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Effect of Theory-Based Individual Counseling on Physical Activity and Glycemic Control in Patients with Type 2 Diabetes Mellitus: A Quasi-Experimental Study

Rabiollah Farmanbar [1], Isa Mohammadi Zeidi [2] and Abolhassan Afkar [1, *]

[1] Social Determinants of Health Research Center (SCHRC), Guilan University of Medical Sciences, Rasht, Iran
[2] Associate Professor, Department of Public Health, Qazvin University of Medical Sciences, Qazvin, Iran

[*] *Corresponding author*: Social Determinants of Health Research Center (SCHRC), Guilan University of Medical Sciences, Rasht, Iran. Tel: +98-9112369537, Fax: +98-1333825567, Email: hasanafkar@yahoo.com

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Abstract

Background: Theory-based individual counseling interventions targeting physical activity that produce glycemic control in patients with type 2 diabetes mellitus are warranted. However, little is known about how caregivers should support patients with type 2 diabetes to achieve and sustain a physically active lifestyle.
Objectives: The aim of the present study was to determine the effect of theory-based individual counseling on promoting physical activity and glycemic control in type 2 diabetic patients.
Methods: This quasi-experimental study was conducted from March to September 2016 in Tonekabon, Iran. Using a simple random sampling method, 80 patients, with type 2 diabetes, who were members of the Iranian Diabetes Association were assigned to experimental and control groups. The patients in the experimental group participated in a four-week educational program that included a 90-minute general education session and a 40-minute individual counseling session. The control group did not receive any training program. All the patients were evaluated at a base time, 12 and 24 weeks follow up for demographic data, clinical measures, stages of Change Scale, and a seven-day Physical Activity Recall Questionnaire (PAR).
Results: Individual counseling interventions showed statistically significant increases in HBA1C of patients in the experimental group (from 8.54 $\pm$ 1.35 to 7.73 $\pm$ 1.25) compared to those in the control group (from 8.57 $\pm$ 1.38 to 8.51 $\pm$ 1.43) at 24-weeks follow-up ($P < 0.001$). There was a significant increase in the physical activity of patients in the experimental group (From 224.6 $\pm$ 19.7 to 244.6 $\pm$ 12.9) compared to those in the control group (from 226.3 $\pm$ 17.4 to 231 $\pm$ 11.1) at 24-weeks follow-up ($P < 0.001$).
Conclusions: This study confirmed that education based on the Stages of Change Model and individual consulting can be used as a framework to increase physical activity and improve metabolic profile in type 2 diabetic patients.

Keywords: Body Mass Index, Control, Counseling, Glycemic, Physical Activity, Type 2 Diabetes Mellitus

1. Background

Type 2 diabetes mellitus (T2D) is one of the most critical health problems worldwide associated with high morbidity and mortality, and its prevalence increases every year (1, 2). Research has shown that T2D can severely affect the patient's quality of life due to a long-term complications such as renal, retinol, neurological, cerebrovascular, and coronary artery diseases, which mostly result from poor glycemic control and unhealthy lifestyle (3). It is estimated that the direct costs of diabetes, including medical care and indirect costs specifically related to disability and premature death to be ~99 billion dollars annually worldwide (4). Currently, 3% - 5% of the population in the Islamic Republic of Iran have diabetes. Furthermore, currently more than six million people are at risk of developing diabetes due to unhealthy lifestyles (5). It is also predicted that the number of diabetic population in Iran will reach nine million in 2020, and the country will see a three fold increase in the number of diabetic people over the next 15 years (6, 7). For many years, the combination of exercise, dietary modifications, and hypoglycemic medications has been used as the standard diabetic treatment protocol by specialists. Moreover, many studies have also shown that regular physical activity can reduce the risk of developing diabetes-related complications (8, 9). Dutton and Lewis showed that interventions to modify lifestyle are an ideal option for patients with T2D who want to slow

down the progress to multiple drug therapies. This is due to the fact that such an approach can positively affect physiological function and quality of life in such patients (10). In addition, the finding by Breeze et al. (11), suggested that preventive interventions based on risk identification and lifestyle modification in patients with T2DM are cost-effective. Thus, exercise on a regular and specific pattern should be part of the main strategy to manage patients with T2D (12).

In addition to voluntary regular exercise, Jackson et al. (12) indicated that providing individual counseling sessions by medical professionals, along with information pamphlets, had a greater impact to change exercise behavior and health outcomes in T2D patients compared with manuals or booklet on exercise alone. The patients' willingness and motivation to change current behaviors is the first step to initiate a regular exercise program. However, many behavior intervention programs tend to omit this important issue. Therefore, diabetic patients are often provided by a standard training package regardless of their readiness to start such an exercise program. This type of approach fails to acknowledge individuals psychological, social, and personality conditions that affect physical activities (13, 14). As such, different behavior models and psychological theories have been used to determine and understand the factors that influence exercise behavior (15, 16). Transtheoretical model (TTM) is one of the best known and prestigious models to implement the educational program for behavior change and maintenance such as promoting physical activity in diabetic patients (17). In this model, it is assumed that anyone consciously wants to change their old behavior, which is not a sudden event, however it occurs in a series of phases or stages. In the past decade, TTM has been frequently used in various studies, especially in health education such as smoking, alcohol abuse, substance addiction, obesity, physical activity, oral health, and so on. (18). This model is a complete and coherent model explaining the attitude or timing of behavioral changes. TTM provides a rational framework to understand the process of changes. Previous research has shown that patients need to go through a series of predictable steps to change previous habits and start the recommended behaviors. TTM helps understand when individuals are ready to change (stages of change), how to weigh the pros and cons of such change (decision Balance), how to overcome the temptation to prevent the changes, e.g. self-confidence, environmental factors, and actual/perceived barriers (perceived self-efficacy). Therefore, TTM consists of four constructs: Stages of change, decision balance, perceived self-efficacy, and process of changes.

TTM has been used by Marcus et al. (19), to change physical activity in T2D patients, which showed that the patients who were exposed to TTM based education had a higher physical activity level compared with the control group. Moreover, the findings of Kim et al. (20), indicated that T2D patients participating TTM based counseling reported higher levels of change and physical activity compared with the control group. In addition, studies have suggested that preventative programs to induce weight loss at early stages of diabetes can be more effective to improve glycemic control and prevent the complications of T2D (21, 22). Most of the TTM studies have focused on the behaviors of adults from Western countries. These studies have demonstrated the existence of a significant relationship between physical activity and the TTM constructs (22, 23). There is evidence of cultural variation in style, the meaning of activity, and psychological constructs. Therefore, it is imperative to determine the external validity of those research findings before adopting findings across nations and cultures (24).

2. Objectives

This study fills a critical void in our knowledge and will help determine the efficacy of the TTM to explain physical activity among patients with type 2 diabetes. Specifically, the aim of this study was to investigate the effect of a stage-matched counseling on the improvement of physical activity and glycemic control in T2DM patients.

3. Methods

3.1. Setting

This is a quasi-experimental study conducted in the city of Tonekabon, the northern part of Iran. Diabetic patients who were in inactive stages (pre-contemplation and contemplation) were randomly selected from the member list of the Iranian Diabetes Association.

3.2. Study Participations

This study included 80 patients with type 2 diabetes who were selected from March to September 2016 from the member list of the Iranian Diabetes Association, and agreed to participate in the study. All the participants were subsequently divided randomly into experimental and control groups (n = 40).

This study was approved by the Human Ethics Committee of Qazvin University of Medical Sciences. Prior to the intervention, the objectives were explained to all patients who signed a consent form to voluntarily participate in this study. All questionnaires were anonymous and the patients were assured of the confidentiality of their medical information.

3.3. Inclusion Criteria

Inclusion criteria were as follow: Type 2 diabetes with a regular specialist visit, diagnosed less than two years, with at least two markers above the normal range (blood glucose, HBA1C, BMI, blood lipid, heart rate, blood pressure, heart rate), in the precontemplation and contemplation stage according to the stages of changes algorithm, age 30 - 50 years, and willing to participate.

3.4. Exclusion Criteria

Exclusion criteria for this study were as follows: Patients having mental illness or a history of psychiatric disorders, cardiovascular complications preventing them from daily physical activity, diabetic foot ulcers, other medical conditions in addition to type 2 diabetes such as cancer, rheumatoid arthritis, and chronic back pain, as well as already having regular exercise.

3.5. Sample Size

The sample size was calculated using the formula quasi-experimental survey (23) with a margin of error equal 0.05% and 10%, and an expected power of 90%, and a Z value of 1.96. The mean ± SD in the education group was 8.65 ± 1.74 (mean ± SD) and 7.74 ± 1.58 (mean ± SD) in the control group. Moreover, it was calculated that a sample of 40 patients in each group was required; thus, 80 type 2 diabetic patients were selected to participate in the study.

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 \left(s_1^2 + s_2^2\right)}{d^2}$$

3.6. Instruments

Several tools were used to collect the data.

A demographic questionnaire was used for age, gender, education level, and family history of T2D diabetes, employment status, and marital status, medication for blood lipid and blood pressure control, and number of children.

Blood pressure was measured twice with a few minutes interval and the average of both measurements was recorded (25-27).

Heart rate was measured according to the carotid pulse for one minute by a trained physician. A digital scale with a margin of error of less than 100 g was used to measure the body weight. The participants were in light clothing and without shoes. Height was measured by a measuring tape attached to the wall with an accuracy of 0.1 cm in the standing position. BMI was calculated using weight (kg/height (m^2)).

Overnight fasting blood samples were taken from all patients at the baseline, 12 weeks and 24 weeks after the intervention. Fasting blood glucose was measured by the glucose oxidase method.

HBA1cC triglycerides, and cholesterol was measured using the enzymatic colorimetric method and Roche commercial kites. LDL and HDL was evaluated by enzymatic colorimetric method using Roche Cobas kites. Insulin was measured by a chemiluminescence method (24, 28).

A Stages of Change Scale was used to determine the patient's readiness to change current physical activity behavior. A Physical Activity Stage of Change Questionnaire (PASCQ) for Diabetic patients is a binary form scale (yes/no responses). The patients were divided into five different groups according to their scores of the PASCQ. The reliability of the PASCQ has been well validated in previous studies (29, 30). However, the Persian version of the PASCQ was completed by 20 diabetic patients, twice, within two weeks to assess the test-retest reliability. Test-retest reliability of the Persian version of PASCQ was high (ICC = 0.83). Those patients were excluded from the final study.

The amount of physical activity and energy consumption were assessed by a 7-day Physical Activity Recall Questionnaire (PAR) (Sallis et al.) (31, 32). The 7-day PAR is a semi-structured interview asking the patients to recall their daily physical activity duration and intensity (based on changes in heart rate compared with walking and jogging), types of activity, and the amount of energy consumed in the last seven days week according to the instructions of the questionnaire. The 7-day PAR Questionnaire was validated in several studies by calculating the correlation coefficient between the physical activity, maximum oxygen uptake, heart rate, and body fat percentage (33, 34).

The reliability of 7- day PAR questionnaire has been shown in different studies to have an Intraclass Correlation Coefficient (ICC) ranging between 0.34 and 0.99 (33, 34). In this study, the reliability of PAR was evaluated using the test-retest method and its correlation coefficient was 0.79. A 90-minute educational session was conducted in 7 - 10 groups of patients. During the session, the benefits of regular physical activity, appropriate amount of physical activity, suitable types of physical activity for T2D patients, and the measures of physical activity were explained to the pa-

tients. The exercise test was performed separately for each patient.

3.7. Interventions

A total of three individual educational counseling sessions were provided to each patient. The Counseling session was conducted according to the -5 A's Behavior Change Model. The 5 A's is based on Behavioral Change Theory such as behavior modification, self-efficacy enhancement, readiness evaluation, and self-management support. This model includes five elements, which are assess, advice (receiving scientific advice), agree (goal setting), assist (receiving scientific assistance), and arrange (setting up the next meeting). The main purpose of this model was to improve the care for chronic illness (35, 36). The first session was set up with the aim of eliminating the cons and enhancing the pros. The five steps implemented in this session were:

1. Assess step (assessment of blood pressure, heart rate, type and amount of medications).

2. Advice step (explaining the benefits of physical activity, appropriate physical activity (in terms of intensity, duration and interval), and a variety of physical activities suitable for diabetic patients).

3. Agree step (the patient wrote down a list of obstacles and benefits of physical activity and prioritize them).

4. Assist steps (the booklets containing the benefits of physical activity were given to the patients. Problem–solving process was used to remove the perceived barriers).

5. Arrange step (patients set up the day and time of the second consultation).

The second session aimed to increase family support and strengthen supportive social relationships, which was carried out in the same way as the first session. In this session, diabetes and exercise booklets were given to the patients. Serious consequences of diabetes, their effects on physical and mental health, the causes of diabetes, and regular physical activity as a low-cost and effective strategy to prevent diabetes were discussed in this booklet.

The third session aimed to promote self-efficacy. A CD containing information of appropriate physical activity for diabetic patients, how to prepare the body before exercise, the correct timing of exercise, stretch and relax, and other essential items for exercise was given to the participants. Each session lasted for ~40 minutes. The interval between the first session and the second session was a week, and that between the second and third session there was a two-weeks interval, Stages of Change Scale and 7-day PAR were completed by all patients prior to, and at 12 and 24 weeks post after the intervention. This training program was not provided to the control group; they were, however, provided with a 60-minute diabetes self-care training class along with educational CD and booklets.

3.8. Statistical Analysis

All the statistical analyses were performed using the SPSS statistical software Version 22.0 (IBM Corp., Armonk, N.Y., USA). The Kolmogorov-Smirnov test was also used to describe the normality of the variables and followed by parametric tests. ANOVA, with repeated measures, was used to analyze the differences between the groups in terms of the amount of physical activity. Mann-Whitney U test was used to check the stages of change. The Friedman test was used to analyze the progress of patients' readiness to modify their physical activity behavior in different stages. P value < 0.05 was considered as statistically significant.

4. Results

The mean age of the subjects in this study was 46.8 ± 11.4 years and 72.5% of them were female. The average number of the children was 2.9 ± 2.1. In addition, 93.8% of the patients were married and 37.5% were employed. There were significant differences between female and male patients in terms of employment status, and all of the unemployed participants were female ($P < 0.001$). About 38.8% of the patients had a high school education or diploma and only 7.5% had tertiary education. At least 18.8% of the patients reported having at least one immediate family member with a history of T2D. The results showed an increase in BMI (80.6%), abnormal FBS (73.4%), and HBA1C (66.1%) compared to the other variables. Table 1 does not show any significant differences between the two groups in all parameters before the intervention, which, except for the HDL and Triglyceride, were significantly improved in the experimental group after the intervention ($P < 0.05$). Moreover, there was a significant decrease in BMI (54.5%), abnormal FBS (60.1%) and HBA1C (52.7%) in the experimental group after the theory-based education.

The changes in physical activity derived from 7- day PAR questionnaires at baseline, 12 and 24 weeks after intervention are shown in Table 2. There were significant changes in the amount of physical activity over the time in the experimental group ($P < 0.001$), however, not in the control group ($P = 0.442$). At the baseline, there were no significant differences in the level of physical activity between experimental and control groups ($P < 0.25$). Whereas, there were

Table 1. The Comparison Among Health Condition in the Experimental and Control Groups at Baseline, 12 and 24 Weeks After the Intervention

Patients Group	Baseline	Week 12	Week 24	Repeated Measure P Value
BMI (kg/m^2)				
Experimental	26.6 ± 4.3	25.4 ± 4.0	25.4 ± 4.2	< 0.001
Control	26.6 ± 4.1	26.5 ± 4.3	26.5 ± 4.0	1
FBS (mg/dL)				
Experimental	170.6 ± 49.2	156.5 ± 41.3	157.2 ± 42.1	0.002
Control	172.4 ± 51.0	169.8 ± 49.7	170.5 ± 50.8	0.426
HBA1C				
Experimental	8.54 ± 1.35	7.77 ± 1.22	7.73 ± 1.25	0.036
Control	8.57 ± 1.38	8.49 ± 1.43	8.51 ± 1.43	0.890
Triglyceride (mg/dL)				
Experimental	187.3 ± 72.5	180.1 ± 74.8	173.7 ± 86.3	0.083
Control	185.5 ± 74.7	184.8 ± 74.9	182.2 ± 76.0	0.288
LDL (mg/dL)				
Experimental	115.4 ± 32.6	92.0 ± 26.2	92.7 ± 28.4	0.011
Control	116.1 ± 34.0	111.8 ± 33.1	108.9 ± 35.6	0.537
HDL (mg/dL)				
Experimental	47.7 ± 9.76	44.6 ± 9.11	44.2 ± 9.32	0.107
Control	48.4 ± 8.88	46.3 ± 9.00	46.3 ± 9.19	0.319
BP (mmHg)				
Experimental	131 ± 16	124 ± 15	123 ± 16	0.0004
Control	130 ± 16	131 ± 16	131 ± 15	0.631
Heart rate (per minute)				
Experimental	71 ± 9	64 ± 7	65 ± 8	0.028
Control	70 ± 9	71 ± 9	71 ± 9	0.438

Abbreviations: BMI, body mass index; BP, blood pressure; FBS, fasting blood sugar; HBA1C, hemoglobin H1C; HDKL, high-density lipoprotein; LDL, low-density lipoprotein.

significant differences in the level of physical activity between experimental and control groups in 12 and 24 weeks after the intervention ($P < 0.001$).

Table 3 indicated that a larger proportion of T2D patients in the experimental group were in preparation, action, and maintenance stages compared with the control group 12 and 24 weeks after intervention ($P < 0.001$). Majority of the changes occurred in the pre-action stages, in particular in the Preparation stage. Additionally, only five patients (12.5%) were in the Action stage at the 12 weeks follow-up. Furthermore, four (10%) and one (2.5%) patients in the control group reported being at the action and maintenance stage at 24 weeks after the intervention, respectively. In contrast with the experimental group, 19 (47.5%) patients progressed to the Action stage at 12 weeks; while 28 (70%) and 3 (7.5%) patients progressed to the Action and Maintenance stages in the 24 weeks after intervention.

5. Discussion

The present quasi-experimental study showed that the theory-based education induced positive changes in physical activities. It could also reduce BMI, FBS, HBA1C, LDL, BP, and heart rate and improved HDL in the T2D, which may have important implications in both public health and clinical practices. Many studies have reported that knowledge of nutrition and dietary behavior in patients who have participated in diabetes educational programs have improved. As a result, there was an increase in the intake of vitamins, a reduction in the fat intake, and an improvement in the clinical outcomes such as lowered blood levels of glucose, HBA1C, cholesterol, and triglycerides (37, 38). In addition, the reduction of the FBS and HBA1C in the current study suggests that the improved glycemic control in the intervention group was similar to previous stud-

Table 2. The Comparision of Physical Activity Status in the Experimental and Control Groups at Baseline, 12 and 24 Weeks After the Intervention[a]

Time of Measurement	Experimental	Control	P Value Independent *t*-Test
Baseline	224.6 ± 19.7	226.3 ± 17.4	0.25
Week 12	246.1 ± 13.5	228.7 ± 11.5	0.000
Week 24	244.8 ± 12.9	231.0 ± 11.1	0.000
P value repeated measure	0.0	0.442 ±	

[a] Values are expressed as Mean ± SD.

Table 3. The Comparision Stages of Change in T2D Patients at Baseline, 12 and 24 Weeks After the Intervention

Stage	Baseline	Week 12	Week 24	P Value Friedman
Experimental				0.001
Precontemplation	25 (62.5)	1 (2.5)	1 (2.5)	
Contemplation	15 (37.5)	6 (15)	1 (2.5)	
Preparation	0	15 (35)	7 (17.5)	
Action	0	19 (47.5)	28 (70)	
Maintenance	0	0	3 (7.5)	
Mean of rank	31.84	45.03	45.82	
Control				0.000
Precontemplation	27 (67.5)	14 (35)	8 (20)	
Contemplation	13 (32.5)	13 (32.5)	14 (35)	
Preparation	0	8 (20)	13 (32.5)	
Action	0	5 (12.5)	4 (10)	
Maintenance	0	0	1 (2.5)	
Mean of rank	32.05	23.3	24.5	
P value Mann-Whitney U test	0.641	0.000	0.000	

[a] Values are expressed as No. (%).

ies in T2D patients using a similar interventional approach (30, 38-40). Furthermore, some studies have shown that counseling programs resulted in improved lipid and glucose metabolism, which plays an important role in the prevention of short- term and long-term complications in diabetes, and led to improved quality of life (41, 42). In fact, interventions may increase the level of awareness in the patients, which in turn, strengthens their problem-solving ability. However, it seems that the differences in the impact of interventions on clinical outcomes may be due to demographic differences such as education level.

Since HBA1C is a measure of glycemic control in the last 12 weeks, continuing education using feedback mechanisms such as SMS or brief telephone counseling may more effectively improve HbA1c reading. Moreover, the intervention here significantly decreased blood LDL level. Jalilian et al. (30), showed that stage-matched intervention on physical activity resulted in significant improvements in lipid metabolic factors such as cholesterol, LDL, and HDL. Moreover, a significant reduction in LDL, total cholesterol, and triglyceride levels were observed in the study of Ryan et al. (43). Although the reduction in triglyceride and HDL was not statistically significant in this study, the level of change is clinically noteworthy and may significantly improve the cardiovascular complications. However, it suggests the insufficient duration of education in this study.

The participants in the intervention group in our study showed significant improvement in anthropometric markers. A significant reduction in BMI is consistent with the study of Shabbidar et al. and Lemon et al. (25, 38). In addition, Bello et al., showed that consultation with pharmacists on lifestyle change, medication adherence, and self-medication led to a reduction in BMI of T2D patients. Other studies have emphasized that overweight and obesity are major risk factors in the development of insulin resistance (26, 27). Overweight and obesity result in the complica-

tions of diabetes such as cardiovascular disease. The ideal BMI management plays an important role in the interventions among T2D patients. In this study, blood pressure and heart rate in the intervention group were improved, which is consistent with previous studies (37, 44, 45). This may be the result of strengthening the planned intervention through the incorporation of essential knowledge, urgent skills such as self-care behavior, which has an important role in controlling clinical, metabolic, and glycemic variables.

In addition, the intervention increased moderate physical activity in the experimental group, which was 5 hours and 35 minutes and 5 hours and 5 minutes every week at 12 and 24 weeks, respectively. At the same time, in the control group moderate physical activity per week was 36 minutes and 71 minutes at 12 and 24 weeks, respectively. Therefore, the amount of daily physical activity in the experimental group was more than the recommended period. Previous studies also showed that health education programs based on Social Cognitive Theory or Health Promotion Model can lead to an increase in the physical activity among women with T2D (46). The physical activity of their participants was increased from 42 to 61 minutes per week after six months of intervention. In another study conducted using the 5'A method based on Pender's health promotion model in elderly patients it was shown that their physical activity (according to maximum oxygen uptake) was significantly improved after five sessions of individual counseling (47). Taymoori et al., emphasized that if the intervention is based on the Stages of Change model, it can improve physical activity (48).

In this study, after three months of education, 48% of the T2D patients in the experimental group were in the Action Stage as against 12.5% in the control group. This finding is similar to the study by Jalilian et al. (30), where 4% and 44% of diabetic patients in the control and experimental groups entered Action Stage, respectively. Other studies also have reported a positive impact of stage-matched education on promoting the T2D patients from Inactive stage to Active stage (49). Mohsen et al. (50), conducted a quasi-experimental study to investigate the effect of Transtheoretical Model-based lifestyle modification on the mothers of diabetic children (50). In a two month follow up, 30% and 70% of the patients in the experimental group entered Action and Maintenance stages while only 4% of the patients in the control group reported Action stage. Similarly, in the current study, fewer patients were in the inactive stage (Precontemplation and Contemplation stages) and more patients were in later stages such as Action and Maintenance stages in the intervention group in comparison to the control group, indicating the positive effect of the TTM based educational program. In addition, previous studies have concluded that tailored educational interventions based on the stage of readiness for change are more likely to succeed (20, 30, 49, 50). A review of 16 clinical trials, based on Stage of Change Model, revealed that low success rate is often reported in the studies that have used only a constant and uniform type of educational program. Thus, any educational programs should be tailored to the Stage of Change according to the specific needs of patients in each stag (51). In fact, many stage-matched interventions are more effective in achieving behavior change. Therefore, this study provides evidence-based proof that theory-based intervention can help T2D patients allocate more time for physical activity after education.

5.1. Study Limitations

Despite the above-mentioned evidence, the conclusion still needs be cautiously interrupted due to the fact that the other aspects of TTM, such as self-efficacy, social support, and outcome expectancy have not been evaluated in this study.

5.2. Conclusions

In summary, the theory-based education program exerts a significant effect to increase physical activity and results in the improvement of anthropometry parameters in T2D patients in the long term. The results support the implementation of such educational interventions emerged from Stages of Change Model as a routine care for T2D patients.

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Footnotes

Authors' Contribution: Abolhassan Afkar: Data collection, study concept and design, and drafting of the manuscript; Rabiollah Farmanbar: Study supervision, study concept and design, and critical revision of

manuscript for important intellectual content, administrative technical and material support; Isa Mohammadi Zeidi: Analysis and interpretation of data.

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