

The effect of therapeutic education program on quality of life among type 2 diabetic North-African patients: A randomized controlled trial

L'effet d'un programme d'éducation thérapeutique sur la qualité de vie des patients diabétiques de type 2 Nord-Africains: Un essai contrôlé randomisé

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ABSTRACT

Introduction: Type 2 Diabetes Mellitus (T2DM) is a chronic non-communicable disease with major impact on health in general and quality of life (QoL) in particular. The ultimate goal of all health interventions is to reduce the burden of this disease.

Aim: To evaluate the effect of therapeutic education program on the QoL among patients with T2DM.

Methods: Between May 2021 and July 2022, 320 outpatients were enrolled in a randomized controlled trial in Sfax, Tunisia. The experimental group received the therapeutic education program, whereas the control group received only standard care. For data collection, the Arabic version of the Diabetes Quality of Life (DQoL-Arabic) questionnaire was used.

Results: In total, 263 patients completed the intervention, 132 in the experimental group and 131 in the control group. In terms of the main baseline characteristics, the two groups were comparable. After the intervention, there was a significant difference in all domains of QoL scores (median [interquartile]) between the experimental and control groups: satisfaction (3.14 [2.64-3.36] vs. 3.57 [3.43-3.71], $p < 0.001$, respectively), impact (2.09 [1.91-2.36] vs. 2.45 [2.27-2.64], $p < 0.001$, respectively) and worries (2.50 [2.25-2.75] vs. 3.00 [2.75-3.14], $p < 0.001$, respectively). The QoL improves over time in the experimental group (3.01 [2.79-3.17] vs. 2.59 [2.21-2.80], $p < 0.001$, respectively) and remains comparable in the control group (2.99 [2.81-3.14] vs. 3.01 [2.81-3.15], $p = 0.724$, respectively).

Conclusions: The benefits of implementing an educational program among patients with T2DM are observed in terms of all QoL domains.

Key words: Diabetes Mellitus, Health Promotion, Healthy Lifestyle, Personal Satisfaction, Self-Care, Self-Management.

RÉSUMÉ

Introduction: Le diabète de type 2 (DT2) est une maladie chronique ayant un impact majeur sur la santé en général et la qualité de vie (QDV) en particulier.

Objectif: Évaluer l'effet d'un programme d'éducation thérapeutique sur la QDV des patients ayant un DT2.

Méthodes: Entre mai 2021 et juillet 2022, 320 patients ont été recrutés dans un essai contrôlé randomisé à Sfax, Tunisie. Le groupe expérimental a suivi le programme d'éducation thérapeutique, tandis que le groupe témoin n'a reçu que les soins standards. Pour la collecte des données, la version arabe du questionnaire Diabetes Quality of Life (DQoL-Arabic) a été utilisée.

Résultats: Au total, 263 patients ont terminé l'intervention, 132 dans le groupe expérimental et 131 dans le groupe témoin. En termes de principales caractéristiques de base, les deux groupes étaient comparables. Après l'intervention, il y avait une différence significative dans tous les scores (médiane [interquartile]) des domaines de la QDV entre le groupe expérimental et le groupe témoin: satisfaction (3,14 [2,64 - 3,36] contre 3,57 [3,43-3,71], $p < 0,001$, respectivement), impact (2,09 [1,91-2,36] contre 2,45 [2,27-2,64], $p < 0,001$, respectivement) et inquiétudes (2,50 [2,25-2,75] contre 3,00 [2,75-3,14], $p < 0,001$, respectivement). La QDV s'améliore avec le temps dans le groupe expérimental (3,01 [2,79-3,17] contre 2,59 [2,21-2,80], $p < 0,001$, respectivement) et reste comparable dans le groupe témoin (2,99 [2,81-3,14] contre 3,01 [2,81-3,15], $p = 0,724$, respectivement).

Conclusion: Les avantages de la mise en œuvre d'un programme d'éducation sur le diabète sucré sont observés dans tous les domaines de la QDV.

Mots clés: Autosoins, Diabète sucré, Gestion de soi, Mode de vie sain, Promotion de la santé, Satisfaction personnelle

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INTRODUCTION

Tunisia's epidemiological situation of T2DM (T2DM) is alarming (1). The rising prevalence of T2DM is a public health concern, imposing significant burdens on healthcare system, patients and families (2). In fact, diabetics with a low glycemic index have poor self-care activities, more barriers to daily activities, and a less ability to cope with diabetes mellitus positively, which leads to a lower quality of life (QoL) and a reduced health status (3). Namely, even if not result in premature mortality, T2DM causes significant morbidity including disability, decreased productivity, and reduced QoL (4). Between 1990 and 2019, the average disability-adjusted life year's (DALYs) rates for T2DM increased by nearly 31% (808.3 to 1060.8) in the Middle East and North Africa (MENA) region (5). In 2019, the DALYs rate in most this region's countries was above the global average (5). This rising trend could be attributed to modifiable and non-modifiable risk factors such as population aging, urbanization, economic transformation, sedentary lifestyles, obesity and unhealthy diets. Since most of the burden of T2DM is exacerbated by modifiable risk factors, it is essential for health care systems to establish policies, allocate funding, and adapt educational interventions to promote healthy lifestyles (5).

Patient education is a fundamental component of T2DM treatment. The goal of diabetes mellitus education is not only to provide knowledge and skills, but also to change the patient's behavior, to prepare them for self-care and to adhere to therapeutic recommendations, which leads to improve their QoL (6). However, there is no gold standard for the strategies of the educational interventions due to the variety of methods, contents and providers. Indeed, each of them can effectively improve QoL of patients with T2DM (7).

Therefore, the aim of this study was to evaluate the effect of a therapeutic education program on QoL among patients with T2DM. The main outcome of this study was the QoL. Thus, the null hypothesis proposed that the educational intervention is not superior in improving QoL compared to the standard care in patients with T2DM.

METHODS

Study design and Setting

A single-blinded randomized controlled trial (RCT) with pre-test post-test design was conducted in the "National Fund for Social Security" Polyclinic in Sfax, Tunisia during the coronavirus disease 2019 (COVID-19) pandemic from May 2021 to July 2022. In order to avoid transmission of the virus among patients, the educational intervention was carried out individually in a private office while respecting standard precautions (eg; maintaining social distancing, wearing a properly fitted mask and using an alcohol-based hand sanitizer).

Participants

The target population consisted of adults with T2DM who attend department of general medicine. Patients aged 18 years or older, diagnosed by a physician and under treatment during the last twelve months and having poor glycemic control (glycosylated hemoglobin (HbA1c) >7%) (8) in the three months before the beginning of the trial were included in the study. However, those with an untreated mental disease, unable to communicate verbally or absent in any of the three educational sessions were not included in the trial. Participants meeting the inclusion criteria were randomized in the experimental or the control group. The experimental group received the standard care and participated in the educational intervention, whereas the control group received only the standard diabetes mellitus care.

Sample size

The sample size calculation was based on the effect size from the QoL outcome (effect size = 0.58, mean difference = 9.45, standard deviation (SD) = 16.40) from a previous study conducted in Iran (9). Setting included significance level $\alpha = 0.001$, $\beta = 0.10$, power $1 - \beta = 0.90$, resulting in 131 participants in each group. Due to the COVID-19, we predicted that about 15% of the participants will drop out of the study. Therefore, it was estimated that at least 154 participants per group would be required.

Intervention

The intervention consists of a therapeutic education program. The main goals of this program were to enhance patients' understanding of the physiopathology, types and causes of diabetes mellitus, to provide information about the acute and chronic complications of T2DM and to encourage self-care behaviors, as well as to promote healthy lifestyle, adherence to the treatment and QoL. The randomization procedure consists of the use of sequentially numbered, sealed, opaque envelopes, which were created by a person not involved in the trial, to ensure the allocation concealment. At recruitment, the researcher opens the envelopes for random allocation. The educational program was carried out to each patient individually by the researcher in a private office in the pre-mentioned setting through three sessions. The duration of each session was 45 minutes occurred every three months. The program was delivered face to face and based on a variety of educational methods such as demonstrations, presentations, discussion and supplementary materials including booklet, poster and leaflet. At the end of each session, every patient received take-home illustrated materials written in Tunisian dialect.

The educational program covered a wide range of topics. The first session concentrated on general knowledge of diabetes mellitus, such as the definition, types, risk factors, symptoms, and management of diabetic diet. The second session focused on blood glucose self-monitoring and copying with hypoglycemia and hyperglycemia as well as acute and chronic complications. The last session focused on medication management, physical activities

and foot care.

Measures

The questionnaire used in this study consisted of two parts and the time required to complete it was 15 minutes. The first part is devoted to patient characteristics and the second part to QoL assessment. All measurements were assessed at baseline (three months before the first session) and at end line (three months after the last session).

Patient's characteristics

Data collection sheet consisted of patients' general information covering socio-demographic characteristic and medical data that includes age, sex, schooling level, marital status, T2DM duration, complications, treatment, HbA1c and socioeconomic level. According to "Africa Housing Finance Yearbook 2019", the middle class in Tunisia represents 50% of the population. Sixty percent of them earn less than TD1000 per month and 33% earn less than TD500 per month. The minimum salary is TD403 (US\$142) and the average salary is TD813 (US\$283) (10). Therefore, three socioeconomic level categories were determined [ie; low level (from TD0 to TD403); moderate level (from TD404 to TD999); high level (above TD1000)].

Quality of Life

The Arabic version of the Diabetes Quality of Life (DQoL-Arabic) questionnaire was used to evaluate patients' QoL (11). The tool contains 29 items divided into three domains and each with a 5-point Likert scale response: Satisfaction (14 items), Impact (11 items) and Worries (4 items). Cronbach's coefficient alpha indicated good internal consistency in all three domains. It revealed that the Cronbach's alpha values exceeded 0.88 for all scales. The satisfaction score of each item ranged from 1 (very satisfied) to 5 (very dissatisfied) while Impact and Worries scores ranged from 1 (never) to 5 (Always). The lower the score means the highest is the QoL (11).

Statistical analyses

Shapiro-Wilk test, histograms and Q-Q plots were used to determine the distribution of data. Quantitative data with normal distribution were presented as means and SD; otherwise, they were presented as median (interquartile). Categorical data were presented as frequencies and percentages. To compare groups' baseline data (ie; socio-demographic characteristics, medical data and DQoL-Arabic scores), two sided chi-square test, Student's t-test and Mann Whitney U test were used for categorical, normal and non-normal data, respectively. The DQoL-Arabic baseline and end line scores were compared using the Mann Whitney U test between groups and the Wilcoxon test within the same group. The delta change was calculated between the two groups for the DQoL-Arabic scores. The absolute delta change was calculated using the following formula: larger value – smaller value, and the delta change percentage was calculated using the following formula: |Absolute difference between the

two values/Average of both the values $\times 100$.

Statistical Package for Social Science (SPSS), version 20.0, was used to analyze the study data (12). The results were considered statistically significant when p value was < 0.05.

Ethical considerations

Prior to data collection, permission from the "National Fund for Social Security" Polyclinic in Sfax was acquired. All participants provided their consent after being informed about the study objectives. The Committee for the Protection of Persons granted the ethical approval for this study (CPP SUD N° 0462/2022).

RESULTS

Patients' characteristics

A total of 320 participants were randomized to the experimental or the control groups with 160 participants in each. About 57 patients discontinued the study. Therefore, 263 patients were included in the analysis, 132 in the experimental group and 131 in the control group (Figure 1).

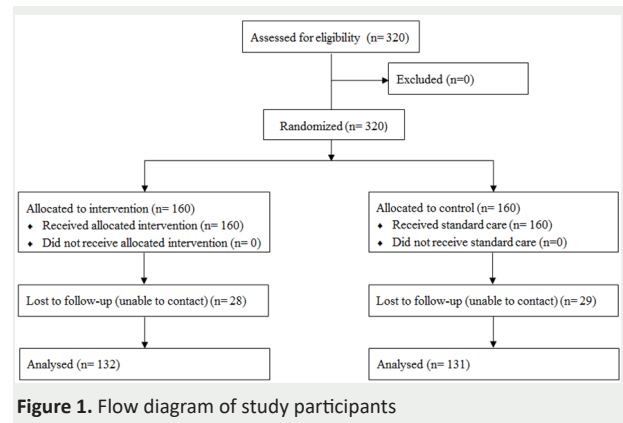


Figure 1. Flow diagram of study participants

At baseline, there was no statistically significant difference between the experimental and control groups. Socio-demographic characteristics and medical data were comparable, indicating that the studied groups were homogenous. Table 1 exposes the baseline socio-demographic characteristics and medical data of study participants.

Quality of life results

After the program implementation, results show that the experimental and the control groups are significantly different in three domains of QoL ($p < 0.001$ in each domain). Additionally, the mean total score of DQoL-Arabic showed a significant difference between the two groups ($p < 0.001$). Within-group comparisons showed an improvement in QoL over time in the intervention group in the three studied domains ($p < 0.001$ in each domain). In contrast, no significant differences were found in the control group ($p > 0.05$) (Table 2).

Table 1. Baseline socio-demographic characteristics and medical data of study participants.

Characteristics	Total sample (N=263)	Experimental Group (N=132)	Control Group (N=131)	P-value
Age (years)				
Mean (SD)	62.77 (9.23)	62.19 (9.35)	63.36 (9.09)	0.305 ^a
Sex (n, %)				
Men	91 (34.6)	44 (33.3)	47 (35.9)	0.664 ^b
Schooling level (n, %)				
Illiterate or Primary	214 (81.4)	106 (80.3)	108 (82.44)	0.656 ^b
Secondary or University	49 (18.6)	26 (19.7)	23 (17.56)	
Marital status (n, %)				
Married	213 (81)	101 (76.5)	112 (85.5)	0.063 ^b
Unmarried	50 (19)	31 (23.5)	19 (14.5)	
Occupation status (n,%)				
Employed	65 (24.7)	35 (26.5)	30 (22.9)	0.568 ^b
Unemployed	198 (75.3)	97 (73.5)	101 (77.1)	
Socio-economic level (n, %)				
Low	112 (42.6)	60 (45.5)	52 (39.7)	0.072 ^b
Moderate	136 (51.7)	61 (46.2)	75 (57.3)	
High	15 (5.7)	11 (8.3)	04 (03.1)	
T2DM duration (years)				
Median [Interquartile]	10.00 [6.00-17.00]	9.00 [6.00-17.00]	10.00 [6.00-16.00]	0.544 ^c
Treatment of T2DM (n, %)				
Oral antidiabetic + Insulin	75 (28.5)	38 (28.8)	37 (28.2)	0.922 ^b
Only oral antidiabetic	188 (71.5)	94 (71.2)	94 (71.8)	
HbA1c (%)				
Median [Interquartile]	8.20 [7.60-9.10]	8.30 [7.60-9.17]	8.00 [7.60-9.00]	0.150 ^c
Body mass index (kg/m²)				
Median [Interquartile]	27.77 [25.39-31.56]	28.10 [25.39-32.02]	27.55 [25.39-31.20]	0.510 ^c
Arterial hypertension (n, %)				
Yes	158 (60.1)	84 (63.6)	74 (56.5)	0.237 ^b
Hyperlipidemia (n, %)				
Yes	167 (63.5)	87 (65.9)	80 (61.1)	0.415 ^b
Retinopathy (n, %)				
Yes	49 (18.6)	21 (15.9)	28 (21.4)	0.255 ^b
Coronary heart disease (n, %)				
Yes	59 (22.4)	29 (22.9)	30 (22.0)	0.856 ^b

HbA1c: Glycosylated hemoglobin; SD: Standard deviation; T2DM: Type 2 diabetes mellitus. ^a Student's t test. ^b Chi-square test. ^c Mann Whitney U test

Table 2. Quality of life data among the Experimental Group/Control Group in pre-test/post-test.

Domains	Experimental Group (N=132)	Control Group (N=131)	Change (%) [*]	P-value ^a
Satisfaction				
Median [Interquartile]				
Pre-test	3.64 [3.36-3.86]	3.57 [3.43-3.79]	0.07 (1.94)	0.232
Post-test	3.14 [2.64-3.36]	3.57 [3.43-3.71]	0.43 (12.82)	< 0.001
P-value ^b	< 0.001	0.757		
Impact				
Median [Interquartile]				
Pre-test	2.45 [2.27-2.64]	2.45 [2.36-2.64]	0 (0)	0.966
Post-test	2.09 [1.91-2.36]	2.45 [2.27-2.64]	0.36 (15.86)	< 0.001
P-value ^b	< 0.001	0.980		
Worries				
Median [Interquartile]				
Pre-test	3.00 [2.50-3.25]	3.00 [2.75-3.00]	0.00 (0)	0.892
Post-test	2.50 [2.25-2.75]	3.00 [2.75-3.14]	0.50 (18.18)	< 0.001
P-value ^b	< 0.001	0.918		
Total score DQoL-Arabic				
Median [Interquartile]				
Pre-test	3.01 [2.79-3.17]	2.99 [2.81-3.14]	0.02 (0.66)	0.729
Post-test	2.59 [2.21-2.80]	3.01 [2.81-3.15]	0.44 (15.00)	< 0.001
P-value ^b	< 0.001	0.724		

DQoL-Arabic: Arabic version of the diabetes quality of life. ^{*} |Change| (%) = |Absolute delta Change| (Delta change percentage). ^a Mann Whitney U test. ^b Wilcoxon test

DISCUSSION

Key findings of the present RCT highlight the importance of the therapeutic education program in promoting QoL among Tunisian patients with T2DM. The results showed a significant improvement in all domains of QoL in the experimental group after the intervention. In contrast, there were no positive changes in the control group. These results are supported by previous studies reporting an improvement in QoL despite the use of different educational techniques and methods such as diabetes self-management education (13–15), self-care educational program (16), psycho-educational program (17), and family-oriented self-management program (18). In fact, the ideal method of patient education in order to improve the QoL cannot be determined due to the wide range of modes, providers, delivery methods and topics (7). Whereas the used educational method in this study was self-management education with supplementary methods, a 2022 scoping review showed that this method can effectively improve QoL (7).

Understanding and identifying factors of QoL is important to prevent diabetes mellitus complications. A systematic review and meta-analyses have reported some related factors of QoL of T2DM patients such as physical exercise, glucose monitoring, complications and diet (19). The implementation of strategies that target these factors can more effectively improve the QoL of these patients (19). Regarding the covered self-management topics in this study, self-care behaviors (ie; healthy diet, physical activities, foot care, self-monitoring of blood glucose and medication adherence), resolving problems (eg; hypoglycemia and hyperglycemia management), and reducing T2DM acute and chronic complications were covered.

The positive impact of educational programs on different domains of QoL is amply supported by various interventional studies covering entirely or partially the covered topics in the present study. A randomized parallel trial has treated the topic of diet by comparing the effects of two different types of diets on the health related QoL. The findings reported an improvement in the domains of physical function ($p=0.009$), bodily pain ($p=0.021$), general health ($p=0.031$) and vitality ($p=0.042$) after one year treatment with low-carbohydrate diet. In contrast, there were no positive changes in the low-fat diet group (20). According to a systematic review and meta-analysis, patients who follow a six-month low-carbohydrate diet are more likely to achieve diabetes mellitus remission without complications compared to other diets that are frequently suggested for the management of T2DM, such as low-fat diet (21).

Daily physical activity has a variable degree of influence on QoL and its dimensions (22). A RCT showed that 150 minutes of moderate physical activity per week had a significant impact ($p<0.01$ in each domain) on the physical, psychological and environmental domains of QoL of patients with T2DM except the social relationships domain ($p=0.53$) (23). A systematic review has concluded that among four modes of exercise, aerobic exercise has a positive impact on QoL of patients with T2DM (24).

Resistance exercise and combination exercise had mixed impacts, while the effect of yoga requires more research (24).

In addition to dietary restrictions and exercise, self-monitoring of blood glucose is a crucial component of an effective diabetes mellitus management (25). An interventional study showed that a six-month structured self-monitoring of blood glucose program significantly improved all QoL domains among insulin-treated type 2 diabetic patients, particularly the physical role functioning and the emotional role functioning domains ($p<0.0001$ for each domain) (25). In contrast, a RCT revealed that once-daily self-monitoring of blood glucose has no effect on glycemic control or health-related QoL among non-insulin-treated type 2 diabetic patients. Moreover, there were no observable variations in the frequency of major adverse events, such as hypoglycemia (26).

Symptom management helps patients with T2DM to recognize and manage their symptoms (27). A RCT demonstrated that a diabetes mellitus symptom management program may enhance self-care practices and QoL beginning three months after the intervention and continuing for six months. Furthermore, it may prevent the symptom intensity from getting worse among patients with minor symptom severity (27). In fact, diabetic foot is undeniably the most devastating repercussion of diabetes mellitus, dramatically impacting patients' QoL. According to a RCT conducted in India, employing leaflets to educate patients has a favorable impact on all aspects of health related QoL among diabetic foot ulcer patients after a six-month follow-up (28). Additionally, an Indonesian quasi-experimental study demonstrated that diabetes self-management education and support program improve self-care and QoL of patients with diabetic foot ulcer while decreasing its degree (29). A systematic review of the impact of educational intervention on diabetic foot ulcer outcomes supported these results. This review revealed that educational programs helped diabetic foot ulcer patients improve self-care foot practices and knowledge as well as reduce foot amputations and ulcers (30).

There are some limitations in this study that must be recognized. The major limitation is the non-registration of our trial in a clinical trials registry. Besides, this study was conducted during the COVID-19 pandemic, which itself may alter the QoL (31). The data was only obtained from one health-care setting. As a consequence, the results could not be generalized to the total T2DM population of Tunisia. On the other hand, due to the large sample size, the findings could be representative of all diabetic patients treated in the "National Fund for Social Security" polyclinic. Moreover, another limitation lies in the study design. It was a non-blind trial given the context of the educational intervention. The program's impact was evaluated during one year follow-up. Therefore, we cannot assess the duration of the improvement of QoL after the intervention. In addition, a specific scale to evaluate QoL among patients with T2DM was used. However, other secondary clinical parameters such as hematological findings, renal and liver functioning can be used to determine diabetes mellitus related comorbidity.

Therefore, further studies using specific medical criteria are needed to evaluate the long-term impact of the intervention.

CONCLUSION

The results of this RCT support the effectiveness of therapeutic educational program in improving QoL outcomes among Tunisian patients with T2DM. After the application of an interactive and patient-centered approach intervention, significant changes have been seen in the three domains of QoL (Satisfaction, Impact and Worries).

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