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Research article

Determinants of medication adherence among Iranian patients with type 2 diabetes: An application of health action process approach

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ABSTRACT

To identify determinants of medication adherence among patients with type 2 diabetes based on the health action process approach. This cross-sectional study was conducted among 734 patients with type 2 diabetes attending to south Tehran health centers during June to December 2018. Data were gathered using the Morisky Medication Adherence Scale (MMAS-8-Item) and the health action process approach questionnaire. We used Mann-Whitney, Pearson Chi-Squared, Fisher's Exact and Independent Samples Tests for comparison of adherence medication by demographic characteristics; and linear regression analysis to predict factors related to medication adherence based on HAPA. P-value less than 0.05 considered statistically significant. A total of 232 men and 502 women participated in the study, Mean age was 61.61 ± 9.74. Most participants (82.3%) reported low medication adherence (females: 68.4%). Medication adherence was significantly associated with gender ($p = 0.03$). Medication adherence was significantly predicted by intention ($\beta = 0.172$, $p = 0.0001$), task self-efficacy ($\beta = 0.172$, $p = 0.01$), copping planning ($\beta = 0.6$, $p = 0.0001$) and copping self-efficacy ($\beta = -0.244$, $p = 0.001$). The level of adherence to medications among type 2 diabetes patients was low. The behavior intention, task self-efficacy, copping planning and copping self-efficacy were significant determinants contributed to the medication adherence. HAPA inventory includes various factors, especially types of self-efficacy. Thus, utilization of this comprehensive model in interventional studies is suggested. These determinants should be considered in developing interventional programs to improve adherence.

1. Introduction

Diabetes directly caused 1.6 million deaths in 2015 [1,2]; and it is estimated that more than 690 million people will have diabetes by 2045 [3]. In Iran, 11% of people over 25 years old have type 2 diabetes [3]. Diabetes is a main cause of premature death, blindness, kidney failure, heart attack, stroke and lower limb amputation [1].

Low adherence to medication is one of the important common problems in patients. Many patients face difficulties in following treatment recommendations [4]. Evidence shows that adherence to oral hypoglycemic agents (OHAs) in both type 1 and type 2 diabetes ranges from 36% to 93%; and adherence to insulin is almost 63% [5]. Non-adherent patients are at high risk of expanding complications that affect their health condition and quality of life [6]. Patients' adherence to medications is a crucial and important factor for preventing serious complications and decreasing the health care costs [7].

Medication adherence is defined as "voluntary cooperation of the patient in taking drugs or medicine as prescribed. This includes timing, dosage, and frequency" [8]. Patients with diabetes often face several complications in entirely adhering to their prescribed medication regimens. Reasons of non-adherence include demographic factors, disease-related factors (such as disease duration, occupation, and monitoring), and medication-related factors (such as side effects, complicacy of the regimen, and type of medication) [9,10,11]. The reasons of medication non-adherent are not completely known. A study conducted in Shiraz, Iran in 2017 investigated the factors affecting insulin compliance among 457 patients with Type 2 Diabetes. Reasons of insulin non-adherence were insurance coverage issues, illiteracy, and

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non-diabetic diet regimens, misapprehension and illogical fear of insulin injection [12].

Studies have showed that patients should be categorized according to their level of preparation to pursue health recommendations [4].

Theories of health behavior change are needed to determine, describe, and effectively promote self-regulation of individuals and to optimize treatment [13]. In recent years, some theoretical determinants of medication adherence have been introduced through well-designed theories and models. Health action process approach (HAPA) is one of the most known and helpful ones to identify effective cognitive factors in adherence. HAPA is an open framework of various motivational and volitional constructs that are assumed to explain and predict individual changes in health behaviors [14]. According to the HAPA, the adoption, initiation, and maintenance of health behaviors should be assumed as a structured process including a motivation phase and a volition phase [15]. Motivation phase includes the intention foundation and the latter phase mentions to planning, and action (initiative, maintenance, recovery) [15]. According to this model, there is a distinction between pre-intentional motivation phase that leads to a behavioral intention, and post-intentional volition phase that leads to the real health behavior [16]. In the motivation phase, a person extends an intention to behavior. Intention is person's motivation towards a target behavior [15]. In this phase, task self-efficacy is ones belief in his/her ability to perform a desired behavior [16]. It can help form a behavioral intention. After the intention is formed, the individual enters the volitional phase. In this phase, good intention should be converted to accurate instructions on how to do the desired action [16]. This change must be planned, initiated, and maintained, and relapses have to be managed. An action plan usually is concrete ideas about "when," "where," and "how" to act for the purpose of the formed intention [15]. But action planning is strongly influenced by self-efficacy. Task self-efficacy in the motivational phase is different from volitional self-efficacy (e.g., coping self-efficacy, recovery self-efficacy) [17]. Optimistic beliefs about one's capability to overcome barriers that arise during the maintenance process is called coping self-efficacy [15]. Recovery self-efficacy describes person's notion to get back on route after a setback or failure [15]. Coping planning is a self-regulatory strategy with a focus on barriers [18]. Perceived barriers is potential negative aspects of a particular health behavior (e.g., side effects, painful, difficult) [19]. Acceptance of individual susceptibility to a condition also believed to be serious is called perceived benefits [19]. Different factors influence the adherence medication; and HAPA inventory includes various factors, especially types of self-efficacy at different stages of health behavior change too.

It became necessary to highlight the recent status of adherence to diabetic medications among type 2 diabetes patients in Tehran and show the cultural differences within the same Iranian population. So, the aim of this study was to identify determinants of medication adherence based on the HAPA among patients with type 2 diabetes attending to the South Tehran health centers.

2. Materials and methods

2.1. Research design and participants

This cross-sectional study carried out at South Tehran Health Centers, affiliated to Tehran University of Medical Sciences from June to December 2018. We used multi state cluster sampling (assuming the centers as cluster). In this sampling the sample size in each center was proportional to their population coverage. Sample selection within each centers was performed using consecutive sampling in random days until the required sample size is achieved in that center.

The inclusion criteria were: being diagnosed with type 2 diabetes for more than six months, absence of any mental, visual, and learning disabilities (according to the clinical diagnosis by physician), and having consent to participate in the study. The exclusion criteria were other types of diabetes including type 1 diabetes or gestational diabetes; and having acute mental and disabling disorders.

2.2. Data collection tools and scoring

Demographic characteristics including participants' age, marital status, job status, income, gender, duration of disease, and education level were measured. A HAPA self-structured questionnaire consisted of eight sections and 38 items were developed (Appendix 1) based on a literature [20,21,22,23]. The sections consisted of: (a) Intention to medications adherence (2 items) (e.g., "During the next months, I intend to take my medications/inject insulin as prescribed."), measured using seven-interval Likert scales, ranging from 1 (strongly disagree) to 7 (strongly agree) with higher scores indicating high level of intention; (b) Task self-efficacy of diabetes medications adherence (6 items) (e.g., "I can take my drugs or medicine/inject my insulin as prescribed even if my surroundings do not remind me to take my medication or inject my insulin."), rated on a 4-point scale ranging from 1 (not at all true) to 4 (exactly true); (c) Copping self-efficacy (7 items) (e.g., "I can keep taking my medications/injecting my insulin as prescribed even if I am tired."), scores for benefits item ranging from 1 (not at all true) to 4 (exactly true), with higher scores determining better condition; (d) Recovery self-efficacy (3 items) (e.g., "I am sure I can retake my medications/inject my insulin as prescribed even if I have paused for several times."), rated on a 4- point scale ranging from 1 (not at all true) to 4 (exactly true); (e) Action planning (2 items) (e.g., "I already have concrete plans how to take my medications or inject my insulin on time."), rated on a 4- point scale ranging from 1 (not at all true) to 4 (exactly true); (f) Copping planning (6 items) (e.g., "I already have concrete plans how to deal with relapses not to take my medications/not to inject my insulin as prescribed."), rated on a 4- point scale ranging from 1 (not at all true) to 4 (exactly true), scores were recoded to show a better condition; (g) Barriers to adherence (9 items) (e.g., "It is difficult for me to take medications or inject insulin on time."), scores for this item ranged from 1 (strongly disagree) to 7 (strongly agree), higher scores represented a high level of barriers; (h) Resources and benefits (3 items) (e.g., "My blood glucose is regulated by taking my medications/or injecting my insulin as prescribed. ").

We transformed the scores of each item to 0–100 using the following formula:

The new score of item = 100 * (Score of item – Minimum possible score)/Range of possible scores. Then we calculated the section score as the average of item scores in that section for each subject.

2.2.1. Face validity

First, in order to confirm difficulty, proportionality and ambiguity of the items, the HAPA inventory was distributed to 20 type 2 diabetes patients (10 males and 10 females) for purification purposes before reliability testing.

2.2.2. Content validity

Content Validity Ratio (CVR) and Content Validity Index (CVI) have been measured by means of a quantitative method in accordance to the Lawshe table [24]. These two ways are applied to evaluate essentiality, relevance, clarity and simplicity, respectively. We asked 10 experts in the fields of health education and promotion, biostatistics and endocrinology to complete the items. The CVI>0.9 and CVR>0.8 were computed. The test-retest reliability of each scale has been determined.

2.2.3. Reliability

The Cronbach alpha, as an internal consistency indicator, were examined to estimate true score variance with a 95% confidence interval. The cut point of 0.70 was set for Cronbach alpha to detect acceptable items for the new scales. The questionnaire was completed by 20 patients after two weeks to calculate test-retest reliabilities. Total scale scores from the first and second interview were put into the analysis. Then, the

test-retest reliability of each scale was determined. The Cronbach's alpha for the HAPA-based questionnaire was more than 0.7 and ICC[1] was more than 0.81.

The patients' adherence to medication regimen was measured using the MMAS-8-Item [25]. Each item in Morisky questionnaire measures a specific medication-taking behavior. Responds categories were yes/no for each item and a 5-point Likert response for the last item [25]. The correlation coefficient was calculated by Negarandeh ($r = 0.8$) and the Chronbach's alphas was more than 0.7 [26]. All questionnaires were completed by one of the researchers through face-to-face interviews with the patients.

2.3. Ethics statement

The Ethics Committee of Tehran University of Medical Sciences (code: IR.TUMS.SPH.REC.1396.4200) approved the study. Before enlistment in the study, the participants received a complete explanation of the plan and objectives of the study and those willing to participate provided written informed consent.

2.4. Statistical analysis

We analyzed the associations between HAPA constructs and medication adherence behavior using the Linear Regression test. We used the chi-square test (for nominal variables which have assumption of this test), Fisher exact test (for nominal variables which could not pass the assumption of chi-square test) and Mann-Whitney test (for ordinal variables) to evaluate significant difference between medication adherence status by the demographic variables. All statistical tests were assessed using SPSS (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.). P-value less than 0.05 was considered statistically significant.

Since we had eight sections (latent variables) and 38 items to calculate, we had 46 variable totally considering 10 samples for each item. So we needed 460 samples, however as we performed cluster sampling we considered a design effect of 1.6 and recruited 734 participants to the study.

3. Results

3.1. Demographic characteristics

A total of 734 participants met the criteria for inclusion. Table 1 describes the demographic characteristics of the participants. Most of the participants (82.3%) met the criteria for non-adherence. Most of them (68.4%) were female, 36.9% had primary education, 73.6% had low income (10,000,000 to 20,000,000 Rls), and 81.5% were married. There was a significant association between the medication adherence behavior with gender ($p = 0.036$); men were more non-adherent in comparison to women.

3.2. Association between medication adherence and the HAPA constructs

Table 2 presents the linear regression analysis correlations between the medication adherence behavior and the HAPA constructs. Statistically significant correlations were found between the medication adherence behavior and HAPA constructs, except for recovery self-efficacy, action planning, barriers and resources. Patients who had more intention to medication adherence ($\beta = 0.172$, 95% CI = 0.07, 0.22), had higher level of task self-efficacy ($\beta = 0.172$, 95% CI = 0.03, 0.27), higher coping self-efficacy ($\beta = -0.244$, 95% CI = - 0.33, - 0.08) and higher coping planning ($\beta = 0.6$, 95% CI = 0.4, 0.62) tend to more likely engage in medication adherence behavior. Table 3 shows the patient responses to the medication adherence questions. Feeling hassled about sticking to the anti diabetic treatment plan highlighted by 97.6% of patients. 94.6% of patients forgot to take their diabetes medications. 91.8% of patients' answers to the question "Did you take your anti-diabetic medicines yesterday?" were "no". When patients felt like their diabetes was under control, they stopped taking their medications.

4. Discussion

Our study showed that most of participants were non-adherent to medication. Similar findings have been reported from other studies in Mexico (82.8%) [27]. In a study conducted by Alatawi et al., 60% of patients did not take the number of prescribed doses per day; and up to 40% reported low adherence [28]. Many patients with diabetes are poor compliers with treatment, including both OHAs and insulin [5]. Problems with poor adherence may deteriorate the burden of diabetes and end up with poor health outcomes, lower quality of life, and increased health care costs. So, it is important to investigate the reasons behind the issue.

Our study showed that there was a significant relationship between the medication adherence with gender. This was consistent with the findings reported by Alatewi in Saudi Arabia [28], Raum and et al. [29], and Elsous and et al. [30], But Jarab presented that there was no significant relationship between gender and medication non-adherence in patients with type 2 diabetes [31]. This difference in results of studies may be due to diversity in culture. According to these findings, the gender difference should be considered in order to improve the medication adherence.

Intention, task self-efficacy, coping planning and copping self-efficacy predicted medication adherence behavior significantly; which would corroborate previous research findings. Intention is an important factor in adopting healthy behaviors. Nevertheless, good intentions do not necessarily guarantee corresponding actions. Therefore, the other factors are determinant in medication adherence behavior. Individuals would fail to adopt, initiate, and maintain a planned action when they do not believe in their own capability to do it [15]. Trevisan's study showed that using behavioral strategies, including action planning and coping planning helped to improve adherence to medication adherence [32]. Self-efficacy is needed all over the entire behavior change process. Because different challenges occur as people progress from one phase to the next, specific self-efficacy is required [33] such as task self-efficacy and coping self-efficacy. It is necessary to increase self-efficacy in these patients. When setbacks occur, individuals with high coping self-efficacy recover more quickly and maintain commitment to their goals [22]. In coping planning, people should be able to imagine scenarios that they barricade to do their intended behavior and they design one or more plans to cope with these conditions and obstacles [34]. Because planning facilitates the transition from intention to behavior [33]. This shows coping planning can play key role in adherence to medication behavior in patients with Type 2 diabetes. Purpose of the interventions should be coping planning and coping self-efficacy for patients who are in the volitional phase. The results pointed to the effective role self-regulatory strategies (such as planning) in turning goals into action [35]. It is essential to attend this factor in healthy interventions by health educators. In one study low adherence was associated with patients who are not participated in the decision-making process or do not have an understanding of the problem or treatment, and creating confidence [36]. To promote medication adherence in patients with type 2 diabetes, providing information to patients about feasibility issues concerning medication intake and increasing self-efficacy is beneficial [37]. Our study showed that most patients forgot to take their diabetes medications. Feeling hassled about anti diabetic treatment plan and forgetfulness were the most common reasons for non-medication adherence. This confirms that feeling hassled from treatment programs is a common problem in chronic diseases such as diabetes; and this highlights the importance of self-efficacy beliefs in these groups of patients. Patients'

[1] Intra Class Correlation.

Table 1. Characteristics of the participants (n = 734).

Patients' characteristics		Adherent to medication		Non-adherent to medication		*p-value*
		N (%) (n=130)		*N (%) (n=604)*		
Level of Education	Illiterate	51	19%	218	81%	0.464*
	Elementary	36	13.3%	235	86.7%	
	Middle school	17	17.9%	78	82.1%	
	High school	21	25.6%	61	74.4%	
	University degree	5	29.4%	12	70.6%	
Age (Yrs)	≤ 45	9	20.9%	34	79.1%	0.899*
	46–55	29	18.8%	125	81.2%	
	56–65	43	14.6%	252	85.4%	
	66–75	43	22.6%	147	77.4%	
	76+	6	11.5%	46	88.5%	
Gender (n)	Female	99	19.7%	403	80.3%	0.036**
	Male	31	13.4%	201	86.6%	
Marital status (n)	Married	104	17.4%	494	82.6%	0.890**
	Single	2	18.2%	9	81.8%	
	Died	24	19.2%	101	80.8%	
Job (n)	Unemployment	0	0	8	100%	0.147***
	Retired	22	12.6%	152	87.4%	
	Clerk	5	21.7%	18	78.3%	
	Free job	11	15.7%	59	84.3%	
	Housewife	92	20%	367	80%	
Income (Rls)	‘500,000	8	12.1%	58	87.9%	0.103*
	500,000–1000,000	19	18.1%	86	81.9%	
	1000,000–2000,000	94	17.4%	446	82.6%	
	>2000,000	9	39.1%	14	60.9%	
Duration of diabetes (Yrs)	≤5	36	14.8%	208	85.2%	0.121*
	5.01–10	36	18%	164	82%	
	10.01–15	24	20.3%	94	79.7%	
	15.01–20	21	18.6%	92	81.4%	
	20.01+	13	22%	46	78%	
Medications (n)	Tablet	80	16.3%	412	83.7%	0.068**
	Tablet & Insulin	26	17.4%	123	82.6%	
	Insulin	24	26.4%	67	73.6%	

$p < 0.05$, * Mann-Whitney Test, **Pearson Chi-Square Test, ***Fisher's Exact Test.

Table 2. Linear Regression analysis to predict medication adherence behavior.

variable	R2	B	SE	p-value	Standardized Coefficients Beta	Confidence Interval 95%	
						Lower	Upper
	0.34						
Constant		1.94	4.92	0.693			
Intention		0.150	0.03	0.000	0.172	0.076	0.223
Task Self -efficacy		0.157	0.06	0.01	0.172	0.037	0.276
Copping Self -efficacy		-0.211	0.06	0.001	- 0.244	-0.334	-0.089
Recovery Self- efficacy		-0.099	0.05	0.055	- 0.133	-0.199	0.002
Action Planning		-0.015	0.05	0.768	- 0.020	-0.115	0.085
Copping Planning		0.516	0.05	0.000	0.6	0.407	0.624
Barriers		0.008	0.04	0.842	0.007	-0.072	0.088
Resources and benefits		-0.007	0.03	0.848	-0.006	-0.079	0.065

($R2 = 0.34$, $F = 41.48$, $p < 0.05$).

perceptions of their ability to adhere to medication are affected by forgetfulness [38]. Guénette and et al., presented adherence to medication associated with having signs to remember to take them [39], Gouveia also reported that forgetting to take medication in patient with type 2 diabetes was not a barrier of adherence because it was perceived as an unaware behavior by patients; however, if this behavior was repeated it could be on purpose. At this stage, patient paid little attention to take their medications [40]. Most of the patients had taken their anti-diabetic medicines the previous day. Hence, it is important to identify the motivational and voluntary reasons of this behavior in these patients. About half of the patients who felt like their diabetes was under control, stopped taking their medications. This was consistent with the findings reported

Table 3. Patient responses to the medication adherence questionnaire (n = 734).

Questions	Responses n (%)			
	Yes		No	
Do you sometimes forget to take your diabetes pills/injections?	694 (94.6)		40 (5.4)	
People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past 2 weeks, were there any days when you did not take your diabetes medicine?	377 (51.4)		357 (48.6)	
Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?	306 (41.7)		428 (58.3)	
When you travel or leave home, do you sometimes forget to bring along your diabetes medication?	508 (69.2)		226 (30.8)	
Did you take your anti-diabetic medicines yesterday?	674 (91.8)		60 (8.2)	
When you feel like your diabetes is under control, do you sometimes stop taking your medicine?	321 (43.7)		413 (56.3)	
Do you ever feel hassled about sticking to your anti diabetic treatment plan?	717 (97.6)		17 (2.3)	
How often do you have difficulty remembering to take all your medications?	**Never**	**Rarely**	**Sometimes**	**Always**
	19 (2.6)	215 (29.3)	391 (53.3)	109 (14.9)

by Devin and et al., that 23% believed that if their blood sugar was under control, they did not need to take medications [41]. Low perception of susceptibility and severity of the disease can make low medication adherence in these patients [42]. Considering these findings, it is essential to pay more attention to patients with poor medication adherence, especially women. This study identified the predictors of medication adherence among patient with type 2 diabetes that can inform interventional studies in the area.

Like other cross-sectional studies, there are some limitations in our study. We have to be careful about interpreting the associations and direction of associations from a cross-sectional survey. Moreover, data were collected via self-report questionnaires that can potentially cause biases.

4.1. Implications for practice and future research

Patients who fully adhere to their doctors' advice and treatment plan have less complications. Our study showed that medication adherence is low among our patients. The reasons behind the low adherence should be investigated through future research studies; and identified reasons should be considered to be resolved via well-designed health promotive programs. In this study, we identified a series of cognitive factors that can predict medication adherence. These cognitive factors that facilitate or hinder medication adherence behavior and should be considered by the diabetes program planners. Our study showed that intention, task self-efficacy, coping planning and coping self-efficacy predict the medication adherence behavior among patients. Using related theory-driven and evidence-based methods and practical applications to improve these factors can help patients to more adhere to medication.

In this study, factors influencing medication adherence among patients with type 2 diabetes was identified according to HAPA. Data were collected using face-to-face interviews, which helped us to gather valid data from low literate patients. Most available studies have worked on health behavior changes for the same time, regardless of the health behavior models and or theories. This study identified the constructs of HAPA that could help health program planners to develop interventions that might be more effective in maintaining the interventions' effects.

5. Conclusion

We identified various cognitive factors influencing the adherence to medication, especially the types of self-efficacy based on the HAPA model. We found intention, task self-efficacy, coping planning and coping self-efficacy as the most important determinants contributed to medication adherence among patients with type 2 diabetes. The HAPA was found to be helpful in determining the predictors of medication adherence among these patients. Designing interventional programs aiming at promoting medication adherence level considering these determinants are promising. Diabetes educators and healthcare providers should have a specific focus on patients' self-efficacy and planning while designing such interventions.

Declarations

Author contribution statement

E. Shakibazadeh: Conceived and designed the experiments; Performed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper.

S. Ranjbaran: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

D. Shojaeizadeh: Conceived and designed the experiments; Contributed reagents, materials, analysis tools or data.

T. Dehdari: Performed the experiments; Contributed reagents, materials, analysis tools or data.

M. Yaseri: Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data.

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Competing interest statement

The authors declare no conflict of interest.

Additional information

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