ORIGINAL ARTICLE

The Effect of Family-Centered Empowerment Program on Self-Efficacy of Adolescents with Thalassemia Major: A Randomized Controlled Clinical Trial

Leili Borimnejad[1], PhD; Soroor Parvizy[2], PhD; Hamid Haghaani[3], PhD; Belgheis Sheibani[4], MS

[1]Nursing Care Research Center, School of Nursing and Midwifery, Iran University of Medical Sciences, Tehran, Iran;
[2]Department of Nursing, School of Nursing and Midwifery, Iran University of Medical Sciences, Tehran, Iran;
[3]Department of Biostatistics, School of Public Health, Iran University of Medical Sciences, Tehran, Iran;
[4]Department of Nursing, School of Nursing and Midwifery, Hormozgan University of Medical Sciences, Bandar Abbas, Iran

Corresponding author:
Belgheis Sheibani, MS; Department of Nursing, School of Nursing and Midwifery, Hormozgan University of Medical Sciences, Southern Mission, Bandar Abbas, Iran,
Tel: +98 76 33666367; Fax: +98 71 16670724; Email: farideh.sheibany@gmail.com

ABSTRACT

Background: Chronic nature of thalassemia causes changes in different aspects of life in patients, including their self-efficacy. The aim of this study was to determine the effect of family-centered empowerment program on the self-efficacy of adolescents with Thalassemia major.

Methods: A quasi-experimental study was performed on adolescents with thalassemia major in 2013 in Bandar Abbas, Iran. The participants were divided into intervention and control groups, respectively. Research instruments included demographic data questionnaire, need assessment self-made questionnaire, general self-efficacy scale, and sickle cell self-efficacy scale. After collecting the data from the pre-intervention step, family-centered empowerment program was implemented for the intervention group and secondary test was conducted six weeks after the intervention and the results were analyzed by statistical SPSS-21 software, using independent t-test, paired t-test, Chi-square and Fisher's exact test, and descriptive statistics. A significance level of $P<0.05$ was considered as significant.

Results: The mean and standard deviation of the adolescents' age were 16 ± 1.9 in the intervention group and 15.2 ± 2 in the control group. Independent t-test showed a significant difference between the two groups after the intervention for both self-efficacies ($P<0.01$ and $P=0.02$). In the control group, the results of general self-efficacy scores after six weeks' time were reduced compared to the previous one while disease-related self-efficacy scores in the same group after six weeks' time increased and paired t-test indicated a significant difference in the mean scores for both self-efficacies in both groups.

Conclusion: Implementation of family-centered empowerment program for patients with thalassemia major is practically feasible and it can increase self-efficacy in these patients. It is suggested that the program should be used in comprehensive care protocols of children and adolescents.

Trial Registration Number: IRCT201407211788N8

KEYWORDS: Family, Self-efficacy, Thalassemia

INTRODUCTION

Thalassemia is one of the most common chronic and hereditary diseases. 240 million people suffer from beta thalassemia worldwide. Thalassemia is not only a health problem for patients and their families, but it is too expensive for public health system including costs for regular blood transfusions, excess iron excretion from body and frequent admissions to hospital.[1-4]

Beta-thalassemia leads to a significant impairment in social and educational activities of children and adolescents so that children cannot attend school because of hospitalization, blood transfusions and treatment. These factors lead to the compromise of their identity and their greater dependence on others.[5]

Many adolescents and young adults with chronic conditions experience reduced self-support, independent living, communication skills, and self-efficacy. The term that is very important for compliance of adolescents with a chronic disease with life is self-efficacy.[6] The term self-efficacy was first introduced by Bandura and refers to the ability of performing a particular function that a person expects from his/her ability to do in different situations. According to Bandura, self-efficacy is the most important precondition to change behavior.[7-9] Measuring self-efficacy can be a predictor of a person's ability to change his/her behavior and decision to increase self-care.[10]

Self-efficacy is one of the concepts of family-centered empowerment model. In fact, empowering the patient and his family and increasing the involvement of patients in self-care reflects the emphasis on health, prevention and health education, not just focusing only on illness and its treatment.[11] Empowerment skills include problem solving, self-confidence and trust building strategies. Empowering the patient and his or her family leads to maximizing the patient's potential for health and well-being.[12] Family-centered empowerment pattern is designed with emphasis on the effectiveness of individual and other family member's role in three dimensions: motivational, psychological (self-esteem and self-control) and self-problematic features (knowledge, attitudes and perceived threat).[11,13-16] This pattern has been used in some chronic diseases. The use of this pattern in patients with type 2 diabetes has increased the self-care and has led to an increase in quality of life in patients with asthma.[11,16]

Considering the chronic nature of thalassemia major and its widespread prevalence and considering the fact that there has been no study on the effect of this model on the self-efficacy of patients with thalassemia major, this study aimed to determine the effect of family-centered empowerment program on self-efficacy in adolescents with thalassemia major.

MATERIALS AND METHODS

A quasi-experimental study was conducted using pre- and post-test including a control group.

This study was conducted in March 2013 and for 6 months in Bandar Abbas on two intervention and control groups before and after the intervention. The researcher referred to one of specific disease centers in Bandar Abbas after obtaining approval from the ethics committee of Tehran University of Medical Sciences with the Code 92/d/130 .2376/

The sampling site was Abu-Reyhan Specific Diseases Centre in Bandar Abbas. The center was a two-story building with separate sections that provided therapeutic services for patients with thalassemia major of all ages, throughout the week, except for holidays.

Before the interventions, all the participants were informed about the goal and method of the study, voluntary nature of the research and confidentiality of their information. After obtaining the written and oral consent from the participants, simple random sampling was performed by the researcher.

Inclusion criteria were collaborating of a family member with the adolescent, patient and an active member being at least able to read and write, having medical records at the center in the past year; undergoing no training

in relation to the disease by the center, having a field of study irrelevant to the medical education of the active member, having no specific mental health problems, and being able to participate in the program. The exclusion criteria included unwillingness of patient and active member to participate in the study or training sessions and inappropriate clinical situation that causes the participant to withdraw from the program.

By referring to the patient file, the people who had the criteria for entering the study were selected to participate in the study. According to the results of the table of random allocation software, version 1/0/0, they were divided into two groups of intervention and control. The participants were blind about their group allocation. After legal processes, the sampling was performed consecutively in order to prevent bias and contacts of the samples in both intervention and control groups. The questionnaires were completed by the control group in two phases with an interval of six weeks and then sampling for the intervention group began six weeks later

(Figure 1).

Based on a similar study conducted by Vahedian Azimi et al. (2010),[13] the sample size with a 95% confidence interval and 80% statistical power was calculated: 35 individuals for each of the intervention and control groups. There were 35 adolescents aged 12 to 18 years with a family member in the control group and 35 adolescents aged 12 to 18 years with a family member in the intervention group.

$$n = \frac{2\sigma^2 (Z_{1-\alpha/2} + Z_{1-\beta})^2}{d^2} =$$

$$\frac{(1.96 + 0.84)^2 \times (2) \times 20^2}{13} = 35$$

The study tools included demographic information questionnaires for adolescent and active member, need-assessment self-made questionnaire, general self-efficacy scale (GSE-10) and sickle cell self-efficacy scale (SCSES).

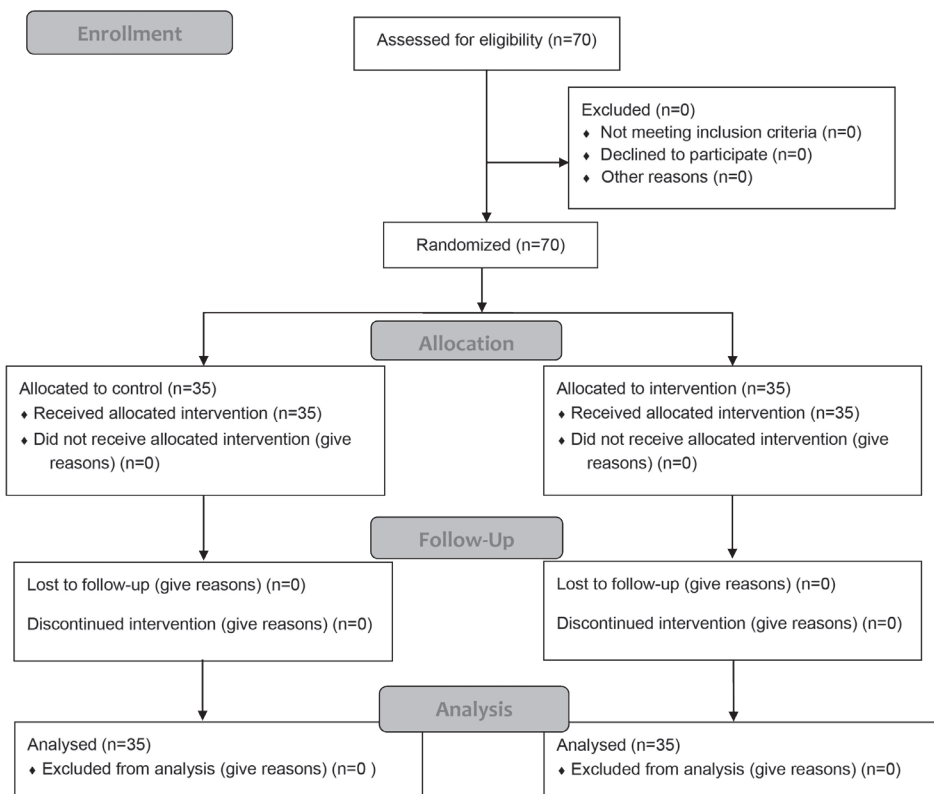Need-assessment self-made questionnaire was made in two sections. The first section

Figure 1: The process of the study

measured the knowledge level of the active member and adolescent including 22 questions in 3 areas of knowledge on the disease nature, feeding and prevention of disease and was set in "yes", "no" or "I do not know" forms. The second part was to examine the needs of the patient and the active member of the family for training on issues such as the nature of the disease, complications and symptoms of the disease, new drugs, new therapies, and so on which included 24 phrases. This section was set in "very high, high, low and never" forms; the person determined his training needs by selecting each option.

Content validity was used to determine the questionnaire's validity. To this end, they were given to ten members of Iran and Tehran Nursing and Midwifery Faculties in order to correct the ambiguous texts and balance in terms of the participants' understanding. Cronbach's alpha was used for reliability of the questionnaire where ten adolescents with thalassemia major (12-18 years old) and one family member was selected from the center and the questionnaires were given to them to be filled out. Data were examined; Cronbach's alpha for the questionnaire of adolescents was 0.93 and that of active members was 0.86.

General self-efficacy scale contains 10 psychometric items and is designed in order to evaluate the person's belief about his compatibility with life stresses. Responses are scored based on 4 point likert scale ranging from "Not at all true" (1) to "Exactly true" (4); the minimum and maximum scores are 10 and 40, respectively. Higher scores indicate greater self-efficacy. The scale was designed by Matthias Jerusalem and Ralf Schwarzer for the first time in Germany in 1981, being conducted with hundreds of participants in many studies. The scale was designed for people aged 12 years old and above and was translated by Nezamee et al in 1996 into Persian;[17] it was applied in several national and international studies in Iran,[18,19] being standardized and validated. This tool has a high reliability. Reliability of this tool was r=0.82 in Rajabi's study in 2006 entitled "the

reliability and validity of general self-efficacy scale".[18]

The sickle cell self-efficacy scale (SCSES) is the first valid tool designed in order to examine the efficacy of adolescents with sickle cell. The scale includes 9 items and responses are scored in 5 point likert scale ranging from "not at all sure" to "very sure". The scores range is from 9-45. Higher scores indicate greater self-efficacy associated with the disease.[16] It is applicable for thalassemia due to the similarity of disease features.[6,20] In the present study, this scale was translated into Persian using standard method of backward-forward. That way, in the first step, 2 indigenous Persian translators translated the original version into Persian, separately. After discussing between them, two versions were combined and the final version of the first step of translation was prepared. In the second step, the translated version of the first step was back-translated into English by 2 expert translators. Then for integrating the two English questionnaires, the back-translated version was compared to the original one and after discussion between all translators, the final translation version was prepared. Cronbach's alpha was used in order to determine its reliability. Ten adolescents with thalassemia major (12-18 years old) were selected from the center and the questionnaires were given to them. Data were examined and its Cronbach's alpha was calculated (0.81), reflecting the internal consistency of this scale.

It was necessary to specify and approve the content of the program before the implementation of the empowerment program. The content was given to a number of active members and adolescents with different ages; strengths and weaknesses were determined so that content was understandable for adolescents and their family members. The content of the program included definition of thalassemia, types and causes of the disease, blood transfusion, new treatments, nutrition, exercise, travel and so on. After collecting the opinions of family members and adolescent,

its reliability was approved by the experts and professors. This work was done by six members of Iran and Tehran Nursing and Midwifery Faculties, three nurses and a doctor at Abu-Reyhan Specific Diseases Centre. This content was used equally for all participants.

Initially, 35 adolescents with one of the family members were selected and they completed the questionnaires with the aim of positioning in the control group. Then, the tools were completed after six weeks. In the intervention group, 35 adolescents with one of the family members who had the inclusion criteria were selected. In the next step, family-centered empowerment program was carried out in this group. Empowering the patients in this program was based on four constructs including knowledge, self-efficacy, training participation and evaluation.

In the first step (perceived threat) of the empowerment program, adolescent's knowledge was increased by instructional booklet and group discussion. According to the needs of adolescents, three training sessions of 30-45 minutes were conducted, including two sessions of group discussion and problem solving and an individual counseling session. For group discussion and problem solving, the adolescents were divided into groups of five who discussed issues like "nutrition in a disease". Also at the individual counseling session, the adolescent, active member of the family and researcher were present. Meetings were led by the researcher. The interval between sessions was 14 days. The blood transfusion room was selected for educational sessions in this stage, the adolescents were asked to teach the active member of the family the issues taught in the same session after returning home. To better transfer the content by adolescent, the adolescent was provided with educational pamphlets related to the subject designed by the researcher; the adolescent was asked to give it to the family active member to read and write the questions that come to his/him mind in a sheet and the adolescent then delivered it to the researcher at the next meeting. Thus, all the notes were obtained and reviewed at the next session. The advantage was that it led to increased self-efficacy of patients and qualities of training sessions were determined.

The second step of empowerment was on self-efficacy. This was done through training sessions with group discussion and problem solving in the first step. Because the problem-solving technique leads to increased self-esteem and self-esteem has a positive impact on self-efficacy.[19,21]

In the third step (training participation), the aim was increasing self-efficacy through educational participation. As mentioned in the first step, the participants were requested to transfer information from the training sessions and pamphlets to the active member of the family.

The fourth step was the evaluation program which was completed in two steps. The first stage included asking 2 oral questions at the beginning of each training session and the second phase was the final evaluation. Six weeks after the completion of the program, the instruments were returned to the samples and the data collected from the questionnaires were collected and analyzed. Data analysis was done through statistical SPSS-21 software and using descriptive and analytical statistics (Chi-square test, Fisher's exact test, ANOVA test, paired t-test and independent t-test). The significance level of 5% and power of 80% were considered in all of these tests.

Results

The adolescents were 12 to 18 years old. The mean and standard deviation of the adolescents' age 'were 16 ± 1.9 in the intervention group and 15.2 ± 2 in the control group. Independent t-test was used in order to test the two groups in terms of matched age, which showed that the two groups were identical (P=0.09). Demographic characteristics of the adolescents and active members are shown in Table 1. There were no statistically significant differences between the groups in terms of demographic characteristics (P>0.05), except for "access to knowledge of the

Table 1: Comparison of demographic characteristics of participants in the intervention and control groups

Variables		Control group N (%)	Intervention group N (%)	P value
Gender of adolescents	Boy	9 (25.7)	5 (14.3)	0.23*
	Girl	26 (74.3)	30 (85.7)	
Literacy status of adolescents	Primary level	1 (2.9)	2 (5.7)	0.42**
	Secondary level	29 (82. 9)	24 (68.6)	
	Diploma	5 (14.3)	9 (25.7)	
Underlying disease	Heart disease	1 (2.9)	1 (2.9)	0.42**
	Respiratory disease	2 (5.7)	1 (2.9)	
	Diabetes disease	0 (0.0)	3 (8.6)	
	None	32 (91. 4)	30 (85.7)	
Members of thalassemia committee	Yes	11 (3.4)	9 (25.7)	0.59*
	No	24 (68. 6)	26 (74.3)	
Receive any instruction leaflet	Yes	6 (17.1)	1 (2.9)	0.1**
	No	29 (82.9)	34 (97.1)	
Access to knowledge of the principles of care	Medium	4 (11.4)	12 (34.4)	0.02*
	Friend	23 (65.7)	21 (60)	
	Physician	8 (22. 9)	2 (5.7)	
Gender of active members	Male	9 (25.7)	0 (0.0)	<0.01**
	Female	26 (74.3)	35 (100)	
Literacy status of active members	Elementary level	12 (31.4)	11 (31.4)	0.22**
	Guidance school	14 (40)	10 (28.6)	
	Diploma to top	9 (25.7)	14 (40)	

*Chi-square test; **Fisher's exact test

principles of care in adolescent" and "gender of the active members of the family". Chi-square and Fisher's exact test were used in order to check the items' homogeneity. ANOVA test was used to examine the relationship between the general self-efficacy and disease-related self-efficacy scores with access to knowledge of the principles of care in adolescents; the results showed that there was no significant difference between general self-efficacy scores with access to knowledge of the principles of care in adolescents in the two groups (P=0.1 and P=0.49). Also, there was no significant difference between disease-related self-efficacy scores with access to knowledge of the principles of care in adolescents in the two groups (P=0.13 and P=0.67).

Independent t-test was used to examine the relationship between the general self-efficacy and disease-related self-efficacy scores with the sex of the active members in the two groups; the results showed that there was no significant difference between general self-efficacy scores with the sex of the active members in the two groups (P=0.13 and P=0.83). Also there was no significant difference between

disease-related self-efficacy scores with the sex of the active members in the two groups (P=0.82 and P=0.96).

The results of general self-efficacy scores in the control group after six weeks' time were reduced compared to the previous one and paired t-test indicated a significant difference in the mean scores for this self-efficacy. Also, disease-related self-efficacy scores in the control group after six weeks' time increased and paired t-test indicated a significant difference in the mean scores for this self-efficacy. The results of the intervention group showed that the mean of general self-efficacy and disease-related self-efficacy scores increased after the intervention and paired t-test indicated a significant difference in the comparison mean scores for both self-efficacies (Table 2).

Independent t-test indicated a significant difference in the mean score of general self-efficacy and disease-related self-efficacy after the intervention in both studied groups while no statistically significant difference was obtained prior to the intervention in the two groups (Table 2).

Table 2: Comparison of the mean of general self-efficacy and disease-related self-efficacy scores before and after the intervention in the control and intervention groups (within-group and between-group)

Questionnaire	Group	Time	Before intervention (Mean±SD)	After intervention (Mean±SD)	P value
General self-efficacy	Control		29.42±4.34	28.02±4.17	0.02*
	Intervention		29.25±5.93	31.45±5.49	<0.01*
	P value		0.89**	<0.01**	
Disease-related self-efficacy	Control		28.97±6.48	30.6±5.53	0.02*
	Intervention		30.77±5.71	33.94±6.73	0.02*
	P value		0.22**	0.02**	

*Paired t-test; **Independent t-test

DISCUSSION

In this study, the effect of family-centered empowerment program on self-efficacy in adolescents with thalassemia major was studied and the results showed that the use of empowerment program and the participation of a family member helped to increase the self-efficacy of adolescents.

According to the results of the between group comparison, there was no significant difference between the mean scores of the general self-efficacy and disease-related self-efficacy in the two groups before the intervention, but after the intervention this difference was significant, showing the effectiveness of implementing family-centered empowerment program on improvement of general self-efficacy and disease-related self-efficacy scores of adolescents with thalassemia major.

The findings of the present study are in agreement with other findings from studies on family-centered empowerment programs. Research on adolescents with diabetes showed that using family-centered empowerment program led to enhanced quality of life and self-efficacy of adolescents.[15] Another study showed that conducting family-centered empowerment pattern was effective in increasing the quality of life of school-age children with thalassemia.[14] Also, another study showed that using family-centered empowerment pattern in school-age children with asthma led to increased quality of life in different aspects, especially in disease and asthma treatment dimensions.[16] Results of other study showed that using educational program based on empowerment model could improve the self-care behaviors among type 2 diabetic patients.[22] In the studies mentioned, four steps in the family-centered empowerment program have been used to empower the patient. Also, the results of a study in Taiwan showed that the use of family empowerment program had a positive effect on family functioning relative to the control of disease and reduction of symptoms of the disease in a child.[23] A study in the USA showed that the empowerment of patients with type 2 diabetes through weekly teaching had a great impact on weight control, diet, and blood glucose levels.[24] In other studies, the positive impact of this model was emphasized in the improvement of quality of life and self-efficacy in care givers of patients.[25,26] Moreover, the results of a study in Egypt showed that the use of educational sessions for children with thalassemia and their families reduced depression and anxiety in children.[27] In this study, like the present study, educational sessions were in accordance with the needs of parents and children with thalassemia and training was done during blood transfusion.

In the control group, general self-efficacy scores after six weeks' time were reduced compared to the previous one while disease-related self-efficacy scores in the same group after six weeks' time increased. Also, within-group comparison mean of general self-efficacy and disease-related self-efficacy scores in the control group was significant.

In the intervention group, mean scores of general self-efficacy and disease-related

self-efficacy increased after the intervention and a significant difference was observed in the within-group comparison of mean scores for both self-efficacies.

The reason for the decrease in general self-efficacy scores in the control group can be instrumental measurement error, distance between pre-test and post-test and events possibly occurring during this period, such as incidence of disease complication in a person and death of a member of the center. The occurrence of some events in the duration of the pre-test and post-test was beyond the control of the researcher. The results of a study showed that the coincidence of pre-test and post-test with the end-year exams was the reason that the mean scores of children's quality of life were not significant after the intervention in the intervention group.[14]

The reason for increased disease-related self-efficacy scores in the control group can be due the fact that people usually pay attention to their illness more than their health. Therefore, disease-related self-efficacy had a positive effect compared to general self-efficacy. Also, it was possible that some adolescents became sensitive to their illness when they observed the questionnaires in the pre-test phase, and participated in out-center training courses. However, the difference between self-efficacy scores of the intervention group was more significant and this is due to the regular use of training by the intervention group and focus of empowerment program on the perceived threat (First step of empowerment program) and self-efficacy (second step of empowerment program) in the intervention group.

Family-centered empowerment program, with the participation of an active member of the family and the emphasis on educating patients with thalassemia major, had an important role in increasing the self-efficacy of these patients. Therefore, it is recommended that this program should be considered in teaching these patients.

The limitation of this study was the psychological state of the participants that affected their response. The situation was out of the researcher's control. Another limitation was the low willingness of the boys and active male members to participate in the study. Since the consent of participants in study was the entrance term, the situation was out of researcher's control.

CONCLUSION

Implementation of family-center empowerment program for patients with thalassemia major is practically feasible and it can increase the self-efficacy in these patients. It is suggested that this design should be conducted for thalassemia patients at other ages and other chronic diseases and in a wider range.

A patient with thalassemia major affects the whole family. Pediatric nurses and nurses working in specific diseases centers can help them with regular educational programs and increase their self-efficacy during the referral of patients and families to the center.

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