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The development and validation of the Factors Affecting Adherence Scale in Greece

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Abstract

Background: Despite hypertension is a major cardiovascular risk factor; only few patients are adherent to therapy. Therefore, it is essential the acknowledgement of factors affecting adherence.

Aims: the development and validation of a scale assessing factors affecting patients' adherence to therapeutic regimen.

Methods: From a pool of questions derived from a review of literature, 23 items included in the scale. Participants indicate their degree of agreement with each statement on a five-point Likert scale. Data collection for this research occurred between February 2013 and March 2013.

Results: The sample included 225 patients with mean age 67.8 (SD=11.9) years old. The Cronbach alpha values were 0.78 for the entire scale, 0.62 for the medication regimen, 0.76 for medical appointments and 0.60 for non-medication regimen. The coefficients for the second application were 0.75, 0.62, 0.77 and 0.52 respectively. One item excluded. Following the test-retest analysis, a high positive correlation was observed between the total scores of the two applications ($r=0.825$, $P<0.001$).

Conclusion: The tool is appropriate to assess factors affecting adherence in self-behaviours.

Keywords: Instrument Development; Hypertension; Factors; Adherence; Self-behaviour

Introduction

Adherence to a therapeutic regimen is defined as the extent to which a patient follows the instructions which health care providers give to him [1]. There are six divisions of adherence: medication regimen, smoking, alcohol, physical activity, diet and keeping medical appointments. The major problem in management of diseases and especial chronic health conditions is patients' poor adherence in therapeutic regimen. Warren-Findlow *et al.* found that only 58.6% of people with hypertension are adherent to medication therapy, 25% to dietary recommendations, 75% do not smoke, 33% to alcohol recommendations and only 52% exercise any physical activity [2]. Additionally, Ahmad et al. proved that half of patients with diabetes mellitus type 2 are characterized as non-adherents [3]. From all the above emerged the necessity to investigate the factors which affect patients' adherence.

According to World Health Organization (WHO), the main factors which affect adherence are associated with patients' socioeconomical status, the healthcare system, the chronic health condition, the therapeutic regimen and other factors related to patient [4]. From the literature review through electronic databases many studies were found which examine the impact of above factors in patients' adherence, however the majority of them investigate only the impact of demographic characteristic of patients, their beliefs, knowledge and attitudes about medication and their health condition on patients' level of adherence. In addition, only few studies negotiate the impact of all other factors, which the WHO defines like economic status, accessibility to healthcare

system, relationship between patients and health care providers or with caregivers. However none of these studies used a valid and reliable scale in order to assess the impact of the examined factors in level of adherence. Therefore, it is obvious the gap of knowledge in this field.

Despite long-standing efforts to increase the level of adherence in therapeutic regimen among patients with chronic diseases, poor adherence still remains a huge burden in management of chronic health conditions [5-6]. The WHO reported that the level of adherence ranges from 40% to 70% in developed countries, whereas the percentage is significant lower in developing countries (26-43%) [4]. The inadequate adherence leads to significant deteriorations in patients' lives, like poor quality of life, high rate of hospitalizations, experience of depression and anxiety and loss of patients' social roles [7-9].

In an effort to improve the level of adherence, a large number of studies conducted in order to identify factors affecting adherence to therapeutic regimen [10-13]. Although many of these studies focused on factors that adversely impact patients' level of adherence, factors contributing to the improvement of adherence have received less attention [14].

The present study aimed to develop a scale which examines both factors that improve and deteriorate level of adherence in therapeutic regimen. In addition, we aimed to investigate the validity and reliability of the developed scale. More specific, it is examined the impact of socioeconomic factors, such as age, sex, marital and economic status. Also, it is checked out the association between adherence and the relationship patient-health care provider and patient-caregiver. Finally, it is questioned the impact of factors related to health care system, like the level of accessibility and cost of health care services, in adherence.

Materials and Methods

Establish Face and Content Validity of Factors Affecting Adherence Scale (FAAS)

Recent data from the literature and reports from the WHO and international health associations were reviewed for the development of the scale. During the development of the Factors Affecting Adherence Scale (FAAS), a 33–item scale was prepared by authors. Each item was a full sentence that entitled with a five-point Likert scale from totally disagree (0 points) to totally agree (4 points). The items questioned the socioeconomic status, level of accessibility to healthcare services, relationship between patients and health care providers as well as the relationship between patients and caregivers. All items assess the impact of their presence in level of adherence in therapeutic regimen during the last three month. More specific, it is assessed 5 domains of adherence: medication regimen, diet, smoking, physical activity and medical appointments.

In an effort to assess the content validity of the scale, so as to identify whether items were or not representative of factors affecting adherence, the opinions of seven experts (two physicians, two cardiologists, one primary care physician and two experts of psychometric) were requested via an assessment form. The experts were asked to grade each item as "essential," "useful but inadequate" or "unnecessary". The expert opinions were taken into consideration, and 10 items were excluded from the scale. All items were evaluated in terms of clarity and relevant changes were made.

At a next stage, 10 persons who did not have research backgrounds were also asked to provide feedback on the questionnaire in terms of its language and clarity. These participants were not included in the final sample of the study.

Study Design and Selection

The study conducted in a General Hospital in Athens between February 2013 and March 2013. The sample consisted of 225 men and women who visited the hospital since they had an appointment for routine blood test. The sample size was calculated in order the ratio item question/ participant to be 1/10 (Galanis, 2013). The inclusion and exclusion criteria were: 1) at least 18 years old of age, 2) Caucasian, 3) absence of psychiatric disorder, 4) absence of a life threatening disease, 5) willingness to participate in the study and written informed consent and 6) able to read and write Greek.

Data collection

At the first assessment, the study authors, who were trained on the questionnaire, collect their data through face-to-face interview. At second stage, researchers communicated with participants after one month via phone in order the sample to re-answer the questionnaire (test-retest reliability). Research team decided to distribute the tool one month later of the first time so as to avoid the possibility participants to recall their answers (memory effect) [15]. The FAAS was applied to all participants, and demographic characteristics (age, gender, education level, occupational status and marital status) were evaluated. Patients needed 15 to 20 min to answer all items of the scale.

Ethics

Approval by the local committee (certification number: 17929/19-7-13) and written consent from the participants were received prior to participants' enrollment in the study. The investigation conforms to the principles outlined in the Declaration of Helsinki.

Statistics

The mean, standard deviation (SD), median and interquartile range was used in order to describe the quantitative data, whereas percentage (%) and frequencies (N) were used for qualitative variables. In order to determine the qualifications measured by the

scale, construct validity was assessed by factor analysis. Factor analysis adequacy was demonstrated by applying the Kaiser-Meyer-Olkin (KMO) test to the scale. Because the KMO result was >0.50, factor analysis was performed Cam, M.O. 2010 Qualitative and quantitative steps on attitude scale construction. The Cronbach alpha coefficient was calculated for the reliability analysis of each sub-dimension. For each factor, a Cronbach coefficient alpha value of >0.59 and <0.95 was considered acceptable [16-17]. Correlation analysis was used to assess internal consistency reliability. The correlation coefficient must not be negative or below 0.20 [18]. Qualitative and quantitative steps on attitude scale development. Pearson's rank correlation coefficient was used to measure the level of agreement between responses at test and re-test. In addition, a linear regression model with level of adherence as the dependent variable and one independent variable (such as socioeconomic factors, relationship between patient-health care providers) was used to assess a relationship between level of adherence and the added independent variable. The level of significance was at 0.05. The analysis was conducted via SPSS 19.0.

Results

Distribution of the study group according to various demographic and medical characteristics

The sample included 225 patients with mean (±SD) age 67.8 (11.9) years old. The 44% of participants was men and 56% women. According to the educational level, 29.3% had primary level education, whereas 54.9% of the sample had secondary educational level. The majority of participants was retired and married. The demographic characteristic of the sample are showed in Table 1.

		N	%
Gender	Male	48	42,9
	Female	64	57.1
Age (SD)		67.5 (11.7)	
Education level	Primary	170	30.4
	Compulsory	130	23.2
	Secondary	260	46.4
Marital status	Unmarried	3	2,7
	Married	105	93.8
	Divorced	1	0.9
	Widowed/widow	3	2.7
Occupational status	Household	26	23.2
	Retired	64	57.1
	Officer worker	13	11.6
	Manual labor	9	8.0

Table 1: Demographic characteristics of the sample

Construct Validity

Exploratory factor analysis

The KMO and Barlett tests were applied before evaluating the results of exploratory factor analysis. The KMO measurement of sampling adequacy was 0.70 and Barlett test results were quite significant (χ^2=3837.51, df=253, p=0.000). Later, we used exploratory factor analysis to guide the factor structure. Principal components factoring was performed. In the analysis excluded one item, since there was not any variance. A minimal factor-item correlation of 0.40 was set for inclusion of an item in a factor [19]. The results of the factor analysis are presented in Table 2 and 3.

Factor	Factor Loading
Health System	
Item A1	0,638
Item A5	**0,553**
Item A6	0,682
Item A11	0,882
Item A12	0,888
Economical	
Item A2	0,841
Item A4	0,600

Factor	Factor Loading
Relationship Patient-Health Care Provider	
Item A7	0,718
Item A8	0,693
Item A9	0,788
Item A10	0,746
Item A13	0,858
Item A14	0,849
Item A15	0,506
Item A16	0,788
Item A17	0,767
Item A18	0,641
Item A19	0,790
Relationship Patient-CareGiver	
Item A3	0,686
Item A20	0,875
Item A21	0,879
Item A22	0,819

Table 2: Factor loading for FAAS

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22	Q23
Q1	1,000																						
Q2	0,589	1,000																					
Q3	0,578	,856	1,000																				
Q4	0,381	,411	0,357	1,000																			
Q5	0,408	,246	0,247	0,320	1,000																		
Q6	0,330	,123	0,107	0,482	0,475	1,000																	
Q7	0,372	,199	0,201	0,395	0,352	0,415	1,000																
Q8	0,340	,214	0,209	0,402	0,409	0,456	0,664	1,000															
Q9	0,323	,206	0,192	0,442	0,346	0,429	0,770	0,688	1,000														
Q10	0,294	,147	0,137	0,318	0,219	0,390	0,646	0,556	0,757	1,000													
Q11	0,347	,560	0,531	0,431	0,246	0,151	0,129	0,101	0,094	0,086	1,000												
Q12	0,365	,578	0,536	0,448	0,261	0,162	0,128	0,126	0,107	0073	,982	1,000											
Q13	0,099	,163	0,176	0,192	0,244	0,205	0,040	0,114	0,018	0,079	,374	,399	1,000										
Q14	0,154	,210	0,202	0,178	0,247	0,173	0,015	0,100	0,007	0,131	,370	,395	,939	1,000									
Q15	0,030	-,101	0,121	0,013	0,016	0,171	0,036	0,003	0,057	0,164	,085	,059	,190	,189	1,000								
Q16	0,046	-,030	0,124	0,126	0,265	0,110	0,274	0,366	0,280	0,104	,001		,122	,131	-,072	1,000							
Q17	0,184	,259	0,172	0,294	0,159	0,170	0,404	0,363	0,428	0,308	,232		,057	,088	,098	,490	1,000						

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22	Q23
Q18	0,0 87	-,1 88	0,2 26	0,0 56	0,1 07	0,0 36	0,0 16	0,0 07	0,0 28	0,0 44	,0 43		,2 11	,2 12	,2 84	-,2 87	-,0 92	1,0 00					
Q19	0,0 66	-,0 66	0,0 96	0,0 66	0,1 07	0,1 68	0,0 64	0,1 13	0,0 16	0,1 01	,0 79		,1 55	,1 11	,1 67	,0 95	,1 49	,0 79					
Q20	0,1 00	-,0 69	0,0 62	0,1 00	0,0 55	0,1 75	0,2 83	0,3 37	0,2 57	0,3 68	,0 49		,0 63	,0 41	,1 56	,0 24	,1 60	,4 30		1,0 00			
Q21	0,1 92	-,0 84	0,0 09	0,0 87	0,2 12	0,0 50	0,1 31	0,0 54	0,0 92	0,1 73	,0 68		,1 40	,1 57	,2 05	-,0 76	,0 04	,1 81		,1 08	1,0 00		
Q22	0,0 57	-,0 51	0,0 59	0,0 29	0,0 04	0,0 66	0,0 74	0,0 13	0,0 74	0,1 64	,0 07		,2 58	,2 59	,1 05	,0 54	,0 13	-,0 67		-,1 41	,7 86	1,0 00	
Q23	0,0 21	,0 34	0,1 48	0,0 08	0,0 04	0,0 41	0,0 34	0,0 30	0,0 39	0,1 64	,0 08		,1 40	,1 58	,0 64	,0 87	,1 20	-,1 59		-,2 59	,6 16	,7 53	1,0 00

Table 3: Inter-item correlation matrix for FAAS

Instrument reliability

The Cronbach alpha values were as follows: 0.78 for the entire scale, 0.62 for the medication regimen, 0.76 for medical appointments and 0.60 for non-medication regimen. The coefficients for the second application were 0.75, 0.62, 0.77 and 0.52 respectively.

Test –Retest Reliability

Following the test-retest, a high positive correlation was observed between the total scores of the two applications using Pearson's rank correlation analysis (r=0.825, P<0.001). The scores of the FAAS in a scatter plot are listed in Figure 1.

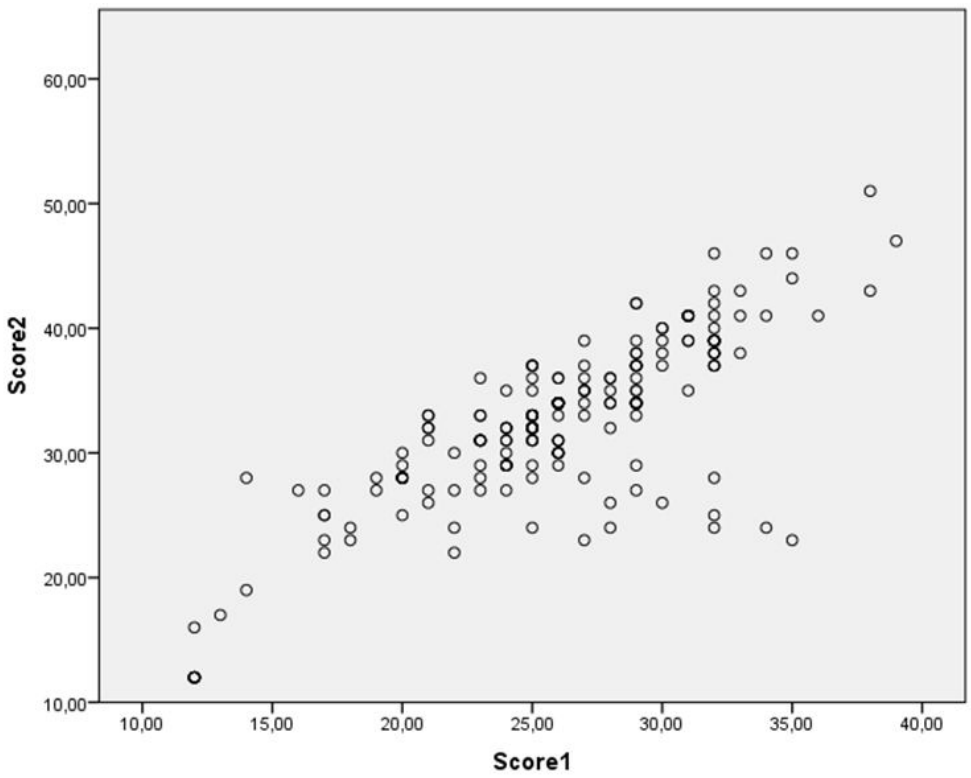

Figure 1: Scatter plot of the FAAS test-retest score

Discussions

The survey clearly demonstrates that the developed scale «Factors Affecting Adherence Scale» is a valid and reliable scale in order to use it in patients with chronic diseases. In addition, it is essential that the FAAS differentiates from all the other available scales, since FAAS examines not only factors which act inversely to patients; adherence, but also factors which improve the level of adherence. For instance, the relationship between patient and health care provider and the relationship between patient and care giver.

The level of adherence in hypertension is constantly decreasing leading to major impairment in patients' lives and a majority of factors plays significant role in patients' non-adherence. The knowledge of factors affecting adherence will contribute to understand the reasons that patients are not adherent to therapeutic regimen. In addition, health care providers will be able to recognize the presence of these factors and to provide educational intervention in order to eliminate these factors.

The present study was conducted to develop a scale that accurately reflects culturally consistent social norms and viewpoints in an attempt to determine factors which may affect patients' adherence to therapeutic regimen. Validity is the extent to which an instrument measures exactly what it is supposed to measure without mistaking it with another issue15. Reliability is the extent to which an instrument gives consistent results in repeated measurements under similar conditions. The main difference between these meanings is that reliability is not sufficient on its own for validity, since scales could be reliable but not necessarily valid. On the other hand, the method of factor analysis is used to group interdependent variables into a specific cluster [15].

Twenty-three items divided into 5 sub-dimensions were determined following the factor and reliability analysis of FAAS. The Cronbach alpha coefficient should be higher than 0.59 and lower than 0.95 [16]. The reliability analysis indicated that Cronbach alpha coefficients for entire scale was 0.78 and higher than 0.52 for all sub-dimensions. Corrected item-total score correlation coefficients were calculated to estimate the contribution of items to the conceptual construct of the scale. Items with a corrected item-total score correlation coefficient of >0.40 are regarded as highly discriminative [19]. The minimum corrected item-total score correlation coefficient of the items was 0.55, therefore all corrected item-total score correlation coefficient were above of >0.40. In addition, the test-retest reliability was used in order to assess scales' stability. According to test-retest, we applied the scale twice to the same sample under the same conditions with a time interval of one month. Statistically significant results for the test-retest reliability assessment of FAAS found during the analysis. More specific, the correlation coefficient was above of 70 which indicates that the scale is stable over time ($r = 0.825$; $p < 0.001$).

However, the main limitation of the present study was the lack of valid and reliable scale which negotiates the same issue; therefore it was not possible to examine the concurrent validity of the scale [19].

Conclusions

The validity analysis ended that FAAS is an appropriate scale for assessing the factors which affects patients' adherence to therapeutic regimen. In addition, the reliability analysis determined that FAAS collects data accurately and is a repeatable scale.

FAAS is the first scale that will be used in future studies in order to enhance patients' level of adherence to therapeutic regimen, not only among people with hypertension but also among people with other chronic conditions, since FAAS is not a disease specific tool. The main contribution will be the optimal management of chronic conditions and the decrease of mortality and health care cost.

The psychometric testing and validation of an instrument assessing factors which affect patients' level of adherence to therapeutic regimen contribute to assessing the provided health care services and the relationship between patients and care givers. Health care providers will have the opportunity to amplify their role in patients' adherence in therapeutic regimen and develop a relationship based on honesty and respect. Simultaneously, it is mentioned how important is the role of care givers on patients' adherence resulting in optimum management of their health condition. Thus, it is significant nurses assign a leading role to patients' family in order to achieve the best nursing management.

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