item	Factor			Uniqueness ^a	p_i	r_{it}
		1	2	3			
21	I try to avoid certain external stimuli (such as light, crowds, or noise) in order not to provoke migraine attacks			0.64	0.43	0.71	0.61
22	I avoid certain behaviors (for example, overexertion, irregular sleep, or certain foods) in order not to provoke migraine attacks			0.80	0.41	0.75	0.44
23	I avoid certain internal states (such as strong emotions, stress, or fatigue) so as not to provoke migraine attacks			0.70	0.43	0.66	0.55
24	I shield myself from certain external stimuli (for example, with headphones, a scarf, or sunglasses) so as not to provoke migraine attacks			0.60	0.57	0.65	0.49
25	I cancel appointments, out of concern that they might provoke a migraine attack			0.33	0.69	0.42	0.52
26	After experiencing certain internal states (such as strong emotions, stress, or fatigue) I pay particular attention to signs of an upcoming migraine attack		0.59 ^b	0.33	0.41	0.68	0.66
27	I regularly watch myself for signs of an upcoming migraine attack		0.70		0.39	0.67	0.64
28	I pay particular attention to the first signs of an upcoming migraine attack to be able to react as early as possible		0.62		0.58	0.75	0.52
29	I sense my fear of an upcoming migraine attack with physical symptoms (such as a dry mouth, palpitations, or restlessness)		0.42		0.66	0.54	0.56

Note: Factor 1: Fear of negative consequences. Factor 2: Attention and anticipation. Factor 3: Fear-avoidance.

^aVariance that is "unique" to the variable and not shared with other variables.

^bAssigned to factor 1 (item 5) or factor 2 (item 26).

an upcoming migraine attack"). The third factor consists of eight items and was interpreted as *fear-avoidance* (item 22 with the highest loading: "I avoid certain behaviors (for example, overexertion, irregular sleep, or certain foods) in order not to provoke migraine attacks"). Two items had a double loading. Item 5 ("Before important appointments, I worry about the way past migraine attacks interfered with my effectiveness") was allocated to factors 1 and 2 but had a higher loading on the former. Item 26 ("After experiencing certain internal states (such as strong emotions, stress, or fatigue) I pay particular attention to signs of an upcoming migraine attack") was allocated to factors 2 and 3 and had a higher loading on the former. The eigenvalues of the factors were $\lambda_1 = 5.52$, $\lambda_2 = 4.92$, and $\lambda_3 = 3.14$. Factors 1 and 2 ($r = 0.62$), 1 and 3 ($r = 0.41$), and 2 and 3 ($r = 0.57$) were correlated.

The CFA yielded an acceptable to good model fit ($\chi^2(3) = 1328.84$, $p = 0.001$, $\chi^2/df = 3.55$, $RMSEA = 0.085$, $SRMR = 0.073$, $CFI = 0.98$, $TLI = 0.97$). The factor covariances were 0.72 (factor 1 and 2), 0.60 (factor 1 and 3), and 0.74 (factors 2 and 3). Factor loadings of the CFA can be found in Table S2.

Reliability and item statistics

McDonald's ω of the subscale *fear of negative consequences* was excellent ($\omega = 0.91$), for the subscales *attention and anticipation* ($\omega = 0.88$) and *fear-avoidance* ($\omega = 0.85$) was good, respectively. Item difficulty ranged between $p_i = 0.42$ and $p_i = 0.84$ indicating rather easy items. Item discrimination ranged between $r_{it} = 0.19$ and 0.70 (Table 2).

Validity

Concerning clinical characteristics (Table 3), the FAMI sum score, as well as all three subscales were significantly positively associated with headache days and days with acute medication intake during the last month. All FAMI scales but the subscale *attention and anticipation* significantly correlated with migraine days during the last month. Further demonstrating convergent validity, the FAMI sum score, as well as all subscales, showed significant small to medium-sized correlations with the convergent questionnaires

TABLE 3 Measures of criterion validity: Spearman correlations of questionnaires scores and clinical characteristics with the subscales of the FAMI

	FAMI sum score	FAMI subscale fear of negative consequences	FAMI subscale attention and anticipation	FAMI subscale fear-avoidance
Convergent validity				
Headache days ^a	0.20 (<0.001)	0.27 (<0.001)	0.11 (0.037)	0.13 (0.014)
Migraine days ^a	0.19 (0.001)	0.30 (<0.001)	0.04 (0.428)	0.12 (0.018)
Days with acute medications intake ^a	0.21 (<0.001)	0.28 (<0.001)	0.11 (0.032)	0.13 (0.012)
HDI	0.69 (0.001)	0.76 (<0.001)	0.51 (<0.001)	0.49 (<0.001)
HIT-6	0.50 (<0.001)	0.53 (<0.001)	0.40 (<0.001)	0.33 (<0.001)
DASS				
Depression	0.50 (<0.001)	0.58 (<0.001)	0.44 (<0.001)	0.30 (<0.001)
Anxiety	0.52 (<0.001)	0.48 (<0.001)	0.48 (<0.001)	0.33 (<0.001)
Stress	0.52 (<0.001)	0.54 (<0.001)	0.45 (<0.001)	0.31 (<0.001)
GAD-7	0.54 (<0.001)	0.54 (<0.001)	0.48 (<0.001)	0.33 (<0.001)
PASS-20	0.62 (<0.001)	0.53 (<0.001)	0.60 (<0.001)	0.39 (<0.001)
HTSAQ-SF				
Triggers	0.60 (<0.001)	0.49 (<0.001)	0.49 (<0.001)	0.56 (<0.001)
Avoidance	0.55 (<0.001)	0.37 (<0.001)	0.45 (<0.001)	0.60 (<0.001)
HMSE-G-SF	0.08 (0.105)	-0.04 (0.454)	0.12 (0.024)	0.17 (0.001)
PVAQ	0.49 (<0.001)	0.35 (<0.001)	0.51 (<0.001)	0.34 (<0.001)
Discriminant validity				
NEO_E	-0.23 (<0.001)	-0.24 (<0.001)	-0.20 (<0.001)	-0.17 (0.001)
NEO_O	0.06 (0.249)	-0.01 (0.811)	0.05 (0.338)	0.10 (0.041)
NEO_A	-0.09 (0.074)	-0.12 (0.016)	-0.07 (0.180)	-0.09 (0.087)
NEO_C	-0.02 (0.676)	-0.09 (0.072)	<0.01 (0.964)	0.03 (0.504)

Abbreviations: DASS, Depression Anxiety Stress Scales; FAMI, Fear of Attacks in Migraine Inventory; GAD-7, Generalized Anxiety Disorder Screener; HDI, Headache Disability Inventory; HIT-6, Headache Impact Test; HMSE-G-SF, short form of the Headache Management Self-efficacy Scale; HTSAQ-SF, Headache Trigger Sensitivity and Avoidance Questionnaire, short form, with the subscales *triggers* and *avoidance*; NEO, NEO-Five-Factor Inventory with the subscales *extraversion*, *openness*, *agreeableness*, and *conscientiousness*; PASS-20, Pain Anxiety Symptom Scale 20; PVAQ, Pain Vigilance and Awareness Questionnaire.

^aReferring to the past month.

assessed, with an exception of the HMSE-G-SF (Table 3). This questionnaire, assessing self-efficacy in the management of headaches, significantly correlated only with the *attention and anticipation* and *fear-avoidance* subscales of the FAMI, each with a very small-sized correlation. As could be expected, the HDI showed the largest correlations with the *fear of negative consequences* subscale of the FAMI, the PASS-20 showed the highest correlations with the *attention and anticipation* subscale of the FAMI, while the subscale *avoidance* of the HTSAQ-SF had the largest correlation with the *fear-avoidance* subscale of the FAMI. Compared with participants with migraine with/without aura, participants with chronic migraine showed significantly higher values on fear in the FAMI subscales *fear of negative consequences* and *fear-avoidance* as well as in the FAMI sum score (Table 4).

Regarding discriminant validity, the subscales of the NEO-FFI showed marginal, mostly nonsignificant correlations with the FAMI (Table 3), except for the extraversion subscale that consistently showed significant correlations with the FAMI.

Because some items of the MIDAS do not address all participants (e.g., items 1 and 2 only refer to people who work or go to school), and because some items of the MIDAS were obviously not answered correctly by some participants (e.g., entering 90 days for both item 1 and item 2), the values of this questionnaire were excluded from further analyses.

Subgroup analyses

Compared with participants with migraine with/without aura, participants with chronic migraine showed a significantly higher level of attack-related fear (FAMI sum score, subscales *fear of negative consequences* and *fear-avoidance*; Table 4). Accordingly, participants with chronic migraine had a higher emotional burden (significantly higher values in the DASS and GAD-7), a higher extent of triggers and trigger avoidance (significantly higher values in the HTSAQ-SF), and a higher impact of migraine (significantly higher values in the HIT-6)

TABLE 4 Mean values (SD) of the used scales and comparison between the subgroups of participants (migraine with/without aura and chronic migraine)

	Migraine with/without aura (n = 238)	Chronic migraine (n = 149)	t ^a (p)
FAMI sum score	101.5 (20.3)	108.7 (18.2)	3.53 (<0.001)
FAMI subscale fear of negative consequences	33.3 (8.3)	37.8 (6.4)	6.00 (<0.001)
FAMI subscale attention and anticipation	44.7 (9.4)	45.8 (9.1)	1.15 (0.252)
FAMI subscale fear-avoidance	23.5 (5.8)	25.1 (5.5)	2.63 (<0.001)
HDI	45.1 (10.2)	38.3 (9.0)	6.79 (<0.001)
HIT-6	21.5 (3.5)	22.9 (2.8)	4.29 (<0.001)
DASS			
Depression	14.6 (5.7)	16.8 (6.2)	3.68 (<0.001)
Anxiety	12.3 (4.6)	14.2 (5.5)	3.42 (<0.001)
Stress	16.6 (5.3)	18.5 (5.3)	3.33 (0.001)
GAD-7	15.2 (4.5)	16.8 (4.9)	3.28 (0.001)
PASS-20	69.2 (17.7)	72.4 (17.7)	1.78 (0.076)
HTSAQ-SF			
Triggers	42.7 (10.0)	46.8 (9.1)	4.11 (<0.001)
Avoidance	42.4 (9.7)	45.2 (10.8)	2.72 (0.007)
HMSE-G-SF	23.3 (7.6)	22.0 (7.5)	1.68 (0.095)
PVAQ	62.2 (12.4)	62.5 (12.9)	0.22 (0.826)

Note: Data are mean (SD) unless otherwise stated.

Abbreviations: DASS, Depression Anxiety Stress Scales; FAMI, Fear of Attacks in Migraine Inventory; GAD-7, Generalized Anxiety Disorder Screener; HDI, Headache Disability Inventory; HIT-6, Headache Impact Test; HMSE-G-SF, short form of the Headache Management Self-Efficacy Scale; HTSAQ-SF, Headache Trigger Sensitivity and Avoidance Questionnaire, short form, with the subscales *triggers* and *avoidance*; PASS-20, Pain Anxiety Symptom Scale 20; PVAQ, Pain Vigilance and Awareness Questionnaire.

^aThe t-test for independent samples (two-tailed α of 0.05).

compared with those with migraine with/without aura. In contrast, the level of headache-associated disability (HDI) was significantly higher in the subsample of persons with migraine with/without aura (Table 4).

Compared with participants without mental health disorders, participants with at least one comorbid mental health disorder showed a significantly higher level of attack-related fear (FAMI sum score, subscales *fear of negative consequences* and *fear-avoidance*; Table S3). Compared with participants without pMOH, participants with pMOH had a significantly higher level of attack-related fear (FAMI sum score, subscales *fear of negative consequences* and *fear-avoidance*; Table S4).

DISCUSSION

Anxiety in general and fear of attacks, particularly, are important potential pathogenetic factors in migraine. Because high fear of attacks is assumed to have a negative impact on the course of the disease, a comprehensive and psychometrically sound assessment should be considered in clinical care as well as in clinical research. However, the dimensions of attack-related fear in migraine are still unknown, and an instrument for the broad assessment of this fear is lacking.

In this study, a self-report questionnaire for the migraine-specific assessment of attack-related fear (FAMI) was developed

and evaluated. Based on literature as well as on interviews with experienced practitioners and persons with migraine, a questionnaire with 45 items and assuming seven underlying factors of attack-related fear was constructed. By item selection, the questionnaire could be reduced to 29 items. The EFA yielded three clearly interpretable factors, (i) *fear of negative consequences*, (ii) *attention and anticipation*, and (iii) *fear-avoidance*, with an acceptable to good model fit in the CFA. The number of factors identified by the EFA and CFA was lower than the initially expected seven factors. However, the presumed dimensions of fear are largely reflected in these three factors. The factor (i) *fear of negative consequences* comprises a social and a hedonistic facet. Whereas the social facet includes the fear of social failure (e.g., being unable to meet social obligations, item 11), the hedonistic facet refers to the fear of missing nice experiences in life (e.g., item 13). The factor (ii) *attention and anticipation* comprises attention-related aspects such as “I watch myself” (e.g., item 27), as well as a general fear of the occurrence of a future attack (e.g., item 1). Surprisingly, item 8 (fear of negative health consequences) is also included under this factor, although it refers to a negative consequence. The factor (iii) *fear-avoidance* addresses behavioral aspects of attack-related fear in the sense of avoiding headache triggers (e.g., overexertion, noise, and stress). Contrary to our expectation, there was no factor related to fear-related medication intake or medication overuse. The corresponding items had already been sorted out as

part of the item selection process. The only remaining question that refers to “taking attack medication” (i.e., item 17) was factor-analytically assigned to the subscale *attention and anticipation*. This finding contradicts the assumptions of previous authors who conceptualized the fear of attacks (“cephalalgophobia”) mainly by overuse of acute pain or triptan medication.^{11,13} Even though in this sample a high level of fear (indicated by high FAMI sum score as well as FAMI subscales) is significantly correlated with higher acute medication intake, the lack of a separate factor “medication intake” indicates that this aspect obviously only plays a subordinate role in the overall construct “fear of attacks.” Almost all items addressing medication intake were excluded already at the stage of item selection due to excessive skewness and kurtosis, which indicates that these items were rarely suitable. Although the proportion of patients with migraine in the population of patients with medication overuse headache may be very high (e.g., 96.3% in an epidemiological study in Latin America⁴¹), the reverse case is likely to be less common. The proportion of patients with acute medication overuse among persons with migraine is estimated at about 15%.⁴² Presumably, medication overuse is relevant only in a minority of persons with migraine. Most persons with migraine are probably taking their acute medication very conscientiously, even though these persons may also experience a high level of fear of attacks. Further, clinical experience shows that quite a few patients tend to take acute medication too little or too late due to fear of developing a medication overuse headache or experiencing side effects.

The pattern of correlational analyses (i.e., statistically significant correlations of FAMI scores with established questionnaires as well as with clinical parameters) confirms the convergent validity of the FAMI. The small-sized correlation coefficients for the HMSE-SF indicate that self-efficacy seems to be largely independent of attack-related fear. The finding that participants with chronic migraine tend to have a higher attack-related fear compared with those with migraine with/without aura is in line with previous results.⁹ The nonsignificant, close to zero correlations of the FAMI with the three NEO subscales *openness*, *agreeableness*, and *conscientiousness* indicate discriminant validity. The negative correlation coefficients between the FAMI and the NEO subscale *extraversion*, which are small-sized but significant, can be explained by the fact that extraversion can, to a certain extent, be seen as contrary to anxiety.⁴³

The MIDAS is cited in the literature to assess migraine-associated disability and its use is still recommended.¹⁸ However, some of the MIDAS items are difficult to understand, and items 2 and 4 are especially confusing, where the tested person is expected to perform subtraction (e.g., item 2, “How many days in the last 3 months was your productivity at work or school reduced by half or more because of your headaches (do not include days you counted in question 1 where you missed work or school)?”).⁴⁴ The values in our dataset confirmed that this questionnaire was misunderstood and incorrectly filled out by quite a few patients so that the future use of this measuring instrument is questionable.

The comparison of subgroups each yielded higher values in the FAMI scales for participants who had chronic migraine, a comorbid mental health disorder, or pMOH. In other words, the obviously higher disease burden in these subgroups was also reflected in higher attack-related fear (measured with the FAMI). This result is an additional indication for the construct validity of the present questionnaire. Interestingly, the same pattern was found for all subgroup comparisons, in that statistically significant differences were each found in the FAMI total and in the subscales *fear of negative consequences* and *fear-avoidance*, whereas there was no significant difference in the subscale *attention and anticipation*. This could indicate that central characteristics of chronification can be seen in the (negative) assessment of the consequences of an attack and in (avoidance) behavior, whereas attention processes may be less relevant.

A strength of the study is the elaborate construction of the questionnaire, including an expert panel as well as the inclusion of persons with migraine. Further strengths are the exact assessment of the migraine diagnosis, which was provided by the targeted query of criteria according to the ICHD-3, as well as a large sample with indicators of good data quality (reasonable completion time of all participants and very low frequency of missing values). Techniques to identify potential duplicate entries from a participant (e.g., IP check) were not applied. Due to the relatively long processing time and the lack of incentive to repeat the survey, we consider it extremely unlikely that a survey was completed more than once. A limitation is that the sample is not representative. The excessive proportion of people fulfilling the criteria of chronic migraine and migraine with aura introduces a bias so that the obtained standard values must be interpreted with caution. Because the development and evaluation of the FAMI were carried out in German, a future evaluation in English would be desirable. Future research should aim to assess a more representative prevalence of attack-related fear in migraine, and additional parameters (e.g., ethnicity) should be recorded. Furthermore, it would be promising and informative to collect data in the clinical care context as well as to record headache activity and medication intake more precisely. This would make possible a more valid assessment of comorbid diagnoses (such as medication-overuse headache or mental health disorders).

In routine care, the FAMI could be used for the diagnostic screening of attack-related fear in migraine. This would require the determination of a suitable cutoff (e.g., a percentile rank of ≥ 84 in a representative sample). At least patients with excessive or above-average fear of attacks should be offered a specific behavioral intervention. Appropriate interventions to address migraine-specific fear (i.e., cognitive-behavioral therapy to improve coping with the fear of attacks) already exist.^{45,46} Because fear of attacks can be viewed as modifiable, another promising research approach is the assessment of the FAMI’s sensitivity to detect change. In addition to decreasing headache activity, interventions for migraine prophylaxis also aim to reduce disability, emotional stress, and anxiety. Because the FAMI expands the armamentarium of migraine-specific measuring

instruments it could be used to evaluate both behavioral and pharmacological interventions for the treatment of migraine.

CONCLUSIONS

The FAMI is a novel self-report questionnaire, comprising 29 items. It allows the assessment of attack-related fear on the subscales (i) fear of negative consequences, (ii) attention and anticipation, and (iii) fear-avoidance. The FAMI showed good psychometric properties, including high reliability as well as a given criterion and discriminant validity. Further, it is easy to apply. Thus, the FAMI is suitable for the assessment of attack-related fear in persons with migraine in clinical care and research.

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CONFLICT OF INTEREST

A.-L. Guth has received honoraria for lectures within the past 3 years from Allergan Pharma, Novartis Pharma, Ratiopharm, Sanofi-Aventis, and TEVA. C. Gaul has received honoraria for consulting and lectures within the past three years from Allergan Pharma, Lilly, Novartis Pharma, Hormosan Pharma, Grünenthal, Sanofi-Aventis, Weber & Weber, Lundbeck Perfood, and TEVA. He is honorary secretary of the German Migraine and Headache Society. A. Diezemann-Pröbldorf is a member of the presidium of the German Society for Psychological Pain Therapy and Research. All other authors declare no competing interests.

AUTHOR CONTRIBUTIONS

Study concept and design: Timo Klan, Anke Diezemann-Pröbldorf, Anna-Lena Guth, Charly Gaul, Michael Witthöft. *Acquisition of data:* Timo Klan, Silja Klein. *Analysis and interpretation of data:* Timo Klan, Silja Klein, Anne-Kathrin Bräscher, Michael Witthöft. *Drafting of the manuscript:* Timo Klan, Anne-Kathrin Bräscher. *Revising it for intellectual content:* Anke Diezemann-Pröbldorf, Charly Gaul, Anna-Lena Guth, Michael Witthöft. *Final approval of the completed manuscript:* Timo Klan, Anne-Kathrin Bräscher, Silja Klein, Anke Diezemann-Pröbldorf, Anna-Lena Guth, Charly Gaul, Michael Witthöft.

CLINICAL TRIALS REGISTRATION NUMBER

This study (as part of the ODIN-migraine-project) is registered with the German Clinical Trials Register (DRKS-ID: DRKS00022812).

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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