



ORIGINAL ARTICLE

A theory of planned behavior-enhanced intervention to promote health literacy and self-care behaviors of type 2 diabetic patients

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Keywords

Diabetes • Self-care behavior • Health literacy • Attitude • Behavior change

Summary

Background. Improved health literacy and awareness could help type 2 diabetic patients to control the disease complications.

Objective. The current study aimed to evaluate the impact of theory-based educational intervention on health literacy and self-care behaviors of type 2 diabetic patients in Tonekabon city.

Methods. This randomized controlled trial study was conducted at health care centers in Tonekabon city, Iran, from April 5, 2017, to October 22, 2018. Using multistage random sampling, 166 patients with type 2 diabetes divided into two groups: theory-based intervention ($n = 83$) and custom education ($n = 83$). The data collection tools consisted of demographic information, Theory of Planned Behavior (TPB) measures, health literacy for Iranian adults (HELIA) and summary of diabetes self-care activities (SDSCA). The five 45-minute group training sessions based on the baseline assessment and model constructs along with the targeted

pamphlet and m-health strategy were designed for the experimental group. Data were analyzed using chi-square, independent and paired t-test and Analysis of covariance (ANCOVA).

Results. After controlling for pre-test effect, there was a significant difference between the two groups in terms of mean scores of attitudes, subjective norms, perceived behavior control and intention in post-test ($P < 0.001$). Also, after controlling for the pre-test effect, the results showed a significant difference in the self-care domain in the post-test ($P < 0.001$). Finally, after controlling for the pre-test variable effect, covariance analysis reflects significant difference in total health literacy score and its dimension at posttest ($P < 0.001$).

Conclusions. Applying TPB based education is suggested to maintain and improve self-care behaviors and health literacy in type 2 diabetic patients and other chronic diseases.

Background

TYPE 2 DIABETES AND ITS CONSEQUENCES

Diabetes, a chronic metabolic disorder and one of the major public health concerns, is regarded as a global epidemic [1]. The risk factors contributing to the development of type 2 diabetes (T2D) are comprised of age 45 years and older, obesity and overweight, sedentary lifestyle, polycystic ovary syndrome, high blood pressure, impairment in lactose tolerance test, unhealthy diet and cigarette smoking [2]. Complications associated with diabetes are comprised of visual impairments, kidney dysfunction, cardiovascular disease, impaired wound healing, diabetic foot ulcers and eventually death. Moreover, the rate of diabetic patient's hospitalization is said to be nearly 4.2 times more than other chronic diseases and patients' life expectancy be five to fifteen years shorter than other people's [3].

Having numerous complications, T2D adversely affects quality of patients' lives. Besides, with regard to non-communicable and chronic nature of T2D as well as imposing heavy financial burden on families and health care system, it is essential to take serious heed of the disease outcomes [4, 5].

PREVALENCE OF TYPE 2 DIABETES WORLDWIDE AND IN IRAN

Yearly, more than 7 million people worldwide suffer from diabetes, which would lead to nearly 3.8 million death related to it. Furthermore, every 10 seconds equates to a diabetic patient death. It is expected that the number of diabetic patients will approximately double by 2030 if no intervention is considered, developing countries to encounter with a 69% increase in diabetes prevalence [6]. In addition, estimations suggesting that 14% of Iranian population aged over 30 are diabetic, which their number will rise to 9 million by 2021 [7].

Considering the increasing trend of diabetes all around the world, World Health Organization (WHO) has regarded it as a hidden epidemic and requested all countries to deal with it. Therefore, given the lack of a certain cure for diabetes, what could play a key role in preventing its sever complications is to concentrate on appropriate cares such as regular blood sugar control and maintaining it in an optimum level [8].

SELF-CARE AND ITS ROLE IN DIABETES CONTROL

Studies have shown that maintaining blood glucose level in a normal range may cause eye and renal complications to delay by 8 and 6 years, respectively. There is no

denying that patients' responsibility in controlling blood sugar and effective management of the disease are an integral part of self-care behaviors [9].

Generally, self-care is an evolutionary process on enhancing knowledge and awareness through learning that improves life quality and leads to patient's better adaptation to stress, despite the complex nature of diabetes. Self-care comprises all the actions that each individual performs to take care of their health relying on knowledge, skills and capacities [10]. As a result, one of the changeable and effective risk factors in the incidence of T2D is the lack of adherence to self-care behaviors. Moreover, no adherence to self-care principles is the momentous underlying cause of mortality in individuals with diabetes. Several studies have reported that self-care can lead to longevity increasing, decreasing the incidence of disease complications or postpone it, and improving the quality of life (QOL) of diabetic patients [11, 12].

Despite the importance of self-care, research findings indicate that only 16.2% of diabetic patients adhere to self-care behaviors [9]. In addition, the results of Vosoghi et al. (2012) study revealed that 68.5% of patients with T2D have poor self-care ability [13]. Similarly, Parham et al. found that 53.5% of the patients do not perform self-care behaviors [14].

HEALTH LITERACY AND ITS RELATIONSHIP WITH SELF-CARE

Self-care is influenced by a set of knowledge, personal beliefs and attitudes, as well as the values and sociocultural characteristics. Among these, the role of knowledge about the nature of the disease and its preventive strategies strongly affects the control of the disease [15]. In contrast, patients should not only be able to obtain sufficient information about the disease and the necessary care skills but also to take advantage of their knowledge in different circumstances. Patients' skills to access, understand and use information from various sources will have an impressive effect on their behavior and health condition. Such skills are termed health literacy. Indeed, health literacy refers to an individual's capacity to gain access to, interpret, and understand the basic information, which is integral to make effective health related decisions [16]. Low health literacy could lead to patient's poor performance in activities such as blood glucose monitoring, medicine intake adjusting, consumed carbohydrate calculating [17].

WHO has identified health literacy as one of the greatest health determinant [18]. It is less probable that individuals with limited health literacy could perceive written and spoken information given by health experts [19]. Limited access to health care, self-care deficit, less adherence to treatment, continual hospitalization, and lack of confidence to health experts are of consequences of low health literacy [20]. Results of the latest national study in the United States demonstrated that 36% of adults have limited health literacy (adequate or borderline health literacy) [21]. Additionally, findings of Tehrani et al. indicated that 56.6% of

the individuals undergoing treatment have inadequate health literacy [22].

THE EFFECT OF EDUCATION ON SELF-CARE AND HEALTH LITERACY

Education, improved health literacy and awareness could help diabetic patients to control the disease conditions, reduce the level of perceived stress, and apply effective coping strategies. WHO has considered education as the foundation of diabetes treatment, and identified attitude change, self-care promotion and increased awareness as the key goals of diabetes education [23]. Appropriate education could lead to a decrease in diabetes complications up to 80% [24].

Theoretical framework of educational intervention

Despite the importance of education and improving health literacy in diabetic patients, previous studies on behavior changing have revealed that elevating knowledge is not sufficient to achieve it and is required to address other behavior determinants such as attitudes, social norms and environmental factors. In fact, the value of health education programs depends on the effectiveness of them, and subsequently the capacity of such programs to change behavior depends largely on the application of health education models. Moreover, most of the interventions using behavior change models have been more successful in achieving their goals [25]. The Theory of Planned Behavior (TPB), one of the social-cognitive models introduced by Ajzen and Fishbein in 1988, provides a useful framework for predicting and understanding of health-related behaviors. From the perspective of TPB, optimal behavior could be predicted by behavioral intention. Intention is the main indicator by which it can be understood how much people are willing to do things and try to plan for implementation of a particular behavior. It is, for its part, the result of attitude (positive or negative evaluation of the behavior), subjective norm (whether the significant individuals confirm the behavior or not) and perceived behavioral control or PBC (the expanse that individuals believe could control the behavior performance). Perceived behavioral control, additionally, could anticipate a behavior directly, which occurs when the behavior is not fully under individual's intention. Review studies have emphasized that the TPB is the most comprehensive and appropriate theory for studying diverse behavior [26-29].

SUMMARY AND PURPOSE OF THE PRESENT RESEARCH

Despite this, the application of this theory for designing interventions and assessing the degree of changes in behavioral psychology's predictions has not been well investigated. Moreover, there are limited studies on the educational interventions' assessing with the purpose of promoting health literacy and self-care in diabetic patients simultaneously, and most of research have focused only on the prediction and description of self-care determinants and correlation between the variables, or measured the effect of intervention on one of the self-care behaviors such as physical activity or foot care,

separately. To this end, the current study was undertaken to determine the effect of educational intervention based on TPB on the self-care behaviors and health literacy of T2D patients.

Material and methods

SETTING AND SAMPLING

The present study was a randomized controlled trial (RCT) conducted from March 2018 to April 2019. The purpose of this study was to determine the effect of theory-based education on health literacy and self-care behaviors in patients with T2D in Tonekabon, Mazandaran province, Iran.

The research society consisted of all T2D patients who referred regularly to 4 Tonekabon urban health care centers. The method of multistage random sampling was used for the sample selection. Firstly, through the 13 healthcare centers located in different parts of the city, 4 of them were randomly selected. Afterwards, among the volunteer patients of each center, eligible Participants were randomly selected on the basis of random numbers table.

Sample size was calculated based on previous studies, the confidence interval of 95%, test power of 80% and using G*power software about 66 patients. Due to simple random sampling, the effect size of 0.50 and probability of 20% drop in participants, 83 patients were considered for each of the experimental and control groups, finally.

Inclusion criteria were comprised of reading and writing ability, the history of at least six months of diabetes definite diagnosis, the history of drug therapy, living in the city up to a following year later, the lack of suffering from grade 2 diabetic foot ulcers and higher (based on Wagner's criteria and the confirmation of clinic specialist) and voluntary participation. While Inclusion criteria consisted of suffering from gestational diabetes, mental and physical disorders and uncontrolled underlying disease as high blood pressure (160/90 mmHg) despite taking medicine.

All participants signed an informed consent form before participation. The study protocol was approved by the University of Alberta Research Ethics Board and Alberta Health Services.

DATA COLLECTION

Data in the present study were gathered with the use of self-administered questionnaire including the following sections.

Demographic questionnaire

This questionnaire includes age, gender, education, employment status, marital status, economic status, history of having diabetes, medicine utilization, weight, and length.

Theory of Planned Behavior (TPB) constructs-related items

According to the of Fishbein & Ajzen (2010) Questionnaire

Design guidance, a semi structural interviewing was carried out from 10 T2D patients, and silent belief related to constructs were extracted. Subsequently, the first version of the items was designed on the basis of the extracted beliefs and previous studies. Then, an expert panel (including 2 health education assistants, 2 internal specialists, 2 nutrition experts, 2 public health expert) assessed the content validity of the questions and confirmed Content Validity Index (CVI) and Content Validity Rate (CVR). The values of 0.83 and 0.86 in CVI and CVR, respectively indicated the content validity of the scales. Then, in order to determine the reliability by the method of test retest reliability and also measure face validity, the questionnaire was completed by a sample composed of 10 T2D patients, with two weeks interval. In addition, Cronbach's alpha coefficient was used to determine the internal consistency. At last, the following scales were applied to measure the TPB-related structures:

- *subjective norms (5 items)*: patients were asked to express their agreement with each item on a 5-point Likert scale from 1 (completely disagree) to 5 (completely agree). The responses ranged from 5 to 25, and the higher was the score, the stronger was the social support for self-care. The Cronbach's alpha coefficient of 0.83 indicated good internal consistency, and the test-retest coefficient of 0.93 confirmed the reliability of the scale;
- *attitude (8 items)*: it was measured based on the 5-points Likert scale ranging from 1 (completely disagree) to 5 (completely agree). The scores ranged from 8 to 40, and the lower were the grades, the weaker were the attitude and vice versa. Moreover, the values of $r = 0.79$ and $\alpha = 0.76$ were the confirmative of internal consistency and acceptable reliability;
- *PBC (5 items)*: it was evaluated on the 5-points Likert scale ranging from 1 (not sure at all) to 5 (completely sure). The responses ranged from 5 to 25, and the higher was the score, the more was the intentional perceived control of patients on the desired behavior. Finally, the internal consistency and reliability of the questions of this scale were confirmed by Cronbach's alpha coefficient and test-retest;
- *behavioral intention (5 items)*: patients were requested to answer questions based on the 5-point Likert scale from 1 (completely disagree) to 5 (completely agree). The scores ranged from 5 to 25, and the lower were the scores, the weaker were the targets and vice versa. The Cronbach's alpha coefficient of 0.83 and the test coefficient of 0.93 indicated an internal consistency and a good reliability of the scale, respectively.

Short Test of Functional Health Literacy in Adults (STOHFLA)

This test is used to assess the health literacy of diabetic patients. The questionnaire is one of the most common and comprehensive general standard instruments in health literacy appraisal. The number of questions in

this questionnaire is 33, with the first 27 questions being answered based on the 5-point Likert scale from 1 (never) to 5 (ever). Answering to the rest of questions (the 7 remained ones) is done by means of Likert scale ranging from completely easy to completely hard. The questionnaire consisted of five dimensions as follows: *reading skills* (6 questions), *information accessibility* (6 questions), *information comprehension* (6 questions), *information analysis* (6 questions), and *decision making and information behavior* (9 questions). The final score of health literacy is considered between 33 and 165. Eventually, the scores are divided into three levels including inadequate literacy (77-123), borderline (123-149), and adequate health literacy (150-165). Validity and reliability of the questionnaire have been emphasized in previous studies [31, 32].

The Summary of Diabetes Self-Care Activities (SDSCA)

The questionnaire is composed of 15 questions on diet, physical activity, blood glucose monitoring, foot care and medication use. Each question is given a score from 0 to 7 in terms of the number of days in the last week that a person has performed self-care behaviors. As example, eight questions are related to nutritional behaviors with the range of scores from 0 to 56 dividing into undesirable (0-16), somewhat desirable (17-32) and desirable (33-56). Moreover, the total score of self-care is divided into the following levels: poor self-care (0-37), moderate self-care (38-71) and good self-care (72-105). The validity and reliability of the questionnaire has been confirmed in previous studies [33].

DATA COLLECTION PROCESS

After initial coordination and allocation of patients to experimental and control groups, they were asked to complete the questionnaires in the health centers in two stages of before and 2 months after the theory-based intervention. To this end, according to a pre-prepared timetable agreed upon by patients, they were requested to complete the research tool after receiving the health services. The questionnaires were filled out at approximately 45 minutes in the presence of one of the researchers. The researchers attended not only to answer possible questions, explain the method of completing scales, and make ensure from responding to all questions, but also to elucidate on the way of answering to the questions and emphasize on providing honest responses. In addition, they stressed on the anonymity and confidentiality of the contained information in the questionnaires.

THEORY BASED EDUCATION

After analyzing the patients' responses to the questionnaires in the first phase, the patients assigned to the experimental group participated in a multi-part training program. Participants in the intervention group consisting of 7-15 T2D patients were involved in five 45-minute training sessions. The goals of each session were determined by TPB constructs as well as first phase response analysis. A set of educational strategies tailored to the purpose of each session was used such as lecture, role

playing, focus group discussion, Q&A methods, brain storming and practical implementation of skills. Moreover, a 10-minute educational film, targeted pamphlet and educational booklet were given to the experimental group patients was used to remind the educational content presented at each session.

With regard to the capabilities and access of patients to the use of cyberspace and online social networking information, all the provided information in educational package were presented to all T2D patients involved in the experimental group with the use of m-health strategy and based on the WhatsApp application. Detailed information on the content and purpose of the training sessions is provided in Table I.

DATA ANALYSIS

SPSS software (version 23) was applied for data analysis. Data normality was confirmed based on Kolmogorov-Smirnov test. Descriptive statistics including mean and standard deviation, along with analytic statistics tests were used for data analysis. Moreover, the data were subjected to parametric tests as paired and independent t-test, chi-square and one-way analysis of variance (ANOVA). The significance level was considered of 5%. The present investigation was approved by the ethics committee of Qazvin University of Medical Sciences (IR.QUMS.REC.1396.354). Moreover, in order to respect for human dignity, after collecting the second stage data, all patients in the control group participated in an intensive educational course including two 60-minute training sessions. In addition, all the educational provision presented to the experimental group was also provided to T2D patients in the control group.

Results

The findings of Table I show the demographic and background characteristics of the patients participating in the study. The mean age of the patients was 57.3 ± 9.5 years and frequency of patients older than 50 years was higher than other age groups. Also, the mean BMI of patients was 27.5 ± 4.5 and approximately 50% of patients in both groups had BMI of 25-30. Moreover, half of the patients had primary education and almost 10% had a university education. In addition, about 2/3 of patients are retired and 12.05% of patients in the experimental group and 15.67% of the control group were housewives. The results of Chi-square test didn't show significant difference between the two groups in terms of demographic variables. Further results are shown in Table II.

The results of comparing the mean of self-care domains between the two groups before and after the educational intervention are shown in Table III. Results of independent t-test showed that there was no significant difference between the two groups in terms of mentioned variables before intervention. However, the mean of all self-care domains such as Diet, Blood Glucose Control, Regular Physical Activity, Medication Adherence and Foot Care increased significantly in the experimental

Tab. I. Details of the training program presented in the experimental group.

Session	Specific objective	Educational strategies	Training material	Instructional technology
Informing and awareness	<ul style="list-style-type: none"> Explain the blood sugar and its indicators, symptoms and T2D mechanism Identify the risk factors for T2D Describe the consequences of T2D Explain the relationship between risk factors and prevention of the consequences of T2D 	Lecture, Q&A	Tailored pamphlet, CD, booklet	Data projector, white board
Health literacy and self-care	<ul style="list-style-type: none"> Have access to appropriate information about foot care Have sufficient information about how to measure and interpret blood glucose Can learn how to properly evaluate physical activity status Patients understand the importance of taking medicines in a timely manner and in accordance with the physician's instructions Patients know how to measure the calorie content of different foods and are able to determine the amount of calories they need in meals 	Lecture with Q&A	Educational booklet and tailored pamphlet	Data projector and white board
Attitude change	<ul style="list-style-type: none"> Patients know that the consequence of the disease is preventable Patients know that the consequences of diabetes can be severe Patients know that self-care is the best way to maintain good health Patients emphasize the role of self-care and personal behaviors in comparison to environmental factors, luck, and appreciation Patients know that the consequences are likely to occur for them Understanding and evaluating the importance of self-care in preventing the consequences of diabetes 	Focus group discussion	Fear appeals photos and videos of diabetic foot ulcer patients	White board
Increase self-efficacy	<ul style="list-style-type: none"> Identify the physical barriers to implementing and maintaining self-care behavior Identifying individual potentials and capacities Identify environmental and external opportunities and facilities Examine available solutions for to implement and maintain self-care behavior Dividing tasks into smaller executable and more practical and easier steps Psychological and personal commitment to perform self-care tasks Implement self-care behaviors, group encouragement, and verbal persuasion 	Teamwork and role playing, individual counseling	-	White board
Practical skills	<ul style="list-style-type: none"> Practical display of blood glucose measurement and comparison with standards Practical display of foot examination & care A practical method for evaluating breathing and heart rate during physical activity A practical method for calculating food calories and comparing healthy and unhealthy foods Repeat and practice self-care skills and provide feedback 	Teamwork, practical presentation, individual counseling	Tailored pamphlet, educational booklet, CD	Data projector, white board

group after the intervention ($P < 0.001$). Despite this, the results of paired t-test did not show a significant change in the mean of these domains in the control group. Further results are shown in Table III.

The results of covariance analysis showed that the differ-

ence between the pre-test and post-test scores of the two groups was significant for the mean of attitude construct ($F = 621.77$, $P < 0.001$). Also, the eta coefficient indicates that Theory based educational intervention is able to explain 31.5% of the variance of attitude constructs in

Tab. II. Distribution of demographic characteristics of T2D patients in experimental and control groups.

Variables		Intervention (n = 83)		Control (n = 83)		P value
		Number	Frequency	Number	Frequency	
Age (years)	Less than 45	2	2.41	2	2.41	P = 0.39 $\chi^2 = 0.512$ df = 118
	46-50	7	8.43	6	7.23	
	51-55	14	16.9	13	15.66	
	56-60	19	22.9	18	21.69	
	60-65	20	24.1	24	28.92	
	Total	83	100	83	100	
BMI	Less than 25	20	24.1	21	25.31	P = 0.436 $\chi^2 = 0.271$ df = 118
	25.1-30	43	51.81	45	54.22	
	More than 30	20	24.10	17	20.48	
	Total	83	100	83	100	
Education	Elementary	43	51.81	41	49.4	P = 0.193 $\chi^2 = 6.079$ df = 4
	Middle school	17	20.49	19	22.9	
	High school	14	16.87	13	15.67	
	University	9	10.85	10	12.05	
	Total	83	100	83	100	
Job status	Housewife	10	12.05	13	15.67	P = 0.690 $\chi^2 = 2.249$ df = 4
	Retired	58	69.88	56	67.47	
	Employed	15	18.08	14	16.87	
	Total	83	100	83	100	

Tab. III. Comparison of mean and standard deviation of self-care and related dimensions in diabetic patients in experimental and control groups before and after educational intervention.

Self-care dimension		Intervention (n = 83)	Control (n = 83)	P value between two group
		Mean \pm SD	Mean \pm SD	
Physical activity	Before	1.80 \pm 0.78	1.75 \pm 0.75	0.41
	After	3.60 \pm 0.52	1.82 \pm 0.77	P < 0.001
	P value pre-post	P < 0.001	0.19	
Nutrition	Before	26.18 \pm 3.9	26.39 \pm 3.4	0.53
	After	41.30 \pm 10.1	26.33 \pm 3.91	P < 0.001
	P value pre-post	P < 0.001	0.53	
Foot care	Before	7.14 \pm 3.72	6.93 \pm 3.67	0.26
	After	18.38 \pm 2.16	7.10 \pm 3.72	P < 0.001
	P value pre-post	P < 0.001	0.20	
Medication adherence	Before	5.43 \pm 0.94	6.21 \pm 0.85	0.11
	After	10.09 \pm 0.47	6.35 \pm 0.91	P < 0.001
	P value pre-post	P < 0.001	0.16	
Blood glucose control	Before	2.40 \pm 0.76	2.30 \pm 0.85	0.18
	After	3.90 \pm 0.54	2.24 \pm 0.72	P < 0.001
	P value pre-post	P < 0.05	0.47	
Total self-care	Before	31.11 \pm 3.47	30.74 \pm 4.07	0.13
	After	63.05 \pm 5.18	31.35 \pm 3.22	P < 0.001
	P value pre-post	P < 0.001	0.63	

T2D patients ($F = 67.75$, $P < 0.001$). Moreover, the results of Table IV show there was a significant difference between the groups in terms of the subjective norms in the post-test ($F = 52.26$, $P < 0.001$). Also, Eta coefficient indicates that 26% of the variance of subjective norms is explained by theory based educational intervention. In addition, results showed that after controlling for pre-test effect, there was a significant difference between

the two groups in terms of PBC in post-test ($F = 23.69$, $P < 0.001$). According to Eta coefficient, it can be deduced that 13.9% of the variance of PBC is described by theory based educational intervention. Finally, after controlling for pretest effect, the results of covariance analysis showed a significant difference in posttest regarding behavioral intention ($F = 23.69$, $P < 0.001$). Also, Eta coefficient indicates that 27.3% of the variance in behav-

Tab. IV. Covariance analysis of the effect of theory-based educational intervention on mean of Theory of Planned Behavior (TPB) constructs in diabetic patients.

TPB constructs	Source	Sum of squares	df	Mean square	F	Sig	Partial eta squared
Attitude	Pre-test	3388.64	1	3388.64	621.771	0.82	0.809
	Group	369.24	1	369.24	67.750	0.000	0.315
Subjective norms	Pre-test	7.83	1	7.83	6.34	0.013	0.041
	Group	64.58	1	64.58	52.26	0.000	0.262
PBC	Pre-test	1095.56	1	1095.56	2684.72	0.138	0.948
	Group	9.67	1	9.67	23.69	0.000	0.139
Intention	Pre-test	6.99	1	6.99	22.198	0.097	0.131
	Group	17.36	1	17.36	55.106	0.000	0.273

Tab. V. Covariance analysis of the effect of theory-based educational intervention on self-care domains in diabetic patients.

Self-care domains	Sources	Sum of squares	df	Mean square	F	Sig	Partial eta squared
Physical activity	Pre-test	74.45	1	74.45	34.96	0.048	0.192
	Group	198.97	1	198.97	93.44	0.000	0.389
Diet	Pre-test	319.1	1	319.1	31.91	0.46	0.178
	Group	238.59	1	238.59	23.86	0.000	0.140
Foot care	Pre-test	5.782	1	5.782	0.703	0.003	0.005
	Group	1639.32	1	1639.32	199.31	0.000	0.576
Medication adherence	Pre-test	18.21	1	18.21	2.12	0.160	0.092
	Group	1002.26	1	1002.26	116.85	0.000	0.85
Glycemic control	Pre-test	0.11	1	0.11	0.007	0.035	0.001
	Group	1908.37	1	1908.37	119.34	0.000	0.88
Total self-care	Pre-test	146.48	1	146.48	12.9	0.042	0.381
	Group	749.89	1	749.89	66.1	0.001	0.76

ioral intention is explained by theory based educational intervention. Further results are shown in Table IV.

The findings are listed in Table V show the result of One-way covariance analysis regarding the effect of theory based educational intervention on self-care domains in patients with type 2 diabetes. After removing the pre-test effect, there was a significant difference between the mean scores of physical activity in the post-test ($F = 93.44$, $P < 0.001$, $\eta^2 = 38.9$). In addition, Eta coefficient indicates that 38.9% of variance in physical activity domain is predicted by educational theory-based education. Moreover, after controlling for the pre-test effect, the results showed a significant difference in the nutrition domain in the post-test ($F = 23.86$, $P < 0.001$, $\eta^2 = 14.0$) and Eta coefficient also indicates that 14% of the variance in nutrition domain is explained by theory-based education. Finally, after controlling for the pre-test variable effect, results of one-way ANCOVA reflect significant difference in foot care ($F = 199.31$, $P < 0.001$, $\eta^2 = 57.6$), medication adherence ($F = 116.85$, $P < 0.001$, $\eta^2 = 8.5$), blood glucose control ($F = 119.34$, $P < 0.001$, $\eta^2 = 8.8$) and total self-care ($F = 66.1$, $P < 0.001$, $\eta^2 = 7.6$) in posttest. In addition, theory-based educational intervention was able to describe 57.6, 5.8, 8.8 and 7.6% of the variance in foot care, medication adherence, glycemic control, and self-care behaviors, respectively ($P < 0.05$). Further results are shown in Table V. The results of Table VI are related to the mean and stan-

dard deviation of the total health literacy score and its dimensions in the experimental and control group patients before and after the educational intervention. Results of independent t-test before the intervention did not show any significant difference between the two groups in terms of the mentioned variable and its dimensions. However, the mean scores of reading skills, accessibility, comprehension, analysis and decision making significantly improved in the experimental group after the intervention ($P < 0.001$). Also, the mean score of total health literacy in the experimental group increased significantly after the educational intervention ($P < 0.001$). Table VII shows the results of the analysis of covariance regarding the effect of theory-based educational intervention on health literacy dimensions and its total score in T2D patients in the experimental and control groups. The findings indicate that after controlling the pre-test effect, there was a significant difference between the mean of reading skills in the post-test ($F = 65.49$, $P < 0.001$, $\eta^2 = 0.76$). Eta coefficient also indicates that 76% of the variance of reading skill dimension is predicted by educational intervention. In addition, after controlling for the pretest effect, the results indicated a significant difference in the mean score of information accessibility ($F = 28.82$, $P < 0.001$, $\eta^2 = 0.50$), Information Comprehension ($F = 96.16$, $P < 0.001$, $\eta^2 = 0.78$), information analysis ($F = 85.87$, $P < 0.001$, $\eta^2 = 0.80$), decision making and information behavior ($F = 105.48$,

Tab. VI. Comparison of the mean and standard deviation of different dimensions of health literacy and its total score in diabetic patients in experimental and control groups before and after the theory based educational intervention.

Health literacy dimension	Number of items	Range of score	Follow-up time	Group		Sig
				Control (n = 83) Mean ± SD	Intervention (n = 83) Mean ± SD	
Reading skills	6	6-30	Baseline	16.83 ± 4.42	17.57 ± 4.13	0.542
			2 months after	17.15 ± 4.28	26.22 ± 3.41	P < 0.001
			P value*	0.611	P < 0.001	
Information accessibility	6	6-30	Baseline	15.31 ± 3.52	16.09 ± 4.11	0.307
			2 months after	16.45 ± 2.81	24.76 ± 3.51	P < 0.001
			P value*	0.264	P < 0.001	
Information comprehension	6	6-30	Baseline	13.94 ± 4.27	15.00 ± 3.92	0.097
			2 months after	15.55 ± 3.73	24.80 ± 4.33	P < 0.001
			P value*	0.831	P < 0.001	
Information analysis	6	6-30	Baseline	16.82 ± 3.55	17.19 ± 2.90	0.733
			2 months after	18.1 ± 3.05	25.76 ± 2.64	P < 0.001
			P value*	0.229	P < 0.001	
Decision Making and information behavior	9	9-45	Baseline	24.66 ± 5.25	25.10 ± 4.83	0.561
			2 months after	26.02 ± 4.66	35.6 ± 4.68	P < 0.001
			P value*	0.188	P < 0.001	
Total score of health literacy	33	33-165	Baseline	92.86 ± 11.89	93.27 ± 12.72	0.108
			2 months after	94.33 ± 12.64	132.14 ± 13.81	P < 0.001
			P value*	0.429	P < 0.001	

P value*: significant value pre-post intervention.

Tab. VII. Covariance analysis of the effect of theory-based educational intervention on the dimensions of health literacy in diabetic patients.

Health literacy dimension	Sources	Sum of squares	df	Mean square	F	Sig	Partial eta squared
Reading skills	Pre-test	1.34	1	1.34	0.076	0.78	0.004
	Group	1161.8	1	1161.8	65.49	0.001	0.760
Information accessibility	Pre-test	42.22	1	42.22	6.31	0.01	0.19
	Group	945.37	1	945.37	28.82	0.001	0.50
Information comprehension	Pre-test	284.38	1	284.38	10.13	0.009	0.21
	Group	769.36	1	769.36	94.16	0.001	0.78
Information analysis	Pre-test	102.97	1	102.97	5.88	0.024	0.22
	Group	1501.38	1	1501.38	85.87	0.001	0.80
Decision making	Pre-test	4.99	1	4.99	0.43	0.521	0.020
	Group	1237.26	1	1237.26	105.48	0.001	0.83
Total score of health literacy	Pre-test	137.25	1	137.25	6.93	0.370	0.21
	Group	1911.42	1	1911.42	91.41	0.001	0.84

P < 0.001, $\eta^2 = 0.83$) in the post-test. Also, Eta coefficients associated with each dimension showed that theory-based intervention was able to describe 50, 78, 80 and 83% of the variance in the information accessibility, comprehension, analysis and decision making dimensions, respectively. Finally, after controlling for the pre-test variable effect, covariance analysis reflect significant difference in total health literacy score at post test and theory-based education was able to explain 84% of the variance in total score of health literacy in diabetics patients (F = 91.41, P < 0.001, $\eta^2 = 0.84$).

Discussion

The purpose of present study was to determine the ef-

fect of a theory-based educational intervention on health literacy and self-care behaviors in T2D patients. Generally, the findings showed that the intervention based on TPB could improve the health literacy and self-care behaviors in the participated patients. In accordance with the current study, in a meta-analysis conducted on the effect of diabetes self-care interventions with a focus on health literacy, positive changes were obtained in cognitive-psychological health, along with desirable health outcomes and self-care improvement [34]. Furthermore, the results of a systematic review of Berkman et al. (2011) indicated a health literacy intervention has a significant effect on prevalence of disease, knowledge, self-efficacy and medication adherence [35]. The findings of the study by Zhao et al. (2015) are consistent with the results of the present study [36].

One of the major results of this study was the score enhancement of all domains and the total score of health literacy among experimental group after intervention. Health literacy is the capacity of individuals to acquire, process, and understand basic health services and information in order to make appropriate health decisions [16]. Limited health literacy is influenced by complex mechanisms that affect health and health outcomes including reduced access to health care, poor interactions between patient and health care providers, and a lack of proper self-care under specific circumstances, all of which are crucial to the diabetes management [37]. In fact, inadequate health literacy refers to the patients who are incapable of acquiring, interpreting, and understanding health-related information, which is of paramount importance for making correct decision in health care system. As a result, they need to be informed and educated in a different way than others. Given the findings of present study, most of the patients in experimental group had insufficient health literacy before intervention, and the number of those with borderline and adequate health literacy was low, respectively, which was in line with the results reported by Esfahrood et al. (2016), and Fransen et al. (2012) [38, 39]. After the educational intervention, the number of patients whose health literacy was improved significantly increased and it is reasonable to expect a significant decrease in the percentage of T2D patients with low levels of health literacy. Similar results in consistent with ours have been reported on the enhancing of health literacy as a function of theory-based education impact [40, 41]. Some studies have emphasized the necessity of designing and implementing educational interventions equal to the level of health literacy of patients, and shown that the determinants of health behaviors in patients with various levels of health literacy significantly differ; to this end, the same interventional strategies shouldn't be designated. In addition, the following strategies could be employed to improve health literacy in patients: simple and understandable communication, gradual presentation of information and an emphasis on information curtailment, limiting information provided at each patient referral, repeating information in various ways, repeatedly receiving feedback and refining the education process, encouraging patients to be curious, and focusing on simple media utilization [42, 43]. Overall, it is recommended that health care experts be familiar with the concept and strategies of health literacy, and apply these skills while educating patients in order to better returnee's perception of represented information in addition to the enhancement of effectiveness of educational interventions.

Another important finding of the present study was that the TPB theory constructs comprising attitude, subjective norms, PBC, and behavioral intention improved significantly after intervention in the experimental group. This is in accordance with the results obtained by Beiranvand et al. (2016), Taha et al. (2016) and Reisi et al. (2017) [44-46]. Also, a review of 20 RCT by Zhao et al. (2017) revealed that theory-based self-management educational interventions on patients with T2D were able

to significantly improve patients' self-efficacy, diabetes knowledge and other psychological variables [47]. So, the multidimensional nature and complexities associated with self-care behaviors justify the necessity of using theories and patterns of behavioral change to describe factors influencing the foregoing behavior. The association between TPB constructs and self-care behaviors in diabetic patients has been well predicted in various studies. Identification of psychological factors affecting self-care behavior is an indispensable and undeniable step in the design of interventions [48].

Amongst the TPB constructs used in this study, the mean score of attitudes of the experimental group significantly improved after the intervention, which is in agreement with the results of previous investigation [44, 45]. Generally, adopting health behaviors in diabetic patients will arise from an individual's evaluation of positive and negative consequences of the recommended behavior, perceived benefits and barriers, understanding the outcomes of not following the advised behavior, the severity of the complications, and the perceived risk [49]. It could be hypothesized that the reason for the improvement of attitude and self-care behaviors is considering attitude as one of the principal components of the educational program. Particular concentration on perceived threats and sensitization to various complications of a disease, being negligible before the educational intervention, promises the effectiveness of education in designing educational content. Developing a positive attitude in diabetic patients could cause adherence to self-care behaviors. Besides, there is a positive correlation between attitude and the level of health literacy in diabetic patients. Therefore, patients' health literacy enhancement could in turn affect attitude changes positively. It is recommended that health experts reinforce positive attitudes and reduce negative beliefs using techniques such as qualitative interviewing, and effective intervention strategies like focus groups.

Moreover, to attitude change, the experimental group achieved significantly higher mean score in subjective norms after the intervention, which is in line with previous research findings [49-51]. Song et al. (2017) after reviewing 28 interventional studies concluded that there was a moderate and significant relationship between social support and self-care in diabetic patients [52]. In this regard, research has revealed that the level of psychological vulnerability of individuals with higher social support is lower than others. Social support could be effective in controlling diabetes through two major processes: the direct impact of social support via health-related behaviors such as encouraging healthy behaviors, and the shield effect of social support that contributes to the adjustment of acute and chronic neurotic stress effects on health, as well as increased adaptation to diabetes neurotic pressure [53, 54]. In fact, the relationship between social support and improvement in behaviors controlling disease, diet adherence and self-management in diabetic patients has been approved. Whenever stress levels were high, diabetic patients who received more social support would have better glycemic control. Also, family sup-

port is the momentous predictor of adherence to treatment in patients with type 2 diabetes, whereas family's non-supportive interactions predict poorer adherence to diabetes self-care program. Consequently, forming small groups and participating in focus group discussions, expressing the barriers of self-care by other patients, the presence of family members and their involvement in education, along with building up the sense of care, being loved, self-esteem, and feeling valued would lead to improvement of self-care behaviors [55]. Thus, special places should be considered for engagement of family members' participation in self-care education programs. The present study also found a significant improvement of mean score for PBC after educational intervention in the experimental group. These results are in consistence with those obtained by Beyranvand et al. (2016) and as well as other researchers [44, 45, 50]. With regard to the results of investigations, a strong comprehension of disease controllability is likely to be accompanied by stronger self-regulatory behaviors.

Moreover, individuals with higher self-efficacy expect better outcomes, and consider barriers to self-care as overcoming challenges. Previous studies have reported a significant and positive correlation between patients' level of health literacy and PBC and identified health literacy as the predictor of PBC [48, 49, 56]. Hence, it could be speculated that such improvement in PBC is due to the focus of the educational program on promoting health literacy in the first place. It is also worth noting that strengthening social support, along with improving self-efficacy, could contribute to increasing of the perception of disease controllability and the potential for behavior change [56]. Overall, given the significant impact of self-efficacy on self-care, its reinforcement with proprietary strategies should be amongst the particular goals of interventions.

The most momentous finding in our study was changes in self-care behaviors of diabetic patients in experimental group after theory-based educational intervention, which is line with those obtained by Al-Hashmi et al. [57] and Mohammadi et al. [58]. Diabetic patients may have diverse plans for controlling their disease and use various tactics unconsciously; yet irregular and unplanned utilization of control guidelines to overcome temptation, different social pressures, as well as lack of motivation due to low self-efficacy would result in loss of self-care [59]. In such circumstances, education and intervention will be needed to make self-care behaviors part of their daily routine. Consequently, patients' mental capacity to accept the recommended changes will increase.

Following self-care behaviors regularly is a highly complex process influenced by a variety of factors and changing these behaviors requires a comprehensive theory-based approach. Accordingly, considering the nature of self-care behaviors in diabetic patients and the role of personal beliefs, as well as the predictive feature of personal beliefs in adherence to self-care behaviors, the choice of TPB theory could be one of the main points of the present study.

It is worth noting that due to the complicated nature of

health behaviors, none of theories of behavior change can independently describe and predict all aspects of health behaviors. And applying a combination of theories and models is needed to ameliorate significantly the efficiency and effectiveness of educational interventions. Thus, following studies can implement other models to enhance the effectiveness of interventions and design more effective pamphlets such as Transtheoretical Model, Pender's Health Promotion Model, Health Action Process Approach Model, Health Belief Model, Social Cognitive Theory, and/or Stage of Change Model.

STUDY LIMITATION

The current study had several limitations, including: first, due to budget constraints and time of project implementation, the findings of experimental group were compared merely with the results of a control group, which makes it difficult to judge the effectiveness of the TPB based intervention as compared to other models of behavior change. So, in order to increase the ability to evaluate the impact of theory-based intervention it is essential that a traditional training group and a group receiving training based on other behavior change included in the intervention design. Second, it is proposed to focus on a specific behavior such as regular insulin injection or foot care instead of focusing on a complex set of behaviors or complex behaviors such as healthy eating. Third, lots of environmental and external factors affect patients' adherence to self-care behaviors, which are changing constantly; therefore, it should not be expected that a brief educational program by itself solve the problems. Changing behaviors is a continuous process influenced by a chain of behavior change techniques that is gradually provided by different channels. Continuing the education process, maintaining a healthy relationship with the audience, and providing reminders can reduce relapse. In addition, education through mass media, Community-Based Intervention and Online education can maintain behavioral change. Fourth, in the current study follow-up was performed only 2 months after Theory based education, and obviously, decision-making about the stability of education would require several follow-ups. It is recommended that future studies use either a Washout design or one- and two-year follow-up. And lastly, self-report and self-administered questionnaires were applied for collecting data in this study that will be accompanied by bias although the validity and reliability of this method have been confirmed in studies. Hence, it is recommended that future research apply other direct measuring methods of behavior such as the laboratory (HbA1c and FBS measurement) or anthropometric indices (BMI).

Conclusions

The results implied that educational intervention based on the constructs of TPB can considerably elevate the level of health literacy, attitude, subjective norms, PBC, and behavioral intention in patients with T2D. Further-

more, the effectiveness of theory-based education in promoting self-care behaviors such as regular adherence to the prescribed medication, foot care, regular physical activity, healthy diet, and blood glucose self-monitoring were confirmed. Therefore, applying this model of behavior change is suggested to maintain and improve self-care behaviors in both T2D patients and other chronic diseases.

Ethical approval

The study protocol was approved by the Ethics Committee of Qazvin University of Medical Sciences (IR.QUMS.REC.1396.354- January 2016).

Acknowledgements

The present manuscript was extracted from a research project in biochemistry. Special thanks and appreciation go to the physicians, health care experts, nurses and other personnel of Tonekabon Health Centers who collaborated in conducting different phases of this study. We also appreciate all the type 2 diabetes patients who participated in the study.

Funding sources: the present study was supported by Vice-Chancellor for Research and Technology of Qazvin University of Medical Sciences.

Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

IMZ was involved in the study concept, design, analysis, interpretation of data, and drafting of the manuscript. HM and HAO supervised the conduct of the study.

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Received on March 17, 2020. Accepted on August 12, 2020.

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How to cite this article: Zeidi IM, Morshedi H, Alizadeh Otaghvar H. A theory of planned behavior-enhanced intervention to promote health literacy and self-care behaviors of type 2 diabetic patients. *Prev Med Hyg* 2020;61:E601-E613. <https://doi.org/10.15167/2421-4248/jpmh2020.61.4.1504>

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