Received: 24 July 2020 | Accepted: 6 October 2020

DOI: 10.1111/head.14049

RESEARCH SUBMISSION

# Measurement properties of the Headache Impact Test (HIT-6™ Brazil) in primary and secondary headaches

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**Funding information**
Coordenação de Aperfeiçoamento de Pessoal de Nível Superior, Grant/Award Number: 001

## Abstract

**Background:** The Headache Impact Test-6™ is a widely recommended questionnaire to evaluate the impact of headaches. However, its measurement properties were never evaluated in both primary and secondary headaches, and the Brazilian Portuguese version of the questionnaire was never assessed at all.

**Objective:** To assess the reliability, and structural and construct validity of the Headache Impact Test-Brazil™ in patients with primary and secondary headaches.

**Methods:** In total, 132 patients with primary and secondary headaches were included, screened from a headache tertiary clinic. They completed the Headache Impact Test-Brazil™ questionnaire, the 12-Item Short-Form Survey (SF-12), and the Headache Disability Inventory—Brazil. Pearson's correlation analysis was performed among the three questionnaires for validity assessment. One to three weeks after the first application, the Headache Impact Test-Brazil™ was answered again by 67 patients for reliability assessment.

**Results:** The validity sample consisted of 86/132 (65.1%) patients with primary and 46/132 (34.9%) secondary headaches, with mean age of 39.6 (SD: 12.7) years. The reliability sample consisted of 39/67 (58.2%) patients with primary and 28/67 (41.8%) secondary headaches, with mean age of 36.8 (12.5) years. According to the confirmatory factor analysis, the Headache Impact Test-Brazil™ consists of single factor. Its internal consistency was $\alpha$ = 0.97 and the question number 3 had the lowest factor loading (0.31). The Headache Impact Test-Brazil™ exhibited a moderate correlation with both the SF-12 questionnaire ($r$ = −0.64, 95%CI: −0.72 to −0.52, $p$ = 0.001) and the Headache Disability Inventory-Brazil ($r$ = 0.67, 95%CI: 0.56 to 0.75, $p$ = 0.001). The correlation between the Headache Impact Test-Brazil™ and the headache frequency was weak ($r$ = 0.22, 95%CI: 0.04 to 0.39, $p$ = 0.001), and with the headache intensity, moderate ($r$ = 0.44, 95%CI: 0.23 to 0.62, $p$ = 0.001). The Headache Impact

**Abbreviations:** CFI, comparative adjustment index; CMIN, chi-square; COSMIN, Consensus-based Standards for the Selection of Health Status Measurement Instruments; GFI, fit quality index; HDI-Brazil, Brazilian version of Headache Disability Inventory; HIT-6™, Headache Impact Test; ICC, intraclass correlation coefficient; MIDAS, Migraine Disability Assessment; NVS, numeric visual scale; RMSEA, mean square root of approach error; SDC, smallest detectable change; SEM, standard error of measurement; SF-8, 8-Item Short-Form Survey; SF-12, 12-Item Short-Form Survey.

Test-Brazil™ test–retest reliability was excellent (ICC = 0.95) with a standard error of 1.58 and a smallest detectable change of 4.38 points.

**Conclusion:** The Headache Impact Test-6-Brazil™ can be considered as a valid and reliable tool to assess the impact of several headache types. Future studies may revise the questionnaire items to confirm its redundancy.

**KEYWORDS**
disability evaluation, headache, psychometrics, questionnaires, surveys

## INTRODUCTION

According to the Global Burden of Headache, headaches are the second most common cause of the greatest number of years lived with disability in the world.[1] Migraine by itself is considered the pre-eminent cause of disability in individuals under 50 years.[2] High disability levels are often associated with personal, professional, social, and socioeconomic burden.[1,3]

A headache evaluation considering only the frequency of pain, intensity, and duration can provide incomplete information that is not always directly correlated to the disability levels caused by the headache. Furthermore, since the most prevalent headaches are considered chronic diseases and can persist for decades, changes across the pain variables may not be observed after a treatment. For this reason, many experts recommend the evaluation of the disability and impact related to headaches.[4–6]

The Consolidated Standards of Reporting Trials[7] and also specific outcome measurement guidelines for headaches[3,4] encourage the use of measurement tools related to impact in both clinical practice and research. The use of structured questionnaires to assess disability levels can provide a more accurate evaluation and facilitate the proposal of a tailored treatment plan, according to the patient's needs. It also complements the therapeutic response assessment than allowing an interprofessional and multicentric communication. Multisite research and direct comparison with other studies across the world can then be performed.[7]

The assessment of headache impact can be performed through the Headache Impact Test questionnaire (HIT-6™, GlaxoSmithKline), which is composed of six questions addressing headache burden.[8] The HIT-6™ is widely used for headache impact assessment,[9–11] encompassing relevant questions to assess headache-related disability.[12] It has so far been translated into 27 different languages[13] and in 9 of these translated versions, its psychometric properties have been analyzed.[14] According to a Delphi study,[15] the HIT-6™ is considered as one of the most useful tools to assess effectiveness of non-pharmacological interventions for headache disorders.

However, despite already being translated and adapted to the Brazilian population, the HIT-6™ Brazil questionnaire has not until now had its measurement properties analyzed and compared to the original version. Therefore, the aim of this study was to assess the reliability, and structural and construct validity of the HIT-6™ Brazil in patients with primary and secondary headaches.

## MATERIAL AND METHODS

### Sample

This study was approved by the Local Research Ethics Committee (process number 3622/2017) and written informed consent was obtained from all patients before enrolment. Consecutive patients with primary and secondary headaches, aged between 18 and 65 years, were screened at a tertiary headache outpatient clinic in Ribeirão Preto, Brazil. Patients were included if they had at least one headache day within the last month, diagnosed by headache experts according to International Classification of Headache Disorders III.[16] Patients were excluded if they had inconclusive or concomitant headache diagnosis (i.e., medication overuse headache). Non-literate individuals were excluded for the reliability stage. In accordance with the adequate-to-very good sample size suggested by the Consensus-based Standards for the Selection of Health Status Measurement Instruments (COSMIN),[14] 132 patients were included for the validity analysis and 67 patients were included for the reliability analysis.

### Procedures

The study was performed between June 2018 and August 2019. After the patients' routine medical appointment at the headache outpatient clinic, HIT-6™ Brazil[8]—the Brazilian version of Headache Disability Inventory (HDI-Brazil)—and the 12-Item Short Form Survey (SF-12)[17] questionnaires were administered. Under the supervision of the main researcher (J.P.), the patients were instructed to complete the questionnaires in a self-administered form and to only consider their headache. Non-literate individuals answered the questionnaire through an interview process. Furthermore, demographic data, along with information related to headache diagnosis, attack frequency, intensity, and duration were collected.

We followed the COSMIN recommendations for the evaluation of measurement proprieties of the Brazilian version of the HIT-6™.[14] This approach considered the test–retest reliability and the structural and construct validity analysis. The test–retest reliability was assessed through in-person appointments within a time interval from 1 to 3 weeks between the first and second application.[14] In the two appointments, patients were asked about the frequency and intensity of headache during the last 30 days, in

order to ensure the clinical stability of the sample. The following outcomes were used as a reference for the construct validity assessment: pain intensity (numeric visual scale, NVS), headache frequency within the last month, the SF-12,[18] and the HDI-Brazil questionnaires.[19]

The SF-12[17] questionnaire contains 12 questions regarding the self-perception of quality of life. The total score ranges from 37 to 123 points, and greater scores are related to a greater quality of life.[20] This questionnaire was included since the impact of a disease has a direct consequence on the quality of life.[21] Furthermore, it has been previously used to validate impact questionnaires,[22] including the HIT-6™.[23,24]

The HDI-Brazil questionnaire measures headache disability by considering functional and emotional dimensions. It is composed of 25 questions and its total score ranges from 0 to 100 points, classifying patients from the complete absence to the maximum disability level caused by headaches.[25] Compared to the HIT-6™, the HDI-Brazil requires more time to be completed and it is not widely used.[15,25,26]

## Statistical analysis

We report the primary analysis of this data derived from a preplanned study design. Descriptive statistics including headache diagnosis, and participant's gender and education level were described as frequency and percentage. The participants' age and mean questionnaire scores were described as mean and standard deviation (SD). Furthermore, a comparison between the sample who participated in one and in both appointments was performed using a t-test or chi-square tests to evaluate the potential bias among the validity and reliability samples.

The structural validity of the HIT-6™ Brazil was performed by a confirmatory factor analysis,[27] in order to investigate if the Brazilian Portuguese version of the questionnaire also presents a single factor, as the original version. In addition, this analysis aimed to measure the factor loading of each questionnaire item, represented by the model fit analysis. Items with a factor loading <0.3 are not considered relevant for the questionnaire construct and may be excluded.[28] The model fit evaluates the correlation between the questions and suggest if the proposed model is adequate, based on the following parameters: chi-square (CMIN) values <3, *p* values >0.5, mean square root of approach error (RMSEA) <0.05, fit quality index (GFI), and comparative adjustment index (CFI) >0.95.[28]

For the construct validity analysis, the Pearson's correlation was performed between the HIT-6™ Brazil questionnaire score and headache frequency, pain intensity, total scores of the HDI-Brazil, and SF-12. Correlation values lower than 0.3 indicated weak correlation, between 0.3 and 0.7 moderate correlation, and values above 0.7 indicated strong correlations.[27] The test–retest reliability analysis was performed through the intraclass correlation coefficient (ICC) calculation. The ICC was classified as poor (<0.45), satisfactory (0.50 <ICC <0.75), and excellent (>0.75).[28] The internal consistency of the questionnaire items was analyzed through the Cronbach's $\alpha$ coefficient, and adequate values between 0.7 and 0.95 were considered. Values below 0.7 would indicate a lack of correlation between items and values above 0.95 would indicate a redundancy between items.[28] In addition, the standard error of measurement (SEM, SEM = SD × √1−ICC) and the smallest detectable change ($SDC_{individual}$, SDC = SEM × 1.96 × √2) were calculated.[28]

The confirmatory factor analysis was performed using the AMOS® software. The construct validity and reliability analysis were carried out in SPSS, version 21. There was no missing data in the dataset. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

# RESULTS

## Sample

During the data collection period, 530 patients who had appointments at the tertiary headache outpatient clinic were screened for the study. From the total sample, 398 patients were excluded due to the presence of concomitant headaches (*n* = 149), less than one headache attack per month (*n* = 84), inconclusive diagnosis (*n* = 103), and the ones who did not accept to participate in the study (*n* = 62). Therefore, 132 patients were included in the validity stage. For the reliability assessment, from the 132 patients included in the previous stage, 65 patients were excluded since they had no availability to come for the second appointment (*n* = 42) or did not accept to participate in the study (*n* = 23). Therefore, 67 patients completed the questionnaire for the second time. The patients who attended two appointments (validity *plus* reliability, *n* = 67) presented lower age (*p* = 0.01), lower headache intensity (*p* = 0.02), lower HDI-Brazil score (*p* = 0.007), and greater SF-12 (*p* = 0.005) scores in contrast to the ones who attended just one appointment (validity, *n* = 65) (Table 1).

## Structural validity

The HIT-6™ Brazil confirmatory factor analysis revealed that the questionnaire items are related to a single construct of *disability*, being considered a one-dimensional questionnaire. All questions had factor loading >0.3, represented by the fit model in Figure 1A. However, among all the HIT-6™ questions, question number 3 (*when you have a headache, how often would you like to be able to lie down to rest?*) presented the lowest factor loading (0.31). After removing the question number 3, the other five questions presented an increment of the respective factor loadings, ranging from 0.44 to 0.91 (Figure 1B).

Therefore, the model fit summary was calculated with (model 1) and without the question number 3 (model 2). The model 2 was a post hoc analysis after checking a reduced factor load for question number 3. The results demonstrated that the CMIN is better in the model 2, since it exhibited values <3. In the second model, the values of GFI

**TABLE 1** Comparison of sample and headache features of the participants who attended one (validity) or two appointments (validity *plus* reliability) in the study

| | Validity + Reliability | Validity | Statistics |
|---|---|---|---|
| Sample size | 67 | 65 | – |
| Primary headaches (%) | 40/67 (59.7%) | 48/65 (73.8%) | $x^2 = 2.97$, $p = 0.09$ |
| Secondary headaches (%) | 27/67 (40.3%) | 17/65 (26.2%) | |
| Age (years) | 36.8 (12.5) | 42.4 (12.4) | **$t = -2.5$, $p = 0.01$** |
| Sex (% women) | 50/67 (74.6%) | 44/65 (67.7%) | $x^2 = 0.77$, $p = 0.44$ |
| Frequency of headache (monthly) | 12.0 (10.7) | 15.4 (10.7) | $t = -1.8$, $p = 0.07$ |
| Headache duration (hours) | 12.8 (19.0) | 20.1 (22.3) | $t = -2.0$, $p = 0.05$ |
| Headache intensity (NVS) | 6.9 (2.4) | 7.8 (1.9) | **$t = -2.3$, $p = 0.02$** |
| HIT-6™ | 51.3 (7.1) | 53.3 (6.4) | $t = -1.7$, $p = 0.08$ |
| HDI-Brazil | 47.7 (26.5) | 60.6 (27.4) | **$t = -2.7$, $p = 0.007$** |
| SF-12 | 84.2 (16.5) | 75.9 (16.8) | **$t = -2.9$, $p = 0.005$** |
| Level of education | | | |
| Illiterate | 0/67 (0.0%) | 1/65 (1.5%) | $x^2 = 1.44$, $p = 0.69$ |
| Incomplete basic education | 19/67 (28.4%) | 18/65 (27.7%) | |
| Completed basic education | 24/67 (35.8%) | 20/65 (30.8%) | |
| University education | 24/67 (35.8%) | 26/65 (40.0%) | |

Abbreviations: HDI-Brazil, Headache Disability Inventory-Brazil; HIT-6™, Headache Impact Test-Brazil™; NVS, numeric visual scale; SF-12, 12-Item Short-Form Survey.

Values marked in bold represent significant differences.

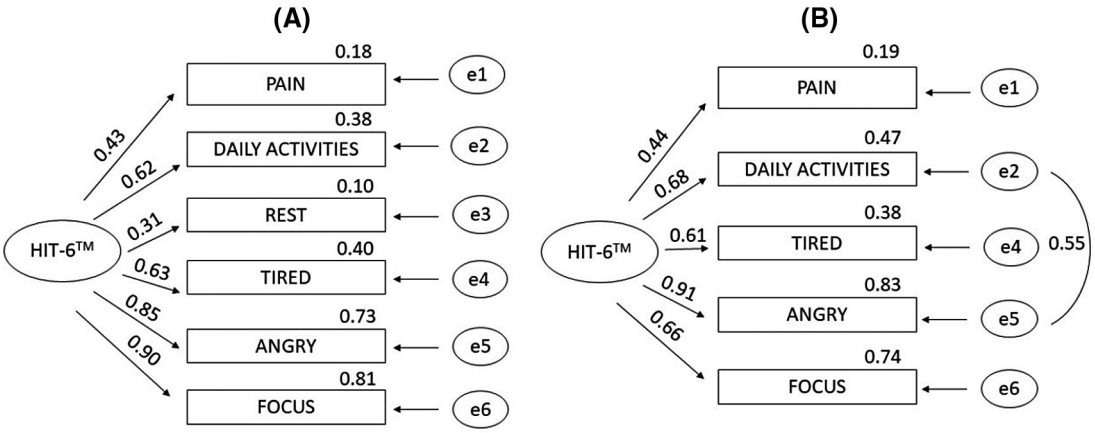


**FIGURE 1** (A) Model fit representation of the factorial load of the six questions. (B) Model fit representation of the factor loading without the question 3

and CFI are a bit higher in comparison to model 1. Furthermore, the model without the question number 3 presented an excellent RMSEA value, in contrast to a moderate one verified in the model 1. The lack of fit *p* value of model 1 was $p = 0.083$ and the model 2 is $p = 0.677$. In summary, it is possible to notice a considerably model improvement after the removal of the question number 3 (Table 2).

## Construct validity

Among the 132 patients included in this stage, 86 (65.1%) had primary and 46 (34.9%) had secondary headaches. The mean sample age was 39.6 (12.7) years and 38/132 (28.8%) patients were men. Patients with primary headaches ($n = 86$) had the following diagnosis: migraine 52/86 (60.4%), tension-type headache 17/86 (19.8%), and trigeminal autonomic headaches 17/86 (19.8%). Up to 46 patients had the following secondary headaches: headache attributed to trauma or injury to the head and/or neck 7/46 (15.2%); headache attributed to a substance or its withdrawal 14/46 (30.3%); headache attributed to infection 2/46 (4.4%); headache or facial pain attributed to disorder of the cranium, neck, eyes, ears, nose, sinuses, teeth, mouth, or other facial or cervical structure 12/46 (26.1%); headache attributed to cranial and/or cervical vascular disorder 6/46 (13.0%); headache attributed to disorder of homoeostasis

**TABLE 2** Comparison of variables in the fit model of confirmatory factor analysis with question number 3 and without question number 3 of the HIT-6™

| | CMIN | DF | CMIN/DF | GFI | CFI | RMSEA | *p* |
|---|---|---|---|---|---|---|---|
| Model 1[a] | 12.58 | 7 | 1.79 | 0.97 | 0.98 | 0.07 | 0.08 |
| Model 2[b] | 2.32 | 4 | 0.58 | 0.99 | 1.00 | 0.00 | 0.68 |

[a]With the question number 3.

**TABLE 3** Sample characteristics and questionnaires scores during the validity and reliability stages (mean and standard deviation)

| | Validity | | Reliability | |
|---|---|---|---|---|
| | Primary headaches (*n* = 88) | Secondary headaches (*n* = 44) | Primary headaches (*n* = 39) | Secondary headaches (*n* = 28) |
| Age (years) | 37.6 (11.9) | 44.6 (12.7) | 35.0 (10.6) | 43.1 (12.2) |
| Sex (% women) | 61/88 (69.3%) | 33/44 (75.0%) | 74.3 | 75.0 |
| Frequency of headache (monthly) | 12.2 (9.7) | 16.6 (12.2) | 10.7 (8.8) | 13.7 (12.2) |
| Headache duration (hours) | 17.3 (21.2) | 14.5 (20.5) | 6.8 (6.7) | 16.1 (24.5) |
| Headache intensity (NVS) | 7.6 (2.0) | 6.9 (2.6) | 7.7 (2.0) | 6.2 (2.8) |
| HDI-Brazil | 55.0 (26.8) | 52.1 (29.6) | – | – |
| SF-12 | 81.2 (16.2) | 77.9 (18.6) | – | – |
| HIT-6™[a] | 52.8 (5.8) | 51.2 (8.3) | 64.1(5.2) | 59.8 (10.5) |
| HIT-6™[b] | – | – | 64.0 (6.0) | 60.3 (10.6) |

Abbreviations: HDI-Brazil, Headache Disability Inventory-Brazil; HIT-6™, Headache Impact Test-Brazil™; NVS, numeric visual scale; SF-12, 12-Item Short-Form Survey.

[a]HIT-6™ scores of the first application in the reliability process.

[b]HIT-6™ scores of the second application in the reliability process.

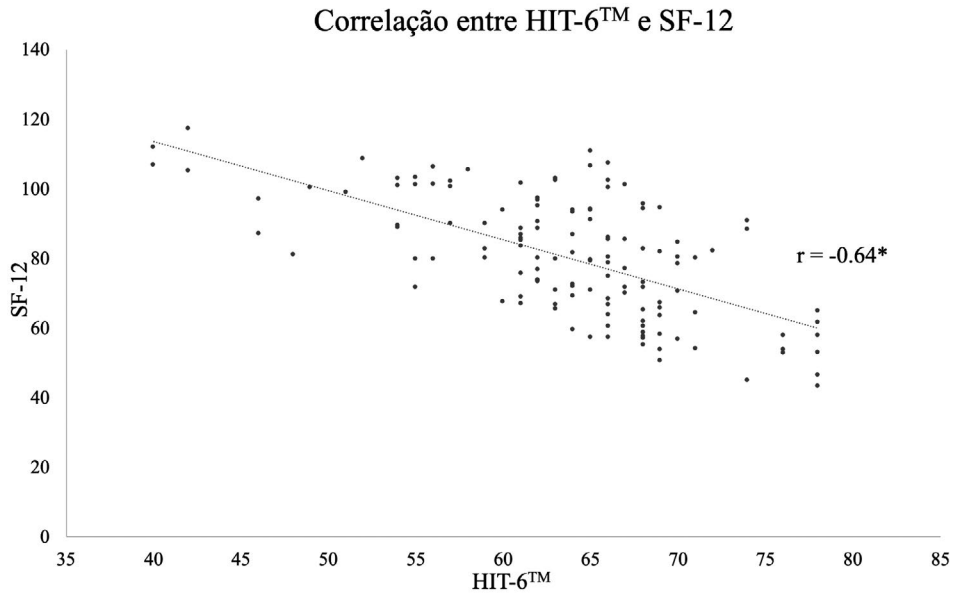


**FIGURE 2** Correlation between HIT-6™ and SF-12 total score, *$p = 0.001$

[b]Without the question number 3.

3/46 (6.6%), and headache attributed to non-vascular intracranial disorder 2/46 (4.4%).

The education level ranged from illiterate to university education: 1/132 (0.8%) was illiterate, 37/132 (28.0%) did not complete basic education, 44/132 (33.3%) completed basic education, and 50/132 (37.9%) attended university education. The mean score of each questionnaire considering the whole sample was: 63.7 (SD: 7.6) for the HIT-6™ Brazil, 79.1 (SD: 17.6) for the SF-12, and 54.0 (SD: 27.7) for

the HDI-Brazil. The sample characteristics according to the primary and secondary headaches subgroups are represented in Table 3.

The total score of the HIT-6™ Brazil questionnaire demonstrated a moderate and negative correlation with the SF-12 questionnaire ($r$ = −0.64, 95%CI: −0.72 to −0.52, $p$ = 0.001, Figure 2) and a moderate positive correlation with the HDI-Brazil ($r$ = 0.67, 95%CI: 0.56 to 0.75, $p$ = 0.001, Figure 3). The correlation between the HIT-6™ Brazil total score and the frequency of headache was positive but weak ($r$ = 0.22, 95%CI: 0.04 to 0.39, $p$ = 0.001). However, the HIT-6™ score and was positively and moderately correlated to the headache intensity ($r$ = 0.44, 95%CI: 0.23 to 0.62, $p$ = 0.001, Figure 4).

## Reliability

One to three weeks after the first evaluation, 67 patients completed the HIT-6™ Brazil again. Among the patients included in this stage, 39/67 (58.2%) had primary and 28/67 (41.8%) secondary headaches. The mean sample age was 36.8 (12.5) years and 17/67 (25.4%) patients were men. The primary headaches included were migraine 24/39 (35.8%), tension-type headache 8/39 (12.0%), and autonomic trigeminal headaches 7/39 (10.5%). The secondary headaches included were headache attributed to trauma or injury to the head and/or neck 9/28 (13.5%), headache attributed to cranial and/or cervical vascular disorder 7/28 (10.3%), headache attributed to a substance or its withdrawal 12/28 (12.0%), headache or facial pain attributed to disorder of the cranium, neck, eyes, ears, nose, sinuses, teeth, mouth, or other facial or cervical structure 2/28 (3.0%), and headache attributed to non-vascular intracranial disorder 2/28 (3.0%). The education level ranged from elementary school to university education: 19/67 (28.4%) did not complete basic education, 24/67 (35.8%) completed basic education, and 24/67 (35.8%) finished university education. All participants reported similar frequency and intensity of headache within the last month in the first and second appointments. The sample characteristics according to primary and secondary headaches are represented in Table 3.

The average HIT-6™ Brazil score for the total sample was 63.7 (7.6) in the first application and 62.6 (8.3) in the second application. The HIT-6™ Brazil reliability was excellent (ICC: 0.95, $p$ = 0.001), the SEM was 1.58 points, and the $SDC_{individual}$ was 4.38 points. The HIT-6™ Brazil had a Cronbach's $\alpha$ coefficient of 0.97 with and without the question number 3.

## DISCUSSION

Our study showed that the HIT-6™ Brazil has only one domain, the disability. Furthermore, question number 3 presented the lowest factor loading and with its withdrawn, the model fit had a significant improvement. The HIT-6™ Brazil was correlated with quality of life, headache intensity and another disability assessment instrument, the HDI—Brazil. It exhibited excellent reliability and had a low SEM. However, high internal consistency was found, and it may suggest redundancy among the questionnaire items.

Similar to our study, the exploratory factor analysis of the original HIT-6™ Brazil revealed just a single domain.[23,29] However, we found a low factor loading in the question number 3 in the Brazilian Portuguese version. The study by Rendas-Baum et al.[30] also showed that question number 3 had the lowest factor loading among the six questions, corroborating to our findings. Despite its factor loading was considered acceptable, the model fit results had a significant improvement after its withdrawal. It can be suggested that this question has a small contribution to the disability construct. However,

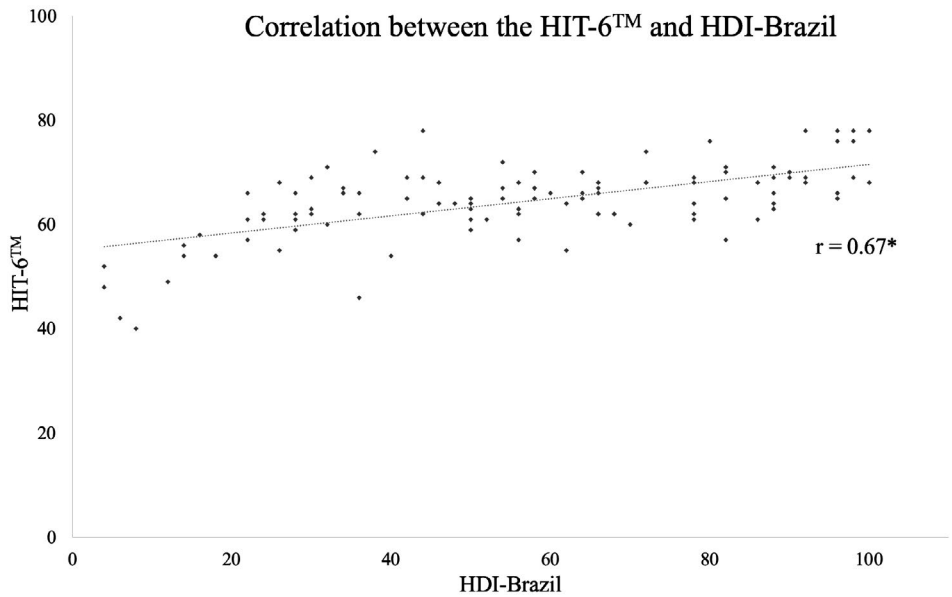


**FIGURE 3** Correlation between HIT-6™ and HDI-Brazil total score, *$p$ = 0.001

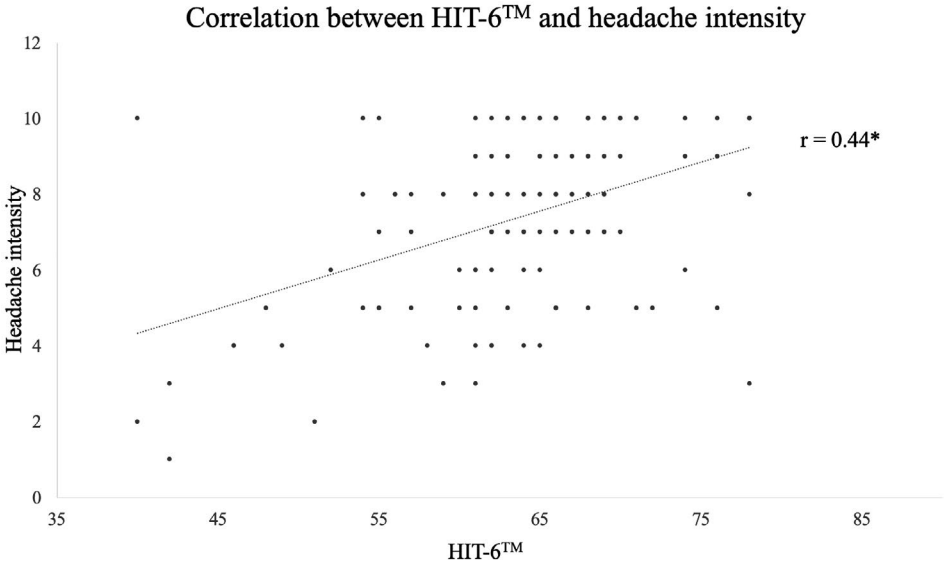


**FIGURE 4** Correlation between HIT-6™ and the headache intensity, *$p$ = 0.001

these results should be interpreted with caution, since they were not reproduced in the original and other HIT-6™ version. Therefore, further studies must confirm these results, since they may be a explained by a particular pattern of our dataset.

The construct of the original HIT-6™ in English was validated online and contrasted to the 8-Item Short-Form Survey (SF-8) questionnaire.[8] The Brazilian Portuguese version was also assessed in a self-report form, compared to the SF-12 questionnaire and with an additional impact instrument, the Brazilian Portuguese version of the HDI.[19] The original version had a moderate and negative correlation with the physical (−0.35) and mental (−0.31) scales of the SF-8,[8] just as the Portuguese version in contrast with the SF-12 total score.

The questionnaire Migraine Disability Assessment (MIDAS), considered the most used instrument to evaluate the disability in migraine, presented also moderate correlation with the HIT-6™.[9] Our study also verified a moderate correlation between HIT-6™ Brazil and HDI-Brazil, which confirms that the HIT-6™ Brazil measures the construct it proposes to. Even though the MIDAS is a valid and reliable tool to evaluate the migraine impact, it cannot be used to evaluate the disability in every type of headache, such as the HDI.[25]

The construct validity of the English version of HIT-6™ was also previously tested in contrast to the headache frequency, measured through monthly diaries. The results demonstrated a weak correlation between both tools.[31] Our study also demonstrated a weak correlation between the HIT-6™ Brazil and the headache frequency during the last month. This could be explained by the different headache types included in our sample, and how patients with the same headache frequency may experience very distinct disability levels (i.e., cluster headache vs. tension-type headache). Magnusson and Becker[32] also verified the above, showing that the headache frequency is not clearly related to disability or other psychological factors. In contrast, the results demonstrated that the disability levels are clearly correlated to the intensity of the headache.

Both the original[8] and the HIT-6™ Brazil exhibited excellent test–retest reliability. The French HIT-6™ also had an excellent reliability (ICC: 0.78), showing that the questionnaire is consistent over time. However, the Persian HIT-6™ was different from the Portuguese, French, and from the original version, since it had a satisfactory reliability (ICC: 0.50).[24]

The internal consistency among the HIT-6™ versions was not similar. The original version had an internal consistency of 0.89,[8] and the Persian version ranged between $\alpha$ = 0.73 and 0.77, according to the headache type.[24] All of them were considered excellent, while the Brazilian Portuguese version demonstrated a very high correlation among the items ($\alpha$ = 0.97), even after question number 3 is withdrawn. While it can be interpreted that the questionnaire may have redundant items,[28] it can be influenced by the patients' characteristics and response pattern. Therefore, it should be interpreted carefully and confirmed in further studies with different populations.

The HIT-6™ Brazil showed a SDC comparable to the original version (4.38 vs. 5.0).[33] In this way, a difference of at least 5 points on the HIT-6™ Brazil score is necessary to ensure that the observed change is clinically meaningful and not just a measurement error. Such result will help clinicians and researchers on how to interpret what is a meaningful clinically important change on the HIT-6™ scores. However, we recognize that future studies assessing responsiveness and demonstrating minimal important clinically change are necessary.

There are some limitations to this study. First, we did not use the MIDAS questionnaire[34] as a reference to assess the HIT-6™ Brazil validity. Since we aimed to assess both primary and secondary headaches, we opted for measurement tools that would encompass a wide range of diagnosis. The data were collected from a tertiary center, where a large proportion of patients have severe headaches, such as migraine and secondary headaches. This limited the assessment of more prevalent and less impacting headaches. However, we included a very diverse sample, composed by several diagnosis and

therefore, the study has a wide external validity. Another limitation was the small number of male patients and the small number of each headache diagnosis. Thus, the measurement properties assessment considering the gender or the headache subgroup was not possible. Furthermore, it is important to highlight that a great proportion of the sample did not come for the second appointment, and therefore were excluded from the reliability analysis. Despite the reasons given by the patients including lack of availability, we verified differences among the sample who attended one in comparison to sample who attended the two appointments. Nevertheless, it is currently unknown if this sample differences are clinically meaningful to introduce substantial bias in the analysis.

Despite these limitations, our study accomplished the intended evaluation of the measurement proprieties of a very relevant questionnaire for headache impact assessment. The study strengths include the selection of a diversified sample of headache patients, screened from a specialized center, with a reliable diagnosis. Furthermore, it includes an adequate sample size to analyze reliability, and construct and structural validity, according to the COSMIN consensus.[14] Therefore, the measured proprieties of HIT-6™ Brazil allows its application in both clinical and research settings.

## CONCLUSION

The HIT-6™ Brazil is composed of disability construct. As with the original version, it is considered as a valid and reliable tool to assess the impact of both primary and secondary headaches. However, the Brazilian Portuguese version presented some redundancy of the questionnaire items, and the model without question number 3 exhibited better structural validity.

### ACKNOWLEDGMENTS

The authors thank the clinical team of the Ambulatory of Craniofacial Pain from Ribeirão Preto Clinics Hospital.

### CONFLICT OF INTEREST

The authors declare there are no relevant conflicts of interest.

### AUTHOR CONTRIBUTIONS

*Study concept and design*: Gabriela F. Carvalho and Juliana Pradela. *Acquisition of data*: Juliana Pradela. *Analysis and interpretation of data*: Gabriela F. Carvalho, Thais C. Chaves, Débora Bevilaqua-Grossi, Fabiola Dach, and Juliana Pradela. *Drafting of the manuscript*: Gabriela F. Carvalho and Juliana Pradela. *Revising it for intellectual content*: Gabriela F. Carvalho, Thais C. Chaves, Débora Bevilaqua-Grossi, Fabiola Dach, and Juliana Pradela. *Final approval of the completed manuscript*: Gabriela F. Carvalho, Thais C. Chaves, Débora Bevilaqua-Grossi, Fabiola Dach, and Juliana Pradela.

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**How to cite this article:** Pradela J, Bevilaqua-Grossi D, Chaves TC, Dach F, Carvalho GF. Measurement properties of the Headache Impact Test (HIT-6™ Brazil) in primary and secondary headaches. *Headache*. 2021;61:527–535. https://doi.org/10.1111/head.14049