Migraine Clinical Assessment Scales

A MEDICAL EDUCATION RESOURCE FOR CLINICIANS AND HEALTHCARE PROVIDERS

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MIGRAINE CLINICAL ASSESSMENT SCALES: SUMMARY

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ASSESSMENT OF ICTAL FUNCTIONAL IMPAIRMENT, INCLUDING IMPACT OF MIGRAINE ON FAMILY MEMBERS

MIDAS

The Migraine Disability Assessment Score

The **MIDAS Questionnaire** is a brief, easy to use and self-administered instrument to assess headache-related disability.

It was published in 1999[1].

It was validated in a group of 144 patients and compared to a 90-day diary[2]. The MIDAS score was found to be reliable over time[2], and its internal consistency was demonstrated across countries[3].
The questionnaire contains five questions about the number of days, in the past 3 months, of several activity limitations due to migraine.
The questions inquire about productivity at work (pay work and household work) and non-work activities (social, family and recreation). People with migraine are asked to score the number of days of missed work and the number of days with halved or less productivity. For non-work activities the scoring is based only on the number of missed days.
The sum of responses to five questions is the MIDAS score, ranging from 0 to 270. A higher value is indicative of more disability[1,4].
There are two additional questions about the number of headaches and average pain level associated over the past 3 months. These two questions are not used in scoring, but can help physicians in better understanding clinical and chronological features of headache for each patient[2].

The internal consistency, test-retest reliability, and validity (accuracy) of the questionnaire were assessed in separate population-based studies of people with migraine[3]. In addition, the face validity, ease of use, and clinical utility of the questionnaire were evaluated in a group of 49 physicians who independently rated disease severity and need for care in a diverse sample of migraine case histories[4]. The test-retest Pearson correlation coefficient for the total MIDAS score was approximately 0.8[3]. The MIDAS score was valid when compared with a reference diary-based measure of disability; the overall correlation between MIDAS and the diary-based measure was 0.63[3]. The MIDAS score was also correlated with physicians' assessments of need for medical care ($r = 0.69$)[4]. The strong correlation with clinical judgement is one of the features that supports MIDAS' suitability for use in clinical practice.

Use of the MIDAS Questionnaire may improve physician-patient communication about headache-related disability and may favorably influence health-care delivery for patients with migraine.

1. Stewart WF, Lipton RB, Kolodner K, Liberman JN, Sawyer J. Reliability of the Migraine Disability Assessment (MIDAS) score in a population-based sample of headache sufferers. Cephalalgia 1999;19:107±114.
2. Stewart WF, Lipton RB, Kolodner KB, Sawyer J, Lee C, Liberman JN. Validity of the Migraine Disability Assessment (MIDAS) score in comparison to a diary-based measure in a population sample of migraine sufferers. Pain. 2000 Oct;88(1):41-52. doi: 10.1016/S0304-3959(00)00305-5. PMID: 11098098.
3. Stewart WF, Lipton RB, Whyte J, Dowson A, Kolodner K, Liberman JN, Sawyer J. An international study to assess reliability of the Migraine Disability Assessment (MIDAS) score. Neurology 2000;53:988±994.
4. Stewart WF, Lipton RB, Dowson AJ, Sawyer J. Development and testing of the Migraine Disability Assessment (MIDAS) Questionnaire to assess headache-related disability. Neurology. 2001;56(6 Suppl 1):S20-8. doi: 10.1212/wnl.56.suppl_1.s20. PMID: 11294956.

MIDAS

The Migraine Disability Assessment Score

INSTRUCTIONS

Please answer the following questions about ALL the headaches you have hadover the last 3 months. Write your answer in the box next to each question. Write zero if you did not do the activity in the last 3 months. (Please refer to the calendar below, if necessary.)

1. On how many days in the last 3 months did you miss work or school because of your headaches? ☐
2. How many days in the last 3 months was your productivity at work or school reduced byhalf or more because of your headaches (do not include days you counted in question 1 where you missed work or school)? ☐
3. On how many days in the last 3 months did you not do household work because of your headaches? ☐
4. How many days in the last 3 months was your productivity in household work reduced byhalf or more because of your headaches (do not include days you counted in question 3 where you did not do household work)? ☐
5. On how many days in the last 3 months did you miss family, social, or leisure activities because of your headaches? ☐

Total score ☐

MIDAS Score	Disability	MIDAS Grade
0-5	Little or No Disability	I
6-10	Mild Disability	II
11-20	Moderate Disability	II
21+	Severe Disability	IV

ADDITIONAL MIGRAINE QUESTIONS

The frequency and intensity of your migraines are important for your doctor to know when prescribing a treatment plan. Over the past three months:

A. On how many days in the last 3 months did you have any headache (if a headache lasted more than one day, count each day)? ☐

B. On a scale of 0 to 10, on average how painful were these headaches (0 = no pain at all, and 10 = pain is as bad as it can be)? ☐

HALT

Headache Attributed Lost Time indices

HALT is a self administered test based on the first five questions of MIDAS[2,3]. Is is used to estimate productive time lost through the disabling effect of headache; the result is expressed by a number with intuitively meaningful units (eg, days/month).

HALT has five questions. Questions 1 and 2 ask about absenteeism due to headache, and reduced productivity at work despite headache (presenteeism). To estimate total lost productive time from work, days wholly lost through absenteeism are added to days of presenteeism with less than 50% productivity; by way of counterbalance, headache-affected days are ignored in which productivity was nevertheless more than 50%. Questions 3 and 4 address household work in the same manner. An instruction is given to avoid double-counting (on a single day, productivity both at work and in the performance of housework may suffer reductions of more than 50%). Question 5 relates to days on which social occasions are missed because of headache.

Three versions of the HALT Indices serve different purposes as measures of headache-attributed burden, and offer different means of scoring:

- HALT-90 counts days affected by headache during the preceding three months (90 days);
- HALT-30 records days affected during the preceding one month (30 days);
- HALT-7/30 enquiries into lost work days only, in the preceding month (30 days) and week (7 days).

Assessment of individual patients prior to treatment is better evaluated by HALT-90, except in cases where headache is highly frequent. Follow-up in clinical management may be better served by HALT-30. For population-based studies of headache-attributed burden, including financial cost, HALT-7/ 30 is more suitable.

HALT can generate three summed scores from the first four questions, the unit of each being whole days per period of enquiry: a) lost work time; b) lost household work time; and c) total lost productive time. Question five, however, gives rise to a simple count for which the unit is not whole days. An error is introduced when this count is added to any of the scores above. **Nevertheless, the count of lost social events does reflect additional burden, so question five is retained in HALT-90 and included in the total summed score, which gives rise to grading, as with MIDAS[1]: 0-5 minimal or infrequent I, 6-10 mild or infrequent II, 11-20 moderate III (indicates high need for care), ≥20 severe IV (indicates high need for care). Grading is not used by HALT-30.**

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1. Stewart WF, Lipton RB, Kolodner K, Sawyer J, Lee C, Liberman JN (2000) Validity of the migraine disability assessment (MIDAS) score in comparison to a diary-based measure in a population sample of migraine sufferers. Pain 88:41–52.
2. Steiner TJ (2007) The HALT and HART indices. J Headache Pain 8(suppl 1):S22–S25.
3. Steiner, T.J., Lipton, R.B. & on behalf of Lifting The Burden: The Global Campaign against Headache. The Headache-Attributed Lost Time (HALT) Indices: measures of burden for clinical management and population-based research. J Headache Pain 19, 12 (2018).

HALT-90 Index

Headache Attributed Lost Time – 90 days

PLEASE ANSWER THESE QUESTIONS CAREFULLY

1. On how many **days** in the **last three months** could you **not go** to work or school because of your headaches? ☐

2. On how many **days** in the **last three months** could you do **less than half** your usual amount in your job or schoolwork because of your headaches?
(Do not include days you counted in question 1 where you missed work or school.) ☐

3. On how many **days** in the **last three months** could you **not do any** household work because of your headaches?
(Do not include days you counted in questions 1 or 2.) ☐

4. On how many **days** in the **last three months** could you do **less than half** your usual amount of household work because of your headaches?
(Do not include days you counted in question 3 where you did not do household work.) ☐

5. On how many **days** in the **last three months** did you **miss** family, social or leisure activities because of your headaches? ☐

Total ☐

Grading (I-IV indicate, in order, increasing need for medical care; either III or IV indicates high need)		
0-5	Minimal or infrequent impact	Grade I
6-10	Mild or infrequent impact	Grade II
11-20	Moderate impact	Grade II
20+	Severe impact	Grade IV

HALT-30 Index

Headache Attributed Lost Time – 30 days

PLEASE ANSWER THESE QUESTIONS CAREFULLY

1. On how many **days** in the **last month** could you **not go** to work or school because of your headaches?	
2. On how many **days** in the **last month** could you do **less than half** your usual amount in your job or schoolwork because of your headaches? (Do not include days you counted in question 1 where you missed work or school.)	
3. On how many **days** in the **last month** could you **not do any** household work because of your headaches? (Do not include days you counted in questions 1 or 2.)	
4. On how many **days** in the **last month** could you do **less than half** your usual amount of household work because of your headaches? (Do not include days you counted in any of the previous questions.)	
5. On how many **days** in the **last month** did you **miss** family, social or leisure activities because of your headaches?	
Total	

HALT-7/30 Index

Headache Attributed Lost Time – 7 and 30 days

PLEASE ANSWER THESE QUESTIONS CAREFULLY

1. On how many **days** in the **last month** did you have a headache? (enter the number between 0 and 30) ☐

The next two questions are about **days when you could not go to work at all** because of your headache.

2. On how many **days** in the **last month** could you **not go** to work or school because of a headache? (enter the number between 0 and 30) ☐

3. On how many **days** in the **last week** could you **not go** to work or school because of a headache? (enter the number between 0 and 7) ☐

The next two questions are about **days when you went to work** but **could not work properly** because of your headache.

Do not include days you counted in questions 2 and 3 where you missed work altogether.

4. On how many **days** in the **last month** could you do **less than half** your usual amount at work or school because of a headache? (enter the number between 0 and 30) ☐

5. On how many **days** in the **last week** could you do **less than half** your usual amount at work or school because of a headache? (enter the number between 0 and 7) ☐

IMPAC

Impact of Migraine on Partners and Adolescent Children Scale

IMPAC scale, is a measure designed to quantify the impact of migraine on family members as perceived by the proband[2].
It is a brief, robust, and psychometrically sound instrument designed to measure the impact of migraine on the family using information gathered from the migraine proband. **The goal is to have questions that focus on everyone with migraine, those with partners, and those with children[1,2].**
The questionnaire is composed of 12 items covering 3 family social factors (ie, activity, partner interaction, child interaction). These measures cover the 4 types of families: M-O migraine probands only (no partner/ child[ren]), M-P migraine probands with partner, M-PC migraine probands with partner and child(ren)[2].

The items of the scale were developed based on literature review, focus group discussions with probands and proband family members, and clinical expertise followed by psychometric methods to optimize the clinical relevance, the discriminant and construct validity as well as precision of the final instrument[2].

This assessment tool is widely accessible and user friendly for both research and clinical use, thanks to the easy scoring strategy. Item responses were summed and converted into standardized general family impact scores corresponding to 4-category family impact grades: Grade I, "none/ mild" (<0.5 SD below mean); Grade II, "moderate" (0.5 SD below mean to <0.5 SD above mean); Grade III, "severe" (0.5 SD above mean to <1.5 SD above mean); and Grade IV, "very severe" (1.5 SD above mean. Each of the Scoring Appendix tables provides a range of sum scores (translated to standardized scores) corresponding to each IMPAC scale grade/severity level. Separate ranges are provided depending on the number of items answered as "not applicable"; the grade/severity level cannot be determined if the number of "not applicable" responses is >3 for M-PC or >2 for M-P, M-C, and M-O.

Quantifying family impact begins the process of understanding the effect of migraine on family members and provides an opportunity for clinicians to develop strategies to reduce migraine burden with patients and family members. This scale may also be useful in a research context for evaluating the impact of migraine on family members.

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1. Lipton RB, Bigal ME, Kolodner K, Stewart WF, Liberman JN, Steiner TJ. The family impact of migraine: Population-based studies in the USA and UK. Cephalalgia. 2003;23:429-440.
2. Lipton RB, Buse DC, Adams AM, Varon SF, Fanning KM, Reed ML. Family Impact of Migraine: Development of the Impact of Migraine on Partners and Adolescent Children (IMPAC) Scale. Headache. 2017 Apr;57(4):570-585. doi: 10.1111/head.13028. Epub 2017 Feb 10. PMID: 28185239; PMCID: PMC5396278.

IMPAC

Impact of Migraine on Partners and Adolescent Children Scale

Circle one response for each statement below or circle – if that family activity is **Not Applicable** (N/A) to you or your family situation.
If you don't remember the exact number of times, please give the best answer you can.

PART A – Answer if YOU have migraine
Answer questions 1-4 about how your family activities are affected by your headaches.

Because of your headaches, how many TIMES during the past 30 days...	0 Times	1-3 Times	4-9 Times	10+ Times	N/A
1. ...did you not participate in family activities at home (eg, meals, playing games, watching TV)?	0	1	2	3	–
2. ...did you not do anything "physical" with your family (eg, taking a walk, dancing, bowling, exercising)?	0	1	2	3	–
3. ...did you let your share of the housework go undone (eg, let the dishes or laundry pile up, not cut the grass)?	0	1	2	3	–
4. ...was your involvement in (or enjoyment of) family activities significantly reduced?	0	1	2	3	–

Part A Total: Sum of cicled items 1-4 _____ Part A: Number of N/A responses _____

PART B – Answer if you have a SPOUSE/PARTNER living with you
Answer questions 5-8 about how your relationship with your SPOUSE/PARTNER is affected by your headaches.

Because of your headaches, how many TIMES during the past 30 days...	0 Times	1-3 Times	4-9 Times	10+ Times	N/A
5. ...was you enjoyment of time spent with your partner significantly reduced?	0	1	2	3	–
How much do you agree with each of the following statements?	**Disagree Completely**	**Disagree Somewhat**	**Agree Somewhat**	**Agree Completely**	**N/A**
6. My partner gets upset or angry at me for having headaches.	0	1	2	3	–
7. My partner avoids me at times because of my headaches.	0	1	2	3	–
8. My partner resents having to do everything when I have a headache.	0	1	2	3	–

Part B Total: Sum of cicled items 5-8 _____ Part B: Number of N/A responses _____

PART C – Answer if you have a CHILD/CHILDREN living with you

Answer questions 9-12 about how your relationship with your CHILD(REN) is affected by your headaches.

Because of your headaches, how many TIMES during the past 30 days...	0 Times	1-3 Times	4-9 Times	10+ Times	N/A
9. ...was you enjoyment of time spent with your child(ren)'s activities significantly reduced?	0	1	2	3	–
How much do you agree with each of the following statements?	**Disagree Completely**	**Disagree Somewhat**	**Agree Somewhat**	**Agree Completely**	**N/A**
10. Because of my headaches, I get angry or annoyed more easily with my child(ren).	0	1	2	3	–
11. If I didn't have headaches, I would be a better parent.	0	1	2	3	–
12. The noise of my child(ren)'s usual activities can give me a headache or make it worse.	0	1	2	3	–

Part C Total: Sum of cicled items 9-12 _____ Part C: Number of N/A responses _____

SCORING

Sum of Circled Items in Part A, B, and C: _____ **N/A Total for Part A, B, and/or C: _____**

Instructions

1. Determine which sections to use based on family composition (Parts A, B, and/or C).
2. Sum the scores from each applicable section for a total score.
3. Sum the number of N/A responses for each applicable section.
4. Use the attached tables to estimate the level of headache-related family impact

Part A N/A Total: _____ Part B N/A Total: _____ Part C N/A Total: _____ Total N/A: _____

Part A Total: _____ Part B Total: _____ Part C Total: _____ Total Score: _____

IMPAC

Impact of Migraine on Partners and Adolescent Children Scale

Part A Only: Households without Partner/Spouse and/or Child(ren)

Sum	0 N/A	1 N/A	2 N/A*
0			
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			

Parts A and B: Households with Partner/Spouse, no Child(ren)

Sum	0 N/A	1 N/A	2 N/A*
0			
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			

LEGEND

Grade I (Mild) | Grade II (Moderate) | Grade III (Severe) | Grade IV (Very Severe)

IMPAC

Impact of Migraine on Partners and Adolescent Children Scale

Parts A and C: Households with Child(ren), no Partner/Spouse

Sum	0 N/A	1 N/A	2 N/A*
0			
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			

Parts A, B, and C: Households with Partner/Spouse and Child(ren)

Sum	0 N/A	1 N/A	2 N/A	3 N/A†	Sum	0 N/A	1 N/A	2 N/A	3 N/A†
0					19				
1					20				
2					21				
3					22				
4					23				
5					24				
6					25				
7					26				
8					27				
9					28				
10					29				
11					30				
12					31				
13					32				
14					33				
15					34				
16					35				
17					36				
18					-				

* If the number of N/A responses is >2, the severity cannot be determined. † If the number of N/A responses is >3, the severity cannot be determined.

LEGEND

Grade I (Mild) | Grade II (Moderate) | Grade III (Severe) | Grade IV (Very Severe)

ASSESSMENT OF INTERICTAL BURDEN

MIBS-4

Migraine Interictal Burden Scale

MIBS-4 is a 4 item self-administered instrument for measuring the burden of migraine between attacks. It was designed for clinical use or screening purposes.

The Migraine Interictal Burden Scale (MIBS) measures interictal migraine-related burden in 4 domains: impairment in work or school, impairment in family and social life, difficulty making plans or commitments, and emotional/affective and cognitive distress[1].

Patients are asked to score the effects of their headache in the past 4 weeks on days when they are not having an attack. Each item is scored by choosing one of the following options: don't know/never/rarely/some of the time/much of the time/most of all the times. The final score is calculated by multiplying the number of checks by value 0 for don't know and never, 1 for rarely, 2 for some of the time and 3 for the last two options.

Because the burden of migraine during attacks only partially predicts the burden between attacks, physicians should routinely ask their patients about the interictal burden of their headaches as a prelude to developing an optimal treatment plan[2].
Anxiety in anticipation of the next migraine attack (interictal anxiety) may lead migraineurs to take pain medications before any symptoms of an attack occur, ultimately resulting in overuse of these medications. Phobic avoidance of activities because of fear of migraine or headache (cephalalgiaphobia) is a contributor to the interictal burden of migraine. As the MIBS-4 score increases, so does the prevalence of anxiety disorder, panic disorder, and major depressive disorder. This shows the importance of evaluating interictal burden of migraine in order to manage any psychiatric comorbidities[3].

1. Buse DC, Bigal M, Rupnow M, Reed M, Serrano D, & Lipton R. Development and validation of the Migraine Interictal Burden Scale (MIBS): A self-administered instrument for measuring the burden of migraine between attacks. Neurology. 2007;68(suppl 1):A89.
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MIBS-4

Migraine Interictal Burden Scale

Please answer each of the following statements about the effect of your headaches in the past 4 weeks on days when you are not having an attack. **(X one box for each statement)**

BETWEEN HEADACHE ATTACKS OR AT TIMES WHEN I DO NOT HAVE A HEADACHE

1. My headaches affect my work or school at times when I do not have a headache	○ Don't know/NA	○ Never	○ Rarely	○ Some of the time	○ Much of the time	○ Most or all of the time
2. I worry about planning social or leisure activities because I might have a headache	○ Don't know/NA	○ Never	○ Rarely	○ Some of the time	○ Much of the time	○ Most or all of the time
3. My headaches impact my life at times when I do not have a headache	○ Don't know/NA	○ Never	○ Rarely	○ Some of the time	○ Much of the time	○ Most or all of the time
4. At times when I do not have a headache, I feel helpless because of my headaches	○ Don't know/NA	○ Never	○ Rarely	○ Some of the time	○ Much of the time	○ Most or all of the time
Total number of checks in column	☐	☐	☐	☐	☐	☐
Multiply number of checks by value = total score per column	X 0	X 0	X 1	X 2	X 3	X 3
Total score per column	☐ +	☐ +	☐ +	☐ +	☐ +	☐
Total score			=	☐		

MIBS-4 scoring key		
Score	**Level of interictal burden**	**Treatment recommendations**
0	None	• No action needed
1-2	Mild	• Offer non-pharmacological strategies for reducing interictal burden • Offer/optimize acute pharmacological treatment
3-4	Moderate	• Offer non-pharmacological strategies for reducing interictal burden • Offer/optimize acute pharmacological treatment • Consider preventive pharmacological treatment
5+	Severe	• Offer non-pharmacological strategies for reducing interictal burden • Offer/optimize acute pharmacological treatment • Offer preventive pharmacological treatment

CLINICAL IMPRESSION AND OTHER HEALTH OUTCOME MEASURES

PGI-S Patient Global Impression Severity
PGI-C Patient Global Impression of Change

The **Patient Global Impression scale (PGI)** is the subjective counterpart to the Clinical Global Impressions scale, (CGI), which was published in 1976 by the National Institute of Mental Health (United States). It is a self report of the clinical condition of the patient and it consists of one item based on the CGI and adapted to the patient. The PGI is a simple, single-item, rating scale[1].
It can measure change in clinical status (PGI-C) or measure disease severity (PGI-S).
Over the years, PGI scales were used in a broad range of diseases and were modified for the purpose of clinical settings (item label, number of response options and response options).

The Patient Global Impression-Severity (PGI-S) scale rates the severity of their symptom/condition at, or over, a particular point in time using a categorical scale, for example none (0), mild (1), moderate (2), severe (3). The PGI-S has been shown to be a valid assessment in patients and it is a recommended outcome measure in clinical trials for agents to treat headache pain[2].

The PGI-C involves a single question about the patient's impression of the overall change in their disease status since an established point in time, and encompasses multiple domains of health: activity limitations, symptoms, emotions, and overall quality of life. This scale evaluates all aspects of patients' health and assesses if there has been an improvement or decline in clinical status. The Patient Global Impression of Change (PGI-C), has been used to assess global impression of change in migraine trials[2].

1. Guy W (ed). ECDEU Assessment Manual for Psychopharmacology. Rockville, MD: US Department of Heath,Education, and Welfare Public Health Service Alcohol, Drug Abuse, and Mental Health Administration, 1976
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PGI-S Patient Global Impression Severity
PGI-C Patient Global Impression of Change

PGI-S
Please rate the severity of your symptoms currently (place an X next to the rating/status)

1. Not present	◯
2. Very mild	◯
3. Mild	◯
4. Moderate	◯
5. Moderately severe	◯
6. Severe	◯
7. Extremely severe	◯

PGI-C
Since the start of the study, my overall status is: (place an X next to the rating/status)

1. Very much improved	◯
2. Much improved	◯
3. Minimally improved	◯
4. No change	◯
5. Minimally worse	◯
6. Much worse	◯
7. Very much worse	◯

EQ-5D-5L

European Quality of Life 5-Dimensions 5-Levels

The **EQ-5D-5L** (European Quality of Life 5-Dimensions 5-Levels) was introduced by the EuroQol Group in 2009 to improve the instrument's sensitivity and to reduce ceiling effects, by increasing the number of severity levels[1] of the EQ-5D-3L.
The EQ-5D-5L is a reliable and valid generic instrument that describes health status which can be applied to a broad range of populations and settings[3].

It is divided in two parts: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The descriptive system comprises five **dimensions**: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The patient is asked to indicate his/her health state by ticking the box next to the most appropriate statement in each of the five dimensions. This decision results in a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the patient's health state. For example: state 12345 indicates no problems with mobility, slight problems with washing or dressing, moderate problems with doing usual activities, severe pain or discomfort and extreme anxiety or depression, while state 11111 indicates no problems on any of the five dimensions[2].

The EQ VAS records the patient's self-rated health on a vertical visual analogue scale, where the endpoints are labeled from 100: **"The best health you can imagine" to 0: "The worst health you can imagine". The VAS can be used as a quantitative measure of health outcomes that reflect the patient's own judgment.**

EQ-5D-5L health states can be summarized using the 5-digit code or represented by a single summary number (index value), which reflects how good or bad a health state is according to the preferences of the general population of a country/region.
A standardized valuation study protocol (called EQ-VT) was developed by the EuroQol Group to create standard value sets for the EQ-5D-5L. EQ-5D-5L users are recommended to use these standard value sets produced with EQ-VT[2].

1. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, Bonsel G, Badia X Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L) Qual Life Res 2011 Dec;20(10):1727-1736 Published : 01-12-2011.
2. EuroQol Research Foundation. EQ-5D-5L User Guide, 2019. Available from: https://euroqol.org/publications/user-guides.
3. Feng YS, Kohlmann T, Janssen MF & Buchholz I. Psychometric properties of the EQ-5D-5L: a systematic review of the literature. Qual Life Res 30, 647–673 (2021). https://doi.org/10.1007/s11136-020-02688-y.

EQ-5D-5L

European Quality of Life
5-Dimensions 5-Levels

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about ○
- I have slight problems in walking about ○
- I have moderate problems in walking about ○
- I have severe problems in walking about ○
- I am unable to walk about ○

SELF-CARE

- I have no problems washing or dressing myself ○
- I have slight problems washing or dressing myself ○
- I have moderate problems washing or dressing myself ○
- I have severe problems washing or dressing myself ○
- I am unable to wash or dress myself ○

USUAL ACTIVITIES
(e.g. work, study, housework, family or leisure activities).

- I have no problems doing my usual activities ○
- I have slight problems doing my usual activities ○
- I have moderate problems doing my usual activities ○
- I have severe problems doing my usual activities ○
- I am unable to do my usual activities ○

EQ-5D-5L

European Quality of Life
5-Dimensions 5-Levels

PAIN / DISCOMFORT

I have no pain or discomfort	◯
I have slight pain or discomfort	◯
I have moderate pain or discomfort	◯
I have severe pain or discomfort	◯
I have extreme pain or discomfort	◯

ANXIETY / DEPRESSION

I am not anxious or depressed	◯
I am slightly anxious or depressed	◯
I am moderately anxious or depressed	◯
I am severely anxious or depressed	◯
I am extremely anxious or depressed	◯

EQ-5DTM is a trade mark of the EuroQol Group. All EQ-5D products are distributed exclusively from the EuroQol Executive Office (userinformationservice@euroqol.org).

WPAI

Work Productivity and Activity Impairment questionnaire

The **WPAI** is a patient-reported quantitative assessment of the amount of absenteeism, presenteeism and daily activity impairment attributable to general health (WPAI:GH) or a specific health problem (WPAI:SHP).

The WPAI:GH and the WPAI:SHP (special Health Problem) were created simultaneously and use the same template, but in the GH version the subject is instructed to respond with reference to general health status while in the SHP version, the subject responds with reference to a specified health problem, disease or condition, like migraine[2].
In the combination version, WPAI:GH/SHP respondents are asked about impairment due to a specified health problem and impairment due to other health reasons. The sum of impairment due to the specified problem and other health reasons is considered impairment due to all health problems. The WPAI:GH/SHP, therefore, measures impairment due to the specified problem and all health problems.
The 6 questions in the WPAI are about work productivity in the last seven days. The first question inquires about employment status: if the patient is not working for pay, he or she has to skip directly to the last question about the impact of health problems on daily regular activities. Items 2 and 3 concern self-reported work hours missed due to the specific health problem, or to any other situation. Item 4 asks for the number of worked hours and item 5 measures productivity on the job.
A one-week recall period was selected because there could be a significant decrease in the accuracy of reporting work productivity data with a lengthy recall interval[1].
The WPAI yields four types of scores:

1. Absenteeism (work time missed)
2. Presenteeism (impairment at work / reduced on-the-job effectiveness)
3. Work productivity loss (overall work impairment / absenteeism plus presenteeism)
4. Activity Impairment

The sum of specific health problem impairment and impairment due to other health reasons is equal to impairment due to all health reasons. WPAI outcomes are expressed as impairment percentages, with higher numbers indicating greater impairment and less productivity, i.e., worse outcomes.

1. Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. Pharmaco economics. 1993;4:353–365.
2. Wong LP, Alias H, Bhoo-Pathy N, Chung I, Chong YC, Kalra S, Shah ZUBS. Impact of migraine on workplace productivity and monetary loss: a study of employees in banking sector in Malaysia. J Headache Pain. 2020 Jun 8;21(1):68. doi: 10.1186/s10194-020-01144-z. Erratum in: J Headache Pain. 2020 Aug 18;21(1):104. PMID: 32513174; PMCID: PMC7282083.

WPAI

Work Productivity and Activity Impairment questionnaire

The following questions ask about the effect of your health problems on your ability to work and perform regular activities. By health problems we mean any physical or emotional problem or symptom. *Please fill in the blanks or circle a number, as indicated.*

1. Are you currently employed (working for pay)?

If NO, check "NO" and skip to question 6.

○ No ○ Yes

The next questions are about the **past seven days**, not including today.

2. During the past seven days, how many hours did you miss from work because of problems associated with your migraine?

Include hours you missed on sick days, times you went in late, left early, etc., because of your migraine.

☐ Hours

3. During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study?

☐ Hours

4. During the past seven days, how many hours did you actually work?

☐ Hours (If "0", skip to question 6.)

5. During the past seven days, how much did your migraine affect your productivity while you were working?

Think about days you were limited in the amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as usual. If migraine affected your work only a little, choose a low number. Choose a high number if migraine affected your work a great deal.

Consider only how much migraine affected productivity while you were working.

Migraine had no effect on my work	0	1	2	3	4	5	6	7	8	9	10	Migraine completely prevented me from working
	○	○	○	○	○	○	○	○	○	○	○	

Check a number

6. During the past seven days, how much did your migraine affect your ability to do your regular daily activities, other than work at a job?

By regular activities, we mean the usual activities you do, such as work around the house, shopping, childcare, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could do and times you accomplished less than you would like. If migraine affected your activities only a little, choose a low number. Choose a high number if PROBLEM affected your activities a great deal.

Consider only how much migraine affected your ability to do your regular daily activities, other than work at a job.

Migraine had no effect on my daily activities	0	1	2	3	4	5	6	7	8	9	10	Migraine completely prevented me from doing my daily activities
	○	○	○	○	○	○	○	○	○	○	○	

Check a number

WPAI:SHP

WPAI outcomes are expressed as impairment percentages, with higher numbers indicating greater impairment and less productivity, i.e., worse outcomes, as follows:

Questions

1 = currently employed
2 = hours missed due to specified problem
3 = hours missed other reasons
4 = hours actually worked
5 = degree problem affected productivity while working
6 = degree problem affected regular activities

Scores

Multiply scores by 100 to express in percentages.

- *Percent work time missed due to problem:* Q2/(Q2+Q4)
- *Percent impairment while working due to problem:* Q5/10
- *Percent overall work impairment due to problem:*
- Q2/(Q2+Q4)+[(1-(Q2/(Q2+Q4)))x(Q5/10)]
- *Percent activity impairment due to problem:* Q6/10

ASSESSMENT OF SPECIFIC FEATURES OF MIGRAINE

VAS
for Migraine Visual Analogue Scale

Visual Analogue Scale (VAS) is a self-administered graphic scale that can be used in migraine to measure pain ranging across a continuum of value.

The amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain. From the patient's perspective, this spectrum appears continuous ± their pain does not take discrete jumps, as a categorization of none, mild, moderate and severe would suggest. It was to capture this idea of an underlying continuum that the VAS was devised.

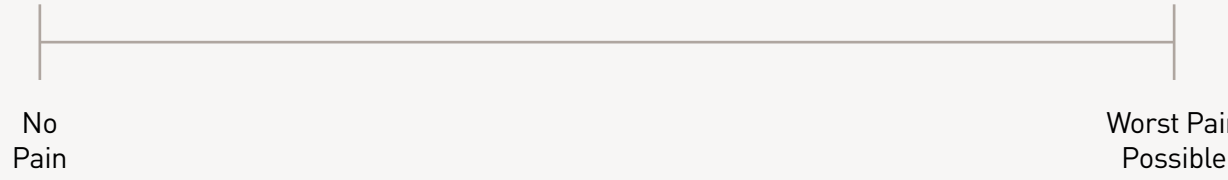
The visual analogue scale should be displayed horizontally with the words spread out along the whole length of the line.The results of pain severity measured by these methods showed a very good correlation with pain severity measured by the simple descriptive pain scale. Changes in visual analogue scores also correlated well with changes in simple descriptive pain scores. The visual analogue scales were more sensitive than the traditional simple descriptive pain scale. Most patients could readily use visual analogue and graphic rating scales despite having no previous experience[1].

Use of these scales is a good method for measuring pain or pain relief also in migraine attacks[2].

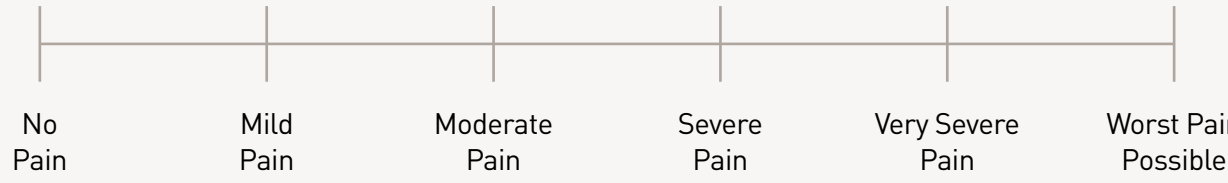
1. Scott J, Huskisson EC. Graphic representation of pain, Pain: June 1976 - Volume 2 - Issue 2 - p 175-184 doi:10.1016/0304-3959(76)90113-5.
2. Herd CP, Tomlinson CL, Rick C, Scotton WJ, Edwards J, Ives N, Clarke CE, Sinclair A. Botulinum toxins for the prevention of migraine in adults. Cochrane Database Syst Rev. 2018 Jun 25;6(6):CD011616. doi: 10.1002/14651858.CD011616.pub2. PMID: 29939406; PMCID: PMC6513576.

VAS
for Migraine Visual Analogue Scale

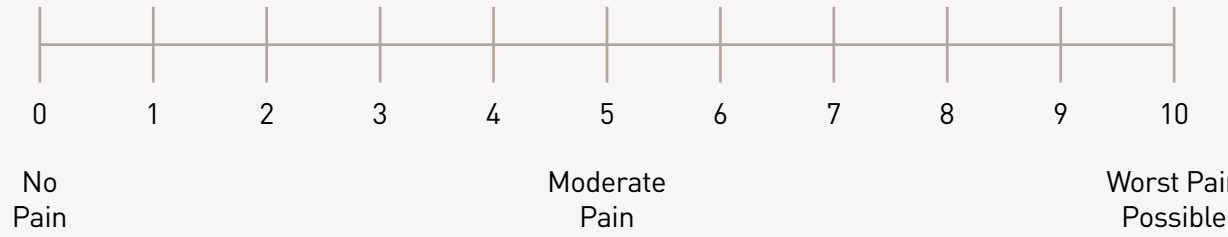
Visual Analogue Scale



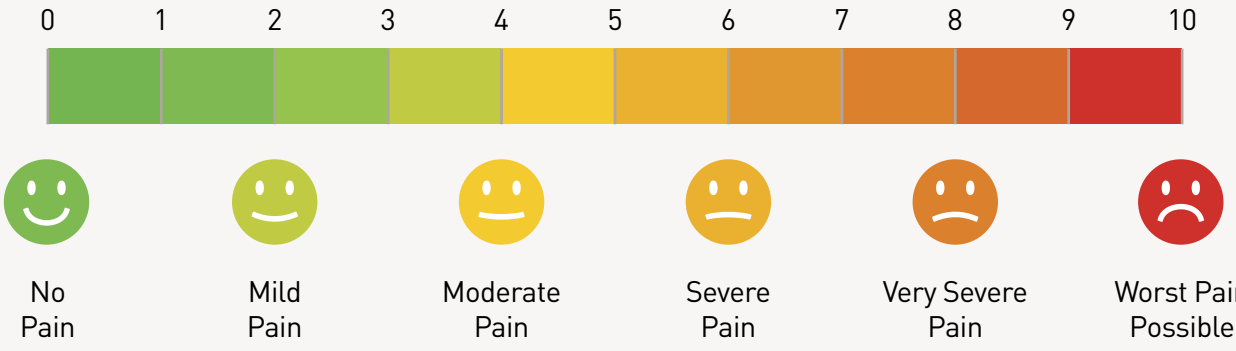
Verbal Pain Intensity Scale



0-10 Numeric Pain Intensity Scale



Numeric Pain Intensity Scale combined with Faces Scale



TPB
Total Pain Burden

Total Pain Burden has been conceptualized as a composite measure involving: frequency of migraine headache days in a month, duration of migraine headache on a given day, and maximum severity of migraine headache on a given day. The total pain burden for a given month (severity-weighted duration) is calculated by multiplying duration (h=hours) of migraine headache and maximum pain severity (0 = none, 1 = mild, 2 = moderate, 3 = severe) for each migraine headache day and summing these over the days in a month[1].
As an example, consider a patient who has 2 days of migraine headache in a month. The patient reports 2 h of migraine headache on Day 1, which is of mild severity (score = 1) and 3 h of migraine headache on Day 2, which is of moderate severity (score = 2). The total pain burden score for that month would be calculated as the sum of (2 h × 1) and (3 h × 2) which equals 8 severity-weighted hours of total pain burden.

Focus on the frequency of migraine pain may undervalue the total burden of migraine as pain duration and severity may present a unique, additive burden. A composite measure of total pain burden (TPB; frequency, severity, and duration) may provide a more comprehensive characterization of pain burden and treatment response in people with migraine. Total pain burden may better reflect what clinicians and patients discuss regarding the individual's pain experience and could prove useful to further patient-centric discussions regarding treatment expectations when clinicians are evaluating options for migraine prevention.
The current findings suggest that assessing total pain burden in a research or clinical setting allows for a more robust evaluation of the potential benefit of a preventive treatment for migraine in reducing the overall pain experience.

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1. Ailani J, Andrews JS, Rettiganti M & Nicholson RA. Impact of galcanezumab on total pain burden: findings from phase 3 randomized, double-blind, placebo-controlled studies in patients with episodic or chronic migraine (EVOLVE-1, EVOLVE-2, and REGAIN trials). J Headache Pain 21, 123 (2020). https://doi.org/10.1186/s10194-020-01190-7.

TPB
Total Pain Burden

The total pain burden for a given month (severity-weighted duration) was calculated by **multiplying duration (hours) of migraine headache and maximum pain severity** (0=none, 1=mild, 2=moderate, 3=severe) for each migraine headache day and summing these over the days in a month[1].

MIGRAINE HEADACHE DAYS	Migraine Hours (0-24)		Maximum Severity (0-3)		Severity Weighted Hours
		x		=	
		x		=	
		x		=	
		x		=	
		x		=	
		x		=	
		x		=	
		x		=	
		x		=	
		x		=	
TOTAL Severity-Weighted Hours					

VARS
Visual Aura Rating Scale

The **Visual Aura Rating Scale (VARS)** was developed to supplement the traditional ICHD-2 (International Classification of Headache Disorders 2nd edition) diagnosis for migraine with aura (MA).[1]

VARS is a self-administered, simple diagnostic tool that further operationalizes the diagnosis of MA. According to VARS an outcome diagnosis of MA depends on a predictive score based on the presence or absence of five specific characteristics of visual aura: duration 5–60 min (3 points), develops gradually ⩾ 5 min (2 points), scotoma (2 points), zig-zag lines (2 points), and unilateral (1 point).
The predictive VARS score is the weighted sum of the number of characteristics present. The maximum score is 10 points. A VARS score of 5 or more diagnoses MA with a sensitivity of 91% and a specificity of 96%[1].

The VARS adds evidence based weights to a number of clearly specified characteristics; it is easy to learn, apply and teach.

This questionnaire is a valid and reliable instrument for the screening of visual aura in patients with migraine in neurology outpatient clinics[2].

1. Eriksen M, Thomsen L, Olesen J. The Visual Aura Rating Scale (VARS) for Migraine Aura Diagnosis. Cephalalgia. 2005;25(10):801-810. doi:10.1111/j.1468-2982.2005.00955.x
2. Kim BK, Cho S, Kim HY, Chu MK. Validity and reliability of the self-administered Visual Aura Rating Scale questionnaire for migraine with aura diagnosis: A prospective clinic-based study. Headache. 2021 Jun;61(6):863-871. doi: 10.1111/head.14133. Epub 2021 Jun 9. PMID: 34106459.

VARS
Visual Aura Rating Scale

Visual symptom characteristic	Risk score
Duration 5–60 mins	3
Develops gradually ⩾ 5 mins	2
Scotoma	2
Zig-zag line (fortificaiton)	2
Unilateral (homonymous)	1

Maximum VARS score	10
Migraine with aura diagnosis	⩾5

ASC-12

Allodynia Symptom Checklist 12

The **Allodynia Symptom Checklist 12 (ASC-12)** was developed for assessing cutaneous allodynia (CA), and to estimate the prevalence and severity of CA in the migraine population[1].

The ASC includes 12 questions about the frequency of various allodynia symptoms in association with headache attacks. ASC items are scored as 0 (i.e., never or rarely or does not apply to me), 1 (less than half the time), and 2 (half the time or more), yielding scores that range from 0 to 24. In the development of ASC, alternative scoring strategies were evaluated but did not alter the results. The validation process defined the following categories based on the ASC12 CA scores: no allodynia (0–2), mild (3–5), moderate (6–8), and severe (9 or higher)[2].

The ASC-12 was developed and validated in a large migraine population[1].It showed a close correlation with frequency and headache intensity as well as migraine-related disability[3].

1. Lipton RB, Bigal ME, Ashina S, Burstein R, Silberstein S, Reed ML, Serrano D, Stewart, WF. (2008), Cutaneous allodynia in the migraine population. Ann Neurol., 63: 148-158. https://doi.org/10.1002/ana.21211
2. Bigal ME, Ashina S, Burstein R, Reed ML, Buse D, Serrano D, Lipton RB; AMPP Group. Prevalence and characteristics of allodynia in headache sufferers: a population study. Neurology. 2008;70(17):1525-1533. doi:10.1212/01.wnl.0000310645.31020.b1
3. Han SM, Kim KM, Cho SJ, Kwang Ik Yang, Kim D, Yun C-H & Chu MK. Prevalence and characteristics of cutaneous allodynia in probable migraine. Sci Rep 11, 2467 (2021). https://doi.org/10.1038/s41598-021-82080-z

ASC-12
Allodynia Symptom Checklist 12

12-ITEM ALLODYNIA SYMPTOM CHECKLIST (ASC-12)

Question: How often do you experience increased pain or an unpleasant sensation on your skin during your most severe type of headache when you engage each of the following?	Does not apply to me	Never	Rarely	Less than half of the time	Half of the time or more
	Score: 0	Score: 0	Score: 0	Score: 1	Score: 2
wearing a necklace					
wearing earrings					
wearing glasses					
wearing tight clothes					
wearing a pony tail					
wearing contact lenses					
shaving the face					
taking a shower					
combing the hair					
resting the head on a pillow					
exposure to cold					
exposure to heat					
Total score		+	+	+	+
Sum of score				=	

ASC-12 scoring key	
Allodynia	**ASC range**
None	0-2
Mild	3-5
Moderate	6-8
Severe	9 or more

ASSESSMENT OF COMORBIDITIES

PHQ-9
Patient Health Questionnaire

The **Patient Health Questionnaire (PHQ) 9** is the nine items depression module of the PHQ, an instrument created to make criteria-based diagnoses of Depression and other Psychiatric conditions in primary care[1].

A patient self-report measure (although it can also be administered by doctors), the PHQ-9 was developed with the aim of providing a questionnaire that combined brevity with "construct and criterion validity"[2]. The PHQ-9 asks patients to rate, on a four-point scale ranging from "not at all" to "most days," the frequency with which they have experienced certain depression symptoms in the preceding 2 weeks[4].Major depression is diagnosed if 5 or more of the 9 depressive symptom criteria have been present at least "more than half the days" in the past 2 weeks, and 1 of the symptoms is depressed mood or anhedonia. Other depression is diagnosed if 2, 3, or 4 depressive symptoms have been present at least "more than half the days" in the past 2 weeks, and 1 of the symptoms is depressed mood or anhedonia. One of the 9 symptom criteria ("thoughts that you would be better off dead or of hurting yourself in some way") counts if present at all, regardless of duration. The clinician is also expected to rule out physical causes of depression, normal bereavement, and history of a manic episode[2].

In addition to making criteria-based diagnoses of depressive disorders, the PHQ-9 is also a reliable and valid measure of depression severity. The PHQ-9 score can range from 0 to 27, since each of the 9 items can be scored from 0 (not at all) to 3 (nearly every day). An item was also added to the end of the diagnostic portion of the PHQ-9 asking patients who checked off any problems on the questionnaire: "How difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?"[2].

Patients with migraine are more likely to develop depression than those without migraine. Comorbid depression in patients with migraine may have important clinical implications.
In a busy clinical setting, psychiatric interviews take a long time to conduct. Therefore, the application of the PHQ-9 (and PHQ-2) could lead to a better recognition of depression in patients with migraine[3].

1. Spitzer RL, Kroenke K, Williams JB. Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study. Primary Care Evaluation of Mental Disorders. Patient Health Questionnaire. JAMA. 1999 Nov 10;282(18):1737-44. doi: 10.1001/jama.282.18.1737. PMID: 10568646.
2. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001 Sep;16(9):606-13. doi: 10.1046/j.1525-1497.2001.016009606.x. PMID: 11556941; PMCID: PMC1495268.
3. Seo JG, Park SP. Validation of the Patient Health Questionnaire-9 (PHQ-9) and PHQ-2 in patients with migraine. The Journal of Headache and Pain (2015) 16:65.
4. Ford J, Thomas F, Byng R, McCabe R. Use of the Patient Health Questionnaire (PHQ-9) in Practice: Interactions between patients and physicians. Qual Health Res. 2020;30(13):2146-2159. doi:10.1177/1049732320924625.

PHQ-9

Patient Health Questionnaire

Use "X" to indicate your answer

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Not at all
1. Little interest or pleasure in doing things	◯ 0	◯ 1	◯ 2	◯ 3
2. Feeling down, depressed, or hopeless	◯ 0	◯ 1	◯ 2	◯ 3
3. Trouble falling or staying asleep, or sleeping too much	◯ 0	◯ 1	◯ 2	◯ 3
4. Feeling tired or having little energy	◯ 0	◯ 1	◯ 2	◯ 3
5. Poor appetite or overeating	◯ 0	◯ 1	◯ 2	◯ 3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	◯ 0	◯ 1	◯ 2	◯ 3
7. Trouble concentrating on things, such as reading the newspaper or watching television	◯ 0	◯ 1	◯ 2	◯ 3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual	◯ 0	◯ 1	◯ 2	◯ 3
9. Thoughts that you would be better off dead or of hurting yourself in some way	◯ 0	◯ 1	◯ 2	◯ 3
For office coding	☐ +	☐ +	☐ +	☐
Total score			=	☐

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

◯ Not difficult at all	◯ Somewhat difficult	◯ Very difficult	◯ Extremely difficult

PHQ-2

Patient Health Questionnaire

The **Patient Health Questionnaire (PHQ) 2** is the two item version of the PHQ depression module, an instrument created to make criteria-based diagnoses of Depression in primary care[1].
The PHQ-2 includes only the first two items of the PHQ-9, which are critical for the diagnosis of major depressive disorder as defined by Diagnostic and Statistical Manual for Mental Disorders IV (DSMIV).

The PHQ-2 inquires about the frequency of depressed mood and anhedonia over the past 2 weeks, scoring each as 0 ("not at all") to 3 ("nearly every day")[2].The recommended cutpoint for depression screening is a score of 3 or greater. It also provides a measure of severity, increasing from 0 to 6.

The PSQ2 is a simple and quick instrument conceived for busy clinical settings or as part of comprehensive health questionnaires.The operating characteristics of this ultra-brief measure, its construct and its criterion validity make the PSQ2 an attractive instrument for depression screening[2].

Patients with migraine are more likely to develop depression than those without migraine. Comorbid depression in patients with migraine may have important clinical implications.
In a busy clinical setting, psychiatric interviews take a long time to conduct. Therefore, the application of the PHQ-2 (and PHQ-9) could lead to a better recognition of depression in patients with migraine[3].

1. Spitzer RL, Kroenke K, Williams JB. Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study. Primary Care Evaluation of Mental Disorders. Patient Health Questionnaire. JAMA. 1999 Nov 10;282(18):1737-44. doi: 10.1001/jama.282.18.1737. PMID: 10568646.
2. Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. Med Care. 2003 Nov;41(11):1284-92. doi: 10.1097/01.MLR.0000093487.78664.3C. PMID: 14583691.
3. Seo JG, Park SP. Validation of the Patient Health Questionnaire-9 (PHQ-9) and PHQ-2 in patients with migraine. The Journal of Headache and Pain (2015) 16:65

PHQ-2
Patient Health Questionnaire

PATIENT HEALTH QUESTIONNAIRE-2 TOOL

Over the past two weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	○ 0	○ 1	○ 2	○ 3
2. Feeling down, depressed or hopeless	○ 0	○ 1	○ 2	○ 3
Score		+	+	+
Total score			=	

GAD-7

Generalized Anxiety Disorder-7 questionnaire

The **Generalized Anxiety Disorder-7 questionnaire (GAD-7)** was developed in the USA as a valuable screening tool for detecting GAD in primary care patients[1].
Given the popularity of the PHQ-9 (Patient Health Questionnaire-9) for assessing and monitoring depression severity, a new 7-item anxiety scale using a response set similar to the PHQ-9 was initially developed by the same authors to diagnose generalized anxiety disorder[1].

The GAD-7 consists of a self-report questionnaire that allows for the rapid detection of Generalized Anxiety Disorder. Subjects are asked if they were bothered by anxiety related problems over the past two weeks by answering seven items on a 4-point scale. The total scores range from 0 to 21. At a cutoff score of 9, the GAD-7 had a sensitivity of 89 % and a specificity of 82 % for detecting GAD compared with a structured psychiatric interview[1].

The GAD-7 and its brief version GAD-2 are simple screening instruments for detecting Generalized Anxiety Disorder in patients with migraine. The timely identification of anxiety in patients with migraine is important, as is proper management after diagnosis[2].

1. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006 May 22;166(10):1092-7. doi: 10.1001/archinte.166.10.1092. PMID: 16717171.
2. Seo JG, Park SP. Validation of the Generalized Anxiety Disorder-7 (GAD-7) and GAD-2 in patients with migraine. J Headache Pain. 2015;16:97. doi: 10.1186/s10194-015-0583-8. Epub 2015 Nov 23. PMID: 26596588; PMCID: PMC4656257.

GAD-7

Generalized Anxiety Disorder-7 questionnaire

Use "X" to indicate your answer

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	○ 0	○ 1	○ 2	○ 3
2. Not being able to stop or control worrying	○ 0	○ 1	○ 2	○ 3
3. Worrying too much about different things	○ 0	○ 1	○ 2	○ 3
4. Trouble relaxing	○ 0	○ 1	○ 2	○ 3
5. Being so restless that it is hard to sit still	○ 0	○ 1	○ 2	○ 3
6. Becoming easily annoyed or irritable	○ 0	○ 1	○ 2	○ 3
7. Feeling afraid as if something awful might happen	○ 0	○ 1	○ 2	○ 3
For office coding		+	+	+
Total score				=

MEASURES TO ASSESS TREATMENT EFFECT AND GUIDE OUTCOMES IMPROVEMENT

mTOQ-6

Migraine Treatment Optimization Questionnaire

The **mTOQ** is a validated, self administered questionnaire that assesses the efficacy of current acute treatment and is demonstrated to measure an autonomous outcome domain related to, but distinct from, functioning and health-related quality of life over a 4-week period[1].The original validation work was conducted on the 19-item mTOQ using dichotomous yes/no response options[1]. The ordinal 6-item version was included in the AMPP Study survey in 2006 and 2007. Additional validation work has been done on this version of the questionnaire[2].

The 6 items version (mTOQ-6) is a Likert-type, self reporting questionnaire. The items assess the domains of functioning, rapid relief, consistency, recurrence, and side effects[3], with responses ranging from "Never" to "Half The Time Or More" with the following response scores: Never=1, Rarely=2, Less Than Half The Time=3, Half The Time Or More=4.
The dichotomous response options used in the 19-items version were expanded so that respondents were asked to rate the frequency of each item producing a range of scores from 1 to 24[3].

This tool represents a useful clinical instrument to measure acute treatment efficacy, tolerability and impact on quality of life.

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mTOQ-6

migraine Treatment Optimization Questionnaire

PLEASE ANSWER THE FOLLOWING QUESTIONS
about the medication(s) that you currently use to treat headaches

1. Are you able to quickly return to your normal activities (i.e., work, family, leisure, social activities) after taking your migraine medication?

Never (1)	Rarely (2)	Less than half the time (3)	Half the time or more (4)

2. After taking your migraine medication, are you pain free within 2 hours for most attacks?

Never (1)	Rarely (2)	Less than half the time (3)	Half the time or more (4)

3. Does one dose of your migraine medication usually relieve your headache and keep it away for at least 24 hours?

Never (1)	Rarely (2)	Less than half the time (3)	Half the time or more (4)

4. Is your migraine medication well tolerated?

Never (1)	Rarely (2)	Less than half the time (3)	Half the time or more (4)

5. Are you comfortable enough with your migraine medication to be able to plan your daily activities?

Never (1)	Rarely (2)	Less than half the time (3)	Half the time or more (4)

6. After taking your migraine medication, do you feel in control of your migraines enough so that you feel there will be no disruption to your daily activities?

Never (1)	Rarely (2)	Less than half the time (3)	Half the time or more (4)

OTHER MIGRAINE CLINICAL ASSESSMENT SCALES

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MIGRAINE ASSESSMENT SCALES: USAGE DISCLAIMER

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4-VRS

4 points Verbal Rating Scale

The **Verbal Rating Scale (VRS)**[2] consists of a list of adjectives describing different levels of pain intensity. It is self administered.
Patients are asked to select the adjective that best represents their pain from

no pain = 0
to **extremely intense pain or unbearable pain = 4**.

The gradations of pain intensity that may be experienced between extremes are defined in ranks, as:

mild pain = 1
moderate pain = 2
severe pain = 3

VRS assumes equal intervals between the ranks, and this is a limit as the interval between no pain and mild pain may be much smaller than that between moderate pain and severe pain.
The VRS is easy to administer on paper or verbally, and to understand, but it is not very sensitive to change because it is composed of few data points.

This scale is a good and simple clinical tool and it is used to measure pain in migraine studies[1].

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HIT-6

Headache Impact Test-6 items

The Headache Impact Test-6 items **HIT-6** is a brief measure of headache impact that is psychometrically sound and clinically relevant[1].
This self-administered questionnaire proved to be reliable and valid for group-level comparisons, patient-level screening, and responsive to changes in headache impact.

The starting point for selecting the HIT-6 items was the 54 items in the HIT item pool previously analysed by Items Response Theory (IRT) methods. Using data from the National Survey of Headache Impact (NSHI) the best candidate items were evaluated based on IRT information functions and content validity (in relation to widely used surveys and clinician judgment)[1].
The HIT-6 items were shown to cover a substantial range of headache impact as defined by a much larger pool of items and include content areas found in most widely used tools for measuring headache impact. Modifications made to HIT-6 items resulted in an instrument that was more easily translated into other languages[1] (172 so far).

The HIT-6 has questions covering the following **issues**: limitations in daily activities, needing to lie down during headaches, feeling tired, being irritated by headaches, difficulty concentrating, and the experience of pain. The questions ask about the frequency (how often) of the problems listed[2].
Each of the HIT-6 item is rated as follows: never (6 points), rarely (8 points), sometimes (10 points), very often (11 points), and always (13 points)[2].
The final score is obtained from a simple summation of the six items ranging between 36 and 78, with larger scores reflecting a more significant impact[2].

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SF-36 and SF-12

Short Form 36 and 12 items

A **36-item short-form (SF-36)** was constructed to survey health status in the Medical Outcomes Study (MOS), an observational study of adult patients with chronic conditions. The SF-36 was designed for use in clinical practice and research, health policy evaluations, and general population surveys. The SF-36 includes one multi-item scale that assesses **eight health concepts**: 1) limitations in physical activities because of health problems; 2) limitations in social activities because of physical or emotional problems; 3) limitations in usual role activities because of physical health problems; 4) bodily pain; 5) general mental health (psychological distress and well-being); 6) limitations in usual role activities because of emotional problems; 7) vitality (energy and fatigue); and 8) general health perceptions[1]. Scores for each domain range from 0 to 100, with a higher score defining a more favorable health state.
The SF-36 has been widely translated in 213 languages.

Although the SF-36 health survey has proved to be useful for a variety of purposes, it is too long for inclusion in some large-scale health measurement and monitoring efforts.(2) That is why a shorter form was developed and validated: **SF-12**.
This questionnaire is composed by 12 items to reduce the length sufficient to print the form on one to two questionnaire pages and sufficient for self-administration in 2 minutes or less[2].
It assesses the **same eight health domains** as the SF-36 with one or two questions per domain. There are 205 validated translations to date.
The SF-12 physical and mental component summary scales are scored using norm-based methods. Whereas simple equal-interval (linear) scoring has proven satisfactory for all but two of the SF-36 questionnaire items, more complicated scoring yielded significant gains in reproducibility of the SF-12. The reason is that the information value for each questionnaire item is crucial when there are many fewer items[3].

In **choosing between these two forms**, it is important to consider that the SF-36 defines more levels of health and better represents the content of health measures than does the SF-12. Consequently, SF-36 summary measures, particularly the eight-scale SF-36 profile, yield more reliable estimates of individual levels of health, giving the SF-36 a decided advantage over the SF-12 in smaller studies. Therefore, the choice of the SF-12 over the SF-36 is most justified in studies with large sample sizes and in studies focusing on patient-based assessments of physical and mental health[2].

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MSQ 2.1

Migraine Specific Quality of Life Questionnaire version 2.1

The **Migraine-Specific Quality of Life Questionnaire (MSQ)** is a disease-specific, quality-of-life instrument that has been developed, tested, and revised[1].
The MSQ version 2.1 is composed by 14 items that measure the impact of migraine on quality of life[2].

The **14-item** MSQ is designed to measure how migraines affect and/or limit daily functioning across three domains:

Role Restrictive: 7 items (family, leisure, activity, work, contract, tired, energy) assessing how migraines limit one's daily social and work-related activities;
Role Preventive: 4 items (cancel, help, stop, social) assessing how migraines prevent these activities);
Emotional Functioning: 3 items (frustration, burden, afraid) assessing the emotions associated with migraines[2].

Patients respond to items using a 6-point scale: "none of the time", "a little bit of the time", "some of the time", "a good bit of the time", "most of the time", and "all of the time", which are assigned scores of 1 to 6, respectively. Raw dimension scores are computed as a sum of item responses and rescaled from a 0 to 100 scale such that higher scores indicate better quality of life[2].

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24hrMQoLQ

24-Hour Migraine Quality of Life Questionnaire

The **24-Hour Migraine Quality of Life Questionnaire (24-Hr MQoLQ)** is a reliable, valid, self-administered measure specifically developed to capture the health-related quality of life (HRQoL) of patients with migraine within 24 hours of taking migraine medication[1,2].

The instrument was developed to reflect areas of health and functioning important to adults with migraine, reflect areas of health and functioning identified through statistical modeling, and to be responsive to change in HRQoL in the 24-hour period following migraine onset[2].

The self-administered 24-hour MQoLQ consists of 15 items across five domains. There are three items within each domain:
Work functioning domain: ability to do normal everyday work, ability to operate machinery or a motor vehicle, and ability to stay alert.
Social functioning domain: interactions with people who are close to you, interactions with other people, and ability to enjoylife.
Energy/vitality domain: energy level, ability to have a good night's sleep, and mood.
Migraine symptoms domain: have throbbing head pain, have increased sensitivity to light and/or noise, and have nausea.
Feelings/concerns domain: feel upset about having migraine headaches, feel physically uncomfortable, and feel concern that your migraine medication wouldn't relieve your migraine headache symptoms.
Response options for each of the items are on a 7-point scale where 1 indicates maximum impairment of quality of life and 7 indicates no impairment. Each domain has a maximum score of 21 and a minimum score of 3[2].

The MqoLQ should not be used as an instrument to assess QoL in between headache episodes, nor to provide a global measure of QoL in subjects with migraine headache[2].

Supportive evidence for the content validity of the 24-Hr MQoLQ ePRO (electronic Patient Reported Outcome) in the population of patients with migraine has also been provided[3].

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HURT

Headache Under-Response to Treatment

The **HURT** is an 8-item self-administered questionnaire which addresses headache frequency, disability, medication use and effect, patients' perceptions of headache "control" and their understanding of their diagnoses[2]. **It provides an outcome measure coupled with guidance to improve outcome.**

The HURT is meant to be used:

1. In both primary and specialist care;
2. Across the range of headache disorders of public-health importance;
3. Across countries and cultures, despite wide variation in resources, services and expectations[2].

The current version of HURT consists of eight questions to be administered during the course of intervention. The first three questions (HURT-3) relate to frequency of and disability caused by the headache disorder(s) being treated, and the last five (HURT-5) to different aspects of management (medication use and its effects, perception of headache 'control', and understanding of diagnosis). In analysing clinical outcome, the responses are scored according to the four gradations indicating whether change is needed in management; in HURT, these are colour-coded: white (good headache control, no action needed), light grey, medium grey and dark grey (increasingly disabling and inadequately treated headache; action required). The first four questions establish frequency of all headaches and of disabling headaches under current treatment; ticks towards the right suggest increasing need for treatment review. The last four questions suggest how current management might be improved.

HURT might be used at baseline, but this is not its purpose. Responses are graded according to whether they are indicative of change needed in management[1]. The HURT should be used several times during the course of treatment, not only at baseline and discharge. The questionnaire may help patients understand that management of their headache proceeds along many fronts, not only seeking a reduction in headache days[1].

Psychometric evaluation revealed a two-factor model (headache frequency, disability and medication use; and medication efficacy and headache control), with scale properties apparently stable across disorders and correlating well and in the expected directions with external validators[1]. In European specialist care, it showed utility as an outcome measure across headache disorders. In Saudi Arabian primary care, HURT (translated into Arabic) was reliable and responsive to clinical change[2].

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please contact: https://rdcu.be/cNjMU

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HARDSHIP

Headache-Attributed Restriction, Disability, Social Handicap and Impaired Participation

The **Headache-Attributed Restriction, Disability, Social Handicap and Impaired Participation** (HARDSHIP) questionnaire is a structured questionnaire which may be administered by medical or (more usually) trained lay interviewers.
HARDSHIP already has demonstrated validity and acceptability in multiple languages and cultures[2].

The Global Campaign against Headache required the developement of a survey instrument with proven cross-cultural validity to improve and standardize methods in use for cross-sectional studies. The HARDSHIP represents an answer to this need[2].

The 101 questions are arranged in a modular design: separate question sets cover demographic characteristics, screen for caseness (headache disorder present or not), diagnose headache type and address each of the several quantifiable components of burden. Headache occurring on ≥15 days/month, including MOH (Medication Overuse Headache), is separated from episodic headache. Diagnostic questions based on the criteria of the International Classification of Headache Disorders, 3rd edition beta version (ICHD-3 beta)[1], and enquiries into burden are directed at the headache that is subjectively the most bothersome.
Responses to the diagnostic questions are transformed into diagnoses algorithmically: diagnoses are not made by the interviewer(s).

Separate modules (each of which may be included or not according to study purpose, time constraints, resources available and cultural appropriateness) cover the following aspects of headache-attributed burden: symptom burden; health-care utilization; disability and productive time losses; impact on education, career and earnings; perception of control; interictal burden; overall individual burden (as willingness to pay for treatment); effects on relationships, love life and family dynamics; effects on others, including household partner and children; quality of life; wellbeing; obesity as a comorbidity[2].

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please contact: https://rdcu.be/cNjMi

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