Jundishapur J Chronic Dis Care. 2024 October; 13(4): e142606. https://doi.org/10.5812/jjcdc-142606.

Published online: 2024 August 21. **Research Article**

Impact of Group Reality Therapy on Treatment Adherence and Health Indicators in Patients with Type 2 Diabetes Mellitus: A Randomized Controlled Trial

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Received 2023 October 31; **Revised** 2024 May 19; **Accepted** 2024 May 31.

Abstract

Background: The use of non-pharmacological therapies is important in reducing the complications and consequences of diabetes.

Objectives: This study aimed to determine the effect of group reality therapy on adherence to treatment regimens and health indicators in patients with type 2 diabetes.

Methods: This randomized controlled trial was performed on 60 patients with diabetes who were referred to Amir Al-Momenin Hospital in Ahvaz. Patients were randomly assigned to either the intervention group (N = 30) or the control group (N = 30). Both groups completed health indicator tests, questionnaires on demographic and clinical information, perceived adherence to the treatment regimen, and the Perceived Stress Scale. The intervention group received reality therapy training, which consisted of 10 sessions of 45 minutes each (one session per week) over 2 months, delivered through lectures and face-to-face training sessions. The control group received only routine hospital interventions. The collected data were then analyzed using a one-way *t*-test and one-way analysis of variance (ANOVA).

Results: Twenty-seven patients in the intervention group and 27 in the control group completed the study. After analyzing the data, it was revealed that the mean age of the patients in the control group was 55.30 ± 7.95, while it was 51.96 ± 10.55 in the intervention group. Findings showed that scores for the dimensions of adherence to the treatment regimen in the intervention group significantly increased compared to the control group ($P < 0.001$). Additionally, the mean health indicators in the intervention group showed a significant decrease compared to the control group ($P < 0.001$). Moreover, the mean blood sugar level of patients in the intervention group decreased from 229.63 ± 98.76 to 123.59 ± 42.03. Likewise, the level of glycosylated hemoglobin and blood cholesterol significantly decreased from 8.19 ± 2.09 to 6.11 ± 1.86 and from 176.52 ± 51.53 to 146.22 ± 34.68, respectively.

Conclusions: A reality therapy training program can be effectively used to increase treatment adherence and improve health indicators in patients with type 2 diabetes.

Keywords: Reality Therapy, Treatment Adherence, Type 2 Diabetes Mellitus, Health Indicator

1. Background

Diabetes is one of the most common chronic diseases and a leading cause of death and disability worldwide. Today, diabetes is considered one of the most important health-related and socioeconomic problems globally (1). It is estimated that one person dies because of diabetes or its resulting complications every second; 50% of these mortalities (a total of 4 million people per year) occur in individuals younger than 60 years (2). The global prevalence of diabetes in adults was 6.4% in 2010, which equaled 285 million people, and in 2012, it was estimated to be around 371 million people. By 2030, it is estimated that 552 million people will be affected

globally (3). Geographically, this disease has a different distribution worldwide, with the largest prevalence reported in India, China, and the USA (4). According to a global study, the prevalence of diabetes in Iran in 2023 was estimated at around 17.9%. It is estimated that by 2030, nearly 9 million Iranian people will likely have diabetes (5, 6). Managing diabetes to prevent complications is essential (7).

Diabetes can be controlled and managed through various methods, including planning meals and following a proper diet, regular exercise, adhering to the instructions for medications, controlling blood pressure and blood glucose at home, and undergoing tests prescribed by a physician (8). In addition to pharmacotherapy, various non-pharmacological methods have been presented for controlling blood glucose. Many studies have shown the positive effects of various non-pharmacological interventions in controlling diabetes (9, 10). These interventions include adhering to a proper diet, regular exercise, cessation of smoking, taking medications, controlling stress, and adhering to the treatment regimen (11, 12). Some studies have reported the degree of failure to adhere to treatment regimens among diabetics as 23-93%, while other studies have reported it in up to one-third of patients (13, 14). Additionally, the results obtained by Demoz et al. indicated poor treatment adherence in T2DM patients (15).

Reality therapy is a counseling method developed by William Glasser in 1965 based on "choice theory" and is widely established as a therapeutic approach (16). Various studies worldwide suggest the effectiveness of reality therapy in addressing psychological components, issues, and disorders, including adult depression, treatment adherence, and reducing stress and anxiety (17, 18). For instance, the study by Farshchi et al. indicated that reality therapy can reduce anxiety and depression and increase treatment adherence among patients with type I diabetes (19). However, limited studies have examined the effectiveness of reality therapy interventions on health indicators and treatment adherence in patients with T2DM.

2. Objectives

The present study aimed to determine the effect of group reality therapy on treatment adherence and health indicators in patients with T2DM.

3. Methods

3.1. Study Design

This research was a Randomized Controlled Trial (RCT) conducted in a diabetes clinic in Ahvaz, southwest Iran, in 2020. The research population consisted of diabetic patients referred to this center, and the research sample was randomly assigned to intervention and control groups. This study was approved by the Iranian Register of Clinical Trials (IRCT) with the number IRCT20181210041915N2.

3.2. Sampling

The sample size was calculated as 60 people using a mean comparison formula and based on a similar study (19). Initially, 60 patients referred to Amir Almomenin Hospital in Ahvaz were selected based on inclusion criteria. They were then randomly allocated into two groups of 30 people each (the intervention and the control groups) by a coin toss. In the intervention group, three subjects, and in the control group, three subjects dropped out due to unwillingness to continue with the study. Accordingly, 54 subjects completed the study in the intervention group (n = 27) and in the control group (n = 27) (Figure 1).

The inclusion criteria were literacy in reading and writing, no history of uncontrolled underlying diseases such as epilepsy, no history of receiving any reality therapy training, and non-smoking status. Exclusion criteria included hospitalization during the study, absence from more than one training session, severe psychiatric disorders, or the use of psychotropic drugs or substance abuse.

3.3. Data Collection and Instruments

In this study, data collection instruments included questionnaires and checklists, specifically the questionnaire of demographic-clinical characteristics, compliance to treatment, the checklist of health indicators, and Cohen's stress questionnaire. The demographic questionnaire captured personal characteristics and clinical status of subjects, including age, gender, level of education, marital status, household income, HbA1C, cholesterol, triglyceride levels, and participation in training classes. The compliance to treatment questionnaire included 56 items covering three areas: Diet, exercise, and medications. The total sum of the scores was calculated based on 100 and classified into three groups: Desired (75% - 100%), semi-desired (50% - 75%), and undesired (less than 50%) (19). The reliability and validity of this questionnaire were previously measured by Sanaei et al.; the reliability was estimated at (r = 0.83) using the test-retest method, and content validity was employed for

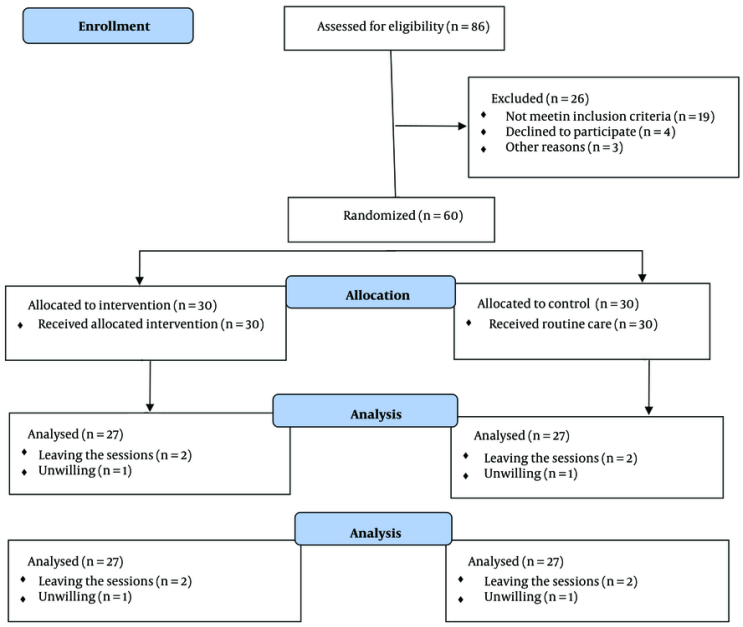

Figure 1. Consolidated standards of reporting trials (CONSORT) flow chart

validity (20). Cohen's perceived stress questionnaire consists of 14 items, each responded to on a 5-point Likert scale (none, low, moderate, high, and very high) (21). Reliability was obtained through the Cronbach alpha coefficient, with a score of 0.71 for positive perception of tension and 0.75 for negative perception of tension (22). The checklist of health indicators captured metabolic control indicators (HbA1C, fasting blood glucose, cholesterol, triglyceride). To ensure consistency, the study used laboratory kits from the laboratory at Amiralmomenin Hospital in Ahvaz City for all participants.

3.4. Intervention

After providing a written informed consent form and explaining the research objectives to the participants, they were assured that their information would remain confidential. A sufficient explanation was given to all participants about completing the questionnaires. Before any intervention, laboratory tests were taken for both groups to measure health indicators (blood glucose, cholesterol, triglyceride, HbA1c, etc.). Thereafter, the therapeutic protocol was implemented over ten 45-minute sessions (once per week) for 2 months as lecture and face-to-face training for the intervention group (Table 1). The control group patients received only routine hospital interventions. Educational materials were provided to both groups as pamphlets and CDs after completing the study. After completing the training course, tests were performed and questionnaires were completed by both groups; the final test was conducted one month after the last training session (test and re-completion of questionnaires) by both groups.

3.5. Data Analysis

Data analysis was performed using SPSS 22 and included descriptive statistics such as mean, standard deviation, number, and percentage. The following tests were utilized: Repeated measures tests, independent *t*-test, Mann-Whitney test, paired *t*-test, correlation coefficient test, analysis of variance, and Kruskal-Wallis. The significance level was set at $P < 0.05$.

4. Results

The results showed that both groups were homogeneous in demographic variables, with no significant difference between them in this regard ($P > 0.05$). To compare the variables of gender, marital status, occupation, household income, and smoking status, the chi-square test was used (Table 2).

Table 1. Contents and Assignments of Reality Therapy Sessions Provided to Participants

No.	Content	Assignments
1	The initial session introduces members, sets expectations, outlines group rules, ensures regular meetings, performs weekly tasks and presents them in subsequent sessions.	Members are asked to list their three most important health wishes, focusing on how they differ, how they share similar needs, and how they meet them.
2	The session's assignments were reviewed, and explanations were given on selecting ineffective behaviors like non-compliance with treatment regimens, and the reasons and methods behind such tendencies.	The assignment of this session aims to determine the level of health members desire and their current level of health, based on a continuum from 1 to 100.
3	Review the assignments of the previous session. Explanation about general behavior and its four components (thought, action, physiology, and feeling), machine learning of behavior in humans, and explanation of aggression as a general behavior	Members should explain the components of non-compliant behaviors.
4	The session focuses on understanding behavior, self-control, and positive aspects while teaching members about behavior, feelings, and internal and external control. It also emphasizes non-compliance as an internal choice.	The tasks of this session focus on the control of human behavior, examining both external and internal factors, and the actions taken to achieve desired outcomes.
5	The fifth session emphasized the importance of contrasting qualitative and real-world behavior, emphasizing responsibility, familiarizing members with responsibilities, and promoting responsible behavior choices.	Participants were asked if their goals would lead them to their desired destination and if they had a roadmap to guide them.
6	The session provided feedback, reviewed assignments, and taught seven destructive and seven effective behaviors to achieve goals, emphasizing the importance of avoiding excuses.	Past failures and excuses highlight unrealistic behaviors and the need for alternative ways to achieve desired outcomes.
7	Review the assignments of the last session. Determining the ways to achieve the demands from the members' language. Explanation of effective and ineffective solutions considering the two characteristics of being realistic and responsible	Checking whether the specified ways have been effective?
8	Explanation regarding the components of the therapeutic diet (exercise, medicine, nutrition) and the effect of each one on diabetes control	Members can briefly explain the effects of each component in diabetes control for the next meetings.
9	The session discussed the importance of a SMART plan to achieve goals, identify member solutions, and introduce program features.	Writing the program in writing with the SMART feature of the program
10	The tenth session emphasized the importance of commitment, requiring written commitment from members, and personal goals, emphasizing responsibility and goal achievement.	

Table 2. Comparison of Demographic Variables of Diabetic Patients in Intervention and Control Groups Before Reality Therapy Intervention (N = 54)

Variables	Intervention (n = 27)	Control (n = 27)	Total (N = 54)	Test Statistic	P-Value
Age	51.96 ± 10.56	55.30 ± 7.9	53.63 ± 9.41	-1.31	0.196
BMI	27.17 ± 5.63	29.16 ± 5.16	28.12 ± 5.45	-1.35	0.182
Gender				1.94	0.264
Female	14 (51.9)	19 (70.4)	21 (38.9)		
Male	13 (48.1)	8 (29.6)	33 (68.1)		
Marital status				0.750	0.386
Single	4 (14.8)	2 (7.4)	6 (11.1)		
Married	23 (85.2)	25 (92.8)	48 (88.9)		
Education				2.03	0.362
Primary school	6 (22.2)	10 (37.0)	16 (29.6)		
Middle and high school	15 (55.6)	14 (51.9)	29 (53.7)		
University education	6 (22.2)	3 (11.1)	9 (16.7)		
Source of information				1.24	0.538
Treatment staff	17 (85.5)	20 (87.0)	37 (86.0)		
Self-learning	3 (15.0)	2 (8.7)	5 (11.6)		
Media	0 (0.0)	1 (4.3)	1 (2.3)		
Income				3.97	0.137
Desirable	3 (11.1)	2 (7.4)	5 (9.3)		
Relatively desirable	18 (66.7)	12 (44.4)	30 (55.6)		
Undesirable	6 (22.2)	13 (48.1)	19 (35.2)		
Smoking				1.41	0.493
Yes	3 (11.1)	1 (33.7)	4 (7.4)		
No	24 (88.9)	26 (96.3)	50 (92.6)		
Duration of Diabetes				0.18	0.915
Less than 5	9 (33.3)	9 (33.3)	18 (33.3)		
5 - 10	3 (11.1)	4 (14.8)	7 (13.0)		
More than 10	15 (55.6)	14 (51.9)	29 (53.7)		
Family history of Diabetes				1.54	0.352
Yes	18 (66.7)	22 (81.5)	40 (74.1)		
No	9 (33.3)	5 (18.5)	14 (25.9)		

The results also showed that the mean scores for exercises, dietary instructions, and drug instructions had no significant difference between the two groups before the intervention, according to *t*-test results ($P > 0.05$). However, immediately after the intervention and one month post-intervention, a significant difference was found between the two groups in terms of exercise and dietary instructions ($P < 0.001$), while the difference in drug instructions was not significant ($P > 0.05$) (Table 3).

The results also showed that there was no significant difference in the stress scores between the pre-intervention and post-intervention phases, according to repeated measurement tests ($P > 0.05$). Regarding the analysis of health indicators, the findings indicated that the mean FBS, cholesterol, and triglyceride levels had no significant difference between the two groups before the intervention ($P > 0.05$). However, immediately after the intervention and one month post-intervention, a significant difference was found between the two groups ($P < 0.001$). Additionally, the mean HbA1c levels showed no significant difference between the two groups before and after the intervention ($P > 0.05$) (Table 4, Figures 2 and 3).

5. Discussion

Table 3. Comparison of Trends in Variables Included: Diet, Treatment Regimen, Exercise, Medication, and Stress at Different Times by Groups (N = 54) [a]

Variables	Intervention (n = 27)	Control (n = 27)	Test Statistic	P-Value	Total (N = 54)
Compliance to treatment regimen					
Exercise activity					
Baseline	33.59 ± 16.74	22.52 ± 11.34	2.85	0.006	28.06 ± 15.22
1.5 months later	45.11 ± 6.62	6.28 ± 8.09	19.19	< 0.001	25.79 ± 20.82
3 months later	47.00 ± 8.45	4.75 ± 7.11	19.83	< 0.001	25.92 ± 22.63
Diet					
Baseline	68.52 ± 10.34	58.15 ± 4.79	4.73	< 0.001	63.33 ± 9.54
1.5 months later	71.78 ± 4.85	41.41 ± 4.02	25.03	< 0.001	56.59 ± 15.95
3 months later	73.78 ± 6.60	40.85 ± 4.69	21.13	< 0.001	57.31 ± 17.56
Stress					
Baseline	3.07 ± 1.54	3.81 ± 1.92	-1.54	0.130	3.43 ± 1.76
1.5 months later	5.70 ± 3.49	6.26 ± 2.84	-0.64	0.524	5.98 ± 3.16
3 months later	5.48 ± 3.63	4.78 ± 2.31	0.85	0.339	5.13 ±3.03
Medication instructions					
Baseline	31.43 ± 1354	28.26±9.97	0.98	0.331	29.84 ± 11.88
1.5 months later	23.00 ± 7.57	18.85±6.61	2.14	0.037	20.92 ± 7.35
3 months later	19.59 ± 8.11	12.22 ± 3.63	4.31	< 0.001	15.91 ± 7.25
Total score					
Baseline	119.05 ± 26.92	124.67 ± 15.64	-0.94	0.353	121.86 ± 21.98
1.5 months later	113.70 ± 10.96	84.96 ± 14.66	8.16	< 0.001	99.33 ± 19.36
3 months later	112.78 ± 13.64	76.78 ± 12.64	10.06	< 0.001	94.78 ± 22.35
Health Indicators					
FBS					
Baseline	229.63 ± 118.11	193.19 ± 77.58	1.34	0.186	211.41 ± 100.6
1.5 months later	123.59 ± 42.04	203.7 ± 76.14	-4.79	< 0.001	163.65 ± 73.11
3 months later	123.22 ± 44.20	238.26 ± 92.49	-5.83	< 0.001	180.74±92.33
Triglyceride					
Baseline	207.81 ± 74.38	175.33 ± 78.47	1.56	0.125	191.57 ± 77.48
1.5 months later	162.59 ± 51.58	199.0 ± 117.1	-1.48	0.145	180.8 ± 91.49
3 months later	154.96 ± 50.44	244.15 ± 152.6	-2.88	0.006	199.56 ± 121.3
Cholesterol					
Baseline	176.52 ± 51.54	161.04 ± 38.44	1.25	0.216	168.78 ± 45.71
1.5 months later	162.56 ± 46.29	167.44 ± 38.01	-0.42	0.674	165.0 ± 42.06
3 months later	146.22 ± 34.69	189.70 ± 43.62	-4.05	< 0.001	167.96 ± 44.78
HBA1C					
Baseline	8.15 ± 2.07	8.12 ± 1.90	0.22	0.827	8.13 ± 1.97
3 months later	6.19 ± 1.87	9.03 ± 1.85	-5.77	< 0.001	7.56 ± 2.33

[a] Values are presented as mean ± SD.

This study was conducted to determine the effect of reality therapy on treatment adherence and health indicators in 54 T2DM patients. The results showed that the physical activity dimension score increased significantly in the intervention group compared to the control group after group reality therapy. In other words, participants in the intervention group were more successful in adopting an exercise routine to maintain their health compared to the control group. Confirming these findings, a study by Farshchi et al. indicated that diabetic patients often have an unsuitable lifestyle due to the disease and its complications, with physical activity and proper diet not being common. However, reality therapy, a common psychological treatment, can effectively help in controlling the disease (19).

Furthermore, the present study found that the score for the dietary instructions dimension increased significantly in the intervention group compared to the control group after implementing the intervention. Similarly, Massah et al. showed that an educational program based on reality therapy could improve dietary behaviors in diabetic patients, aligning with the findings of this study (23).

On the other hand, the score for the drug dimension did not differ significantly in the intervention group compared to the control group after implementing the reality therapy intervention. A study by Naderyanfar et al. found that the scores for the drug behavior subscale did not increase significantly in the intervention group, which aligns with the findings of this study (24). However, Farshchi et al. found that group reality therapy was effective in improving adherence to a proper diet, exercise, drug regimen, and blood glucose control (19). Additionally, studies by Matteson and Russell, and Kreps et al. suggested that cognitive-behavioral intervention was more effective than other interventions for drug regimen adherence in patients with chronic diseases (25, 26). The differing results of these studies compared to the present study could be attributed to varying educational conditions and interpersonal differences among patients in learning, which may explain the differences in the drug behavior dimension.

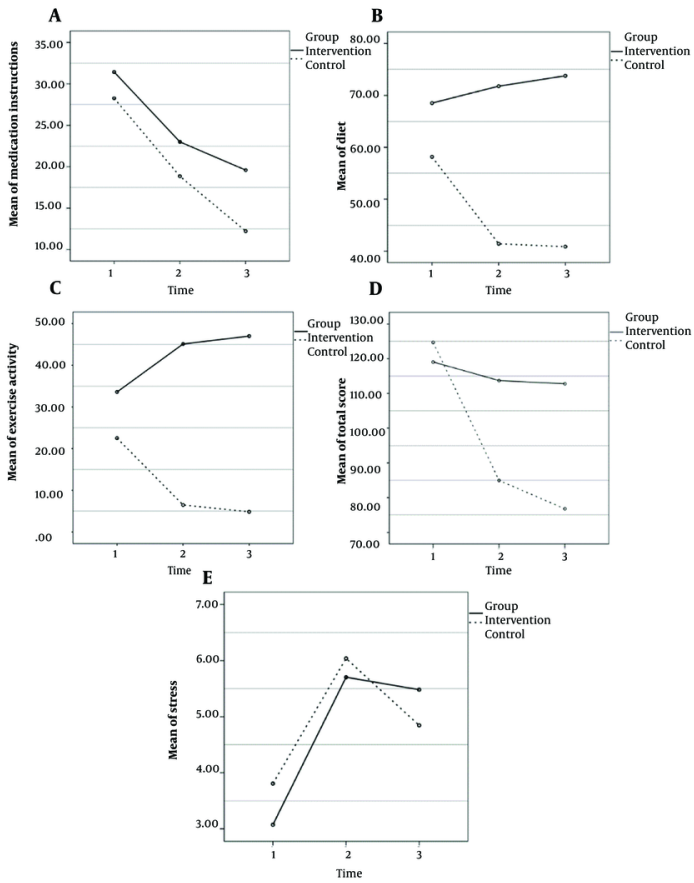

Figure 2. Chart of changes in the two groups of intervention and control in the components of compliance to treatment, including A, medication; B, diet; C, exercise, D, mean of total score; and E, stress.

The results also showed that the reality therapy training method is not effective in reducing stress in diabetic patients. In line with this finding, Fuladvandi et al. showed that reality therapy did not significantly reduce the stress levels of diabetic patients, which is similar to the present study's findings (27). Heenan et al. found that factors such as a friendly and respectful atmosphere, free expression of group sympathetic emotions, and sympathetic understanding during group therapy, with an emphasis on self-related concepts, led to a different attitude in patients compared to the beginning of the treatment course. This positive change was attributed to the therapy method, which, by establishing sympathy and deep relations among patients over sessions, allowed for better expression of their problems and increased acceptance of disease symptoms, thereby enhancing the effectiveness of the educational method in diabetic patients (28). This finding, however, does not align with the present study's results, which could be due to the socio-cultural conditions and average age of the patients.

The results of the present study also showed that FBS, triglyceride, and cholesterol levels decreased significantly in the intervention group compared to the control group after the intervention. These findings are in congruence with the findings of Tachanivate et al., Wilson et al., and Velázquez-López et al. (29-31). However, the present study also showed that HbA1c levels did not change significantly in either group before or after the intervention, indicating that reality therapy did not affect HbA1c levels in T2DM patients. In line with this finding, DiClemente showed that after the educational intervention, there was no significant difference in

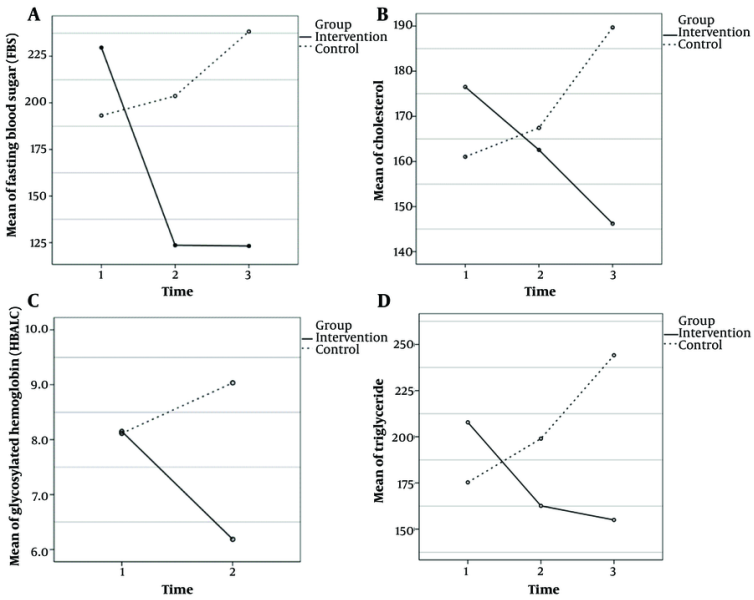

Figure 3. Chart of changes in the intervention and control groups in health indicators including A, blood sugar; B, cholesterol ; C, hemoglobin HBA1C; and D, blood triglyceride.

health indicators such as FBS and HDL, which concurs with the present study's findings (32). On the other hand, Ahmadi et al. found that training self-care behaviors by a nurse effectively reduced HbA1c levels in diabetic patients (33). This difference in findings may be attributed to the different training methods used.

It should be noted that the psychological status, as well as familial, personal, and social problems of the participants, may have affected their responses and thus the research findings. These factors were beyond the researcher's control and could limit the generalizability of these findings.

5.1. Conclusions

The present study found that reality therapy, by changing thought components and patients' understanding, could lead to improved adherence to treatment regimens regarding diet and physical activity, and improve the health indicators of T2DM patients. Thus, nurses, counselors, therapists, and clinical psychologists can use educational programs based on reality therapy to promote self-care behavior in diabetic patients. Furthermore, training experts in relevant organizations on reality therapy to hold educational workshops can be beneficial for vulnerable groups.

Acknowledgements

This paper is a part of the first author's thesis under the ethics code IR.AJUMS.REC.1398.657 from the ethical committee of Ahvaz Jundishapur University of Medical Sciences. The researcher highly appreciates the authorities of Amir-Almomenin Hospital and the participants for their cooperation in this study.

Footnotes

Authors' Contribution: All authors were involved in the design of the study. N. Z. collected the data under the supervision of K. Z., H. T., and S. Gh, were involved in data analysis and interpretation. N. Z. prepared the first draft of the manuscript. All authors read and approved the final version of the manuscript..

Clinical Trial Registration Code: The protocol of the study was registered in the Iranian Registry of Randomized Controlled Trials with the reference code: IRCT20181210041915N2 .

Conflict of Interests Statement: The second author is the journal's EIC.

Data Availability: Data of this study will be available upon the reasonable request from corresponding author.

Ethical Approval: This paper is part of a thesis composed by Negin Zangenehzadeh with the ethics code IR.AJUMS.REC.1398.657 from the research deputy of the Ahvaz Jundishapur University of Medical Sciences.

Funding/Support: All expenses for this research were provided by Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran. The funder did not have any role in the design, data collection, data interpretation, writing, or submission of the manuscript to a journal.

Informed Consent: All participants provided written informed consent prior to data collection.

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Table 4. Comparison of Trends in Health Indicators at Different Times by Groups Using Repeated Measures Test (N = 54)

Variables	Mean Square	F	P-Value	η^2
Compliance to Treatment Regimen				
Exercise activity				
Overall				
Time	86.91	1.37	0.258	0.026
Time*group	3908.89	61.69	< 0.001	0.543
Group	37965.43	196.47	< 0.001	0.791
Control				
Time	2573.79	44.81	< 0.001	0.633
Intervention				
Time	1422.01	20.53	< 0.001	0.441
Diet				
Overall				
Time	739.64	25.72	< 0.001	0.331
Time*group	2059.39	71.62	< 0.001	0.579
Group	24420.50	9415.86	< 0.001	0.887
Control				
Time	2608.75	160.76	< 0.001	0.861
Intervention				
Time	190.27	4.61	< 0.001	0.151
Stress				
Overall				
Time	82.78	15.74	< 0.001	0.236
Time*group	6.57	1.25	0.291	0.024
Group	3700.70	0.07	0.790	0.001
Medication instructions				
Overall				
Time	2691.16	53.26	< 0.001	0.506
Time*group	65.15	1.29	0.280	0.024
Group	971.23	7.45	0.009	0.125
Total score				
Overall				
Time	11353.04	57.91	< 0.001	0.527
Time*group	6671.67	34.03	< 0.001	0.396
Group	15730.06	36.34	< 0.001	0.411
Control				
Time	17715.27	119.14	< 0.001	0.047
Intervention				
Time	309.44	1.27	0.289	0.821
Health Indicators				
FBS				
Overall				
Time	31621.93	21.49	< 0.001	0.292
Time*group	84941.23	57.71	< 0.001	0.526
Group	113340.89	7.05	0.010	0.119
Control				
Time	15013.79	32.239	< 0.001	0.554
Intervention				
Time	101549.37	40.98	< 0.001	0.612
Triglyceride				
Overall				

Variables	Mean Square	F	P-Value	η^2
Time	4785.97	2.37	0.098	0.044
Time*group	50251.39	24.90	< 0.001	0.324
Group	39013.56	1.702	0.198	0.032
Control				
Time	33002.75	11.02	< 0.001	0.298
Intervention				
Time	22034.61	21.18	< 0.001	0.449
Cholesterol				
Overall				
Time	213.43	0.621	0.539	0.012
Time*group	12107.19	35.24	< 0.001	0.404
Group	4867.56	1.03	0.315	0.019
Control				
Time	6112.38	22.49	0.135	0.464
Intervention				
Time	6208.24	14.95	< 0.001	0.365
HBA1C				
Overall				
Time	8.96	20.19	< 0.001	0.280
Time*group	61.20	138.02	< 0.001	0.726
Group	51.95	7.53	0.008	0.127
Control				
Time	11.67	82.02	< 0.001	0.759
Intervention				
Time	58.49	78.55	< 0.001	0.751