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Validating the Persian Version of the Hill-Bone's Scale of "Compliance to High Blood Pressure Therapy"

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Authors' contributions

This whole work was carried out in collaboration between all authors. Author MD designed the study, performed the statistical analysis, wrote the protocol and managed the literature searches and wrote the first draft of the manuscript. Author NDN provided advice for the study design and managed the analyses of the study and supervised writing the manuscript. Author SI provided advice for the study design and supervised writing the manuscript. All authors read and approved the final manuscript.

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ABSTRACT

Introduction: Hypertension is a global public health concern. Among the factors that contribute to this crisis, the poor control of hypertensive patients is a major concern. Patients' lack of adherence to the medication regimen is often considered to be the main reason for this failure. Several medication-adherence scales were designed to measure the extent to which patients adhere to their medication and treatment regimens. Since these scales must be very reliable and have strong validity if they are to be used in clinics and research, this study was performed to test the reliability and validity of the Hill-Bone's scale of "Compliance to High Blood Pressure Therapy."
Methods: After using a modified forward/backward translation procedure to create a Persian version of the Hill-Bone's scale, we conducted a cross-sectional study in which two hundred and eighty hypertensive patients participated to validate the Persian version. Exploratory and

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confirmatory factor analysis, criterion validity, Cronbach's alpha, and test-retest reliability were used to determine the validity and reliability of the Persian scales' psychometric properties.
Results: The analysis of the data showed that the scale had excellent stability (Intraclass Correlation Coefficient = 0.97) and low acceptability of internal consistency (Cronbach's Alpha = 0.44). The exploratory factor analysis did not clarify meaningful patterns among the subscales. The confirmatory factor analysis failed to fit the observed items with the latent subscales. The scale scores were not correlated with blood pressure (P > 0.05).
Conclusion: Although some of the psychometric properties of the Persian version of the Hill-Bone's scale and its modified version were acceptable, they were not sufficient to recommend the Persian version for general use. More studies are needed to revise and develop a more comprehensive scale that is appropriate for use in the context of the mentioned population.

Keywords: Hypertension; medication adherence; psychometrics; scale.

1. INTRODUCTION

1.1 Background

High blood pressure is the most common risk factor for cardiovascular diseases that can lead to myocardial infarction, stroke, heart failure, renal failure and premature death [1-3]. There has been a hypertension crisis in the early part of the 21st century, and hypertension is considered a global public health threat [4]. A meta-analysis in Iran showed that the prevalence of hypertension between the ages of 30-55 is 23% [5]. The analysis also showed that hypertension was present in 50% of people over the age of 55 [5].

One of the contributing factors to this crisis is poorly-controlled hypertensive patients (5, 6), and patients' lack of adherence to the recommended medication regimen is often considered to be the main reason for the failure to control hypertension [6]. According to the World Health Organization (WHO), more than half of the patients who are treated for hypertension abandon the treatment during the first year, with the rest continuing the treatment by consuming at least 80% of the prescribed medications. Thus, because of poor adherence to the treatment regimen, approximately 75% of hypertensive patients are not sufficiently controlled [7]. Non-adherence to medication regimen is associated with the worsening of disease, increased mortality, frequent hospitalization, high morbidity rates and significant healthcare costs [8,9].

The current "gold standards" for assessing adherence to the recommended medication regimen are measuring drug levels in plasma and the use of Medication-Events monitoring systems that electronically record every opening of a pill box. However, these measures are costly and impractical to use in a large community and in clinical practice (6, 8, and 10). Therefore, to estimate the patient's adherence to the prescribed medication regimen, the medical staff at medical centers should ask patients about their adherence to the regimen, and the best option for doing this could be a short and valid adherence measurement based on the patient's self-report [6,10]. These scales, when used in conjunction with the gold standards methods, can be useful in differentiating between low adherence and non-response to anti-hypertensive medication [11].

Several medication-adherence scales have been designed and used in various therapeutic areas [6,8,12,13]. The Hill-Bone Compliance Scale was developed by Kim et al. to determine patient-reported compliance levels to anti-hypertensive therapy [14]. The Medication Adherence Questionnaire (MAQ) was developed by Morisky et al. in 1986 and revised in 2008. The first version of the MAQ consisted of four items, and the revised form consists of eight items [15,16]. The Self-efficacy for Appropriate Medication Use Scale (SEAMS) designed by Risser et al. has 13 items, and it is used to assess medication adherence in chronic patients with a broad range of literacy skills [17]. Svarstad et al. constructed the Brief Medication Questionnaire (BMQ) for monitoring adherence. Their tool consists of a 5-item regimen screen (about taking medication in the past week), a 2-item belief screen (about drug effects and bothersome features) and a 2-item recall screen about potential difficulties remembering [18]. The 10-item Medication Adherence Rating Scale (MARS) created by Thompson et al. assesses adherence in psychiatric patients [19]. Each scale has specific pros and cons. According to Lavsa et al. "MAQ is the shortest scale and identifies barriers to non-adherence but not self-efficacy. The SEAMS and the BMQ both assess barriers and self-efficacy;

however, scoring is difficult. The Hill-Bone Compliance Scale and the MARS address barriers and self-efficacy but are limited in their generalizability." Note that the MAQ, SEAMS, and MARS have been used in different therapeutic fields, e.g., hypertension, dyslipidemia, and diabetes [8], while the MARS is specific to psychiatric populations [19] and the Hill-Bone Compliance Scale focuses on hypertensives [14].

1.2 Statement of the Problem

One scale that is used frequently in hypertensive medication adherence studies is the Hill-Bone's scale of "Compliance to High Blood Pressure Therapy" (Hill-Bone Scale). The Hill-Bone Scale assesses patient's behaviors in three domains, i.e., 1) medication taking, 2) reduced sodium intake, and 3) appointment keeping [14]. Its psychometric properties have been evaluated in several countries, including the United States, Germany, Korea, Turkey, and Saudi Arabia (6,13,20-22). Although Kim et al. [14] and Karademir et al. [21] reported sufficient psychometric properties for the Hill-Bone Scale, some studies that used the scale showed sufficient internal consistency and validity of the factorial construct only for the subscale of medication taking [10,13,22]. Koschack et al. reported that the Hill-Bone Scale lacked adequate reliability and strong evidence of validity [6].

In the Iranian context, most medication adherence studies have used researcher-designed questionnaires that did not assess psychometric properties [23,24]. Only one study used the Hill-Bone Scale, and the psychometric properties of this scale were not reported [25]. It is apparent that there is a lack of a valid, reliable, and concise scale to measure medication adherence in Iranian hypertensive patients. The validation of the scale in a sufficient sample of hypertensive patients would improve the understanding of its respective utility in the clinic and in research. Iran is a large country located in southwest Asia and the Middle East. It has a population of about 76 million people of different ethnicities (Turkish in the northwest, Kurdish in the west, Arab in the south and southwest, Fars in the center, Turkmen in the northeast, and Baluch in the east). They have different cultures, lifestyles, and socioeconomic statuses, which might cause variations in the adherence to the anti-hypertensive treatment regimen. Kerman is the largest province, and it is located in southeast Iran. The ecological characteristics of this Province results in the cardiovascular departments of the educational hospitals in the Province admitting people of different ethnicities, those of Arab ethnicity in the south, Fars in the center, and Baluch in the east.

1.3 Objective of Research

The aim of this research was to assess the reliability and validity of the Hill-Bone's scale of "Compliance to High Blood Pressure Therapy". The followings were set as the specific objectives of the study:

1) To develop the Persian version of the Hill-Bone's scale of "Compliance to High Blood Pressure Therapy"
2) To examine the exploratory and confirmatory construct validity of the scale.
3) To determine the association between the scale and blood pressure measurements (concurrent criterion validity).
4) To determine the reliability of the measurement tool using the internal consistency reliability and test-retest reliability methods.

2. MATERIALS AND METHODS

2.1 Study Design and Setting

This was a cross-sectional study conducted in the cardiovascular departments of teaching hospitals affiliated with the Kerman University of Medical Sciences in 2014. Kerman is the largest city in southeastern Iran, and its population is more than 722,000.

2.2 Sampling

2.2.1 Sample size

In their study, Costello and Osborne suggested that an appropriate sample size would be a subject-to-item ratio of 20:1. According to their study, the most replicable results for exploratory factor analysis are obtained by using large samples [26]. Therefore, 280 subjects were required to validate the construct. We selected 30 and 25 subjects for reliability (internal consistency and repeatability, respectively).

2.2.2. Sampling method

The convenience sampling technique was used to select hypertensive subjects. A certified nurse

was referred to the cardiovascular departments and gathered the required sample in different work shifts (morning, afternoon and night). The sampling lasted from November 2013 through February 2014.

2.3 Medication Adherence Scale

The Hill-Bone's scale of "Compliance to High Blood Pressure Therapy" was developed by Kim et al. in 2000 (14). This scale assesses patients' behaviors for three behavioral domains for the treatment of hypertension, and it is comprised of 14 items divided into three subscales, including: 1) ''medication taking'' (nine items), 2) reduced sodium intake'' (three items), and 3) ''appointment keeping'' (two items). Each item is assessed using a four-point Likert scale (1 = none of the time, 2 = some of the time, 3 = most of the time, and 4 = all of the time). The items are additive, and the total scale score can range from 14 (minimum) to 56 (maximum), with a higher score reflecting poorer compliance with the anti-hypertensive therapy regimen. Kim et al. reported sufficient psychometric properties (internal consistency, constructive and prospective validity) [14]. In this study, the original scale with all 14 items was used.

2.4 Translation

We generated a version of this scale for the first time in the Persian language using a modified forward/backward translation procedure (27, 28). In this procedure, two experienced Iranian health experts independently translated the original English version of the scale into Persian (the first language of the Iranian community). In case there were any differences between the two translations, the problem was resolved through discussion with the translators and the research team to yield a consensus forward translation. To check the quality of the first translation, the initial Persian version was translated back into English by two independent translators who had no previous knowledge about the scale. The purpose of this step was to determine whether the translated version had the same content as the original (28). The original and back-translated versions were discussed by a bilingual expert panel to check the semantic, idiomatic, experiential, and conceptual equivalences and to resolve the discrepancies.

In the next step, 25 illiterate or low literacy hypertensive patients were selected to test the current version of the Persian scale. Each patient completed the scale and was interviewed about the meaning of each item. In addition, they asked their opinions of the difficulty of reading the items on the scale. Based on the results of this pilot study, the final version of the Persian scale was confirmed after revising the questions that were difficult to understand and confusing.

2.5 Data Collection

The subjects consisted of hypertensive patients who were 18 or older and who had taken at least one anti-hypertensive medication. The subjects were asked about some socio-demographic data, such as age, gender, marital status, education, occupational status, the duration of their hypertension, and when their drug treatment was initiated. Blood pressure was measured with an aneroid sphygmomanometer (ALPK2, Japan) using the average of two measurements taken five minutes apart. This device was validated by comparing its results to those of a mercury sphygmomanometer. Systolic and diastolic blood pressures were obtained from the right arm of the subjects while they were in a seated position. Subjects were required to avoid caffeine intake (coffee and colas), and they were not allowed to smoke for 30 minutes prior to the blood pressure measurement. All patients who participated in this study did so during their hospitalization. For illiterate individuals, interviews were used instead of the self-administered method. We used telephone contacts to gather data from those who participated in the test-retest reliability assessment for the second time.

2.6 Ethical Consideration

This project was approved by Kerman University of Medical Sciences (KUMS). The Ethics Committee of KUMS confirmed all processes and procedures used in the study. After approval of KUMS and the clinical centers, we provided information sheets and consent forms to the subjects. The information sheet addressed 1) the goal and objectives of the study, 2) the confidentiality of the data, and 3) that the participants would be anonymous and were free to withdraw from the study at any time. We explained the content of the information sheet to those who were illiterate. Those who chose to participate in the study were required to sign informed consent forms. No special ethical issue had occurred during study development and data collection. Finally we appreciated those who participated.

2.7 Statistical Analysis

All analyses were performed using SPSS version 17 (SPSS Inc., Chicago, Illinois, United States) and LISREL version 8.70 (Scientific Software International, Chicago, Illinois, United States). Descriptive statistics (frequency and percentage, mean, and standard deviation) and analytical statistics (Spearman's rho coefficient and factor analysis) were used to analyze the data. The 0.05 significance level was used in this study.

2.7.1 Validity

2.7.1.1 Construct validity

To verify the validity of the construct, the factorial design of the Persian Hill-Bone Scale (PHBS) was analyzed by using both exploratory and confirmatory factor analysis (EFA and CFA). EFA was performed to investigate the factor structure of the scales by principal-component analysis (PCA) with varimax rotation [29]. The following criteria were used to determine the number of factors in the scales: eigenvalues >1, scree plots, and items with loadings of 0.4 or greater on any one factor [26].

The validity of the construct was further assessed by CFA. CFA was used to test the goodness-of-fit of the structural equation model in which the observed variables (items) correlated with their underlying latent constructs (subscales). The adequacy of the model was evaluated by the chi-squared test. Goodness-of-Fit Index (GFI), Adjusted Goodness-of-Fit Index (AGFI), Comparative Fit Index (CFI), Incremental Fit Index (IFI), Non-Normed Fit Index (NNFI), Root Mean Squared Error of Approximation (RMSEA), and the Standardized Root Mean Square Residual (SRMR) were the main indices used to determine the fit of the model. Acceptable fit of the model was indicated by χ^2/d.f. < 3.0, RMSEA < .08, and SRMR < .05. The values of the GFI, AGFI, CFI, IFI, and NNFI indices were .9 or greater [29-31].

2.7.1.2 Criterion validity: Concurrent validity

Criterion validity is the extent to which the scale's scores are correlated with other variables or criteria that reflect the same construct. When the criterion is something that will happen or be assessed in the future, this is called predictive criterion validity. When the criterion is something that is happening or being assessed at the same time as the construct of interest, it is called concurrent criterion validity. A consistent relationship between the scores from the two measurement procedures shows that they are measuring the same thing (i.e., the same construct). Thus, to assess concurrent validity, the correlation between the scale and the blood pressure measure (systolic and diastolic) was calculated by using Spearman's rho coefficient.

2.7.2 Reliability

The evaluation of the reliability of internal consistency alone often is inadequate since it provides no information on the stability of participants' responses [32]. Thus, we used both internal consistency and test-retest reliability. Internal consistency refers to the extent to which items of the scale measure the same construct (i.e., homogeneity of the scale), and it was assessed in our study by Cronbach's α (should be >0.70) for 30 hypertensive patients. To evaluate the repeatability of the PHBS, the intraclass correlation coefficient (ICC) was used to assess test-retest reliability at two-week intervals. To interpret the coefficients that were obtained, we considered values below 0.4 as poor reliability, values above 0.7 as excellent reliability, and values between 0.4 and 0.7 as fair-to-good reliability [33].

3. RESULTS

3.1 Socio-demographic Characteristics

In total, 280 hypertensive patients were assessed. The mean age of the participants was 55.5 $\pm$ 8.86. More than 60% of them were men. Nearly 75% were married, and less than 40% were illiterate. More than half of patients were employed. The average duration of having hypertension was 41.18 $\pm$ 27.03 months, and the average time since the initiation of treatment for hypertension was 39.63 $\pm$ 26.83 months. More than 80% of the patients had been prescribed angiotensin Π receptor antagonist agents. Less than 15% currently were controlled their blood pressure. The average adherence to the treatment for hypertension was 23.78 $\pm$ 3.42 according to the PHBS (Table 1). The distribution of the responses to each item in the PHBS is presented in Table 2. More than 50% of the respondents reported perfect adherence for only four of the fourteen items (items 2, 5, 8, and 12).

3.2.1. Construct validity

For the validity of the construct, the PHBS was examined by undertaking principal-component

factor analysis (PCA) with a varimax rotation. First Bartlett's test of sphericity was used to determine if the sample size were appropriate for a factor analysis and to determine if the data came from a sample of the normal distributed population. This test showed statistical significance (χ^2 = 1309.163, d.f. = 91, P < 0.001). In addition to Bartlett's test, the Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy was examined. Williams et al. reported the KMO measure of satisfactory sample adequacy with 0.50 to be suitable for factor analysis [28]. In the present study, the KMO coefficient was 0.53, confirming factorability of the correlation matrix of the PHBS.

PCA with varimax rotation was conducted, and a six-factor solution with an eigen value > 1 was retrieved. The total variance explained by these six factors was 75.35%. Note the scree plot begins to level off after three components, with a decrease of the eigen values from 1.76 to 1.30, which was consistent with the number of subscales. Therefore, we preferred the three-factor solution with an eigen value (% variance explained) of 2.87 (20.50%), 2.38 (16.98%), and 1.76 (12.58%), which together accounted for 50.06% variance. Twelve of the 14 fourteen items loaded above 0.4. Four of the nine items of the medication-taking subscale loaded on the first factor.

Four of the nine items of the medication-taking subscale and only one item of the appointment-keeping subscale loaded on the second factor. Two of the three items of the salt-intake subscale and one item of the appointment-keeping subscale loaded on the third factor. Therefore, the first and second factors were related to 'medication taking' and the third factor 'salt intake'. Although the F3-related items were meaningful, the remaining factor-related items were not exactly interpretable. EFA showed that the appointment-keeping items failed to be a distinct factor in the observed variables in the Iranian context (Table 3). Since item 13 was negatively correlated with the third factor, this item and the two items (4 and 12) that were not loaded in any factors were candidates for omission (Table 3). Note that, in order to calculate the factor analysis, 13 missing responses were replaced with means.

Following the identification of a three-factor solution using EFA, CFA was performed to further test the factor model that emerged from EFA. The first- and second-order confirmatory factor analysis models were used. In Model 1 (first-order model), we assumed that the PHBS was composed of three separate correlated dimensions, and, in Model 2 (second-order model), we assumed that a higher-order factor accounted for the relationships between the individual factors. Goodness-of-fit indices

Table 1. Description of the study sample (n = 280)

Variables	Mean (SD)/ frequency (%)
Age (yr)	55.50±8.86
Gender	
Female	92 (32.90)
Male	188 (67.10)
Marital status	
Single	7 (2.50)
Married	208 (74.80)
Divorced	9 (3.20)
Widow(er)	54 (19.40)
Education status	
Illiterate	111 (39.90)
Under Diploma	76 (27.40)
Diploma	61 (21.90)
Bachelor's degree	30 (10.80)
Above Bachelor's degree	-
Occupation	
Unemployed	47 (16.80)
Worker	23 (8.20)
Employee	32 (11.50)
Self-employed	69 (24.70)
Pensioner	38 (13.70)
Housewife	42 (15.10)
Other	28 (10.00)
Duration of having hypertension (mo)	41.18 ± 27.03
Duration of treatment for hypertension (mo)	39.63 ± 26.83
Prescribed cardiovascular drugs*	
Angiotensin Π receptor antagonist	235 (83.90)
Beta blocker	91 (32.50)
ACE** inhibitor	93 (33.20)
Calcium channel blocker	3 (1.1)
Diuretic	6 (2.10)
Antiadrenergic	2 (0.70)
Nitrate	17 (6.10)
Blood pressure	
Systolic	140.05±13.61
Diastolic	97.92±13.07
Hill-Bone Scale score	23.78±3.42

**Some patient used more than one drug, **ACE: Angiotensin converting Enzyme*

Table 2. Distribution of the responses to the Persian Hill-Bone scale

Question: How often do you …..	Mean (SD)	Response, n (%*)			
		None of the time	Some of the time	Most of the time	All of the time
1. Forget to take your HBP medicine?	1.58 (.58)	131 (46.8)	137 (48.9)	12 (4.3)	-
2. Decide not to take your HBP medicine?	1.39 (.52)	175 (62.5)	101 (36.1)	4 (1.4)	-
3. Forget to get prescription refilled?	1.69 (.62)	110 (39.3)	147 (52.5)	23 (8.2)	-
4. Run out of HBP pills?	1.64 (.59)	114 (40.7)	154 (55.0)	10 (3.6)	2 (.7)
5. Skip your HBP medicine before you go to the doctor?	1.32 (.69)	219 (78.2)	39 (13.9)	15 (5.4)	7 (2.5)
6. Miss taking your HBP pills when you feel better?	1.62 (.58)	120 (43.0)	146 (52.3)	13 (4.7)	-
7. Miss taking your HBP pills when you feel sick?	1.51 (.52)	139 (49.8)	137 (49.1)	3 (1.1)	-
8. Take someone else's HBP pills?	1.24 (.53)	224 (80.3)	42 (15.1)	13 (4.7)	-
9. Miss taking your HBP pills when you are careless?	1.86 (.64)	76 (27.2)	171 (61.3)	28 (10.0)	4 (1.4)
10. Eat salty food?	2.04 (.82)	84 (30.1)	102 (36.6)	90 (32.3)	3 (1.1)
11. Shake salt on your food before you eat it?	1.96 (.81)	94 (33.7)	103 (36.9)	80 (28.7)	2 (.7)
12. Eat fast food?	1.38 (.64)	194 (69.8)	65 (23.4)	16 (5.8)	3 (1.1)
13. Make the next appointment before you leave the doctor's office?	2.69 (1.01)	28 (10.1)	113 (40.6)	54 (19.4)	83 (29.9)
14. Miss scheduled appointments?	1.86 (.77)	90 (32.5)	152 (54.9)	20 (7.2)	15 (5.4)

** Valid percent, SD: Standard Deviation, HBP: high blood pressure, –: zero responses received*

were examined to determine the degree of fit between the data and the results of the hypothesized models. In M1, the loadings of items and factors were statistically significant at the 0.05 level (t values > 1.96) except for item 13. In M2, all of the item loadings were significant (t values > 1.96). The χ^2-associated P value was below the 0.05 significance level in both models (M1: χ^2 = 521.66, d.f. = 74, and $P < 0.001$; M2: χ^2 = 648.28, d.f. = 87, and $P < 0.001$). None of the fit indices reached acceptable levels in either model (M1: χ^2/d.f. = 7.05, RMSEA = .15, SRMR = .13, GFI = .79, AGFI = .70, CFI = .55, IFI = .56, and NNFI = .45; M2: χ^2/d.f. = 7.45, RMSEA = .15, SRMR = .16, GFI = .75, AGFI = .70, CFI = .42, IFI = .42, and NNFI = .39). Consequently, based on these models, we could not confirm the structure resulting from the exploratory factor analysis. Since item 13 was not significant in the confirmatory model and item 4 and 12 were not loaded on any factors in EFA, these items were removed from the model. The modification of the structures in M2 showed that the fit indices did not improve considerably (Modified second-order CFA model: χ^2 = 329.57, d.f. = 51 and $P < 0.001$; χ^2/d.f. = 6.46, RMSEA = .14, SRMR = .13, GFI = .82, AGFI = .77, CFI = .59, IFI = .59, and NNFI = .46). Based on the fit indices, the modified model did not provide a reasonable fit to the data.

3.2.2 Concurrent criterion validity

To measure the concurrent validity, the correlation was assessed between blood pressure (systolic and diastolic) and the PHBS-14 item (and medication taking subscale) and the PHBS-11 item (Table 4). None of them was correlated with SBP or DBP ($P > 0.05$).

3.3 Reliability

The value of Cronbach's α for the PHBS-14 item was 0.44, and it was 0.72 for the medication-taking dimension. The Cronbach's α was not calculated for ''sodium intake'' or the ''appointment keeping'' subscales because they consisted of just three and two items, respectively. The PHBS item-total correlations ranged from -0.37 (Item 13) to 0.62 (Item 4).The Cronbach's α coefficient of the PHBS was 0.61

when item 13 was not used in the calculation. The value of Cronbach's α for the PHBS-11 item was 0.59. The test-retest reliability of the PHBS indicated excellent reliability at a two-week interval, with an ICC of 0.97 (CI: 0.94-0.99) (Table 5).

Table 3. Rotated factor matrix: the Persian Hill-Bone Scale

Question: How often do you …	Rotated matrix		
	Factor 1	Factor 2	Factor 3
1. Forget to take your HBP medicine?	**.79**	-.19	.12
2. Decide not to take your HBP medicine?	**.71**	.04	-.30
3. Forget to get prescription refilled?	**.76**	.12	.08
6. Miss taking your HBP pills when you feel better?	**.58**	.13	.18
5. Skip your HBP medicine before you go to the doctor?	-.03	**.67**	-.24
7. Miss taking your HBP pills when you feel sick?	.21	**.48**	.31
8. Take someone else's HBP pills?	-.24	**.75**	-.06
9. Miss taking your HBP pills when you are careless?	.24	**.43**	.15
14. Miss scheduled appointments?	-.07	**.73**	.26
10. Eat salty food?	.10	.07	**.86**
11. Shake salt on your food before you eat it?	.01	-.06	**.89**
13. Make the next appointment before you leave the doctor's office?	.08	-.36	**-.50**
4. Run out of HBP pills?	.38	.34	.22
12. Eat fast food?	-.30	.15	.09
Eigenvalue	2.87	2.38	1.76
Percentage of explained variance	20.50	16.98	12.58

Correlations between variables and factors > .40 are bold, HBP: high blood pressure

Table 4. Association between the Persian Hill-Bone Scale and blood pressure

Variables	Systolic blood pressure	Diastolic blood pressure
The Persian Hill-Bone scale (14 items)	ρ = .01 (*P* = .93)	ρ = .10 (*P* = .09)
Medication-taking subscale	ρ = .06 (*P* = .35)	ρ = .10 (*P* = .11)
The Modified Persian Hill-Bone scale (11 items)	ρ = .02 (*P* = .78)	ρ = .09 (*P* = .13)

4. DISCUSSION

According to the results, ''Hill-Bone Compliance to High Blood Pressure Therapy Scale'' had insufficient psychometric quality in the different aspects of internal consistency, construct, and criterion validity. The repeatability of the PHBS-14 item was excellent. The internal consistency of the medication-taking subscale was acceptable. The modified Hill-Bone scale that contained 11 items had better internal consistency, but it failed to have meaningful construct validity or significant criterion validity.

4.1 Construct Validity

The exploratory factor analysis of the PHBS showed the three-factor solution explained only 50.06% of the total variance. The medication-taking subscale items were loaded in the first and second factors. Latent constructs, such as intentional/unintentional medication non-adherence and appointment keeping, had no meaningful patterns in these factors. Two of the salt-intake subscale items loaded in the third factor, and one of the items, which related to fast food, was not loaded in any factor. EFA showed that the appointment-keeping items failed to be a distinct factor in the observed variables in the Iranian context. This may be due to the Iranian healthcare system. In Iran, there is neither an early diagnosis system nor a follow-up for chronic diseases, such as hypertension. Iranian patients do not follow up regularly and do not check their health status appropriately. Most Iranian patients do not make another appointment before they leave the doctor's office, and this practice is not in the best interest of their health. The confirmatory factor analysis failed to fit with the proposed underlying latent constructs (subscales). Even after modifying the model, the fit indices were not improved significantly. It seems that eating fast food has another latent meaning in the Iranian context. In Iran, fast foods

are considered to be unsafe foods, especially for the elderly. The original Hill-Bone Compliance to High Blood Pressure Therapy Scale had three dimensions theoretically. However Kim et al., reported that the principal component analysis extracted five factors from their first hypertensive population with eigen value (% variance explained) 3.74 (27%), 1.66 (12%), 1.30 (9%), 1.11 (8%), and 1.02 (7%), respectively. They stated that four factors were extracted from second hypertensive population with eigen value (% variance explained) 4.97 (35%), 1.65 (12%), 1.08 (8%), and 1.01 (8%), respectively. Therefore the number of factors extracted was different from the originally predicted number of compliance domains. However, They concluded that factor loading of each item to the first factor were consistent in both studies, which indicated that only the first factor was meaningful for interpretation across items used in the two studies. They continued that the large drop from the first to second factor, 3.74 to 1.66 in Study 1 and 4.97 to 1.65 in Study 2, confirmed that all 14 items could be represented by a single factor [14]. This was in contrast with our findings. Karademir et al. found a three-factor structure that represented unintentional medication non-adherence; intentional medication non-adherence; and salt intake adherence. They found a cluster of salt intake and medication adherence when they forced a two-factor structure [21]. It seems that the meaningful pattern in the medication-taking subscale in the Turkish version and the meaningless pattern in the medication-taking subscale in the Persian version (the present study) depended on the items in the appointment-keeping subscale. Karademir et al. did not include the items in the appointment-keeping subscale in their study due to the Turkish health service [21]. Some previous studies found that the only meaningful factor that could be interpreted is the medication-taking subscale [6,22]. A review of the literature indicated that there had been no study that supported the findings of the confirmatory factor analysis. Thus, the low inter-correlation of the items and the non-meaningful pattern among the factors' items suggested that hypertension-treatment adherence is a more complex construct and cannot be appropriately measured by the PHBS. Therefore, a revised version of the scale is needed that is designed specifically for the Iranian context.

Table 5. Reliability of the Persian Hill-Bone Scale

Question: How often do you …..	Corrected item-to-total correlation (n = 30)	Cronbach's α if item deleted	Intraclass correlation (CI)(n = 25)
1. Forget to take your HBP medicine?	.11	.43	.92 (.83 - .96)
2. Decide not to take your HBP medicine?	.58	.35	.96 (.90 - .98)
3. Forget to get prescription refilled?	.35	.37	.52 (.17 - .75)
4. Run out of HBP pills?	.62	.33	.97 (.93 - .96)
5. Skip your HBP medicine before you go to the doctor?	.35	.35	.99 (.98 - 1)
6. Miss taking your HBP pills when you feel better?	.49	.35	.98 (.96 - .99)
7. Miss taking your HBP pills when you feel sick?	.20	.40	.99 (.98 - 1)
8. Take someone else's HBP pills?	-.03	.45	.99 (.98 - 1)
9. Miss taking your HBP pills when you are careless?	.16	.41	.93 (.85 - .97)
10. Eat salty food?	.14	.42	.91 (.82 - .96)
11. Shake salt on your food before you eat it?	.08	.45	.94 (.87 - .97)
12. Eat fast food?	-.03	.47	.96 (.91 - .98)
13. Make the next appointment before you leave the doctor's office?	-.37	.61	.83 (.66 - .92)
14. Miss scheduled appointments?	.26	.38	.75 (.51 - .88)

HBP: high blood pressure, The Persian Hill-Bone Scale (14 items) Cronbach's α = .44 and ICC = .97 (CI: .94 - .99)

4.2 Criterion Validity

The finding showed that there was no significant correlation between the PHBS-14 item and blood pressure or between the medication-taking subscale and blood pressure. The modified PHBS, which consisted of 11 items, was not correlated significantly with blood pressure. Kim et al. reported that high compliance scale scores at the baseline were significantly associated with blood pressure control at both baseline and at follow up in the two independent samples [14]. In Lambert et al.'s study, the correlation between HBS-14 items and blood pressure was not significant. It was positively significant about the modified 10-item scale, which disagrees with the findings of this study [10]. Koschack et al. also reported that the power of HBS to predict controlled blood pressure was low and essentially a chance [6].

4.3 Internal Consistency and Repeatability

The internal consistency of the PHBS-14 items was not acceptable (Cronbach's alpha = 0.44), which was comparable with Krousel-Wood et al.'s report (Cronbach's alpha = 0.43) [17]. The item 13, i.e., "Make the next appointment before you leave the doctor's office?" had a significant impact on the internal consistency of PHBS. As mentioned earlier, Iranian hypertensive patients do not make their next medical appointments regularly, except in particular cases. Pharmacological mechanisms of the drugs and their side effects are different between male and female; for example: the ACE inhibitors and their hormonal influence after long term treatment. In the present study, compare to other prescribed medicines, 33% of patients used ACE inhibitors. This may affect on long term medication adherence among females and therefore may influence on internal consistency. In the original version of the scale internal consistency reliability were evaluated using two community based samples of hypertensive adults. The standardized alphas for the total scale were 0.74 and 0.84 respectively [14]. Some other studies, such as Koschack et al. [6]; Lambert et al. [10]; Karademir et al. [21], and Esmaili et al. [25], reported an acceptable internal consistency of HBS (Cronbach's alpha = 0.73, 0.77, 0.72, and 0.71 respectively). In the current study, the modified PHBS (11 items) and the medication-taking subscale had moderate and good internal consistency respectively (Cronbach's alpha values of 0.59 and 0.72, respectively). This was in agreement with the reliability coefficients reported by earlier validation studies, with the exception of Krousel-Wood et al.'s study [6,10,13,20-22]. In this study, the internal consistency of the subscales of ''salt intake'' and ''appointment keeping'' was not calculated due to the lack of sufficient items (three and two, respectively). However, the salt-intake subscale has been reported as being unacceptable in some studies [21,22]. In this study, the repeatability of the PHBS-14 item after a two-week interval was excellent. No study was found to support this finding.

4.4 Limitations

Hospitalized patients participated in the study. We paid attention to the patients' comfort status, and their blood pressure was measured in a standard approach, but their responses may have been affected by their hospitalization. Other limitations were convenience sampling and the small sample size for assessing the test–retest reliability. Since the Iranian healthcare system does not encourage regular appointments with physicians and there is no well-designed follow-up system, Iranian patients do not get regular examinations and do not check on their health status appropriately. This culture may have affected the answers that were provided for the two items related to the appointment-keeping subscale, consequentially affecting the correlation among the scale items. Another limitations might be the age and gender of study population. The mean age of our sample was above 50 year old. As the antihypertensive medication adherence is different in patient before 50 in compare to patients above 60 years old, this may affect on our results. Also the difference between the number of male (more than 60%) and female patients could interfere in the main results.

5. CONCLUSION

The results of this study showed that Hill-Bone's scale of "Compliance to High Blood Pressure Therapy" had excellent stability, unacceptable internal consistency, non-meaningful construct validity, and non-significant criterion validity. Although some of the psychometric properties of the Persian Hill-Bone's scale of "Compliance to High Blood Pressure Therapy" and the modified version were acceptable (i.e., repeatability), the Persian Hill-Bone scales failed to meet the standard of validity and internal consistency. Thus, judging its feasibility is difficult. It seems

that the Persian Hill-Bone Scale failed to help healthcare providers assess adherence to the hypertension treatment regimen appropriately. The results suggested that further study is needed to assess the medication-taking subscale's psychometric properties, which have previously been shown to have acceptable validity and reliability. Further studies also are needed to develop and test a more comprehensive and multi-dimensional tool to measure hypertension-adherence behaviors in the Iranian context.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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