

Effectiveness of Family Empowerment Therapy Based on Self-Compassion on Self-Care and Glycosylated Hemoglobin in Female Patients with Type 2 Diabetes Mellitus: A Randomized Controlled Clinical Trial

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Abstract

Background: Diabetes can be successfully controlled by metabolic, psychological, social, and interpersonal factors. The present study aimed to determine the effectiveness of family empowerment therapy based on self-compassion on self-care and glycosylated hemoglobin in female patients with type 2 diabetes mellitus.

Methods: In a randomized controlled clinical trial with control group, pre-test, and post-test, 60 women with type 2 diabetes referred to the endocrinology department of Imam Hossein Hospital in Tehran province from December 2018 to April 2019 were randomly selected from the 73 patients narrowed down according to the inclusion criteria. Afterwards, they were randomly assigned to experimental and control groups. The experimental group (n=30) was treated with family empowerment therapy based on self-compassion for eight weekly 90-minute sessions while the control group (n=30) received usual hospital treatments. Data collection instrument was Summary of Diabetes Self-Care Activities; glycosylated hemoglobin measurements were performed in three phases of baseline, after intervention, and three-month follow-up and analyzed by multivariate repeated measures analysis of variance and Bonferroni post-hoc test using the SPSS-21 software.

Results: The results of repeated measures analysis of variance showed significant differences after the intervention between the experimental and control groups regarding self-care ($P=0.001$, $F=561.086$) and glycosylated hemoglobin ($P=0.001$, $F=304.953$); furthermore, comparison of the means indicated the effectiveness of the treatment in improving self-care and reducing glycosylated hemoglobin levels in the experimental group compared to the control group. Moreover, the Bonferroni test results showed that in the pretest stage, there was no significant difference between the two groups in terms of self-care ($P=0.447$) and glycosylated hemoglobin ($P=0.887$); however, in the post-test and follow-up stages, the two groups showed were significantly different concerning self-care ($P=0.001$) and glycosylated hemoglobin ($P=0.001$), implying the effectiveness of the intervention and the sustainability of its effects.

Conclusions: The results of the present study revealed that family empowerment therapy based on self-compassion can be effective in improving self-care and reducing glycosylated hemoglobin in women with type 2 diabetes.

Keywords: Self-care, Type 2 diabetes mellitus, Family empowerment therapy based on self-compassion, Glycosylated hemoglobin

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1. Introduction

Diabetes is a complex metabolic disorder characterized by high blood glucose levels resulting in impaired insulin secretion, functioning, or both (1). Chronic complications caused by diabetes can generally be categorized into vascular and non-vascular. Vascular complications include heart disease, retinopathy, neuropathy, nephropathy, and cataract. Non-vascular complications comprise infections, skin changes, hearing loss, digestive diseases, and sexual dysfunction (2). In all societies, prevalence of type 2 diabetes increases with age while it is more common in women and reduces life expectancy by an average of

10 years (3). Over 435 million people are estimated to suffer from diabetes due to conditions such as aging, lifestyle changes, and lack of proper diet and exercise (4). In Iran, diabetes is a serious threat to the health of the population. Currently, there are more than three million people suffering from diabetes in Iran, a number which, according to the World Health Organization's estimates, will reach nearly 7 million by 2030 if no effective measures are taken. With a prevalence rate of more than 8%, Iran is among the regions where diabetes is highly common (5). In addition, the age of diabetes in Iran is 10-15 years lower than the global standards (6). Therefore, the actual prevalence of diabetes in Iran is expected to exceed the reported figures (7). Chronic

hyperglycemia is responsible for certain short-term acute symptoms as well as long-term complications affecting all systems and organs of the body (8). Given the importance of controlling blood glucose and the relationship between its daily changes and glycosylated hemoglobin (HbA1C), fasting blood glucose should be monitored two hours after breakfast every day (9, 10). Control and treatment of diabetes require serious and effective adherence to dietary avoidance, insulin injection, and regular blood glucose testing (11). Self-care behaviors associated with diabetes are a set of practices that patients perform in order to successfully manage their illness (12). These behaviors are comprised of seven essential activities for controlling diabetes, including a healthy diet, physical activity, regular blood glucose monitoring, and timely medication use, foot care, complying with the recommended self-care activities, and reducing risky behaviors such as smoking (13).

The first essential step is to empower the patients and promote diabetes self-care education, without which patients cannot consciously take care of themselves. Empowerment in diabetes self-care education aims to increase knowledge, self-care skills, self-awareness, and a sense of individual independence, enabling patients to accept diabetes self-care (14). Successful diabetes care requires the ability to effectively set targets and make decisions tailored to the patient's life style while taking into account many metabolic, psychological, social, and interpersonal factors (15). For this reason, over recent years, the empowerment of patients and their families has found a prominent place in nursing and medical studies and referred to as a necessity for patient care (16). Diabetes is also a family disease because it affects the people who love, live with, or care for the patient; also, their reactions influence how the patients feel about interacting with others and taking care of themselves. Patients who do not have support and struggle to manage their lives consider diabetes as a major source of distress. Despite its importance, research has overlooked the issues related to diabetes patients' perspectives and their ability to care for themselves (17). An effective approach to empowering chronic patients is to implement family-centered empowerment models (18). As the most important pillar of society, family is in charge of providing the patients and those around them with proper health care (19). Educating family members about disease control and even prevention can be highly conducive because there exists a strong relationship between families and the health of their members. When dealing with chronic illnesses, patients are particularly dependent on their

family members and even their attitudes are affected by them (20). Moreover, the family environment can play a significant role in the adaptation of the diabetes patients to lifestyle changes involving properly controlling blood sugar and precluding further complications (21). In order to increase self-care in patients, a family-centered empowerment model was designed with emphasis on the role of the patient and other family members in terms of motivational and psychological (self-esteem, self-control, and self-efficacy) dimensions and the characteristics associated with the problem (knowledge, attitude, and perceived threat (22)). The results of empowerment included positive self-esteem, ability to achieve goals, and a sense of control over life and its change processes along with a sense of hope for the future (23).

In 2005, Gilbert used compassion-focused therapy constructs in his therapeutic sessions and proposed it as a primary or complementary means of therapy that was later developed into the theory of compassion-focused therapy (24). Self-compassion gives people a balanced approach towards emotional experiences so that individuals neither escape nor mangle with and drown in their experiences. Self-compassion is further related to emotional intelligence. People with higher self-compassion report greater emotional coping skills and are more capable of distinguishing between their emotions and the emotional reconstruction of their negative states, which is an essential part of the self-care process in diabetes patients (25). Combining family empowerment and self-compassion therapy can be effective in controlling the symptoms of diabetes. Therefore, the aim of the present study was to specify the effectiveness of family empowerment therapy based on self-compassion in self-care and glycosylated hemoglobin in female patients with type 2 diabetes.

This study aimed to determine the effectiveness of family empowerment therapy based on self-compassion regarding self-care and glycosylated hemoglobin in female patients with type 2 diabetes mellitus.

2. Methods

This randomized controlled clinical trial comprised a control group, pre-test, post-test, and follow-up measurements. The study was single-blind, the participants were not aware of the selection process, and the groups did not interact with each other during the intervention.

The statistical population included all women

diagnosed with type 2 diabetes referred to Imam Hossein Hospital in Tehran from winter 2018 to spring 2019. The sample size was determined according to Basa RP who measured the mean changes of HbA1c before and three months after an intervention program ($8.8-7.1=1.7$) with a standard deviation of (2.2) ($\alpha=0.05$ and $\beta=0.2$). As a result, the required sample calculated in the present study was 30 people for each group (26). Sixty participants were selected according to the entry criteria. Using Random Allocation Software, they were then randomly divided into two experimental and control groups (each consisting of 30 subjects).

Inclusion criteria in this study were: 40-45 years of age, type 2 diabetes diagnosis based on ADA evidence, diagnosis by a specialist physician for at least six months, education level of high school diploma or higher, no history of neurological and mental illnesses and hospitalization, no history of substance abuse, and ability and willingness to attend group therapy sessions. Exclusion criteria were: absence from intervention sessions for more than two sessions and unwillingness to continue participation in the intervention sessions. The RCT flowchart of the study is demonstrated in Figure 1.

The instruments used for data collection were as follows:

The goal of this questionnaire was to collect the

basic demographic data such as age, marital status, education, socio-economic status, educational background, and career history as well as questions on how to control diabetes, amount of insulin intake, alcohol consumption, and smoking.

2.1. Summary of Diabetes Self-Care Activities (SDSCA)

Designed by Toobert, Hampson, and Glasgow, the SDSCA scale is a valid self-descriptive measure for diabetes self-care and assessing adherence to self-care behaviors in type 2 diabetes patients (27). It has 25 items that allow individuals to report the quality of their diabetes self-care activities over the past seven days. These activities include having a healthy diet, insulin injections or taking pills, blood glucose testing, exercise, foot care, and refraining from smoking. Cronbach's alpha for the construct of self-care activities was 0.66 in the pilot study and 0.68 for the total sample with a validity of 0.75 (28). In the current study, the internal consistency [Cronbach's alpha coefficient] of the self-care scale was calculated to be 0.93 for a sample size of ($n=56$). The Cronbach's alpha was above 0.7, indicating the high validity of the scale. To determine the desirability level for the self-care variable, in addition to average scores, the scores ranging from 0-70 are divided into three parts and a general compliance score is obtained via adding the scores for each question. A score of 0-23 indicates undesirable self-care, scores between 24 and 47 imply a

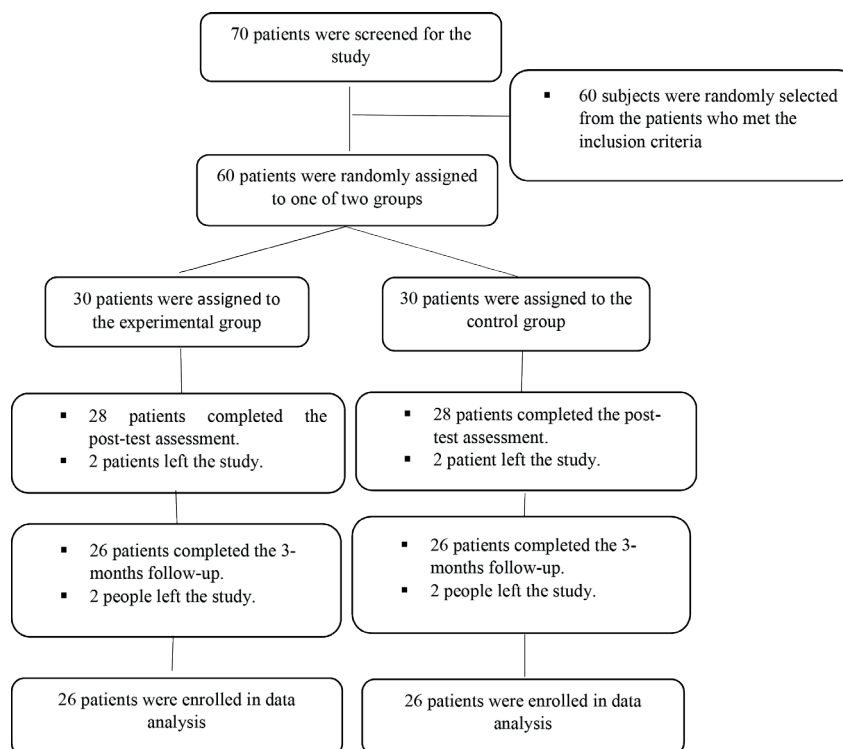


Figure 1: The Participant's CONSORT Flow Diagram

semi-desirable self-care, while any scores ranging from 48 to 70 show a desirable level of self-care activities.

2.2. Intervention Protocol and Procedure

In this study, the researcher obtained the approval of the Ethics Committee (IR.IAU.K.REC.1398.021) with a clinical trial registration (IRCT20190528043744N1) followed by a written permission from Islamic Azad University of Karaj for referring to Shahid Beheshti University of Medical Sciences and Health Services. There, a recommendation letter was obtained to work in Imam Hossein Hospital. Research objectives and procedure were explained to the respective authorities, which resulted in the approval of the department of endocrinology at Imam Hossein Hospital. Afterwards, sampling was commenced under the supervision of an endocrinology and metabolism specialist. Primarily, the patients who met the inclusion criteria had their medical records examined, completed the initial questionnaire for screening, and were ultimately selected. During the initial assessment phase, 70 eligible patients were identified, 60 of whom were randomly selected for the study. After obtaining their informed consent, Random Allocation Software was employed to divide the subjects into intervention group (receiving family empowerment therapy based on self-compassion) and control group (receiving routine medical and educational treatments provided by the diabetes department of the hospital). Random Allocation Software has been designed to generate random sequences consisting of Unique Identifier (UI) and group name pairs while maintaining additional control over the output format and type. It addresses certain problems and limitations in other randomization software concerning the number of groups, the name of each group, UI generation, and control over the output. Therefore, this software is mainly applied to randomization in parallel group trials.

All participants completed demographics and self-care questionnaires in pre-test and post-test stages. So as to determine glycosylated hemoglobin levels in patients, HbA1c blood test was performed before and after intervention in the hospital's laboratory. The experimental group was subjected to the mentioned intervention. In line with the research objectives, three months after the intervention, a follow-up session was held to assess the effectiveness of the intervention. In the follow-up stage, another round of HbA1c blood test was performed in the hospital laboratory, and the results were reported to the researcher. In the first, second, third, and fourth intervention sessions, the patients participated with a family member (in three

groups of 10 people); the main goal of the family-based empowerment model was to empower the patients' active family members to improve their health, self-care, and adherence to treatment. The control group did not receive any intervention during the study period; only the demographic and self-care questionnaires were used prior to and following the intervention in the experimental group in order to simultaneously evaluate the controls and the intervention group. For ethical reasons, there were no interactions between the control and experimental groups during the study. The control group was treated according to the usual protocols by a specialist, and the researcher did not intervene. However, at the end of the study, all the materials taught to the experimental group were also presented to the control group in the form of a training package. Finally, the obtained data were analyzed through multivariate repeated measures analysis of variance (repeated MANOVA) and Bonfroni post-hoc test by use of the SPSS-21 software (Table 1).

3. Results

Fifty-two patients aged 40-45 (out of 60 patients at the beginning of the study, eight patients left the program later on, seven due to unwillingness to continue participation and one due to pregnancy) with type 2 diabetes participated (26 people in the control group and 26 in the experimental group) in the present study. The mean and standard deviation of the subjects' age for the control and experimental groups were 43.80 ± 4.49 and 45.03 ± 4.59 , respectively

Moreover, the frequency difference analysis and the results of Chi-square test showed no significant difference in terms of marital status, education level, and income level between the control and experimental groups (Table 2). Prior to testing the research hypotheses, the research data were first investigated for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests. The normality tests were performed separately for each group (control-experimental) and each testing phase (pre-test, post-test, and follow-up). The results of Shapiro-Wilk's normal distribution test in the experimental and control groups showed that the assumption of normality was valid in the pre-test ($P=0.424$) and follow-up ($P=0.641$) phases for the self-care variable and in the post-test ($P=0.051$) and follow-up ($P=0.055$) phases for the hemoglobin variable.

Table 3 shows no significant differences between the two groups in terms of the mean level of glycosylated hemoglobin and self-care score in the pre-test phase,

Table 1: Structure of family empowerment therapy based on self-compassion (25)

Sessions	The content of each session
First session	Introduction, welcoming the clients, setting the goals and general policies of the group, introducing the blood glucose test device to the patients and their companions, talking about diabetes and the role of families in controlling diabetes, elucidating the physical, psychosocial, and social impacts of diabetes and the role of self-care in controlling diabetes, defining the role of positive psychological factors in diabetes and psychological symptoms in people, introducing compassion-based therapy and new psychological approaches to treating diabetes, defining the outlines and general structure of the meetings, introduction to compassion and self-compassion, explaining meditation exercises, and assignments for the next session
Second session	Receiving feedback and reviewing the contents of the previous session, clarifying the role of goals, values, and spiritual life in supporting important aspects of life, identifying the philosophies of life, performing goal-setting exercises, defining emotion and specifying positive and negative emotions, practicing how to record desirable events, focus on daily activities with mindfulness, and eat with mindfulness to control the ingested sugar, explaining meditation exercises, and assignments for the next session
Third session	Practicing how to examine the body, focusing on daily activities with mindfulness, ten minutes of breathing with concentration and mindfulness, practicing thoughts and emotions according to compassion therapy, presenting techniques for increasing hope, introducing self-care activities in diabetes patients, compassionate understanding of fears and threats, and immunization (shame reduction) strategies (explaining the concept of developed mind, social mind, and grieving mind and explaining the model), explaining meditation exercises, and assignments for the next session
Fourth session	Compassionate awareness: establishing a relationship based on acceptance and free of judgment with thoughts, emotions, and behaviors (which means using mindfulness techniques), Visual and vocal meditation, sitting in meditation (mindfulness about breathing and the body), walking with mindfulness, practicing the three-minute breathing space, explaining how recording negative events tends to increase concerns, planning daily activities to create values, getting feedback, review of the previous session, using attitude changes to improve satisfaction in areas where there is not enough satisfaction, teaching how to change attitudes based on cognitive therapy principles, practicing thinking about behaviors and identifying risky behaviors, receiving feedback and reviewing the previous sessions, training on how to change goals and criteria using the night insight technique and awareness, training on how to change priorities, receiving feedback, reviewing the previous session, teaching the key principles of compassion, including the principles of lifestyle and seeking solace with a sympathetic person, explaining meditation exercises, and assignments for the next session
Fifth session	Receiving feedback and reviewing the previous session, teaching the basic principles of optimism, kindness to friends, solitude, relaxed breathing and feeling comfortable, ignoring and forgiving, and postponing, accepting, and forgetting, teaching how to write letters with compassion, empathy-based techniques, and how to create effective empathetic relationships, explaining meditation exercises, assignments for the next session, and receiving feedback
Sixth session	Reviewing the previous session, teaching the key principles of compassion, including the principles of lifestyle and seeking solace with a sympathetic individual, sitting in meditation (awareness about breathing, body, sounds, and thoughts), relating with one's thoughts and feelings, expanding and accepting thoughts and unpleasant emotions without judgment, discussing the argument that "thoughts are not real", introducing strategies for respiratory relaxation and gaining effective social support..., providing necessary feedback, reviewing the previous session, teaching breath counting, self-expression, and how to face one's own needs and forgiving oneself, providing feedback, explaining meditation exercises, and assignments for the next session
Seventh session	Three minutes of regular and coping breathing, sitting in meditation (awareness about breathing, body, sounds, and thoughts), understanding the relationship between activities and moods, making a list of enjoyable activities and activities that make one feel empowered, explaining meditation exercises, and assignments for the next session
Eighth session	Three minutes of regular and coping breathing, practicing body inspection, an overview of the entire course, approaches to maintaining the learned skills, selecting a home exercise program that can be continued until the next month, discussing the positive outcomes and possible issues associated with continuing the exercises after the end of the course, participants filling out the questionnaires, explaining meditation exercises, assignments for the next session, and ending the sessions

indicating the homogeneity of the two groups in the pre-test phase ($P=0.344$). However, the group differences the post-test and follow-up stages were statistically significant ($P=0.001$), implying the effectiveness of the intervention regarding glycosylated hemoglobin and self-care variables as well as the sustainability of the effects at the follow-up phase ($P=0.001$).

Multivariate repeated measures analysis of

variance was used to evaluate the effectiveness of self-compassion family empowerment model in self-care and glycosylated hemoglobin dimensions. Therefore, the assumptions of this test for each variable were primarily examined. The results of the Bartlett's test of sphericity ($X^2=440.221$, $P=0.001$) revealed that the assumption (correlation between dependent variables) was established for this test. Next, Box's M test was done to examine the assumption of homogeneity

Table 2: Demographic characteristics of the intervention and control groups

		Empowerment		Control group		Chi-Square Test of Homogeneity	
		Frequency	Percent	Frequency	Percent	value	P value
Marital status	Single	-	-	4	15.4	6.88	0.142
	Married	15	57.7	16	61.5		
	Divorced	11	42.3	6	23.1		
Education level	Below diploma	3	11.5	1	3.8	5.51	0.480
	High school diploma	5	19.2	10	38.5		
	Bachelor's degree	15	57.7	12	46.2		
	Master's degree- PhD	3	11.5	3	11.5		
Income level	Low	2	7.7	4	15.4	0.754	0.686
	Average	24	92.3	22	84.6		

Table 3: Mean and standard deviation of self-care and hemoglobin in patients with diabetes

Modality	Experimental(n=26)			Control(n=26)		
	Pre-test	Post-test	Follow-up	Pre-test	Post-test	Follow-up
Self-care	33.38±2.17	78.34±3.52	74.23±3.24	34.96±5.99	32.30±10.02	24.33±1.92
Hemoglobin	6.79±0.24	4.88±0.53	5.390.38±	6.76±0.48	6.77±0.28	6.79±0.24

Table 4: Repeated measurement results for the effects of time and interaction time and group

Variable	Total square	Df	Mean Square	F	P value
Self-care	10740.521	1	10740.521	561.086	0.001
Hemoglobin	15.373	1	15.373	304.953	0.001

of the covariance matrix. The results showed that this assumption could not be established for the components (BoxM=629.145, $F_{231,7627.42}=1.472$, $P=0.001$). However, considering the large sample size in both groups, multivariate repeated measures ANOVA can be used though the assumption of homogeneity of the covariance matrix is not met.

The sphericity assumption was further investigated for all the variables using the Mauchly's test, with the results showing that this assumption was not fulfilled for the self-care and hemoglobin variables ($P=0.001$). Accordingly, the results of Greenhouse - Geisser Correction were used. After that, the assumption of homogeneity of error variance was investigated using Levene's test, and the results indicated the validity of this assumption the self-care component ($P=0.141$) and hemoglobin variables ($P=0.594$). Results of multivariate tests showed that self-compassion family empowerment model was significantly effective regarding the group factor ($P=0.001$, $F=210.108$, Pillai's trace=0.971), time factor ($P=0.001$, $F=194.589$, Pillai's trace=0.987), and the interaction of time and group ($P=0.001$, $F=146.805$, Pillai's trace=0.982). The between-group test examined the effectiveness of empowerment on each dimension, and the results indicated significant

differences between the experimental and control groups concerning self-care ($F=561.086$, $P=0.001$) and glycosylated hemoglobin ($F=304.953$, $P=0.001$) variables; therefore, the mean self-care score was higher in the experimental group whereas the average reading for the glycosylated hemoglobin was reduced compared to the control group. In addition, the results of the within-group effect test showed that time factor had a significant effect on self-care ($P=0.001$, $F_{GG1.28}=251.684$) and glycosylated hemoglobin ($P=0.001$, $F_{GG1.73}=87.455$) variables.

Paired comparisons were also performed to compare the means of the two groups in all three phases of the study and assess the outcome stability during follow-up. The results of this analysis are presented in Table 4. The effectiveness of family empowerment model based on self-compassion was compared between the two groups using the Bonferroni post-hoc test (Table 5).

The results of the present study showed that unlike the control group, self-compassion family empowerment model affected the experimental group. Comparison of the mean scores of the two groups during post-test and follow-up revealed the stability of the intervention effect in the experimental group (Figures 2 and 3).

Table 5: Bonferroni post-hoc test results of pairwise comparisons

Element	Test	Group 1	Group 2	Mean difference	Standard error	P value
Self-care	Pre-test	Empowerment	Control	1.577-	1.251	0.213
	Post-test	Empowerment	Control	46.038	2.084	0.001
	Follow up	Empowerment	Control	41.769	1.688	0.001
Hemoglobin	Pre-test	Empowerment	Control	.0.26	0.107	0.807
	Post-test	Empowerment	Control	1.890-	0.120	0.001
	Follow up	Empowerment	Control	1.399-	0.090	0.001

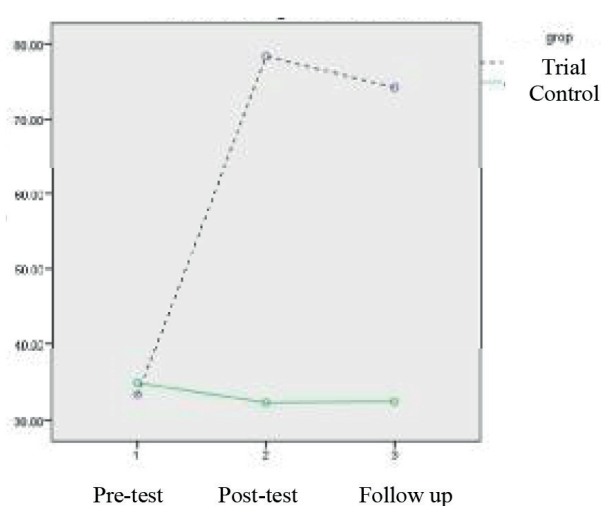


Figure 2: Comparing the mean self-care scores between the two groups in three evaluation phases

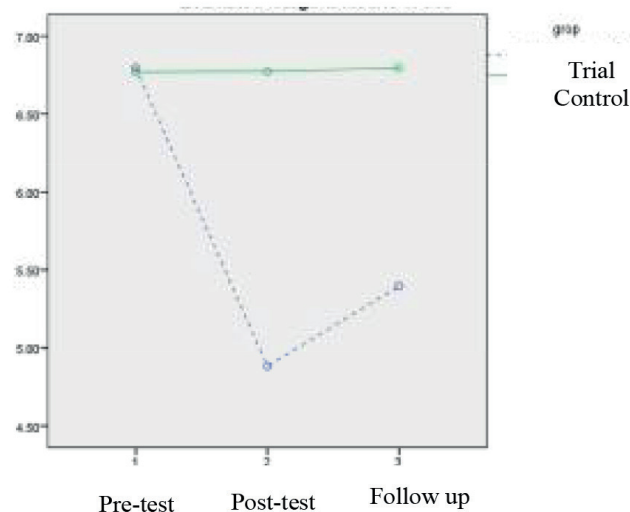


Figure 3: Comparing the mean hemoglobin scores between the two groups in three evaluation phases

4. Discussion

The goal of this study was to determine the effect of self-compassion family empowerment therapy on self-care and glycosylated hemoglobin in female patients with type 2 diabetes. Analysis of demographic data indicated no statistically significant differences between the two groups as far as individual characteristics are concerned. In other words, the two groups were homogeneous with regard to these characteristics, resulting in a better comparison to identify the intervention effects.

The hypothesis of the present study was that self-compassion family empowerment therapy is effective in improving self-care and glycosylated hemoglobin levels. The results showed that self-compassion family empowerment therapy was effective in promoting self-care and reducing glycosylated hemoglobin levels. These findings are in line with the results reported by Albertson, Neff, Dill-Shackleford (29); Gonzalez-Hernandez, Romero et al. (30); Tol, Baghbanian et al. (31); Arda et al. (32); Serrano-Gil, Jacob et al. (33); Teli (2019) (34). In their study, which focused on the effectiveness of family-centered psychological intervention in diabetic patients with poor control,

Mansouri et al. (2019) observed a greater reduction in HbA1C in the experimental group compared to the control group, concluding that adding family-based psychological intervention to usual treatments can be effective in enhancing diabetes management (35). In his study, Madmoli (2019) also concluded that presence of a family member with the patient in diabetes education classes would augment the effectiveness of these classes (36). In yet another study, Łuczyński and Łazarczyk held that family played a major role in the treatment of these patients and that better family performance was associated with better blood sugar control. Therefore, they proposed that family members also participate in the educational programs of these patients (37).

These findings can be explained by saying that in diabetes patients with psychological disorders such as depression and anxiety, the threat and self-preservation system is severely hyperactive, entailing high levels of stress and anxiety which lead to inadequate self-care activities. Moreover, the satisfaction and relief system in these people is less developed because they have never had the opportunity to develop this system. Subsequently, adherence to treatment and self-care decreases in these patients, resulting in their increased glycosylated hemoglobin levels (24).

For such individuals, compassion-based treatment acts like the physiotherapy of the mind. In other words, stimulating the relief system facilitates its development, enhancing the patient's resilience against depression and anxiety. This will in turn improve their mental health and self-care activities. Accordingly, the basis of compassion-focused therapy is to educate the mind to be compassionate towards oneself and others. In this technique, the patients learn skills and qualities associated with compassion, and they are assisted in changing their problematic cognitive and emotional patterns. By altering these problematic mental patterns, the patients become more sympathetic to themselves and others and less vulnerable to shortcomings and adversities. These changes result in mental relaxation and increased self-care (23). Positive emotions are further enhanced in these patients following compassion therapy, resulting in increased quality of life.

Moreover, the social support such as kindness, companionship, care, respect, attention, and assistance received by the patients from their families increases during this treatment, which can be effective in ameliorating self-care and adherence to treatment.

The findings of this study can be explained by saying that the therapist gradually elucidated and described compassionate skills and characteristics to the patients over the course of the therapy. Therefore, the clients came into Therefore, the clients are helped by building or enhancing a compassionate relationship with themselves instead of self-criticizing, blaming, and condemning themselves. The two main objectives of compassion-focused therapy (CFT) are 1) reducing self-directed hostility and 2) developing one's abilities to create a sense of self-confidence, kindness, and self-consolation that can act as an antidote to the feeling of being threatened. Many of CFT's activities focus on building the capacity to show compassion.

5. Conclusion

Compassion-focused therapy is a context-based approach that challenges people to embrace their own thoughts and feelings and commit themselves to necessary changes. Although the present study did not have many drop outs, its small sample size was among the limitations that prevented the accurate estimation of the effect size for the program. The second limitation concerns the use of self-report instruments. Instruments of such ilk have inherent shortcomings, among which mention can be made of measurement error and lack of self-observation. Furthermore, the

sample of this study was limited to female patients with diabetes, which requires more caution in generalizing the findings. Future studies are recommended to employ placebo programs to control for expectation effects, use larger samples to obtain better estimates of the program's effect size, and extend the scope of the findings of the current research through studying the effect of acceptance and commitment therapy on similar patients in other hospitals.

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Ethical Approval

the researcher obtained the approval of the Ethics Committee (IR.IAU.K.REC.1398.021) with a clinical trial registration (IRCT20190528043744N1) followed by a written permission from Islamic Azad University of Karaj for referring to Shahid Beheshti University of Medical Sciences and Health Services. There, a recommendation letter was obtained to work in Imam Hossein Hospital. Research objectives and procedure were explained to the respective authorities, which resulted in the approval of the department of endocrinology at Imam Hossein Hospital.

Conflict of interest

The authors declared no conflict of interest.

References

- Hayden MR, Grant DG, Aroor AR, DeMarco VG. Empagliflozin ameliorates type 2 diabetes-induced ultrastructural remodeling of the neurovascular unit and neuroglia in the female db/db mouse. *Brain Sci.* 2019;**9**(3):57. doi: 10.3390/brainsci9030057. [PubMed:30866531]; [PubMed Central: PMC6468773].
- Rådholm K, Zhou Z, Clemens K, Neal B, Woodward M. Effects of sodium-glucose co-transporter-2 inhibitors in type 2 diabetes in women versus men. *Diabetes, Obesity and Metabolism.* 2020; **22**(2):263-6. doi: 10.1111/dom.13876.13876.

3. Banitalebi E, Kazemi A, Faramarzi M, Nasiri S, Haghighi MM. Effects of sprint interval or combined aerobic and resistance training on myokines in overweight women with type 2 diabetes: A randomized controlled trial. *Life Sci*. 2019;**15**,217:101-9. doi:10.1016/j.lfs.2018.11.062. [PubMed: 30508516].
4. Razavizadeh Tabadkan B B Z, Jajarmi M. The Effectiveness of Mindfulness-Based Cognitive Therapy on Ruminative Thoughts, Perceived Stress and Difficulties in Emotion Regulation of Women With Type 2 Diabetes. *Iranian Journal Psychiatry & clinical Psychology*. 2019;**11**(1) :1-8. doi: 10.32598/ijpcp.24.4.370.
5. Assarzadegan, M., Raeisi, Z. The Effectiveness of Training Based on Positive-Psychology on Quality of life and Happiness of Patients with Type 2 Diabetes. *Avicenna J Neuro Psycho Physiology*. 2018;**5**(2): 43-52. doi: 10.32598/ajnpp.5.2.43
6. Ballon A, Neuenschwander M, Schlesinger S. Breakfast skipping is associated with increased risk of type 2 diabetes among adults: A systematic review and meta-analysis of prospective cohort studies. *J Nutr*. 2019;**149**(1):106-13. doi: 10.1093/jn/nxy194. [PubMed: 30418612].
7. Gadgil MD, Oza-Frank R, Kandula NR, Kanaya AM. Type 2 diabetes after gestational diabetes mellitus in South Asian women in the United States. *Diabetes Metab Res Rev*. 2017;**33**(5): 2891. doi:10.1002/dmrr.2891. [PubMed: 28224756]; [PubMed Central: PMC5495618].
8. Dennison RA, Ward RJ, Griffin SJ, Usher-Smith JA. Women's views on lifestyle changes to reduce the risk of developing type 2 diabetes after gestational diabetes: a systematic review, qualitative synthesis and recommendations for practice. *Diabet Med*. 2019;**36**(6):702-17. doi: 10.1111/dme.13926. [PubMed: 30723968]; [PubMed Central: PMC6563496].
9. Wang L, Li T, Liu J, Wu X, Wang H, Li X, et al. Association between glycosylated hemoglobin A1c and bone biochemical markers in type 2 diabetic postmenopausal women: a cross-sectional study. *BMC Endocr Disord*. 2019;**19**(1):31. doi: 10.1186/s12902-019-0357-4. [PubMed:30866902]; [PubMed Central: PMC6416956].
10. Jang JE, Cho Y, Lee BW, Shin ES, Lee SH. Effectiveness of exercise intervention in reducing body weight and glycosylated hemoglobin levels in patients with type 2 diabetes mellitus in Korea: a systematic review and meta-analysis. *Diabetes Metab J*. 2019;**43**(3):302-18. doi: 10.4093/dmj.2018.0062. [PubMed: 30604592]; [PubMed Central: PMC6581545].
11. Kav S, Yilmaz AA, Bulut Y, Doga. Self-efficacy, depression and self-care activities of people with type 2 diabetes in Turkey. *Collegian*. 2017;**24**(1):27-35. doi:10.1016/j.colegn.2015.09.005. [PubMed: 29218959].
12. Tan CCL, Cheng KKF, Sum CF, Shew JSH, Holydard E, Wang W. Perceptions of Diabetes Self-Care Management Among Older Singaporeans With Type 2 Diabetes: A Qualitative Study. *J Nurs Res*. 2018;**26**(4):242-9. [PubMed: 29016464].
13. Williams JS, Walker RJ, Smalls BL, Hill R, Egede LE. Patient-Centered Care, Glycemic Control, Diabetes Self-Care, and Quality of Life in Adults with Type 2 Diabetes. *Diabetes Technol Ther*. 2016;**18**(10):644-9. doi: 10.1089/dia.2016.0079. [PubMed: 27541872]; [PubMed Central: PMC5069713].
14. Alshehri MM, Alenazi AM, Hoover JC, Alothman SA, Phadnis MA, Miles JM, et al. A comparison of diabetes self-care behavior in people with type 2 diabetes with and without insomnia symptoms. *Acta Diabetol*. 2020;**7**:1-9. doi: 10.1007/s00592-019-01470-y. [PubMed: 31909434].
15. Ching SM, Yee A, Lee PY, Ramachandran V, Shum KM, Ismael NF, et al. Psychometric properties of the Malay version of the diabetes empowerment scale among hospital Serdang type 2 diabetes mellitus patients using exploratory factor analysis. *Health Qual Life Outcomes*. 2020;**18**(1):23. doi: 10.1186/s12955-020-1280-0. [PubMed: 32033609]; [PubMed Central:PMC7006206].
16. Zhu TH, Mooi CS, Shamsuddin NH, Mooi CS. Diabetes empowerment scores among type 2 diabetes mellitus patients and its correlated factors: A cross-sectional study in a primary care setting in Malaysia. *World J Diabetes*. 2019;**10**(7):403. doi:10.4239/wjd.v10.i7.403. [PubMed: 31363387]; [PubMed Central: PMC6656707].
17. Ching SM, Yee A, Lee PY, Ramachandran V, Shum KM, Ismael NF, et al. Psychometric properties of the Malay version of the diabetes empowerment scale among hospital Serdang type 2 diabetes mellitus patients using exploratory factor analysis. *Health Qual Life Outcomes*. 2020;**18**(1):23. doi: 10.1186/s12955-020-1280-0. [PubMed: 32033609]; [PubMed Central: PMC7006206].
18. Lian J, McGhee SM, So C, Chau J, Wong CKH, Wong WCW, et al. Long-term cost-effectiveness of a Patient Empowerment Programme for type 2 diabetes mellitus in primary care. *Diabetes Obes Metab*. 2019;**21**(1):73-83. doi:10.1111/dom.13485. [PubMed: 30058268]
19. NR, Aquino JA, Sanches-Giraud C, Di Lorenzo Oliveira C, de Figueiredo RC, Cardoso CS, et

- al. Pharmacotherapeutic empowerment and its effectiveness in glycemic control in patients with diabetes mellitus. A systematic review and meta-analysis. *Prim Care Diabetes*. 2019;**13**(1):137-42. doi: 10.1016/j.pcd.2016.09.006. [PubMed: 27780683]
20. Sadeghi M, Pedram Razi S, Nikbakht Nasrabadi A, Ebrahimi H, Kazemnejad A. Comparison of the impact of education based on the empowerment model and family-center empowerment model on knowledge and metabolic control of patients with type 2 diabetes mellitus. *Journal of Nursing Education*. 2013;**2**(3) :18-27.
 21. Pedram Razi S, Sadeghi M, Nikbakht Nasrabadi A, Ebrahimi H, & Kazemnejad A. The Effect of Family-Centered Empowerment Model on Knowledge and Metabolic Control of Patients with Type 2 Diabetes. *Journal of Knowledge & Health in Basic Medical Sciences*. 2013;**9**(1), 48-54. doi: 10.1234/knh.v9i1.348.
 22. Mansouri Z, Mansouri A, Zardosht F, Nazarnia P, Sarabandi noe A. Effect of Family-centered Empowerment Model on Glycemic Control and Drug Compliance in Patients with Type II Diabetes. *Journal of Diabetes Nursing*. 2019;**6**(4):596-606.
 23. Madmoli M. A systematic review study on the results of empowerment-based interventions in diabetic patients. *Int. Res. International Research in Medical and Health Science*. 2019;**28**,2(1):1-7. doi: 10.36437/irmhs.2019.2.1.1
 24. Ribeiro da Silva D, Rijo D, Castilho P, Gilbert P. The efficacy of a Compassion-Focused Therapy-Based intervention in reducing psychopathic traits and disruptive behavior: A clinical case study with a juvenile detainee. *Clinical Case Studies*. 2019;**18**(5):323-43. doi: 10.1177/1534650119849491.
 25. Bell T, Montague J, Elander J, Gilbert P. "A definite feel-it moment": Embodiment, externalisation and emotion during chair-work in compassion-focused therapy. *Counselling and Psychotherapy Research*. 2020;**20**(1):143-53. doi: 10.1002/capr.12248
 26. Basa RP. (1995). Evaluation of a diabetes specialty center: Structure, process and outcome. *Patient Education and Counseling*. 1995;**25**:23-29. doi: 10.1016/0738-3991(94)00677-E
 27. Toobert D, Hampson S, Glasgow R. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care*. 2000; **23**(7):943-50. doi:10.2337/diacare.23.7.943. [PubMed: 10895844]
 28. Kordi M, Banaei Heravan M. The Relationship of depression, anxiety, and stress with self-care behaviors in women with gestational diabetes. *Journal of Midwifery and Reproductive Health*. 2020; **8**(1):2083-95. doi: 10.22038/jmrh.2019.41459.1471.
 29. Albertson, E, Neff, K, Dill-Shackleford E. Self-compassion and body dissatisfaction in women: A randomized controlled trial of a brief meditation intervention. *Mindfulness*. 2014;**6**(3):444-454. doi:10.1007/s12671-014-0277-3.
 30. Gonzalez-Hernandez E, Romero R, Campos D, Burychka D, Diego-Pedro R, Baños R. Cognitively-Based Compassion Training (CBCT) in Breast Cancer Survivors: A Randomized Clinical Trial. *Integr Cancer Ther*.2018;**17**(3):684-696. doi: 10.1177/1534735418772095. [PubMed: 29681185]; [PubMed Central: PMC6142100].
 31. Tol A, Baghbanian A, Mohebbi B, Shojaeizadeh D, Azam K, Shahmirzadi SE, et al. Empowerment assessment and influential factors among patients with type 2 diabetes. *J Diabetes Metab Disord*. 2013; **12**(1):6. doi: 10.1186/2251-6581-12-6. [PubMed: 23497631]; [PubMed Central: PMC3598211].
 32. Arda Sürücü H, Büyükkaya Besen D, Erbil EY. Empowerment and social support as predictors of self-care behaviors and glycemic control in individuals with type 2 diabetes. *Clin Nurs Res*. 2018; **27**(4):395-413. doi: 10.1177/1054773816688940. [PubMed: 28132513].
 33. Serrano-Gil M, Jacob S. Engaging and empowering patients to manage their type 2 diabetes, Part I: a knowledge, attitude, and practice gap? *Adv Ther*. 2010; **27**(6):321-33. doi: 10.1007/s12325-010-0034-5. [PubMed: 20552306].
 34. Teli M. Family Empowerment Model for Type 2 DM Management: Integration of Self-care Model by Orem and Family Centered Nursing by Friedman in Sikumana Health Center-Kupang. *Jurnal Info Kesehatan*. 2019;**17**(1):75-87. doi: 10.31965/infokes. Vol17.Iss1.261
 35. Mansouri Z, Mansouri A, Zardosht F, Nazarnia P. Effect of Family-centered Empowerment Model on Glycemic Control and Drug Compliance in Patients with Type II Diabetes. *Journal of Diabetes Nursing*. 2019; **6**(4):596-606.
 36. Madmoli M, Madmoli M, Aliabad MA, Khodadadi M, Ahmadi FP. A systematic review on the impact of empowerment in improving self-care behaviors and some other factors in diabetic patients. *International Journal of Health and Biological Sciences*. 2019; **2**(1):11-6.
 37. Łuczyński W, Łazarczyk I, Szlachcikowska I, Kiernożek Ż, Kaczmarek A, Szylaj O, et al. The Empowerment of Adolescents with Type 1 Diabetes Is Associated with Their Executive Functions. *Biomed Res Int*. 2019;**30**:5184682. doi: 10.1155/2019/5184682. [PubMed: 31183368]; [PubMed Central: PMC6515027].