

# Validity and reliability of the Malay version of the Hill-Bone compliance to high blood pressure therapy scale for use in primary healthcare settings in Malaysia: A cross-sectional study

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## Abstract

**Introduction:** Hill-Bone compliance to high blood pressure therapy scale (HBTS) is one of the useful scales in primary care settings. It has been tested in America, Africa and Turkey with variable validity and reliability. The aim of this paper was to determine the validity and reliability of the Malay version of HBTS (HBTS-M) for the Malaysian population.

**Materials and methods:** HBTS comprises three subscales assessing compliance to medication, appointment and salt intake. The content validity of HBTS to the local population was agreed through consensus of expert panel. The 14 items used in the HBTS were adapted to reflect the local situations. It was translated into Malay and then back-translated into English. The translated version was piloted in 30 participants. This was followed by structural and predictive validity, and internal consistency testing in 262 patients with hypertension, who were on anti-hypertensive agent(s) for at least 1 year in two primary healthcare clinics in Kuala Lumpur, Malaysia. Exploratory factor analyses and the correlation between HBTS-M total score and blood pressure were performed. The Cronbach's alpha was calculated accordingly.

**Results:** Factor analysis revealed a three-component structure represented by two components on medication adherence and one on salt intake adherence. The Kaiser-Meyer-Olkin statistic was 0.764. The variance explained by each factors were 23.6%, 10.4% and 9.8%, respectively. However, the internal consistency for each component was suboptimal with Cronbach's alpha of 0.64, 0.55 and 0.29, respectively. Although there were two components representing medication adherence, the theoretical concepts underlying each concept cannot be differentiated. In addition, there was no correlation between the HBTS-M total score and blood pressure.

**Conclusion:** HBTS-M did not conform to the structural and predictive validity of the original scale. Its reliability on assessing medication and salt intake adherence would most probably to be suboptimal in the Malaysian primary care setting.

## Introduction

Hypertension is prevalent worldwide,<sup>1</sup> but only about one-third of the hypertension patient on treatment has reached their control target.<sup>2,3</sup> Treatment adherence is one of the important factors affecting blood pressure control. In order to address and research on the issue of treatment adherence, availability of a valid good measuring tool is paramount. A few methods are available to assess patients' medication adherence. It ranges from the

simple self-report methods, pill counts to the electronic adherence monitoring devices and questionnaires.<sup>4</sup> The optimal methods to be used in the primary care setting have to be valid, reliable, non-invasive, cost-effective and acceptable to the patients. Several multi-item questionnaires have been developed, tested and found to be useful in primary care setting to assess medication adherence.<sup>5-7</sup>

Hill-Bone compliance to high blood pressure therapy scale (HBTS) is one of the

multi-item questionnaires, developed for assessing patients' adherence of hypertensive management in outpatient settings.<sup>5</sup> In addition to measuring medication adherence, it also measures therapeutic lifestyle, which is salt intake. With results showing variable validity and reliability, HBTS has been tested in the local languages of Turkey and South Africa,<sup>8,9</sup> and on the medication adherence subscale in American English and Korean language for Korean Americans.<sup>10,11</sup> Morisky medication adherence scale (MMAS) is another validated questionnaire.<sup>6,7</sup> However, MMAS only measured adherence to medication and not to salt intake and appointment keeping in contrast to the three components of HBTS. The salt intake component was considered relevant as the Malaysian Adult Nutrition Survey found that the mean intake of sodium among adults was 2575 mg daily, which was higher than the recommended daily salt intake that should be less than 2000 mg of sodium.<sup>12</sup> Reduced salt intake is closely related to the improved blood pressure control.<sup>13</sup> The objective of this study was to assess the structural validity, predictive validity and reliability of the Malay version of the HBTS (HBTS-M), after content and face validation, for its use in the primary care settings in Malaysia.

### Materials and methods

Original HBTS consists of 14 items in three subscales assessing adherence to medication,

appointment keeping and salt intake. The 4-point Likert scale was used and the score ranged from 1 (all the time) to 4 (none of the time). Higher scores indicated better adherence. One of the items, which was item 6, "How often do you make the next appointment before you leave the clinic?" needed reverse coding on analysis.

The original items in HBTS underwent face and content validity through consensus of expert panel. The expert panel consisted of three academic and two practicing bilingual (Malay and English) family physicians. The examples of changes made were shown in Table 1. The changes were made to suit the local language and culture of food and salt intake. It was then translated into Malay language (HBTS-M) and back-translated into English (HBTS2). We followed the WHO guideline for linguistic validation and translation.<sup>14</sup> The discrepancy between the original HBTS and HBTS2 was discussed and resolved in relation to the HBTS-M by the expert panel. The main issue identified was the structure of the sentence. The meaning of the items was similar to the original HBTS. The HBTS-M (translated version) was piloted in 30 patients with hypertension to assess the clarity of the questionnaire. During the pilot, participants had no problems in understanding the statements from the questionnaire. Hence, no changes were made to the translated version.

**Table 1.** Changes made to original HBTS items

Original items in HBTS	Modified items for HBTS-M	Reasons for changes
How often do you shake salt on your food before you eat it?	How often do you add salt, ketchup or sauce on your food before you eat it?	Adding ketchup and source are common practice than adding salt in our culture
How often do you eat fast food?	How often do you eat fast food? (KFC, McDonald, chips, eat out)?	Fast food may not be ready understood, hence examples are given
How often do you make the next appointment before you leave the doctor's office?	How often do you make the next appointment before you leave the clinic?	Clinic is a more common terminology than doctor's office
How often do you forget to get prescriptions filled?	How often do you forget to get your repeat medication?	Repeat medication is a more common terminology than prescription filled

The validity and reliability of the final version questionnaire was assessed using the HBTS-M. Convenience sampling of hypertensive patients was used to recruit participants from two public primary healthcare clinics in the Federal Territory, Malaysia over 3-month period. These two clinics represented the typical clinics for urban public health clinics in Malaysia. Most hypertension patients in the clinics had three monthly consultations with the treating doctor and collected medication monthly from the in-house pharmacy. The inclusion criteria were patients with hypertension, aged 18 years or more, and were prescribed anti-hypertensive agent(s) for at least 1 year. Foreigners, pregnant women, medically unstable patients (such as patients with acute renal failure and acute myocardial infarction) and patients with concurrent psychiatric problems (such as depression and schizophrenia) were excluded from this study. Participants were offered to response in three languages i.e. Malay, Chinese, and Tamil. We analysed the Malay version of HBTS, as most participants responded to HBTS-M; hence, we assumed the participants were competent in reading and understanding HBTS-M.

The estimated sample size required was 280. This was based on the item-participant ratio, which was 1:20. There is no fix rule to the sample size in analysis. A review of published literature on sample size in factor analysis noted majority of the study used up to 1 in 20.<sup>15</sup> The broad contents of the questionnaire consisted of socio-demographic data (e.g., age, sex, ethnicity, staying alone, education level and working status), clinical information (e.g., duration of hypertension, family history of hypertension and smoking status) and 14 items of HBTS-M. Participants were recruited during their follow-up appointment in the clinics. The socio-demographic and clinical histories were obtained through face-to-face interview and the compliance questionnaire was self-administered before the participants consulted their doctors. In order to determine the predictive validity of HBTS-M, blood pressure was measured with the assumption that good adherence to hypertensive management should result in better blood pressure. Blood pressure was determined from the average of two BP readings measured twice with an interval of 5 min apart during the follow-up. Trained registered nurses in respective clinics measured blood pressure by using calibrated mercury sphygmomanometers.

We had obtained permission from Martha N Hill of John Hopkins University to translate and validate the HBTS.<sup>5</sup> The Universiti Putra Malaysia's [UPM/FPSK/PADS/T7-MJKEtikaPer/F01 (LECT\_FEB (09)33] and the Malaysian Ministry of Health's [NMRR-09-301-3349] Medical Research Ethics Committees had approved this study.

### Statistical analysis

Data were analysed with statistical packages for social sciences (SPSS) version 19.0. In descriptive analysis, we presented the categorical data as frequency and percentage. We reported mean and standard deviation (SD) for normally distributed continuous data and median with interquartile range (IQR) for non-normally distributed continuous data. The structural validity of HBTS-M was assessed using exploratory factor analysis with pro-max rotation. Pro-max rotation was chosen with assumption that the extracted components might be correlated. The assessment of adequacy in sampling and appropriateness of data for factor procedures were performed by estimating Kaiser-Meyer-Olkin (KMNO) statistic and Bartlett's test of sphericity, respectively. The predictive validity of HBTS-M was assessed by determining the correlation between HBTS-M total score and blood pressure by using Spearman's rank-order correlation. The Cronbach's alpha was calculated to assess the internal consistency of the items within a construct.

### Results

Out of 299 patients with hypertension, 262 patients agreed to participate and completed the HBTS-M (response rate of 87.6%). Majority of the patients were Malay (69.8%) and women (63.7%) with the mean age of 56.3 (SD 8.7) years. The median duration of having hypertension was 6.0 (IQR 7.0) years. The socio-demographic and clinical characteristics are presented in Table 2.

**Table 2.** Socio-demographic and clinical characteristics of the patients with hypertension

Socio-demographic and clinical information	Frequency ( <i>n</i> = 262)	Percentage
<b><i>Gender</i></b>		
Male	95	36.3
Female	167	63.7
<b><i>Ethnicity</i></b>		
Malay	183	69.8
Chinese	37	14.1
Indian	36	13.8
Others	6	2.3
<b><i>Staying alone</i></b>		
Yes	18	6.9
<b><i>Working status</i></b>		
Yes	102	38.9
<b><i>Education level</i></b>		
Tertiary	21	8.0
Secondary	144	55.0
Primary	87	33.2
No formal education	10	3.8
<b><i>Family history of hypertension</i></b>		
Yes	27	10.3
No	233	88.9
Unknown	2	0.8
<b><i>Duration of hypertension (years)</i></b>		
1–5	121	46.2
6–10	80	30.5
>10	61	23.3

The Kaiser–Meyer–Olkin statistic was 0.764 denoting adequate sample size for exploratory factor analysis. From the procedure, three items (item 6, 7 and 13) were excluded, as they did not correlate with any extracted components (Table 3). Furthermore, the bivariate correlations between these items and other items were small ( $r = 0.007–0.158$ ; Table 4). The exploratory factor analysis revealed a five-component structure represented by two on medication adherence

(component 1 and 2), one on salt intake adherence (component 3) and remaining two components with single item loading (Table 3). Component 1 consists of 5 items, component 2 consists of 4 items and component 3 consists of 3 items (Table 3). Percentages of variance explained by component 1, 2 and 3 were 23.6%, 10.4% and 9.8%, respectively. The loading factors for each of the items to the component extracted were all  $>0.4$ .

**Table 3.** Construct validity of the Malay version of HBTS

Items	Component (initial factor analysis)					Component (final factor analysis) <sup>b</sup>		
	1	2	3	4	5	1	2	3
1 How often do you forget to take your blood pressure medicine?	0.701					0.653		
14 How often do you miss taking your high blood pressure pills when you are careless?	0.691					0.725		
10 How often do you skip your high blood pressure medicine before you go to the doctor?	0.654					0.676		
8 How often do you forget to get your repeat medication?	0.548			0.475		0.536		
2 How often do you decide NOT to take your blood pressure medicine?	0.547	0.425				0.536		
12 How often do you miss taking your high blood pressure pills when you feel sick?		0.734					0.739	
11 How often do you miss taking your high blood pressure pills when you feel better?		0.687					0.686	
9 How often do you run out of high blood pressure pills?		0.629					0.595	
5 How often do you eat fast food (KFC, McDonald, eat out)?			0.640					0.734
3 How often do you eat salty food?			0.562					0.565
4 How often do you add salt, ketchup or sauce on your food before you eat it?			0.480					0.562
7 How often do you miss your follow up appointments?			-0.516					
13 How often do you take someone else's high blood pressure pills?				0.828				
6 How often do you make the next appointment before you leave the clinic? <sup>a</sup>					0.790			

Factor analysis. Extraction method: Principal component analysis. Rotation method: Promax with Kaiser normalisation. Component 1: medication adherence, component 2: medication adherence, component 3: salt intake

<sup>a</sup>This item needs reverse coding before analysis

<sup>b</sup>Final factor analysis excluding items 6,7 and 13

**Table 4.** Bivariate correlation between items in HBTS-M

	Item 1	Item 2	Item 3	Item 4	Item 5	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12	Item 13	Item 14	Item 6*
Item 1	1.000													
Item 2	0.270	1.000												
Item 3	0.061	0.021	1.000											
Item 4	0.115	0.149	0.147	1.000										
Item 5	0.123	0.070	0.082	0.147	1.000									
Item 7	0.068	0.149	-0.044	0.023	-0.110	1.000								
Item 8	0.253	0.203	0.020	0.141	-0.004	0.137	1.000							
Item 9	0.026	0.132	0.064	0.201	0.100	0.153	0.195	1.000						
Item 10	0.235	0.264	0.055	0.109	0.091	0.126	0.288	0.261	1.000					
Item 11	0.157	0.271	0.093	0.158	-0.016	0.151	0.138	0.169	0.227	1.000				
Item 12	0.161	0.257	0.096	0.189	0.076	0.087	0.241	0.336	0.209	0.374	1.000			
Item 13	-0.064	-0.007	0.045	0.102	-0.012	0.101	0.158	0.118	-0.029	-0.004	0.006	1.000		
Item 14	0.260	0.237	0.023	0.121	0.181	0.117	0.247	0.155	0.426	0.180	0.210	0.123	1.000	
Item 6*	0.075	-0.056	0.032	-0.065	-0.105	-0.051	-0.036	-0.103	-0.114	0.012	0.020	-0.073	-0.142	1.000

\*Analysis after reverse coding

In determining the predictive validity, the total score of HBTS-M did not correlate with the systolic blood pressure ( $r_s = -0.014$ ,  $p = 0.827$ ) and marginally correlate with diastolic blood pressure ( $r_s = -0.158$ ,  $p = 0.011$ ). In determining the internal consistency, Cronbach's alpha for each of the extracted components was 0.64 (component 1), 0.55 (component 2) and 0.29 (component 3), respectively.

### Discussion

We set out to assess the construct validity and reliability of the HBTS-M for its use in the primary care setting in Malaysia. The results showed that the HBTS-M did not conform to the three subscales of the original HBTS.<sup>5</sup> Firstly, the two items related to appointment keeping (item 6 and 7) did not show its structural validity during the analysis. Furthermore, the components of medication adherence and salt intake did not show satisfactory reliability in the local population and the total percentages of explained variance of these components to patient adherence were less than 50%.

The initial factor analysis generated five components and deleting three items (item 6, 7 and 13) resulted in more appropriate clustering of items into three components. This suggested that these three items had poor correlation with remaining items and hence should be deleted. The original HBTS has three components—for medication adherence, appointment keeping and salt intake, whereas, our study showed two components for medication adherence and one component for salt intake. Although, the two components of medication adherence were identified through factor analysis in our study, meaningful concept could not be rationalised. This could be due to participants had different interpretation of these items from the original concept. The item “How often do you take someone else's high blood pressure pills?” was dropped because it might not reflect the concept of non-adherence in Malaysia. The items of salt intake component were similar for HBTS and our study. The two items on appointment keeping were not appropriate to local setting. The patients in local setting do not usually make appointments but are given appointment by the healthcare professionals, which was in contrast with the setting from original study.

**Table 5.** Comparison of the constructs of medication adherence between Turkish HBTS and HBTS-M

Turkish HBTS	HBTS-M
<i>Unintentional medication non-adherence</i>	<i>Medication adherence (component 1)</i>
<ul style="list-style-type: none"> <li>• Forget to take your hypertension medicine?</li> <li>• Miss taking your hypertension pills when you are careless?</li> <li>• Skip your hypertension medicine before you go to the doctor?</li> <li>• Forget to get prescriptions filled?</li> <li>• Run out of hypertension pills?<sup>a</sup></li> <li>• Take someone else's hypertension pills?<sup>a</sup></li> </ul>	<ul style="list-style-type: none"> <li>• How often do you forget to take your blood pressure medicine?</li> <li>• How often do you miss taking your high blood pressure pills when you are careless?</li> <li>• How often do you skip your high blood pressure medicine before you go to the doctor?</li> <li>• How often do you forget to get your repeat medication?</li> <li>• How often do you decide NOT to take your blood pressure medicine?<sup>a</sup></li> </ul>
<i>Intentional medication non-adherence</i>	<i>Medication adherence (component 2)</i>
<ul style="list-style-type: none"> <li>• Miss taking your hypertension pills when you feel better?</li> <li>• Miss taking your hypertension pills when you feel sick?</li> <li>• Decide not to take your hypertension medicine?<sup>a</sup></li> </ul>	<ul style="list-style-type: none"> <li>• How often do you miss taking your high blood pressure pills when you feel sick?</li> <li>• How often do you miss taking your high blood pressure pills when you feel better?</li> <li>• How often do you run out of high blood pressure pills?<sup>a</sup></li> </ul>

<sup>a</sup>Signify differences of items within the construct

The two components for medical adherence identified in our study are similar to the result reported in the Turkish version of HBTS.8 The Turkish HBTS found that the two factors related to medication adherence scale were unintentional medication non-adherence and intentional medication non-adherence. However, in our study the theoretical concepts underlying each concept of these two components could not be identified. Although the Turkish study had identified intentional and unintentional medication adherence, some of the items did not conform to the concepts suggested, for example "Take someone else's hypertension pills" was not an unintentional act but it was classified as unintentional. Comparison of the constructs of medication adherence between Turkish HBTS and HBTS-M is shown in Table 5. Koschack et al. also found three components in their factor analysis for German HBTS; however, only one component had the meaningful pattern i.e. medication adherence.<sup>16</sup> On the other hand, Song et al., who had validated the Korean language of HBTS in America, found that the subscale of medication adherence was similar to the original HBTS.<sup>11</sup> Thus, the structural validity of this questionnaire was different from country to country, with the exception of America.

Although, the predictive validity analysis in our study showed significant correlation between HBTS-M and diastolic pressure, the correlation is poor. Similarly, Lambert et al. had reported that the modified scale of HBTS in local language in South Africa had significant predictive validity for diastolic blood pressure but not systolic blood pressure.<sup>9</sup> Koschack et al. also found that the power of German HBTS to predict controlled blood pressure was low.<sup>16</sup> In contrast, Song et al. showed that the mean scores for Korean language of HBTS medication adherence subscale had a significant correlation with systolic and diastolic blood pressure.<sup>11</sup> This positive result may be due to the tested population were Korean American, which had some similar culture from original HBTS population since both were from America. Hence, the predictive validity of HBTS of this questionnaire is unsatisfactory in other country besides America.

For the component of salt intake, the literature consistently showed that the reliability of this construct were less satisfactory. Its alpha coefficient reported in few studies ranged from 0.41 to 0.62.<sup>5,8-10</sup> In this study, our finding is even lower with the alpha coefficient of 0.29. This may be due to the insufficient items in this component as there were only three items

that contribute to the construct of salt intake. For the medication adherence component, the alpha coefficient is also lower than the other studies because the number of items included in internal consistency testing in other studies were higher.<sup>8-11</sup> The alpha coefficient for medication subscale was reported as 0.76 (total of eight items), 0.83 (total of nine items) and 0.80 (total of eight items), respectively in study from South African, Turkish and Korean Americans. The poor Cronbach's alpha is due to poor inter-items correlation.

In focusing the analysis on items related medication adherence subscales of HBTS-M, factor analysis also identified two component of medication adherence, as same as the initial analysis involving all 14 items. In determining the predictive validity of medication adherence subscales, the total score also did not correlate well with systolic ( $r_s = -0.024$ ,  $p = 0.697$ ) and diastolic blood pressure ( $r_s = -0.119$ ,  $p = 0.053$ ). Therefore, by analysing only the medication subscales, the result is similar when analysing the full scale.

Although HBTS has shown to have good construct validity and reliability in various population of different cultural background on medication adherence,<sup>8-11</sup> we were unable to reproduce satisfactory results in our population. Further research is needed to explore the themes, which could possibly be used for the development of adherence questionnaire in the Malaysian setting.

### Strength and limitations

This study was conducted in the public health clinics catering for the majority of the chronic

disease care in Malaysia.<sup>17</sup> The participants' educational level typically represents the pattern of education level in the same age group. Participants were the patients who were Malay literate, thus these results do not represent the minority group who are unable to use this language. Ideally reliability of the questionnaire also should include test and retest besides determining internal consistency. However, test retest was not performed because of poor structure and predictive validity of the questionnaire.

### Conclusion

The Malay version of HBTS did not conform to the structural and predictive validity of the original scale. Its reliability on assessing medication and salt intake adherence would most probably to be sub-optimal in the Malaysian primary care setting.

### Conflicting of interests

The author(s) declared no potential conflicts of interest with respect to the authorship and/or publication of this article.

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### How does this paper make a difference to general practice?

- The adherence to hypertensive management measured using HBTS is likely invalid in Malaysian primary care settings.

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