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Impact of Continuous Care Model on the Quality of Life of Patients with Thalassemia Major: A Clinical Trial Study

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Abstract

Background: Major thalassemia has a significant impact on the personal performance and life of the affected person and leads to reduced quality of life (QoL) of the patient. One of the ways to improve quality of life is to use the Continuous Care Model (CCM).

Aim: This study aimed to determine the impact of CCM on the QoL of patients with thalassemia major.

Method: A clinical trial was performed with 60 thalassemia patients referring to Aliasghar Hospital in Zahedan, Iran. Eligible candidates were selected by convenience sampling method and randomly assigned to the intervention and control groups (n=30 each). Data collection tools included a demographic form, the quality of life questionnaire the brief version of the World Health Organization's QoL, and a self-control checklist. The intervention was performed in six training sessions three times a week in the presence of the patient and a family member; however, the control group received no intervention. Data analysis was performed in SPSS software (version 21).

Results: The mean scores of QoL and its dimensions showed no significant difference between the intervention and control groups before the intervention ($P>0.05$); nevertheless, a significant difference was observed one and three months after the implementation of the model regarding ($P<0.05$).

Implications for Practice: The finding indicated that the CCM improved the QoL of patients with major thalassemia. The model can be suggested as an intervention in nursing care to increase patients' QoL.

Keywords: Continuous care model, Quality of life, Thalassemia major

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Introduction

Thalassemia is one of the most common inherited hemoglobin disorders on the surface in the world (1). Approximately 240 million people carry the gene for the disease, and about 200,000 babies are born with thalassemia throughout the world every year (2, 3). In Iran, thalassemia is known as the most prevalent chronic disease, and there are over 30,000 thalassemia patients in this country (4). Considering this number of patients, Iran holds the first rank in terms of the ratio of thalassemia patients to the total population on the global scale (5). Domestically speaking, such factors as having about 6-10 residents of the province as carriers of thalassemia, the highest fertility rate in all provinces of the country, and failure in the premarital screening plan (6) has led Sistan-and-Baluchestan Province with 2,700 thalassemia major patients to have the highest ratio of thalassemia patients in comparison to the general population (1:1000) among the provinces of the country (7).

Thalassemia major is usually diagnosed when the child is a few months old. The patients need regular blood transfusions and iron-chelating agents from childhood to survive (8). Blood transfusions in thalassemia major are associated with growth retardation, paleness, jaundice, muscle weakness, hepatosplenomegaly, and skeletal and facial changes that can present as head, jaw, and other facial abnormalities (9). Additionally, increased iron load in such patients can lead to cardiac complications (10), reduced growth, defective or delayed puberty, and cardiomyopathy (11). Continuous blood transfusions and chelation therapy would ultimately reduce the patient's quality of life (QoL) (12).

The results of studies indicate that the QoL of patients with thalassemia is not at an acceptable level (4, 8, 13). Impaired quality of life in these patients not only harms their social, familial, and recreational activities but also increases the risk of hospitalization and death among them (14). The primary goal of medical care is to improve the QoL of these patients using nursing models (15). In Iran, Ahmadi et al. (2001) has developed a model, namely the Continuous Care Model (CCM), and assessed it in the context of chronic coronary heart disease. The model has four stages, including orientation, sensitization, control, and evaluation, and aims to establish an effective, interactive, and consistent relationship of the client with his/her family and the nurse as a follow-up care agent and service provider. The goal is to identify the needs and problems of the patient, sensitize the client to accept continuous health behaviors, and help maintain recovery and promote health. Therefore, it is hoped that the model can lead to improved QoL, reduced complications, and increased patient satisfaction and care quality. The primary functions of the care model for the patient include understanding the disease and its nature, recognizing actual and potential problems related to the disease, accepting the disease and its effects as a shadow on life, accepting responsibility for continuous self-control, establishing family participation in treatment and care, and understanding the care and treatment team (16).

Given the recent developments and considering that a patient with thalassemia has a good potential for social participation if cured well, it is necessary to be careful when performing routine interventions for such patients (17). In this regard, planning to improve the health of patients suffering from thalassemia requires sufficient information about the QoL of these patients. Understanding the QoL of thalassemia patients and contributors to it helps us plan in a way that can increase the patient's ability to perform daily activities without relying on others and have a positive effect on his/her QoL.

To the best of our knowledge, this model has not been performed for thalassemia patients; consequently, further investigation is needed in this field. This study was conducted to determine the effect of CCM on the QoL of patients with thalassemia major.

Methods

This randomized controlled clinical trial, without blinding, was conducted on 60 patients with thalassemia major in Hazrat Aliasghar (HA) Hospital of Zahedan University of Medical Sciences, Zahedan, Iran, within June-January 2020. The research population included all patients with thalassemia having over 18 years of age, having an available active file in the thalassemia ward of HA Hospital, lacking health problems (e.g., mental retardation, behavioral and mental disorders, and hearing and speech disorder according to medical records), and having the possibility to access and follow the patient for 3 months. On the other hand, the patients who were not willing to continue participation and developed severe physical complications due to the disease and a specific disease during the study were excluded from the study.

The patients were chosen using the convenience sampling method and then randomized into the intervention and control groups (n=30 each). To determine the group of patients, 60 envelopes containing the name of one of the two groups were prepared and randomly distributed. As patients referred to the ward, they were assigned to one of the cards in succession (Figure 1).
The sample size was estimated at 13 participants in each group using the formula for "the average score of total QoL" with 95% confidence interval and α=0.05 based on a study performed by Razazan et al. (18). Nonetheless, 30 samples were recruited in each group to guarantee the adequacy of the sample size and possible attrition.
Data collection tools included a demographic form (information such as age, gender, and education level), a self-control checklist (researcher-administered), and the brief version of the WHO's QoL scale (WHOQOL-BREF). The 24-item WHOQOL-BREF questionnaire consists of four domains of physical health, mental health, social relations, and environmental health with 7, 6, 3, and 8 items, respectively, and has two general questions that are not related to any of these domains (19). The questionnaire is scored on a 5-point Likert scale, with a total range score of 24-120. Nejat et al. standardized this instrument in Iran and calculated its reliability by the test-retest method at 0.77, 0.77, 0.75, and 0.84 for physical health, mental health, social relations, environmental health, respectively. The internal consistency scores of the questionnaire for different dimensions, using

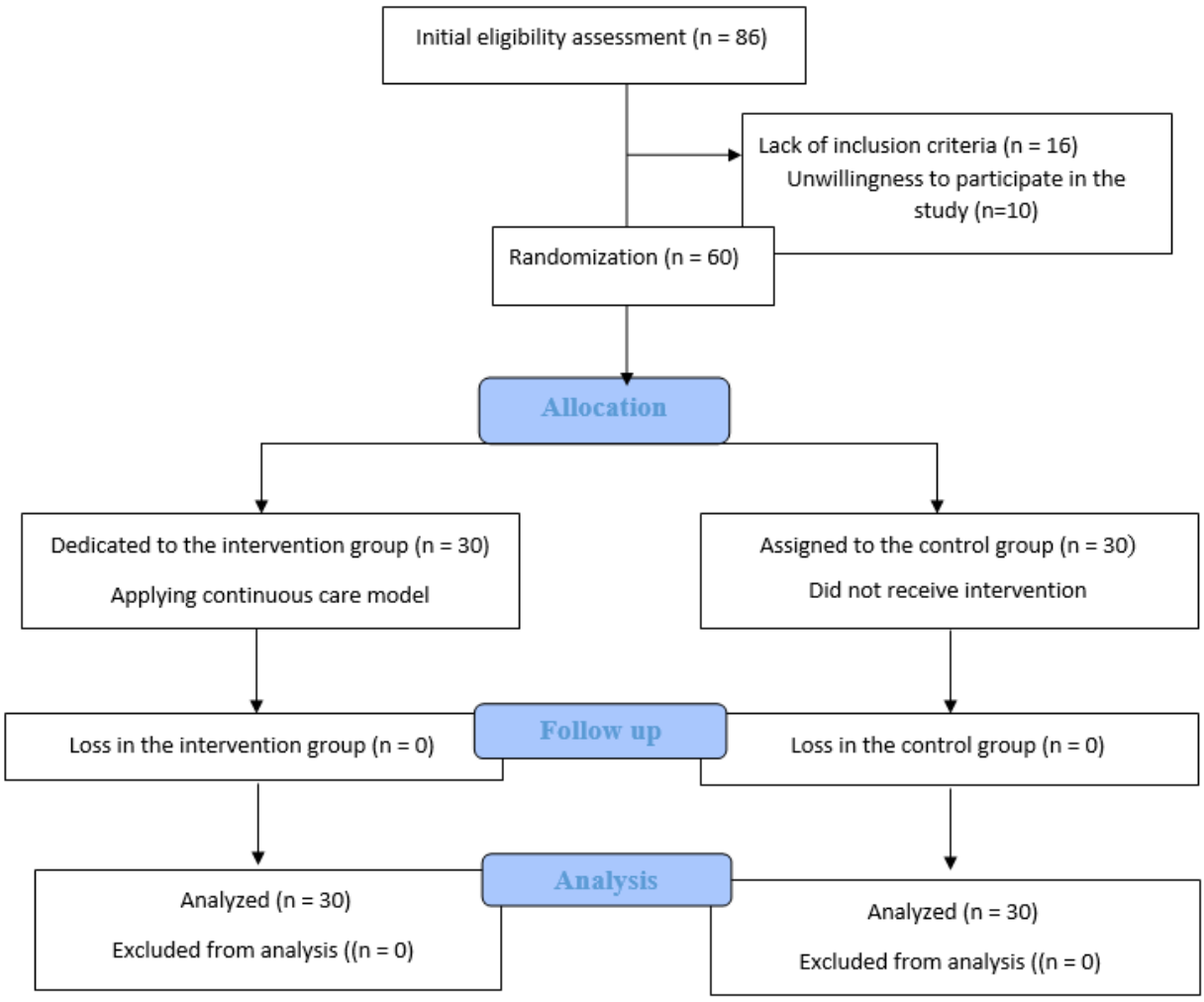

Figure 1. Flowchart of the design, groups, and participants in the study

Cronbach's alpha coefficient method, were obtained at between 0.52 and 0.84 for healthy and sick people (20). Moradi et al. estimated the internal consistency of the questionnaire at 0.60 and its reliability, using Cronbach's alpha coefficient method, at 0.92 (21). The internal consistency of the instrument in the present study was estimated at 0.86 through the Cronbach's alpha coefficient method.

The researcher obtained the required permits and an introduction letter from the Vice-Chancellor for the Research and Technology and Ethics Committee of Zahedan University of Medical Sciences. The letter was presented to HA Hospital officials to allow the performance of the research. After that the participants received explanations about the objectives and procedures of the study, they signed the written consent forms for participation. The CCM was performed individually for each patient in the intervention group for 14 weeks. The steps of the model were as follows:

Orientation: A 30-40-minute session was held in the presence of the patient and his/her family to justify and persuade them about the need for the patient's follow-up process. During the session, the members introduced themselves, and the patient completed the demographic form and QoL questionnaire. An agreement was also reached concerning the time of the patient's visit to the clinic and telephone calls and the manner of contact.

Sensitization: The sessions associated with this step were held in person at the hospital clinic to involve the patient and his/her family in care provision. Each session lasted from 45 to 60 min, depending on the tolerance of the individual. At the beginning of each session, the patient's knowledge level was assessed by asking questions related to thalassemia and the educational content of the preceding session. The educational content was based on the dimensions of QoL and prepared using textbooks and articles under the supervision of two faculty members of nursing with a PhD and an oncologist degree. The intervention was performed in six training sessions three times a week in the presence of the patient and a family member. The first session covered the anatomy and physiology of the blood and the causes of the disease. The second session concerned the complications of thalassemia and treatment procedures. The third session was related to the diet of a patient with thalassemia and the role of exercise. Session four addressed basic treatments for thalassemia and the associated side effects. The fifth session focused on training relaxation techniques, and the last session covered social skills training. Furthermore, in the final session, an educational package was provided to the patient and his/her family in the form of a booklet, CD, and a self-control checklist.

Control: Subsequently, the control step initiated. Each patient was contacted twice a week (once via a phone call and once in person) to ensure the training given to the patient was performed continuously for 3 months.

Evaluation: Evaluation was performed at two points: first, 1 month after the intervention and, second, 3 months after the intervention. The subjects completed the QoL questionnaire at each stage. In the control group, the patient completed the demographic form and the QoL questionnaire at the baseline. They did not receive any intervention except for routine care. Similar to the intervention group, they completed the QoL questionnaire 1 and 3 months later. After that the data of the intervention group were collected, the training package was provided to the patient and his/her family in this group in the form of booklets and CDs.

All ethical principles were observed in the research. All participants signed written informed consent and were fully aware of the research process. Moreover, they were informed of the possibility of study withdrawal at any research stage and the confidentiality of information in this study.

All data were presented as mean, standard deviation, and percentage. The statistical analysis was performed using the descriptive statistics, Shapiro-Wilk tests (to determine the normality of the variables), Chi-square test, paired t-test, repeated measures of variance analysis. All analyses were carried out in the SPSS software (version 21) (IBM Corp, Armonk, NY, USA). A p-value less than 0.05 was considered statistically significant.

Results

A total of 60 participants completed the study. The results showed that the mean age scores of the participants in the intervention and control groups were 22.57 ± 4.19 and 27.20 ± 5.20 years, respectively. Moreover, the mean scores of the number of visits per month to receive blood were 1.40 ± 0.5 and 1.50 ± 0.5 in the intervention and control groups, respectively. There was no significant

Table 1. Frequency distribution of demographic characteristics of thalassemia major patients in the intervention and control groups

Variable		Control group		Intervention group		P-value
		Frequency	Percentage	Frequency	Percentage	
Gender	Female	15	50	15	50	*0.67
	Male	15	50	15	50	
	Total	30	100	30	100	
Education level	Illiterate or primary	7	23.3	9	30	*0.62
	High school	16	53.4	13	43.3	
	Tertiary	7	23.3	8	26.7	
	Total	30	100	30	100	
Family status	Parents alive	23	76.7	24	80	*0.98
	Parents separated or (one) deceased	7	23.3	6	20	
	Total	30	100	30	100	
Economic status	Weak	4	13.3	2	6.7	**0.96
	Moderate	19	63.4	22	73.3	
	Good	7	23.3	6	20	
	Total	30	100	30	100	
Complications of the disease	Yes	15	50	18	60	*0.43
	No	15	50	12	40	
	Total	30	100	30	100	

* Chi-square

** Exact tests based on Monte Carlo Markov chain method

difference between the two groups in terms of age and the number of visits per month to receive blood (P>0.05). Similarly, the two groups did not differ significantly regarding other demographic characteristics (P>0.05) (Table 1).

The results concerning the mean and standard deviation of the QoL and its dimensions score with repeated measures at the baseline and 1 and 3 months after the intervention showed that the mean scores at post-intervention time points increased in the intervention group. In the control group, however, the scores did not change significantly at the follow-up points.

The results of the analysis of variance showed repeated measures of significant interaction between time and group, meaning that the pattern of changes in the mean scores of the QoL and its dimensions were different in the intervention and control groups in the three measurement points (i.e., at the baseline and 1 and 3 months after the intervention; P<0.001) (Table2).

In the intervention group, pairwise comparisons by the Bonferroni test showed that the mean scores of the QoL and its dimensions at the baseline and 1 month after the intervention were significantly different (P<0.05). Similarly, the scores were significantly different at the baseline and 3 months after the intervention (P<0.05) and 1 and 3 months (P<0.05) after the intervention.

In the control group, pairwise comparisons by Bonferroni test indicated that the mean scores of the QoL and its dimensions in any of the three measurement times; namely at the baseline and 1 month after the intervention, at the baseline and 3 months after the intervention, and 1 and 3 months after the intervention; were not significantly different from each other (P>0.99). The results of the study regarding the mean scores of the QoL and its dimensions in patients with thalassemia major in the control and intervention groups revealed that there was no statistically significant difference in the mean score of QoL before the intervention in the intervention and control groups (P>0.05). Nonetheless, 1 and 3 months after the intervention, a significant difference was observed in the mean scores of the QoL and its dimensions between the intervention and control groups with higher scores in the intervention group (P<0.05).

Table 2. Comparison of mean scores of the quality of life and its dimensions in two groups at the baseline and 1 and 3 months after the intervention

Variable	Group	Before the intervention	1 month after the intervention	3 months after the intervention
Quality of life	Intervention	44.74±6.77	59.46±12.45	64.30±13.03
	Control	45.57±4.60	44.62±4.64	44.74±4.75
Comparison between two groups at three points		P>0.001*	P<0.001*	P<0.001*
Physical health	Intervention	47.38±9.83	61.07±14.14	65.24±12.04
	Control	48.45±9.12	47.12±7.98	46.90±8.47
Comparison between two groups at three points		P>0.001*	P<0.001*	P<0.001*
Mental health	Intervention	42.08±9.93	57.78±14.99	63.19±15.04
	Control	45.56±10.60	44.86±10.64	44.86±10.12
Comparison between two groups at three points		P>0.001*	P<0.001*	P<0.001*
Social relations	Intervention	41.94±10.82	57.22±19.54	62.78±20.02
	Control	45.28±13.25	47.69±13.68	44.72±12.66
Comparison between two groups at three points		P>0.001*	P<0.001*	P<0.001*
Environmental health	Intervention	45.63±9.90	59.17±13.90	63.65±14.15
	Control	46.88±9.39	46.67±8.95	45.52±9.66
Comparison between two groups at three points		P>0.001*	P<0.001*	P<0.001*
Bonferroni		Time effect P≤0.001 Group effect P>0.05 Interaction between time and group P≤0.001		

* Repeated measure ANOVA

Discussion

This study was conducted to determine the effect of CCM on QoL among patients with thalassemia major. The results showed that the QoL scores were statistically significant in the intervention group after the implementation of the CCM. The results of the present study are consistent with those of studies conducted by Daei et al. (22), Baqaei et al. (23), Khodaveisi et al. (24), Rahimi (15), and Khoshnevis et al. (25). Nevertheless, the difference between the results of the present study and those of previous ones was the comparison of changes in QoL during the three periods (i.e., at the baseline and 1 and 3 months after the intervention). Khankeh et al. observed that the implementation of CCM had no effect on the QoL of schizophrenic patients (26). This finding is inconsistent with those of the present study that can be due to the nature of the disease and different patients.

The results of the present study showed that the scores of QoL and its dimensions in the control group reduced or stayed unchanged in the three measurement times. Therefore, it is necessary to consider a special care program for patients (27), and one of the ways to increase the QoL is the implementation of the CCM.

In the present study, the QoL increased in all dimensions after 1 month. Daei et al. (22) indicated that 1 month after CCM, all dimensions of patients' QoL increased; whereas, in a study conducted by SadeghiSherme et al. (28), only one dimension of QoL increased after 1 month. This difference was due to the nature of the disease, the patient's age, and the individual differences of the patient.

A significant increase in the QoL score was observed in all dimensions 3 months after the implementation of the model, compared to the QoL before the intervention. Daei et al. (22), Khayyam Nekouei et al. (27) reported that all dimensions of patients' QoL increased 2 months after the implementation of CCM. Similar to any chronic disease, thalassemia will harm the patient's QoL; therefore, nurses need to consider this matter and devote some time to train the patient during hospitalization or discharge, as a result of which, patients can care for themselves and be encouraged to overcome the disease and the problems associated with it.

One of the limitations of the present study was related to some uncontrollable variables, such as health seekers' knowledge, experiences, interest in accepting the model and its details, and emotional-psychological characteristics, as well as cultural contexts of patients and their families, which could affect their learning, interests, and motivations. These issues made the researcher encounter problems

in some cases. Moreover, the long research duration was an important factor as it could bore some patients.

Implications for Practice

The results of this study showed the beneficial effects of implementing a CCM on the QoL of patients with thalassemia major. Accordingly, nurses are recommended to use the CCM as an effective non-pharmacological intervention for chronic patients, including patients with thalassemia major.

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Conflicts of Interest

The authors declare that there is no conflict of interest.

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