TOPICS IN STROKE REHABILITATION
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The effect of education based on the seven-step (7E) learning cycle on the quality of life of stroke patients and the care burden of their caregivers: a randomized clinical trial

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ABSTRACT

Introduction: Education deficiency increases caregiver burden, worsening patient's Quality of Life (QoL). The Seven-Step (7E) model enhances critical thinking and problem-solving skills using previous experiences. This study aimed at evaluating the influence of education using 7E model on the stroke patients' QoL and the caregivers' burden.

Methods: Following a single-blind parallel-group randomized controlled trial, 110 patient-caregiver dyads were included in the present study from 10 July 2024 to 15 November 2024. The study was conducted in two hospitals and one clinic affiliated with the Shahid Beheshti University of Medical Sciences. They were randomly divided into two groups: 7E model ($n = 55$) and routine education ($n = 55$). Data was collected with the Stroke-Specific Quality of Life Scale and Caregiver Burden Inventory (CBI). In the experimental group, training was conducted based on the 7E model. The questionnaires were completed at the pre-test stage and eight weeks later as post-tests.

Results: Before the intervention, the two groups did not have a statistically significant difference in demographic information and the total score of QoL and CBI ($p > 0.05$). After intervention, the analysis showed that the mean scores were significantly higher in all dimensions except mobility and self-care in the experimental group compared to the control group ($p < 0.05$). Also, regarding caregiver burden, after removing the effect of age, results showed that the CBI in all dimensions' scores in the experimental group were significantly lower compared to the control group ($p = 0.004$).

Conclusion: Compared to conventional educational approaches, 7E model demonstrated greater efficacy in improving patients' quality of life and reducing caregiver burden.

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7E learning cycle model; education; caregiver burden; quality of life; stroke

Introduction

The occurrence of cerebrovascular accidents (CVAs) leads to the demise of brain cells due to inadequate oxygenation in the blood flow or cerebral arteries.[1] Furthermore, these patients may exhibit substantial functional and psychosocial impairments, leading to restricted mobility and compromised performance regarding activities of daily living.[2] Stroke is commonly categorized into two main types, namely ischemic and hemorrhagic, with ischemic stroke being the most prevalent (constituting approximately 80% of all strokes).[3] An Iranian cohort study analysis revealed a standardized incidence rate of 185.2 first-ever strokes per 100,000 person-years (95% CI: 173.2–197.2).[4] Stroke currently ranks as the second leading cause of death and the primary cause of permanent disability among individuals, constituting 11.3% of all disease-related fatalities.[5] Nearly 50% of patients with stroke suffer from dependence on others for their daily activities due to their disability.[1,2,5,6]

Risk factors associated with stroke include hypertension, elevated blood cholesterol levels, tobacco use, excessive alcohol consumption, and oral contraceptive use.[7] It has been observed that around 60% of stroke survivors experience ongoing dysfunction.[8] This condition hinders the patient's ability to carry out daily activities independently, resulting in increased feelings of depression, anxiety, sleep deprivation, helplessness, and a potential decline in quality of life.[8–10]

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Quality of life (QoL) is characterized as individuals' perception of their status in society, considering the cultural and value system they belong to and their objectives, expectations, standards, and concerns.[11–13] Additionally, deficiencies in education can heighten both depression levels and caregiver burden, thereby exacerbating the patient's diminished QoL.[12–14]

Stroke patients experience reliance on their families, adversely affecting both the patients and their families.[14] As informal caregivers, the family is crucial in patient care.[15,16] The caregivers are burdened with a heavy responsibility in caring for stroke patients.[16] Psychological disorders, including anxiety and depression, are commonly observed among caregivers of stroke patients, with a prevalence ranging from 20–40%.[17] The term "caring burden" is utilized to denote the emotional, economic, and physical toll experienced by caregivers, encompassing both internal (emotional reactions of the caregiver with the act of caregiving) and external (disruptions and alterations in various aspects of the caregiver's life) components.[17] As the disease progresses, the caregiver burden intensifies,[15] resulting in multiple consequences such as compromised health and isolation from family, inadequate patient care, sleep disturbances, difficulties in fulfilling the roles of both patient and caregiver, strained social relationships, heightened mental stress, and ultimately, the rejection of the patient.[15–17]

The combination of education and functional interventions, such as rehabilitation, which includes speech therapy and occupational therapy, has the potential to enhance the adaptation of patients and their caregivers to the disease and its complications.[18] The educational model based on the 7-step learning cycle (7E) is one of the recently introduced cooperative educational models. Devised by Eisencroft in 2003, the E7 learning model is highly appropriate for developing concept-based activities. A significant outcome of education using this model is enhancing cognitive development and individuals' comprehension skills through a structured approach.[19,20]

The learning-oriented model, known as the 7-step learning cycle, consists of various steps, including elicit, engaging, exploration, explanation, elaboration, evaluation, and extend, all aimed at enhancing skills.[21,22] Through this cycle, the learner can leverage critical thinking, independent and creative problem-solving, and utilize previous experiences and essential skills.[23–26] While employing a scientific approach to acquire the necessary knowledge,[27] this matter fosters a more effective and enjoyable learning experience for learners.[22] The application of this method has been predominantly confined to educational settings, and its clinical efficacy has been the subject of only a few studies. One of these studies was the study by Nekouei et al. Compared to conventional teaching methodologies, this study found the 7E learning cycle model to be more effective in improving nursing students' understanding of diabetic foot ulcer prevention, critical thinking abilities, and self-efficacy.[28]

Given the primary role of nurses, which encompasses the provision of care and education, the prevalence of stroke disease and its harmful consequences, the exceptional importance placed on the QoL of stroke patients, the profound effects this condition has on the life of their caregivers, and the close relationship between caregivers and patients` health, greater attention is needed in this field. The model presented in this research has had minimal utilization, particularly in the context of patient care. Consequently, our research team decided to conduct a study to assess the impact of education utilizing the seven-step learning cycle on the QoL of stroke patients and the caregiver burden experienced by their caregivers.

Method

Trial design

This study was conducted from 10 July 2024 to 15 November 2024 using a single-blind, parallel-group, randomized clinical trial (RCT) in two hospitals and one clinic affiliated with Shahid Beheshti University of Medical Sciences, Tehran, Iran. It is written based on the relevant reporting guideline, Consolidated Standards of Reporting Trials (CONSORT 2010) (Supplementary Material 1). A total of 110 patient-caregiver dyads were initially involved in this study. Exclusions were made for 5 patient-caregiver dyads throughout the study and follow-up period in each group. Subsequently, the analyses were performed using a sample size of 100 dyads (50 in each group; experimental group (A) and control group (B)) (Figure 1).

Participants

The research sample for this study comprised stroke patients and their caregivers who met the inclusion criteria and were admitted to the neurology department of hospitals affiliated with Shahid Beheshti University of Medical Sciences. The inclusion and exclusion criteria regarding stroke survivors and their caregivers are defined as follows:

Stroke survivors

Inclusion Criteria

The inclusion criteria were as follows: Adult participants, aged 18 to 70 years, were admitted to the neurology department of hospitals affiliated with Shahid Beheshti University of Medical Sciences or referred to the Center Stroke Clinic and expressed their desire to participate in this research. Also, patients should be alert and aware of the time, place, and person and should have the ability to be trained. Patient orientation was assessed by employing the following queries: “What is your name? Where are you? What day is it?” To be included, participants had to meet the criteria of not receiving thrombolytic drugs and not being hospitalized due to stroke complications.

Exclusion criteria

Suffering from known physical and mental diseases that affect the QoL, such as dialysis, or other known mental problems, like depression

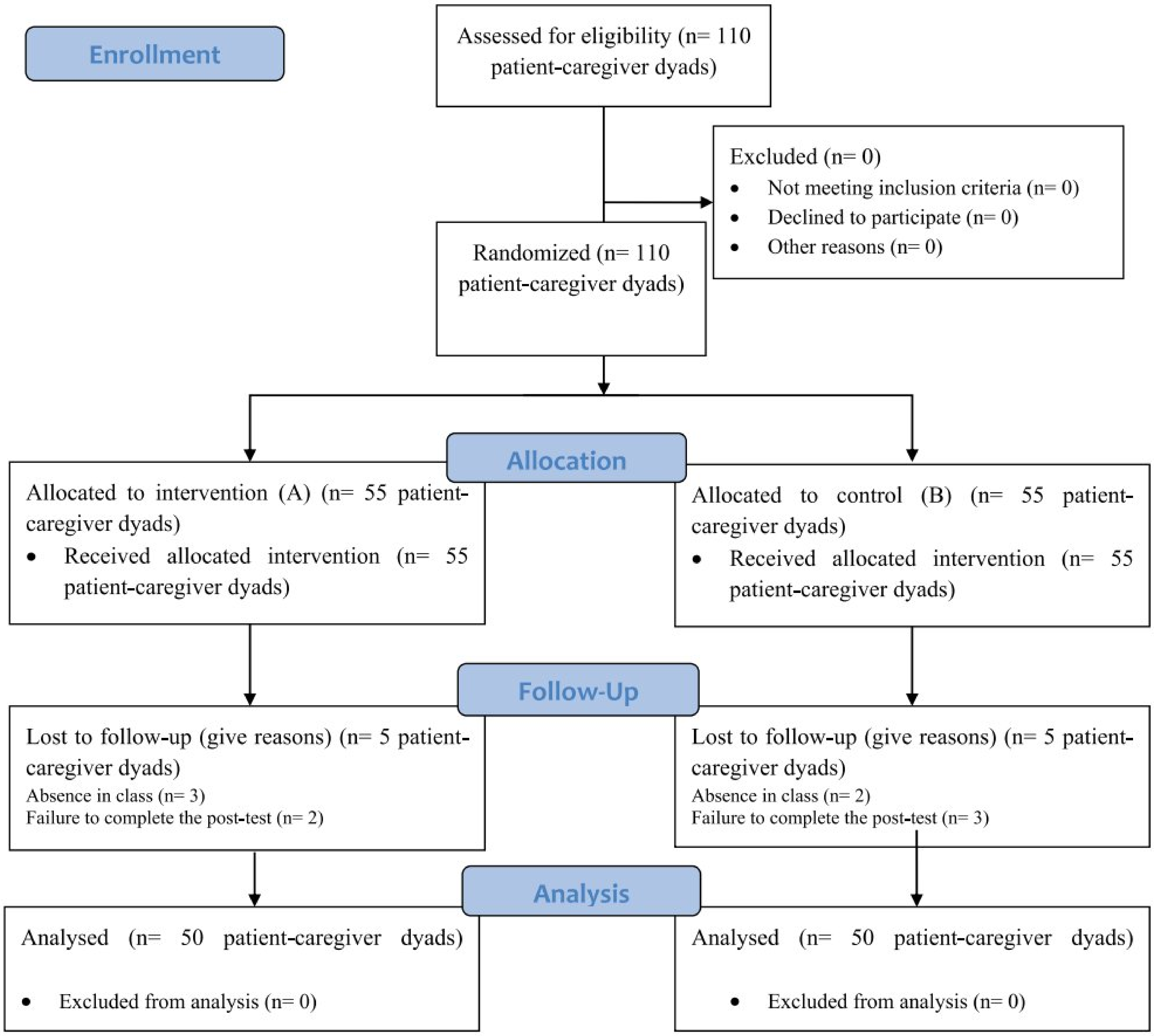

Figure 1. CONSORT 2010 flow diagram of participants allocations.

and schizophrenia, which require particular medication or diet (according to the patient's self-report), not attending in two (or more) sessions out of the total number of follow-up sessions, participating in another educational program during the research, needing readmission in the acute phase, having hearing, visual and touch problems or not being able to speak Persian language, and failure to complete or have incomplete fulfillment of questionnaires, were among our exclusion criteria.

Caregivers

Inclusion Criteria

Adult informal caregivers who were accountable for patients' care and provided care to the patient at least twice a week were deemed eligible for inclusion. Also, they should not have had the experience of caring for a stroke patient in the past and should expressed a desire to partake in the study. Moreover, the caregiver must possess the ability to read and write, as well as communicate effectively.

Exclusion criteria

Caregivers` patients dying during the study, previously participating in education sessions related to this research, taking care of another patient in addition to the patient suffering from stroke, having a known mental disorder or being complicated with any severe disease or poorly controlled comorbidities (e.g. advanced cancer, advanced heart failure, severe/major neurological disease, etc.) (according to self-report), and being a healthcare worker were among the exclusion criteria.

Sample size

Sample sizes for each group were calculated using the following equation:

$$n \geq 2\frac{\left(Z_{\alpha/2} + Z_{\beta}\right)^{2}\sigma^{2}}{\left(\mu_{1} - \mu_{2}\right)^{2}}$$

The probability of committing a Type I error was considered equal to: $\alpha = 0.05 \Rightarrow Z_{\alpha/2} = 1.96$, and the probability of committing a Type II error was considered equal to: $\beta = 0.10 \Rightarrow Z_{\beta} = 1.28$. The observed effect size was the mean difference in QoL scores, which was obtained from Urcan et al. `s study (Control Group: Mean = 159.08 and Standard Deviation = 40.28, Experimental group: Mean = 183.52 and Standard Deviation = 33.50).[29] A sample size of 50 participants per group was determined using a power analysis of 90%, a mean difference of 24.44, and a standard deviation of 40.28 and 33.50 for the control and experimental group, respectively. Considering a 10% drop-out rate, the desired sample size was determined as 55 participants in each group.

Randomization and blinding

Randomizations were implemented using the random block method. First, a random allocation sequence and list of blocks were obtained. The website https://www.sealedenvelope.com was used to generate a random sequence for block-type randomization so that there was no limit on the number of blocks for random allocation. This research used the block method with four blocks to create a random allocation sequence. According to the total number of samples required for the study, which was 110 patient-caregiver dyads (55 patient-caregiver dyads in experimental group A and 55 patient-caregiver dyads in control group B), quadruple blocks including two groups A and B, were randomly obtained through the site. Based on the list of randomly prepared quadruple blocks, a trained nursing expert outside the research group registered the participants and randomly allocated patients. After the entry of each patient according to the quadruple blocks prepared in the first stage, patients were randomly assigned to groups A (experimental group) or B (control group). For example, after randomly selecting the BBAB block, the patients were assigned to the control, control, experimental, and control groups in the order of arrival. The sampling process was carried out sequentially in the same way until the sampling was completed, and the code of each patient was also assigned to their family member.

Due to the nature of this research, it was impossible to blind the researcher, the patient, and the family. Also, the data analyst was blind regarding the allocation of the groups. Data entry was implemented in a manner that ensured the statistician could not differentiate the experimental and control groups, thus mitigating bias.

Educational material

The first step in formulating the educational material involved a literature review. Reliable English and Persian databases were searched using keywords to find articles, books, programs, and academic booklets. Experts' review validated the provided content. Then, we made improvements based on reviews. The program was administered to two patients and their caregivers to assess the face validity. Their feedback regarding the program's user-friendliness and satisfaction with its design elements (shapes, font size, etc.) was analyzed. Structural adjustments were implemented in response to their comments. To ensure the content's validity, the program underwent a thorough examination by three experts who assessed its structure, content, and usability. Following necessary revisions, the program was implemented.

7E learning model

Atkin and Karplus developed a learning cycle comprising three stages: exploration, invention, and discovery. Subsequently, the learning cycle was formulated to encompass five stages: Engagement, Exploration, Explanation, Elaboration, and Evaluation. Later on, Arthur Eisenkraft made revisions to the 7E learning cycle by introducing instructional steps associated with the concept of the teaching process while maintaining the essential steps of the 5E learning cycle. This recognition guarantees that the trainer considers all significant aspects of the learning process and effectively establishes associations between prior understanding and concepts[28] (Figure 2). The seven-step learning cycle model 7E components are also presented in Supplementary Material 2.

Ethical consideration

The researcher obtained the code of ethics to carry out this research (IR.SBMU.PHARMACY.REC.1402.198) from the Ethics Committee of Shahid Beheshti University of Medical Sciences and received permission to conduct the research from the Research Vice-Chancellor of Shahid Beheshti University of Medical Sciences. Also, the protocol of this study was prospectively registered in IRCT under the code IRCT20240205060913N1. This research was conducted in compliance with the guidelines outlined in the Declaration of Helsinki. A thorough explanation of the study's aims and methods was subsequently given to the head nurses and neurology ward nurses. We ensured the strict confidentiality of all participant data and identities. Participants were further informed of their voluntary status and right to discontinue participation as desired. Written informed consent was obtained from all participants before their involvement in the study. Upon completion of data collection, the control group received our educational materials.

Intervention

The experimental group participants were given teaching based on the 7E learning cycle model. The training program, which followed the seven-step learning model, was conducted in the experimental group over five sessions. These sessions consisted of 30–40 minutes of face-to-face training, with one individual and two group sessions comprising four to six participants' dyads. Additionally, two online training sessions were provided individually after discharge.

The educational material encompasses the definition of stroke disease, the various types of strokes (ischemic, hemorrhagic, transient ischemic), the significance of treatment adherence, adherence to medication regimen and its importance, as well as the complications faced by stroke patients (specific dietary program for patients with swallowing difficulties, rehabilitation programs, and speech therapy). In addition, the presentation addressed the principles of preventing re-occurrence and outlined the team structure for treatment. It highlighted the value of family presence and active participation in the educational program, the role played by patients and their families in various meetings, and the formulation of the treatment and care plan. In re-occurrence education, individuals were taught multiple recommendations aimed at preventing the re-occurrence of stroke, such as anger control, stress management, proper nutrition, medication adherence, and following instructions. Furthermore, the session covered the reasons behind re-occurrence, such as noncompliance with medication and care plans, lack of family cooperation in the patient's treatment and care process, the patient's non-cooperation with the treatment staff, and noncompliance with the treatment and medication plans. All the educational materials were structured and delivered following the 7E learning cycle model, which includes the stages of elicit, engaging, exploration, explanation, elaboration, evaluation, and extension (Supplementary Material 2).

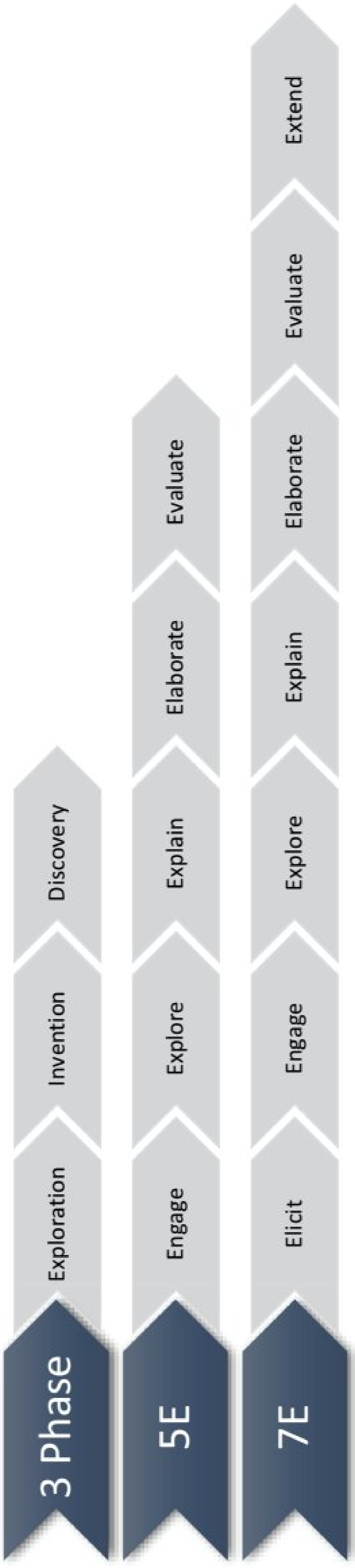

Figure 2. A brief history of 7E.

Control

The control group was given standard and routine training. The questionnaires were completed before and eight weeks after the training. Finally, to ensure compliance with ethical standards, educational material was developed based on the information presented during the meetings and distributed to all participants in the control group.

Instrumentation

This study utilized four instruments: a patient's demographic questionnaire, a caregivers' demographic questionnaire, a Stroke-Specific Quality of Life Scale (SS-QoL), and a Caregiver Burden Inventory (CBI). Questionnaires were completed just before the intervention, and post-tests were completed in a two-month follow-up. The following are the research instruments utilized:

Patients' demographic questionnaire

The first portion encompasses demographic characteristics, including age, gender, marital status, occupation, education level, residential location, insurance coverage, and stroke classification. The second portion pertains to underlying comorbidities.

Caregivers' demographic questionnaire

The information encompasses age, gender, relationship between caregiver and patient, marital status, educational level, occupation, and living with the patient.

Stroke-Specific Quality of Life questionnaire (SSQoL)

The Stroke Specific Quality of Life Scale was developed by William et al.[30] This tool assesses stroke patients' physical, psychological, and social conditions. It consists of 49 questions. The questionnaire comprises multiple dimensions: energy (Q1-Q3), family roles (Q4-Q6), language (Q7-Q11), mobility (Q12-Q17), mood (Q18-Q22), personality (Q23-Q25), self-care (Q26-Q30), social roles (Q31-Q35), thinking (Q36-Q38), upper extremity function (Q39-Q43), vision (Q44-Q46), work/productivity (Q47-Q49).[31,] The original version of the questionnaire is provided in Supplementary Material 3.

The reliability of this instrument was examined by Williams et al. (1999) for internal consistency in 34 individuals with stroke and found that Cronbach's alpha ranged from adequate (alpha =.75 for the work/productivity subscale) to excellent (alpha =. 89 for self-care), indicating that SS-QOL has a strong internal consistency.[32–34] Azimi et al. conducted a validation and reliability study of the questionnaire in Iran. Cronbach's alpha coefficient was utilized to assess reliability, resulting in a value of 0.95.[35]

The English questionnaire was translated into Persian using the Forward-Backward method in this research. Experienced Persian translators initially translated the instrument. Our translation process prioritized the preservation of the original meaning. Experts reviewed and compared the translated version with the originals, resolving and integrating discrepancies. To ensure accuracy, a second translation was performed by a native English speaker with Persian language skills, who was unaware of the initial translation. A qualitative assessment of face validity was conducted, in which ten participants evaluated the clarity and coherence of phrasing, item relevance, potential ambiguities, and the need for item reduction or combination. Furthermore, a panel of two nursing professors and two psychometric specialists reviewed the scale to ascertain its construct validity. Furthermore, a panel of academic and senior clinical experts reviewed the materials for content validity, ensuring comprehensiveness, accuracy, and applicability. Necessary modifications were implemented. The tool's reliability was measured in this study by the internal consistency method, which led to a Cronbach's alpha coefficient of 0.87 in total. Also, regarding subscales, including energy, family roles, mood, personality, social roles, mobility, thinking, upper extremity function, vision, work/productivity, language, and self-care, resulted in reliability scores of 0.79, 0.70, 0.85, 0.77, 0.80, 0.79, 0.75, 0.70, 0.71, 0.83, 0.86, and 0.93.

Caregiver Burden Inventory (CBI)

The Questionnaire (CBI), developed by Novak and Guest in 1989, serves as a tool to assess both objective and subjective care burdens.[36] Novak et al. conducted a study specifically focused on measuring the validity and reliability of the CBI questionnaire. The translation of this tool into multiple languages has enabled its utilization in various countries such as Brazil, Turkey, China, and Italy.[37–40] With a total of 24 statements, the CBI questionnaire encompasses five dimensions: time-dependent (five statements), developmental (five statements), physical (four statements), social (five statements), and emotional (five statements). This questionnaire is based on a five-point Likert scale from completely disagree (Score= 1) to completely agree (Score= 5). Scores on this questionnaire range from 0 to 96; the higher the total score, the greater the burden of care. The original version of the questionnaire is provided in Supplementary Material 4.

In a study, Novak and Guest assessed the validity and reliability of this questionnaire, leading to Cronbach's alpha reliability coefficients of 0.85 and 0.87 for the first and second subscales, respectively, and 0.86, 0.73, and 0.77 for the third, fourth, and fifth subscales, respectively.[41]

Shafizadeh et al. examined the validity and reliability of the Persian version of the Caregiving Burden Measurement Questionnaire in 150 caregivers of Alzheimer's patients (CBI). Considering the experts' opinions, the face and content validity were qualitatively assessed and confirmed. Also, Cronbach's alpha coefficient for this scale was 0.93 in this study. The test-retest reliability coefficient of the intra-cluster correlation with a two-week interval was 0.96.[42] Furthermore, Abbasi et al. (2011) reported a Cronbach's alpha coefficient of 0.90 for this questionnaire in their Iranian study; subscale reliabilities ranged from 0.72 to 0.82.[43] The instrument's reliability was 0.80, as analyzed through internal consistency and test-retest analysis in our research.

Statistical analysis

The analysis of the collected data was conducted using SPSS software version 20. The data was normally distributed. We applied chi-squared tests and independent sample t-tests to evaluate the qualitative and quantitative demographic variables between the two groups. Additionally, non-parametric Fisher exact test, parametric ANCOVA, and paired sample t-tests were employed to compare the means of quantitative variables across the two groups. A significance level of < 0.05 was considered for evaluation.

Results

Demographic characteristics

The results of the chi-squared and independent sample t-tests revealed no significant difference in the demographic characteristics between the two groups except the age of caregivers, implying that the demographic characteristics of both groups were homogeneous for patients (Table 1).

Stroke survivor's quality of life

The mean QoL score of stroke patients did not display any significant differences between the two groups before the implementation of the intervention. In experimental group, the mean overall score of the QoL of the patients after the intervention (142.74 ± 27.18) was higher than the mean score before the intervention (88.44 ± 19.19) ($p < 0.001$). There was a significant mean difference of 54.30 before and after the intervention. Additionally, there was a significant improvement in all dimensions of QoL in experimental group post-intervention compared to pre-intervention ($p < 0.05$). The control group's QoL pre-posttest mean difference was also 34.08, which showed a significant increase in participants' QoL in control group after the intervention ($p < 0.001$). Also, all dimensions in the control group had a significant increase after the intervention ($p < 0.05$) (Table 2). The mean overall QoL score before the intervention was homogenous between the two groups ($p = 0.371$). After the intervention, the mean score of QoL in the experimental group (142.74 ± 27.18) was significantly higher than the control group (119.38 ± 16.69) ($p <$ 0.001) (Table 2). After adjustment for pre-test scores, the analysis of covariance showed that the mean post-test scores were significantly higher in all dimensions except mobility and self-care in experimental group compared to control group ($p < 0.05$).

Caregiver burden

Regarding caregiver burden, except for the social subscale of CBI ($p = 0.004$), no significant difference was observed between the two groups before the intervention. The experimental group's mean post-test overall CBI score (57.58 ± 17.10) exhibited a significant decrease compared to the mean pre-test scores (93.42 ± 13.63). A significant difference of − 35.84 was observed before and after the intervention ($p <$ 0.001). All subscales of CBI showed a significant decrease after intervention in experimental group, compared to baseline. The control group's mean pre-test and post-test CBI scores were 92.00 ± 16.26 and 77.12 ± 12.98, respectively. The post-test mean scores exhibited a reduction of 14.88 compared to the pre-test scores, which was statistically significant ($p <$ 0.001). After removing the effect of the age and pre-test scores, results showed that the CBI post-test scores in experimental group were significantly lower compared to control group ($p = 0.004$) (Table 3).

Discussion

The findings of the current study indicated that stroke patients had low quality of life scores at the baseline. Before the intervention, there was no significant difference between the two groups

Table 1. The participating stroke survivors and caregivers' demographic characteristics.

Participants	Variables		Frequency number (%)	
Patients	sex		**Experiment**	**Control**
		Male	26 (52%)	28 (56%)
		Female	24 (48%)	22 (44%)
	Marital status	Single	7 (14%)	4 (8%)
		Married	30 (60%)	26 (52%)
		Widowed	16 (32%)	17 (34%)
	Education level	Undergraduates	18 (36%)	22 (44%)
		Diploma	23 (48%)	18 (36%)
		Bachelor's degree	9 (18%)	10 (20%)
	Occupational status	Employee	11 (22%)	10 (20%)
		Free	9 (18%)	10 (20%)
		Retired	7 (14%)	9 (18%)
		Worker	3 (6%)	3 (6%)
		Housekeeper	16 (32%)	12 (24%)
		Disabled	4 (8%)	6 (12%)
	Age, Mean (SD)		55.68 (11.51)	54.24 (12.44)
Caregiver	sex	Male	15 (30%)	16(32%)
		Female	35 (70%)	34 (68%)
	Marital status	Single	19 (38%)	16 (32%)
		Married	30 (60%)	32 (64%)
		Widowed	1 (2%)	2 (4%)
	Education level	Undergraduates	4 (8%)	8 (16%)
		Diploma	18 (36%)	18 (36%)
		Bachelor's	26 (52%)	21 (42%)
		Master and Doctorate	2 (4%)	3 (6%)
	Occupational status	Employee	28 (56%)	25 (50%)
		Free	11(22%)	11 (22%)
		Retired	2 (4%)	0 (0%)
		Worker	0 (0%)	1 (2%)
		Housekeeper	9 (18%)	13 (26%)
	Being Housemate	Yes	34(68%)	36(72%)
		No	16 (32%)	14 (28%)
	Relation with patient	Partner	14 (28%)	29 (58%)
		Child	27 (54%)	16 (32%)
		Parents	6 (12%)	3(6%)
		Friends	3 (6%)	2 (4%)
	Age, Mean (SD)		39.64 (12.51)	45.60 (10.92)

in terms of patients' quality of life and caregiver burden. Following the training, the QoL scores for both groups exhibited a significant increase. However, the training group that utilized the seven-step learning cycle demonstrated a more significant increase in all dimensions except for self-care and mobility. Furthermore, regarding the caregiver burden experienced by caregivers, both groups had reported significantly high scores across all dimensions before the education. Except for the social dimension, the two groups were homogeneous in all other dimensions in the baseline. Post-training, there was a significant decrease in the caregiver burden score for both groups. Notably, the seven-step learning cycle training group exhibited a significantly higher decrease in all dimensions. Regarding the dimension of social pressure, before the intervention in the experimental group, the burden of care was notably higher compared to the control group. However, following the intervention, the group that underwent the seven-step training intervention demonstrated significantly reduced levels of care burden in comparison to the control group.

According to the results of a population-based prospective cohort study, stroke survivors exhibited a diminished health-related QoL in the first six months post-stroke, with slight improvement observed at the 12-month mark.[44] These findings align with the results of our study, which indicate that both groups initially reported a significantly low QoL. Furthermore, it was observed that the control group exhibited a slight improvement compared to the experimental group after two months. These outcomes highlight the necessity to implement effective strategies that address the needs of these patients throughout their hospitalization and subsequent transition to post-discharge care, with the ultimate goal of improving their QoL.

Caregivers of individuals who have experienced a stroke frequently lack sufficient preparation for

Table 2. Quality of life in two groups before and after the intervention.

		Pre			Post			
Quality of Life		N	Mean	SD	N	Mean	SD	P value**
Overall	Experiment	50	88/44	19/19	50	142/74	27/18	.000
	Control	50	85/30	15/51	50	119/38	16/69	.000
	P value*		0/371			<0.001		
Energy	Experiment	50	4.88	1.77	50	10.06	3.19	.000
	Control	50	4.80	1.55	50	8.18	2.63	.000
	P value*		.811			.001		
Family role	Experiment	50	5.18	1.76	50	8.78	2.58	.000
	Control	50	4.80	1.66	50	7.32	1.82	.000
	P value*		.270			.002		
Language	Experiment	50	9.64	3.39	50	14.16	4.11	.000
	Control	50	9.30	2.70	50	12.56	3.17	.000
	P value*		.580			.011		
Mobility	Experiment	50	11.28	3.41	50	15.56	3.86	.000
	Control	50	10.58	2.50	50	14.20	3.17	.000
	P value*		.244			.243		
Mood	Experiment	50	8.70	2.54	50	18.68	3.48	.000
	Control	50	8.74	2.99	50	11.70	1.88	.000
	P value*		.943			<0.001		
Personality	Experiment	50	5.04	1.75	50	9.26	2.93	.000
	Control	50	4.58	1.47	50	7.16	1.72	.000
	P value*		.158			<0.001		
Self-care	Experiment	50	8.64	2.69	50	12.78	3.44	.000
	Control	50	8.56	1.96	50	12.14	2.47	.000
	P value*		.866			.287		
Social role	Experiment	50	8.28	2.18	50	14.18	3.34	.000
	Control	50	8.18	1.61	50	12.54	2.62	.000
	P value*		.795			.003		
Thinking	Experiment	50	5.42	1.67	50	8.62	1.91	.000
	Control	50	5.26	1.68	50	7.42	1.83	.000
	P value*		.633			<0.001		
Upper extremity	Experiment	50	9.78	3.25	50	13.94	3.54	.000
	Control	50	9.50	3.06	50	12.50	2.27	.000
	P value*		.658			.012		
Vision	Experiment	50	5.84	2.11	50	8.68	2.64	.000
	Control	50	5.60	2.31	50	7.34	2.11	.000
	P value*		.589			.011		
Working	Experiment	50	5.76	2.08	50	9.90	2.52	.000
	Control	50	5.40	2.12	50	7.62	1.81	.000
	P value*		0.453			<0.001		

*Independent T test - **Paired T test.

their caregiving responsibilities, leading to negative impacts on their overall well-being. Various studies have reported different levels of caregiving burden among stroke caregivers, ranging from mild to high. The study conducted by Achilike et al. found that 49% of caregivers reported low caregiver burden. In comparison, 34% reported mild to moderate caregiver burden, and 17% reported moderate to severe caregiver burden.[45] According to an Iranian study, most caregivers reported experiencing mild to moderate burdens.[46] In Nigeria, a study also found that the care burden of stroke caregivers in the sample population was determined to be high.[47] The findings from these studies align with our research regarding caregiver burden.

Furthermore, the findings from a multicenter cohort study conducted in 2018 indicate that the majority of caregivers for stroke patients experience a persistent perceived burden of caregiving over an extended period. Nevertheless, a minority of caregivers experience a shift in caregiver burden between 6 and 12 months.[48] These findings are different from the results of our study. Our study showed that caregivers' burden was decreased significantly in both groups two months after the stroke. The discrepancy may be attributed to the insufficiency of our intervention study, which focused on a narrow population to assess the impact on stroke caregivers within the community accurately. An overarching theme in these studies is the crucial role of educational programs and group training for stroke caregivers in hospital departments. Such initiatives are essential for enhancing social support and self-efficacy, significantly reducing caregiver burden.[46,47,49]

Table 3. Caregiver burden in two groups before and after the intervention.

		Pre			Post			
Caregiver Burden		N	Mean	SD	N	Mean	SD	P value**
Overall	Experiment	50	93.42	13.63	50	57.58	17.10	.000
	Control	50	92.00	16.26	50	77.12	12.98	.000
	P value*		.637			<0.001		
Time dependent	Experiment	50	20.78	4.13	50	13.66	5.16	.000
	Control	50	20.90	3.91	50	16.46	4.17	.000
	P value*		.882			<0.001		
Developmental	Experiment	50	20.12	3.61	50	13.02	4.25	.000
	Control	50	20.94	4.03	50	15.68	3.16	.000
	P value*		.286			.001		
Physical	Experiment	50	15.96	2.86	50	9.66	3.25	.000
	Control	50	15.04	2.63	50	12.46	3.08	.000
	P value*		.097			<0.001		
Social	Experiment	50	16.00	4.02	50	8.26	3.61	.000
	Control	50	13.96	2.73	50	16.01	2.89	.000
	P value*		.004			<0.001		
Emotional	Experiment	50	20.56	3.45	50	12.98	4.72	.000
	Control	50	21.16	3.82	50	16.52	2.82	.000
	P value*		.412			<0.001		

*Independent T test - ** Paired T test.

Over the past few years, several studies have been conducted to explore the requirements of patients who have experienced strokes. The findings of a qualitative meta-synthesis conducted using the Joanna Bridges Institute's methodology revealed that the primary and most prevalent category of needs among stroke patients is the lack of information about the disease. Within the scope of this study, individuals who had experienced a stroke expressed dissatisfaction regarding the insufficient provision of information about symptoms, treatment, and prognosis of the disease.[50] In a separate review conducted by Zawawi et al. the objective was to investigate the unmet needs of stroke survivors and their caregivers following hospital discharge. The study also aimed to identify factors linked to the reported needs. Within this study, the prevailing unmet needs frequently revolved around the lack of information about the disease's nature, post-discharge care, and rehabilitation. Survivors mentioned in the studies of this review have indicated that their information requirements may persist for three years post-stroke, thereby necessitating professionals to supply information repeatedly.[51] Insufficiently addressed needs significantly exacerbate caregiver burden, compromising patients' QoL. Various strategies can be employed to meet the educational needs. Face-to-face, written, and internet-based education methods for disease-related information are practical approaches, each with advantages and disadvantages.[52] In a review study conducted by Rumiati et al. the objective was to determine the efficacy, techniques, and outcomes of educational interventions for stroke caregivers. The study revealed that educational interventions can be delivered through various methods such as direct bedside education, lectures, Q&A sessions, distribution of booklets, and home visits or telephone follow-up. Educational interventions can enhance caregiver knowledge and skills in delivering daily care for post-stroke patients. Educational interventions yielded positive outcomes for post-stroke patients, such as improved QoL, functional abilities, and daily activity performance, as well as reduced cognitive impairments, anxiety, and depression.[53] This review's findings align with our study's results concerning the efficacy of a specialized care program in mitigating caregiving burdens and enhancing patients' QoL.

Numerous studies have assessed interventions and educational programs following stroke, particularly those conducted by nurses. An Australian study investigated the impact of incorporating an additional specialized care program alongside standard care. The program entailed an outpatient appointment, scheduled three months post-stroke, lasting two to three hours, for both patients and caregivers. The program was executed by a diverse team of professionals, including stroke physicians, nurses, physical therapists, and occupational and speech therapists. The findings of this study demonstrated that the implementation of STROKE-CARD care led to improvements in all dimensions of the QoL questionnaire used over 12 months.[54] A study conducted by Lin et al. in 2021 aimed to examine the consequences of a nurse-led health support program on stroke survivors and their family caregivers during the transition from hospital to home. The study consisted of 140 couples. The results of this study demonstrated a substantial enhancement in the QoL, stroke knowledge, and a decrease in hospital readmissions and caregiver burden among stroke survivors.[55]

Furthermore, a separate interventional study in Iran revealed that the introduction of an empowerment program for caregivers and families was linked to a substantial decrease in caregiver burden among the experimental group, compared to the control group, for up to two months after the intervention. The results indicate that nurses can utilize the family-centered empowerment program to enhance stroke patients' well-being and alleviate their families' caregiving responsibilities.[56] Our study's results align with those mentioned, indicating improved patients' QoL and caregiver burden. It seems that nurse-oriented interventions after stroke, especially in education, can be very effective.

Our research demonstrated that the designed intervention proved ineffective in improving participants' mobility and self-care. Significant complexities appear inherent in improving these two domains of quality of life for stroke patients. The problems mentioned above also impose a significant financial hardship on individuals. A recent study revealed substantial difficulties stroke survivors face in older, elevator-less residential buildings, necessitating the daily negotiation of four to six flights of stairs. Consequently, they have requested governmental support for elevator installation to enhance their QoL.[57]

Furthermore, individuals in the advanced stages of stroke frequently experience challenges with self-care, thereby imposing a considerable burden on their families. Extensive caregiving responsibilities often fall upon a family member of a stroke patient. Among the principal obstacles is the restrictive eligibility criteria, commonly precluding access to long-term care insurance for stroke survivors below the age of 60.[57] To improve the quality of life in these areas, the design of specific programs and policy adjustments are required.

In recent years, nurses have presented several models designed to educate patients. The 7-step learning cycle is an educational model involving active learners that encourages them to analyze their findings and assess their decision-making in unfamiliar circumstances.[22] In their 2024 publication, Nekouei et al. conducted a study to evaluate the impact of training based on the 7-stage learning cycle model on nursing students' awareness of diabetic foot ulcer prevention, critical thinking, and self-efficacy. The findings revealed that this approach was significantly more effective than conventional methods in all studied variables.[28] Most studies on this educational approach have been conducted within academic and educational settings, with limited application within clinical environments and with patients. Our research is among a handful of studies that have explored the impact of this training method on patients recovering from stroke. The findings of our study indicated a significant association between the training method based on the 7-step cycle and improvements in patients' QoL and reduction in care burden, when compared to the usual method. Our studies have yielded evidence supporting the feasibility of implementing this educational methodology within clinical contexts. Hence, forthcoming research is expected to devote greater consideration to these applications.

Limitation

This study was conducted in hospitals affiliated with only one university, which can impede the generalization of the findings. The acceptance of cultural differences can influence the effectiveness of a teaching method. Hence, it is imperative to implement this approach in additional urban areas and other communities. In this study, blinding was not applicable to educators, patients, and their caregivers. However, we tried to blind the analysis. Except for the teaching method, which was different in both groups, the instructor attempted to have the same expression and behavior in both groups to minimize the halo effect. In this study, only one post-test was conducted; perhaps more follow-ups in future studies are necessary to evaluate the impact of this educational intervention. Several studies have suggested follow-up up to 12 months. The use of self-report questionnaires creates the possibility of overestimating the findings.

Conclusion

The results of our study indicate that both the control and experimental groups exhibited significant improvements in patients` QoL and reduction of caregiver burden following training in the seven-step pattern method. The experimental group has demonstrated significantly greater enhancement in all aspects of quality of life, except for mobility and self-care, compared to the control group. When considering the burden of care placed on caregivers, our educational intervention has proven to be effective in reducing all dimensions. Utilizing diverse teaching methods may yield greater effectiveness than conventional approaches for patients and their caregivers following a stroke. Future research endeavors are suggested to encompass a larger sample size and incorporate a comprehensive seven-step training intervention. This will facilitate the integration of evidence, ensuring definitive outcomes suitable for broad implementation in clinical environments. Additionally, comparing different training methods will assist us in identifying the most cost-effective form of training.

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Availability of data and materials

The datasets generated and analyzed during the current study are not publicly available due to the necessity of ensuring participant confidentiality policies and the country’s laws. Still, they are available from the corresponding author upon reasonable request.

Clinical trial number

The protocol of this study was registered on 6 July 2024 with the following registration code: IRCT20240205060913N1.

Authors contributions

CRediT: **Sogand Sarmadi**: Investigation, Methodology, Project administration, writing – original draft, Writing – review & editing; **Neda Sanaie**: Conceptualization, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Writing – review & editing; **Fereshteh Javaheri Tehrani**: Investigation, Methodology, Writing – review & editing; **Malihe Nasiri**: Data curation, Formal analysis, Investigation; **Esmail Shariati**: Writing – review & editing, Formal analysis.

Ethics approval and consent to participate

The researcher obtained the code of ethics to carry out this research (IR.SBMU.PHARMACY.REC.1402.198) from the Ethics Committee of Shahid Beheshti University of Medical Sciences, registered in IRCT under the code IRCT20240205060913N1 and received permission to conduct the study from the Research Vice-Chancellor of Shahid Beheshti University of Medical Sciences All the participants provided written informed consent. They were informed of the right to withdraw from participation at any time during the research until publication. Data confidentiality was ensured, and the results were provided to the participants at their request. Also, we confirm that all experiments were performed following relevant guidelines and regulations. The ethical principles of the Declaration of Helsinki were followed throughout the study.

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