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Cost-Effectiveness of Health Literacy Enhancement Intervention on Patients with Type II Diabetes

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Abstract

Background: Type II diabetes is considered a chronic disease that influences the affected person's quality of life and imposes a high economic burden on the patient and society. The enhancement of health literacy seems essential for self-management and disease control in patients with type II diabetes. Consequently, this study was performed to evaluate the cost-effectiveness of enhanced health literacy in type II diabetes patients.

Methods: This study was of quantitative and economic evaluation type. A population of 232 patients was selected among those referred to the Tafihan Shiraz clinic based on the quality of entry and exit. The health literacy educational intervention was carried out for three months. In order to collect information, researchers used the SF36 questionnaire and the checklist of costs. The Cost Effectiveness Ratio (CER) and Incremental Cost Effectiveness Ratio (ICER) were calculated. Moreover, the costs of each unit of increasing the quality of life before and after the intervention were calculated. A decision was made to determine the cost-effectiveness of the intervention.

Results: According to the results, 40% of the participants were females, and 34.5% were 30-40 years old. Examination of the quality of life in patients before the intervention indicated that the mean and standard deviation of the patients' quality of life before the intervention was 18.43±44.99, and the mean and standard deviation of the quality of life after the intervention was 49.57±16.21. Moreover, the patients' quality of life increased after the educational intervention. The total direct medical costs were \$717,484 and \$685,620 before and after the intervention, respectively. The total indirect medical costs were \$604,122 and \$493,011 before and after the intervention, respectively. Moreover, the total indirect costs were \$122,535 and \$122,119 before and after the intervention, respectively. The study was cost-effective with CER=0.9 and ICER= - 140,000 per increase in the quality of life.

Conclusion: Improving health literacy can have a range of benefits and improve the quality of life of patients with type II diabetes and reduce their treatment costs, and thereby, this may be seen as an effective step toward the recovery of patients with type II diabetes.

Keywords: Cost-Effectiveness, Quality of Life, Health Literacy

Conflicts of Interest: None declared

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Introduction

Health literacy is an acquired skill and is necessary for managing individual health. In addition, health literacy is related to literacy and requires people's knowledge, motivation, and competencies in accessing, understanding,

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evaluating, and using health information for decision-making. In order to remain compliant with their treatment and achieve desirable health outcomes, patients must have a high level of health literacy (1). People with inadequate

↑What is "already known" in this topic:

The improvement of health literacy improves the quality of life of type 2 diabetes patients. The improvement of health literacy reduces treatment costs for patients with type 2 diabetes.

→What this article adds:

Considering the cost-effectiveness of the health literacy intervention, the improvement of the health literacy of type 2 diabetes patients in Iran has many limitations, most of which are due to the lack of expertise and specialist staff in treatment centers for type 2 diabetes patients.

health literacy have worse health outcomes (1, 2). Approximately 25% of Americans have difficulty understanding health care information. In Iran, 50% of adults have limited health literacy (3). Additionally, racial and ethnic minorities with low health literacy rates among older adults are more susceptible to chronic illnesses (4).

Diabetes is a chronic disease. According to the International Diabetes Federation estimates, 463 million people around the world have diabetes, and this is expected to increase by up to 700 million patients. Most diabetic patients have type II diabetes, which accounts for 95% of the total population of diabetic patients. Currently, 8.5% of the American adult population is suffering from type II diabetes (5). Developing type II diabetes is caused by unhealthy lifestyle activities such as physical inactivity and poor diet (6). People with type II diabetes usually get aware of their disease late, and about 30%-80% of people with type II diabetes have not yet been diagnosed. The treatment of type II diabetes needs constant management of the lifestyle aspects such as diet, exercise, glucose monitoring, and especially some specific medications to achieve glycemic control goals. People with type II diabetes are expected to reduce or stop the progression of their disease by employing different intervention approaches (7).

Studies have demonstrated inadequate health literacy as one of the biggest challenges in the management and treatment of type 2 diabetes (5). Health literacy describes how much patients can acquire, process, and understand basic health information about managing and controlling type II diabetes. It is particularly important and crucial that the patients can understand the instructions related to the drugs prescribed for their treatment (8, 9). The low health literacy of type II diabetes patients about diet and adequate physical activity are known as the most important predisposing factors for developing complications, and the mortality of patients with type II diabetes increases since more than 95% of the care measures are accomplished by the patients (10, 11).

In Iran, 43.47% of people have inadequate and borderline health literacy, and 26.3% have adequate health literacy (12). A low level of health literacy is common in type II diabetic patients (13, 14). Coherent educational programs promote the awareness, attitude, and performance of diabetic patients and reduce treatment costs (15, 16).

The provision of proper conditions for training and increasing the knowledge of patients can decrease the costs of the health system. Some significant steps in reducing treatment costs include self-care programs and persuading type II diabetes patients to adhere to such programs (10). The cost-effectiveness method is an economic evaluation approach that focuses on the method to achieve objectives. This method helps decision-makers choose and implement different strategies. The examination of the cost-effectiveness of various types of therapeutic and non-therapeutic interventions plays a substantial role in the design and evaluation of health systems (17). Abdul Ahad et al. (2019) showed that examining the cost-effectiveness of health literacy provides ways to waste resources and costs. It also determines the effectiveness of health literacy intervention in treatment and has an effective role in the management of health care services in the field of diabetes (11-13, 18). The effect of enhancing health literacy in reducing direct medical and non-medical costs and increasing patients' quality of life has not been studied in Iran. Therefore, the present research was conducted to evaluate the cost-effectiveness of health literacy intervention in type II diabetic patients.

Methods

This research was of the type of economic evaluation. The sampling of patients was performed by a random sampling method, and samples were selected based on the inclusion and exclusion criteria. The sample size was obtained using the study of Pourreza et al. in 2013 (19). The mean and standard deviation in the same study was 71.97±13 before the intervention and 76.06±11.08 after the intervention. According to similar studies, the following formula was used to estimate the sample size as 210 subjects (19). According to the inclusion and exclusion criteria and the number of type II diabetes patients referred to Tafihan Shiraz clinic, and considering the probability of sample drop, a total of 232 patients were selected.

$$N = 2C \times \left[\frac{\sqrt{SD_1^2 + SD_2^2}}{m_1 - m_2} \right]^2$$

The inclusion criteria were as the following:

- 1. Patients aged 20-60 years old referred to the clinic
- 2. Diagnosed with type II diabetes by endocrinologists
- 3. Diagnosed with type II diabetes a year before the research
- 4. Ability to understand the Persian language
- 5. Willingness and informed consent to participate in the research
- 6. Referring to the clinic and having a medical record with the attending physician

The exclusion criteria were as the following:

- 1. Suffering from other chronic diseases except those related to the complications of diabetes
- 2. Suffering from mental retardation or the diagnosis of other psychological disorders, such as mood disorders and anxiety, before the diagnosis of diabetes

In this research, the cost-effectiveness of health literacy improvement in patients with type 2 diabetes in Shiraz City was investigated before and after the intervention. The demographic information questionnaire was utilized in this research to gather and determine the patients' age, gender, education level, economic status, marital status, and duration of the disease. Moreover, the 36-Item Short Form Survey (SF-36) questionnaire was employed to evaluate the quality of life of patients. This 36-item questionnaire is not limited to a certain age range, group, or disease. The goal of this questionnaire is to evaluate the state of health from physical and mental perspectives, which is obtained by combining the scores of the eight health domains. Eight areas of the SF-36 questionnaire are as follows:

- 1. General Health
- 2. Physical functioning
- 3. Role limitation due to physical reasons

- 4. Role limitation due to emotional reasons
- 5. Physical pain
- 6. Social functioning
- 7. Energy and vitality
- 8. Mental health

The reliability of the SF-36 questionnaire has been obtained to be 0.9 for diabetic patients (16). It should be noted that the benchmark in this study was to calculate the costs from the society's viewpoint, which encompassed direct treatment and non-treatment costs, and indirect costs. The information collection form included two parts. The first part involved the demographic information of the patient. The second part included information related to direct medical costs (e.g., the cost of physicians' visits, the cost of diabetes drugs, hospital costs, diagnostic and laboratory procedures), direct non-medical costs (e.g., transportation, lodging, and telephone costs, and the cost of informal care), and indirect costs (e.g., the lost productivity of the patient and lost productivity of the patient's companion) all of which were extracted through the form and calculated with the human capital approach method. Each dollar was considered to be equal to 41,790 Rials in this research, which is the official currency rate (17).

The researcher was present at Tafihan Health Center for three months (December, January, and February 2019). Accordingly, 24 face-to-face training sessions of 30-45 min were held in the form of small 13-20 people groups on Sundays and Wednesdays. The health literacy of the sample patients was improved with the help of the DELNET 2 educational model (18). This tool contains educational materials about blood sugar, nutrition, and various drugs in the area of diabetes, which is recognized as a standard tool by the American Diabetes Association and has been designed by nutritionists, physicians, and nurses. The educational materials of this tool were provided to all patients in the form of in-person training. Moreover, the researcher introduced and presented educational information sources and other useful treatment guides available in the field of type II diabetes (brochures, book introduction) to the patients. The intervention related to health literacy enhancement was carried out for three months, and the patients were followed up by the researcher for three months. The data obtained from the questionnaires were analyzed by the SPSS software (version 21) using the descriptive statistics method and the frequency distribution table before and after the health literacy intervention. The mean and standard deviation values were calculated before and after the intervention. In addition, the paired t-test was used to examine the changes before and after the intervention. Finally, the costeffectiveness of health literacy enhancement was calculated and described using the cost-effectiveness formula.

Data analysis

Cost-Effectiveness Ratio (CER)

The cost-effectiveness ratio in this research is the average cost of increasing the quality of life of each patient after the health literacy intervention compared to that before the intervention (17).

Costs Before Health Literacy Intervention

The costs of type 2 diabetes patients decreased before the intervention (xa).

The costs of type 2 diabetes patients did not decrease before the intervention (xb).

Costs After Health Literacy Intervention

The costs of type 2 diabetes patients have decreased after the intervention (yc).

The costs of type 2 diabetes patients have not decreased after the intervention (yd).

$$CER = xa / yc$$

Where,

CER < 1 means that the intervention is cost-effective.

CER > 1 means that the intervention is not cost-effective

Incremental Cost-Effectiveness Ratio (ICER)

The incremental effectiveness cost ratio is defined as the difference in costs before and after the intervention to increase health literacy divided by the difference in the increase in quality of life before and after the intervention. The incremental cost-effectiveness ratio represents the incremental average associated with a unit of measurement (17).

ICER=xa - yc/ difference in a% - difference in c%

Decision rules

(i) If the incremental cost is negative and the incremental effect is positive (SE quadrant), the intervention is unequivocally cost-effective (it is dominant, achieving better outcomes at lower cost). (ii) If the incremental cost is positive and the incremental effect is negative (NW quadrant), the intervention is unequivocally not cost-effective (it is dominated, achieving poorer outcomes at a higher cost). (iii) If both the incremental cost and the incremental effect are negative (SW quadrant) or both the incremental cost and the incremental effect are positive (NE quadrant), no such unequivocal statements can be made. Determining whether the intervention is cost-effective depends on a threshold value (λ), defined as the maximum amount society is willing to pay for an incremental health gain or, equivalently, as the minimum amount society is willing to accept for foregoing an incremental health gain. The intervention will be regarded as cost-effective if its incremental cost-effectiveness ratio is lower than the threshold ($\Delta C/\Delta E < \lambda$) for ICERs in the NE quadrant or higher than the threshold $(\Delta C/\Delta E > \lambda)$ for ICERs in the SW quadrant (17, 20) (Diagram 1).

The data obtained from the questionnaires were analyzed in the SPSS software (version 21) using the descriptive statistics method, the frequency distribution table before and after the health literacy intervention, and the mean and standard deviation before and after the intervention were expressed. The paired t-test was used to examine the changes before and after the intervention. Finally, using the cost-effectiveness calculation, the incremental cost-effectiveness was expressed as the cost-effectiveness of health literacy improvement.

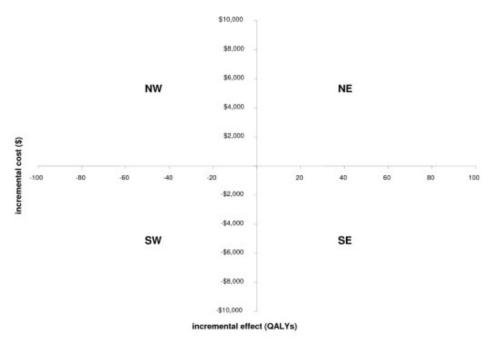


Diagram 1. Cost-effectiveness plane for after and before Intervention

Results

The findings obtained from the demographic information are presented in Tables 1 and 2. The data were analyzed to investigate the relationship between demographic information and quality of life.

According to the findings, most of the study participants were women (39.1%). Most of the participants were aged 30-39 (34.5%) and had high school education (32.3%), and their income was between \$238-\$450 (37.9%). According to the results of Table 1 and Table 2, there was a significant relationship between demographic characteristics and quality of life before and after the intervention (P<0.001).

According to Table 3, the mean and standard deviation of the three dimensions of "role limitations due to physical health," "role limitations due to emotional problems," and "physical functioning" were obtained higher than other dimensions, while the "pain" dimension had the lowest values. Moreover, there was a significant relationship between quality of life and improvement of health literacy before and after the intervention (*P*<0.001).

According to Table 4, the total cost of the consuming items for all patients was obtained to be \$708.

According to Table 5, the cost of admission to the emergency unit and the costs of the physicians' visits and medications before the intervention were estimated to be more than others, and the cost of MRI was obtained lower than others. After performing the health literacy intervention, the cost of admission to the emergency unit and the costs of the physicians' visits and surgical services were calculated to be higher than other costs, and the cost of medications was estimated to be lower than others. According to the research hypothesis, the costs decreased after the educational intervention.

According to Table 6, before the intervention, the expenses paid by the patient for diet, hiring a servant, and changes in the environment were greater than other costs. After the intervention, the total cost paid by the patients decreased, and the expenses paid by the patient for diet, changes in the environment, and auxiliary tools were more significant compared to other costs.

According to Table 7, the lost income of the patient and the patient's companion decreased by \$417 after the intervention. Moreover, the total lost income of the patient and the patient's companion decreased after the intervention with comparison to the state before the educational intervention.

The intention-to-treat analysis method was utilized to estimate the effect of the intervention accurately. The costs were calculated before and after the health literacy intervention. Moreover, the information related to the quality of life before and after the intervention was expressed as mean±standard deviation. The rate of changes in the patients' costs and quality of life before and after the intervention was calculated using the following formula, and the rate of cost-effectiveness was specified.

$ICER = \Delta cost/\Delta effectiveness = -1773350$

The intention-to-treat analysis method was used to estimate the effect of the intervention appropriately. The costs were calculated before and after the health literacy intervention. The data related to the quality of life before and after the intervention was expressed as mean \pm standard deviation.

According to Table 8, the costs after the intervention decreased by \$141,858, the quality of life increased, and a significant difference was observed between the promotion of health literacy and demographic variables after the educational intervention; therefore, the intervention was effectional intervention.

Table 1. Demographic characteristics of the participants in the study

| Variable | | Number | Mean ± Standard Deviation |
|-----------------|------------------|------------|---------------------------|
| | | (%) | |
| Age | 20-29 | 50 (21.6) | 1.46±0.49 |
| | 30-39 | 80 (34.5) | |
| | 40-49 | 61 (26.3) | |
| | 50-60 | 41 (17.7) | |
| Gender | Female | 125 (39.1) | 2.4±1.01 |
| | Male | 106 (33.1) | |
| Marital Status | Single | 118 (50.9) | 1.62 ± 0.75 |
| | Married | 85 (36.6) | |
| | Divorced | 8 (19.8) | |
| Education Level | Illiterate | 55 (23.7) | 2.5±1.08 |
| | Primary | 49 (21.1) | |
| | High school | 75 (32.3) | |
| | Academic | 53 (22.8) | |
| Occupation | Jobless | 60 (25.9) | 2.97±1.54 |
| • | Housewife | 38 (16.4) | |
| | Employee | 43 (18.9) | |
| | Retired | 29 (12.5) | |
| | Self-Employed | 62 (26.7) | |
| Income | Less than \$237 | 42 (18.1) | 2.88±1.68 |
| | \$238-\$450 | 88 (37.9) | |
| | \$451-\$687 | 31 (13.7) | |
| | \$688-\$924 | 31 (12.9) | |
| | \$925-\$1161 | 22 (9.5) | |
| | \$1162-\$1398 | 16 (6.9) | |
| | \$1399-\$1635 | 2 (0.9) | |
| | More than \$1635 | 0 | |

Table 2. Demographic characteristics of the participants in the study

| Variable | | Number (%) | Mean ± Standard deviation |
|------------------|-------------------|------------|---------------------------|
| Disease Duration | Less than 1 year | 54 (23.3) | 2.43±1.21 |
| | 1-1.9 years | 54 (23.3) | |
| | 2-2.9 years | 80 (34.5) | |
| | 3-4 years | 20 (8.6) | |
| | More than 4 years | 16 (6.9) | |
| Blood Sugar | Less than 100 | 80 (53.3) | 2.12±1.14 |
| | 100-199 | 50 (21.6) | |
| | 200-299 | 60 (25.9) | |
| | 300-400 | 30 (12.9) | |
| | More than 400 | 10 (0.3) | |

tive. Since any economic evaluation is associated with uncertainty, it was attempted in this study to test the generalizability of the results using the sensitivity analysis approach. Therefore, a one-way sensitivity analysis was performed, and the quality of life and costs increased by 20% before and after the intervention. Table 9 indicates the results of the sensitivity analysis before and after the intervention. Before the intervention, the new ICER equals 5,709,607 with a 20% increase in the costs, and with increasing the quality of life by 20%, the new ICER becomes 8,681,775. After the intervention, with a 20% increase in the costs, the new ICER equals 1,571,259, and with a 20% increase in the quality of life, the new ICER becomes 778,372.

Cost-Effectiveness Ratio (CER)

The CER was calculated as follows:

CER = 1301868 / 1443726 = 0.9

As a result, the health literacy intervention is cost-effective.

Incremental Cost-Effectiveness Ratio (ICER)

 $ICER = \Delta cost/\Delta effectiveness = -140000$

Considering that a positive CER and a negative ICER were obtained, there is an intervention in the area (SE quadrant); therefore, the intervention is definitely cost-effective.

Since every type of economic evaluation study is associated with uncertainty, it was attempted in the present study to test the generalizability of the results using sensitivity analysis. Therefore, a one-way sensitivity analysis was performed, and the quality and costs increased by 20% before and after the intervention, and the results were presented. Table 9 indicates the sensitivity analysis before and after the intervention. Diagram 2 demonstrates the fluctuations in price and quality of life before and after the intervention. Before the intervention, with a 20% increase in costs, the new ICER becomes 5,709,607, and with a 20% increase in the quality of life, the new ICER becomes 8,681,775. Moreover, after the intervention, with a 20% increase in costs, the new ICER becomes 1,571,259, and with a 20% increase in the quality of life, the new ICER becomes 778,372. As a result, the insensitivity of CER is variable.

The tornado diagram for sensitivity analysis is presented

Table 3. Evaluation of the quality of life of patients before and after the health literacy intervention

| | Before the Intervention | After the Intervention |
|--|---------------------------|---------------------------|
| Dimensions | Mean ± Standard Deviation | Mean ± Standard Deviation |
| Physical Functioning | 49.50±14.35 | 50.28±16.41 |
| Role Limitations due to Physical Health | 66.95±18.88 | 69.76±24.34 |
| Role Limitations due to Emotional Problems | 58.62±19.18 | 70.83±30.48 |
| Energy/Fatigue | 44.87±20.26 | 42.37±17.44 |
| Emotional Well-Being | 44.91±19.37 | 48.56±19.68 |
| Social Functioning | 33.96±33.44 | 38.72±35.8 |
| Pain | 27.78±25.63 | 24.51±26.45 |
| General Health | 33.40±20.70 | 49.55±26.10 |
| Total Mean | 44.99±18.43 | 49.57±16.21 |

Table 4. Costs paid for the health literacy therapeutic intervention

| Consuming Items | Costs (Dollars) |
|---|-----------------|
| Cost of Printing the DELNET Booklet | 498 |
| Cost of the Instructor's Transportation | 194 |
| Total Cost | 708 |

Table 5. Direct medical costs of type II diabetes before and after the health literacy educational intervention

| Different Types of Direct Costs | Average Cost Per Pa- | Total Cost (Dollars) | Average Cost Per Patient | Total Cost (Dollars) After |
|---------------------------------|------------------------|----------------------|----------------------------|----------------------------|
| | tient (Dollars) Before | Before the Interven- | (Dollars) After the Inter- | the Intervention |
| | the Intervention | tion | vention | |
| Physicians' visits | 55 | 127,221 | 413 | 95,949 |
| Admission to the Emergency | 57 | 132,196 | 470 | 109,216 |
| Unit | | | | |
| Laboratory tests | 427 | 99,029 | 297 | 6894 |
| Medications | 545 | 126,273 | 281 | 65,150 |
| Surgical services | 400 | 92,869 | 393 | 91,211 |
| Physiotherapy | 398 | 92,395 | 398 | 92,158 |
| Radiology | 250 | 58,043 | 409 | 94,764 |
| MRI | 244 | 56,622 | 295 | 68,230 |
| Total Costs | 2377 | 717,484 | 2956 | 685,620 |

Table 6. Direct non-medical costs of type II diabetes before and after health literacy educational intervention

| Different Types of Direct | Average Cost Per Patient | Total Cost (Dollars) Be- | Average Cost Per Patient | Total Cost (Dollars) After |
|---------------------------|--------------------------|--------------------------|--------------------------|----------------------------|
| Non-Medical Costs | (Dollars) Before the In- | fore the Intervention | (Dollars) Before the In- | the Intervention |
| | tervention | | tervention | |
| Auxiliary Tools | 444 | 102,819 | 333 | 77,233 |
| Child Care | 433 | 100,450 | 301 | 6941 |
| Hiring Servants | 610 | 141,436 | 323 | 75,101 |
| Diet Costs | 622 | 144,279 | 600 | 139,303 |
| Changes in the Environ- | 496 | 115,139 | 569 | 131,959 |
| ment | | | | |
| Total Costs | 2604 | 604,122 | 2127 | 493,011 |

Table 7. Indirect costs of type II diabetes before and after the health literacy educational intervention

| rubic 7. mandet costs of type in | diabetes before and after t | ne nearth meracy educational | water 1. maneet costs of type if address before and after the health merce's educational intervention | | | | | |
|----------------------------------|-----------------------------|------------------------------|---|----------------------------|--|--|--|--|
| | Average Cost Per Pa- | Total Cost (Dollars) Be- | Average Cost Per Patient | Total Cost (Dollars) After | | | | |
| Indirect Costs | tient (Dollars) Before | fore the Intervention | (Dollars) After the Inter- | the Intervention | | | | |
| | the Intervention | | vention | | | | | |
| Lost Income of Patient | 501 | 116,560 | 53 | 12,248 | | | | |
| Lost Income of the Patient's | 118 | 5559 | 10 | 518 | | | | |
| Companion | | | | | | | | |
| Total Lost Income | 619 | 122,119 | 63 | 122,535 | | | | |

Table 8. Changes in the cost and quality of life before and after the health literacy intervention

| | Total Cost (Dollars) | Quality of Life | Differences Between the Costs (Dollars) | Quality of Life Difference |
|-------------------------|----------------------|-----------------|---|----------------------------|
| Before the Intervention | 1,443,726 | 0.461094348659 | | |
| After the Intervention | 1,301,868 | 0.54 | 141,868 | 0.08 |

as Diagram 3 for evaluating the strength of the results of the present investigation.

Discussion

This study was designed and conducted to evaluate the

cost-effectiveness of the health literacy intervention in patients with type II diabetes. According to the results, a significant difference was found between demographic variables and quality of life before and after the intervention. The mean and standard deviation for quality-of-life dimensions increased after the intervention. The total mean and

Table 9. One-way sensitivity analysis of costs and the quality of life before and after the intervention

| One-Way Sensitivity Analysis | Result | One-Way Sensitivity Analysis | Result | |
|--|------------|---|------------|--|
| 20% Increase in Quality of Life Before Interven- | 0.60 | 20% Increase in Quality of Life Before Intervention | 0.60 | |
| tion | | | | |
| Cost Difference | 1,425,778 | Cost Difference | 1,425,778 | |
| Quality of Life Difference | 0.02 | Quality of Life Difference | 0.18 | |
| New ICER | 8,681,775 | New ICER | 778,372 | |
| 20% Increase in Cost Before Intervention | 17,411,330 | 20% Increase in Cost Before Intervention | 15,700,396 | |
| Cost Difference | 4,327,666 | Cost Difference | 1,190,955 | |
| Quality of Life Difference | 0.08 | Quality of Life Difference | 0.08 | |
| New ICER | 5,709,607 | New ICER | 1,571,259 | |

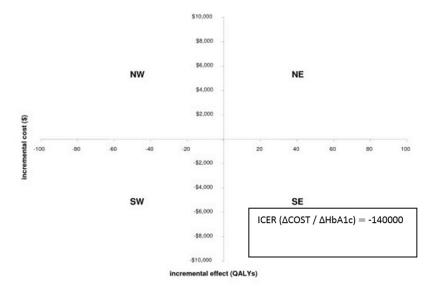


Diagram 2. Incremental Cost-Effectiveness Ratio; after and before Intervention

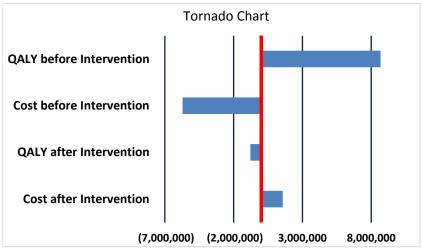


Diagram 3. Tornado diagram for sensitivity analysis to evaluate the strength of the results

standard deviation of the dimensions of self-care was 44.99±18.43 before the intervention, which became 49.57±16.21 after the intervention (20). The research findings indicated that the quality of life has improved after the educational intervention. Chittleborough et al. (21) demonstrated that the quality of life of patients with diabe-

tes has a significant relationship with demographic characteristics, which is consistent with the results of the present investigation. Their results also indicated that the mean and standard deviation values of the quality-of-life dimensions, including mental health, physical functioning, and pain, are less than other dimensions. In the present study, the mean

and standard deviation of social functioning, pain, and general health were higher than other dimensions before the intervention, while the mean and standard deviation of pain, social functioning, and energy/fatigue were lower than other dimensions after the intervention. Regarding the pain dimension, the results of this study were in line with Chittleborough et al.'s study.

Moreover, Cheng et al. (22) indicated that increasing knowledge improves the quality of life of patients with diabetes. In 2011, Vadstrup et al. (23) indicated that increasing the awareness and health literacy of patients with type II diabetes would enhance their quality of life, which is in line with the results of the present study. In recent years, several studies have been conducted regarding the quality of life of patients with diabetes, and the results have shown that the quality of life of these patients is lower than that of healthy people. Moreover, diabetes has a negative effect on a person's understanding and satisfaction with his/her life and causes a decrease in functional capacity, mental states, social functioning, and in general, the quality of life (24-26). Chen et al. (27) revealed that educational intervention in type II diabetes patients reduces blood sugar levels and improves the quality of life of patients, which is in line with the results of the present investigation. Moreover, Yuan et al. (28) indicated that health literacy enhancement intervention increases the quality of life of patients, which is also consistent with the results of this study.

In the present study, the direct and indirect costs of type II diabetes were defined and specified from the patients' perspective before and after the health literacy enhancement intervention. The total direct medical costs before and after the intervention were equal to \$717,484 and \$685,620, respectively. Moreover, the total indirect medical costs before and after the intervention were \$604,122 and \$493,011, respectively. In addition, the total indirect costs before and after the intervention were \$122,535 and \$122,119, respectively. The costs indicated a reduction after the intervention, and the intervention appeared influential. Kieu et al. (29) revealed that the total direct non-medical and indirect costs in 2017 accounted for 239 million dollars. The direct non-medical costs were estimated at 78 million dollars, while indirect costs accounted for 161 million dollars. The costs of being absent, attending sessions, and premature mortality corresponded to 17%, 73%, and 10% of the indirect costs. The average annual direct nonmedical costs for patients were equal to US\$56. The average annual absence and presence costs for working-age patients were equal to US\$61 and US\$267, respectively. Researchers have concluded that patients with type II diabetes have a high economic burden, which is in line with the results of this study. Sulistyaningrum et al. (30) evaluated the direct and indirect costs of diabetes in Indonesia. Accordingly, the average annual cost per patient accounted for 1207.8±673.4 US dollars. The direct cost accounted for the largest share of the total cost (87.95%), and the cost of medications was the significant share after the visiting fee of the general practitioners. Their findings seem consistent with the results of the present study. The average annual cost of using insulin with an oral hypoglycemic agent, the presence of hypertension and dyslipidemia, and poor levels were the highest frequent characteristics in each group. Saha et al. (31) indicated that the average total cost per year was \$600, covering the costs of medication, research, consultation, and transportation. Among them, the costs of medications were the highest (US\$350). Therefore, the cost of treating type II diabetes was proven to be high, which is consistent with the results of the present investigation.

In the present study, the cost-effectiveness of health literacy intervention was defined based on community costs. According to the results, the costs decreased, and the quality of life increased after the intervention. Therefore, the intervention has undoubtedly been predominantly effective. In a review of the studies on the cost-effectiveness of diabetes, it was found that the core emphasis of these studies has been on the economic evaluation of third-level preventions, i.e., various types of medication and behavioral interventions. In 2018, Saifulsyahira et al. (17) indicated that the health literacy improvement intervention reduces blood sugar and the treatment costs of patients with type 2 diabetes, which is in line with the present study.

Conclusion

It is concluded from the results of this research that an increase in health literacy is cost-effective and will increase the quality of life of patients and reduce their treatment costs. Therefore, it seems essential to increase the health literacy of all patients with type II diabetes. In order to improve the status of educating patients, it is necessary to align managers in this field and increase the recruitment of health literacy specialists, including librarians and medical informants. The present study demonstrated that inadequate health literacy is a common problem in patients with type II diabetes and imposes more costs on patients and society. Since the enhancement of the health literacy of patients with type II diabetes requires continuous efforts for several years, it is recommended to perform some relevant investigations on how to include related materials in textbooks as well as utilize them in social media and design mobile applications for patients to improve the health literacy level.

Limitations

One of the limitations of the present study was the non-cooperation of the patients in the educational sessions. Moreover, the patients tried not to mention the treatment costs, which did not affect the participants' responses. In this research, the study samples were limited to Shiraz in Iran. As a result, a limited generalization is considered for obtained results.

Research Suggestions

The results indicated that the training of type 2 diabetes patients increases the quality of life and reduces the costs of the patients. As a result, it is suggested to plan for the training of type 2 diabetes patients in related clinics. Communication should be made to exchange knowledge between type 2 diabetic patients and clinics to increase health literacy. Moreover, future research should be conducted mainly with the aim of evaluating the effectiveness of evidence-based interventions to reduce costs. Furthermore,

systematic reviews are required to better understand the effects of health literacy on the costs that type 2 diabetes patients should pay.

Ethical Approval

This study was conducted with the approval of the ethics committee of Iran University of Medical Sciences, Iran (IR.IUMS.REC.1399.424).

Consent for Participation and Publication

Prior to completing the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire, some explanations were given to patients about the confidentiality and publication of research results, and they completed the questionnaire with satisfaction.

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Conflict of Interests

The authors declare that they have no competing interests.

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