



The psychometric properties of the Hypertensive Treatment Adherence Scale

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Original Article

Abstract

BACKGROUND: Hypertension (HTN) is a public concern and treatment adherence has a key role in its management. This study was conducted to develop and test the reliability and validity of the Hypertensive Treatment Adherence scale (HTA-scale).

METHODS: This was a cross-sectional and methodological study. After item generation using a qualitative study and literature review, the scale was developed. The psychometric properties of the scale were evaluated using face, content, construct, and criterion validity and reliability.

RESULTS: Data analysis showed that the HTA-scale had acceptable face and content validity. The scale had excellent stability [Intraclass correlation coefficient (ICC) = 0.74] and good acceptability and internal consistency (Cronbach's $\alpha = 0.76$). Exploratory factor analysis (EFA) showed that the HTA-scale consisted of 6 meaningful subscales including medication adherence and monitoring, adherence to safe diets, avoiding unsafe diets, self-medication, activity, and smoking. Participants in the controlled blood pressure group had significantly higher HTA-scale scores than the uncontrolled blood pressure group. At the cut-off point of 86, the scale had significant sensitivity and specificity.

CONCLUSION: All of the psychometric properties of the HTA-scale achieved the standard level and were sufficient to recommend this scale for patients with HTN.

Keywords: Hypertension; Treatment Adherence; Psychometrics; Scales

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Introduction

Hypertension (HTN) is one of the most common risk factors for cardiovascular diseases (CVDs) resulting in myocardial infarction (MI), cerebral events, renal and heart failures, and early death. In a meta-analysis conducted by Haghdoost et al., it was shown that 22% of 30-55 year old people and 50% of people older than 55 years were affected by HTN in Iran.¹

Failure to sufficiently control HTN further complicates this situation. Based on the report of the World Health Organization (WHO), more than half of patients with HTN discontinue their treatments in the first year of diagnosis and 80% of patients who continue their treatments, take prescribed medications.² Therefore, 75% of patients do not sufficiently control HTN due to poor adherence to treatment regimen.² Non-adherence to treatment regimen is considered as one of the most important clinical problems in the treatment and management of chronic diseases resulting in increased caring costs, rate of hospitalization, and early death.³

One of important obstacles to the improvement of adherence to treatment regimen is that it is difficult to measure adherence.

Several medication adherence instruments have been mentioned in published papers including the Hill-Bone Compliance to High Blood Pressure Therapy Scale, Morisky Medication Adherence Scale (MMAS), and Brief Medication Adherence Questionnaire (BMAQ), but such instruments have not been used and compared simultaneously in similar populations and the psychometric properties of these instruments have not been validated. However, there is no key standard questionnaire and each of these instruments is suitable for a special setting and scenario.

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The abovementioned instruments are not general questionnaires and most of them measure only medication adherence. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure recommends anti-hypertensive treatment and lifestyle modification for the prevention and treatment of HTN and focuses on non-medicinal interventions to control HTN. Moreover, weight loss, diet improvement, increased exercise, and stress and anger control are systematically effective on HTN. Therefore, adherence should be evaluated as a whole in relation to different aspects of treatment such as diet, exercise, and medication.⁴ The Treatment Adherence Questionnaire for Patients with Hypertension (TAQPH) was designed by Ma et al.⁴ in 2011 in China. The TAQPH contains the highest number of items among related questionnaires; thus, it might potentially provide more information for the research investigation. However, in clinical practice, it is necessary that a questionnaire contains the fewest possible items that could be acceptable to both health care professionals and patients. In addition, in the validation process of the TAQPH, its sensitivity, specificity, positive predictive value, and negative predictive value were not assessed. These items are important for using a scale in clinical practice.⁵ Nevertheless, this instrument has not been tested in other countries and it has not been validated.

It seems that there is no gold standard instrument for the evaluation of treatment adherence in patients with HTN.^{5,6} Therefore, considering the deficiencies and limitations of tools available throughout the world, it is necessary to perform some researches in this regard. The aim of this research was to develop and validate the Hypertensive Treatment Adherence Scale (HTA-scale).

Materials and Methods

This study with methodological design was conducted in educational hospitals of Kerman University of Medical Sciences, Kerman, Iran, and physician's offices. Kerman is the largest city in southeastern Iran with a population of 722,000. To develop a comprehensive scale, a qualitative content analysis and literature review were conducted to generate the item pool. The results of the qualitative content analysis are reported elsewhere in detail.⁷ According to the results, an 84-item pool was developed from participants' quotations. In several meetings among the research team, some items that were similar, redundant, or overlapped were omitted or integrated with other items. At this phase, the scale consisted of 36 items.

To enrich the scale items and to ensure that all aspects of adherence to HTN treatment were considered, a literature review was performed. The PubMed, ScienceDirect, Ovid, and Google Scholar databases were searched using the terms "treatment adherence", "treatment compliance", "treatment concordance", "medication adherence", "medication compliance", "medication concordance", "hypertension or high blood pressure", "questionnaire", "scale", "instrument", and "psychometric property", "test-retest reliability", "internal consistency", "Cronbach's alpha", "construct validity", "content validity", "face validity", "guidelines", "content analysis", and "qualitative study". The search was limited to English articles published online and no publication date restrictions were applied. In total, 147 articles were retrieved. From among these, the most relevant articles that could help us enrich the item pool were selected. At the end of the literature review, phase 9 items were added to the item pool. At the end of the item generation phase, the scale consisted of 45 items. A 5-point Likert scale ranging from 1 (not important) to 5 (completely important) was used for the scoring of items. Higher scores indicate a higher level of adherence to HTN treatment.

Face validity assessment: The opinions of 25 patients with HTN were asked about the relevancy of the scale items. The participants were older than 18 years and took at least 1 antihypertensive agent. Convenience sampling method was used. Patients with HTN, who were interested in participating in the study, were interviewed in regard with the scale items and their suggestions about the items and scale were recorded. Then, they were asked to complete the scale. Data were collected in one interaction with each patient separately between October, 2, 2014 and October, 16, 2014. Following the interviews, the research team analyzed all comments recorded during the scale administration using content analysis. Based on the results of content analysis, consensus was reached on all changes necessary in the scale. Then, the item impact method was used to determine the importance of each item. If the item impact score was above 1.5, the item was important and maintained in the scale for further evaluation.

Content validity assessment: In the first step, 21 experts were asked to write their comments on the fitness, simplicity, and comprehensiveness of each item individually. In the second step, the experts were asked to rate the necessity of each item [content validity ratio (CVR)] on a 3-point Likert scale (1: not necessary, 2: helpful but not necessary, 3: necessary). To determine the relevancy, simplicity, and clarity of

each item and the scale [content validity index (CVI)], the respondents were asked to grade each item on a 4-point Likert scale (1: not relevant, 2: need minor revision, 3: need major revision, 4: relevant). The experts consisted of physicians, nursing faculty members, and epidemiologists (21 experts) who were experts in their research field. This sampling was conducted from October, 27, 2014 to November, 30, 2014. The research team analyzed all experts' written comments using content analysis. According to the results of content analysis, consensus was reached on all changes made in the scale. To quantify agreement on the scale content, CVR and CVI were used.

According to the Lawshe table, when the total number of experts is 21, the cut-off point value is 0.42.⁸ The accepted standard in the literature for item-level CVI (I-CVI) and scale-level CVI (S-CVI) are 0.9 and 0.80, respectively.

Pilot study for the assessment of internal consistency: The third sample (pilot study) was collected to calculate internal consistency evidence and response rate in order to determine homogeneity of the HTA-scale and the appropriateness of the 5-point Likert scale selected for the scale. The participants consisted of 30 patients with HTN in cardiovascular units of 2 educational hospitals, and 3 cardiologists' and 2 nephrologists' offices in Kerman, Iran. Convenience sampling method was used. Patients with HTN were interviewed and were asked to complete the scale using the 5-point Likert scale. Data collection was conducted from December, 10, 2014 to December, 25, 2014. A coefficient value of higher than 0.7 was considered acceptable.⁹

Construct validity assessment: The fourth sample was collected to calculate construct and criterion validity, sensitivity and specificity, internal consistency, and practicability and acceptability of the HTA-scale. Using multistage random cluster sampling, 300 patients with HTN were selected. The selected patients were divided into 2 categories of in-patients and out-patients. Then, 150 subjects were selected from in-patient centers (13 hospital wards; cardiovascular, internal, and emergency wards considered as clusters) and 150 subjects were selected from out-patient centers (12 cardiologists' and nephrologists' offices, and 1 sub-specialty educational clinic considered as clusters). Sociodemographic data, such as age, gender, marital status, educational and occupational status, duration of HTN, duration of taking anti-hypertensive drugs, and having other diseases, were collected. In addition, blood pressure was measured using an aneroid sphygmomanometer (ALPK2, Japan) and the average of 2 measurements

taken 5 minutes apart was presented. Systolic and diastolic blood pressures were obtained from the right arm of the subjects using standard procedure. For illiterate individuals, interviews were used instead of the self-administration method. Data collection was performed from January, 01, 2015 to February, 30, 2015. Exploratory factor analysis (EFA) was conducted to verify the factorial design of the HTA-scale using principal axis factoring (PAF) with varimax rotation. 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.

Criterion validity assessment: To verify concurrent criterion validity, the difference in the HTA-scale score between patients with controlled and uncontrolled HTN was analyzed using t-test (data were distributed normally). Patients younger than 60 years of age who had blood pressure $\geq 140/90$ and 60-year-old or older patients who had blood pressure $\geq 150/90$ were considered as the uncontrolled HTN group. Moreover, patients who had a blood pressure lower than these ranges were considered as the controlled HTN group.^{10,11}

Sensitivity and specificity assessment: The sensitivity and specificity of the HTA-scale were calculated using receiver operating characteristic (ROC) curve analysis. An accuracy of 50-70% was considered as acceptable.⁹ Acceptability or practicability of the HTA-scale was assessed by calculating missing values and the average time needed to complete the scale. Furthermore, floor/ceiling effect was assessed. The amount of missing values and floor/ceiling effect should be less than 10% and 80%, respectively, in order that the scale obtains acceptability.

Stability assessment: The fifth sample was collected to determine the test-retest reliability of the HTA-scale. The scale was completed by 35 patients with HTN twice (with a 2-week interval). Patients with HTN were interviewed. The second data collection was conducted through telephone calls. Data collection was conducted from March, 05, 2015 to March, 25, 2015. The intraclass correlation coefficient (ICC) (two-way mixed) was used to assess the repeatability of the HTA-scale. To interpret the obtained coefficients, values above 0.7 were considered as excellent reliability.⁹ In this study, all analyses were performed using SPSS software (version 19.0, SPSS Inc., Chicago, IL, USA).

Ethical consideration: Kerman University of Medical Sciences approved this project (ethic code: K/93/580). After coordinating with the university,

the clinical centers, sub-specialty educational clinic, and physicians we provided with information for the subjects. The information addressed the objectives of the study, the confidentiality of the data, the anonymity of the participants, and their freedom to withdraw from the study at any time. Then, informed consent was obtained verbally.

Results

Content validity: According to the experts' comments, 1 item was divided into 2 separate items, 1 item was added to the scale, and 4 items were omitted

due to "conceptual overlap", and "lack of comprehensiveness or relevancy". In total, 39 items displayed acceptable (> 0.42) CVR scores, while the CVR scores of 4 items were below the accepted standard (-0.14 to 0.33). The I-CVI scores of all items (between 0.84 and 1) exceeded the accepted standard of > 0.80 . In addition, the S-CVI was 0.95 . At the end of the content validity phase, the HTA-scale contained 40 items. It should be noted that the research team decided to maintain the item "Do you eat votive foods if available?", which did not have an acceptable CVR score, because it was a context-based item (Table 1).

Table 1. Content validity ratio and content validity index scores of the Hypertensive Treatment Adherence scale (n = 21)

No	Items	CVR	CVI
1	Do you eat boiled foods?	0.81	1.00
2	Do you consume high fat food and animal fat?	0.71	0.92
3	Do you eat high fat dairy?	0.6	0.92
4	Do you eat votive food if available?	-0.14	0.84
5	Do you comply with a low salt diet?	0.81	0.92
6	Do you sprinkle salt on your meals?	0.43	0.95
7	Do you eat fast foods such as sandwiches and pizza?	0.71	0.92
8	Do you eat sugar, sugar cubes, or sweets?	0.81	0.93
9	Do you eat junk foods such as chips and cheese puff?	0.71	0.95
10	Do you eat canned foods?	0.62	0.93
11	Do you eat red meat less than before?	0.81	0.95
12	Do you eat eggs less than before?	0.81	0.95
13	Do you eat high fiber foods and vegetables daily?	0.9	0.97
14	Do you eat fruits daily?	0.71	0.97
15	Do you eat whole grain products such as barley bread daily?	0.81	0.94
16	Do you eat beans and cereals?	0.52	0.87
17	Do you sometimes fast?	0.33	0.92
18	Do you overeat?	0.81	0.95
19	Do you take your antihypertensive medication based on its prescription?	0.90	0.98
20	Do you take your antihypertensive medication irregularly?	0.33	0.89
21	Do you ever purchase and continue your previous antihypertensive medication without referring to your physician?	0.62	0.97
22	Do you use medications prescribed for other people with the same symptoms?	0.62	0.98
23	Do you sometimes stop taking your medication due to any reason?	0.90	0.95
24	Do you stop taking your medication without consulting with your physician?	0.71	0.95
25	Have you ever reduced or increased your medication?	0.33	0.95
26	Do you take your antihypertensive medications with or without having symptoms?	0.81	0.87
27	Do you take blood tests as regularly as prescribed by your physician?	0.90	1.00
28	Do you control your blood pressure weekly?	0.81	0.97
29	Do you go to your doctor to monitor your blood pressure status every 3-6 months?	0.90	1.00
30	Do you go to your doctor on pre-determined appointments?	0.81	0.98
31	Do you measure your weight every week?	0.81	0.98
32	Do you measure your waist circumference?	0.62	0.95
33	Do you do exercises such as walking, swimming, or cycling 4-7 days per week?	0.71	0.89
34	Do you exercise or walk for about 30-60 minutes on each exercise session?	0.81	0.95
35	Do you smoke cigarettes?	0.71	0.95
36	Do you consume traditional or industrial drugs such as opium, crack, or crystal?	0.71	0.98
37	Do you smoke hookah (shisha)?	0.71	0.97
38	Are you constantly exposed to cigarette and opium smoke?	0.81	0.95
39	Are you able to control your stress?	0.62	0.90
40	Are you able to control your anger?	0.71	1.00
41	Do you take psychiatric medications?	0.71	0.93
42	Do you drink coffee?	0.52	0.89
43	Do you drink alcohol?	0.71	1.00

CVR: Content validity ratio; CVI: Content validity index

Table 2. Internal consistency of the Hypertensive Treatment Adherence scale [pilot study (n = 30)]

No	Items	Cronbach's alpha if item is deleted	Corrected item-total correlation
1	Do you eat boiled foods?	0.76	0.22
2	Do you consume high fat food and animal fat?	0.76	0.17
3	Do you eat high fat dairy?	0.74	0.51
4	Do you eat votive food if available?	0.74	0.46
5	Do you comply with a low salt diet?	0.77	-0.09
6	Do you sprinkle salt on your meals?	0.76	0.21
7	Do you eat fast foods such as sandwiches and pizza?	0.75	0.28
8	Do you eat sugar, sugar cubes, or sweets?	0.74	0.43
9	Do you eat junk foods such as chips and cheese puff?	0.76	0.13
10	Do you eat canned foods?	0.76	0.02
11	Do you eat red meat less than before?	0.76	0.08
12	Do you eat eggs less than before?	0.77	-0.13
13	Do you eat high fiber foods and vegetables daily?	0.74	0.52
14	Do you eat fruits daily?	0.74	0.57
15	Do you eat whole grain products such as barley bread daily?	0.74	0.51
16	Do you eat beans and cereals?	0.76	0.15
17	Do you overeat?	0.75	0.41
18	Do you take your antihypertensive medication based on its prescription?	0.75	0.38
19	Do you ever purchase and continue your previous antihypertensive medication without referring to your physician?	0.75	0.26
20	Do you use medications prescribed for other people with the same symptoms?	0.77	-0.07
21	Do you sometimes stop taking your medication due to any reason?	0.75	0.31
22	Do you increase or decrease the dosage of your medication without consulting your physician?	0.76	0.10
23	Do you take your antihypertensive medications with or without having symptoms?	0.77	-0.07
24	Do you take blood tests as regularly as prescribed by your physician?	0.73	0.63
25	Do you control your blood pressure weekly?	0.75	0.31
26	Do you refer to your doctor to monitor your blood pressure status every 3-6 months?	0.74	0.53
27	Do you refer to your doctor on pre-determined appointments?	0.74	0.45
28	Do you measure your weight every week?	0.76	0.19
29	Do you measure your waist circumference?	0.76	-0.13
30	Do you do exercises such as walking, swimming, or cycling 4-7 days per week?	0.76	0.20
31	Do you exercise or walk for about 30-60 minutes on each exercise session?	0.75	0.34
32	Do you smoke cigarettes?	0.76	0.16
33	Do you consume traditional or industrial drugs such as opium, crack, or crystal?	0.75	0.46
34	Do you smoke hookah (shisha)?	0.76	0.06
35	Are you constantly exposed to cigarette and opium smoke?	0.75	0.33
36	Are you able to control your stress?	0.77	-0.24
37	Are you able to control your anger?	0.76	0.07
38	Do you take psychiatric medications?	0.76	0.19
39	Do you drink coffee?	0.76	0.20
40	Do you drink alcohol?	0.76	0.19

Face validity: In total, 7 items of the 45-item scale were revised according to respondents' comments. Of these items, 2 had an item impact scores below 1.5. The item impact scores of the other items ranged from 1.68 to 4.72. At the end of this phase, the research team decided to maintain all

items for the next phase (content validity), so no item was omitted at the end of the face validity phase.

Pilot study (Internal consistency and response rate) (Table 2): The value of Cronbach's α for the HTA-scale was 0.76. The HTA-scale item-total correlations ranged from -0.24 to 0.63.

Table 3. Demographic characteristics of the study participants (n = 300)

Quantitative variables		Mean ± SD
Age (year)		59.96 ± 12.12
Duration of hypertension (month)		57.40 ± 39.60
Duration of treatment for hypertension (month)		56.59 ± 37.55
Systolic blood pressure (mmHg)		130.20 ± 7.24
Diastolic blood pressure (mmHg)		87.92 ± 7.54
Qualitative variables		
Quantitative variables		n (%)
Gender	Female	150 (50.2)
	Male	149 (49.8)
Marital status	Single	4 (1.4)
	Married	194 (64.7)
	Divorced	11 (3.7)
	Widowed	86 (29.2)
Educational status	Illiterate	64 (21.8)
	Pre-diploma	114 (38.7)
	Diploma	74 (25.2)
	Bachelor's degree or higher	42 (14.3)
Occupation	Unemployed	30 (10.3)
	Employed	97 (33.3)
	Pensioner	74 (25.2)
	Housewife	91 (31.2)
Antihypertensive drugs	One drug	183 (63.3)
	Two drugs	94 (32.5)
	Three drugs	12 (4.2)
Having diabetes mellitus	Yes	47 (15.7)
	No	252 (84.3)
Having diseases other than diabetes	Yes	133 (44.5)
	No	166 (55.5)

SD: Standard deviation

The item-total correlations were 0.20 or greater for 22 items of the 40-item HTA-scale. To improve the Cronbach's α coefficient of the scale, 5 items that had negative item-total correlation were omitted and the internal consistency was recalculated. As a result, the Cronbach's α coefficient of the scale increased to 0.81. It should be noted that the research team decided to maintain the item "Do you comply with a low salt diet?", which had a negative item-total correlation, in the scale because of its importance.

Construct validity (Socio-demographic characteristics): In total, 300 patients with HTN were assessed. The response rate was more than 98%; 5 patients refused to participate in the study. The mean age of the patients was 59.96 ± 12.12 years. Nearly half of the participants were men (49.8%), 64.7% of the participants were married, less than 22% were illiterate, and 10.3% were unemployed. The mean duration of HTN was 57.4 ± 39.6 months. The mean duration of taking antihypertensive drugs was 56.59 ± 37.55 months. Moreover, 15.7% of the participants had diabetes, and 44.5% of the participants had other diseases (Table 3).

More than 80% of the participants had perfect

adherence to 3 items (28, 29, and 35). In addition, the lowest amount of adherence was related to the items on exercise (26 and 27) (Table 4).

Exploratory factor analysis: To verify the construct validity of the HTA-scale, PAF with varimax rotation was used. In the first step, Bartlett's and Kaiser-Meyer-Olkin (KMO) tests were used to verify the normal distribution of data and adequacy of sample size for EFA. The results of Bartlett's test were significant [$\chi^2 = 3705.36$; degree of freedom (df) = 595; $P < 0.001$] and the KMO coefficient was 0.775 that exceeded the accepted standard of > 0.7 . In the second step, PAF with varimax rotation was conducted and 10 factors with eigenvalues of > 1 were retrieved. The total variance explained by these 10 factors was 63.7%. According to the factor loading of > 0.4 , 3 items (2, 29, and 35) were not loaded in any factors. EFA was conducted again after omitting items 2, 29, and 35. In this stage, KMO coefficient was 0.788 and Bartlett's test was significant ($\chi^2 = 3422.07$; df = 496; $P < 0.001$). Nine factors with eigenvalues of > 1 were retrieved that explained 63.75% of total variance. According to the factor loading of > 0.4 , 5 items (3, 10, 11, 15, and 25) were not loaded in any factors.

Table 4. Distribution of the responses to the Hypertensive Treatment Adherence scale (n = 300)

No	Items	Missing (n)	Response [n (%)*]				
			No	Yes but rarely	Yes, occasionally	Yes, frequently	Yes, always
1	Do you eat boiled foods?	0	28 (9.3)	71 (23.7)	76 (25.3)	81 (27.0)	44 (14.7)
2	Do you consume high fat food and animal fat?	1	52 (17.4)	121 (40.5)	95 (31.8)	30 (10.0)	1 (0.1)
3	Do you eat high fat dairy?	4	38 (12.8)	114 (38.5)	89 (30.1)	45 (15.2)	10 (3.4)
4	Do you eat votive food if available?	1	22 (7.4)	86 (28.8)	64 (21.4)	90 (30.1)	5 (12.4)
5	Do you comply with a low salt diet?	0	12 (4.0)	49 (16.3)	85 (28.3)	96 (32.0)	58 (19.4)
6	Do you sprinkle salt on your meals?	0	96 (32.0)	118 (39.3)	61 (20.3)	17 (5.7)	8 (2.7)
7	Do you eat fast foods such as sandwiches and pizza?	1	119 (39.8)	95 (31.8)	63 (21.1)	21 (7.0)	1 (0.3)
8	Do you eat sugar, sugar cubes, or sweets?	1	53 (17.7)	69 (23.1)	56 (18.7)	74 (24.7)	47 (15.7)
9	Do you eat junk foods such as chips and cheese puff?	0	115 (38.3)	87 (29.0)	74 (24.7)	20 (6.7)	4 (1.3)
10	Do you eat canned foods?	1	85 (28.4)	104 (34.8)	82 (27.4)	24 (8.0)	4 (1.3)
11	Do you eat red meat less than before?	4	5 (1.7)	76 (25.7)	96 (32.4)	99 (33.4)	20 (6.8)
12	Do you eat high fiber foods and vegetables daily?	1	5 (1.7)	33 (11.0)	81 (27.1)	115 (38.5)	65 (21.7)
13	Do you eat fruits daily?	6	1 (0.3)	23 (7.8)	37 (12.6)	96 (32.7)	137 (46.6)
14	Do you eat whole grain products such as barley bread daily?	2	9 (3.0)	59 (19.8)	70 (23.5)	96 (32.2)	64 (21.5)
15	Do you eat beans and cereals?	1	4 (1.3)	52 (17.4)	72 (24.1)	106 (35.5)	65 (21.7)
16	Do you overeat?	7	107 (36.5)	103 (35.2)	59 (20.1)	14 (4.8)	10 (3.4)
17	Do you take your antihypertensive medication based on its prescription?	2	5 (1.7)	15 (5.0)	29 (9.7)	86 (28.9)	163 (54.7)
18	Do you ever purchase and continue your previous antihypertensive medication without referring to your physician?	4	61 (20.6)	75 (25.3)	74 (25.0)	48 (16.2)	38 (12.8)
19	Do you sometimes stop taking your medication due to any reason?	2	69 (23.2)	133 (44.6)	68 (22.8)	23 (7.7)	5 (1.7)
20	Do you increase or decrease the dosage of your medication without consulting with your physician?	4	182 (61.5)	59 (19.9)	30 (10.1)	22 (7.4)	3 (1.0)
21	Do you take blood tests as regularly as prescribed by your physician?	0	14 (4.7)	19 (6.3)	59 (19.7)	99 (33.0)	109 (36.3)
22	Do you control your blood pressure weekly?	1	18 (6.0)	74 (24.7)	70 (23.4)	55 (18.4)	82 (27.4)
23	Do you refer to your doctor to monitor your blood pressure status every 3-6 months?	3	9 (3.0)	47 (15.8)	78 (26.3)	77 (25.9)	86 (29.0)
24	Do you refer to your doctor on pre-determined appointments?	1	10 (3.3)	23 (7.7)	44 (14.7)	89 (29.8)	133 (44.5)

Table 4. Distribution of the responses to the Hypertensive Treatment Adherence scale (n = 300) (continue)

No	Items	Missing (n)	Response [n (%)*]				
			Response [n (%)*]	No	Items	Missing (n)	Response [n (%)*]
25	Do you measure your weight every week?	4	55 (18.6)	110 (37.2)	73 (24.7)	31 (10.5)	26 (8.8)
26	Do you do exercises such as walking, swimming, or cycling 4-7 days per week?	1	74 (24.7)	108 (36.1)	63 (21.1)	38 (12.7)	16 (5.4)
27	Do you exercise or walk for about 30-60 minutes each time?	3	59 (19.9)	130 (43.8)	74 (24.9)	28 (9.4)	6 (2.0)
28	Do you smoke cigarettes?	2	241 (80.9)	21 (7.0)	18 (6.0)	6 (2.0)	12 (4.0)
29	Do you consume traditional or industrial drugs such as opium, crack, or crystal?	0	263 (87.7)	15 (5.0)	12 (4.0)	5 (1.7)	5 (1.7)
30	Do you smoke hookah (shisha)?	3	235 (79.1)	41 (13.8)	19 (6.4)	1 (0.3)	1 (0.3)
31	Are you constantly exposed to cigarette and opium smoke?	3	102 (34.3)	94 (31.6)	61 (20.5)	20 (6.7)	20 (6.7)
32	Are you able to control your anger?	8	21 (7.2)	56 (19.2)	67 (22.9)	70 (24.0)	78 (26.7)
33	Do you take psychiatric medications?	2	177 (59.4)	37 (12.4)	25 (8.4)	25 (8.4)	34 (11.4)
34	Do you drink coffee?	1	124 (41.5)	53 (17.7)	60 (20.1)	40 (13.4)	22 (7.4)
35	Do you drink alcohol?	1	286 (95.7)	11 (3.7)	1 (0.3)	1 (0.3)	-

*Valid percent

We decided to omit these items and perform EFA again. In this stage, the KMO coefficient was 0.792 and Bartlett's test was significant ($\chi^2 = 3017.49$; $df = 351$; $P < 0.001$). Eight factors with eigenvalues of > 1 were retrieved that explained 66.66% of total variance. According to the factor loading of > 0.4 , all items were loaded in the 8 factors. Among 27 items, 3 items (16, 32, and 33) did not have a meaningful pattern in the factors they were loaded on; we could keep these items based on the presumption that these items are hidden conceptual aspects of the variable (factor) or omit them if their interpretation was difficult.¹² Therefore, we decided to omit these non-meaningful items and reanalyze the rest of the items. In this stage, The KMO coefficient was 0.791 and Bartlett's test was significant ($\chi^2 = 2685.26$;

$df = 276$; $P < 0.001$). Eight factors with eigenvalues of > 1 were retrieved that explained 70.58% of total variance. According to the factor loading of > 0.4 , all items were loaded in the 8 factors.

The scree plot begins to level off after the second and third, and slightly after the sixth and eighth factors. Therefore, to determine the best number of factors, EFA was conducted again by limiting PAF to a fixed number of extractions (2-factor, 3-factor, and then, 6-factor extraction) and their results were assessed. The 6-factor extraction was the most meaningful among them. The 6-factor extraction explained 61.69% of total variance. Excluding item 5, all other items were loaded in the factors with a meaningful pattern. At the end of EFA, 12 items were omitted and the HTA-scale contained 23 items (Table 5).

Table 5. Rotated factor matrix of the Hypertensive Treatment Adherence scale

No	Items	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6
		Medication adherence and monitoring	Adherence to safe diets	Avoiding unsafe diets	Self-medication	Activity	Smoking
17	Do you take your antihypertensive medication based on its prescription?	0.56					
21	Do you take blood tests as regularly as prescribed by your physician?	0.70					
22	Do you control your blood pressure weekly?	0.62					

Table 5. Rotated factor matrix of the Hypertensive Treatment Adherence scale (continue)

No	Items	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6
		Medication adherence and monitoring	Adherence to safe diets	Avoiding unsafe diets	Self-medication	Activity	Smoking
23	Do you refer to your doctor to monitor your blood pressure status every 3-6 months?	0.76					
24	Do you refer to your doctor on pre-determined appointments?	0.64					
1	Do you eat boiled foods?		0.64				
4	Do you eat votive foods if available?		0.45				
5	Do you comply with a low salt diet?		0.56				
12	Do you eat high fiber foods and vegetables daily?		0.50				
13	Do you eat fruits daily?		0.56				
14	Do you eat whole grain products such as barley bread daily?		0.61				
7	Do you eat fast foods such as sandwiches and pizza?			0.71			
8	Do you eat sugar, sugar cubes, or sweets?			0.73			
9	Do you eat junk foods such as chips and cheese puff?			0.70			
34	Do you drink coffee?			0.45			
18	Do you ever purchase and continue your previous antihypertensive medication without referring to your physician?				0.57		
19	Do you sometimes stop taking your medication due to any reason?				0.70		
20	Do you increase or decrease the dosage of your medication without consulting your physician?				0.69		
26	Do you do exercises such as walking, swimming, or cycling 4-7 days per week?					0.86	
27	Do you exercise or walk for about 30-60 minutes each time?					0.84	
28	Do you smoke cigarettes?						0.72
29	Do you smoke hookah (shisha)?						0.40
30	Are you constantly exposed to cigarette and opium smoke?						0.79
Eigenvalue		4.80	3.72	1.85	1.71	1.45	1.28
Percentage of explained variance		20.01	15.50	7.71	7.11	6.05	5.31

Factor loads > 0.40 are mentioned.

Table 6. Correlations between the Hypertensive Treatment Adherence scale score and its subscales

Factors	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Total
Factor 1	1						
Factor 2	0.30*	1					
Factor 3	0.10	0.30*	1				
Factor 4	0.29*	-0.04	-0.23*	1			
Factor 5	0.27*	0.28*	-0.10	0.09	1		
Factor 6	0.09	0.22*	0.21*	0.04	0.12*	1	
Total	0.66*	0.77*	0.38*	0.26*	0.45*	0.46*	1

*P < 0.050

In addition, the correlations between HTA-scale score and each dimension ranged from 0.26 to 0.77 and the correlations of each dimension with other dimensions ranged from 0.04 to 0.33 (Table 6). Note that, in order to calculate factor analysis, missing values were replaced with means.

The final HTA-scale included 23 items and respondents were easily able to complete it. The mean time for completing the scale was 9 ± 3.48 minutes (range: 2 to 22 minutes). The time for completing the scale was more than 15 minutes in only 15 patients. The missing values varied between 0% and 2% (mean = 0.61%). Of the 23 items of the scale, only 1 item ("do you smoke?") had floor/ceiling effect.

Criterion validity: The results of independent t-test showed a significant difference in the HTA-scale score between the controlled hypertension group and uncontrolled hypertension group (Table 7).

Sensitivity and specificity: To calculate the ROC curve, the missing values were replaced with their median. Controlled/uncontrolled hypertension was considered as golden standard. The area under the ROC curve was 0.57 [confidence interval (CI): 0.50-0.63] that was significant ($P = 0.048$). On the point of 85.5, the sensitivity and specificity of the scale were 57.2% and 52.5%, respectively. In addition, on the point of 86.6, the sensitivity and specificity of the scale were 60% and 50%, respectively. Therefore, we decided to choose the midpoint of these two numbers, i.e., the point of 86, which had sensitivity and specificity values of 59% and 51%, respectively. According to this cut-point, values ≤ 86 and values > 86 were, respectively, considered as signifying low adherence and high adherence to HTN treatment regimen.

Reliability (Internal consistency and test-retest): The Cronbach's α for total sample size

($n = 300$) and ICC for a sample size of 35 patients were assessed. The value of Cronbach's α for the whole scale was 0.76. The Cronbach's α values of the subscales were within the range of 0.66 to 0.87. The results of test-retest with a 2-week interval showed that the repeatability and stability of the scale was excellent (ICC: 0.74; CI: 0.55-0.86) (Table 8).

Discussion

As a result of the psychometric results of the HTA-scale, a 23-item scale was achieved. This scale includes the 6 dimensions of medication adherence and monitoring, self-medication (8 items), adherence to safe diets, avoiding unsafe diets (10 items), exercise (2 items), and smoking (3 items). The scores resulted from the scale ranged between 23 and 115. Reverse scoring was used in 10 items (2, 3, 4, 15, 16, 17, 18, 21, 22, and 23). In the present study, the CVR, CVI-I, and CVI-S of the HTA-scale were good and acceptable. In this study, 6 factors were extracted using PFA with varimax rotation which explained 61.69% of total variance; the higher the percentage of the variances is, the higher the validity of the model is.¹³ Pituch and Stevens suggested a total variance of higher than 75%,¹⁴ but Henson and Roberts questioned whether a total variance of higher than 75% was rational for psychological researches or not.¹⁵

They stated that the total amount of variance is reduced when the number of items is high.¹⁵ Moreover, the correlation of different dimensions with the total score should be high and their correlation with each other should be low. High dependency of the different dimensions of the instrument on each other results in co-linearity, and using two or more dependent factors is not correct.^{4,9}

Table 7. Comparison of the Hypertensive Treatment Adherence (HTA) scale score between controlled and uncontrolled hypertension

Variable Group	Hypertensive Treatment Adherence scale score		Independent t-test/df	P
	Frequency	Mean \pm SD		
Controlled hypertension	120	85.69 \pm 9.82	t = 2.12 df = 298	0.035
Uncontrolled hypertension	180	83.21 \pm 10.19		

SD: Standard deviation; df: Degree of freedom

Table 8. Internal consistency of the Hypertensive Treatment Adherence scale and intraclass correlation

No	Items	Cronbach's alpha if item is deleted (n = 300)	Corrected Item-Total Correlation	ICC (CI) (n = 35)	P
17	Do you take your antihypertensive medication based on its prescription?	0.76	0.32	0.72 (0.51-0.85)	< 0.001
21	Do you take blood tests as regularly as prescribed by your physician?	0.75	0.45	0.91 (0.83-0.95)	< 0.001
22	Do you control your blood pressure weekly?	0.76	0.21	0.85 (0.72-0.92)	< 0.001
23	Do you refer to your doctor to monitor your blood pressure status every 3-6 months?	0.74	0.51	0.85 (0.72-0.92)	< 0.001
24	Do you refer to your doctor on pre-determined appointments?	0.74	0.56	0.43 (0.71-0.92)	0.005
Medication adherence and monitoring subscale			0.81	0.84 (0.71-0.92)	< 0.001
1	Do you eat boiled foods?	0.74	0.52	0.90 (0.82-0.95)	< 0.001
4	Do you eat votive foods if available?	0.75	0.33	0.76 (0.57-0.87)	< 0.001
5	Do you comply with a low salt diet?	0.74	0.49	0.54 (0.26-0.74)	0.004
12	Do you eat high fiber foods and vegetables daily?	0.75	0.39	0.91 (0.83-0.95)	< 0.001
13	Do you eat fruits daily?	0.75	0.46	0.72 (0.52-0.85)	< 0.001
14	Do you eat whole grain products such as barley bread daily?	0.75	0.41	0.86 (0.74-0.93)	< 0.001
Avoiding unsafe diets subscale			0.76	0.78 (0.60-0.88)	< 0.001
7	Do you eat fast foods such as sandwiches and pizza?	0.75	0.48	0.20 (-0.14-0.49)	0.120
8	Do you eat sugar, sugar cubes, or sweets?	0.77	0.09	0.48 (0.17-0.7)	0.002
9	Do you eat junk foods such as chips and cheese puff?	0.76	0.29	0.28 (-0.05-0.56)	0.047
34	Do you drink coffee?	0.78	-0.02	0.92 (0.84-0.96)	< 0.001
Avoiding unsafe diets subscale			18.00	18.00	18.00
18	Do you ever purchase and continue your previous antihypertensive medication without referring to your physician?	0.78	-0.10	0.87 (0.77-0.93)	< 0.001
19	Do you sometimes stop taking your medication due to any reason?	0.76	0.24	0.94 (0.89-0.97)	< 0.001
20	Do you increase or decrease the dosage of your medication without consulting your physician?	0.77	0.13	0.74 (0.54-0.86)	< 0.001
Self-medication subscale			0.69	0.96 (0.92-0.98)	< 0.001
26	Do you do exercises such as walking, swimming, or cycling 4-7 days per week?	0.76	0.32	0.92 (0.84-0.96)	< 0.001
27	Do you exercise or walk for about 30-60 minutes each time?	0.75	0.35	0.73 (0.53-0.86)	< 0.001
Activity subscale			0.87	0.88 (0.77-0.94)	< 0.001
28	Do you smoke cigarettes?	0.76	0.32	0.90 (0.82-0.95)	< 0.001
30	Do you smoke hookah (shisha)?	0.76	0.31	0.87 (0.76-0.93)	< 0.001
31	Are you constantly exposed to cigarette and opium smoke?	0.76	0.23	0.82 (0.67-0.91)	< 0.001
Smoking subscale			0.66	0.90 (0.81-0.95)	< 0.001

ICC: Intraclass correlation coefficient; CI: Confidence interval

The correlation of the subscales of the HTA-scale with its total score was high, while the correlation of each dimension with other dimensions was low. This shows that the HTA-scale has good construct validity.

Criterion validity determines the accuracy and sufficiency of the score of an instrument as a key standard.¹⁶ In the present study, patients' blood pressure was selected as the key standard (controlled and uncontrolled blood pressure). Although the scale score significantly differed between patients with controlled and uncontrolled hypertension, the difference was not high. This might be due to the key standard selected for criterion validity in this study. Generally, there is no key standard for measuring treatment adherence in patients with HTN, but 2 criteria have been used to determine criterion validity in previous studies. Some studies have considered patients' HTN as the key standard,¹⁷⁻²⁰ and others have used different instruments and questionnaires such as the MMAS.⁴ The most common scales related to medication and treatment adherence in patients with HTN are the MMAS and Hill-Bone Compliance to High Blood Pressure Therapy Scale.

The psychometric properties of both scales have been measured in Iran by Dehghan et al.¹⁰ and Dehghan et al.²¹; neither of them had enough validity in the population under consideration. In addition, the TAQPH was assessed in Iran and it was found to have good reliability and validity, but based on the Iranian context the original 28-item scale was reduced to a 25-item scale.²² This scale has not been assessed in other countries and has not been generally used. The criterion validity of the MMAS has been confirmed in different studies,^{20,21,23-27} while the criterion validity of the Hill-Bone Compliance to High Blood Pressure Therapy Scale has only been confirmed in some studies.²⁸ Its criterion validity was not confirmed in the studies by Dehghan et al.,¹⁰ Koschack et al.,¹⁸ and Lambert et al.²⁸

Lambert Considering its cut-off point of 86, the sensitivity and specificity of the HTA-scale was moderate. The mean amount of sensitivity and specificity can be affected by some factors such as the key standard, sampling, and completion precision of the scale. In the present study, the scale in the validity evaluation phase contained 35 items.

In addition, the mean age of the participants was 60 years; therefore, the length of the scale and old age of the subjects might have had negative effects on scale completion precision, and resulted in low

sensitivity and specificity. In previous studies, the sensitivity and specificity of the MMAS has been reported as 11-93% and 31-73%, respectively.^{20,21,23-27} Furthermore, the sensitivity and specificity of the Brief Medication Questionnaire (BMQ) in different studies have been reported within the ranges of 70-100% and 27-100%, respectively.²⁹⁻³¹

Cronbach's α coefficient of the HTA-scale was acceptable. However, a high alpha value does not always indicate high internal homogeneity because Cronbach's α is strongly affected by the number of items.^{32,33} In the present study, the α value of some subscales of the HTA-scale was less than 0.7. The low alpha values of the "self-medication" and "smoking" subscales can be explained by the effect of the number of items on alpha value. The reliability of some similar scales such as MMAS has been reported to be within the range of 0.4 to 0.83 in different studies.^{20,21,23-27} Moreover, the reliability of the Hill-Bone Compliance to High Blood Pressure Therapy Scale has been reported to be within the range of 0.44 to 0.84 in different studies.^{10,17,28}

Apparently, the reliability of each scale may be different in different populations and countries. Therefore, it is better to use a context-based scale, such as the HTA-scale, to assess treatment adherence in an Iranian community.

The content of the HTA-scale is to some extent different from the other scales available for studying adherence in patients with HTN. Except for the TAQPH⁴ and Hill-Bone Compliance to High Blood Pressure Therapy Scale¹⁷ that have similarities with the HTA-scale, other instruments presented in this field only focus on medication adherence. Although the psychometric properties of most of these instruments have been measured in patients with HTN, they do not assess other aspects of treatment of patients with HTN completely. Therefore, other aspects of treatment of patients with HTN have not been considered in such instruments.^{3,4,17,19,29,34,35} The HTA-scale measures medication adherence based on regular consumption of medication according to the physician's prescription, taking medication higher or lower than the prescribed dosage without referring to the physician, and long-term medication consumption. One of the most important differences of the subscales of the HTA-scale with that of other scales regarding medication adherence is that medication adherence and self-medication are two completely different dimensions in the HTA-scale. Regarding adherence to lifestyle

modifications, the HTA-scale measures issues related to disease monitoring, safe diet, and avoiding unsafe foods and activity, and smoking. Regular blood pressure measurement, regular physician referrals, and periodic examinations based on the doctor's prescription are issues related to disease monitoring. Except for the Hill-Bone Compliance to High Blood Pressure Therapy Scale that includes 2 items related to physician referrals, the other instruments do not focus on disease monitoring.^{4,17}

According to the guidelines for controlling and measuring blood pressure, physician referrals and health status management are components of the anti-hypertensive treatment regimen and patient should adhere to them.^{4,35-38}

In the present study, subscales related to adherence to diet concentrate on issues such as reduction of salt, fat, fast food, sugar, coffee, and nuts and increasing of fruits, vegetables, and whole grains. The HAT-scale is compatible with the latest available guidelines.^{39,40} All recommendations regarding a safe diet are present in the HAT-scale, except consumption of low fat dairy products. According to available guidelines, the weight and waist circumference of the patient should be measured to determine weight gain because maintaining body weight within the normal range [Body mass index (BMI): 18.5-24.9; waist circumference of less than 102 cm in men and less than 88 cm in women] is recommended for the reduction of blood pressure. In order to control weight, dietary regimen and increased exercise are recommended.^{39,40} Weight gain has a direct relationship with high consumption of sugar products, junk food, high fat products, and high-energy foods.⁴¹⁻⁴⁵ Since high consumption of sugar and junk food increases weight that leads to HTN, items related to sugar, junk food, and fast food were included in the HAT-scale. Presence of such items in the scale can implicitly reflect on patient's adherence to weight management.⁴⁶⁻⁵⁰ Although the reduction of salt, fat, and cholesterol has been emphasized in the Hill-Bone Compliance to High Blood Pressure Therapy Scale,¹⁷ other recommendations related to dietary regimen have not been considered in this scale.^{4,51} The HTA-scale and TAQPH were similar in their detailed assessment of dietary adherence,⁴ but the subscale of dietary adherence differed between the HTA-scale and TAQPH in that the items related to safe dietary adherence and avoiding unsafe foods are placed in two separated dimensions in the

HTA-scale. Therefore, the amount of adherence to each dimension can be measured separately because each dimension can be considered as a scale.^{4,52}

Exercise was another dimension of the HTA-scale. This subscale measures the frequency of doing exercises such as walking, swimming, or cycling per week. Evidences indicate that mean intensity aerobic exercises reduce blood pressure in healthy people and those with HTN. Moreover, studies have shown that resistance exercises with higher intensity are not more effective on blood pressure than moderate intensity exercises.^{39,40,53,54} Guidelines available on the management and treatment of HTN recommend moderate intensity exercises, such as walking, cycling, and swimming, 4-7 days per week for 30-60 minutes.^{40,41} Except for the questionnaire designed by Ma *et al.*, other treatment adherence instruments have not considered the measurement of exercise in patients with HTN.⁴

The last subscale of the HTA-scale is smoking. The items of this subscale measure behaviors such as cigarette smoking, hookah (shisha), or exposure to cigarette and opium smoke. Although the role of smoking or being exposed to smoke have been confirmed in CVDs,⁵⁵ the direct role of smoking in HTN has not yet been confirmed. Some studies suggest that the prevalence of HTN is higher among people who smoke or are exposed to smoke compared to other people.⁵⁶⁻⁵⁹ Studies also indicated that hookah increases blood pressure.⁶⁰⁻⁶² Therefore, due to the increasing application of hookah,⁶³⁻⁶⁵ 1 item related to this topic was included in the HTA-scale. Among the instruments available for treatment adherence in patients with HTN, the Hill-Bone Compliance to High Blood Pressure Therapy Scale did not pay attention to smoking and only 1 item was dedicated to this topic, but no items to exposure to smoke or being a passive smoker, in the TAQPH.^{4,17} However, in the present study, issues related to smoking have been addressed in detail.

Based on guidelines on the treatment and management of HTN, reduction of alcohol consumption is one of the most important behaviors that patients should adhere to. Moreover, these guidelines recommend that stress be reduced and psychosomatic diseases be addressed in patients with HTN (whose blood pressures may have been increased by stress).^{39,40,63} In the present study, the omission of the item related to alcoholic drinks was predictable because most Iranian people are Muslims and in Islam alcoholic drinks are forbidden.

According to a systematic review, acute stress is probably not a risk factor for HTN, while chronic stress and non-adaptive response to stress are more likely the causes of sustained elevation of blood pressure.⁶⁶ However, the benefit of specific stress-reduction techniques in patients with HTN remains unproven.⁶⁷ Concerning the lack of emphasis on stress control as a general strategy in guidelines for patients with HTN,⁶⁸ it seems that the omission of items related to stress has no major impact on the comprehensiveness of the HTA-scale.

Conclusion

Recently, treatment adherence in patients with HTN has received much attention. The clinical consequences of adherence are different because there is no suitable instrument to evaluate all treatment aspects such as taking medication and lifestyle in patients with HTN. Therefore, it is important for health providers to correctly measure treatment adherence in these patients. Based on the obtained results, a new scale was designed to measure adherence in patients with HTN.

The psychometric properties of the HTA-scale showed that this scale has suitable internal consistency and stability. Furthermore, the HTA-scale has an acceptable face validity, and content validity ratio and index. In addition, the content validity index of the total scale was very good. The results of factor analysis indicated that this scale included the 6 dimensions of medication adherence and monitoring, self-medication, adherence to safe diets, avoiding unsafe diets, exercise, and smoking. The mean score of the scale significantly differed between the controlled and uncontrolled HTN groups, which illustrates the acceptable criterion validity of the scale.

The HTA-scale had 59% sensitivity and 51% specificity at the cut-off point of 86. Moreover, the scale had a very good acceptability. The results showed that the HTA-scale is valid for use in research investigations and clinical centers.

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Conflict of Interests

Authors have no conflict of interests.

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