

The effects of family based care program on the health status of hemiplegic patients with stroke: A Randomized Control Trial

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Abstract

Background Stroke is a chronic disease requiring continuous and prolonged rehabilitation. A family-based care program can be an effective approach to rehabilitate the patients. This study aimed at determining the effects of family-based care program on the health status of hemiplegic patients with stroke. **Methods** In this clinical trial, 40 hemiplegic stroke patients were randomly selected through convenience sampling and allocated to experiment and control groups. The patients' care providers in the experiment group received the home-based care program for four consecutive sessions (50-60min) in addition to the routine care at the time of discharge. The trainings were then performed by care givers at home for four weeks. The patients in the control group received routine cares during the discharge. The health status of patients in the both groups was evaluated using a health status questionnaire before and one months after implementing the program. The collected data was analyzed using SPSS V.21. **Results** The results indicated that the difference between the mean scores of the health status of the two groups was not significant before the experiment; however, it was significant after the experiment ($P < 0.05$). The mean scores after the experiment were significantly higher in the experiment group compared to those of the pre-intervention; this difference was not significant in the control group. **Conclusion** Providing home care education programs to family members and allowing them to contribute to patient care programs can increase self-care of the patients and improve their health status.

Background

Stroke is one of the health problems in today's civilized society so that it is the third cause of mortality after cardiovascular diseases and cancer worldwide (1). According to the available statistics, each year 500,000 people suffer from stroke for the first time, 100,000 suffer from stroke for the second time, and nearly 160,000 people die from stroke (2). No comprehensive and national study has been performed in Iran on the prevalence and incidence of stroke. Based on provincial and regional studies, the annual incidence rate is estimated between 113 and 149 per 100,000 at all ages and more than 500 cases per 100000 people in the over 45-years old population (3).

In addition to mortality, physical impairment and disorders caused by these diseases remain a major social problem in terms providing cares in the hospital and at home (4). On the other hand, the disabilities of these patients and the resulting psychological problems are of other problems (5). Patients are exposed to several complications following a stroke, including losing balance, musculoskeletal problems, swallowing difficulties, bladder and bowel dysfunction, inability to perform self-care activities, and loss of skin health (2, 6).

The acute phase of the disease may take only a few days, however, the patient's recovery is a gradual and slow process and it usually takes a long time to stabilize the patient's condition (6). Pharmaceutical treatment is used to recover the stroke and multiple complications, while the main treatment is the continuous and long-term rehabilitation (7). When the acute phase of the disease is abolished, the patient care consists of immediate initiation of rehabilitation for any impairment (4, 8). Since stroke has

unexpected and destructive effects on the patients' lives, it leads to changes in their lifestyles and ultimately their quality of lives (7).

Patients suffering from a stroke are restricted in their routine lives and basic daily activities. Rehabilitation plays a key role in improving the status of these patients (9). The results of Clarke et al. study indicated that the functional status of patients with stroke can be improved using care program educations (10).

Considering that more than 60% of stroke survivors experience varying degrees of impairment, rehabilitation should be used as an important part of the health program of these patients in order to improve the quality of life and reduce the destructive impacts of a stroke (11). The rehabilitation process in stroke may take several years (12). Studies have indicated that rehabilitation programs encounter severe constraints due to the factors such as high rehabilitation costs and movement constraints in patients, as well as the difficulties to travel (9). Therefore, designing and using a home-based care program is an effective way to meet these needs for services (4).

Recent changes in health care systems in the world require providing long-term and complex cares at home provided by family members (4, 13). Family-based care is an innovative approach to planning, providing, and evaluating the health cares and promoting health. This approach is imperative as it unifies the patients, health care providers, and families in all aspects of care (14). Considering the long-term complications in these patients, the family is the most effective social institution that can provide physical and emotional supports for patient rehabilitation (4, 11).

Therefore, the effective and powerful presence of family members on the bedside and in the patient care program can have a notable effect on the rehabilitation of the stroke patient. Hence, given the importance of the subject, its helpful results for planning the care and rehabilitation programs for patients, and the need for a study in this field, this study aimed to determine the effect of family-based home care program on the health status of hemiplegic patients with stroke.

Methods

A randomized clinical trial was conducted from Nov 2015 to March 2016 in two groups of experiment and control. The study was registered under the code IRCT2015070214333n38 with the Iranian Clinical Trial Website.

All patients with hemiplegic stroke admitted to the neurology unit of Farabi Hospital, Kermanshah-Iran who were interested in participating in the study had the inclusion criteria. The authors visited the neurology unit of the hospital and selected subjects from the eligible sample group using convenience sampling. The participants were allocated into control and experimental groups randomly and through flipping a coin.

The minimum sample size required in this study was based on the formula for comparing the mean of a quantitative trait in the two groups ($\alpha-1 = 95\%$; $\beta-1 = 90\%$) using the results of various studies (15). The minimum sample size required for each experiment and control group was equal to 9. However, given the probable leave during the study and to increase the test power, the researchers considered the minimum sample size of 20 for each group and totally 40 participants were selected.

The inclusion criteria for the caregivers included living with a hemiplegia patient with stroke, lack of mental disorders, ability to do care services, not using drugs and psychotropic, high school diploma at least, and prior educations in this field. Exclusion criteria include leaving the study, early discharge of the patient, or death of the patient.

Data Collection

Participants were selected from patients with hemiplegic stroke admitted to the neurology unit of Farabi Hospital, Kermanshah City. After obtaining written consent from the patients and their care givers, the patients were randomly assigned to experiment and control groups by flipping a coin. A demographical form including age, sex, marital status, educational level, occupation, family relationships, economic status of the patient's family, and place of residence was filled out by two groups. Furthermore, the health status of both groups was assessed using the SQ2/0 questionnaires. The educational content was designed based on the educational needs of hemiplegic patients, based on the valid sources (1, 8, 16–18), and with family-based attitudes by the researchers. To ensure the validity the valuable comments by three neurologists, four faculty members, and three neurologist nurses. The education included information on the disease, symptoms, complications, effective factors, nutrition, and position change, preventing ulcers, control of bowel and bladder function, and mobility that lasted four consecutive days (50 to 60 min each session). The plan was provided for the patient's care givers during the hospitalization period. In some cases, training sessions increased to six or eight sessions. After training the care program, the care givers were asked to perform the care activities in the hospital according to the program, and their performance were controlled by the researcher using a checklist (this checklist was also validated using the mentioned experts' comments). The care givers were trained comprehensively and evaluated by one person. After assuring the care givers empowerment (more than 95%), they were asked to provide a care program to the patients for a month at home. A training pamphlets and 24/7 contact numbers were provided to the care givers for any help and guidance. During this one-month, the caregivers and patients contacted once every 4 or 5 days and the continuity of care was ensured. One month after the experiment, the control and experiment groups visited the training unit in the hospital to complete the health status questionnaire once more. For the people unable to attend, a researcher assistant visited them at home for completing the questionnaire (Fig. 1). All of questionnaires were collected by a researcher assistant (not part of the research team).

Data collection tools

Data gathering tools were a demographical form and the health status questionnaire. Health Questionnaire, SQ2/ 0, consisted of 37 health status questions [19] in three aspects including physical,

mental, and social and subscales of General Health (two questions), Physical Functioning (10 questions), Role Limitations Attributed to: Physical Health (four questions), Role Limitations Attributed to: Emotional Problems (3 questions), Bodily Pain (one questions), Energy / Fatigue (four questions), Mental Health (five questions), Social Function (two questions) and Health Perception (five questions). Some of the questions were YES/NO questions and the rest were three or five-alternative questions baed on Likert's scale. A higher score in each subscale means a better status in that sub-scale (16). The content validity and reliability of the health status questionnaire were examined by Kafami et al.(17) Using retest and pre and post-correlation coefficient the reliability was obtained and verified for each health status subscale including general health ($r = 0.76$, $\alpha = 0.87$), Physical Functioning ($r = 0.68$, $\alpha = 0.79$), Role Limitations Attributed to: Physical Health ($r = 0.66$, $\alpha = 0.86$), Role Limitations Attributed to: Emotional Problems ($r = 0.66$, $\alpha = 0.86$), pain ($r = 0.80$, $\alpha = 0.89$), Energy/Fatigue ($R = 0.89$, $\alpha = 0.94$), Mental Health ($r = 0.92$, $\alpha = 0.94$) and Health Perception ($r = 0.76$, $\alpha = 0.87$) (20). To further ensure the validity confirmation, the questionnaire and the objectives of the study were provided to five neurologists and three faculty members and they all confirmed it. Moreover, to check the reliability of the tool, 20 individuals in the study population (not included in the study) filled out the questionnaire before initiating the study and Cronbach's alpha was obtained equal to 0.885.

Data analysis

Data analyses were performed in SPSS V.21. The Kolmogorov Smirnov (KS) test was used to check normal distribution of the data, and appropriate parametric tests or their nonparametric equivalents were used based on the distribution of data. The significance level for all tests was 0.05.

Results

This study was performed on 40 subjects including 16 men (40%) and 24 women (60%) in control and experiment groups and none of the participants left the study. The mean age of subjects was 2.54 ± 66.20 years with a minimum of 16 and a maximum of 92 years. The mean age of caregivers was 1.66 ± 37.28 years with a minimum of 16 and a maximum of 57 years. Other demographic information of samples and their care givers are presented in Tables 1 and 2.

Table 1

Demographic characters of clients' base experimental and control group

Variables		Experiment G. N (%)	Control G. N (%)	
Gender	Female	(55) 11	(65) 13	0.417 = χ^2 Sig = 0.519
	Male	(45) 9	(35) 7	
Marital S.	Single	(5) 1	(0) 0	1.26 = Fisher exe. t Sig = 1
	Married	(95) 19	(100) 20	
Place of Residual	Urban	(85) 17	(85) 17	1 = Fisher exe. Sig = 1
	Rural	(15) 3	(15) 3	
Job S.	Unemployed	(5) 1	(0) 0	
	House wife	(50) 10	(65) 13	
	Business	(30) 6	(25) 5	
	Retired	(15) 3	(10) 2	
Economical S.	Weak	(30) 6	(25) 5	0.125 = χ^2 Sig = 0.723
	Moderate	(70) 14	(75) 15	
Illness PH.	Yes	(70) 14	10(50)	$\chi^2 = 0.167$ Sig = 0.192
	No	(30) 6	(50) 10	

Table 2
Demographic characters of caregivers participants in study

		Experiment G. N (%)	Control G. N (%)	
Gender	Female	(70) 14	(60) 12 (40) 8	X ² = 0.44 P = 0.507
	Male	(30) 6		
Job S.	Unemployed	(20) 4	(15) 3 (40) 8	
	Clerk	(45) 9	(45) 9 (0) 0	
	Employed	(25) 5		
	House keeper	(10) 2		
Educational S.	High School	(60) 12	(50) 10 (50) 10	X ² = 0.404 P = 0.525
	Higher education	(40) 8		
Relative to the patient	Parents	(5) 1	(0) 0 (10) 2	
	Spouse	(0) 0	(90) 18 (0) 0	
	Son/Daughter	(90) 18		
	Sibling	(5) 1		

The results showed that the two groups were not significantly different in terms of the mean score of health statue before the experiment. However, a significant difference was found between the two groups in terms of the mean score of health status after the experiment; so that the mean score in the experiment group was significantly higher than that of the control group (Table 3).

Table 3
Mean scores of health statue and its aspect in two groups

Aspects	Time	Control. G	Experiment. G	
		Mean ± SD	Mean ± SD	
General health	Pre	2.95 ± 0.95	3.2 ± 0.77	Z*=-1.005 P = 0.315 Z*=-4.28 P = 0.001
	Post	3.7 ± 0.8	4.95 ± 0.69	
Physical Functioning	Pre	10.45 ± 0.83	10.4 ± 0.598	Z*=-0.181 P = 0.857 T*=-10.88 P = 0.001
	Post	14.1 ± 1.16	15.7 ± 1.25	
Role Limitations Attributed to: Physical Health	Pre	4 ± 0.00	3.65 ± 0.49	Z=-1.91 P = 0.06 Z=-2.93 P = 0.003
	Post	4.05 ± 0.22	4.65 ± 0.83	
Role Limitations Attributed to: Emotional Problems	Pre	3.85 ± 0.037	4.00 ± 0.00	Z=-1.78 P = 0.075 Z=-1.88 P = 0.06
	Post	3.7 ± 0.57	3.95 ± 0.23	
Social function	Pre	5.5 ± 0.61	5.6 ± 0.598	Z=-0.58 P = 0.562 Z=-0.96 P = 0.335
	Post	5.75 ± 0.44	5.95 ± 0.689	
Bodily Pain	Pre	4.75 ± 0.64	5.05 ± 0.69	T=-1.39 P = 0.16 Z=-4.61 P = 0.001
	Post	5.35 ± 0.685	6.9 ± 0.79	
Mental Health	Pre	16.95 ± 1.19	16.65 ± 1.089	T = 0.77 P = 0.45 T=-5.75 P = 0.001
	Post	16.7 ± 1.17	19.1 ± 1.25	
Health Perception	Pre	9.55 ± 1.36	9.75 ± 1.27	T = 0.95 P = 0.145 T=-9.83 P = 0.0001
	Post	10.25 ± 0.91	12.5 ± 0.88	
Energy/Fatigue	Pre	9.7 ± 0.8	9.75 ± 0.91	T = 1.5 P = 0.148
	Post	9.3 ± 1.13	10.6 ± 0.68	

		Z=-1.18 P = 0.236	Z = 0.25 P = 0.769	Z=-2.62 P = 0.009
Health Statue	Pre	67.75 ± 3.013	67.9 ± 2.73	T = 0.055 P = 0.956
	Post	73.15 ± 2.77	84.1 ± 2.29	T=-13.6 P = 0.001
		T=-6.5 P = 0.001	T=-25.029 P = 0.001	

There was no significant difference between the two groups in terms of the health statue subscales in all aspects before the experiment. However, a significant difference was found between the two groups after the experiment in all aspects except for Role Limitations Attributed to: Emotional Problems and Social Function Difference (Table 3).

There was no significant difference in the mean scores in all aspects of health status in the control group before and after the experiment except for the Physical Functioning aspect. In the experiment group, there was a significant difference in all aspects of health status before and after the experiment except for Social Function and Energy / Fatigue (Table 3).

Discussion

The effects of family-based care training were evaluated on the health status of hemiplegic stroke patients over a one-month interval. The results indicated that family-based experiment based on training family members can improve the health status in most aspects. The results of the study showed that care training can be effective and it can improve the health status of the patients. The results of Cordun and Marinescu studies showed that early rehabilitation experiment in patients with stroke can improve the balance of these patients and improve their motion status, which is consistent with the present study (12). Other studies have also indicated the improved health status of stroke patients in relation to care givers training (5, 18). The study by Chuluunbaatar et al. showed that patients with stroke depended on others in their daily activities and they were at a poor health level in terms of other aspects of health, which is consistent with the current study (19). In the study by Chaiyawat and Kulkantrakorn, the majority of elderly people with stroke had significant defects in both physical and social functions (11). In the study by Kafami et al., the health status of the patients in the experiment group was significantly higher than that of the control group in all of the sub-health scales, except for the pain and social function scales. Self-management training improved the health status of the subjects in the experiment group (17). Therefore, social function is affected by numerous factors including family relationships, culture, attitude, and economic status of individuals and changing it requires more energy and time.

The subscales Social Function and Role Limitations of Attributed to: Emotional Problems were not significantly increased, which could be due to the family's attitudes towards the community and the refusal of the family to talk with their relatives and friends about the health problems of the patient so that the family's social interactions decrease during this period. The results of Clark et al. study indicated that after the experiment, the health status of patients in the control group increased compared to the

baseline; however, this level was not sufficient to make a significant difference (9). Dunbar et al. studied the effect of self-care training on patients with heart failure with diabetes and showed that after experiment, physical activity and life quality of the patients in the experiment group were better than the control group (20), which is consistent with results of the present study.

The results of the study indicated that some subscales of health status were also increased significantly in the control group and that the mean scores increased in other subscales. Forster et al. showed that after one year follow-up, there was no evidence of a decrease in the level of dependence in patients, the care burden on caregivers, the care and health costs, and social costs in the experiment group, which is inconsistent with this study (21). The differences in the implementation and measurement methods may explain the inconsistency.

Hebel et al. showed that patients' functional status in the experiment group was better in the first month and in three and 12 months follow up after the implementation of the training program. However, in the second assessment, one year later, the functional status of both groups increased not in a significant way (22). Probably, this is a result of the increased information in the caregivers in the control group over time and that the participants adhered training principles better during the first months.

Since the stroke patients are not able of self-care, the education was provided to their care givers. A health status questionnaire, extensively used in health studies, was utilized and its reliability and validity have been confirmed in Iran by various studies. The inclusion criterion of the study for patients' care givers included literacy, which makes it difficult to generalize the outcomes. In addition, due to limited time and the limited number of samples (most care givers were not willing to participate in the study), the sampling took more than three months and the assessment was inevitably performed one month after the experiment.

Conclusion

The results indicated that care educations and the implementation of a family-based rehabilitation program in stroke patients with hemiplegia can play a significant role in improving the health status of the patients. It is recommended to use this care and rehabilitation plan for other similar patients

List Of Abbreviations

Iranian Registry of Clinical Trails (IRCT)

KUMS: Kermanshah University of Medical Sciences

Declarations

Acknowledgment:

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Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

AN, contributed in study concept, study design, data collection and manuscript preparation.

HF, contributed in study concept, study design, data collection and manuscript preparation.

AJ, contributed in study concept, study design, data Analysis, manuscript preparation and submitting the manuscript.

NS, contributed in study design, data analysis and manuscript preparation.

JR, contributed in study concept, study design and manuscript preparation.

Ethics approval and consent to participate

In this research, the ethical considerations including the principles of confidentiality of information, obtaining written informed consent for participating in study, publication and having the right to withdraw from the research at any time were observed.

This study was approved by research committee (Grant No.94277) and ethical committee of Kermanshah University of Medical Sciences (Kums.Rec.1394.34).

Consent to publication:

Not applicable.

Competing interests:

The authors declare that they have no conflict of interest about this work

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