# The Impact of Self-Care Recommendations with and without Tilt-Training on Quality of Life in Children and Adolescents with Vasovagal Syncope: A Randomized Clinical Trial

## Abstract

Background: Syncope is among the most common paroxysmal disorders in children and adolescents. Vasovagal syncope is the most common syncope in children and adolescents. The aim of this study was to evaluate the impact of self-care recommendations with and without tilt training on the Quality of Life (QoL) of children and adolescents with syncope. Materials and Methods: This randomized controlled clinical trial was conducted in Isfahan, Iran, from April 2017 to June 2021 and included 120 patients with syncope. Eligible children and adolescents (aged 6-18 years) who met inclusion criteria were recruited by the simple sampling method and then assigned randomly into two groups. The intervention group (n = 60) received routine self-care recommendations such as dietary advice, behaviors to prevent syncope, and counter-pressure maneuvers along with tilt training, while the control group (n = 60) received self-care recommendations without tilt training. The education training included two face-to-face sessions, each of which lasted for 45-60 min. Then, both groups were followed up by telephone (once a month) for six months. A researcher-made self-care questionnaire and Pediatric Quality of Life Inventory (PedsQL<sup>TM</sup> 4.0) were completed for both groups before and after the intervention. Data were analyzed using descriptive and inferential statistical methods. Results: The Wilcoxon test results showed a significant difference in the mean scores of physical functioning, emotional functioning, social functioning, school functioning, psychosocial functioning, understanding of health, and total QoL in the intervention and control groups before and after the intervention (p < 0.05). Also, the paired *t*-test results showed a significant difference in the mean scores of self-care domains and total self-care in the intervention and control groups before and after the intervention (p < 0.05). Conclusions: Self-care recommendations with and without tilt training can improve QoL in children and adolescents with syncope.

Keywords: Adolescent, behavior, child, quality of life, self-care, syncope

## Introduction

Syncope is among the most common paroxysmal disorders in children and adolescents.<sup>[1]</sup> A syncope is defined as a sudden, short-term, self-limited loss of consciousness and postural tone followed by automatic and complete recovery without any neurological insult.<sup>[1]</sup>

A syncope event is associated with the premonitory phase and is characterized by non-specific symptoms such as visual dizziness, sweating, blurring, nausea, palpitations, pallor, weakness, and cold skin.<sup>[2]</sup> The symptoms can occur singularly or in combination for a few seconds to 1-2 minutes.<sup>[2]</sup> Syncope occurs more often in females than in males and is more common in both genders at the

age of 15 years.<sup>[3]</sup> Approximately 15.0% of children experience an episode of syncope before the end of the second decade of life, and 1.0% of common pediatric emergency complaints are related to syncope.<sup>[4]</sup>

About 70.0-80.0% of syncope events in children and adolescents such as Vasovagal Syncope (VVS), Orthostatic Hypotension (OH) also called postural hypotension, Postural Orthostatic Tachycardia Syndrome (PoTS), and orthostatic hypertension are autonomic neurally-mediated syncope.<sup>[5]</sup> VVS is the most common syncope in children and adolescents.<sup>[5]</sup> The onset of VVS peaks initially in childhood and adolescence and accounts for 60.0-70.0% of all syncope causes.<sup>[6]</sup>

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These patients may suffer from fall-related injuries and recurrent episodes of anxiety and distress, leading to reduced school attendance or community engagement and a loss of independence and Quality of Life (QoL).<sup>[6]</sup>

Nonpharmacological therapy for the management of patients with syncope based on clinical guidelines includes, patient education and reassurance about its benign nature and avoidance of triggers, monitoring signs and symptoms of exacerbation of the syncope, reducing psychological stress, improving self-care behaviors (class I/recommended), physical counter maneuvers for prevention of syncope (e.g., limb and/or abdominal contraction, squatting, and leg crossing) that are a core management strategy, and increased salt and fluid intake in patients without contraindicated medication (class IIa/can be beneficial), and recommendations for tilt training (class IIb/may be reasonable).<sup>[7]</sup>

The systematic review studies show that physical counter-pressure maneuvers and increased salt and fluid intake were successful in improving syncopal symptoms and reducing syncope or presyncope recurrence rates in children with VVS.<sup>[8,9]</sup> However, in patients who have undergone tilt training, Randomized Controlled Trials (RCT) studies have not shown a sustained benefit in reducing episodes of syncope.<sup>[7]</sup>

Lifestyle education is a potentially effective strategy for the management of syncope and the promotion of self-care in patients.<sup>[10]</sup> Increased self-care abilities and improved self-care behavior in children and adolescents with syncope can empower the patients to have better control over their daily lives, prevent syncope attacks, and increase QoL.<sup>[9,10]</sup>

The results of a systematic review and meta-analytic study by Hockin *et al.*<sup>[8]</sup> that aimed to evaluate the impact of syncope and presyncope on QoL showed that syncope can have a negative impact on patients' QoL.

Despite the importance of self-care and lifestyle education in preventing syncope and reducing accidents, anxiety, and stress in children and adolescents with syncope and their parents, limitations such as inadequate patient education and a lack of time prevent clinicians from educating patients.<sup>[11]</sup>

Research studies show that only 53% of patients receive education about their condition after being diagnosed with VVS.<sup>[7]</sup> This suggests that patients do not receive adequate education about self-care and lifestyle for preventing and managing syncope/presyncope.<sup>[7]</sup>

Considering the limitations of the studies conducted in this field in Iran, and the importance of self-care recommendations for the management of syncope, we sought to examine the effect of self-care behaviors on QoL based on clinical guidelines for definitions of classes of recommendation in children and adolescents with VVS. In addition, we explored whether the addition of tilt training to other routine recommendations is effective in improving QoL. Therefore, this study aimed to assess the effect of self-care recommendations with and without tilt training on QoL in children and adolescents with VVS.

## **Materials and Methods**

This randomized clinical trial was conducted in Isfahan, Iran, from April 2017 to June 2021. This study was registered in the Iranian Registry of the Clinical Trial (IRCT) [registration number: IRCT20150428021987N3] and followed the Consolidated Standards of Reporting Trials (CONSORT) guideline.

The participants of this study consisted of children and adolescents aged 6–18 years with recurrent syncope and positive Upright Tilt Testing (UTT) admitted to pediatric cardiology clinics of the Isfahan University of Medical Sciences (Imam Hossein Hospital and Shahid Chamran Hospital), Isfahan, Iran.

The sample size for the present study was calculated based on sample size tables for clinical studies.<sup>[12]</sup> The confidence interval was 95.0%, while the power of the study (1- $\beta$ ) was set at 80.0%. At least, a 108-subject sample size (n = 54 per group) was determined for the study. By considering a 10.0% attrition rate, the final sample size for both groups was about 120 (n = 60 per group).

Inclusion criteria were patients with a history of at least two episodes of syncope or more in the previous year, no mental or physical disorder, no use of drugs that affect syncope (such as mineralocorticoid and beta-blockers), and a positive tilt test. Exclusion criteria included patients with suspected or overt heart disease with a high probability of cardiac syncope, vascular steal syndrome, and voluntary withdrawal from the study.

All children and adolescents referred to a pediatric cardiology clinic for evaluation of syncope symptoms were visited by a pediatric cardiologist with a complete physical examination and complementary diagnostic tests such as electrocardiogram and echocardiography and were deemed to be potentially eligible participants (for syncope) based on UTT results.

In total, 130 eligible children and adolescents with syncope were assessed for eligibility. The subjects were selected based on a simple sampling method among all children and adolescents who were referred to a pediatric cardiology clinic for the evaluation of syncope symptoms. Before random allocation, six patients did not meet inclusion criteria, and four patients were excluded from the study due to unwillingness to participate in the study. The remaining children and adolescents (n = 120) were randomly divided into control (n = 60) and intervention (n = 60) through block randomization.

Numbered, opaque envelopes were used to conceal the allocation of participants. The patients were blinded in

this study. According to the random sequence generated, cards A (intervention) and B (control) were placed in an opaque envelope. In the next step, envelope number 1 was opened for the first participant, and his or her group was selected on the basis of the envelope card. The same method continued for each patient until 60 patients were allocated to the intervention and control groups. We used an independent person who was not involved in the study to allocate concealment and sampling.

In this study, the participants and statistics analyzers were completely unaware of the assigned intervention.

The CONSORT flow diagram of the included participants in the trial is presented in Figure 1.

In this study, educational needs were assessed based on the participants' responses to the pre-test questionnaire. The content of the education program was developed based on the guidelines for the evaluation and management of patients with syncope,<sup>[7]</sup> and approval by five pediatric cardiologists. Children, adolescents, and their parents in the intervention groups received routine self-care recommendations such as dietary advice, behaviors to prevent syncope, and counter-pressure maneuvers along with tilt training while the control group received usual self-care recommendations without tilt training in two separate individual sessions of 45– 60 minutes each, which were held in Imam Hossein Hospital and Shahid Chamran Hospital. The objectives, content, method, and duration of training sessions are shown in Table 1.

All educational sessions in the intervention and control groups were conducted by a pediatric cardiologist and a health education specialist. At the end of the educational intervention, the intervention group received an educational booklet and the control group received a pamphlet.

In addition, after completion of the intervention program, the children and adolescents who participated in this study were followed up by a researcher by telephone (once a month) at the pediatric cardiovascular research center for six months to ensure the implementation of the educational programs.

Self-care behaviors and QoL were measured using self-report questionnaires for the intervention and control groups before and six months after the intervention.

The evaluation of the effect of self-care behavior on QoL was the primary outcome of the present study. In addition to the socio-demographic variables, including age, gender, education level, number of family members, level of education of parents, occupation of parents, and history of physical, and mental diseases, etc., the following variables were measured:

Self-care behaviors in children and adolescents with syncope were measured using a researcher-made questionnaire. Self-care behaviors were assessed using 20 items in three sections, based on guidelines for the evaluation and management of patients with syncope<sup>[7]</sup>:

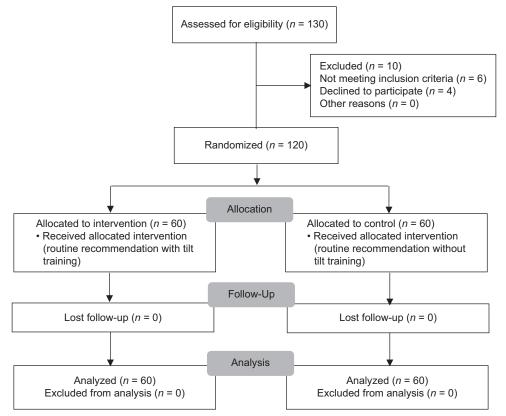


Figure 1: CONSORT flow diagram of participants

	Table 1: Objectives, content, method, and duration of educational sessions					
Sessions	Object	Content**	Training method			
1	Patient education on the diagnosis and prognosis of VVS	<ul> <li>Providing explanations about the basic definition of syncope and an assessment of the cause of syncope</li> <li>Diagnosis, management, and treatment of syncope</li> </ul>	-Lecture -Questions and answers			
		-The importance of self-care behaviors in syncope				
		-Reassuring parents about the benign nature of the condition				
2	Education of patients on self-care behaviors	-Eating breakfast	-Lecture			
		-Increasing daily intake of salt to 5.0 g (equals 5,000 mg or 1 tsp)	-Questions and answers -Role-playing			
		-Eating salty snack	1 7 8			
		-Drinking plenty of water and fluids				
		-Avoiding prolonged standing and sitting in one place				
		-Avoiding exposure to warm environments				
		-Stress management in dental and medical environments				
		-Increasing strengthening exercises in a seated position or lying down, as well as performing isometric muscle tensing (including arm tensing and leg tensing)				
		-Performing physical counter-maneuvers (e.g., limb or abdominal contraction, squatting, leg-crossing)				
		-Increased strengthening exercises in a sitting position or lying down, performing isometric muscle tensing (e.g., arm tensing and leg tensing)				
		-*Standing quietly against a wall (tilt training)				

\*The intervention group received all training on self-care behaviors with tilt training (standing-training). \*\*At the end of the educational intervention, the intervention group received an educational booklet and the control group received a pamphlet

Dietary advice (e.g., eating breakfast, increasing daily salt intake, eating salty snacks, and drinking plenty of water and fluids) (five items).

Behaviors to prevent the recurrence of syncope (e.g., avoidance of prolonged standing or sitting in one place, avoidance of exposure to warm environments, stress management in dental and medical environments, avoidance of sudden movements or changes of position, etc.) (eight items).

Physical counter-maneuvers (e.g., limb or abdominal contraction, squatting, leg-crossing), increased strengthening exercises in a sitting or lying down position, performing isometric muscle tensing (e.g., arms tensing, and leg tensing) (six items), and standing quietly against a wall (tilt training) for the intervention group (one item).

The self-care questions were scored on a five-point rating scale ranging from 1 (never) to 5 (always).

The Content Validity Index (CVI) and Content Validity Ratio (CVR) were used to determine the validity of the instrument after approval by five expert faculty members (pediatric cardiologists).

CVR and CVI of the designed scale ranged from 0.90 to 1.00. The reliability of the instrument was examined using Cronbach's alpha coefficient ( $\alpha = 0.71-0.80$ ).

For measuring the QoL, the Pediatric Quality of Life Inventory<sup>TM</sup> (PedsQL<sup>TM</sup> 4.0) was used. The PedsQL<sup>TM</sup> 4.0 is a questionnaire assessment tool used to evaluate health-related QoL (HRQoL) in children.<sup>[13]</sup> The Persian version of the PedsQL<sup>TM</sup> 4.0 was previously translated and validated by other studies in Iran.<sup>[14,15]</sup> Cronbach's alpha was obtained to be between 0.74 and 0.87.

This questionnaire includes five domains (e.g., physical function (eight items), emotional function (five items), school function (five items), social function (five items), psychosocial function (six items), and general understanding of health (one item)). Each item is rated on a scale from 1 (never) to 5 (always).

Data were analyzed with Statistical Package for the Social Sciences (SPSS) software (version 25.0, IBM Corporation, Armonk, NY, USA).

To investigate the normal distribution of the data, the Kolmogorov-Smirnov test was used. The frequencies and percentages were computed for nominal and ordinal variables and the mean and standard deviation (SD) were calculated for continuous variables.

A Chi-square test was applied for the analysis of the nominal and categorical variables. For the analysis of changes within each group, we used the Wilcoxon test for non-normally distributed data and the paired *t*-test for normally distributed data. The Mann-Whitney U test and the independent-samples test are used to compare differences in the dependent variable between two independent groups for non-normally distributed and normally distributed data, respectively. The significance level was chosen at 5.0%.

#### **Ethical considerations**

The protocol was approved by the ethics committee of the Isfahan University of Medical Sciences (IR.MUI. REC.1396.2.125), and all participants signed the written informed consent before participation.

## Results

Overall, 120 children and adolescents participated in this study. They were randomly assigned to either an intervention group (n = 60) or a control group (n = 60). The intervention and control groups were similar at baseline. According to the results of the Chi-square test, no significant differences were found between the groups in terms of age (p = 0.616), gender (p = 0.118), number of family members (p = 0.651), birth order (p = 0.497), educational level (p = 0.650), parent's education (p = 0.759, p = 0.198), parent's occupation (p = 0.191, p = 0.990), and type of living arrangement (p = 0.402). The mean age in the intervention group and control group was 11.87 (3.11) and 12.55 (3.34) years, respectively. Table 2 demonstrates the socio-demographic characteristics of participants.

The results of the Mann-Whitney test showed that there was no significant difference in the mean scores for all dimensions of QoL in the intervention and control groups before the intervention (p > 0.05).

The Wilcoxon test results showed a significant difference in the mean scores of physical functioning, emotional functioning, social functioning, school functioning, psychosocial functioning, understanding of health, and total QoL in the intervention and control groups before and after the intervention (p < 0.05) [Table 3].

Based on the independent *t*-test results, the intervention and control groups were not statistically different in the mean scores of self-care domains and total self-care before the intervention (p > 0.05). The paired *t*-test results showed a significant difference in the mean scores of self-care domains and total self-care in the intervention and control groups before and after the intervention (p < 0.05) [Table 4].

## Discussion

Self-care is one of the main factors to promote positive health outcomes and prevent frequent syncope episodes in patients.<sup>[6]</sup> The purpose of the present study was to assess the effect of self-care recommendations with and without tilt training on QoL in children and adolescents with VVS.

Generally, the aim of syncope treatment and management is to prevent children and adolescents from accidental injury, reduce syncopal recurrence, and improve patients' QoL.<sup>[11]</sup>

Self-care behavior education including increasing daily salt and fluid intake, avoiding prolonged standing and sitting, avoiding warm environments, physical counter-pressure maneuvers, standing quietly against a wall, etc. are helpful and necessary first strategies, especially for children and adolescents with syncope.<sup>[16,17]</sup>

The result of a systematic review and meta-analysis by Hockin *et al.*<sup>[8]</sup> shows that the frequency of syncopal events with profound impairment in all domains of physical and mental health is the most important factor influencing the QoL of patients with syncope. Syncopal episodes in patients can lead to anxiety, fear, stress, and distress and affect the individual's ability to participate fully in active, independent living and activities of daily living.<sup>[8]</sup> In our study, data analysis showed that the mean scores of physical and mental health, emotional functioning, social functioning, and school functioning domain in the intervention and control groups were significantly lower before the intervention.

The study results are similar to those obtained by Kovalchuk *et al.*<sup>[18]</sup> that the PedsQL scores and psychosocial health, emotional functioning, and social functioning domain scores were reduced in the patients with VVS.

In addition, the results of the study by Jorge *et al.*<sup>[19]</sup> showed activity restrictions in children and adolescents because the frequent syncope episodes may impair school attendance, performance and participation in activities.

Moreover, the results of a qualitative study by Skeldon *et al.*<sup>[20]</sup> on adolescents aged 12–17 years old show that syncope affects their current and future opportunities, psychological well-being, and HRQoL. This evidence suggests that in addition to standard management of syncope, attention to physical, social, and mental health concerns and injury rehabilitation is a priority to prevent school absenteeism in patients with VVS syncope, especially in children and adolescents with frequent syncope episodes.<sup>[20]</sup>

Based on the results of the present study, the score of all PedsQL domains (including physical functioning, emotional functioning, social functioning, school functioning, psychosocial functioning, and understanding of health) increased significantly in all patients with syncope in both groups after the intervention with a six-month follow-up.

Moreover, the results of similar studies by Shigeyasu *et al.*<sup>[21]</sup> showed that patient education, including teaching self-care and healthy lifestyle advice, facilitates self-efficacy, which is a significant predictor of QoL. These results indicate that, due to the usually benign nature of VVS and its frequent remission, the

Characteristics	Intervention	Control		<i>p</i> *
Continuous variables	(self-care with tilt-training) ( <i>n</i> =60) Mean (SD)	(self-care without tilt-training) ( <i>n</i> =60) Mean (SD)		
Age (years)	11.87 (3.11)	12.55 (3.34)	118	0.616
Categorical variables	<i>n</i> %	<i>n</i> %	110	
Gender				P
Boy	15 (25.00)	24 (40.00)		
Girl	45 (75.00)	36 (60.00)	2	0.118
Number of family members	10 (7000)		-	0.110
Three	11 (18.33)	13 (21.67)		
Four	31 (51.67)	34 (56.67)	3	0.651
Five	15 (25.00)	12 (20.00)		
Six	3 (5.00)	1 (1.66)		
Birth order	- ( )			
First-born	30 (50.00)	35 (58.34)		
Second-born	21 (35.00)	21 (35.00)	3	0.497
Third-born	6 (10.00)	3 (5.00)		
Fourth-born	3 (5.00)	1 (1.66)		
Educational level	× ,			
(Grade 1-6) elementary school	33 (55.00)	38 (63.34)		
(Grade 7–8) high school	11 (18.33)	9 (15.00)	2	0.650
(Grade 9–12) high school	16 (26.67)	13 (21.66)		
Mother's education	× ,			
Illiterate	3 (5.00)	1 (1.66)		
Elementary school	3 (5.00)	5 (8.34)		
High school	11 (18.33)	8 (13.33)	5	0.759
Diploma	24 (40.00)	28 (46.67)		
College degree or more	19 (31.67)	18 (30.00)		
Father's education				
Illiterate	6 (10.00)	1 (1.66)		
Elementary school	9 (15.00)	10 (16.66)		
High school	8 (13.33)	10 (16.66)	5	0.198
Diploma	15 (25.00)	22 (36.67)		
College degree or more	22 (36.67)	17 (28.35)		
Mother's occupation				
Housewife	49 (81.70)	54 (90.00)		
Employed	11 (18.30)	6 (10.00)	1	0.191
Father's occupation				
Laborer	16 (26.67)	15 (25.00)		
Employee	11 (18.33)	12 (20.00)		
Retired	3 (5.00)	3 (5.00)	4	0.990
Self-employed	28 (46.67)	27 (45.00)		
Unemployed	2 (3.33)	3 (5.00)		
Type of living arrangement				
Living with father and mother	56 (93.33)	58 (96.67)		
Living with mother	4 (6.67)	2 (3.33)	1	0.402

Significant at 0.05 level, \*p=independent samples t-test, \*\*p-value=Chi-square tests, SD=standard deviation

implementation of self-care recommendations in patients with syncope will improve the QoL of patients with VVS.<sup>[21]</sup>

The results of our study are consistent with these findings and show that teaching self-care behaviors is effective in improving the QoL of children and adolescents with syncope. The results of the present study showed that self-care behaviors (including dietary advice, preventive behaviors, counter-pressure maneuvers, and physical exercise) were significantly increased after six months in both groups of children and adolescents who performed the syncope routine recommendations with and without tilt training (standing-training).

PedsQL domains	Intervention	Control		<i>p</i> *
	(self-care with tilt-training) ( <i>n</i> =60)	(self-care without tilt training) ( <i>n</i> =60)		
	Mean (SD)***	Mean (SD)		
Physical functioning				
Baseline	33.70 (5.72)	32.93 (6.78)	1	0.818
Six months after intervention	37.28 (3.45)	39.90 (3.68)		
$p^{**}$	< 0.001	< 0.001		
Z**	-4.12	-4.42		
Emotional functioning				
Baseline	16.66 (5.57)	17.58 (5.01)	1	0.39
Six months after intervention	20.70 (3.95)	21.60 (3.10)		
$p^{**}$	< 0.001	< 0.001		
Z**	-5.12	-5.58		
Social functioning				
Baseline	19.86 (5.17)	18.53 (5.19)	1	0.09
Six months after intervention	23.78 (2.06)	23.11 (3.31)		
$p^{**}$	< 0.001	< 0.001		
Z**	-5.43	-5.98		
School functioning				
Baseline	21.63 (4.36)	21.83 (3.59)	1	0.63
Six months after intervention	23.35 (2.95)	23.85 (2.71)		
$p^{**}$	0.001	< 0.001		
Z**	-3.35	-3.80		
Psychosocial functioning				
Baseline	19.81 (3.36)	19.76 (4.09)	1	0.97
Six months after intervention	26.90 (3.31)	27.61 (3.39)		
$p^{**}$	< 0.001	< 0.001		
Z**	-4.95	-3.50		
Understanding of health				
Baseline	3.28 (0.90)	3.18 (0.70)	1	0.562
Six months after intervention	4.45 (0.64)	4.13±0.83		
$p^{**}$	< 0.001	< 0.001		
Z**		-5.15		
Total				
Baseline	114.98 (18.14)	113.83 (19.31)	1	0.84
Six months after intervention	131.78 (11.74)	133.35 (11.90)		
<i>p</i> **	<0.001	<0.001		
Z**	-5.70	-6.28		

Table 3: Comparison between the Mean (SD) scores of quality of life (PedsQL) domains in children and adolescents at
haseline and 6 months after intervention in two groups

Significant at 0.05 level, \*the results of the Mann-Whitney test, \*\*the results of the Wilcoxon test, \*\*\*SD=standard deviation

In this study, dietary recommendations, including eating breakfast, increasing daily salt intake and salty snacks, and drinking plenty of water and fluids, were considered to be a dimension of self-care behaviors. Similarly, a meta-analysis published by Wang *et al.*<sup>[22]</sup> with the aim to assess the efficacy of increased salt and water intake on pediatric VVS showed that salt and water intake is an effective measure in the management and treatment of pediatric VVS and can significantly reduce the recurrence rate of syncope or presyncope.

Therefore, it is theoretically believed that salt and water supplementation may increase blood volume and have a role in the prevention and management of VVS in children and adolescents.<sup>[9]</sup> Our results showed the importance of increasing salt and water intake in patients with syncope, indicating that self-care behavior education can help improve VVS and QoL.

In our study, lifestyle modification education programs (including avoiding prolonged standing and sitting in one place, exposure to warm environments, etc.) increased in both groups after education and six-month follow-up. Similar to this research, the results of the study by Dani *et al.*<sup>[23]</sup> showed that a multifaceted approach to syncope management and treatment (including patient education and lifestyle changes) plays a critical role in syncope and reduces physical, psychological, and

Self-care domains	Intervention	Control	<i>p*</i>	df*	<i>t</i> *
	with tilt-training ( <i>n</i> =60)	without tilt-training ( <i>n</i> =60)			
	Mean (SD)***	Mean (SD)			
Dietary advice					
Baseline	9.38 (3.02)	9.78 (3.63)	0.513	118	-0.655
Six months after intervention	18.05 (2.77)	18.50 (2.08)			
<i>p</i> **	< 0.001	< 0.001			
df **	59	59			
<i>t</i> **	-15.39	-17.59			
Behaviors to prevent syncope					
Baseline	18.31 (5.46)	17.68 (6.12)	0.555	118	0.598
Six months after intervention	35.48 (4.50)	33.48 (3.13)			
<i>p</i> **	< 0.001	< 0.001			
df **	59	59			
<i>t</i> **	-16.30	-16.81			
Counter-pressure maneuvers					
Baseline	5.55 (1.88)	4.75 (1.49)	0.291	118	-1.06
Six months after intervention	19.45 (5.16)	16.98 (3.24)			
$p^{**}$	< 0.001	< 0.001			
df **	59	59			
<i>t</i> **	-20.16	-26.28			
Total					
Baseline	32.21 (8.63)	30.83 (8.35)	0.105	118	-1.63
Six months after intervention	72.98 (10.68)	68.96 (6.45)			
$p^{**}$	< 0.001	< 0.001			
df **	59	59			
<i>t</i> **	-20.23	-26.28			

Table 4: Comparison between the mean scores of self-care domains in children and adolescents with syncope at					
baseline and six months after intervention in both groups					

Significant at 0.05 level, \*the results of the independent sample *t*-test, \*\*the results of the paired sample *t*-test, \*\*\*SD=standard deviation Note:

Dietary advice (e.g., eating breakfast, increasing daily salt intake, eating salty snacks, and drinking plenty of water and fluids).

Behaviors to prevent syncope (e.g., avoidance of prolonged standing or sitting in one place, avoidance of exposure to warm environments, stress management in dental and medical environments, and avoidance of sudden movements or changes of position, etc.).

Counter-pressure maneuvers (e.g., limb or abdominal contraction, squatting, leg-crossing), increased strengthening exercises in a sitting position or lying down, and performing isometric muscle tensing (e.g., arm tensing and leg tensing).

psychosocial morbidity in patients, which is associated with improving the QoL in them.

In the present study, we observed an increase in the children's and adolescents' mean scores for exercises and physical counter-pressure maneuvers six months after the intervention completion. Consistent with the present study, the results of a systematic review and meta-analysis by Williams *et al.*<sup>[24]</sup> show that physical counter-pressure maneuvers are a risk-free, cost-effective, and first-line management strategy for syncope prevention.

The results of the study by Loughlin *et al.*<sup>[9]</sup> and Alizadeh *et al.*<sup>[25]</sup> show that QoL in patients is inversely related to the frequency of recurrent syncope. Therefore, training in physical counter-pressure maneuvers for patients with VVS may reduce episodes of syncope, lower syncope burden, and improve QoL.

Our results showed that with the addition of tilt training to the routine recommendations for the management of syncope, there were no large differences in the mean scores for QoL between the two groups. Therefore, tilt training as an adjunctive therapy alone is not superior for the reduction of recurrent syncope and improvement of QoL in patients with syncope.<sup>[7]</sup> Similarly, the results of the study by Sabri *et al.*<sup>[26]</sup> during an eight-year follow-up period on 70 patients (aged 5–20 years) with syncope demonstrated that nonpharmacologic treatment (including diet along with tilt training) is effective in the prevention of syncope relapses.

Therefore, according to the American College of Cardiology guidelines for the evaluation and management of patients with syncope, conventional recommendations such as fluid and salt intake, patient education on the diagnosis and prognosis of VVS, and physical counter-pressure maneuvers along with tilt training are effective in the prevention and management of syncope and improve patients' QoL,<sup>[7]</sup> which has been confirmed by current researchers.

It can be said that self-care education for children and adolescents with syncope leads to increased awareness, prevention of syncope recurrence, and improved QoL in these patients.

Among the strengths of this study is that it was designed and implemented for the first time to investigate the effect of self-care on the QoL of children and adolescents with syncope in Iran and across the world. Other strengths of this study are the investigation of QoL in children and adolescents with syncope in both genders of participants, face-to-face education, and six-month follow-up.

The most important limitation of this study was that the PedsQL<sup>™</sup> inventory was not used for parent reports. Therefore, future studies are recommended to compare the effects of self-care on QoL in children and adolescents with syncope using the PedsQL<sup>™</sup> 4.0 inventory for child self-report and parent proxy. Another limitation of the present study was the use of a self-report questionnaire. Consequently, to increase the generalizability of the results, more studies are warranted in this regard.

### Conclusion

Routine recommendations for self-care behaviors, including dietary advice, preventive behaviors, and performing counter-pressure maneuvers with and without tilt training, can improve the QoL of children and adolescents with syncope. This study also showed that adding tilt training (standing training) to self-care behaviors did not significantly improve QoL scores in children and adolescents with syncope. As a result, clinicians can use all self-care recommendations for the management and prevention of syncope and effectively improve the QoL of patients with syncope.

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#### **Conflicts of interest**

Nothing to declare.

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