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Development, reliability and validity of health action process approach questionnaire for predicting treatment adherence among Iranian hemodialysis patients

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ABSTRACT

Introduction: End-stage renal disease (ESRD) is an advanced stage of chronic kidney disease requiring hemodialysis (HD). The long-term efficacy of HD in ESRD patients highly depends on treatment adherence.

Objectives: This study aimed to validate the health action process approach (HAPA) questionnaire to predict treatment adherence in HD patients.

Patients and Methods: This cross-sectional study was conducted in in three teaching and two private hospitals in Shiraz during 2018. A total of 220 patients with ESRD under HD were selected using convenience sampling method. Furthermore, the validity, clarity, and comprehensiveness of the questionnaire were validated by a group of patients and experts. Then the exploratory factor analysis (EFA) was performed, and the reliability was determined using Cronbach's alpha. Internal consistency was assessed using test-retest method (one-month interval) and calculating intra-class correlation coefficient (ICC) index.

Results: Content validity index (CVI) and content validity ratio (CVR) were obtained 0.98 and 0.95 respectively indicating adequate content validity. Six constructs (risk perception, action self-efficacy, behavioral intention, planning, maintenance self-efficacy and recovery self-efficacy) were extracted using EFA. These constructs explained 51.4% of total variance. The Cronbach's alpha of different constructs ranged from 0.68 to 0.82. Furthermore, the ICC ranged from 0.67 to 0.78 indicating an acceptable internal consistency.

Conclusion: The HAPA questionnaire is a valid and reliable tool for assessing treatment adherence in HD patients. Further studies are recommended on larger sample sizes and other Iranian populations.

Implication for health policy/practice/research/medical education:
Regarding the role of assessment tools in the success of educational interventions, the results of this research can provide a framework for nurses, health education staff and other stakeholders to validate the efficiency of educational interventions.

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Original Article

Introduction

According to the World Health Organization (WHO), long-term therapy adherence rate is lower than 50% in patients with chronic illnesses in developing countries (1). Patients with end-stage renal disease (ESRD) poorly adhere to health care recommendations such as diet/fluids

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restriction regimens, prescribed medications, and dialysis sessions (2,3).

Treatment adherence is critical to achieve a favorable clinical outcome in patients under hemodialysis (HD). However, the importance of this concept has not been well delineated in Eastern countries, especially among Asians (4). It has been reported that 80% of dialysis patients had poor adherence to at least one therapeutic procedure (5). In another report, 50% of HD patients had complete adherence to multiple treatments (6).

Poor adherence to HD reduces patients' quality of life and brain function and leads to depression, lung edema and chronic anemia (7), as well as higher mortality rate and financial costs on health care systems (8,9). The role of psychological factors has been suggested as the determinants predicting non-adherence behavior in HD patients; however, this factor has not been established (1). Some of these psychological determinants include individual beliefs (10), patient's perception from therapeutic efficiency (11), lack of motivation (12), and self-efficacy and coping skills (13). Therefore, it is possible to improve the efficiency of educational interventions by employing behavioral modification theories and models incorporating the above-mentioned psychological factors. (14,15). Accordingly, behavioral modification theories such as social cognitive theory (16), health belief model (17), and planned behavior theory (18) have long been utilized to assess treatment adherence behavior in HD patients. Nonetheless, the outcomes have been unsatisfactory. Therefore, it is recommended to recruit other multi-construct theoretical frameworks such as health action process approach (HAPA) to predict treatment adherence behavior.

The HAPA is the most comprehensive behavioral modification model covering a wide spectrum of psychological determinants. This model has been used to develop treatment adherence assessment tools in HD patients. The HAPA model consists of two motivational and volitional aspects. The first aspect (i.e. pre-intention) includes three constructs as risk perception, outcome expectancy, and action self-efficacy. The second aspect (i.e. post-intentional) consists of action and coping planning, maintenance self-efficacy and recovery self-efficacy constructs (19,20). The HAPA model has been used to assess adherence to treatment and other health behaviors such as cardiac rehabilitation programs (21), physical activity protocols in patients with schizophrenia, adherence to dietary regimens in adolescents (20,22), and oral hygiene behavior (23). These studies have suggested the HAPA model as a functional and effective framework to predict individuals' health behaviors. In accordance, the HAPA -based questionnaire can maximize the effectiveness of educational interventions.

Objectives

To our best knowledge, no HAPA-based questionnaire is available to assess treatment adherence in HD patients. The purpose of this study was to develop and validate a HAPA-based questionnaire as a tool for evaluating treatment adherence behavior in Iranian HD patients.

Patients and Methods

Study design

This cross-sectional study was conducted in HD wards of five hospitals (three teaching and two private) located in Shiraz, the largest city in southern Iran.

Inclusion and exclusion criteria

The inclusion criteria were age ≥18 years old, verified diagnosis of ESRD, undergoing HD for at least three months, ability to listen and answer, no evidence of cognitive disability, willing to participate in the study and signing a written informed consent form. Being transferred to another hospital, undergoing kidney transplantation, hospitalization in the intensive-care unit and death were considered as exclusion criteria.

Sampling and procedures

A total of 226 HD patients were selected through convenience sampling method from February 2018 to June 2018. During the study, six patients were excluded due to kidney transplantation and being transferred to other hospitals. Finally, questionnaires were completed by face to face interviews which lasted an average time of 30 minutes (20 minutes for collecting the data and 10 minutes for answering patients' questions).

Item development procedure

The questionnaire was developed based on the HAPA constructs and through comprehensive literature review and group discussions with the participation of health education experts. Primary items were pooled to develop six constructs of the HAPA model.

Face validity

Face validity was conducted to determine the compatibility of statements with the study's purpose regarding relevancy and simplicity. For this purpose, the questionnaire was given to a number of experts and patients and the feedbacks were then executed on the questionnaire.

Content validity

Content validity was assessed using two qualitative and quantitative methods to determine the compatibility of the questionnaire's content with the study's purpose. In qualitative content validity, a panel of 10 experts of health education verified the statements concerning

representativeness, writing style, word order, appropriate scoring, and grammatical errors. The content validity ratio (CVR) and content validity index (CVI) were used for quantitative validity assessment. For CVR analysis, experts were asked to rate each statement as 1; necessary, 2; useful but not necessary, and 3; not required. Then answers were tabulated and confirmed based on the CVR formula and the Lawshe table. An acceptable CVR cut off for a 10-expert panel is 0.62. The simplicity, specificity (relevance), and clarity were independently rated using a 4-point Likert scale by the 10 same experts to determine CVI. The minimum acceptable CVI was considered as 0.78 (24).

Construct validity

The exploratory factor analysis (EFA) was applied using principal axis factor analysis (PAFA) and varimax rotation for determining construct validity. The Kaiser-Meyer-Olkin (KMO) measurement was utilized to estimate sample adequacy for factor analysis. A value greater than 0.6 indicated the adequacy of the data for factor analysis. Additionally, a statistically significant Bartlett's test indicated interrelated variables (i.e. constructs). Based on factor analysis, factor loadings equal to or greater than 0.4 were considered acceptable. According to some researchers; however, factor loadings > 0.3 are considered significant (25).

Reliability

The internal consistencies of the entire questionnaire and constructs were evaluated using Cronbach's alpha coefficient. Based on the study design, a minimum Cronbach's alpha value of 0.6 to 0.7 is acceptable (26). The intra-class reliability test was performed using a test-retest approach (one-month interval) and was based on the data from 30 HD patients. The intra-class correlation coefficient (ICC) index was then used to evaluate the scores obtained at these two phases. ICC indices of 0.4-0.59, 0.6-0.74, and >0.74 were considered acceptable, good, and excellent respect1ively (27). Pearson's correlation coefficient was recruited to estimate the correlations of individual items in each construct with the total score of that construct. A correlation >0.4 was regarded as acceptable. All analyzes were performed in SPSS software version 19. The significance level was regarded as $P< 0.05$.

HAPA constructs

The HAPA questionnaire included six constructs measuring treatment adherence in four domains (i.e. dietary regimen, fluid restriction, medications, and regular attendance to dialysis sessions). Items belonged to each construct were evaluated based on a five-point Likert scale. The scores of the items were used to calculate total score for each construct. Higher scores represented more positive responses in each item.

Risk perception

Risk perception was assessed based on two sub-constructs (i.e. vulnerability and severity). The vulnerability domain addressed the most common complications of non-adherent behavior in HD patients (i.e. anemia, itching, hypertension, bone problems (pain-fracture), infections, bleeding, myocardial infarction, stroke, depression, and hospitalization). The severity domain consisted of items regarding the risk of hypertension associated stroke and hospitalization. The items were scored on a 5-point Likert scale, (ranging from 1=very unlikely to 5=very likely). The construct's total score ranged from 13 to 65 based on the number of items.

Outcome expectancies

Outcome expectancies were estimated using six items scored on a 5-point Likert scale (1=Completely False to 5=Completely True). The construct's total score ranged from 6 to 30 based on the number of items.

Action self-efficacy

Self-efficacy is a factor of individuals' knowledge and skills (28). This construct was measured using three items assessing patient's confidence to adhere to therapeutic regimens. These items were scored on a 5-point Likert scale (1=not confident at all to 5= completely confident). The construct's total score ranged from 4 to 20 based on the number of items.

Behavioral intentions

Intention is a robust predictor of treatment adherence behavior (29). This construct was measured employing three items representing the patient's commitment to adhere to treatment during the upcoming month. The items were scored on a 5-point Likert scale (1=very unlikely to 5=very likely). The construct's total score varied between 3 and 15 based on the number of items.

Planning

Action planning

This construct consisted of seven items regarding when, where and how an act can increase the likelihood of accomplishment of one's intentions. Action planning was scored on a 5-point Likert scale (1= I don't have a plan to 5=I have a plan and always stick to it). The score of this construct ranged from 7 to 35 depending on the number of items.

Coping planning

This construct identifies barriers of adherence to an action and assesses behavioral responses to cope with these barriers. This construct consisted of 5 items scored based on a 5-point Likert scale (1=strongly disagree to 5=strongly agree). The construct's total score varied from 5 to 25 based on the number of items.

Maintenance self-efficacy

This construct refers to optimistic beliefs about the perceived capability to deal with unexpected barriers arising during the maintenance period. The construct was developed applying three items (i.e. the taste of dietary foods, dissimilarity of patient's diet from that of other family members, and taking medications in all places and at all times) and scored based on a 5-point Likert scale (1=not confident at all to 5= completely confident). The total score of this construct ranged from 3 to 15 based on the number of items.

Recovery self-efficacy

This construct addresses one's beliefs about the ability to recover from setbacks. This construct was scored based on a 5-point Likert scale (1=not confident at all to 5= completely confident). The construct's total score ranged from 3 to 15 based on the number of items.

Ethical issues

This research followed the tenets of the Declaration of Helsinki. Written informed consent was obtained from all the patients. This study was extracted from the master's thesis of Sadaf Sadeghi. The study was approved by the Ethics Committee of Shiraz University of Medical Sciences (ethical code #IR.SUMS.REC.1396.S137). This study was financially supported by Shiraz University of Medical Sciences, Shiraz, Iran (Grant # 96-01-109-14806).

Data analysis

All statistical analyses were performed in IBM's SPSS 19.0 software. The Cronbach's alpha with a 95% confidence interval was used to estimate internal consistency. Test–retest reliability was measured using Pearson's correlation coefficient. The KMO and Bartlett test values were calculated to evaluate the validity of the data. The EFA was applied using PAFA and Varimax Rotation. All reported values were two-sided. The statistical significance level was $P<0.05$.

Results

The mean age of the participants was 49.18 ± 15.55 years old. Males comprised 62.5% out of 220 participants. Furthermore, 68.8% of the patients were married, and the highest educational level was diploma (31.6%, Table 1).

Table 1. Demographic characteristics of the participants

Variables	Classification	
Gender, No. (%)	Male	138(62.5)
	Female	82(37.5)
Age (Mean ± SD)		49.18±15.55
Education, No. (%)	Not educated	12(5.3)
	Elementary	61(27.6)
	Secondary	40(18.4)
	Diploma	69(31.6)
	Graduated	29(13.2)
	Post graduated	9(3.9)
Marital status, No. (%)	Single	46(20.8)
	Married	151(68.8)
	Divorced or widowed	23(10.4)

According to the face validity results, minor modifications were applied to simplify words and phrases and to improve patient's perception of the statements. The content validity of HAPA questionnaire was also confirmed using both qualitative (i.e. expert view) and quantitative (i.e. agreement among experts) methods. Based on the related formulas, the validities of all statements were within acceptable limits. Considering the validity, 95% of the participants declared the necessity of the statements. Additionally, based on the CVI, 98% of the participants believed that the statements were either relevant or highly relevant. Based on the EFA, the KMO value was obtained as 0.74 and the Bartlett test was statistically significant ($P<0.001$) confirming the structural validity and sample adequacy for performing factor analysis. Overall, six constructs consisting of 38 items were extracted based on the health practice process. Table 2 shows factor loadings for 38 items of the questionnaire.

Based on the concepts of the constructs, items related to vulnerability and severity was classified into a perceived risk. In addition, action and coping planning were grouped as a planning construct. Due to the lack of validity and reliability, items related to adverse outcomes of non-adherent behaviors were removed. Items that were sufficiently loaded (i.e. 0.4) and those loaded > 0.3 (i.e. conceptually important items) were included.

The six constructs explained 51.4% of the total variance. The internal consistency and ICC indices of the HAPA-based questionnaire were satisfactory indicating adequate reliability. The correlation between individual items of a construct and the construct's total score was greater than 0.4. The Cronbach's alpha of the whole questionnaire was obtained as 0.905 (range of 0.82 to 0.86). The ICC of the items ranged from 0.67 to 0.78 indicating acceptable internal consistency (Table 3). Figure 1 shows the re-specified model with standardized path coefficients.

Discussion

Table 2. Results obtained from factor analysis for HAPA questionnaire

Risk perception		Action self-efficacy		Behavioral intentions		Planning		Maintenance self-efficacy		Recovery self-efficacy	
Item	F	Item	F	Item	F	Item	F	Item	F	Item	F
Vulnerability		1.	0.72	1.	0.81	Action. P		1.	0.74	1.	0.79
1.	0.55	2.	0.71	2.	0.73	1.	0.50	2.	0.75	2.	0.65
2.	0.59	3.	0.37	3.	0.34	2.	0.49	3.	0.34	3.	0.31
3.	0.72	4.	0.32			3.	0.49				
4.	0.62					4.	0.48				
5.	0.41					5.	0.83				
6.	0.50					6.	0.80				
7.	0.66					7.	0.65				
8.	0.58					Coping. P					
9.	0.52					1.	0.81				
10.	0.47					2.	0.76				
11.	0.42					3.	0.32				
Severity						4.	0.54				
1.	0.37					5.	0.48				
2.	0.42										

Note. Action. P = Action. Planning. Coping. P = Coping. Planning.

Table 3. Summary of psychometric properties of health action process approaches questionnaire

Construct	Items	Mean (SD)	Median (IQR)	Cronbach's alpha	ICC
Risk perception	13	58.58 (7.34)	61 (54-65)	0.80	0.76
Action self-efficacy	4	16.45 (3.74)	18 (14-20)	0.68	0.78
Behavioral intentions	3	13.47 (2.54)	15 (13-15)	0.78	---- [a]
Planning	12	53.50 (6.17)	56 (50-58)	0.82	0.67
Maintenance self-efficacy	3	11.77 (3.49)	13 (9-15)	0.76	0.75
Recovery self-efficacy	3	13.73 (2.0)	15 (13-15)	0.70	0.76

IQR, Interquartile range.

[a] ICC could not be computed.

This study was the first report assessing the validity of a HAPA-based questionnaire in HD patients. Previous studies have assessed other behavioral theories and models to predict treatment adherence in patients with ESRD (30,31). We here demonstrated appropriate internal consistency and test–retest reliability of the HAPA questionnaire which was in accordance with the study of Arbor et al who showed a good predictability for HAPA

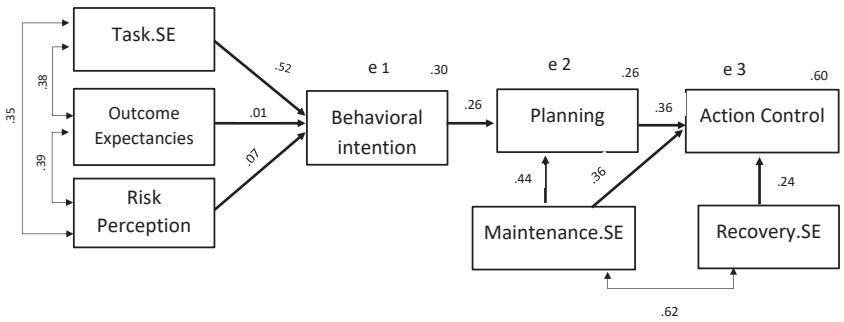

Figure 1. The HAPA treatment adherence model in hemodialysis patients. Note: SE, self-efficacy.

constructs regarding health behaviors (22).

At the first step of this study, 66 items were prepared from which 28 items including those related to outcomes expectancies were omitted due to low Cronbach's alpha coefficients. Therefore, the final questionnaire consisted of 38 items. Accordingly, it is recommended that future studies to evaluate outcome expectancies in HD patients, particularly regarding negative outcomes which are inherent and unsatisfactory. The low Cronbach's alpha of outcome expectancies construct can be related to either inadequate or irrelevant items (32). In fact, the items of this construct did not comprehensively encompass negative outcomes of treatment in HD patients.

Overall, the Cronbach's alpha for the whole questionnaire was 0.905 which is considered as an excellent value. Consistent with the assumptions of the HAPA model, self-efficacy, outcome expectancies and risk perception were predictors of treatment adherence behavior at the pre-intentional motivational phase. In this study, the action self-efficacy construct showed a strong correlation with behavioral intention (r = 0.545). In this regard, patients with higher self-efficacy more commonly intended to adhere to treatment. These findings are in accordance with the Ajzen's theory too (29). Furthermore, Bandura's social cognitive theory claims that self-efficacy has larger effects on behavioral intentions than outcome expectancies (33). Likewise, a strong correlation (r=0.911) was observed between action self-efficacy (motivational phase) and maintenance self-efficacy (volitional phase). Further studies are required to identify other important HAPA-based predictors of HD patients' intentions to adhere to treatment.

In another study, the internal consistencies of the HAPA-based constructs varied from 0.75 to 0.90 (34) indicating the reliability of all the constructs. In this study, the ICC of planning construct was 0.67 which was lower than other constructs. Our findings were in line with the study by Scholz et al (35) who also described the lowest ICC values for the planning construct (0.74 and 0.45, respectively).

Conclusion

Most constructs of the HAPA-based questionnaire were valid and reliable to predict treatment adherence at both intentional and behavioral phases in HD patients. Further studies with larger sample sizes are needed in other populations. Overall, our study supported the reliability and validity of the HAPA questionnaire for evaluating predictors of treatment adherence among HD patients. Studies aiming to augment treatment adherence in HD patients can benefit from this questionnaire to manage the disease course and improve patients' quality of life. The applicability of HAPA questionnaire for HD patients should be verified and validated in future studies.

Limitations of the study

Our sample size was relatively small that may have contributed to the low Cronbach's alpha and ICC in some constructs. These low values may have also been related to either low number of items or minor variations in grades of these constructs. The outcome expectancies construct showed inadequate validity and reliability and should be examined in future studies with different approaches. Considering that the HAPA is not a life-long model, more studies are needed to determine the most important items and constructs for predicting treatment adherence in HD patients. It is suggested to validate HAPA model in studies on larger and different populations with different cultural, social and economic characteristics.

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Conflicts of interest

The authors declare no conflict of interest.

Ethical considerations

Ethical issues (including plagiarism, data fabrication, and double publication) were completely observed by the authors.

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