

The Effectiveness of Theory Based Educational Intervention on Health Literacy, Medication Adherence and Self-Manag

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Keywords

Health Literacy • Self-Care • Type 2 Diabetes • Medication Adherence • Education

Summary

Introduction

Theory-based educational interventions can play an important role in improving health literacy and promoting self-care behaviors and preventing diabetes complications. This study was conducted with the aim of investigating the effectiveness of educational intervention based on the Extended Theory of Planned Behavior on health literacy, medication adherence, self-care behaviors and metabolic indicators in T2D patients.

Methods

The present research was a Quasi-experimental study with a control group and measuring outcome variables at baseline and 3 months after the theory-based intervention. With multi-stage sampling, 112 patients with T2D referred to healthcare centers of Qazvin city were assigned to experimental and control groups equally. The intervention included six online group education along with educational video, pamphlets and 60 SMS reminders using strategies as role-playing, lecture, and scenario presentation. The data collection tools were: Demographic items, summary of diabetes self-care activities scale, short test of functional health literacy

in adults, The Morisky 8-item medication adherence scale, Sub-Scales of extended TPB (36 items). Paired and independent t-test, chi-square, ANOVA and ANCOVA were used to data analysis.

Results

The mean of attitude, subjective norms, perceived behavioral control, action planning, coping planning, trust and the intention associated with health literacy and medication adherence increased significantly in the experimental group in the post-test by controlling the effect of the pre-test variable ($P < 0.001$). In addition, the results of ANCOVA showed the improvement in the total mean score of self-care and its dimension along with the meaning of FBS and HbA1c in the experimental group in the post-test ($P < 0.001$).

Conclusions

The focus of nurses and other medical staffs on improving health literacy, action & coping planning and psychological variables in the design of cognitive behavioral interventions can lead to improving self-care and medication adherence in T2D patients.

Introduction

Type 2 diabetes (T2D) is a chronic disease caused by various individual and environmental factors. Statistics emphasize the high prevalence of T2D as a major concern of healthcare systems and the main threat to the health of millions of people worldwide [1]. The estimation showed that 9.3% of adults aged 20-79 years worldwide have T2D, and on average, one out of every 11 adults might be diagnosed with diabetes [2]. In addition, almost two-thirds of people with diabetes do not reach treatment goals (HbA1c less than 7%) due to various reasons, such as non-adherence to the medication regimen or lack of adequate access to healthcare [3]. Therefore, a long-term increase in HbA1c (Glycated haemoglobin) and fasting blood sugar (FBS) levels have serious consequences, such as increasing the readmission rate, treatment costs, and premature mortality [4]. Moreover, non-communicable diseases cause almost three-quarters of deaths, and premature death from T2D has increased

by approximately 5% between 2000 and 2016, despite the downward trend of non-communicable diseases [5]. Behaviors are the main factors affecting the health of T2D patients, and self-care plays an important role in controlling the short- and long-term consequences of T2D [6]. In addition, diabetes education is essential to improve self-care and reduce HbA1c. Moreover, the theoretical foundations and various strategies for educating T2D patients by nurses, midwives, and other healthcare workers (HCWs) have been increasingly strengthened in the past decade, and self-management education and empowerment have been recognized as an effective strategy for increasing self-care and reducing HbA1c [7]. However, nursing research and patient education studies have highlighted the low level of self-care behaviors, low participation in self-management and poor control of metabolic indicators in many T2D patients [3, 8, 9]. Many studies have confirmed the relationship between self-care behaviors and health literacy. In addition, there is a clear relationship between

the ability to access, understand, and use information from different sources and health and disease status [10, 11]. Health literacy refers to people's capacity to access, interpret, and understand basic information, which plays a fundamental role in making correct health decisions [12]. A low level of health literacy can lead to poor self-care behaviors such as lack of proper blood glucose monitoring and lack of ability to assess health status in general [13]. Unfortunately, despite the WHO's emphasis on the role of health literacy as a major determinant of health, many T2D patients do not have an optimal level of health literacy. For example, Mohammadi et al. (2015) emphasized that only 18.2% of T2D patients participating in the research had adequate health literacy skills, 11.8% had marginal, and 70.0% had inadequate health literacy skills [14]. Moreover, a review study by Momeni et al. (2020) showed that the mean score of health literacy in Iranian T2D patients is 56.65 and the status of health literacy in both sexes is not satisfactory [15]. In addition, Maleki Chollou et al. (2020) emphasized the low level of health literacy in T2D patients in Iran; health literacy and self-care behaviors described 80% of the variation in HbA1c [16]. Patients with different psychosocial characteristics may have different perceptions and beliefs about the educational programs provided by nurses or other medical staff, and the impact of such psychosocial variables on educational outcomes is often ignored [17] and as a result, one of the reasons for the failure of patients' education programs to achieve the desired level of behavior change can be the provision of the same educational content without considering psychological differences [18]. Additionally, the effectiveness of educational programs depends on the correct use of behavior change models by nurses, midwives, and other medical staff members. Choosing an appropriate behavioral change model is the first step in designing cognitive behavioral interventions [19].

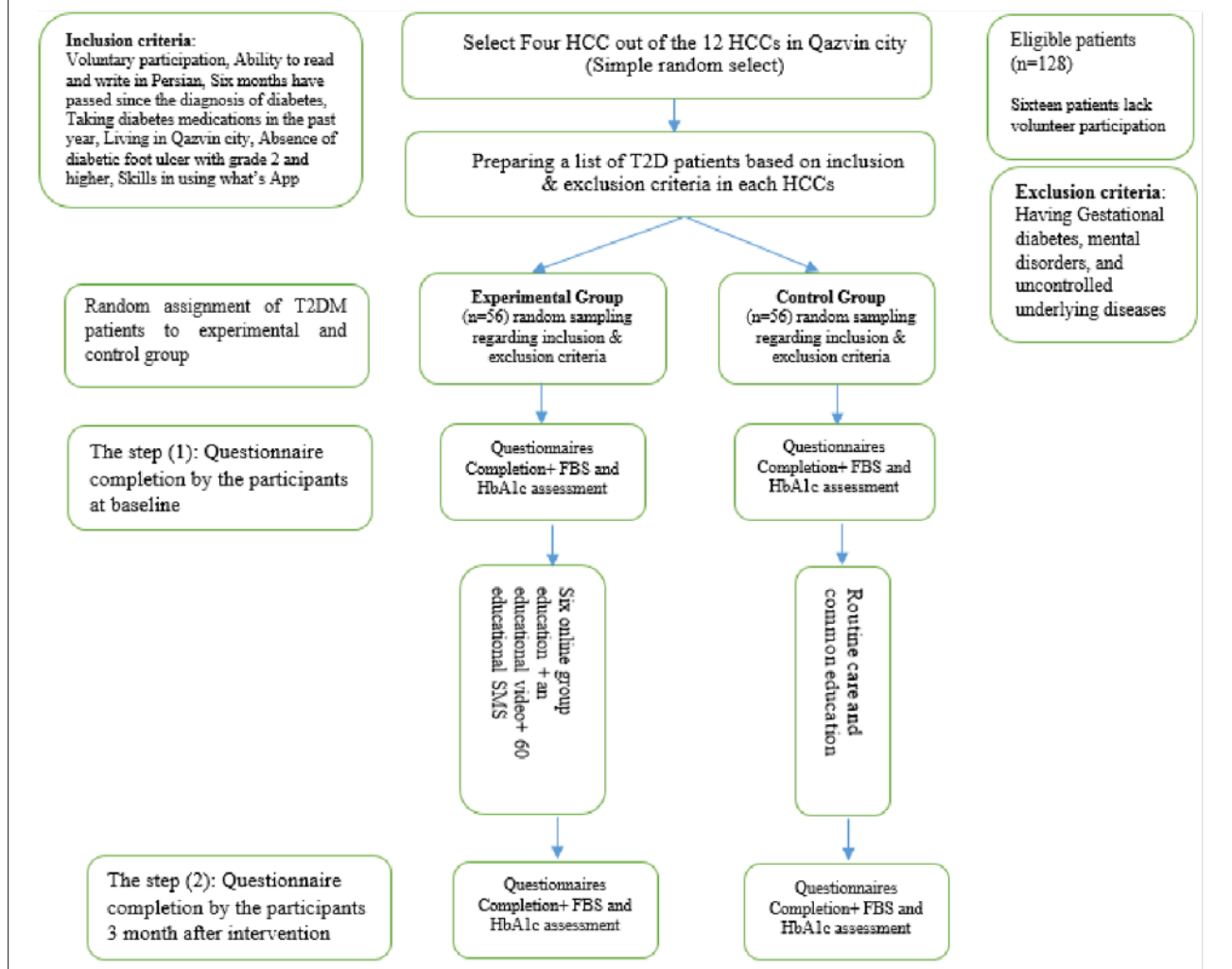
A comprehensive and useful theoretical framework for discovering and changing factors affecting self-care behaviors in T2D patients is the Theory of Planned Behavior (TPB). Ajzen and Fishbein (1987) established this theory, considering its central role. Additionally, the design of the model based on value expectation theory can play an important role in explaining the factors related to health and social behaviors [20]. TPB has paid special attention to the contribution of effective involuntary and environmental factors in creating behavior in addition to individual voluntary factors [21, 22].

This model consists of attitude, subjective norms, perceived behavioral control (PBC), intention, and behavior, and predicts the occurrence of a specific behavior when the individual intends to perform it. This model is one of the most effective and comprehensive for describing the relationship between attitude and behavior [23]. The main assumption in this theory is that intention is the main predictor and influencing variable on behavior, and includes the desire, planning, and intention to perform the behavior. Intention, in turn, is influenced by other constructs, including attitudes,

subjective norms, and PBC. Attitude is the result of a person's assessment of the positive and negative consequences of performing a behavior and refers to the general feeling of liking and disliking a certain behavior. The more favorable the attitude towards a behavior, the more likely a person is to perform that behavior. The subjective norm also refers to a person's belief about the influence of significant others; in other words, it reflects the degree to which a person perceives approval and disapproval for performing a behavior from significant others, such as family members, colleagues, and close friends. For example, if the patient imagines that nurses and other medical professionals approve of self-care behaviors, the probability of continuing certain behaviors will be higher. PBC refers to the fact that a person feels that the desired behavior is under their voluntary control; in other words, the perceived difficulty or ease of a certain behavior is reflected in these constructs [21, 22, 24]. Previous studies have emphasized the effectiveness of TPB in explaining the psychosocial variables affecting self-care behaviors in T2D patients [25-27]. For example, Pan et al. (2023) showed that attitude, subjective norms, and PBC were strong predictors of intention, whereas intention and PBC had a direct effect on self-care behaviors [26]. Moreover, the relationship between behavioral intention and exercise, blood glucose monitoring, and foot care was also confirmed in a study by Lin et al. (2020) [27]. In addition, many studies have shown that interventions based on TPB lead to improvements in self-care behaviors and health literacy in T2D patients [14, 28-31]. For example, Kazemi and Rahmati (2021) found that T2D patients' lifestyles improved after participating in a theory-based educational program associated with motivational interviewing [30]. The improvement in preventive nutritional behaviors and TPB constructs after participating in a 6-week educational workshop based on TPB was also confirmed by Maleki et al. (2016) [31]. Despite the efficiency and effectiveness of TPB in predicting and changing self-care behavior in T2D patients, this theory has been criticized by some researchers [32, 33]. For example, some researchers believe that TPB often ignores the emotional aspects of attitudes and considers only logical and cognitive factors. In addition, the amount of variance predicted by TPB constructs can be significantly improved by adding new psychological variables. In other words, the relationship between intention and behavior can be influenced by other variables. For example, White et al. (2012) showed that an educational intervention based on extended TPB led to more short-term improvements in physical activity in T2D and cardiovascular patients, and adding a planning construct can make a significant contribution to improving training outcomes [32]. Ferreira et al. (2017) also emphasized the improvement of the potential of predicting the variance of physical activity after adding trust in the physician, action, and coping planning to the TPB framework [33].

Therefore, considering the increasing prevalence of T2D and the serious consequences resulting from it,

Fig. 1. Consort diagram of research stages.



the efficiency of theory-based educational interventions in improving self-care behaviors and health literacy, and the necessity of familiarizing nurses with the design of theory-based interventions, the present study was conducted with the aim of investigating the effectiveness of the educational intervention based on the Extended Theory of Planned Behavior on health literacy, medication adherence, self-care, and metabolic indicators in T2D patients with in Qazvin city.

Materials and Methods

STUDY TYPE

The current research is a quasi-experimental study aimed at measuring self-efficacy, self-care behaviors, and metabolic indicators (FBS and HbA1c) in T2D patients (experimental and control groups) in Qazvin city before and three months after the theory-oriented educational intervention, conducted between June 2021 and March 2022.

PARTICIPANT, SAMPLE SIZE AND SAMPLING PROCESS

The research population included all patients with type 2 diabetes receiving healthcare and covered by healthcare centers in Qazvin city. The sample size required to conduct the previous study was calculated based on previous studies [14, 28], according to a 95% confidence level, 80% power, and an effect size of 0.45, and 112 patients with type 2 diabetes were randomly and equally assigned to the experimental and control groups. To select the participants, four healthcare centers (HCC) were selected from all HCC of Qazvin city by simple random sampling, and then registered nurses based on the inclusion and exclusion criteria prepared a list of T2D patients in each center. In the next step, patients were assigned to one of the experimental or control groups using a table of random numbers. The steps for assigning patients to the study groups are shown in a consort diagram (Fig. 1).

INCLUSION AND EXCLUSION CRITERIA

The entry criteria were voluntary participation, ability to read and write in Persian, age between 18 and 60

years, at least six months since the definitive diagnosis of type 2 diabetes, history of drug treatment, willingness to receive nursing care and treatment at home, living in Qazvin city, and actively visiting HCCs for at least one year. Not suffering from diabetic foot ulcer (grade 2 or higher based on Wagner's diagnosis criteria and endocrinologist confirmation) and the ability to use WhatsApp application. In addition, the exclusion criteria were as follows: returning incomplete questionnaires or refusing to answer all items, non-participation in part of training sessions (less than 50% of sessions), unwillingness to test blood glucose and HbA1c, uncontrolled underlying diseases such as uncontrolled hypertension (90/160 mmHg) despite taking medication, suffering from severe diseases or disabilities such as blindness, limb amputation, cardiovascular diseases, respiratory disorders, brain damage, and kidney failure leading to dialysis, and finally using any type of psychoactive drugs (except insulin drugs).

INTERVENTION PLAN AND CONTENT

In addition to routine patient education, an educational program based on the extended TPB was prepared, and an expert panel approved its scientific content validity. Routine education includes short-term, face-to-face, in-person, and daily training provided by healthcare personnel to remind them of the importance of self-care. This program included six online group training sessions (approximately 45 minutes). The groups consisted of 6 to 9 patients, and the educational sessions were held weekly. The hours and days of online training sessions were provided to each of the participants by two text messages: one day and one hour before the training sessions. The content of the educational sessions was compiled according to the extended TPB constructs and the evaluation of the answers to the questionnaires collected from the first stage. Based on the objectives of each session, several educational strategies, including lectures, group discussions, question-answers, role-playing, and brainstorming, were used to transfer information, change beliefs, and promote behavior. At the same time, to remember the contents of the sessions, two short educational video clips (7 minutes) along with two targeted pamphlets were given to the experimental group. Online group training was conducted on WhatsApp, and a free internet package (5 GB) was given to each patient to increase participation in online sessions. Moreover, 10 educational messages were designed for each session to remember the content of each session in one-week intervals between online sessions. In addition, in the final phase of the study and after completing the questionnaire, all patients in the experimental and control groups were given a certificate of participation in the research, along with a pocket calendar and a stationery package as a gift. The contents of the educational sessions are presented in Table I.

DATA COLLECTION INSTRUMENTS

The patients with T2D in two groups completed the data collection tools, which included a multi-part

questionnaire and a clinical assessment of metabolic indexes as FBS and HbA1c, before and 3 months after the educational intervention. The research tools were:

1. Demographic and medical history items include age, gender, economic status, marital status, education level, family history of diabetes, BMI (body mass index), and employment status.
2. Fasting blood sugar (FBS) and Glycated hemoglobin A1C (HbA1c): These indicators were measured based on the guidelines for measuring FBS and HbA1c of the Iranian Ministry of Health and Medical Education regarding 8 hours of fasting [34].
3. Summary of Diabetes Self-Care Activities (SDSCA), which consisted of 15 questions about diet, physical activity, blood sugar monitoring, foot care, and medication use. Each question was scored from 0 to 7 in terms of the number of days the person performed self-care behaviors in the past week. The total score ranges from 0 to 56 and is divided into three levels: unfavorable (0-16), somewhat favorable (17-32) and favorable (33-56). In addition, the final scores for physical activity and blood sugar control were classified into three levels: unfavorable (0-2), somewhat favorable (3-4) and favorable (5-7). Three questions were used to assess foot care behaviors, and the range of scores was 0-21, classified into unfavorable (0-6), somewhat favorable (7-12) and favorable (12-21) levels. Finally, two questions were used to assess medication adherence. The scores in this section range from 0 to 14, which is divided into three levels: unfavorable (0-4), somewhat favorable (5-8) and favorable (9-14). The total self-care score was divided into the following levels: poor self-care (0-37), moderate self-care (38-71), and good self-care (72-105). The psychometric properties of the mentioned scale have been confirmed in the previous studies [35, 36].
4. Short Test of Functional Health Literacy in Adults (S-TOFHLA): This questionnaire is one of the most comprehensive general standard tools for evaluating health literacy. It consists of 33 questions, with the first 27 answered based on a 5-point Likert scale from 1 (never) to 5 (always). The remaining 7 items are answered using a Likert scale from completely easy to completely difficult. The questionnaire includes five dimensions as follows: reading (6 items), access to information (6 items), understanding (6 items), appraisal (6 items), and decision making (9 items). The final health literacy score ranges from 33 to 165. The total mean score is divided into three levels: insufficient literacy (33-77), marginal literacy (78-122), and adequate health literacy (123-165). The validity and reliability of the S-TOFHLA have been emphasized in previous Iranian studies [37, 38].
5. The Morisky 8-Item Medication Adherence Scale (MMAS-8): The MMAS-8 has 8 items and is scored based on the Likert scale (yes and no). The range of total scores for this scale is between 0 and 8, with a higher total score indicating better medication adherence. The validity and reliability of this scale have been confirmed among patients with T2D in Iran [39-41].

Tab. I. Educational content, goals and strategies based on the extended TPB for experimental group.

No	Title of Session	Objective	Educational Strategies	Learning Assist Materials
First session	Type 2 diabetes, Self-care and Medication Adherence	Definition & Symptoms of T2D Mechanism of T2D development Complications of T2D T2D risk factors Importance of Medication Adherence	Lecture and Question & Answers	Slide Show, Pamphlet, Booklet, Reminder Messages
Second session	Self-care and its role in controlling the consequences of diabetes	Normal blood glucose and its measurement Foot care methods Types of physical activity Healthy diet and calorie intake Compliance with the prescribed medication and physician prescriptions	Lecture, Role Playing, Question & Answers	Video & Photo Show, Slide Show, Pamphlet, Booklet, Reminder Messages
Third session	Attitude change	Severity of T2D consequences The ability to control T2D with self-care The importance of foot care Various risks regarding unhealthy eating Sensitivity of each patient Mortality and terrible long-term outcomes	Lecture, Group Discussion, Scenario Presentation	Educational Movie (5 Minute) + Brochure and Booklet, Reminder Messages
Fourth session	Barriers, benefits and Self-efficacy promoting	personal and environmental barriers providing different solutions Strengthening social support Practical demonstration of self-care skills Verbal feedback and persuasion	Group Discussion + Role playing along with Question & Answer	Slide Show, Pamphlets, Reminder Messages
Fifth session	Action & coping planning	Goal setting Setting up a plan to overcome time, place and skill barriers Strengthening Self-regulation Planning to access information, experts, etc.	Short Lecture + Individual consultation	Brochure, Reminder Messages
Sixth session	Feedback and behavior enforcing	Self-monitoring and strengthening beliefs Internal control and encouraging problem analysis Offering different individual solutions Assessing individual needs and identifying and resolving irrational feelings and strengthening individual insight	Short Lecture + Individual consultation	Brochure, Reminder Messages

6. Sub-Scales of extended TPB: F) Sub-Scales of Extended TPB: According to the guidance of Ajzen (2016) [20], a semi-structured interview with 10 patients with T2D was conducted to extract silent beliefs related to the TPB constructs, and the initial version of the scales was designed based on these extracted beliefs. An expert panel evaluated the face and content validity of the questions, and the content validity index (CVI) and content validity rate (CVR) were confirmed. In the next step, the subscales of the extended TPB were distributed and completed by a sample of 12 T2D patients over an interval of 15 days to determine test-retest validity. Additionally, Cronbach's alpha coefficient was used to assess the internal consistency of each construct. Finally, the following sub-scales were used to measure the constructs related to the extended TPB: The Subjective Norms Scale consists of 4 items, where patients were asked to respond to each item on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). The range of answers was between 4 and 20, with higher mean scores indicating stronger social support and social norms for self-care. A Cronbach's alpha coefficient of 0.85 indicates good internal consistency, and a test-retest coefficient of 0.92 also confirms the

reliability of the subjective norms. The Attitude Scale consists of 8 items measured on a 5-point Likert scale from 1 (completely disagree) to 5 (completely agree). The range of scores was between 8 and 40, with lower scores indicating a poor attitude and vice versa. Furthermore, the internal consistency and acceptable reliability of this scale were confirmed by Cronbach's alpha coefficient ($\alpha = 0.81$) and test-retest coefficient ($r = 0.84$). The Perceived Behavioral Control Scale consists of 6 items answered on a 5-point Likert scale from 1 (not at all sure) to 5 (completely sure). The range of answers varied from 6 to 30, with a higher score indicating greater control and the patients' perceived ability to perform the desired self-care behaviors. Moreover, the internal consistency and reliability of this scale were confirmed by Cronbach's alpha coefficient ($\alpha = 0.86$) and test-retest coefficient ($r = 0.89$). The Behavioral Intention Scale consisted of 5 questions, and patients were asked to respond on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). Scores ranged from 5 to 25, with a lower score reflecting weaker intention and vice versa. The psychometric properties of the mentioned subscale were also confirmed in the pilot study ($\alpha = 0.82$, $r = 0.90$). Action and Coping Plan Scales: To evaluate

Tab. II. Comparison of demographic characteristics between experimental and control groups before the theory based educational intervention.

Variables	Group	Control Group Mean \pm SD	Experimental group Mean \pm SD	P-value
Age (Year)		51.3 \pm 13.2	49.7 \pm 11.5	0.26
BMI (kg/m ²)		28.32 \pm 3.73	27.95 \pm 3.68	0.23
History of Disease		8.58 \pm 7.36	9.46 \pm 7.11	0.34
Variables		Control Group Frequency (%)	Experimental group Frequency (%)	P-value
Gender	Male	21 (37.50)	19 (33.93)	0.58
	Female	35 (62.50)	37 (66.07)	
Employment status	Employed	25 (44.64)	24 (42.86)	0.46
	Housewife	24 (42.86)	27 (48.21)	
	Unemployed	7 (12.50)	5 (8.93)	
Marital Status	Married	49 (87.50)	51 (91.7)	0.85
	Single, divorced, etc.	7 (12.50)	5 (8.93)	
Educational Status	Elementary & middle school	9 (16.07)	11 (19.64)	0.72
	High school & Diploma	27 (48.21)	16 (28.57)	
	University	20 (35.71)	19 (33.93)	
Family History of T2D	Yes	30 (53.57)	28 (50.0)	0.41
	No	26 (46.42)	28 (50.0)	
Treatment Type	Hypoglycemic drugs	27 (48.21)	26 (46.42)	0.18
	Insulin	14 (25.0)	16 (28.57)	
	Hypoglycemic drugs+ Insulin	15 (26.79)	15 (26.79)	

action planning and coping planning, a 9-item scale was used (action planning with 5 items and coping planning with 4 items). Patients were asked to respond to questions using 5-point response options. The range score for the action planning scale was between 5 and 25, while the coping planning scale ranged from 4 to 20. The psychometric validity of this scale has been confirmed in previous studies [14, 42, 43]. Trust Scale: Trust in treatment methods and healthcare providers was evaluated using a 4-item scale. Patients were asked to respond to the questions of this scale using 5-point Likert response options. The range of responses was between 4 and 20, with higher scores indicating deeper trust in treatment methods and healthcare professionals, and vice versa. This scale has been used in many studies, and its psychometric properties have also been confirmed [44, 45].

Questionnaires were administered to the experimental and control groups at the training office of healthcare centers, and they were asked to answer the questions in approximately 45 minutes. A member of the research team was present while the questionnaires were completed to address any questions, explain how to fill out the instrument, emphasize the importance of providing honest answers, and ensure that all questions were answered.

Ethical considerations

The Ethics Committee of Qazvin University of Medical Sciences approved the present study (IR. QUMS.REC.1400.179). Additionally, all participants were informed about their voluntary participation in the research, and all of them signed the voluntary

participation form. Furthermore, all patients were reminded that the questionnaires are anonymous and do not contain tracking codes, and all information will remain confidential with the research team. The information will be provided to health authorities in the form of a general report.

Statistical analysis

The data was entered into SPSS 25.0 and the normality of the data distribution was confirmed by the Kolmogorov-Smirnov test. Statistical tests such as paired and independent t-tests, chi-square tests, one-way analysis of variance (ANOVA), and analysis of covariance (ANCOVA) were used for data analysis. The significance level in the current study was considered less than 0.05.

Results

The mean age of patients participating in the present study was 50.8 ± 12.7 years, and 64.29% of the patients were female. In addition, 43.75% were employed, 89.29% were married, and more than 83.0% had poor to moderate economic status. The statistics showed that 51.76% had a family history of illness, and 34.82% had a university education. The demographic characteristics of the patients were compared between the experimental and control groups, and the results showed that there was no statistically significant difference between the two groups in terms of the mentioned variables before the educational intervention. Other details has showed in Table II.

The comparison of the means of the Extended TPB

Tab. III. Covariance analysis of the effect of the educational intervention on constructs of the Extended Theory of Planned Behavior in the experimental and control groups.

Variables	Sources	Type III sum of Squares	df	Mean Square	F	p-value	η^2
Attitude	Pretest	2533.52	1	2533.52	128.45	0.000	0.74
	Group	432.47	1	432.47	24.36	0.001	0.43
Subjective Norms	Pretest	142.30	1	142.30	61.45	0.000	0.67
	Group	20.285	1	20.28	9.61	0.003	0.42
PBC	Pretest	776.37	1	776.37	284.74	0.000	0.78
	Group	164.26	1	164.26	162.35	0.000	0.54
Action planning	Pretest	379.12	1	379.12	122.65	0.000	0.71
	Group	142.16	1	142.16	53.21	0.000	0.49
Coping Planning	Pretest	213.87	1	213.87	98.37	0.003	0.40
	Group	108.33	1	108.33	26.44	0.000	0.38
Trust	Pretest	1922.65	1	1922.65	119.83	0.000	0.61
	Group	336.55	1	336.55	29.69	0.002	0.41
Intention	Pretest	862.44	1	862.44	145.75	0.001	0.59
	Group	203.51	1	203.51	83.42	0.000	0.54

Tab. IV. Covariance analysis of the effect of the educational intervention based on the extended TPB on self-care and its dimensions in the experimental and control groups.

Self-Care Dimensions	Sources	Type III sum of Squares	df	Mean Square	F	P-value	η^2
Regular Physical Activity	Pre-Test	215.36	1	215.36	232.45	0.001	0.18
	Group	75.63	1	75.63	35.16	0.000	0.39
Healthy Diet	Pre-Test	460.26	1	460.26	173.27	0.000	0.10
	Group	149.5	1	149.5	41.33	0.433	0.21
Foot care	Pre-Test	1008.48	1	1008.48	213.36	0.000	0.01
	Group	20.57	1	20.57	12.55	0.002	0.41
Medication Adherence	Pre-Test	1123.52	1	1123.52	164.50	0.000	0.11
	Group	32.43	1	32.43	10.89	0.254	0.48
Blood Sugar Control	Pre-Test	1417.36	1	1417.36	178.81	0.000	0.16
	Group	72.90	1	72.90	27.34	0.108	0.37
Total Score	Pre-Test	944.83	1	944.83	127.5	0.000	0.38
	Group	194.36	1	194.36	31.07	0.001	0.65

constructs is shown in Table III. The results indicate that the mean of attitude ($F = 24.36$, $p = 0.001$), subjective norms ($F = 9.61$, $p = 0.003$), PBC ($F = 162.35$, $p < 0.001$), action planning ($F = 53.21$, $p = 0.001$), coping planning ($F = 26.44$, $p = 0.001$), trust ($F = 29.69$, $p = 0.002$), and intention ($F = 83.42$, $p < 0.001$) increased significantly in the experimental group in the post-test while controlling for the effect of the pre-test variable. Additionally, η^2 showed that 43.6%, 42.2%, 54.3%, 49.2%, 38.6%, 41.1%, and 54.2% of the changes in attitudes, subjective norms, PBC, action planning, coping planning, trust, and intention were explained by the theory-based educational intervention.

Table IV shows the results of ANCOVA related to the effect of a theory-based educational intervention on self-care dimensions in T2D patients. After controlling for the effect of the pre-test, the results of ANCOVA indicated significant differences in mean scores for regular physical activity ($F = 35.16$, $P < 0.001$), healthy diet ($F = 41.33$, $P < 0.001$), food care ($F = 12.55$, $P < 0.001$), medication adherence ($F = 10.89$, $P < 0.001$), blood sugar control ($F = 27.34$, $P < 0.001$), and the total

mean score of self-care ($F = 31.07$, $P < 0.001$) in the post-test. Additionally, the η^2 values showed that the theory-based educational intervention accounted for 39.8%, 21.9%, 41.5%, 48.2%, 37.7%, and 65.5% of the variance in regular physical activity, healthy diet, food care, medication adherence, blood sugar control, and total self-care in T2D patients, respectively.

The results of the independent t-test and the comparison of the means of FBS and HbA1c between the experimental and control groups before the theory-based intervention showed that there was no significant difference between the two groups in terms of the mentioned variables. Nevertheless, the mean of FBS (from 166.7 ± 51.50 to 122.4 ± 47.6) and HbA1c (from 7.88 ± 1.85 to 6.23 ± 1.37) decreased significantly after the education in the experimental group. Moreover, the results in Table V emphasized that the mean scores of health literacy (from 67.25 ± 22.15 to 119.50 ± 38.7) and medication adherence (from 3.37 ± 2.05 to 5.94 ± 3.14) in the experimental group increased significantly after the theory-based educational intervention.

Tab. V. The results of educational intervention based on the extended TPB on HbA1c and FBS level in the experimental and control groups.

		Before Education	After Education	
Metabolic indexes	Group	Mean \pm SD	Mean \pm SD	P-value
FBS	Control	172.6 \pm 49.25	166.5 \pm 50.3	0.21
	Experimental	166.7 \pm 51.50	122.4 \pm 47.6	P < 0.001
	**p-value	0.42	P < 0.001	
HbA1c	Control	8.05 \pm 1.81	7.94 \pm 1.86	0.553
	Experimental	7.88 \pm 1.85	6.23 \pm 1.37	P < 0.001
	**p-value	0.63	P < 0.001	
Health Literacy	Control	71.46 \pm 25.63	74.87 \pm 26.5	0.32
	Experimental	67.25 \pm 22.15	119.50 \pm 38.7	P < 0.001
	**p-value	0.28	P < 0.001	
Medication Adherence	Control	3.12 \pm 1.68	3.46 \pm 2.18	0.315
	Experimental	3.37 \pm 2.05	5.94 \pm 3.14	P < 0.001
	**p-value	0.42	P < 0.001	

Tab. VI. Covariance analysis of the effect of the educational intervention based on the extended TPB on medication adherence and health literacy in the experimental and control groups.

Variables	Sources	Type III sum of Squares	df	Mean Square	F	P-value	η^2
FBS	Pretest	4823.28	1	4823.28	63.81	0.000	0.10
	Group	1511.01	1	1511.01	12.35	0.002	0.42
HbA1c	Pretest	1524.31	1	1524.31	84.57	0.000	0.16
	Group	372.26	1	372.26	21.55	0.000	0.67
Health literacy	Pretest	1288.25	1	1288.25	90.13	0.000	0.19
	Group	512.60	1	512.60	14.65	0.035	0.3
Medication Adherence	Pretest	1739.62	1	1739.62	52.86	0.000	0.21

The results of the ANCOVA showed that the mean of FBS ($F = 12.35$, $P < 0.001$) and HbA1c ($F = 21.55$, $P < 0.001$) in the experimental group decreased significantly after the intervention while controlling for the effect of the pre-test. Additionally, the covariance results listed in Table VI indicated that the mean score of health literacy ($F = 14.65$, $P < 0.001$) and medication adherence ($F = 18.52$, $P < 0.001$) in the experimental group improved significantly after controlling for the effect of the pre-test. The results of the ANCOVA showed that the mean of FBS ($F = 12.35$, $P < 0.001$) and HbA1c ($F = 21.55$, $P < 0.001$) in the experimental group decreased significantly after the intervention while controlling for the effect of the pre-test. Additionally, the covariance results listed in Table VI indicated that the mean score of health literacy ($F = 14.65$, $P < 0.001$) and medication adherence ($F = 18.52$, $P < 0.001$) in the experimental group improved significantly after controlling for the effect of the pre-test.

Discussion

The present study was conducted to determine the effect of an educational intervention based on the extended Theory of Planned Behavior (TPB) on self-care behaviors, health literacy, medication adherence, and metabolic indicators of people with Type 2 Diabetes (T2D) in Qazvin city. The results generally show a significant improvement in the mentioned variables

after the theory-based educational intervention in the experimental group.

One of the most important findings of this study was the promotion of psychological variables related to the extended TPB after the educational intervention in the experimental group, which aligns with the findings of previous studies [46, 47]. For example, Riangkam et al. (2021) demonstrated that theory-based self-care education delivered via mobile phones increased the knowledge and awareness of T2D patients, leading to improvements in psychological predictors such as attitude, social support, and self-efficacy [46]. Additionally, the results of Aliabad et al. (2014) revealed the preservation of physical activity capacity in coronary heart patients, along with improvements in psychological constructs related to the Health Action Process Approach (HAPA) model in the experimental group after participating in the theory-based educational program that promoted family support [47]. It seems that providing simple and comprehensible information about the relationships between self-care behaviors and controlling the consequences of diabetes, along with their repetition in the form of Short Message Service (SMS), has increased patients' awareness of self-care behaviors.

Also, the emphasis of cognitive behavioral interventions – routinely provided by nurses or other personnel in hospitals or health centers – should be on the importance of assessing the benefits and barriers of self-care in T2D patients. Online training can be effective in strengthening

behavioral intention and improving self-management in patients with diabetes by clarifying the social, physical, and psychological consequences of diabetes and providing frequent and diverse constructive feedback through internet networks and mobile phones.

The results of the current research indicated that the means of trust, action, and coping planning in the experimental group improved significantly after the theory-based intervention, which was consistent with the findings of Aliabad et al. (2022) [47], Labudek et al. (2022) [48], Schroé et al. (2022) [49], and Daryabigi et al. (2021) [50]. The findings of Labudek et al. (2022) showed that the implementation of a group theory-based educational intervention, along with the improvement of psychological determinants, especially action planning and coping planning, ultimately led to positive changes in lifestyle, improved physical activity status, and prevention of falls in the elderly [48]. In the present study, trust, action, and coping planning were added to the TPB to strengthen the potential to describe the variance of self-care behavior. Planning is a prospective self-regulatory strategy that connects individual responses and anticipated situational guiding factors. Planning regarding the time, place, and method to achieve the main goals facilitates the realization of behavioral objectives [49]. Nurses and HCWs can reduce the gap between intention and behavior by focusing on improving self-regulation skills and encouraging the audience to consider the conditions and context in which self-care behaviors occur [51]. Goal setting, describing complete behavioral goals, outlining the necessary actions to achieve the goals, determining the necessary resources—equipment and time, establishing criteria and methods for measuring progress, and providing diverse practical solutions to address possible obstacles were part of the strategies used in theory-based educational sessions to strengthen "action planning" and "coping planning." Mirzaei et al. (2020) emphasized the improvement of health literacy and nutritional performance of the elderly with diabetes after a theory-based educational intervention [52]. Additionally, Hejazi et al. (2018) emphasized the increase in self-efficacy, self-care, and health literacy scores following a theory-based educational intervention [53]. The relationship between low levels of health literacy and poor self-care behaviors in T2D patients has been confirmed in many studies [54]. In other words, patients need to receive correct and valid information from various channels, such as nurses, HCWs, or social media, to understand their condition and cooperate in self-care programs. In fact, patients' skills to obtain, correctly understand, and apply this information will significantly impact their behavior and health status [55]. Furthermore, patients with insufficient health literacy have poorer health status, a higher rate of hospital admissions, and require more nursing care. Nursing reports indicate that the death rate among these patients is almost twice as high as that of other chronic patients [56]. A review of educational interventions shows that educational methods and materials have been chosen in a way that is more suitable

for learners with sufficient health literacy, while clients with insufficient health literacy do not benefit much from these interventions [17]. Learning theories emphasize that without considering the characteristics of the target audience in health education interventions, especially their level of health literacy, it is not possible to bridge the learning gap between individuals with sufficient and insufficient health literacy [18]. Therefore, cognitive-behavioral interventions should pay special attention to assessing the status of patients based on their health literacy level and designing educational interventions according to their psychological stages of readiness for change and the level of health literacy and awareness.

In line with the findings of previous research [28, 57-59], the results of the present study showed improvement in FBS and HbA1c levels in experimental group patients after a theory-based educational intervention. For example, Beiranvand et al. (2015) demonstrated that the mean score of attitudes towards foot care performance in the experimental group improved significantly after an educational intervention based on TPB [58]. Moreover, Hosseini et al. (2021) determined that, along with the improvement in retinopathy prevention, the mean FBS and HbA1c levels in the experimental group were significantly reduced after the theory-based educational intervention [28]. It seems that displaying practical strategies, along with role-playing and providing efficient feedback while improving patients' self-efficacy, had positive effects on reducing FBS and HbA1c and increasing self-care behaviors in T2D patients. The main goal of treating patients with diabetes is to achieve optimal control (HbA1c less than 7%), which is related to the reduction of morbidity and mortality. Additionally, considering that a 1% increase in this variable causes a 12% increase in coronary artery diseases, the reduction of this index should be prioritized by nurses and HCWs in various counseling programs and cognitive-behavioral interventions. Clinical indicators such as HbA1c and FBS have a significant relationship with LDL, HDL, BMI, and the amount of physical activity, and incorporating a regular physical activity program and weight loss program can significantly enhance the effectiveness of interventions.

The improvement of medication adherence in the experimental group after the intervention was another finding of the present study, which was consistent with the results of the study by Dashtian et al. (2018) [60] and other studies [61-64]. For example, Razavi et al. (2017) showed that the educational intervention based on the AIM model led to an increase in knowledge, motivation, and ability, as well as a decrease in HbA1c and an increase in the mean of medication adherence [63]. Additionally, the findings of the Zamani et al. (2020) study confirmed the improvement of medication adherence after five sessions of group training based on the Extended Parallel Process Model [64]. The findings of Tajari et al. (2019) also confirmed the effect of the SMS and Telegram reminder system on diet compliance among adolescents with type 1 diabetes [61]. When patients adhere to the treatment and the recommendations of the nurses who

have the necessary information, they possess enough motivation to control the disease. On the other hand, the patient's thorough understanding of the treatment process is a fundamental condition for voluntary medication adherence. Therefore, educational programs should provide the foundation for improving self-care behaviors and medication adherence by changing entrenched beliefs about the importance of continuing treatment, strengthening self-efficacy in relation to controlling the disease's consequences, and increasing health literacy and health awareness.

The change in self-care behaviors in T2D patients after the theory-based educational intervention is considered the most important finding of the current research, which is consistent with the results of previous meta-analyses [65, 66]. The meta-analysis by Zhao et al. (2017) showed that educational interventions designed based on one or more theories were able to improve HbA1c, self-efficacy, diabetes knowledge, and self-care [65]. Zare et al. (2020), after a systematic review of 20 studies, concluded that educational interventions based on behavior change models such as the health belief model, empowerment theory, precede-proceed model, and theory of planned behavior were able to change awareness and attitude, and improve self-care skills in T2D patients [66]. Additionally, the improvement of psychological constructs along with the promotion of self-care behaviors after the educational intervention based on the theory of reasoned action was confirmed by Babazadeh et al. (2017) [67]. Furthermore, the findings of the study by Hajipour et al. (2022) also showed a significant decrease in the mean of FBS and HbA1c, as well as an improvement in self-care behaviors after an intensive educational intervention based on the transtheoretical model [68]. Moreover, the findings of Ebadi Fardazer et al. (2017) showed a significant increase in the mean total score of self-care and all its domains in the 2 and 3 months following the educational intervention based on the locus of control in T2D patients [35]. Understanding exactly what factors can increase the success rate of patients in the path of behavior change is considered a basic concern of many studies [17, 18]. Most motivational and self-regulation theories emphasize that the identification and accurate determination of psychological variables affecting behavior is a fundamental step in designing interventions, and insufficient attention to this will reduce the effectiveness of interventions [51]. Patients may have different plans to control the disease and may unconsciously use various strategies, but the unplanned use of coping strategies to manage temptations and various social pressures, or insufficient motivation due to low self-efficacy, ultimately reduces the level of self-care [18, 19]. Improving health literacy, strengthening positive beliefs, encouraging self-efficacy, and enhancing the social support network have positively influenced the psychological readiness of patients to accept the necessity of change and to initiate the process of behavior change. This research faced several limitations: first, the findings were compared with only one control group, which limits the researchers' ability to judge the effectiveness

of the educational intervention in comparison with other behavior change models. Therefore, it is recommended that nursing researchers design the study based on traditional education groups and education based on other behavior change models or patient education based on web-based strategies, etc. Secondly, the final goal of the present study was to change self-care behaviors. A set of behaviors whose change through theory-based educational intervention requires the design of targeted educational content and a relatively long time for training, as well as the use of expert nurses or HCWs to manage the training courses. It is evident that focusing on specific and limited behavior in the design of educational interventions, such as regular insulin injections or foot care, instead of a complex set of behaviors, significantly improves the probability of achieving goals. Thirdly, many environmental and external factors affect patients' adherence to self-care behaviors, which are constantly changing. Therefore, it should not be expected that simply providing a temporary and brief training program would solve the problems permanently and completely. Finally, the evaluation of the results in the present study was conducted 3 months after the training, making it impossible to make a correct judgment about the stability of the educational intervention. To make a more decisive decision about the stability of the results of the educational intervention, several follow-ups with time intervals of 6 months and one year will be necessary.

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Data availability statement

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

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Conflict of interest statement

No conflicts of interest are declared by the authors.

Authors' contributions

IMZ: Conceptualization, Methodology and data analysis and FSB data collection and manuscript writing.

All Authors revised the manuscript and gave their contribution to improve the paper. All authors read and approved the final manuscript.

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