ISSN: 2345-2897; Health Education and Health Promotion. 2022;10(4):805-812.

Effect of the Continuity Self-Preservation Model on Compliance with the Care-treatment Regimen and Its Consequences in Patients with Type 2 Diabetes

ARTICLE INFO

Article Type
Original Research

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How to cite this article
Mohammadi E, Pournamdar Z, Vahedparast H, Kazemnejad A. Effect of the Continuity Self-Preservation Model on Compliance with the Care-treatment Regimen and Its Consequences in Patients with Type 2 Diabetes. Health Education and Health Promotion. 2022 ;10(4):805-812.

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Article History
Received: September 24, 2022
Accepted: December 1, 2022
ePublished: December 1, 2022

ABSTRACT

Aims Failure to comply with the treatment plan is a challenge and a problem to control chronic diseases. The present study aimed to evaluate the effect of the continuity self-preservation model on compliance with the care-treatment regimen in patients with type 2 diabetes.

Materials & Methods This quasi-experimental clinical trial study was performed on 80 patients with type 2 diabetes (intervention and control groups) admitted to a hospital in Zahedan, Iran, from 2020 to 2021. Questionnaires and blood samples were used as data-gathering methods. The intervention program was designed and implemented based on the self-preservation continuity model. The dependent variables were then assessed during a four-stage period. Descriptive and inferential statistics were used in SPSS 9 software to analyze the data.

Findings Before the intervention, there was no significant difference in the two groups. However, there was a significant difference in the mean scores of compliance with treatment, quality of life, health belief, and mean glycosylated hemoglobin after the intervention between the two groups (p=0.001).

Conclusion The self-preservation continuity model is effective in metabolic control and compliance with the treatment of diabetic patients.

Keywords Self Care; Diabetes Type 2; Treatment Adherence and Compliance; Quality of Life

CITATION LINKS

[1] Nationwide prevalence of ... [2] Poor adherence to treatment ... [3] Patient adherence to medical ... [4] The patient-provider relationship ... [5] Patient adherence to ... [6] The process of concordance ... [7] Effects of an outpatient diabetes ... [8] The summary of diabetes self-care ... [9] Questionnaire of diabetes self-care ... [10] Compliance with the treatment ... [11] An application of health behaviour ... [12] The self-care and its related ... [13] Telephone intervention to improve ... [14] The relationship between ... [15] Effect of a brief, regular ... [16] The relationship between ... [17] Role of cultural and psychological ... [18] Effectiveness of self-management ... [19] The role of coping with disease ... [20] Illness perception of Type 2 ... [21] Assessing self-management ... [22] Development of diabetes-specific ... [23] Psychometric properties ... [24] Perceived severity and ... [25] Treatment adherence in diabetic ... [26] Medication adherence ... [27] Adherence to treatment ... [28] The importance of health ... [29] Coping styles and self-care ... [30] Influence of patients' ... [31] The relationship between ... [32] The relationship between ... [33] The relationship between ... [34] Factors associated with ... [35] A nurse-led inpatient ... [36] An explanatory randomised ... [37] The role of education ...

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Introduction

Diabetes mellitus is one of the most important metabolic diseases worldwide by an alarming prevalence, which has increased by 50% over the past 10 years [1]. The global prevalence of diabetes in 2019 was 9.3% (463 million people) which it is estimated to reach 10.2% (578 million people) in 2030 and 10.9% (700 million people) by 2045 [2]. In a study conducted from 2014 to 2020 on participants aged 35 to 70 years among different Iranian races, 15% of the adult population were diabetic, and more than 25% of them were pre-diabetic [2].

Diabetes patients often do not follow their treatment plan, which makes blood sugar management challenging [3]. The interplay of numerous elements or dimensions determines treatment adherence, which is a multidimensional phenomenon [4]. The ultimate goal of any recommended treatment is to achieve the desired outcome for the patient. While despite all the attention and efforts made by the healthcare team, if the patient does not adhere to the treatment, this will not be achieved [5].

Despite the scientific efforts and application of various theories and programs of professional interventions, nursing, and non-nursing, it has been reported that there is still a lack of adherence, as a challenge and problem, to control chronic diseases, which is a major expanding obstacle to achieving therapeutic goals. On the other hand, although non-compliance is a universal phenomenon, it does not have a fixed, common, and equal nature, as it is unique for individuals and social and is a completely contextual phenomenon, and even has a different nature and function in different diseases and patients, so that it cannot be explained and addressed by fixed and uniform theory, model or formula and program all over the world [3].

Thus, Vahedparast [6] conducted a study to design an effective model and intervention based on this model to promote compliance with care-treatment regimens in the patient's social life. They developed an emergency-based self-protection approach in which patients with chronic illness used to live, which is the leading cause of noncompliance with care-treatment regimens among individuals with chronic diseases. Considering that most cases of this disease have no obvious symptoms or consequences, patients do not feel threatened. This fear is superficial and periodic, which could be the main identified root causes of hesitation and failure in accepting adjusted behaviors and failure to comply with care-treatment regimens. According to these findings, they designed and presented a “continuity of self-preservation model”. They argue that self-preservation is not static, but a dynamic process and should be initiated at the beginning of a person's awareness of their chronic illness and be accompanied by a conscious and active search for the patient and the support and participation of nurses and other health professionals in the process of compliance with care-treatment regimens, leading to the best behavior in line with care-treatment regimens compliance. This model introduces the idea of a mediator notion termed a motivator, which is crucial for sustaining behavioral stimulus and motivation. It is possible to identify and use the support resources of their living environment (spouse, family, supportive spouses, peers and role models, and care-treatment team) to further advance the process of continuing self-protection.

The ultimate goal of this model is to continue the self-preservation of individuals with chronic diseases in compliance with care-treatment regimens, and strategies to optimize and maintain the recommended regimens are presented [6]. Therefore, this research aimed to design and evaluate an intervention program to improve compliance with treatment in patients with diabetes (one of the most common chronic diseases) based on the self-preservation continuity model.

Materials and Methods

Study design

This study is a quasi-experimental clinical trial in which the study population was patients with type 2 diabetes admitted to the internal wards of two hospitals in Zahedan (Iran) from 2020 to 2021. Randomization was not possible due to the limited number of specific treatment centers for this disease (two centers).

Samples and research environment

The sample size was determined based on the findings of a prior research [7]. With a 95% confidence interval and a 95% test power, 40 individuals were identified for each group, totaling 80 individuals. One treatment center was selected as the research environment for the intervention group, and another center was selected for the control group. Inclusion criteria were as follows: having at least a compliance with the treatment-care regimen using a questionnaire and blood test, age of at least 30, access to smart phone for patient or informal caregiver (family).

Collecting data

Data collection tools in this study included the following:

Summary of Diabetes Self-Care Activities (SDSCA) Scale: This scale was first designed by Toobert and

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Glasgow, and then Toobert *et al*. [8] modified it. Numerous studies in different countries, including Iran, used this tool to examine the compliance with self-care behaviors and treatment regimen in patients with diabetes [7, 9-21].

This scale is an accurate 12-item self-report instrument that looks at five aspects of a diabetes treatment plan (diet, exercise, proper tablet intake, self-monitoring blood sugar levels, foot care, and smoking). This tool is scored on a seven-choice scale from 0 to 7. The total score on the scale is 0 to 77. A score of 0 to 22 is considered a poor score. The internal consistency method was used to calculate the reliability, and Cronbach's alpha for the self-care activity scale was 91%.

Diabetes – Mellitus Specific Quality Of Life (DMQOL): This questionnaire was first developed to assess health-related quality of life in patients with diabetes in Taiwan based on the World Health Organization Quality of Life Scale Brief Version (WHOQOL) [22]. Saffari *et al*. [23] translated it into Persian, and based on its psychometric properties, they concluded that it is an appropriate instrument for evaluating the quality of life of diabetic patients in Iran. This questionnaire has four dimensions, including Satisfaction with one's condition, the impact of diabetes on a person's life, concerns related to diabetes and social and occupational concerns. A higher score on this instrument, which bases its options on the Likert scale, implies more unhappiness with life quality [23]. The researcher evaluated the reliability of this questionnaire with Cronbach's alpha of 84%.

Diabetes Specific Health Beliefs Scale: This scale is used to assess the perceived sensitivity and severity of complications of diabetes. This tool was used by Sharifabad and Rouhani [24], which is a translation of the Lewis and Bradley Diabetes Specific Health Beliefs Scale. This scale contains 20 questions. The achievable score in these structures is from 0 to 40 [24]. Cronbach's alpha was estimated in the perceived sensitivity section as 85%, for the perceived severity section was 92%, and for the total questionnaire was 73%.

Glycosylated hemoglobin: Glycosylated hemoglobin levels in the patient were measured twice, before and after the intervention. In a regulated and certified laboratory, HbA1C was also determined using a specific test kit.

Procedure

Following obtaining the necessary permits, the researcher implemented the designed program (based on the model) to improve the cognitive structure of the nurses working in the ward.

The approach of cognitive structure improvement is performed in three dimensions: 1) health care providers (nurses), 2) patients, and 3) patients' families. In this regard, first, a training program for nurses working in the intervention group was held in 3 sessions. Nurses were asked to consider the issues raised during the hospitalization of patients in the ward, discharge time, and during education programs. Patients were sampled once the nurses had finished their training. Blood was drawn with the patient's permission to test for glycosylated hemoglobin. The patient's treatment compliance questionnaire was filled out, and based on the predetermined criteria, patient was assigned to either the intervention group or the control group. The purpose of this stage in the intervention group was to modify the cognitive structure of patients to keep them sensitive in symptomatic and asymptomatic conditions and to create sensitivity to the hidden long-term effects of diabetes (such as heart attacks, strokes, wounds, amputations, blindness, etc.). For this purpose, first, a WhatsApp group of participants in the intervention group was by the researcher.

During the research, at least two educational messages containing educational items on diabetes self-care in the areas of diet, physical activity, medication use, related complications to diabetes, and its management were sent to the group by the researcher daily. Furthermore, warning messages related to complications (text or video messages) were sent every day both in groups and individually to the participants to keep them alert and sensitive to continue. The development of self-preservation skills in patients is a dimension related to the modification of the cognitive structure in this model. So in the following stage, training materials, including information about diabetes and self-care activities for disease control were held separately for patients in the group. To improve the cognitive structure of the family (one of the dimensions of the self-protection model), virtual groups of caregivers were formed, and educational materials and messages were sent to this group. During this time, the control group, from another hospital, received routine care. To assess the effect of the intervention, the scales of diabetes-related self-care activities and quality of life was completed 1, 3, and 6 months after the intervention, and the Health Belief Questionnaire 3 and 6 months after the intervention was completed again for both groups. Moreover, a blood sample for HbA1C was taken 6 months after the intervention.

Statistical analysis

Descriptive statistics, Chi-square test, repeated measures analysis of variance, Bonferroni post hoc

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test, independent t-test, and paired t-test were all used to examine the data. Data analysis was performed using SPSS 9 software.

Findings

The mean age of the patients in the intervention and control groups was 46.17±10.44 and 47.02±8.6 years, respectively. The mean duration of diagnosis in the intervention and control groups was 7.6±4.6 and 8.1±3.5 years, respectively. There was no significant difference between the two groups before the intervention in age and disease duration (p>0.05). Also, there was no significant difference in the frequency distribution of the participants in terms of demographic characteristics in the intervention and control groups (Table 1).

Table 1) Comparison of frequency distribution of demographic variables in the intervention and control groups using chi-square test

Variable	Intervention group	Control group	P-value
Sex			
Women	22 (55.0)	17 (42.5)	0.04
Men	18 (45.0)	23 (57.5)	
Marital status			
Married	28 (70.0)	25 (62.5)	
Single	7 (17.5)	6 (15.0)	0.2
Other	3 (7.5)	8 (20.0)	
Employment status			
Employee	6 (15.0)	9 (22.5)	
Housewife	17 (42.5)	11 (27.5)	0.1
Freelance	11 (27.5)	15 (37.5)	
Unemployed	6 (15.0)	5 (12.5)	
Education status			
Undergraduate	11 (27.5)	13 (12.5)	
Diploma	17 (42.5)	15 (37.5)	0.7
Postgraduate	7 (17.5)	4 (10.0)	
Bachelor	5 (12.5)	8 (20.0)	

Before the intervention, there was no significant difference between the two groups of intervention and control in the variables of compliance with treatment, quality of life, and health beliefs (p>0.05). However, one month after the intervention, there was a significant difference in the means of compliance with treatment in the two groups, and the score of compliance with treatment in the intervention group increased. The quality of life was also significantly impacted by this disparity. Although both groups' quality-of-life scores dropped (a lower score implies a higher quality of life), the intervention group's mean change was greater. On the other hand, the levels of treatment compliance, quality of life, and health beliefs significantly varied between the two groups three months and six months following the intervention. Compliance with treatment and health beliefs increased, and quality of life decreased (a lower score indicates a higher quality of life). The mean score of HbA1C in the two groups significantly reduced six months after the intervention. Moreover, the coefficient effect of 1.55 showed the high positive impact of the intervention (Table 2).

Besides, the inter-group and intra-group effects in different phases of the intervention are shown in Table 3. According to the results of an intergroup and intragroup analysis of variance with repeated measures of four measurements (before the intervention, 1, 3, and 6 months after the intervention) in the intervention and control groups, there was a significant difference in the factor scores, the groups' scores for treatment compliance, and the overall quality of life score (p<0.001). Repeated measurements of three measurements (before the intervention, 3, and 6 months after the intervention) in the intervention and control groups showed that there is a significant relationship between the scores and the groups in the total score of health belief (p<0.001).

These results indicated that the intervention was effective in increasing the score of compliance with treatment and decreasing the quality of life scores (according to the tools used, the lower score indicates a higher quality of life) (p<0.001). There was a significant difference among the mean scores of compliance with treatment, quality of life, and health belief in the two groups with a strong effect according to the Cohen coefficient of 0.9.

There was a statistically significant difference between the scores of compliance with treatment, quality of life, and health beliefs in four time periods in the intervention group before and six months after the intervention (Table 4).

Table 2) Comparison of the mean variables in the two groups before, 1, 3 and 6 months after the intervention

Variable	Before intervention		One month after the intervention		Three months after the intervention		Six months after the intervention	
	Mean±SD	p	Mean±SD	p	Mean±SD	p	Mean±SD	Statistical results
Compliance with treatment								
Intervention	27.02±4.80	0.1	29.57±5.79	<0.001	63.6±14.5	<0.001	76.4±9.33	p<0.001; d=6.6; r=0.9*
Control	25.1±5.5		25.72±5.50		26.7±5.21		27.52±5.49	
Total quality of life score								
Intervention	187.73±20.01	0.2	177.33±19.69	0.003	149.90±14.85	<0.001	92.27±16.24	p<0.001; d=2.5; r=9.0*
Control	191.85±11.32		188.23±11.05		185.18±10.76		182.27±15.47	
Total health belief score								
Intervention	36.7±5.84	0.08	-	-	69.3±7.9	<0.001	77.92±2.57	p<0.001; d=1.9; r=9.0*
Control	39.9±9.85		-		41.7±8.33		48.07±9.78	
HbA1C (%)								
Intervention	11.8±1.95	-	-	-	-	-	8.4±2.0	T=3.87; p<0.001; d=1.55; r=0.6*
Control	12.63±1.99		-		-		12.03±2.65	p<0.001; d=6.6; r=0.9*

* Cohen's kappa coefficient

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In addition, the paired t-test revealed a significant difference in the mean Hb1AC before and six months after the intervention in the two groups (Table 2).

Table 3) Results of repeated measures analysis of variance in the two groups at different stages of the intervention

Variable analysis	Source of effect	Total squares	Degrees of freedom	Average squares	F
Compliance with treatment					
Between group	Group	37845	1	37845	367.29**
	Error	98.8036	78	103.03	-
Intergroup	Factor	47450.81	2.22	21304.5	459.9**
	Factor* Group	35823.27	2.22	16083.96	347.26**
	Error	8046.41	173.72	44.36	-
Total quality of life score					
Between group	Group	98035	1	98035	153.2**
	Error	49897.6	78	639.71	-
Intergroup	Factor	84780.6	1.91	44170.8	322.9**
	Factor* Group	53508	1.91	27877.8	203.8**
	Error	20475.05	155.37	131.77	-
Total health belief score					
Between group	Group	19170.93	1	19170.93	150.41**
	Error	9941.32	78	127.455	-
Intergroup	Factor	895959.75	1.19	749892.09	150.41**
	Factor *Group	19532.32	1.19	16347.98	83.61**
	Error	18353.25	93.11	196.93	-

**p<0.001

Table 4) Examining the differences in scores of compliance with treatment, quality of life and health beliefs in intervention and control groups in 4 stages using Bonferroni post hoc test

Variable		Intervention group			Control group		
		Means difference	Standard error	p	Means difference	Standard error	p
Compliance with treatment							
Before	One month after	-2.55	0.56	<0.001	-.62	0.16	0.2
	Three months after	-36.57	2.12	<0.001	-1.6	0.26	<0.001
	Six months after	-49.42	1.43	<0.001	-2.42	0.29	<0.001
One month after	Three months after	-340.2	2.13	<0.001	0.97	0.24	0.02
	Six months after	-46.87	1.4	<0.001	-1.8	0.28	<0.001
Three months after	Six months after	-12.85	1.81	<0.001	-0.82	0.22	0.06
Quality of life							
Before	One month after	10.4	1.05	<0.001	3.35	0.41	<0.001
	Three months after	37.82	2.5	<0.001	6.4	0.66	<0.001
	Six months after	95.45	4	<0.001	9.3	1.27	<0.001
One month after	Three months after	27.42	2.37	<0.001	3.05	0.54	<0.001
	Six months after	85.05	4.02	<0.001	5.95	1.25	<0.001
Three months after	Six months after	57.62	2.95	<0.001	2.9	1.21	0.1
Health belief							
Before	Three months after	-32.62	1.48	<0.001	-1.8	0.64	0.02
	Six months after	-41.22	0.9	<0.001	-0.81	1.27	<0.001
Three months after	Six months after	-8.6	1.33	<0.001	-6.37	1.19	<0.001

Discussion

Regarding the findings, the intervention program based on the self-protection continuity model improved compliance with treatment and its consequences, including quality of life, health beliefs, and HbA1C in patients with type 2 diabetes.

Various studies showed that the main problem of patients with chronic disease, especially diabetic patients, is the lack of continuity and failure of patients to accompany and comply with care and treatment standards [25-30]. Previous research has also shown that patients and even service providers' inadequate awareness of the need for ongoing monitoring and care in the absence of symptoms and disease complications, as well as their inappropriate mentalities, are the main causes of this lack of continuity and compliance [27, 29, 31-34]. Meanwhile, it is not enough to just increase awareness, it is necessary to change and continue the behavior and provide the necessary mechanism for this work. Macido [35] evaluated the knowledge and adherence to the treatment of type 2 diabetic patients using self-

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management and support training program. After the intervention, the patients' awareness in the intervention group increased, but there was no significant change in treatment adherence behaviors in the two groups, which was probably due to the short duration of training. However, it seems that self-sufficiency and lack of continuous intervention are the more important reason. Also, the training program was still available to patients in the intervention group until the end of the study, and after the training program, communication with the patients via discussion in the virtual group, telephone communication and sending messages was available to motivate and increase sensitivity in patients, which it was effective to promote the treatment compliance among these patients.

Farmer *et al*. [36], in a study to determine the effect of a counseling-oriented nursing intervention on the support of diabetic patients to follow using the hypoglycemic medications showed that the specialized counseling of the nurse in the intervention group caused patients did not discontinue the medication during the period of study, but there was no significant difference between the intervention and control groups in secondary outcomes (quality of life and satisfaction with treatment). Counseling-oriented intervention emphasize on the correct and timely use of medications by patients, which is one of the dimensions of treatment. Patients were motivated to adhere to these suggestions as they received suitable feedback after complying with therapy and were aware of the improvement in their quality of life. In line with the findings of the present study, Rezai Asl *et al*. [32], who investigated the effect of family-centered empowerment model on adherence to treatment regimen in the patients with type 2 diabetes, reported that the rate of adherence of patients with diabetes in the family-centered care group was significantly increased after the intervention. Although care was family-centered, the patient's primary caregiver did not participate directly in the training program. Moreover, the effect of the intervention program was evaluated only one month later. The family actively participated in the intervention and the group, and messages were sent to inform and warn them. Also, the effect of the intervention program was observed even up to six months later, which indicates the continuation of self-care behaviors.

Faramarzi *et al*. [37] conducted a study to investigate the effect of education based on the health belief model in promoting kidney care behaviors in type 2 diabetic patients, which patients' performance in the intervention group showed a substantial improvement three months after the educational intervention, and fasting blood sugar index marginally dropped. In this investigation, increased scores were seen in the health beliefs-related aspects but not in the perceived severity and sensitivity [37]. The intervention was performed in the form of three training sessions for patients. Although educational intervention could increase some aspects of health belief, to continue self-care behaviors, it is necessary to constantly stimulate the patient and create sensitivity among them and their family to increase perceived severity and sensitivity to complications. In order to create fear and increase sensitivity in patients, the complications of the disease and the problems caused by the lack of blood sugar control and its complications were emphasized by regularly sending messages in groups and personally and by phone. This fear promoted health idea in two dimensions of perceived severity and sensitivity. The model of self-preservation continuity arises from the views, experiences and perceptions of chronic patients and is based on Iranian culture and society. Therefore, this model, considering the influential factors, offers solutions based on which the researcher designed and implemented the interventions.

The implementation of a continuum and self-preservation model can be recommended to improve compliance with treatment and its consequences among patients with chronic disease.

The limitation of this research is the patients' differences in terms of religion, spirituality, social and culture, beliefs, and economic issues, which may have caused differences in the implementation of the recommended items for the patients, and the complete control of these items was beyond the responsibility of the researcher.

It is suggested that the effect of the used model on treatment concordance in other chronic diseases such as high blood pressure, heart disease, asthma, etc., and in patients with type 1 diabetes also be investigated.

Conclusion

The self-preservation continuity model can be implemented even in the Covid-19 pandemic and is more effective in metabolic control and compliance with the treatment of diabetic patients than interventions based on other models that are purely educational.

Acknowledgements: The authors would like to thank the Vice Chancellor for Education and Research of the Faculty of Medical Sciences and Tarbiat Modares University, Zahedan University of Medical Sciences and its affiliated hospitals, the patients, and the nurses participating in this study.

Ethical Permission: This article was approved by the Ethics Committee of the Faculty of Medical Sciences with

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code IR.MODARES.REC.1398.138. Before the study, the objectives of the study and ensuring the confidentiality of information were explained to the patients, and they entered the study with the necessary knowledge and consent. Considering the ethical considerations, after the study, educational materials and messages were sent to patients in the control group. The educational program designed based on the model was given to the control group for nurses to use after the research.

Conflict of Interests: The authors declare no conflict of interests.

Authors' Contribution: Mohammadi E (First Author), Introduction Writer/Methodologist/Main Researcher/Discussion Writer (30%); Pournamdar Z (Second Author), Introduction Writer/Methodologist/Main Researcher/Discussion Writer (30%); Vahedparast H (Third Author), Methodologist/Assistant Researcher (20%); Kazemnejad A (Fourth Author), Statistical Analyst/Discussion Writer (20%)

Funding: This study is a part of the doctoral dissertation on Nursing in the Faculty of Medical Sciences of Tarbiat Modares University.

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