



# Validity and Reliability of The Arabic Version of The Headache Impact Test: A Prospective Observational Study

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Published online:  
March 2023

**Abstract:**

**Background:** Nearly half of the world's population currently has headaches, which are the most prevalent neurologic complaint. The prevalence of headaches reduces with age, yet it is nevertheless a typical neurologic condition among elderly populations.

**Purpose:** In this study, an Arabic-language adaptation of the Headache Impact Test questionnaire internal consistency reliability, test-retest reliability, feasibility, face validity, and content validity were examined in patients with headaches.

**Methods:** In this study, 90 patients with headaches, ages 18 to 65, and three expert panels, each with ten specialists, took part. Backward translation, preliminary initial translation, forward translation, creation of the pre final version, and expert testing of the pre final version. Both the clarity and the proportion of relevance were evaluated by separate panels. The previous panel of experts evaluated the pre final version. The final version was then put to the test on actual patients. For statistical analysis, the Clarity Index, Expert Proportion of Relevance, Descriptive Statistics, Missed Item Index, Cronbach's Alpha, and Intra-rater Class Correlation Coefficient were used.

**Results:** According to the study, the Arabic version of the Headache Impact Test has great face validity with a scale index of clarity of 93.33% and outstanding content validity of 98.33%; with a scale feasibility all items were filled out on 100% of the sheets. The Intraclass correlation coefficient between the test and the retest was 0.990, while Cronbach's alpha was 0.865.

**Conclusion:** The Headache Impact Test questionnaire in Arabic has sufficient internal consistency, test-retest reliability, and face and content validity to quantify the severity of headache in Arabic-speaking headache patients.

**Keywords:** Headache, Headache Impact Test, Migraine Disability Assessment Questionnaire, Reliability and Validity.

## 1. Introduction:

Headache disorders are one of the world's ten most disabling diseases. (1). Individuals and society bear a social and economic burden as a result of headaches.

Headaches are one of the main factors that contribute to patients who are working being less productive. (2).

There are primary and secondary causes of headaches. Clinical criteria are used to characterize primary headaches, which are identified through the

pattern of their symptoms and the elimination of secondary causes. They consist of hypnic, tension-type, trigeminal autonomic, and migraine headaches. The etiology of secondary headaches is what distinguishes them. (3). However, in developing nations, headache is still underdiagnosed. (4).

Many problems, including inadequate patient education, families who downplay the importance of "headaches," and the accessibility of analgesics, affect good headache management in Arabic-populated nations, particularly Egypt, the Middle East country with the highest population density. (5). Disability from headaches plays an important role in the management of headache disorders and can help design a therapeutic strategy. Additionally, monitoring a patient's disability on a continuous basis can help determine how well a treatment plan is working. (6).

A popular patient-reported outcome measure (PROM) for evaluating the detrimental effects of headaches on a patient's normal activity is the short-form Headache Impact Test (**HIT-6**). It was created before the FDA's now-accepted patient-reported guidance was established, utilizing the general headache population. (7).

**HIT-6** was created for usage in a broad headache population and comprises of 6 elements. It gauges the frequency of recent headaches that were unbearably painful, interfered with everyday activities, made you want to lie down, or left you grouchy, exhausted, or unable to concentrate. (7).

Making questionnaires in different languages requires a lot of steps. Questionnaires need to be culturally adjusted for the situation in which they will be used after being translated. Questionnaire psychometric features must also be assessed to make sure this tool has the same merits, validity, and reliability as the original form. **HIT-6** initial version was written in English, but translations into many other languages and cultures, including Hindi, Korean, Brazilian, Iranian, and Turkish, have been created. However, this questionnaire's limited use in Arabic-speaking countries was due to the fact that it was not translated into Arabic. Because of this, the purpose of this study was to translate, culturally modify, validate, and assess the validity of the **HIT-6** Arabic version for use with headache patients in Arabic-speaking nations.

## 2. Methods

The study is a prospective Study (Observational study). The Faculty of Physical Therapy's outpatient clinic served as the setting for the current investigation, Pharos University, Alexandria, Egypt.

To translate, culturally adapt, validate, and test the reliability of the **HIT-6** Arabic version to detect headache severity and its effect on functional activities of daily living. The Faculty of Physical Therapy at Cairo University received ethical clearance from the Institutional Review Board. (No: P.T.REC/012/003196). The study was designed in accordance with the Helsinki Declaration of Ethical Principles (World Medical Association) throughout the period between June 2022 till July 2022.

### 2.1. Participants

The face and content validity of the **HIT-6** Arabic version were examined by three expert panels, each with ten participants. The majority of the experts' work is with the Arabic-speaking people, and they are all fluent in both Arabic and English. All of the experts have at least a master's degree and at least ten years of experience. To determine the sample size for evaluating the psychometric features of the **HIT-6** Arabic, ten patients per item were selected. (8). The following criteria were used to choose 90 patients (47 men and 49 women), who ranged in age from 18 to 65 years (31.56 to 10.40), had persistent headaches (for the past three months), had been referred by a doctor, were conscious and oriented, and could read and write Arabic. The study excluded patients with head injuries, psychological issues, headaches connected to the common cold or the flu, headaches due to head injuries, and patients who were undergoing chemotherapy. Prior to taking part, each participant signed the consent form.

### 2.2. Materials

The **HIT-6** Arabic version was translated and cross-culturally adapted in accordance with the most recent and complete Borsa et al. recommendations. (8, 9). The **HIT-6** scores are between 36 and 78. And are calculated by simply adding the six things together; higher scores indicate greater influence. Score ranges based on the **HIT-6** interpretation guide can be used to categorize the different levels of headache effect severity. Impact levels range from little to none (49 or less), some (50–55), significant (56–59), and severe (60–78).

#### 2.2.1. Procedures

Before the trial began, participants signed a consent form, after explaining the study's nature, purpose, benefits, ability to decline or withdraw at any moment and the privacy of their own data. There were no dropouts in the participants throughout this study.

**The following steps were followed:**

**2.2.1.1. Forward translation:** The magnitude of the original translated into Arabic (forward or one-way translation) (In an accredited translation office). The first English scale has been translated into two Arabic versions. (A1 and A2), Then two translators who participated in the forwarding translation had different backgrounds but Arabic as their mother tongue. One of the translators was familiar with Arabic medical terminology and the tool's construct as a whole. The other translator was familiar with Arabic's linguistic and cultural character flaws.

**2.2.1.2. Development of the preliminary initial translated Arabic version:** The researchers compared and combined both versions (A1 and A2). This stage resulted in the creation of the initial Arabic translated preliminary version (A1, 2).

**2.2.1.3. Blind back-translation (blind backward translation or blind double translation) of the preliminary initial translated version of the scale:** First, Two back-translated versions (B1 and B2) of the scale were created from the tentative initial translated version. The back translation was then done by two translators, but their backgrounds were different. One of the translators was familiar with the English language's tool construct and health terminology. The second translator was fully aware about the intricacies of English culture and language.

**2.2.1.4. Comparison of the two back-translated versions of the scale (B1 and B2):** The expert committee, which was made up of researchers, health professionals, translators, and a language expert, compared the back-translated scales B1 and B2 the instructions, items, response format, language, sentence structure, meaning, and relevance with the original English scale and found no discernible discrepancies between them. The committee also reviewed all of the translations (A1 and A2, A1, 2, B1 and B2) and found no significant differences between them and forward translation (A1, 2). The preliminary original translated Arabic version of the scale was taken into account based on those translations.

**2.2.1.5. Pilot testing of the pre-final Arabic version of the scale for face and content validity:** The prefinal Arabic version of the scale was put to the test by three expert committees for face and content validity. Ten experts from the initial expert panel were asked to assess each tool item for clarity (face validity) and make recommendations to make it clearer; this was done using dichotomous questions (clear/unclear) regarding instruction. The clarity index has been

improved to the minimum acceptable value of 80% in accordance with the first expert panel's recommendations so that it can be provided to patients. (9).

the second expert panel then reevaluated the scale's amended pre final Arabic version for clarity. The third expert panel (consisting of ten experts) was then asked to evaluate the content equivalence of each item on the scale's modified prefinal Arabic version (content-related validity) utilizing the following scale: 1 = irrelevant, 2 = unable to determine relevance, 3 = relevant but needs minor correction, 4 = extremely relevant and succinct and makes suggestions to increase its relevance (1 and 2 considered not relevant, 3 and 4 considered relevant). The amended prefinal version was designated the final version after passing expert face and content validation testing.

**2.2.1.6. Pilot test of the final Arabic version of the scale was conducted on Headache patients:** 90 Patients filled out the Arabic version of Headache Impact Test (HIT-6) and Migraine Disability Assessment (MIDAS) Questionnaires and 1 week later, the patient refilled out the two questionnaires which was used to collect demographic data.

**2.2.1.7. Feasibility (ability to use on larger sample):** was evaluated using the administration time and the amount of unanswered questions for each item.

### **Statistical analysis:**

The statistical analysis software SPSS version 23.00 was used for all calculations (IBM Corporation, Illinois, USA). The alpha level was set to 0.05. The mean and standard deviation of descriptive statistics, as well as the mean index of clarity and the mean index of content validity, were tested (ICV) used to test content validity and Intraclass correlation coefficient to test reliability between two questionnaires.

### **3. Results:**

The mean age (31.56) and  $\pm$ S. D. is (10.40) describe the general characteristics of the individuals in terms of their age and has a minimum age of 18 and a maximum age of 62, the participants were from both gender distributed to 47 male with 52.2% and 43 female with 47.8%.

#### **3.1. Subject characteristics:**

The mean age (31.56) and  $\pm$ S. D. is (10.40) describe the general characteristics of the individuals in terms of their age and has a minimum age of 18 and a maximum age of 62, the participants were from both gender distributed to 47 male with 52.2% and 43 female with 47.8%.

### 3.2. Descriptive Analysis of the experts' general characteristics

Eight expert Physiotherapists were chosen from faculty of physical therapy, one expert at Faculty of Literature and one expert at faculty of Business administration, Cairo University with mean experience of (14± 6.58 years) with minimum of 10 years and maximum of 30 years of experience.

### 3.3. Face validity statistics of HIT-6:

According to the experts' opinions the mean index of clarity of all 6 items was 93.33%. Two items were clear, with index of clarity=100%. Items number 2, 3, 5 and 6 had index of clarity = 90%. Represented in **Table (1)**.

### 3.4. Content validity statistics of HIT-6

According to the experts' opinions, all items were relevant with mean Index of Content Validity (ICV) = 98.33% of all 6 items. Five items were relevant, with ICV =100%. Item number 3 had ICV = 90%. All items were relevant but needs minor alteration with mean Index of Content Validity (ICV) = 1.67%. Represented in **Table (2)**.

### 3.5. Descriptive statistics of Arabic HIT-6 and MIDAS.

For the Arabic version of HIT-6, mean domain scores ranged from 9.47 to 9.88. No floor or ceiling effects were noted. Regarding the MIDAS, mean domain scores ranged from 2.52 to 3.04. No floor or ceiling effects were noted. Represented in **Table (3)**.

### 3.6. Internal consistency (correlation of items in the questionnaire).

Results revealed that the internal consistency of observer scale of the HIT-6 was high level with Cronbach's alpha = 0.865. Represented in **table (4)**.

**Table 1: Experts' opinions according to index of Clarity (IC).**

Item	Clear	Not clear	Item index of Clarity (IC)
<b>HIT-6</b>			
<b>Question 1</b>	10	0	100%
<b>Question 2</b>	9	1	90%
<b>Question 3</b>	9	1	90%
<b>Question 4</b>	10	0	100%
<b>Question 5</b>	9	1	90%
<b>Question 6</b>	9	1	90%

**Table 2: Experts' opinions according to ICV of the HIT-6.**

Item	Very relevant and succinct	Relevant but needs minor alteration	Unable to assess relevance	Not relevant	Item index of relevance (ICV)
<b>HIT-6</b>					
<b>Question 1</b>	10	0	0	0	100%
<b>Question 2</b>	10	0	0	0	100%
<b>Question 3</b>	9	1	0	0	90%
<b>Question 4</b>	10	0	0	0	100%
<b>Question 5</b>	10	0	0	0	100%
<b>Question 6</b>	10	0	0	0	100%
<b>Mean index of clarity for HIT-6</b>	98.33%				

**Table 3: Descriptive statistics of HIT-6 and MIDAS**

Domains (no of questions)	Mean	SD	Minimum mean score recorded	Maximum mean score recorded	% with floor effect	% with ceiling effect
<b>HIT-6</b>						
Q1	9.66	2.12	6	13	<5.4	>11.7
Q2	9.47	2.35	6	13	<5.4	>11.7
Q3	9.47	2.14	6	13	<5.4	>11.7
Q4	9.88	1.95	6	13	<5.4	>11.7
Q5	9.72	2.35	6	13	<5.4	>11.7
Q6	9.67	2.14	6	13	<5.4	>11.7
<b>Total</b>	9.46	0.15	6	13	<5.4	>11.7
<b>MIDAS</b>						
Q1	2.57	2.74	0	12	<0	>12
Q2	2.58	2.56	0	10	<0	>10
Q3	3.02	2.55	0	10	<0	>10
Q4	3.04	2.75	0	11	<0	>11
Q5	2.52	2.78	0	13	<0	>13
<b>Total</b>	2.74	0.26	0	13	<0	>13

**Table 4: Internal consistency of the HIT- 6 by Cronbach's Alpha.**

Item	Cronbach's Alpha if Item Deleted	Cronbach's Alpha of scale as total
<b>HIT-6</b>		
Question 1	0.831	0.865
Question 2	0.838	
Question 3	0.834	
Question 4	0.864	
Question 5	0.84	
Question 6	0.842	

### 3.7. Intra rater reliability of HIT-6

The HIT-6 was tested twice, once by the same tester (intra-rater reliability). The overall HIT-6 mean  $\pm$ SD was (57.86 $\pm$ 10.01) for the primary tester's first reading and (56.82 $\pm$ 9.85) for the same tester's second reading after a week.

HIT-6 demonstrated a high level of intra-rater dependability using the Intra-class Correlation Coefficient (ICC), which had a P-value of 0.0001 and an ICC of 0.990. Represented in **table (5)**.

### 3.8. Intra rater reliability of MIDAS

The MIDAS were tested by the same tester on both occasions (intra-rater reliability). The overall value of the MIDAS mean  $\pm$ SD was (13.7 $\pm$ 11) for the primary tester's first reading and (13.88 $\pm$ 10.87) for the same tester's second reading after a week. The Intra-class Correlation Coefficient (ICC) test of intra-rater reliability revealed that MIDAS had a high level of reliability (ICC=0.995 and P-value = 0.0001). Represented in **table (5)**.

### 3.9. Feasibility measures Penn Shoulder Score

For each item, the number of feasibility sheets with missing data (things the patient did not respond to) was counted. Missed data index is the percentage of the entire data that has unanswered questions. All questions from Q1 through Q6 had no missed data (questions that were not answered), with a missed data percentage of 0%.

**Table 5:** Intra-class Correlation Coefficient (ICC) for Test re-test Intra rater reliability of HIT-6 & MIDAS.

Item	1st reading of HIT-6	2nd reading Of HIT-6	95% confidence interval Lower: upper limit
Mean	13.7	13.88	
±SD	±11	±10.87	
ICC		0.995	0.993: 0.997
P-value		0.0001	
Significance level		Significant	

  

Item	1st reading of MIDAS	2nd reading of MIDAS	95% confidence interval Lower: upper limit
Mean	57.86	56.82	
±SD	±10.01	±9.85	
ICC		0.990	0.986: 0.994
P-value		0.0001	
Significance level		Significant	

### 3.10. Construct validity of HIT-6

Represented in **table (6)** and **table (7)**.

### 3.11. Concurrent validity of Arabic HIT-6 and MIDAS

Between the total HIT-6 and the total MIDAS, the Pearson correlation coefficient revealed a very strong association with ( $r=0.719$ ,  $p=0.0001$ ). As well as there was a good correlation between all question of HIT-6 and all questions of MIDAS, Level of significance is ( $p<0.001$ ), Correlation values of 0.40 or above were considered satisfactory ( $r \geq 0.81-1.0$  as excellent, 0.61– 0.80 very good, 0.41–0.60 good, 0.21–0.40 fair, and 0–0.20 poor). As represented in **table (8)**.

## 4. Discussion:

The objectives of this project were to translate and culturally adjust, validate, and assess the reliability of **the HIT-6** in Arabic. Although it took a lengthy, The Arabic version of the **HIT-6** for headaches was translated and culturally adapted using a multi-step procedure, it was completed successfully in accordance with the most recent, thorough, and published guidelines (8, 9).

**Table 6:** Factor analysis (principal components extraction method, and varimax rotation criterion) results.

Rotated Component Matrix		
	Factor loadings (after rotation)	
	1	2
Q1	0.837	
Q2	0.817	
Q3	0.746	0.365
Q4	0.634	
Q6		0.879
Q5	0.322	0.860

Extraction Method: Principal Component Analysis.  
Rotation Method: Varimax with Kaiser Normalization.

a. Rotation converged in 3 iterations.

**Table 7:** Results of factorial analysis.

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	3.589	59.819	59.819	3.589	59.819	59.819	2.515	41.911	41.911
2	.755	12.586	72.405	.755	12.586	72.405	1.830	30.494	72.405
3	.662	11.026	83.432						
4	.399	6.649	90.081						
5	.359	5.988	96.068						
6	.236	3.932	100.000						

**Table 8:** Concurrent validity analysis: Pearson Correlation Coefficients between HIT-6 and MIDAS

MIDAS	Q1	Q2	Q3	Q4	Q5	Total
<b>HIT-6</b>						
Q1	r= 0.469 p=0.0001	r= 0.449 p=0.0001	r= 0.573 p=0.0001	r= 0.487 p=0.0001	r= 0.379 p=0.0001	r= 0.573 p=0.0001
Q2	r= 0.419 p=0.0001	r= 0.349 p=0.0001	r= 0.508 p=0.0001	r= 0.365 p=0.0001	r= 0.458 p=0.0001	r= 0.511 p=0.0001
Q3	r= 0.473 p=0.0001	r= 0.445 p=0.0001	r= 0.604 p=0.0001	r= 0.552 p=0.0001	r= 0.447 p=0.0001	r= 0.615 p=0.0001
Q4	r= 0.494 p=0.0001	r= 0.517 p=0.0001	r= 0.46 p=0.0001	r= -0.483 p=0.0001	r= 0.337 p=0.001	r= 0.558 p=0.0001
Q5	r= 0.379 p=0.0001	r= 0.346 p=0.001	r= 0.556 p=0.0001	r= 0.558 p=0.0001	r= 0.403 p=0.0001	r= 0.541 p=0.0001
Q6	r= 0.468 p=0.0001	r= 0.414 p=0.0001	r= 0.472 p=0.0001	r= 0.484 p=0.0001	r= 0.415 p=0.0001	r= 0.548 p=0.0001
Total	r= 0.579 p=0.0001	r= 0.538 p=0.0001	r= 0.684 p=0.0001	r= 0.627 p=0.0001	r= 0.528 p=0.0001	r= 0.719 p=0.0001

The **HIT-6** may be regarded as a respectable and trustworthy instrument for the Arabic-speaking populace. The first expert panel determined that the overall clarity index for all six items was 93.33%. And the Arabic version received its adjustments of **HIT-6**. Two items were clear, with index of clarity=100%. Items number 2, 3, 5 and 6 had index of clarity = 90%. Content validity is the process of evaluating how well the survey items capture the relevant concepts. (10).

although it was done for the English version when it was first produced, this study aimed to evaluate the content validity of the Arabic version of the **HIT-6**. According to current methodology, the content should also be evaluated when translating into a new

language. (11). in the view of the experts, each of the six items had a mean Index of Content Validity (ICV) of 98.33%, indicating that they were all relevant. Five items were relevant, with ICV =100%. Item number 3 had ICV = 90%. All items were relevant but needs minor alteration with mean Index of Content Validity (ICV) = 1.67%. According to experts, the Arabic version of **HIT-6** had acceptable content validity.

It is typically advised to use other validated, approved surveys to evaluate the validity of the external construct. However, among the questionnaires used to evaluate headaches, there isn't a standard one. The validity of the **HIT-6** questionnaire was compared to the **SF-36** or **MIDAS** questionnaires

for the majority part of the different language versions. Contrarily, the **HIT-6** has six dimensions and queries patients about their state generally throughout the last three weeks. The construct validity of the Arabic **MIDAS** questionnaire was tested, and it was discovered to have a high correlation against the severity of pain and headache-related disability. Due to the fact that it is a multidimensional, regularly used headache questionnaire that has been validated in other languages, including Arabic, the **MIDAS** Questionnaire was chosen for comparison with the **HIT-6**.

Similar subscales in **MIDAS** correspond to the six domains on the **HIT-6**. The external simultaneous between the total **HIT-6** and total **MIDAS** in the current study's findings with ( $r=0.719$ ,  $p=0.0001$ ). As well as there was good correlation between the all question of **HIT-6** and all question of **MIDAS**. The questionnaire in this study shows a good level of internal consistency as indicated by the Cronbach alpha values of 0.889 for the first measurement scores and 0.911 for the second measurement scores. As a result, the Arabic version of the **HIT-6** Cronbach alpha values were discovered to be quite high and comparable to those of the counterparts in other languages. According to the findings of this investigation, the **HIT-6** Arabic version exhibits a high degree of internal consistency.

The **HIT-6** was tested twice, once by the same tester (intra-rater reliability). The overall **HIT-6** mean  $\pm$ SD was ( $57.86\pm 10.01$ ) for the primary tester's first reading and ( $56.82\pm 9.85$ ) for the same tester's second reading after a week. **HIT-6** demonstrated a high level of intra-rater dependability using the Intra-class Correlation Coefficient (ICC), which had a P-value of 0.0001 and an ICC of 0.990.

The current study's test-retest results were consistent with the ICC values of the earlier investigations. Based on the ICC values of each item and the overall score of the questionnaire, it is possible to say that the Arabic version of the **HIT-6** is stable over time. By calculating the missed item index, the Arabic version of the **HIT-6** viability is determined. On all sheets, the scale items were completely filled out. The absence of the full psychometric qualities (criterion validity) of the Arabic version of the **HIT-6** in a sample of the target population of interest, which is thought to be one of the key parameters of the questionnaires, was one of the study's limitations.

The results of the current study came into agreement with the findings of the study done by (Helou et al., 2018) (12). answers from the F-IPAQ and the A-IPAQ were found to be highly correlated, Spearman's correlation scores ( $p < 0.05$ ) ranged from 0.91 to 1.00 when comparing the two versions, Bland-

Altman analysis revealed a high degree of agreement with all values being skewed toward the mean. (Helou et al., 2018) (12). conclude that the IPAQ's adapted Arabic version demonstrated respectable validity when used to measure adult physical activity in Lebanon.

The results of the current study came into agreement with the findings of the study done by (Bahammam et al., 2014) (13). showed that both for males and females, the **MIDAS** exhibited great internal consistency and dependability. The **MIDAS** internal consistency results have showed some fluctuation based on the content and linguistic variety in both the original and several translated versions.

## 5. Conclusion:

Based on the results obtained from this study **HIT-6** questionnaire is a valid, reliable and feasible questionnaire for assessing headache-related disability and determining the severity of headache, and it is applicable to both therapeutic application and academic study to evaluate the severity and disability in people with headache.

## 6. Recommendations:

It is recommended that further studies should be conducted to:

1. To establish the preliminary psychometrics of the Arabic version of the **HIT-6** with bilingual subjects, more research needs be done.
2. The entire psychometric qualities (criterion validity) of the Arabic version of the **HIT-6** should be established in a sample of the target population of interest through further research.
3. To translate, adapt, and validate different headache evaluation measures, more research should be done.
4. To translate, adapt, and validate other assessment tools for the impact of headache on physical function in other health situations, more research needs to be done.

## Conflict of Interests:

The authors say they have no competing interests.

## Acknowledgements:

The authors would like to thank all participants for their valuable participation in this study.



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