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The Effectiveness of Cognitive Behavioral Stress Management on Health-Related Quality of Life, Diabetes Management Self-Efficacy, and **Treatment Adherence in Type 2 Diabetes**

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<u>Abstract</u>

Objective: This study aimed to investigate the effectiveness of cognitive behavioral stress management (CBSM) on health-related quality of life (HRQOL), self-efficacy of diabetes management, and adherence to treatment of patients with type 2 diabetes.

Materials and Methods: The present study was a semi-experimental study with a control group. The research samples included 30 patients with type 2 diabetes. Data collection tools in this study included the Boyer & Earp quality of life (QOL) scale for patients with diabetes (D-39), the diabetes management selfefficacy scale (DMSES), and treatment adherence questionnaire in patients with chronic diseases. The CBSM therapy was performed in 8 sessions for the experimental group. To analyze the data, a univariate analysis of covariance was used with SPSS-23 software.

Results: The results showed that the CBSM had a significant effect on the overall health-based QOL (F=8.620; P=0.007), diabetes management self-ffficacy (F=12.021; P=0.002), and treatment adherence (F=83.253; P=0.0001). In addition, the CBSM has a significant effect on diabetes control (F=8.932; P=0.007), anxiety and worry (F=5.023; P=0.035), and sexual functioning (F=7.611; P=0.011), diet (F=10.041; P=0.004), therapeutic regimen (F=24.250; P=0.0001), making effort for treatment (F=22.987; P=0.0001), intention to take the treatment (F=108.001; P=0.0001), adaptability (F=28.704; P=0.0001), and integrating illness into life (F=38.263; P=0.0001).

Conclusion: The CBSM intervention can be used to improve health-based QOL, diabetes management selfefficacy, and treatment adherence in type 2 diabetes patients.

Keywords: Cognitive-behavioral therapy, Stress reduction, Quality of life, Adherence to treatment, Selfefficacy, Diabetes



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Introduction

iabetes Mellitus Type 2 is one of the most common chronic metabolic diseases that is characterized by glucose intolerance or hyperglycemia and is associated with abnormalities in carbohydrate, protein and fat metabolism (1). Diabetes has an increasing trend and has many negative psychological consequences that harm the quality of life (QOL) of patients (2). Diabetes prominent psychosocial dimensions has requires patient education and tailored interventions (3,4). Health-related quality of life (HRQOL) is considered one of the important indicators of the outcomes of therapeutic and care interventions in diabetes (5). HRQOL is a subset of overall QOL, which includes mental, emotional, social, and physical well-being and is a subjective evaluation of patients and how they respond to the patient (6). A HRQOL, including a healthy diet and physical activity, is effective in improving blood glucose control and is an important psychosocial dimension in the treatment of diabetes (7,8). Decreased QOL and deteriored health-oriented lifestyle in diabetic patients has a negative impact on various aspects of the patients' lives (9,10). Also, Self-efficacy plays an important role in diabetes management and determines the success of psychological interventions in helping diabetic patients to modify their lifestyle, self-care and adherence to treatments (11). Self-efficacy refers to a person's beliefs or perception about her abilities to perform specific actions or activities and is effective on performing behavior (12). Effective prevention and treatment of diabetes type 2 largely depends on the self-efficacy in selfperforming management and self-care behaviors (13). In fact, increasing patients' trust and confidence in their ability to take care of the disease is an essential factor in selfmanagement of the disease (14). One of the important problems in the treatment and control of diabetes is the patient's nonadherence to the prescribed treatment and

treatment strategies (15). Treatment adherence is the extent to which a patient's behaviors, including adherence to diet, medication, and lifestyle changes (16). Due to the chronic nature of type 2 diabetes, non-adherence to treatment is considered an important challenge in this disease, and in order to prevent the complications of diabetes in time, urgent and appropriate interventions are needed. Poor adherence to treatment is a warning sign for both type 2 diabetes patients and health care systems (17,18).

Psychological interventions play a valuable role in improving HRQO dimensions, selfmanagement, self-efficacy and adherence to treatment (19-21). One of these interventions is cognitive behavioral stress management (CBSM). The CBSM training program is a type of psychological intervention that increases individual's ability to reduce stress and adjust to stressful situations by focusing on cognitive strategies, behavioral strategies, and educational components (22). The CBSM includes teaching and awareness increasing about stress, physical relaxation, identifying challenging automatic and thoughts or cognitive distortions, social support, and meditation (23). The CBSM is a combination of relaxation techniques and cognitivebehavioral techniques that have been used to intervene in dimensions related to stress and control in chronic behavioral diseases including diabetes and have had beneficial results (24). Previous studies have shown that experimental interventions based on cognitivebehavioral strategies, and improving the QOL of patients with type 2 diabetes (25-27). Experimental studies showd that CBSM have significant impact on the QOL and psychological and behavioral dimensions of diabetes (28.29). Although the literature review shows that there is rich evidence of the effectiveness of CBSM on the psychosocial dimensions of diabetes (29,30), considering the different cultural contexts and the wide range and types of psychosocial variables

related to diabetes, more research is needed. In addition, the increase in the prevalence of type 2 diabetes, the high level of distress and stress associated with the disease and its treatment, as well as the increasing burden of this disease, increase the need for tailored interventions in the psychosocial aspects of this disease, including QOL, adherence with treatment, and self-care. Therefore, the present study was conducted with the aim of investigating the effectiveness of CBSM programs on HRQOL, self-efficacy of diabetes management, and adherence to treatment of patients with type 2 diabetes.

Materials and Methods

The present research method was a semiexperimental design with a pre-and post-test and control group. The statistical population of the present study included all diabetic patients referred to the Parsian Diabetes Clinic in Tehran in the year 1400. The sampling method was convenience in the present study and PASS software version 2021 was used to determine the sample size. The criterion parameter for determining the sample size was the standard deviation of one of the variables (diabetes management self-efficacy) in previous similar studies. The sample size was calculated with SPSS 2021 software and based on the calculated standard deviation (14.03)for the diabetes management self-efficacy in the study of Ghodrati Mirkohi and Rahimian Boogar (2016), at the error level of 0.05 and power of 80%, the sample size of each group was estimated to be 15 people (30). Participants have an equal chance to be placed in the experimental and control groups and they were randomly placed in the groups. For this purpose, first, 30 patients willing to participate in the research were selected based on the inclusion criteria, and then randomly assigned to experimental and control groups using a series of random numbers. The criteria for entering the research were type 2 diabetes, the age range of 20 to 60 years, and the ability to read and write to complete research questionnaires. In addition, suffering from

simultaneous psychiatric disorders, drug use, other serious medical diseases at the same time, receiving psychosocial interventions at the same time, and the absence of more than two therapeutic sessions were the exclusion criteria. Diagnosing type 2 diabetes as an entry criterion, as well as the diagnosis of psychotic disorders and concurrent medical diseases as exclusion criteria were evaluated based on self-report. physician's diagnosis. and participants' clinical records. After checking the entrance and exclusion criteria, eligible people participated in the research.

QOL Scale for patients with diabetes (D-39):

The QOL Scale for patients with diabetes (D-39) was constructed by Boyer and Earp (1997) to measure health-based QOL in diabetic patients (31). This instrument contains 39 items in the five dimensions of diabetes control (12 items), energy and mobility (15 items), social burden (5 items), anxiety and worry (4 items), and sexual functioning (3 items), which are rated on a Likert scale from 1 to 7. The range of scores is between 30 and 273, and a higher score indicates a lower QOL. According to the results of El Achhab et al. (32), 5 scale factors explain more than 50% of the total variance. The internal consistency coefficient for 5 scales was between -0.81 and 0.93. The correlation of each item with the corresponding subscale score was between 0.45 and 0.84. The negative correlation between diabetic health profile and overall QOL confirmed its construct (convergent) validity.

Diabetes Management Self-Efficacy Scale (DMSES):

To measure self-efficacy in diabetes management, Bijl et al. (1999) diabetes management self-efficacy scale was used (33). This questionnaire contains 20 questions that measure the ability of patients to comply with diet, monitoring the blood glucose, physical exercise, and therapeutic regimen. The questions are scored on a 9-point Likert scale,

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from "I can't at all" (0) to "I definitely can" (8). The factor analysis using the Varimax rotation method has divided the questions into four factors: diet (9 items), monitoring the blood glucose (4 items), physical exercise (4 items), and therapeutic regimen (3 items). All four factors have acceptable and significant internal consistency and retest coefficients over time. In the Iranian population, this questionnaire was standardized by haghayegh et al. (2010) and the Cronbach's alpha of the questionnaire for the subscales of diet, physical exercise, therapeutic regimen, monitoring the blood glucose, and the total score of the questionnaire were obtained 0.79, 0.76, 0.68, 0.71, and 0.83 were respectively (34). In addition, the two-week retest reliability of the subscales of diet, physical exercise, therapeutic regimen, monitoring the blood glucose, and the overall score of the questionnaire were achieved at 0.81, 0.78, 0.81, 0.80, and 0.86, respectively.

Treatment Adherence Questionnaire:

The treatment adherence questionnaire in patients with chronic diseases was used to measure adherence totreatment in diabeticpatients. This questionnaire was designed by Seyed Fatemi et al. (35). To determine the face and content validity, the items of the questionnaire were reviewed by 12 experts. The psychometric characteristics of the designed questionnaire started with 127 items, and the exploratory factor analysis indicated the final 40-item instrument in 7 factors: making effort for treatment (9 items), intention to take the treatment (7 items), adaptability (7 items), integrating illness into life (5 items), stick to the treatment (4 items), commitment to treatment (5 items) and indecisiveness for applying treatment (3 items). The scores were rated based on the 5point Likert scale, respectively, from 1 to 5 points with options of "it is completely important, it is somewhat important, it is moderately important, it is a little important and it is not important at all". The scoring of indecisiveness for applying treatment is done

in reverse. These 7 factors explained 48.51% of the total variance of the questionnaire. The reliability of the test was confirmed by the retest method and through internal consistency and Cronbach's alpha of 0.92. In addition, Cronbach's alpha of each of the subscales of making effort for treatment (0.86), intention to take the treatment (0.85), adaptability (0.83), integrating illness into life (0.72), stick to the treatment (0.54) and indecisiveness for applying treatment (0.82) were appropriate (35).

After the initial coordination and before the of the intervention, implementation the questionnaires were distributed to the participants of the experimental group and the control group in the pre-test phase. It should be noted that due to the health considerations related to the epidemic period of the coronavirus, the questionnaires were uploaded to the Google Form web application and the to the questionnaire was link sent simultaneously to all eligible participants. Due to the easy access to the WhatsApp social network and its generality, the link of the questionnaire was sent to the participants in the study through this social network. The participants were asked to complete the questionnaire no later than 24 hours after sending the link. Then, group training sessions were conducted in the experimental group (CBSM); but the control group did not receive any treatment.

To control attention in the control group, two sessions were held online with the presence of the control group, and neutral information unrelated to the research objectives was presented to them. The CBSM in the present study is a treatment program that was implemented in 8 sessions of 90 minutes (once a week) as a group. This treatment program was based on the CBSM protocol of Pendo et al. (36) and was implemented according to Iranian versions (23,28). This intervention was adapted to the conditions of the participants in the research and was implemented by a person trained in the doctoral degree. In order to better tailor treatment sessions with diabetic

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patients, experiences and examples and situations related to diabetes and the negative consequences of this disease were used. During the intervention, cognitive-behavioral stress coping strategies were taught to the patients, and ineffective thoughts and beliefs that lead to extreme emotional and adverse psychological reactions and disease symptoms were identified and modified. The summary of the content of the CBSM is presented in Table 1.

After the completion of the training sessions for all the members of the experimental group, the link of the questionnaires was again provided to the participants to collect the information for the post-test stage. To collect information, the Boyer & Earp QOL scale for patients with diabetes (D-39), diabetes management self-efficacy scale (DMSES), and adherence questionnaire in patients with chronic diseases were used. To check the statistical assumptions, the Kolmogorov-Smirnov test, Levene's test, Box's M test, and Homogeneity of regression slopes (test of parallelism) were used. The significance level in this study is less than 0.05.

In addition, the research was conducted in compliance with ethical standards, written

informed consent was obtained from the participants, confidentiality and the protection of the rights of the participants were maintained, and there was a possibility for the participants to withdraw from the study at any time. Also, the participants who wanted to be informed about their psychological status were given their grades. In line with ethical considerations, the control group was also assured that after the completion of the research, if they wish, 8 intervention sessions will also be offered to them.

Ethical considerations

This study is derived from the doctoral dissertation of the first author of the article from the Islamic Azad University, Semnan Branch, and this study was reviewed and approved by the Ethics Review Board of Islamic Azad University, Shahrood Branch (approved code: IR.IAU.SHAHROOD. REC.1400.012).

Results

In this study, there were 30 patients with type 2 diabetes. The age mean (standard deviation) of the intervention and control group participants was $47.13 (\pm 4.64)$ and

Table 1. The cognitive behavioral stress management (CBSM) based on Penedo, Antoni, & Schneiderman (36)

Sessions	Content
Session 1	Conducting the pre-test, Introduction to the Program, Providing information about the entire program such as objectives, meeting rules and regulations, Stress Awareness, Physical Responses to stressors, Awareness of the effects of stress on the body, emotions, thoughts and behavior and its possible consequences on Health and 16 muscle-group Progressive Muscle Relaxation
Session 2	Description of the relationship between thoughts and emotions, Stress Awareness and the Appraisal Process, Diaphragmatic Breathing and 8-Muscle-Group Progressive Muscle Relaxation
Session 3	Identifying negative automatic thoughts and cognitive distortions and ways to challenge them, mental imagery, Deep Breathing and Counting, Passive Progressive Muscle Relaxation.
Session 4	Modifying the cognitive distortions andirrational thoughts, Cognitive Restructuring, Special Place Imagery, Spontaneous training to feel heaviness and warmth, Relaxation for Healing and Well-Being
Session 5	Teaching about coping sterategies and effective coping, Autogenic Training, Spontaneous training for heart rate, breathing, abdomen and forehead, Autogenics with Positive Self-Suggestions and Visual Imagery
Session 6	Implementation of effective coping responses, Anger management training, Mantra meditation, self- education along with visualization and self-induction (positive attitude towards the role of social support, diversion of thought and attention)
Session 7	Teaching assertiveness in interpersonal relationships, Assertive Communication, Identification of barriers to expressive behavior and using problem solving for conflicts, Mindfulness meditation and breathing counting meditation.
Session 8	Description of social support and training techniques for maintaining and expanding the social support and social network. Overview of the program and creation of a personal stress management program, Program Wrap-Up, Additional monitoring worksheets Post-test implementation.

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48.13 (±4.40), respectively.

Non-parametric the Mann-Whitney U test was used to compare groups in terms of age. The results showed that there is no significant difference between the two groups in terms of mean of age (P=0.512; Z=0.612). In terms of gender, most members of the intervention group (53.3%) were male and most members of the control group (60.0%) were female. However, the comparison of the two groups in terms of gender using the chi-square test showed that the two groups are equal in terms of gender (P=0.464; $\chi^2 = 0.134$). In terms of education, most of the participants in the experimental group (60.0%) and the control group (53.3%) had a diploma and the difference between the two groups was not statistically significant (P=0.879; $\chi^2=0.093$). The mean and standard deviation of the study variables separately for two groups are presented in Table 2.

Before applying a univariate analysis of covariance, the statistical assumptions of these analyzes were checked. The Kolmogorov-Smirnov test showed that the data of both experimental and control groups in the variables of health-based QOL, self-efficacy in diabetes management and adherence to treatment in the pre-test and post-test stages were not significantly different from the normal curve and the distribution of the data was normal (P> 0.05). Also, Levene's test to

Varibles	Assessment		Intervention	Control		2
varibles		Mean	Standard deviation	Mean	Standard deviation	P
Diabetes control	Pre-test	57.67	6.455	57.13	6.589	0.824
Diabetes control	Post-test	54.47	6.490	57.07	6.606	0.009
Energy and mobility	Pre-test	68.53	4.749	68.40	4.778	0.939
Energy and mobility	Post-test	68.60	2.874	68.53	4.764	0.963
Social burden	Pre-test	26.60	4.823	26.47	4.734	0.940
Social bulueli	Post-test	26.07	5.470	26.47	4.764	0.832
Anxiety and worry	Pre-test	19.73	4.096	20.27	4.367	0.733
Anxiety and worry	Post-test	16.73	5.216	20.27	4.367	0.044
Sexual functioning	Pre-test	15.27	5.203	15.73	4.803	0.800
Sexual functioning	Post-test	11.87	3.833	15.93	4.559	0.013
Health-based quality of life	Pre-test	1.87	13.24	188.01	12.529	0.966
meanin-based quanty of me	Post-test	1.77	14.98	188.27	12.319	0.015
Diet	Pre-test	41.00	18.796	41.67	18.149	0.922
Diet	Post-test	44.67	15.756	41.73	18.136	0.019
Monitoring the blood glocose	Pre-test	24.33	4.220	24.73	4.026	0.792
womtoring the blood glocose	Post-test	24.53	4.015	24.73	3.788	0.889
Physical excercise	Pre-test	18.53	5.357	17.73	5.738	0.696
r nysicai excercise	Post-test	19.13	4.103	17.67	5.740	0.428
Therapeutic regimen	Pre-test	19.60	7.209	19.87	6.917	0.918
I O	Post-test	22.33	5.246	19.73	6.808	0.009
Diabetes management self-	Pre-test	103.46	30.31	103.99	30.144	0.962
ffficacy	Post-test	110.67	23.88	103.87	30.215	0.006
Maling offert for treatment	Pre-test	29.80	2.396	29.53	2.356	0.761
Making effort for treatment	Post-test	33.47	2.326	29.53	2.356	0.001
Intention to take the treatment	Pre-test	26.67	3.976	26.33	3.811	0.816
intention to take the treatment	Post-test	32.20	2.678	26.40	3.641	0.001
Adaptability	Pre-test	21.60	3.180	21.33	3.132	0.819
Adaptability	Post-test	26.53	3.482	21.20	3.364	0.001
Internating illness into life	Pre-test	17.07	2.344	17.40	2.667	0.719
Integrating illness into life	Post-test	20.80	3.144	17.47	2.588	0.004
Stick to the treatment	Pre-test	11.87	2.825	11.20	1.656	0.437
Stick to the treatment	Post-test	12.47	2.446	11.47	1.407	0.181
Commitment to treatment	Pre-test	17.27	2.017	17.40	1.957	0.865
Commitment to treatment	Post-test	17.73	2.017	17.47	1.995	0.719
Indecisiveness for applying	Pre-test	7.87	2.416	7.73	2.251	0.877
treatment	Post-test	8.47	2.669	7.80	2.242	0.465
T	Pre-test	132.13	9.249	130.93	9.114	0.723
Treatment adherence	Post-test	151.67	10.581	131.33	9.163	0.001

check the assumption of equality of error variances showed that the assumption of equality of error variances was valid for the research variables (P > 0.05). In addition, the interaction between covariance and independent variable was not significant in both experimental and control groups (P > 0.05), which shows that the assumption of homogeneity of regression slopes is also established. Therefore, by observing the presuppositions of the parametric test, the use of the covariance analysis test is unimpeded.

The results of univariate analysis of covariance showed that the CBSM had a significant effect on the overall health-based QOL (F= 8.620; P= 0.007), diabetes management self-ffficacy (F= 12.021; P= 0.002), and treatment adherence (F= 83.253; P= 0.0001). In addition, the CBSM has a significant effect on diabetes control (F= 8.932; P = 0.007), anxiety and worry (F= 5.023; P = 0.035), and sexual functioning (F= 7.611; P = 0.011), diet (F= 10.041; P = 0.004), therapeutic regimen (F= 24.250; P= 0.0001), making effort for treatment (F=22.987; P= 0.0001), intention to take the treatment (F= 108.001; P = 0.0001), adaptability (F= 28.704; P= 0.0001), and integrating illness into life (F= 38.263; P= 0.0001).

Discussion

The findings of the present study showed the CBSM program significantly that affectsthe overall health-based QOLscore and diabetes control component. This finding is consistent with the results of previous studies (24,28,29,37). Ghazavi et al. (38) and Markert et al. (21) also showed that CBSM significantly affects he OOL. Penedo et al. (36) explain these findings in such a way that CBSM protocols provide opportunities for patients to obtain information necessary to adapt to the disease, develop emotional and interpersonal skills, and provide social support for patients in the face of stress. It seems thatit improves the QOL. Techniques and skills acquired during the treatment of CBSM facilitate adherence to medication protocols

and improve HRQOL by helping to reduce psychological disturbances. Zaheri et al. (23) also argue that CBSM improves the QOL in people with diabetes by reducing discomfort and negative emotions associated with having a chronic disease and possibly having adverse side effects. In addition, the use of CBSM techniques, and strategies of positive reframing of stress and modification of cognitive processes related to stress facilitate the disease control process and inherently lead to increasing or maintaining the desired OOL.

Furthermore, the findings of the research showed that the CBSM program has a significant effect on the overall score of selfefficacy in diabetes management and the components of diet and therapeutic regimen. This finding is also in line with previous studies (25,27,29). Hajilou et al. (39) state that CBSM training helps to increase resilience and self-efficacy. Therefore, CBSM by focusing on documenting styles, challenging irrational beliefs, relaxing, and coping skills training not alleviates the negative emotional only consequences of disease; it also helps to increase their self-efficacy in diabetes management. Terp et al. (40) argue that CBSM with stress management strategies, relaxation skills and cognitive reconstructing increases self-efficacy and ultimately enables better adjustment to the situations. In fact, it can be said that therapeutic strategies in a CBSM intervention, including relaxation exercises, can facilitate the disease control process by empowering the individual against stressful factors and increasing self-efficacy in disease management.

Also, the effect of the CBSM program on the overall score of treatment adherence the components of making effort for treatment, intention to take the treatment, adaptability, and integrating illness into life was also significant. This finding is also in line with the findings obtained in previous studies (21,38,40). Saranapala et al. (41) argue that the CBSM intervention enables the control of dimensions of psychosocial stress related to health conditions and improves the process of

adherence to treatment plans. According to Higgins et al. (42), the educational intervention based on cognitive behavioral strategies by modifying the patient's beliefs that the disease is treatable and controllable increases the hope of recovery and facilitates adherence to treatment strategies. As a result, making effort for treatment and intention to take the treatment increases in patients. In a research that was similar in terms of content, Pan et al. (43) in a study on patients with type 2 diabetes showed that group-based approach of cognitive behavioral therapy has significant impact on the self-care behaviors and treatment adherence. It can be argued that a CBSM intervention by reducing the use of maladaptive coping strategies (simulation or avoidance) and on the other hand bv increasing the use of strategies focused on problem solving facilitates adherence to treatment, as well as the appropriate use of care services.

The findings of this study are inconsistent with some previous studies in the field of some aspects of adherence to treatment (16,42). This inconsistency can be due to different research designs in the studies, different conceptual operational and definitions of the variables, as well as psychosocial dimensions related to culture in different studies. Although the intervention was not significant on some subscales, according to the effect of the intervention on the overall index of treatment adherence, it can be argued that the focus of the CBSM intervention on the stress of patients, modifying dysfunctionalbeliefs, and providing coping skills in accordance with the conditions of the diabetic patient helps patients to be more committed to the treatment and follow up the treatment.

The general result of this research showed that CBSM as a short-term treatment approach improves the HRQOL, self-efficacy for selfmanagement and adherence to treatment in type 2 diabetic patients. This finding has implications for clinical practice and future studies. Therefore, the design, adaptation, and

implementation of CBSM intervention are suggested as effective clinical interventions. Conducting clinical trials in future studies can provide a suitable road map for this intervention.

Despite its strengths, this research has some limitations. Due to the implementation of the research during the COVID-19 pandemic, it was not possible to measure in the follow-up phase, and therefore, it is not possible to comment on the stability of the results. As another limitation, the measurement tools in the study were quantitative and self-reported, and paying attention to the subjective and qualitative dimensions of the disease with qualitative measurement methods, including interviews, can solve this gap in future research. In addition, the mixed study design (quantitative-qualitative) can bring valuable findings in subsequent studies. Although the studied sample had the necessary sufficiency, this small sample size limits the generalization of the findings to the studied population and emphasizes the repetition of the study in other similar or different samples. Although according to the obtained results, the use of CBSM is one of the implications of this study, it is suggested to conduct more studies to formulate the best intervention procedures in the treatment programs for patients with type 2 diabetes.

Conclusions

The results of this study showed that CBSM on health-based QOL, self-efficacy of diabetes management, and adherence to treatment of patients with type 2 diabetes. As a result, the CBSM intervention can be used to improve health-based QOL, diabetes management selfefficacy, and treatment adherence in type 2 diabetes patients.

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Conflict of Interest

No conflict of interest has been declared by the authors.

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