# Health Literacy and Health-Related Quality of Life in Older Adults with Type 2 Diabetes: The Mediating Role of Treatment Regimen Adherence

### ABSTRACT

**Background and Objective:** It is unclear how health literacy is associated with health-related quality of life. The aim of this study was to examine the mediating role of treatment regimen adherence between health literacy and health-related quality of life (HRQoL) in older adults with type 2 diabetes mellitus (T2DM).

**Material and methods:** In this cross-sectional study, a multi-stage cluster sampling method was used to recruit 300 diabetic patients aged 60 years and over with diabetes. The abbreviated version of the Test of Functional Health Literacy in Adults (S-TOFHLA) and the Swedish Health-related Quality of Life (SWED-QUAL) instrument were used to measure health literacy and HRQoL, respectively. In addition, the Morisky Medication Adherence Scale (MMAS), the diet and exercise adherence questionnaire, were used to assess treatment regimen adherence. The four steps of Baron and Kenny's procedure were implemented to test the mediation hypotheses.

**Results:** The mean age of the respondents was 64.92 years. In addition, the mean of the respondents' health literacy score was 52.82. The prevalence rates of the inadequate, marginal, and adequate health literacy of the respondents were 70%, 14.7%, and 15.3%, respectively. Two items of treatment regimen adherence (medication adherence and diet and exercise adherence) had a partial mediating role between health literacy and quality of life in elderly diabetes patients. The result of Baron and Kenny's procedure and Sobel's test showed a significant mediation role in medication adherence (p = 0.00, Sobel's Z = 2.77) and diet and exercise adherence (p = 0.00, Sobel's Z = 6.26) between health literacy and HRQoL.

**Conclusion:** Medication adherence, diet adherence, and exercise adherence are mediating factors in relationship between health literacy and HRQoL that increase the health literacy and quality of life in older adults with T2DM. **Paper Type:** Research Article

Keywords: Diabetes mellitus, Frail Elderly, Health literacy, Quality of Life, Patient Compliance

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# Introduction

Higher quality of life remains a major challenge for researchers in the present century (1). When the quality of life is mentioned about health and disease, it is called health-related quality of life (HRQoL) (2). Diabetes mellitus, its complications, and treatments burden older adults (3). Measuring quality of life in diabetic patients is a way to evaluate diabetes and its effects on patients (4). The rising global burden of diabetes is accompanied by the failure to achieve desired treatment results; therefore, adherence to treatment in diabetes is an issue that has been an important focus of therapists (5).

Non-adherence to a treatment regimen, especially in older adults with T2DM, is a complex and challenging issue, and it is the subject of interest of many researchers. In addition, many factors may reduce older persons' ability to adhere their medication regimens, including older adults' health literacy (6). Recognizing predictor factors of medication adherence permits practitioners to change treatment regimens to achieve patient care (7). Moreover, health literacy has been introduced as a global challenge in the 21st century. The World Health Organization introduced health literacy as one of the major determinants of health (8). Inadequate health literacy is a significant problem in many countries, and it may be the reason for undesirable and unexpected outcomes in some diabetic patients (9).

While some studies showed that health literacy impacts the quality of life among older adults with T2DM. The exact mechanism underlying this association, specifically in older people with T2DM, is unclear. The relationship between health literacy and HRQoL may sometimes occur due to indirect factors that affect HRQoL. Determining the factors contributing to HRQoL among diabetic individuals could help tailor and target interventional approaches to enhance older adults' quality of life. Hence, the current study aimed to determine the role of treatment regimen adherence as a mediator between health literacy and HRQoL in older adults with T2DM. Furthermore, this study has two hypotheses:

(1) Health literacy has a direct effect on HRQoL, and (2) treatment regimen adherence partially mediates the direct effect of health literacy on HRQoL.

# **Material and methods**

This paper presents a correlational cross-sectional study in older adults with T2DM who were referred to health centers in Mashhad (Iran). The multi-stage cluster sampling method was used. Initially, five health centers were considered cluster heads. Then, half of the older adult care units of these centers were randomly selected as a cluster. At the final stage, we selected all older adults with T2DM in these centers who met the inclusion criteria. The sample size was calculated using the pilot study and calculating the correlation between health literacy and HRQoL. In this study, 36 respondents were excluded, and the final sample size was 300 older adults with T2DM. We selected interviews as the main method of data collection. According to the Helsinki Declaration, this study received ethics approval from the ethics committee at Mashhad University of Medical Sciences (code 91205).

The short version of the Test of Functional Health Literacy in Adults (S-TOFHLA) was used to measure health literacy (10). The score of the S-TOFHLA instrument consists of reading comprehension and numeric calculations. The total score of the S-TOFHLA is between 0 and 100, as categorized on three levels: inadequate health literacy (0–53), marginal health literacy (54–66), and adequate health literacy (67–100) (11). In this study, the internal consistency of the

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S-TOFHLA was measured by Cronbach's alpha coefficients for reading comprehension and the calculating parts were 0.71 and 0.77, respectively. Reisi et al. (2012) reported the internal reliabilities of the S-TOFHLA were 0.79 and 0.88 for the numeracy and the reading comprehension sections, respectively (12). The validity of this instrument was confirmed by Javadzade (13).

In this study, HRQoL was measured by a Swedish HRQoL (SWED-QUAL) instrument. (14,15). The SWED-QUAL is scored on a 0-100 scale, with higher scores indicating better quality of life (14). This instrument includes three dimensions: physical, psychological, and social. The Persian version of SWED\_QUAL is a valid and reliable tool. The validity of this instrument was confirmed in a previous study by Darjani (16). Reliability was estimated for all dimensions of QOL were70%, 90%, 95%, 84%, 89%, 78%, and 91% for

physical function, pain, daily activities, feeling, sleep, overall health, and relationship with relatives , respectively (17).

We used the Morisky Medication Adherence Scale (MMAS) and the Diet and Exercise Adherence Questionnaire to assess treatment regimen adherence. The MMAS consists of eight items with a scoring scheme of "yes" = 1 and "no" = 0 for the first seven items, except for question 5 (which has reverse scoring). A score lower than 6 demonstrates a low medication adherence, scores between 6 to 8show moderate medication adherence, and a score over 8 reveals a high medication adherence. The internal consistency determined by Cronbach's alpha coefficient was 0.83 for the MMAS items (18). Ghanei Gheshlagh et al., confirmed the validity of the Persian version of MMAS.

(19). This questionnaire consist 26 questionson a 4-point Likert scale ("never," "rarely,""often," and "always") to assess diet and exercise

adherence, and its internal consistency level based Cronbach's alpha was 0.88, it was suitable and acceptable level.

### **Statistical analysis**

Statistical analyses were conducted using SPSS version 21. Results were adjusted by potential confounding variables such as age, marital status, social support, HbA1C, insurance status, duration of diabetes, treatment regimen types, family history of diabetes, and attendance of diabetes education programs.

The four steps of Baron and Kenny's procedure were used to test mediation effect based research hypotheses (20). A Sobel test was also used to determine the significance effect of the mediator by testing the hypothesis that there is no difference between the total effect (path c) and the direct effect (path c'). The indirect effect of the mediator is the product of path ab, which is equivalent to (c–c'), as illustrated in Fig 1.





## Results

The mean and standard deviation of the respondents' ages was 64.92±5.22 years, with a minimum of 60 and a maximum of 82 years. In this study, 197 females (65.7% of total participants ) and 103 males (34.3%) were the total respondents. Most respondents (n=240; 80%) were married, and had an elementary education(n=237; 42.3%). In terms of employment status63.7% of participants

(n=191) were homemakers. The mean and standard deviation of the duration of diabetes in the older adults were 7.08±5.65 years. A family history of diabetes was reported by 61.3% of respondents (n=184). The results showed that the mean and standard deviation of respondents' health literacy

scores were 52.82±13.25. The prevalence rates of inadequate, marginal, and adequate health literacy among the respondents were 70%, 14.7%, and 15.3%, respectively. The mean and standard deviation of respondents'HbA1c was 7.78±1.19. See Table 1.

Varia	bles Categories	N (%)	Mean ± SD	Ranges
Social support		300(100)	46.24±19.2	1-100
incomea		125(41.66)	~559k±332k	~59k ± 33k
BMIb		300(100)	27.23 ±4.17	17.9 ± 38.7
	60-74	276(92)		
Age (year)	75 -85	24(8)	1	
	≤7	80 (26.7)		
HbA1cc —	> 7	220(73.3)		
	Single	1 (0.3)	1	
Marital status	Married	240 (80.0)	1	
Marital status —	Divorced	4 (1.3)		
	Widowed	55(18.3)	1	
	Living alone	32 (10.7)	1	
	Living with spouse	135 (45)		
LAd	Living with children	28 (9.3)	1	
	LSCe	105 (35)		
	Elementary school	138 (79.3)		
	Middle school	35(11.7)	1	
Educational status	Diploma	17 (5.7)		
	College and university	10 (3)	1	
Insurance	Yes	268 (89.3)	1	
	No	32 (10.7)	1	
	OHAf alone	254 (84.7)	1	
Treatment method	Injecting insulin alone	21(7)	1	
Γ	OHA and injecting insulin	25(8.3)	1	
	Tenant	20(6.7)	1	
Housing	Owner	273(91)	]	
	other	7 (2.3)	1	
	≤5	167(55.5)	1	
	6-10	108(36)	]	
Duration of diabetes	11-15	19(6.3)	1	
Γ	16-20	2(0.7)	1	
	21-25	4(1.3)	1	
Eamily history	Yes	184 (61.3)	]	
Family history	No	116 (38.7)	1	

## Table 1. General characteristics of respondents (N=300)

<sup>a</sup>Iran currency (Rial).

<sup>c</sup> HbA1c=hemoglobin A1c.

<sup>e</sup>Living with spouse and children.

<sup>b</sup>BMI= Body Mass Index. <sup>d</sup>Living arrangement. <sup>f</sup>OHA= Oral Hypoglycemic Agent. The result of student's t-test reveals thatmean of HRQoL (58.18±10.83) in younger older adults, aged from 60to74, was significantly (t=2.62 P<0.05) higher compare with HRQoL (51.67±11.52) in older adult with age more than 75 years . Further information about HRQoL and the treatment regimen adherence items in older adults with type 2 diabetes was summarized in Table 2.

Table 3 displays the results of correlation analyses between health literacy, medication adherence, adherence to diet and exercise, and HRQoL. Health literacy correlated with medication adherence (r = 0.44), adherence to diet and exercise (r = 0.82), and HRQoL (r = 0.70).

Table 2. Mean, standard deviation, and range of total HRQoL, the treatment regimen adherence items in
older adults with T2DM.

Variables	Mean ± SD	Ranges
Total Health –related quality of life	56.59± 9.88	1-100
Medication adherence	5.11± 1.30	0-8
Diet and Exercise adherence	68.72± 8.51	26-94

Table 3. bivariate correlation among health literacy, medication adherence, adherence to diet and exercise, and HRQoL

Variables	Health literacy	Medication adherence	Diet and Exercise adherence	HRQoL
Health literacy	1	0.44**	0.82**	0.70**
Medication adherence		1	0.46**	0.45**
Diet and Exercise adherence			1	0.77**
HRQoL				1

In this study, treatment regimen adherence was measured based on medication adherence and adherence to diet and exercise. Each item was separately examined to determine the mediating role of treatment regimen adherence between health literacy and HRQoL. A variable has a mediating role when the initial variable affects indirectly the outcome variable through the mediator. In this study, the four steps of Baron and Kenny's procedure were used to demonstrate the mediating role of treatment regimen adherence between health literacy and the HRQoL in older adults with T2DM.

**Step One:** The linear regression between the initial variable (health literacy) and the outcome variable (HRQoL) (path c) showed an association between these two variables (p<0.05).

**Step Two:** The linear regression between the initial variable (health literacy) and the intermediate

variable (treatment regimen adherence) (path a1 and path a2) showed that health literacy has a correlation with two items of treatment regimen adherence including medication adherence, diet and exercise adherence (p<0.05).

**Step Three:** The linear regression was tested between the two items of the mediating variable (treatment regimen adherence) and the outcome variable (HRQoL) (path b1 and path b2) with a controlling initial variable (health literacy). The result showed medication adherence, and diet and exercise adherence have a significant correlation with HRQoL (p<0.05). However, HbA1c and BMI were not significantly associated with HRQoL (p>0.05).

**Step Four:** mediating variables (medication adherence, diet and exercise adherence) were individually controlled to complete mediation roles between the initial and outcome variable.

Then, the effect of the initial variable on the outcome variable was measured (Path c'). The values of  $\beta$  in these pathways were not equal to zero; therefore, the mentioned mediation was partial mediation. The coefficient related to the pathway of c (0.70) was larger than the coefficient related to the pathway of c' (0.62 and

0.33). Consequently, two items of treatment regimen adherence (medication adherence, and diet and exercise adherence) showed a partial mediating role between health literacy and HRQoL in older adults with T2DM. Steps 3 and 4 use the same regression equation. See Table 4.

Table 4. Mediator analysis of health literacy, treatment regimen adherence (medication adherence, diet and exercise adherence), and HRQoL.

Steps	Variables		В	SE B	β	p-Value
1.	Outcome	HRQoL				
Path c	Predictor	Heath Literacy	0.58	0.03	0.70	0.00
2.	Outcome	Medication adherence				
Path a1	Predictor	Heath Literacy	0.04	0.01	0.44	0.00
Path a2	Outcome	Diet and exercise adherence				
	Predictor	Heath Literacy	0.53	0.02	0.83	0.00
	Outcome	HRQoL				
3&4.	Mediatora	Medication adherence	1.46	0.38	0.17	0.00
	Predictor	Health Literacy	0.52	0.04	0.62	0.00
	Outcome	HRQoL				
	Mediatora	Diet and exercise adherence	0.58	0.09	0.45	0.00
	Predictor	Health Literacy	0.27	0.07	0.33	0.00

<sup>a</sup> controlled variable.

Baron and Kenny's causal steps test was used to assess the plausibility of mediation. However, the Sobel test was also used to determine statistical power to detect the true mediation effects(25).

Sobel's Z = 
$$\frac{a \times b}{\sqrt{(a^2 \times Se_b^2) + (b^2 \times Se_a^2)}}$$

a: unstandardized regression coefficient between the independent variable and the mediator variable

Sea: standard error between the independent variable and the mediator variable

b: unstandardized regression coefficient between the mediator variable and the dependent variable

Seb: standard error between the mediator variable and the dependent variable

The result of the Sobel test showed there

were significant mediation roles of medication adherence (p = 0.00, Sobel's Z = 2.77) and diet and exercise adherence (p = 0.00, Sobel's Z = 6.26) between health literacy and HRQoL.

## **Discussion**

The result of this study showed that the level of health literacy among older adults is very low. In line with this study, Bauer et al. (2013) reported 72% of patients had limited health literacy (21). In addition, Reisi et al. (2012) reported that around 79% of people had inadequate health literacy (12). Kosicka et al. (2020) stated that the level of general health literacy and its dimensions (health care, disease prevention, and health promotion) in older people aged 65+ was insufficient (22). Reasons for non-adherence are multifactorial and difficult to identify (23). High levels of health literacy in patients can increase cognitive sensitivity and attention to the consequences of the illness: patients raised their awareness of all aspects of the disease and tried actively to control their disease (24).

Our findings are consistent with prior research suggesting older adults with higher level of health literacy show higher rates of medication adherence. Based on these results, it appears older people with T2DM could better control their diabetes. Medication adherence is important for diabetes management (25). Jackson et al. (2015) and Lee et al. (2020) showed there was a statistically significant correlation between health literacy and medication adherence in patients with T2DM, and improving health literacy may provide better medication adherence in older people with diabetes (26,27). People with adequate health literacy were more likely to remember to take their medications than those with poor health literacy (Hussain, Said, and Khan 2020). Song et al. (2020) found that medication adherence was moderately and positively correlated to health literacy among older adults in a rural community in South Korea (28).

This study also showed that older adults who had a higher level of health literacy showed the higher rates of diet and exercise adherence. Consistent with this study Mehrtak., et al (2018) found that health literacy is effective on diet and exercise adherence (29). Empowerment has a mediating role between health literacy with diet and exercise adherence. It means higher health literacy causes people to feel healthier and confident, and those with higher empowerment were more likely to eat healthy foods and doing exercise (30). In line with this study, Tang et al. (2017) found a strong relationship between health literacy with functional exercise adherence in patients with radical mastectomy (31). Although participating in exercise and sports had obvious benefits, and adherence to long-term exercise

programs can vary between 10 and 80%, specifically in the long term (32). In contrast with our result Yeh et al. (2018) found adherence behavior has a weak association with health literacy in chronic disease management (33).

The results of this study revealed that older adults who had a higher level of health literacy had lower levels of HbA1c. Different studies showed varying results regarding the association between health literacy and glycemic control, and this heterogeneity did not permit the estimation of an overall effect (10). An association between higher levels of health literacy with better glycemic control was demonstrated by some studies (34-36). Some studies showed there were direct and statistically significant relationships between health literacy and blood glucose control (the amount of HbA1c). The patients with better health literacy had lower HbA1c levels and more control over their disease (35-38). This result is inconsistent with the results obtained by Huang et al. (2018) that health literacy was not correlated with medication adherence and glycemic control (HbA1c) among patients with type 2 diabetes. (39). Osborne et al. (2010) found that health literacy did not directly affect knowledge about diabetes, self-care activity, or blood glucose control. However, health literacy had an indirect effect on the blood glucose control and self-care activities of diabetic patients through social support (40).

This study also showed direct and indirect relationships between health literacy and HRQoL in older adults with T2DM. The finding that older adults with T2DM who had adequate health literacy had higher HRQoL is consistent with previous studies. In line with this study, Gaffari-fam and colleagues (2020) found HRQL of the T2DM is low, and about two-thirds of the HRQL of diabetic patients is explained by health literacy (41). Study findings of Code et al.

# (2020) and Salari et al. (2017) also demonstrated that health literacy significantly correlated with quality of life in older adults (42,43). Reisi et al. (2012) found low levels of health literacy led to poorer control of diseases, which was observed through frequent and unnecessary doctor visits, prolonged hospital stays, and increased costs, which subsequently reduce the patient's quality of life (12). On the other hand, Lee et al. (2016) found, although, there is no direct effect between health literacy and HRQoL in older adults with T2DM, health literacy did exert an indirect effect on HRQoL via self-care activities (44).

This study found medication adherence and diet and exercise adherence had a partial mediating role between health literacy and HRQoL among older adults with T2DM. In line with this study Song et al.'s (2017) study results showed the health literacy was indirectly linked with the quality of life by two mediation pathways, including reading drug labels, and understanding prescription instructions. These pathways explained the links between health literacy and medication adherence, and quality of life. Lower health literacy appears to be correlated with lower medication adherence and poor quality of life (45). Lee et al. (2016) found that health literacy had an only indirect effect on HRQOL through self-care activities (44).

This study has some limitations. The first major limitation of this study is its cross-sectional design due to time and budget limitations; a longitudinal design would be better for this kind of study. Secondly, the respondents were recruited from city health care centers so they may not be representative of rural older adults and therefore the findings cannot be generalized. Finally, respondents of this study were drawn from older people who were able to visit health care centers and therefore excluded older people living in nursing homes.

# Conclusions

In summary, the present study found some associations between health literacy and HRQoL in older adults with T2DM. In addition, medication adherence, and diet and exercise adherence had a partial mediating role between health literacy and HRQoL. Therefore, further studies are needed to identify other variables and factors that mediating role mediate in relationship between health literacy and HRQoL among older diabetic patients.

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