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Elaboration and validation of instrument to assess adherence to hypertension treatment

ABSTRACT

OBJECTIVE: To elaborate and validate an instrument of adherence to treatment for systemic arterial hypertension, based on Item Response Theory.

METHODS: The process of developing this instrument involved theoretical, empirical and analytical procedures. The theoretical procedures included defining the construct of adherence to systemic arterial hypertension treatment, identifying areas involved and preparing the instrument. The instrument underwent semantic and conceptual analysis by experts. The empirical procedure involved the application of the instrument to 1,000 users with systemic arterial hypertension treated at a referral center in Fortaleza, CE, Northeastern Brazil, in 2012.. The analytical phase validated the instrument through psychometric analysis and statistical procedures. The Item Response Theory model used in the analysis was the Samejima Gradual Response model.

RESULTS: Twelve of the 23 items of the original instrument were calibrated and remained in the final version. Cronbach's alpha coefficient (α) was 0.81. Items related to the use of medication when presenting symptoms and the use of fat showed good performance as they were more capable of discriminating individuals who adhered to treatment. To ever stop taking the medication and the consumption of white meat showed less power of discrimination. Items related to physical exercise and routinely following the non-pharmacological treatment had most difficulty to respond. The instrument was more suitable for measuring low adherence to hypertension treatment than high.

CONCLUSIONS: The instrument proved to be an adequate tool to assess adherence to treatment for systemic arterial hypertension since it manages to differentiate individuals with high from those with low adherence. Its use could facilitate the identification and verification of compliance to prescribed therapy, besides allowing the establishment of goals to be achieved.

DESCRIPTORS: Patient Compliance. Antihypertensive Agents, administration & dosage. Medication Adherence. Hypertension, prevention & control. Questionnaires. Validation Studies.

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INTRODUCTION

Systemic hypertension (SH) is recognized as a significant public health problem with advances in identifying risk factors, early diagnosis, use of extensive drug treatments and educational campaigns to change lifestyles. In spite of this, it is a disease which is difficult to control and maintaining pressure within the recommended limits is not satisfactory. This evinces the problem of poor adherence to treatment.[4]

It is estimated that around 50.0% of individuals living with chronic disease do not follow their treatment properly.[5] In Malaysia, around 44.2% of hypertensive individuals followed their medical treatment properly.[8] In Chile, 21.6% of hypertensive individuals aged over 65 followed treatment.[10] In Brazil, the figures for control varied from 10.1% in Tubarao, SC, Southern Brazil, in 2003, to 52.4% in Sao José do Rio Preto, SP, Southeastern Brazil, from 2004 to 2005, considering population based studies of hypertensive individuals undergoing treatment, the control criteria of which were systolic and diastolic blood pressure levels of < 140/90 mmHg, respectively.[12]

Non-adherence occasions unnecessary adjustments to treatment regimens due to lack of positive response to treatment, increasing health care costs with higher rates of hospitalizations and treating complications. Moreover, it frustrates the efforts of health care professionals as it impedes their achieving objectives outlined for the health care of hypertensive individuals.[11,13]

Measuring adherence to SH treatment is a complex task. Different methods have been applied, there are different cutoff points and there is no method considered to be the gold standard and which represents the various dimensions involved in the process of adherence to treatment for this syndrome.[17]

The majority of methods used to evaluate adherence to SH treatment focus only on pharmacological treatment, and are also applied to other diseases. There is a gap to be filled.

One alternative for this measurement lies in item response theory (IRT). This theory includes a set of models for latent variables which propose to represent the relationship between the probability of a respondent giving a certain response to an item and their latent trait (characteristic of the individual which cannot be directly observed). This characteristic is measured using secondary variables related to it.[1]

The aim of this study was to draw up and validate a questionnaire on adherence to SH (QATSH) treatment based on IRT.

METHODS

Methodological study based on modern psychometrics (IRT) following the three procedures for constructing evaluation instruments: theoretical, empirical and analytical.[14,15]

At the theoretical stage, an integrative revision was constructed seeking to discover conditioning factors specific to the treatment of this syndrome. The constitutive and operational definitions were described and items drawn up for the measuring instrument based on the 12 criteria recommended by Pasquali (breadth, balance, behavior, simplicity, clarity, relevance, accuracy, modality, typicality, objectivity, variety and credibility).[15]

The first version of the instrument underwent semantic analysis to verify understanding of the items. Two groups of four individuals with different levels of schooling and of different ages were formed from individuals attending the *Centro Integrado de Hipertensão e Diabetes* (CIDH - Integrated Center for Hypertension and Diabetes) in Fortaleza, CE, Northeastern Brazil, in 2012. Changes were made to the phrasing of seven items to correct misunderstanding.

The proposal for the instrument was sent to a panel of experts for the phrasing and understanding of the items to be assessed, along with its conceptual pertinence regarding adherence to SH treatment. Five experts agreed to participate in the research: one doctor, two nurses, a nutritionist and a physical education professional. Each received a 20-item guide to evaluating the instrument. Evaluations were compared and suggestions with agreement of 80.0% or over were included.[15] Several items were excluded (2, 3, 4, 5, 14), others were reformulated (6, 7, 11, 12, 13, 15, 18) and new items included (12, 13, 14). After evaluation by the expert panel, QATSH consisted of 23 items, which were standardized regarding wording and domain.

The empirical procedure encompassed applying the instrument. QATSH was applied to 1,000 individuals with SH under treatment in the CIDH.

As this concerns constructing and validating an instrument using IRT, it was necessary to have a sample large enough to ensure respondents covering all the latent traits studied. There is no consensus on the ideal number of respondents.[1] However, large samples with ≥ 1,000 respondents have a greater chance of covering all latent traits studied.

The analytical stage aimed to validate the instrument using psychometric analysis and statistical procedures to verify the reliability, validity, estimated parameters of the items and level of adherence to SH treatment (parameters of the individuals) through an IRT model.

The internal consistency of the set of items was analyzed using Cronbach's alpha (α) and the *psych*[a] package of free software R[b] was used.

Factor analysis of the complete information was conducted based on response theory models to a multi-dimensional item (MIRT)[18] to understand the latent traits (or subjacent factors) associated with the instrument's response patterns. It is possible to evaluate correlation between the items and possible latent traits (or subjacent factors) through this analysis, enabling it to be verified whether all items belong to a one-dimensional model or whether there are subsets of items justifying other dimensions. This analysis was conducted using the *mirt*[3] package of free software R.[b]

The parameters of the items (*a* and *b*) were estimated using Multilog software[c] at the stage of calibrating the items. It was observed that there was convergence of the algorithm used in applying the estimation method. The Samejima[16] gradual response model was used to analyze the items.

The proficiency (θ) of the respondents was estimated using the marginal maximum likelihood (MML) method in two stages: parameters of abilities were separately integrated and the item parameters were estimated. When the item parameters were estimated, adherence to SH treatment (parameters of the individuals) were predicted.

Next, a scale was created for these latent traits. The anchor items were defined. An item is an anchor for level Z if it meets three conditions for Y< Z:[1] simultaneously

a) $P(U = 1 \mid \theta = Z) \geq 0{,}65$;

b) $P(U = 1 \mid \theta = Y) < 0{,}50$;

c) $P(U = 1 \mid \theta = Z) - P(U = 1 \mid \theta = Y) \geq 0{,}30$.

Given the difficulty in meeting all of these conditions, it was decided to be more flexible with these criteria and consider the anchor level that which met two conditions of those described above, as well as considering probability of > 60.0% in determining the anchor level of the scale.

The values for the item parameters (*a, b*) and for scores for adherence to SH treatment were estimated on the same metric in the scale with mean 0 and standard deviation (SD) 1.0. These values were transformed using mean 100 and SD 10, i.e., scale (100,10) to improve the comprehensibility of the results.

The study was approved by the Research Ethics Committee of the *Universidade Estadual do Ceará* (UECE), Process 11517971-2. All participants signed an informed consent form.

RESULTS

It was possible to construct a theoretical explanation and definition of the domain of the construct from an integrative review of the domains that influence adherence to SH treatment (Table 1). The 20 initial QATSH items were drawn up based on this definition.

The QATHAS had Cronbach's alpha (α) of 0.81.

The first factor explained 22.4% of total variance, evidencing a dominant factor.

The initial 23-item instrument underwent calibration. However, the algorithms of these items did not converge and alterations were necessary in response categories and items were excluded.

Items referring to medication, salt, fat, sweets and physical exercise remained in the initially proposed response categories. Items referring to medication dosage and times remained with four response categories, whereas that referring to white meat intake remained with two response categories.

Items referring to homemade remedies, cigarettes, illegal drugs, alcohol, fruit and vegetable consumption, weight, attending appointments, stress, complications and hospitalization during treatment were excluded from the final analysis. Their presence did not permit convergence of the estimation algorithm, as well as having low parameter *a* values (parameter of discrimination being very low, i.e., not discriminating hypertensive individuals with low adherence to SH treatment from those with high (Annex)).

Table 2 shows estimates of the parameters of the items, discriminating the dimensions of analysis, the 12 QATSH items and the *a* parameters (parameter of discrimination), b_2, b_3, b_4 and b_5 (parameters of difficulty) for categories 2, 3, 4 and 5 of the Likert scale. It is assumed that the data follow normal distribution, with μ = 0 and s = 1, i.e., scale (0.1) for initial determination of the parameters.

The QATSH was shown to have high error (curve in red) from level 0.5 of the scale onwards, compared with the information curve (Figure).

The scale is based on ten of the twelve QATSH items based on the previously described anchor levels. The initial instrument had items including all of the dimensions

[a] Revelle W. Psych: procedures for psychological, psychometric, and personality research. Evanston; 2010 [cited 2012 May 24]. Available from: http://cran.univ-lyon1.fr/web/packages/psych

[b] R Development Core Team. R: a language and environment for statistical computing. Version 2.13.2.Vienna: R Foundation for Statistical Computing; 2011.

[c] Thissen D, Chen W, Bock R. Multilog, version 7 [computer software]. Lincolnwood: Scientific Software International; 2003.

Table 1. Theory of the construct of adherence to systemic hypertension treatment, summary based on integrative review. Fortaleza, CE, Northeastern Brazil, 2012.

Concept adopted	Dimensionality
The degree of matching between user behavior and the prescription of health care professionals, involving both pharmacological and behavioral measures, with everyone involved in the process responsible for treatment.	Adherence to SH treatment is a multi-dimensional phenomenon determined by the junction between four dimensions: user; disease/treatment; health care service and environment.
	User: refers to the individual being treated for hypertension. Encompasses sociodemographic and economic variables, knowledge, attitudes, beliefs, perceptions, expectations and alcohol and cigarette use.
	Disease and treatment: encompasses variables related to the presence of diseases associated with cardiovascular risk factors, medications, time since onset of the disease, altered blood presure values, diet, physical activity and use of alternative therapies.
	Health care services: represent the place where systemic hypertension treatment takes place and is related to variables concerning health care professional-user relationship, quality of service provided, access, educational activities, provision of medication.
	Environment: refers to the wider context in which the users find themselves. Encompasses variables related to interaction with the environment, familial and social support and control over the external environment.

involved. The item referring to the environmental dimension was excluded during calibration as it did not allow convergence of estimates of items. The scale included items referring to three domains: disease/treatment, user and health care services.

When responding to the QATSH, in contrast to questionnaires using classical test theory, the result is not obtained from adding up points or scores. The calculation is made using a mathematical formula which uses the values of the parameters of the items (*a* and *b)* and of a constant. A free web site was set up and made available[d] containing access to the instrument and to the results. On this site, each health care professional can enter the responses of users examined and see the level of the scale (Table 3) at which each respondent is situated. Levels of adherence vary between 60 and 110, i.e., hypertensive individuals with lower adherence reach 60, while those who adhere more are located at level 110.

DISCUSSION

The grouping of the response categories and the exclusion of certain items during calibration show the difficulty of constructing items with high parameters of discrimination. The items were constructed following rigorous scientific methodology, based on theoretical knowledge of the latent trait studied and meeting basic construction criteria.[14,15] In spite of this, some of them had poor discriminatory power and had to be eliminated. Drawing up instruments requires paying attention to the construction of the items, clarity of approach and focus on the latent trait to strengthen discriminatory power and produce items with high *a* parameters.

The lack of convergence may be due to the following factors: the item being poorly drawn up, low number of respondents, not discriminating those who adhered to treatment from those who did not, the item being incompatible with the dimension of analysis or a combination of these factors.

Items related to non-medical treatment (6 to 11) stood out in the exclusion. An alternative for this result is reformulating the items to make them more discriminatory, i.e., possessing a greater quantity of psychometric information and better discrimination.

A curious, and apparently contradictory, finding was the exclusion of the item referring to the figure for blood pressure (BP), as this value is a direct way of knowing if it is being controlled (clinical response). This may be explained by it being an isolated measure, representing just one moment in time. Moreover, the procedure for measuring AP is vulnerable to error, as it should be done properly, e.g., with the patient appropriately prepared, using a standardized technique and calibrated equipment.[6]

The majority of respondents did not use homemade remedies, cigarettes, illegal drugs or alcohol, meaning there was no convergence of the estimation algorithm. An alternative for convergence would be to apply these items to hypertensive users who did use these substances and have respondents for all response categories.

Regarding the interpretation of the *a* parameter, discrimination of the item, values of > 0.6 are acceptable. The higher the *a* value, the higher the item's discriminatory power.[1] None of them had values inferior to the acceptable value for this parameter (Table 2), suggesting that the items remaining in the final instrument were able to

[d] Rodrigues MTP, Moreira TMM. Questionário de adesão ao tratamento da hipertensão arterial sistêmica. Fortaleza, 2012. Available from: www.qathas.com.br

Table 2. Estimation of the parameters of the instrument items assessing adherence to systemic hypertension treatment. Fortaleza, CE, Northeastern Brazil, 2012.

Items	*a*	b_2	b_3	b_4	b_5
01 – Medication use	0.698	-4.816	-2.186	-0.687	0.250
02 – Medication dose	0.939	-4.510	-2.807	-2.005	
03 – Medication time	0.882	-3.805	-1.729	-1.045	
04 – Symptom	1.910	-2.842			
05 – Routine pharmacological treatment	1.507	-2.560			
06 – Salt intake	1.436	-2.378	-1.653	-0.207	
07 – Fat intake	1.770	-2.300	-1.627	-0.465	
08 – White meat consumption	0.768	-3.301			
09 – Sweets and sugary drink consumption	1.163	-2.777	-1.985	-0.556	
10 – Physical exercise	0.715	0.736	1.347	4.602	
11 – Routine non-pharmacological treatment	0.956	0.126			
12 – Attending appointments	1.173	-3.510			

discriminate individuals with better adherence to SH treatment from those with poorer adherence.

Items referring to medication performed well when some kind of symptom was felt (4) and for fat intake (7), as they were better at discriminating individuals adhering to SH treatment compared to those who did not.

Many hypertensive users only used their medication when they had symptoms of high pressure. Thus, they did not adhere satisfactorily to treatment, as anti-hypertension medicine should be taken continuously, whether there are symptoms or not. For those hypertensive individuals with a satisfactory level of adherence to treatment, medication was taken daily, without being associated with the appearance of any symptom. This context explains the higher discriminatory power of this item. Leão & Silva et al[9] (2013) stated that poor adherence was associated with not having symptoms, as "not feeling anything" is understood to be absence of illness, making regular medication use unnecessary.

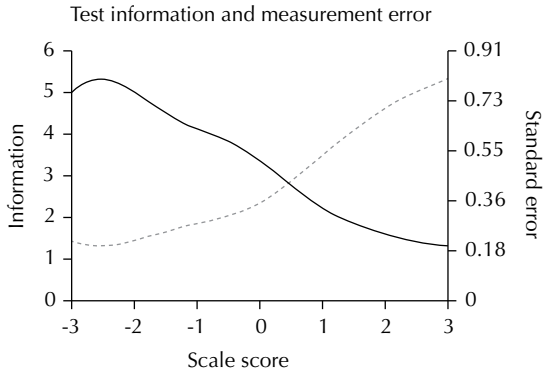

Figure. Full information curve of the instrument of adherence to systemic hypertension treatment. Fortaleza, CE, Northeastern Brazil, 2012.

Low calorie food with low saturated fat, cholesterol and total fat content is recommended, as is eating a diet rich in fruit and vegetables. This has a significant impact on reducing AP, as well as reducing biomarkers of cardiovascular disease.[6] However, it can be difficult to follow this kind of diet, given the availability of ready prepared foods, generally with high calorie content. The cultural context in which hypertensive individuals find themselves also affects the intake of food with a high fat content. There are few individuals who manage to abandon fatty foods and follow the diet recommended for hypertensive individuals, so this is an item with good discrimination.

Items with lower power of discrimination were those concerning having neglected to take medication at some point (1) and white meat intake (8). The expression "have you ever" in item 1 can refer to an isolated episode or to a frequent practice. Even those with the best adherence can neglect to take their medicine at some point, explaining the poorer discriminatory power of this item.

Hypertensive individuals reported two reasons for high white meat consumption: it being cheaper than red meat and preference. Mentioning the fact that white meat was healthier was the exception, and this explains the poor discriminatory power of this item.

The difficulty of the item was measured by parameter *b*, indicating the position on the scale at which the item has the greatest information. The higher the value of parameter *b*, the greater the difficulty of the item. The items which were most difficult to respond to were those regarding doing physical exercise (10) and routinely following non-pharmacological treatments (11), referring to non-pharmacological treatment. As they are the items to which it is most difficult to respond satisfactorily, they tend to be more representative of individuals who adhere to treatment.

Table 3. Scale of adherence to systemic hypertension treatment. Fortaleza, CE, Northeastern Brazil, 2012.

Level on the scale	Description
60	At this level, hypertensive individuals do not take hypertension medication at least once a week. Nor do they take the prescribed dose at least once a week.
70	Hypertensive individuals at this level neglect to take their hypertension medication at the correct time at least once a week. They attend appointments.
80	At this level, hypertensive individuals neglect to take the prescribed dose at least once a month. They take their medication irrespective of having symptoms or not, routinely follow medical treatment and reduce salt and fat intake and sweets and sugary drink consumption by a third.
90	Hypertensive individuals at this level neglect to take their medication at the correct time at least once a month: they reduce salt, fat and sweets and sugary drinks by half.
100	At this level, hypertensive individuals neglect to take their hypertension medication at least once a year and consume practically no fat, sweets or sugary drinks.
110	From this level upwards, hypertensive individuals do not neglect to take their hypertension medication, eat practically no salt and routinely follow non-pharmacological treatments.

Doing aerobic exercise (especially isotonic), which should be complemented by resistance exercises, helps to lower AP and is recommended for preventing and treating SH. The recommendation is to develop the habit of doing regular aerobic exercise, such as walking for 30 minutes a day, three times/week for prevention, and daily for treatment.[6] A peculiarity of SH is that it mainly affects older adults, as shown in this study: 66.1% of those interviewed were aged 60 or over, leading to limitations imposed by age. Many hypertensive individuals also suffer from other health problems, including sequelae of other diseases impeding them from doing exercise.

Urban violence was mentioned as a factor that makes it more difficult to do regular physical activity in public areas or areas near the home.

Despite the lifestyle changes occurring in the Brazilian population, habits that are harmful to health, such as sedentarism, still predominate among users with hypertension.[2,7] Regular physical activity is an obstacle to adherence to SH treatment.[7,9]

Another item to which it was difficult to respond satisfactorily was routinely following non-pharmacological treatment (11). This is a very broad item and covers all non-pharmacological measures recommended for treating SH: weight control, eating patterns, moderate alcohol and tobacco consumption, physical exercise and controlling stress. As it covers many changes in lifestyle, it is an item which is more difficult to fulfill. Studies have shown the difficulty in following non-pharmacological treatment.[2,7,9,12]

Items referring to salt intake (6), consumption of sweets and sugary drinks (9) and attending appointments (12) had intermediate *b* parameter values compared with other items in the QATSH, with a medium level of discrimination and difficulty.

Not all of the proposed domains were kept in the final instrument. Some items were excluded as the estimates did not converge, or for having very low *a* parameter values, i.e., for not discriminating hypertensive individuals with poor adherence to treatment from those with high adherence. The need remains to create and validate items which include all domains involving adherence to SH treatment.

The QATSH was shown to be better at measuring poor adherence to treatment than high adherence. This study contributes to the current Brazilian and world context, characterized by high rates of poor adherence to SH treatment. It is essential that there is an instrument to better identify users with low adherence to treatment, as they are the ones who need to modify their behavior and improve adherence to SH treatment.

Drawing up a list of goals with the patient, according to their individual score, is an innovation of this instrument. Patients at level 70 on the scale know that they need to be more rigorous in taking their medication on time in order to ascend to level 80 on the scale. This facilitates patients' understanding and improves the health care professional's degree of control and decision making. The health care team can make use of a variety of strategies to present the results to the patient, as well as the positive reinforcement of being able to demonstrate improvements in adherence on the scale.

Both the patient and the health care professional perceive advances in treatment with greater clarity, as it facilitates detecting and measuring fulfillment of prescribed treatment, as well as making it viable to establish goals to be achieved. This differential was possible through the use of IRT which, in contrast to the classical test teory (TCT), uses (θ) constructed item by item, rather than only the sum of correct items.

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The authors declare that there is no conflict of interest.

ANNEX

Annex. Questionnaire on adherence to treatment of systemic hypertension (QATSH). Fortaleza, CE, Northeastern Brazil, 2012.

ITEMS
1. Have you ever neglected to take your SH medication?
( ) yes, at least 1 time per day
( ) yes, at least 1 time per week
( ) yes, at least 1 time per month
( ) yes, at least 1 time per year
( ) no
2. Have you ever neglected to take the prescribed dose of your SH medication?
( ) yes, at least 1 time per day
( ) yes, at least 1 time per week
( ) yes, at least 1 time per month
( ) yes, at least 1 time per year or never
3. Have you ever neglected to take your SH medication at the correct time?
( ) yes, at least 1 time per day
( ) yes, at least 1 time per week
( ) yes, at least 1 time per month
( ) yes, at least 1 time per year or never
4. Do you use SH medication only when you have some kind of symptom?
( ) yes ( ) no
5. Has following pharmacological SH treatment become part of your routine?
( ) no ( ) yes
6. When you started SH treatment, did you decrease your salt intake?
( ) no
( ) yes, by a third
( ) yes, by half
( ) yes, I practically do not eat salt
( ) I've always used little salt
7. When you started SH treatment, did you decrease your fat intake?
( ) no
( ) yes, by a third
( ) yes, by half
( ) yes, I practically do not eat fat
( ) I've never eaten much fat
8. When you started SH treatment, did you begin to consume white (poultry, fish) meat rather than red?
( ) no
( ) yes, I eat white meat up to 3 times a week
( ) yes, I eat white meat 4 or more times a week
( ) I always ate white meat at least 4 times a week
9. When you started SH treatment, did you decrease intake of sweets and sugary drinks?
( ) no
( ) yes, by a third
( ) yes, by half
( ) yes, I practically do not consume sweets or sugar
( ) My diet has never included many sweets or much sugar

Continue

Continuation

10. When you started SH treatment, did you begin to do at least 30 minutes of physical activity (walking, swimming, cycling)?

( ) no

( ) yes, fewer than 3 times a week

( ) yes, 3 to 5 times a week

( ) yes, more than 5 times a week

( ) I have always done physical exercise at least 3 times a week.

11. Has following non-pharmacological SH treatment become part of your routine?

( ) no ( ) yes

12. Do you attend appointments for SH treatment?

( ) no ( ) yes