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Development of a Health Literacy Promotion Program (HeLPP) to Promote Self-Care Behaviors and Quality of Life among Rural Patients with Type 2 Diabetes: Preliminary Results

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ABSTRACT

Background and Objectives: We developed a protocol for a health literacy promotion program (HeLPP) to promote self-care behaviors and quality of life (QOL) among T2DM patients in Chaldoran County, Iran. To develop the educational program, we primarily conducted a behavioral and educational assessment on the pre-test data collected from the participants. In this paper, we report a summary of the protocol and the primary results of the pre-test findings.

Materials and Methods: The HeLPP protocol is naturally developed for a randomized controlled trial with Solomon four-group design. Developing the HeLPP, we will conduct it for both test groups. To plan the HeLPP and to find the main predictors of self-care behaviors and QOL, we firstly conducted a cross-sectional study (as a needs assessment phase). So, applying simple random sampling, data on 160 patients were collected and analyzed. The validated scales (Health Literacy Questionnaire (HLQ), Self-care activities scale, and Diabetes QOL Brief Clinical Inventory) were used to collect data.

Results: The mean age of participants was 61.08 ± 11.35. The most significant determinants of self-care behaviors were understanding (β: 0.26), reading skills (β: 0.23), and knowledge (β: -0.19). Self-care behaviors (β: 0.29) and decision-making (β: 0.28) were significant predictors of QOL.

Conclusion: Considering the predicting role of understanding, reading skills, and decision-making for self-care behaviors and QOL of the rural T2DM patients, the focus of HeLPP should be on clear communication, goal-setting, and teach back strategies. The developed protocol seems to be helpful in promoting the outcome variables of the study.

Paper Type: Research Article

Keywords: Health Literacy, Self-care Behaviors, Quality of Life, Type 2 Diabetes, Health Promotion.

Introduction

Diabetes mellitus (DM) is an emerging lifestyle disease. Globally, type 2 diabetes mellitus (T2DM) is the most common form of DM, as 90% of the people diagnosed with DM have T2DM (1). T2DM has quickly become one of the world's most prevalent non-communicable diseases, and one of the most serious concerns in public health (2). Based on the findings of two current studies, the prevalence of T2DM in Iran (as whole) and Naghadeh (a county close to the Chaldoran county) were reported to be 14.2% (95% confidence interval 13.4–14.9) (3) and 13.8% (4), respectively. Its escalating incidence in combination with high rates of morbidity and mortality imposes a significant burden on healthcare systems, and reduces the quality of life (QOL) of those affected (5).

To achieve success in preventing serious morbidity and mortality, diabetes control requires a high level of adherence to rigorous self-care behaviors, including healthy food choices, physical activity, proper medications intake and control of blood glucose (6). Self-care is "a process of maintaining health through health promoting practices and managing illness" (7). Despite its basic role in controlling T2DM and the QOL of the patients, self-care behavior is considered to be a highly challenging issue for the patients, due to the factors such as awareness of diabetes, health beliefs, motivation and health literacy (HL) (8).

HL is defined as the cognitive and social skills which determines the motivation and ability of individuals to gain access to, understand and use information in several ways that promote and maintain good health (8). HL is a relatively new concept in health promotion research, which has increasingly been recognized as a major determinant for health-related behaviors, well-being and QOL (9, 10, 11). Researches show that low or inadequate health literacy is associated with poor adherence to medical regimens, poor understanding of health issues, lack of knowledge about medical care and conditions, poor use of preventive services, unfavorable overall health status and early death (12). It is assumed that being health literate enables patients to engage in health-related behavior such as diabetes self-care (13). This means that patients with higher HL may feel more confident about their ability to accomplish self-care behaviors. Some studies suggested HL to be effective in improving health outcomes such as self-care behaviors (13) and Quality of life (14) among patients with diabetes. The WHO emphasizes on improving T2DM patients' education and health literacy, and considers it as an important strategy in promoting the active participation of these patients in the disease management process (11, 15). Appropriate education could lead to a decrease in diabetes complications up to 80% (16).

Quality of life is an important factor in diabetes because poor quality of life contributes to decreased self-care, which in return leads to worsened glycemic control, increased risks of complications, and an overwhelming deterioration of diabetes in both short run and the long run (17).

In this regard, the results of a study on diabetic patients show that despite the fact that 73% of patients with inadequate health literacy participated in diabetes education classes, 50% of them did not know the signs and symptoms of low blood sugar and 62% of

them were unaware of the treatment methods for reducing blood glucose (18). The results of a systematic review study in Iran showed that health literacy is not high in Iranian diabetic patients and is rather inadequate in most of them (19). However, in spite of inadequacy, we are not aware of any evaluation of health literacy promotion training programs to improve self-care behaviors and quality of life conducted among patients with type 2 diabetes mellitus in Iran. Therefore, there is still a lack of evidence on effective protocols for diabetic patients (20). In 2018, we developed a protocol for a HeLPP to promote self-care behaviors and quality of life among rural type 2 diabetic patients. To develop the educational program, we primarily conducted a behavioral and educational assessment on the pre-test data collected from the participants. In this paper, we report a summary of the protocol and the primary results of the pre-test findings. Therefore, this study has two specific objectives: Goal I: Investigate the associations between dimensions of health literacy with self-care behavior and quality of life (A structural equation modeling approach). Goal II: Designing a health literacy promotion training program protocol for patients with type 2 diabetes mellitus on the pre-test data collected from the participants. Also, the following hypotheses guided our study:

1- The level of health literacy in rural patients with T2DM increases after the intervention.
2- The rate of performing self-care behaviors and QOL in patients with T2DM increases after the intervention. 3- In rural patients with T2DM, the amount of HbA1c decreases after the intervention.

Materials and Methods
Study design in the trial
This study will be a randomized controlled trial with Solomon 4 group design. The classic Solomon four-group design stands for the evaluation of the separate effects of assessment and intervention. Solomon 4 group design is recognized as one of the most powerful research designs. In this study, randomized Solomon four group design will be used to deal with a potential validity threat such as historical event and another educational program in any educational intervention. The four groups include: an experimental group (A) that will receive a pre-test, training program and a post- test, a control group (B) that will receive a pre-test and a post-test, another experimental group (C) that will receive training and a post-test, and another control group with only post-test (D). Participants will be assessed at three stages in time: at baseline, three and six-month's follow-up. Study procedure from enrollment through follow up data collection and analysis are depicted in Figure 1.

Study setting & Participants
The study will be conducted among the patients with type 2 diabetes mellitus who are residents of Chaldoran county of West Azerbaijan, Iran. Samples are randomly selected from rural outpatients with type-2 diabetes. Based on their health records available at the health center of Chaldoran County and applying simple random sampling, 180 patients were invited to participate in the study. To determine the sample size for intervention phase, the means and standard deviations of the two intervention and control groups were obtained from the study of Kheradmand et al.

(21). Considering 95% confidence, 80% test power, 0.66 effect size, and using G Power software, the minimum sample size in each group was 37 cases. To control for attrition in the follow-up phases, 8 cases were added to each group. So, we invited 45 cases for each group (total sample size = 180). Among those invited, 160 individuals approved participation (response rate = 88.8%). They were then contacted through their telephone number and were invited to participate in the study after providing sufficient and appropriate explanations for the purpose of the study.
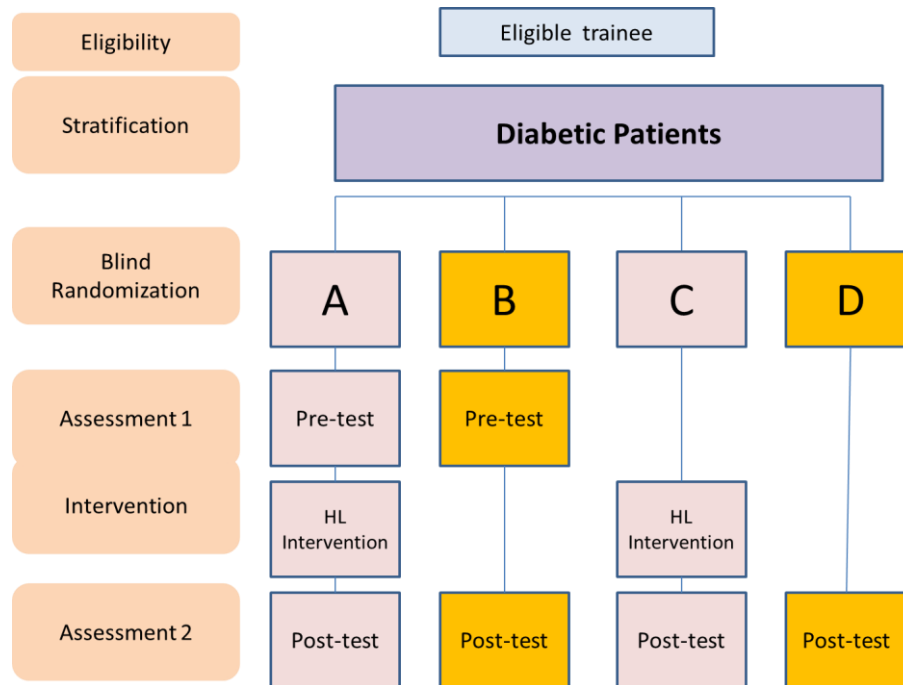

Figure 1: Flowchart of the Solomon four-group design applied in the present study

To comply with ethical issues, a general self-care education session was held for all patients by a nurse with field experience in diabetics. Being informed with the study objectives and details, all patients signed a written consent form. Individuals were free to sign the form and to participate in the study. The patients then participated in the pre-test phase (the cross-sectional study. After analyzing the pre-test data and preparing the intervention program (HeLPP), we will allocate the participants to four groups [two intervention groups (80 patients) and two control groups (80 patients)] (Figure 1). On the same day, the pre-test is conducted, BMI is calculated and HbA1c test is performed. To be uniform in approaching illiterate and illiterate patients, all questionnaires will be completed by interviewing. Based on the Solomon design, pre-test is conducted on two groups (one case and one control), and after implementing the intervention program on the two intervention groups, post-test is conducted on all four groups. As rural health workers had an intimate and trustful relationship with the participants, we decided to involve them in the implementation of the

training program. Moreover, the health centers were equipped with an education class with some educational facilities. So, the health centers at the villages are considered as the best place for training sessions.

Study procedure

The design of the intervention and the target audience's recognition, was based on a review of the literature, and the information obtained from the pre-test data. The HeLPP is designed in order to improve self-care behaviors and quality of life in patients with type 2 diabetes mellitus. The diabetic patients in the intervention group will be invited to attend the program by the rural health workers for one-hour sessions. First, the patients selected for the intervention group are contacted, and are announced about the time of intervention. Then, the venue of intervention is coordinated and prepared for the intervention. The control group also receives the routine services of the health center. Three and six months after the intervention, the questionnaires will be completed by the participants of both intervention and control groups to measure the impact of intervention and the stability of any possible changes. Also, the effects of intervention on the studied variables will be measured in the intervention group, and will be compared with the control group. Main idea, program goal, program objectives, behavioral objectives, learning objectives, key characteristics of the HeLPP, and all the details of the program are explained in the appendix 1. Three and six months after the intervention, the questionnaires are completed by individuals in the four control and test groups, and again HbA1c will be administered once for all groups after final

follow-up. It should be noted that after completion of the study, educational materials are provided to control groups. The implementation phases of the study are shown in Figure 2.

Eligibility criteria

The inclusion criteria for study are: A) subjects with T2DM diagnosed in the last six months (HbA1c ≥7% and ≤10%), B) resident of study areas since at least six months, C) with 30 years of age and older, D) not having a history of formal training in self-care, nutrition, and physical activity in the past six months, E) be willing and able to participate. The exclusion criteria are: A) Having history or current symptoms of poorly controlled diabetes, B) a cardiovascular event in the past 6 months, C) significant history of renal or hepatic disease, D) history of substance abuse in the previous year, E) history of mental disorders such as dementia and Alzheimer, F) having severe motor limitations such as limb disabilities.

Randomization

Randomization will be carried out after obtaining informed consent and baseline measurements. Participants will be randomly assigned to the trial groups. Randomization sequence will be created manually by a biostatistician using Excel software to assign participants to the study arms using a 1:1 allocation ratio with block size of 4. The allocation sequence will conceal the investigators in sequentially numbered, opaque, sealed and stapled envelopes (Figure 2). As the participants were from rural areas with difficulties in accessing them and gathering them for the intervention sessions, and considering that the participants were 60 years and older, we decided not to match

them in terms of age and diabetes characteristics. So, we match the four groups in terms of gender, only. To control for any possible effect of confounding variables (like age, socio-economic status, and diabetes characteristics) we will use Covariance tests while analyzing post-test data.
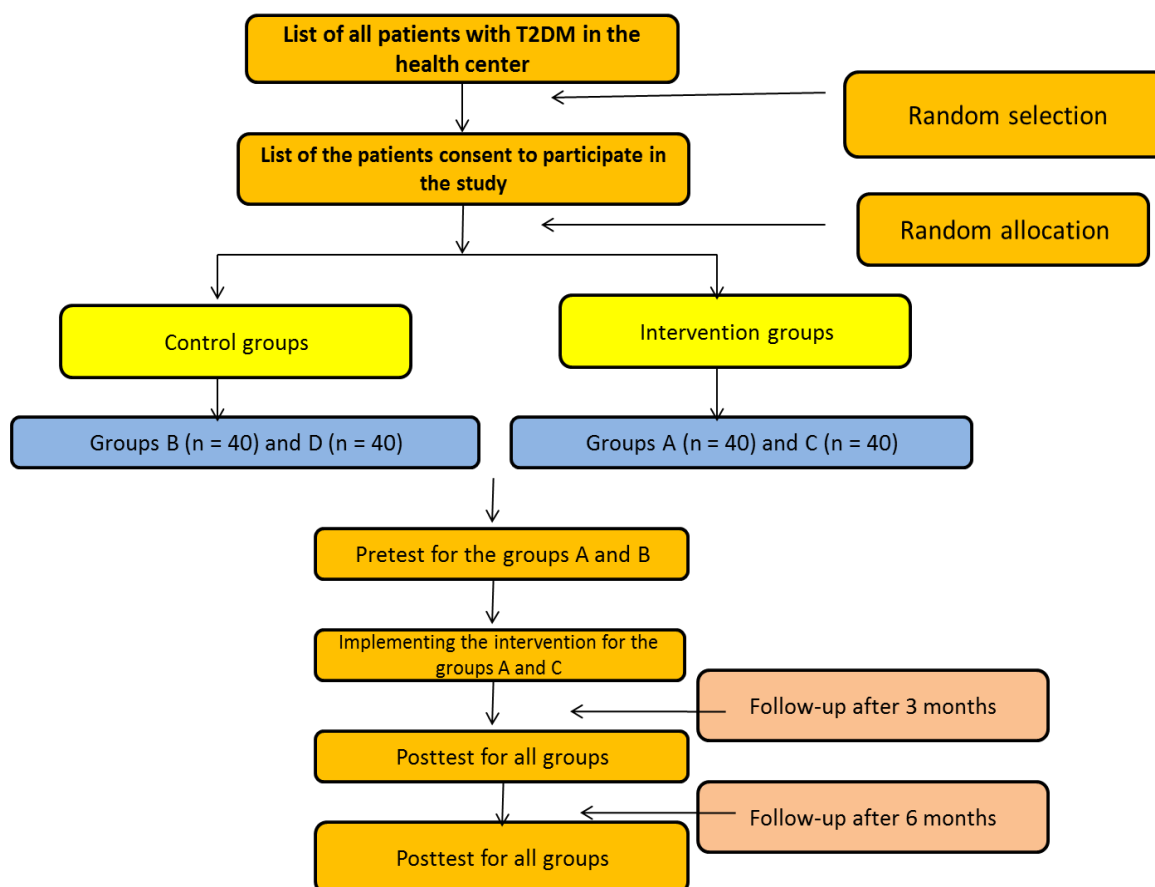
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│ List of all patients with T2DM in the │ ◄─────── ┌──────────────────┐
│            health center             │          │ Random selection │
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│               the study              │              │ Random allocation │
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   │ Control groups │    │ Intervention groups │
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Figure 2: Flowchart of the implementation phases of the study

Intervention

Experimental groups will be encouraged to engage in the HeLPP. The number of patients in the intervention group is 80 .Patients will be divided into 4 groups of 20 participants. For each group, the instructional program will be held in 5 sessions. In each session, 20 participants will be grouped into four 5-person self-help groups (one of the young patients with higher literacy will play the role of a leader), and after each section of the training, the members of each group should review the training subjects with the help of group leader in 5 minutes. Then, the random representative of each group should teach-back the team of trainers a one-minute report of what they learned. At the end of the first, second, and fifth sessions, at least two patients will be asked to provide a reminiscence of their real-life regarding the subjects presented in the session. The intervention program will not be implemented for the control groups during the specified time period. The control groups

will also be assured that our program will be implemented for them after the specified time. A pre-test will be performed for one of the intervention groups (A) and one of the control groups (B). But the post-test will be done for all of the groups (Figure 2).

HeLPP profile

All data were collected through structured questionnaires in an oral face-to-face interview by a single field staff to avoid inter-observer bias. To control for attrition bias, we have informed participants that the $20 compensation will be provided upon completion of their participation and at the end of the second post-test. Furthermore, we have designed the intervention sessions and follow-ups to be brief, flexible, and convenient for participants. At the stage of participant invitation, the researchers are blinded to the characteristics of the participants. In other words, we do not contact the participants in a selective way, and we contact all qualified patients. Considering the nature of study, the implementation team of the intervention cannot be blinded to the participants. However, the researcher who collect the data at two post-test sessions is blinded. Statistician is also blinded in all stages of data analysis. Features of the HeLPP are available in Appendix 1.

Educational Materials

The educational materials were focused on the symptoms and complications of diabetes, control ways, how to prevent complications, physical activity, proper nutrition, when to do tests and take medicine, as well as how to properly perform self-care tasks prepared by them (Supplementary data file 1). As a majority of the participants were older adults

with low literacy levels, we tried to prepare the materials as simple and clear as they can be. So, the materials were developed based on the CDC (Centers for Disease Control and Prevention) clear communication index (22, 23). These materials were prepared in a booklet format and delivered to all participants of intervention and control groups, after the implementation of the program.

Primary/Secondary outcomes and statistics

Primary outcomes are self-care behaviors, knowledge on the disease and BMI. HbA1c and quality of life are included as secondary outcomes in the trial. Chi-square parametric tests, Pearson correlation coefficient, ANOVA, T-test, and Paired t-test will be used. If the distribution of data is not normal, the nonparametric tests such as Man Whitney and Wilcoxon will be used. Covariance analysis will be used to control the effect of confounding variables, like gender, taking medications, and level of education. A significance level of less than 0.05 will be considered. All analyzes will be done with SPSS 20 software.

Study design in the cross-sectional study

We conducted a cross-sectional study from February to September 2018 among T2DM patients. The patients (n = 180) were invited to participate in the study, of which 160 of them were eligible for the inclusion criteria. They agreed to participate in the study and all of them completed the written questionnaire to participate in the study. Inclusion/exclusion criteria were reported above. Participants were selected from the list of patients with health records in the rural health care centers through simple random

sampling. They were then contacted via phone call and invited to participate in the study. In the case of consent, they were included in the study.

Measures

Data collection tools included three questionnaires to assess health literacy, quality of life and self-care behavior questionnaire.

Demographic characteristics of the patients included the following 7 items: age, gender, education, income, married, job, and smoking.

Health Literacy Questionnaire (HLQ)

Health literacy was assessed using the Health Literacy Questionnaire designed by Montazeri et al. (24). The questionnaire consists of 33 items, measuring five subscales of including access (6 items), reading skills (health information, forms, records, tests, etc.);(4 items), understanding and perception (7 items), ability to evaluate (4 items), and application of health information (decision-making) (12 items), using a 5-scale Likert-type scale from "always" to "not at all." The range of possible scores for each subscale was as follows: access, (6–30), reading (4–20), understanding (7–35), appraisal (4–20), and decision (12–60). The final score was derived through converting the scores of the five subscales of health literacy to a standard score from 0 to 100. According to the scoring guideline, a score from 0 to 50.0 indicates an inadequate level of health literacy, 50.1 to 66.0 represents the marginal level of health literacy, 66.1 to 84.0 represents an adequate level of health literacy, and 84.1 to 100 reflects an excellent level of health literacy (24).

Self-care behavior questionnaire

We used a 12-item summary of diabetes self-care activities scale (25) to measure self-care performances. This questionnaire had been validated by Didarloo et al., among people with type 2 diabetes in Iran (26). The Cronbach's alpha was assessed by 0.74. The scale measures frequency of self-care behaviors in the last 7 days in four dimensions of the diet (6 items), glucose testing (2 items), medications (2 items) and physical activity (2 items). The total self-care activities score on this index may range from 0 to 84 in which higher scores indicate higher self-care behaviors adopted by the patients.

Diabetes QOL Brief Clinical Inventory (DQOL-BCI)

Quality of life was assessed using the Diabetes QOL Brief Clinical Inventory designed by Burroughs et al. (27), and validated in Persian by Nasihatkon et al. (28). The questionnaire is consisted of 15 items, the answers to the questions are based on a 5-point Likert scale. The total score of the questionnaire is between 15 and 75. A higher score indicates a better QOL (29). The reliability coefficient, based on our data, was 0.79.

Statistical analysis

The data were analyzed using the Statistical Package for the Social Sciences (SPSS)(Armonk, N.Y, USA: IBM Corp, 2012), STATA 14 (Stata Corp, College Station, TX, USA) and were described in terms of number, frequency, means and standard deviation (SD). We also used Kolmogorov-Smirnov test to assess the normality of data distribution, Chi-squared tests to assess relationship between qualitative variables with quality of life and Self-care behaviors and Pearson

correlation test to assess relationship between the dimensions of health literacy with self-care behaviors and quality of life. To determine the relationship between dimensions of health literacy with self-care behavior and quality of life, Structural Equation Modeling (SEM) was conducted, utilizing maximum-likelihood estimations.

All knowledge, reading skills, accessibility, understanding, evaluation, decision variables with self-care behaviors and quality of life factors were combined into a single SEM. An acceptable fit was confirmed if (1) Root Mean Square Errors of Approximation (RMSEA) < 0.08, (2) Comparative Fit Index (CFI) and Tucker–Lewis Index (TLI) ≥ 0.90, and (3) Standardized Root Mean Square Residual (SRMSR) < 0.05. We were able to examine a series of regression equations by the SEM. We assumed that dimensions of health literacy are related to quality of life through self-care behavior.

Results

A total of 160 subjects agreed to participate in the study. The demographic characteristics of the participants as well as their associations with self-care behaviors and quality of life are shown in table 1. The average age of participants was 61.08 ± 11.35. In terms of gender, significant differences were observed in self-care behaviors (p=0.025) and quality of life (p = 0.003). Also, the pa¬tients' educational level was significantly associated with self-care behaviors (p = 0.001) and quality of life (p= 0.007), and those with higher educational levels had higher self-care behaviors and a better quality of life (Table 1).

Mean (standard deviation) for self-care behaviors was 24.54 (8.96). Mean and standard deviations for the other study variables and their correlation coefficients with self-care behaviors are presented in Table 2.

Figure 3 indicates the associations between dimensions of health literacy with self-care behavior and quality of life. The appropriate indices (X2/ df = 1.57, N = 160, p < 0.05, CFI = 0.94, TLI = 0.82, SRMR = 0.02, RSMEA = 0.06) showed that the model was fitted to the data.

Table 1. Demographic characteristics and their associations with outcome variables among the participants

Variable		F (%)	Self-care behaviors Me (SD)	p-value	Quality of Life Me (SD)	p-value
Age group	50 ≥	32 (20.0)	25.1 (9.64)	0.774	50.31 (7.86)	0.268
	51 to 60	38 (23.8)	25.1 (9.41)		48.21 (7.54)	
	60 <	90 (56.3)	24.08 (8.69)		47.77 (7.51)	
Gender	Male	44 (27.5)	27.16 (10.01)	0.025	51.22 (8.75)	0.003
	Female	116 (72.5)	23.56 (8.45)		47.31 (6.85)	
Level of education	Illiterate	110 (68.8)	23.01 (8.45)	0.001	47.30 (7.40)	0.007
	Reading & Writing	50 (31.2)	27.93 (9.38)		50.78 (7.56)	
Income status (per month)	Lower than 237 $	125 (8.1)	24.33 (9.32)	0.568	47.86 (7.17)	0.102
	237 to 472 $	35 (21.9)	25.29 (7.89)		50.25 (8.83)	
Marital status	Married	116 (73.1)	24.55 (9.51)	0.819	49.35 (8.08)	0.022
	Divorced	4 (2.5)	27.25 (8.50)		48.25 (6.39)	
	Spouse died	38 (24.4)	24.23 (9.02)		45.48 (5.25)	

Table 2. Intercorrelations between HL dimensions with Self-care behaviors and Quality of Life

Variable	Mean (SD)	X1	X2	X3	X 4	X 5	X 6	X 7	X 8
X 1. Knowledge	31.25 (4.98)	1							
X 2. Reading skills	5.56 (3.37)	-0.202*	1						
X 3. Accessibility	11.91 (6.08)	-0.284*	0.287**	1					
X 4. Understanding	16.83 (5.91)	-0.192*	0.390**	0.512**	1				
X 5. Evaluation	7.50 (3.59)	-0.265*	0.462**	0.462**	0.609**	1			
X 6. Decision	38.91 (8.78)	-0.193*	0.234**	0.137	0.257**	0.426**	1		
X 7. Self-care behaviors	24.54 (8.96)	-0.272*	0.339**	0.316**	0.347**	0.197*	0.024	1	
X 8. Quality of Life	48.38 (7.60)	0.057	0.089	0.151	0.231**	0.250**	0.284**	0.238**	1

* p-value is significant at p < 0.01; ** p-value is significant at p < 0.001.

In final model, the most important determinants of self-care were understanding (β: 0.26, P < 0.001), reading skills (β: 0.23, P<0.001), and knowledge (β: -0.19, P < 0.001).

This shows that self-care is increased by higher understanding and reading skills, while the most powerful determinants of life quality were self-care (β: 0.29, P < 0.001) decision making (β: 0.28, P < 0.001), and marital status (β: -0.19, P < 0.001). This indicates that quality of life is increased by higher self-care and decision makings.

Finding the priorities of the program based on pre-test data

Self-care promotion (physical activity (PA), blood glucose testing and medication use)

By descriptive analyzing of pre-test data, we found that 35% of the patients did not exercise at a moderate level of PA (means exercising hard enough to rise heart rate and break a sweat, for 30 minutes a day) even for one day during one week and 32% did so less than three days per week. About 70% of the patients did not have a blood glucose test during the past week, and 75.5% of insulin recipients and 28.8% of those who should have taken pills/tablets did not receive any medications during the previous week. All these findings indicate the low level of self-care behaviors among the patients, which necessitate the development of HL promotion program, with the hope to promote these behaviors and eventually QOL among the patients. Based on descriptive analysis of pre-test data, more than 60% of patients had no/poor knowledge on the complications of diabetes, symptoms of hypoglycemia, nutrition and physical activity. So, awareness raising was considered as one of the priorities for our educational program. Given that most patients are old and illiterate, they need to be educated in small groups so that there would be enough time for them to understand the content.
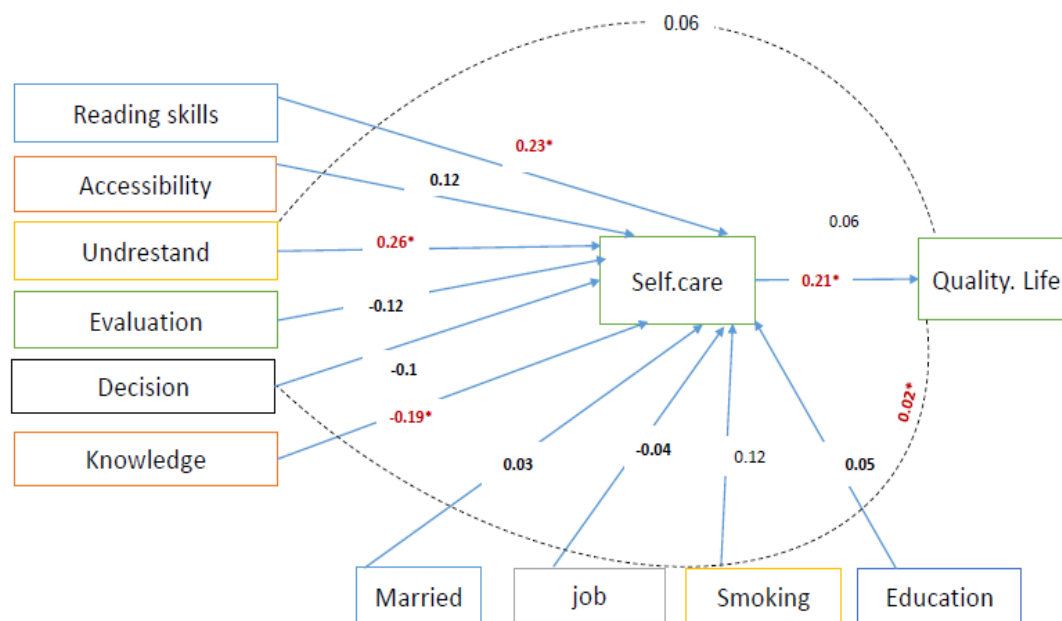
Figure 3. Conceptual model of factors affecting self-care and quality of life. * P < 0.05.

Promoting health literacy (reading, understanding and decision-making skills)

The patients had a poor level of literacy in the following domains of health literacy: reading skills, access to health information resources, understanding of health information, and decision making in health-related situations. More than half of patients did not understand the benefits and disadvantages of prescribed therapies (51%) and did not understand the meaning of medical forms (53%) and the way of taking medication written on the packaging of medications (55%). Also, about 54% had poor level of decision-making skills to perform annual check-ups, and screening tests for cancer in the case of having cancer cases in their close relatives. About 60% did not pay attention to the label of fat percentage on the foods, while shopping. Therefore, another priority of our educational program was considered to be health literacy promotion.

Discussion

The present study designed a health literacy promotion program (HeLPP) protocol for patients with type 2 diabetes mellitus based on the initial findings (pre-test) of the samples. We found a substantial relationship gender with self-care behaviors for both genders. Our findings are consistent with the results of other studies(30). Our results indicate that education level is strongly correlated with self-care behaviors, so that individual with higher levels of education had better self-care behaviors. This is similar to findings of the previous studies(1). As a result, the need for planning to educate patients for increasing self-care behaviors seems to be important.

The results of this study show a clear relationship between a higher educational level and a higher level of life quality. This finding is similar to other previous studies which showed that participants with higher educational level have better QoL(31). This

may be due to educated participants that have greater access to information about their disease, more sensitivity, better economic conditions, and better capacity to evaluate traumatic phenomena. The present study revealed that marital status was associated with quality of life among patients. Older married adults had the highest scores as compared to spouses died and divorced. Our study findings were in parallel with other studies (32). This makes sense; as a married person would have more opportunities to socialize with at least one other person who could be their partner, also married people have families that can be a source of social support. Previous studies identified being married or in a stable relationship as associated to a better QOL, and being unmarried was significantly associated to lower mental and physical dimensions of QOL (33). These results highlight the need to design and implement programs to improve the quality of life among patients whom their spouses were dead.

Our results showed a positive relationship between self-care behavior and dimensions of health literacy except for decision making. Health literacy could be one of the factors affecting self-care behaviors. HL seems to have an impact on the health-related outcomes in patients with diabetes (34). Lee et al. reported that a higher level of health literacy in patients with type 2 DM may increase their confidence in their ability to manage the disease, thereby positively influencing their self-care behavior and influencing glycemic control (35). In this regard, implementing health promotion training programs focusing on the health literacy factor among diabetic patients seems

essential. In the current study, we found a significant association between domains of the health literacy and quality of life which is consistent with other studies (14). Health Literacy (HL) is recognized widely as a strong influencing factor for quality of life proved by studies (36). These findings recommend that interventions should focus on promoting HL, in order to improve health outcomes like quality of life among patients with diabetes (37). It seems, with more attention to improving the health literacy of patients and planning and designing health education programs, we can make progress to improve the quality of life in patients with type 2 diabetes.

In the same vein, Zeidi et al. used a theory of planned behavior-enhanced intervention to promote health literacy and self-care behaviors among type 2 diabetic patients (38). But interventions whose protocol design is based on preliminary data from diabetic patients are rare. Perhaps this study will help in refining the interventions for future research and practice. The results from this study, if successful, might help in several ways. In the first instance it will help to set up similar interventions. Secondly it will help to provide strong information regarding the strategies to improve the quality of life of diabetic patients. Thirdly, the results of this study may influence policy makers to focus on these interventions among diabetic patients. Finally, the current intervention program will have the potential to serve as a guide for health care providers to improve self-care behaviors and quality of life of diabetic patients in health care settings. The strategies of this program could be important and cost effective, and therefore we hope that the

success of such a program is a step forward in improving the quality of life of diabetic patients.

Study Limitations and Strengths: A strength of our study lies in the development of the intervention program, which is tailored to the specific characteristics of the target group following pre-test analysis. To address potential biases in our study, we have implemented several measures. Additionally, we are mindful of co-intervention bias and have taken steps to mitigate it. All participants will be asked about their history of involvement in similar empowerment programs, and those with such a history is excluded from the study. Considering the nature of study, the implementation team of the intervention cannot be blinded to the participants. However, the researcher who collect the data at two post-test sessions is blinded.

Conclusion

Considering the predicting role of understanding, reading skills, and decision-making for self-care behaviors and QOL of the rural T2DM patients, the focus of HeLPP should be on clear communication, goal-setting, and teach back strategies. Our findings revealed the association of HL on the self-care behaviors and quality of life among type 2 diabetes patients. Designing HeLPP with a focus on enhancing practical HL and empowering rural patients with type 2 diabetes, we hope to improve not only the patients' HL, but also their self-care behaviors, QOL, biochemical markers, like HbA1c. Taking into account the priority needs of these rural T2DM patients while planning HeLPP and focusing on clear communication standards while developing the educational

materials are among the strengths of the program. HeLPP is now available to be pilot–tested in other rural settings of developing countries.

Availability of data and materials: The authors confirm that the data generated and analyzed during this study are available per request.

Conflicts of interests: The authors declare no conflict of interest.

Consent for publication: All respondents have given consent for publication, provided that anonymity was ensured.

Ethical approval and consent to participate: This study was approved by the ethics committee in Tabriz University of Medical Sciences (Ethics No: IR.TBZMED.REC.1397.459). The study was performed in line with the principles of Helsinki Declaration.

Author contributions: HN, HA, and TB conceptualized the main idea and designed the project. HN acquired the funding. HH, SS, SN, and BF worked on data acquisition. LZ, HH, KP, HA, and SS conducted data curation and formal analysis. KP, HN and HA wrote the original draft. HN, SS, HH, and LZ reviewed and edited the draft. All author(s) read and approved the final manuscript.

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