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## Translation and validation of the Test of Adherence to Inhalers (TAI) questionnaire among adult patients with asthma in Malaysia

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### ABSTRACT

**Objective:** The Test of Adherence to Inhalers (TAI) is a validated self-reported questionnaire that can reliably assess adherence to inhalers through patient self-report. However, it was not available in Bahasa Melayu (BM) language, nor has it been validated for use in the Malaysian population. The study aimed, therefore, to translate the 10-item TAI questionnaire into BM and evaluate its psychometric properties.

**Methods:** The translation of the English version of the valid 10-item TAI questionnaire into BM was followed by subjecting it to a series of tests establishing factorial, concurrent and known group validities. Concurrent validity was assessed through Spearman's rank correlation coefficient against pharmacy refill-based adherence scores. Known group validity was assessed by cross-tabulation against asthma symptom control and using chi-square test. The internal consistency of the test scale was determined by a test-retest method using Cronbach's alpha ( $\alpha$ ) value and intraclass correlation coefficients.

**Results:** A total of 120 adult asthma patients participated in the study. A 2-factor structure was obtained and confirmed with acceptable fit indices; CFI, NFI, IFI, TLI >0.9 and, RMSEA was 0.08. The reliability of the scale was 0.871. The test-retest reliability coefficient for the total sum score was 0.832 ( $p < 0.01$ ), which indicated good reliability. The 10-item TAI-BM established concurrent and known group validities. The sensitivity and specificity of the tool were >85%.

**Conclusions:** The scale successfully translated into BM and validated. The 10-item TAI-BM appears fit for use in testing inhaler adherence of Malaysian patients with asthma.

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## Introduction

Asthma is a heterogeneous pulmonary disease, usually characterized by chronic airway inflammation (1,2). Asthma treatment options include bronchodilators for symptomatic relief as well as anti-inflammatory medications (controllers) to curtail inflammatory processes that underpin its pathophysiology (1,3). Current global guidelines recommend regular use of anti-inflammatory, inhaled corticosteroids (ICS) for most people with asthma (1,3). Adherence to a controller medication is a critical element in determining treatment outcomes in asthma (1). Based on international consensus, medication adherence may be defined as “the extent to which a patient acts in accordance with the

prescribed interval and dose of a dosing regimen” (4). The effectiveness of controller medications such as ICSs in achieving good asthma symptom control and reducing the frequency or severity of exacerbations is well established; however, patients' adherence to asthma medication is often suboptimal (1,5). A survey conducted in several Asian countries reported that only 14% of asthma patients used their controller inhalers daily (6), and a Malaysian study revealed that more than half of asthma patients surveyed had a controller medication inhaler refill rate that was inconsistent with regular use (7). Poor adherence to prescribed controller medication is associated with inadequate asthma symptom control, increased risk of

exacerbations, higher healthcare utilization/costs, and impaired quality of life (8). Thus, appropriate measurement of treatment adherence in clinical practice or research is becoming increasingly essential and helps healthcare providers to outline optimal management plans (9).

Several methods, either objective or subjective, are available to assess treatment adherence in patients with asthma. Although there are many advantages for using objective measures, such as electronic monitoring devices and biological fluid drug concentrations (blood and urine), the use of these instruments in routine clinical practice is impractical, and they are relatively costly (10). On the other hand, validated self-report questionnaires, such as the Test of Adherence to Inhalers (TAI), offer healthcare providers a straightforward and economical approach to assess medication adherence (9). The TAI questionnaire was developed to provide a new tool specifically designed to measure self-reported adherence to inhaler devices and help clinicians to evaluate non-adherence barriers related to inhaled therapy in adult patients with asthma or chronic obstructive pulmonary disease (COPD). There are two versions of the TAI questionnaire available: the 10-item TAI and the 12-item TAI (9,11). The TAI questionnaire has demonstrated good psychometric characteristics (i.e., it is reliable, homogeneous, and unidimensional), with an excellent internal consistency (Cronbach's alpha coefficient of 0.873) and test-retest reliability (intraclass correlation coefficient [ICC] of 0.883) (9,11,12). TAI scores have correlated with electronic adherence ( $\rho = 0.293$ ,  $p = 0.01$ ) and have shown better psychometric properties compared to the Morisky-Green test (9). The interpretation of adherence based on the 10-item TAI, scoring is that an overall score of 50 points highlights good adherence, while a score of between 46 to 49 points denotes intermediate adherence. A total score  $\leq 45$  points indicates poor adherence (11).

To date, there has been no valid and reliable questionnaire available in the Bahasa Melayu (BM) language to measure inhaler-specific adherence. Therefore, the objective of the present study was to translate the 10-item TAI questionnaire into the BM language and evaluate its psychometric properties among adult patients with asthma in Malaysia.

## Methods

### Study design, duration, and venue

This cross-sectional study was conducted over a period of five months (November 2018 to March

2019) and in a public hospital located in Selangor, Malaysia.

### Participants and eligibility criteria

The patients were included in the present study if they were: (1) Adults aged  $\geq 18$  years old; (2) had doctor-diagnosed asthma; (3) prescribed with and using an ICS or ICS-long-acting beta2-agonist (LABA) combination inhaler (13) for at least 1 year; (4) proficient in BM (able to read and write); and (5) able to provide written informed consent.

Patients with comorbidities—such as vocal cord dysfunction, gastroesophageal reflux disease (GERD), obesity, nasal polyps, uncontrolled rhinitis and sinusitis, coronary artery disease, heart failure, hypertension, diabetes or chronic renal failure, COPD, asthma-COPD overlap (ACO), interstitial lung disease, bronchiectasis, cystic fibrosis, or any other lung disease besides asthma—were deemed ineligible. Patients who were pregnant, smokers, experiencing mental disability or motor-coordination problems, unable to use their inhalers correctly, and/or those with hearing or speech difficulties were also not included.

### Sample size calculation

As per published principles for sampling adequacy in questionnaire validation exercises, the sample size calculation for this study was based on a sample-to-variable ratio (14,15). The TAI comprised 10 questions; therefore, by using 10 respondents to 1 item (10:1) (14,15), the calculated sample size was 100 subjects. However, we recruited 120 subjects, and the final sample to variable ratio was 12:1 (15).

### Research instrument and the translation process

The permission to use the TAI questionnaire was obtained through [www.taitest.com](http://www.taitest.com) prior to the commencement of the study. The translation process was conducted in accordance with the guidelines published by Beaton and colleagues (16). The method was adapted to ensure that the translated version was clear, grammatically appropriate, and relevant for comprehension by Malaysians with asthma. At the same time, effort was made to preserve the intent and meaning of items in the original 10-item TAI questionnaire. Two forward translations were completed: one by a physician (subject-matter expert) and the other by a translator from the Malaysian Translation and Book Institute (non-subject-matter expert). The

two versions were later independently back-translated to English by another translator (non-subject-matter expert) and physician (subject-matter expert). An expert panel then reviewed all five versions (the original and two forward and two backward translated questionnaires) to reconcile any discrepancies. The pre-final BM version of the 10-item TAI was produced by comparing the two back-translated English versions with the original English version. This endeavor was done by choosing the BM version, which produced the back-translation that was closest to the original English version as confirmed by consensus between expert panel members. At the end of this process, the pre-final harmonized BM version was produced.

The harmonized pre-final BM version was tested in 10 adult subjects with asthma who were fluent in English and BM before the authors proceeded with the fieldwork to test the reliability and validity. Each subject was given the BM and English versions in a random sequence, followed by a discussion on each item in the two questionnaires. They were asked whether the words and terms used in the BM version were clear, relevant and understandable. The process was able to identify any flaws in the harmonized version and ensured clarity, comprehensibility, and suitability of the text in the translated version. At the end of the test, the final BM version that was to be tested for validity in this exercise was produced (10-item TAI-BM).

## Validation

### Factorial validity

The validation process of the 10-item TAI-BM questionnaire included exploratory factor analysis (EFA) and partial confirmatory factor analysis (PCFA). EFA was conducted using principal component analysis (PCA), while PCFA was conducted using maximum likelihood analysis (MLA). Varimax rotation was selected in both EFA and PCFA. All items >0.4 loaded on single component and all non-salient loadings <0.4 on other, were considered as a single factor. Fit indices, including normed fit index (NFI), comparative fit index (CFI), incremental fit index (IFI), Tucker Lewis index (TLI), and root mean square error of approximation (RMSEA), were calculated. Values for NFI, CFI, IFI and TLI >0.9 and <0.08 for RMSEA, were considered a good fit (17,18).

### Concurrent validity

For the purpose of establishing the concurrent validity of the 10-item TAI-BM questionnaire, the comparator measure used was the proportion of days covered

(PDC). A PDC calculation is one of the commonly used methods to assess medication adherence based on pharmacy refill data (19). The Pharmacy Quality Alliance (PQA) recommends the PDC to be used in measuring medication adherence, and the Centers for Medicare and Medicaid Services in their Star Rating methodology adopted a similar calculation to approximate adherence (19,20). The PDC score can be calculated as below (21,22):

$$\frac{Nm}{Nd} \times 100\%,$$

where  $Nm$  denotes the number of days covered by the medication, while  $Nd$  indicates the number of days in the study period. Patients are considered to be adherent if their PDC scores are  $\geq 0.8$  or 80% of days covered (23). For this analysis, in order to assess concurrent validity of the 10-item TAI-BM, by comparing with a PDC score, prescription refill data was extracted from the Pharmacy Information System (PhIS) of the hospital from which patients for the study were recruited.

### Known group validity

Known group validity was assessed by cross-tabulation of adherence scores from the 10-item TAI-BM questionnaire responses with patients' level of asthma symptom control (1). We hypothesized that patients with better adherence would exhibit better asthma symptom control. Asthma symptom control was categorized into well-controlled, partly-controlled, and uncontrolled based on the GINA strategic document (1). The chi-square ( $\chi^2$ ) test was used to assess significance. Known group validity was established if the p values was <0.05 (24,25).

### Sensitivity analyses

Sensitivity and specificity of 10-item TAI-BM to identify adherent patients and rule out non-adherent patients based on PDC were assessed. In addition, likelihood ratios, predictive values, and accuracy of the 10-item TAI-BM were also evaluated. All values are reported with their 95% confidence interval (CI). Additionally, sensitivity, specificity, predictive values, and accuracy were reported in percentages. The Clopper-Pearson method was used to calculate the 95% CI for sensitivity, specificity, and accuracy, while the log method was used to estimate 95% CI for likelihood ratios (26). The 95% CI for predictive values was determined using Standard logit method (27,28).

**Table 1.** Demographics and asthma-related variables of the enrolled patients.

| Characteristics                             | n (%)                  |
|---------------------------------------------|------------------------|
| Gender                                      |                        |
| Male                                        | 49 (40.8)              |
| Female                                      | 71 (59.2)              |
| Race                                        |                        |
| Malay                                       | 68 (56.7)              |
| Chinese                                     | 9 (7.5)                |
| Indian                                      | 42 (35)                |
| Others                                      | 1 (0.8)                |
| Level of education                          |                        |
| Primary education                           | 60 (50)                |
| Secondary education                         | 58 (48.3)              |
| College/University                          | 2 (1.7)                |
| Occupation                                  |                        |
| Government servant                          | 11 (9.2)               |
| Private/self-employment                     | 33 (27.5)              |
| Retired                                     | 19 (15.8)              |
| Student                                     | 5 (4.2)                |
| Unemployed                                  | 52 (43.3)              |
| Living status                               |                        |
| Alone                                       | 13 (10.8)              |
| With family members                         | 104 (86.7)             |
| With non-family members                     | 3 (2.5)                |
| Asthma duration, mean (SD)                  | 22 (13) <sup>a</sup>   |
| Controller inhalers                         |                        |
| ICS monotherapy                             | 104 (86.7)             |
| ICS – LABA                                  | 16 (13.3)              |
| Previous asthma education                   |                        |
| Yes                                         | 118 (98.3)             |
| No                                          | 2 (1.7)                |
| Peak expiratory flow rate (PEFR), mean (SD) | 294 (103) <sup>b</sup> |

ICS, inhaled corticosteroids; LABA, long-acting beta2-agonists; SD, standard deviation; <sup>a</sup>years, <sup>b</sup>L/min. Data sets are n (%), unless otherwise specified.

### Internal consistency and reliability

The internal consistency was assessed using Cronbach's alpha. A value above 0.5 was considered acceptable. Moreover, the ICC was calculated and expressed with its 95% CI (24,25). Item total correlation (ITC) was calculated and considered acceptable if the value was >0.2 (29,30). The test-retest reliability of the 10-item TAI-BM was assessed by documenting participating patient response for the questionnaire at two intervals (31,32). Patients were asked to provide their response at the first time point ( $t_1$ ), and a second appointment was given when the 10-item TAI-BM was re-administered, after 4 weeks ( $t_2$ ). The test-retest reliability coefficient was also calculated for the total sum score of the 10-item TAI-BM ( $t_1$  and  $t_2$ ). Each questionnaire administration required approximately 5 minutes to be completed.

### Ethics approval and patient consent

The study protocol was registered with the National Medical Research Register (NMRR-18-2740-44140) and approved by the Medical Research & Ethics Committee (MREC), Ministry of Health Malaysia (KKM.NIHSEC.P18-2068). Written informed

**Table 2.** Factor structure of the 10-item Test of Adherence to Inhalers-Bahasa Melayu (10-item TAI-BM).

|        | Components |       |
|--------|------------|-------|
|        | 1          | 2     |
| TAI 1  | 0.706      |       |
| TAI 2  | 0.792      |       |
| TAI 3  | 0.850      |       |
| TAI 4  | 0.719      |       |
| TAI 5  | 0.506      |       |
| TAI 6  |            | 0.598 |
| TAI 7  |            | 0.553 |
| TAI 8  |            | 0.655 |
| TAI 9  |            | 0.429 |
| TAI 10 |            | 0.846 |

consent was obtained from the participants before enrollment. All eligible patients who fulfilled the inclusion and exclusion criteria were approached face-to-face by the research team personnel and were given informational materials describing the study. Participation was voluntary and sought without any pressure or incentives. Potential participants were informed that their decision would not impact the care they are entitled to receive. Further, potential participants were assured that they could withdraw from the study any time after consent. Potential participants were considered 'recruited into the study' only after the researchers obtained their written informed consent.

### Results

A total of 120 adult asthma patients participated in the study. The mean  $\pm$  SD age of participants was  $48.8 \pm 16.3$  years. Slightly more than half of them were Malay ( $n = 68$ , 56.7%) and female ( $n = 71$ , 59.2%). Half of the participants ( $n = 60$ , 50%) had a primary level education. A relatively larger proportion of participants were unemployed ( $n = 52$ , 43.3%) and lived with family members ( $n = 104$ , 86.7%). The majority of the participants were prescribed ICS monotherapy ( $n = 104$ , 86.7%). The details are presented in Table 1.

### Factorial validity

EFA was conducted using a principal component analysis (PCA) with Varimax rotation. This procedure provided a two-factor structure, with an eigenvalue above 1.0, that explained 60.6% of the total variance. Of that total, factor 1 contributed approximately 49.4% of the variance, while factor 2 contributed around 11.2% of the variance. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was reported at 0.861, i.e. >0.7, with a significant Bartlett's

test of sphericity ( $p < 0.01$ ). Considering the item loading criteria specified in methods, both factor 1 and 2 had 5 items, where the average loading for factor 1 and 2 were 0.714 and 0.616, respectively. This result was confirmed using PCFA using MLA with the same rotation. There was a normal distribution of non-salient factor loadings. The null model chi-square was reported at 521.8 ( $df = 45$ ), while the implied model chi-square was 48.484 ( $df = 26$ ). Values for fit indices, comparative fit indices, namely CFI, NFI, IFI, and TLI, were 0.95, 0.91, 0.95, and 0.92, respectively (i.e.,  $\geq 0.9$ ). RMSEA was 0.08. All fit indices indicated a good model fit. The factor structure is presented in Table 2.

### Concurrent validity

Concurrent validity was assessed by correlating the adherence score with PDC %. The correlation

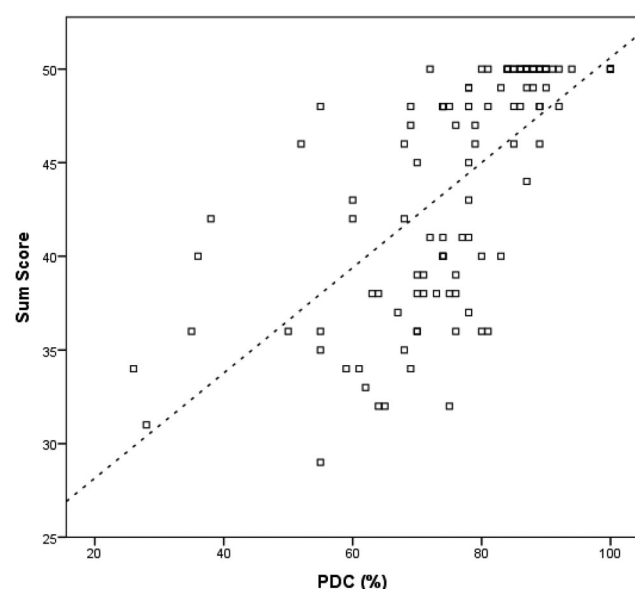


**Figure 1.** Correlation of sum score and proportion of days covered [PDC (%)].

coefficient ( $\rho$ ) was 0.799 ( $p < 0.01$ ), which represents a significantly strong correlation. Hence, concurrent validity was established (Figure 1).

### Known group validity

The adherence status of the participants (based on the 10-item TAI-BM) was cross-tabulated with their level of asthma symptom control, and a significant association ( $p < 0.01$ ) was evident. More participants with good adherence had well-controlled asthma symptoms. By contrast, more participants with poor adherence had uncontrolled asthma symptoms (Table 3).

### Sensitivity analysis

The sensitivity of the 10-item TAI-BM to identify adherent patients, based on PDC, was 88.89% (95% CI: 75.95–96.29%). The scale ruled out non-adherent patients based on PDC with a specificity of 90% (95% CI: 78.19–96.67%). The positive likelihood ratio was 8.89 (95% CI: 3.85–20.55), while the negative likelihood ratio was 0.12 (95% CI: 0.05–0.28). The positive predictive value was 88.89% (95% CI: 77.58–94.87%), while the negative predictive value was 90% (95% CI: 79.67–95.39%). The accuracy of the 10-item TAI-BM was 89.47% (95% CI: 81.49%–94.84%).

### Internal consistency and reliability

The reliability (Cronbach's alpha) of 10-item TAI-BM for all the items was 0.871. For items 1 to 5, the reliability was 0.823, while it was 0.781 for items 6 to 10. The overall ICC was reported at 0.871 (95% CI: 0.833–0.903). The ICC for items 1 to 5 was 0.823 (95% CI: 0.767–0.868), while it was 0.781 (95% CI: 0.712–0.837) for items 6 to 10. The maximum ITC value was 0.687, while the lowest ITC value was 0.376. All items were positively correlated with each other, with a minimum value of coefficient at 0.105 and a

**Table 3.** Cross-tabulation of adherence status of patients with their asthma symptom control.

| Adherence status       |                                 | Asthma symptom control |                   |              |
|------------------------|---------------------------------|------------------------|-------------------|--------------|
|                        |                                 | Well controlled        | Partly controlled | Uncontrolled |
| Good adherence         | Count (expected count)          | 29 (15)                | 7 (14)            | 5 (12)       |
|                        | % within adherence status       | 70.7                   | 17.1              | 12.2         |
|                        | % within asthma symptom control | 65.9                   | 17.1              | 14.3         |
|                        | % of Total                      | 24.2                   | 5.8               | 4.2          |
| Intermediate adherence | Count (expected count)          | 10 (10.6)              | 13 (9.9)          | 6 (8.5)      |
|                        | % within adherence status       | 34.5                   | 44.8              | 20.7         |
|                        | % within asthma symptom control | 22.7                   | 31.7              | 17.1         |
|                        | % of Total                      | 8.3                    | 10.8              | 5.0          |
| Poor adherence         | Count (expected count)          | 5 (18.3)               | 21 (17.1)         | 24 (14.6)    |
|                        | % within adherence status       | 10.0                   | 42.0              | 48.0         |
|                        | % within asthma symptom control | 11.4                   | 51.2              | 68.6         |
|                        | % of Total                      | 4.2                    | 17.5              | 20.0         |

maximum at 0.666. For the test-retest reliability, the questionnaire was handed to patients at  $t_2$ ; the test-retest  $\alpha$  value was 0.789. This result demonstrated acceptable internal consistency of the scale over time. The test-retest reliability coefficient for the total sum score was 0.832 ( $p < 0.01$ ), which indicated good reliability.

## Discussion

Having accessible and appropriate methods to assess patients' medication adherence is important for clinicians to identify poor adherence in clinical practice and research (1). In healthcare settings, self-reported questionnaires are commonly used because of their acceptable reliability, convenience, rapid administration time, non-invasiveness and low-cost (10,33). The TAI is the only validated questionnaire specifically developed to determine adherence to inhalers in adult patients with obstructive lung diseases (11). The present study detailed the validation process of the translated version of TAI, which assessed the adherence to inhalers in patients with asthma. The scale was not available in the BM language and, therefore, translation was a pre-requisite step. We translated the tool into BM by following the guidelines for cross-cultural adaptation for questionnaires. Next, the 10-item TAI-BM was subjected to rigorous multi-pronged validation. The present study is, to the best of our knowledge, the first to translate and validate a questionnaire specific to inhaler adherence for use in the Malaysian population.

The measurement purification of the scale was initiated by exploring its factor structure. The EFA revealed a two-factor structure with acceptable fit indices. This outcome was similar to the findings of Plaza and colleagues (9). The fit indices were above the cutoff value of 0.9. Some indices, namely CFI and IFI, were above 0.95. Previous literature has stated that a fit index value above  $\geq 0.9$  is acceptable. However, there has been a recent consensus that a cutoff value of  $\geq 0.95$  is even better. The RMSEA value was 0.08, which is acceptable, although a value less than 0.08 is better. A value of 0.08 in the study might be due to a low sample size since RMSEA is sensitive to sample size and tends to be larger for smaller samples (34).

Concurrent validity was assessed by correlating the adherence score obtained from the 10-item TAI-BM score with PDC calculations (%); the test scale demonstrated validity in this analysis. Previous studies that strove to evaluate concurrent validity have compared adherence score obtained using the TAI with

other adherence measurement instruments. Plaza and colleagues used the Morisky-Green scale and demonstrated better performance of the TAI (9). Khosravi and colleagues compared the TAI with the General Medication Adherence Scale (GMAS); however, they could not establish its concurrent validity (17,35,36). It would be worthwhile to establish the concurrent validity of 10-item TAI-BM with another patient self-reported adherence measurement instrument in the same language (Bahasa Melayu).

The scale under test (10-item TAI-BM) demonstrated known group validity by comparing adherence scores of patients with their asthma symptom control. It has been hypothesized that patients who have better adherence to inhalers will have better asthma symptom control (1,37,38). Janezic and colleagues reported that improvement in medication adherence increases the odds of achieving good asthma symptom control 1.7 fold (odds ratio [OR] 1.65,  $p = 0.027$ ) (37). Thus, in fact formed the basis of using the asthma symptom control as a variable in a known group validation step. Besides demonstrating known group validity using this approach, the test scale lends credence to the notion that adherence and asthma symptom control are inter-related.

The sensitivity analysis revealed that TAI identified adherent patients and accurately ruled out non-adherent patients based on PDC. The test scale showed better values for sensitivity and specificity than reported in previous psychometric testing (9). Additionally, the scale demonstrated better reliability over time with a test-retest reliability coefficient value  $> 0.8$ . This result was similar to the test-retest reliability value reported for a previous version of the TAI (9). Furthermore, the reliability of the 10-item TAI-BM was also similar to its Persian version—with a similar correlation coefficient value (35). These results indicate the ability of the TAI scale to produce consistent results over time regardless of the language of administration.

The present study had several limitations. First, the electronic pharmacy records primarily provided data on prescription filling, but they were unable to confirm whether the patients actually took their medication. The present study was conducted in a government healthcare setting where the medications were heavily subsidized. This factor might have influenced the adherence rate of the patients who participated. The medication adherence was assessed based on ICS or ICS-LABA inhalers, which are the backbone of asthma treatment; however, we did not assess patients' adherence to other inhalers used in the asthma maintenance

regimen, such as tiotropium (Respimat®), a long-acting muscarinic antagonist (LAMA).

## Conclusions

The 10-item TAI was successfully translated into the BM language. This study established the validity of the 10-item TAI-BM using myriad validation tests. The 10-item TAI-BM can be recommended as a valid and reliable instrument that can be used to assess adherence to inhalers among Malaysian patients with asthma.

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## Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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