

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

Arsalan Naderipor

Kermanshah University of Medical Sciences

Hadith Faramarzi

Kermanshah University of Medical Sciences

Amir Jalali (✉ jalali_amir@yahoo.com)

Kermanshah University of Medical Sciences Taleghani <https://orcid.org/0000-0002-0307-879X>

Nader Salari

Kermanshah University of Medical Sciences

Jahangir Rezaei

Kermanshah University of Medical Sciences

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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 these patients. This study aimed to determine the effect 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 as available and divided into two intervention and control groups. The patients care providers in the intervention group received the home-based care program in addition to routine care at the time of discharge, for four consecutive sessions of 50 to 60 min. This program then was performed by carers at home for four weeks. The patients in the control group received routine care during the discharge. The health status of patients in both groups was evaluated by health status questionnaire before beginning the program, and then one month after the end of the program. Data were analyzed using appropriate statistical tests in 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 intervention; however, it was significant after the intervention ($P < 0.05$). Moreover, the mean scores after the intervention group were significantly higher than the pre-intervention, and the difference was not significant in the control group.

Conclusion: Providing home care training programs to family members and contributing them to patient care programs can increase self-care of the patients and improve their health status.

Keywords: Stroke; Hemiplegia; Nursing care; Family base care

Trial registration number and date of registration: IRCT2015070214333n38, 2015-08-28

Background

Stroke is one of the health problems of today's civilized society, which is the third cause of mortality after cardiovascular diseases and cancer worldwide [1]. According to the available statistics, 500,000 people suffer from stroke for the first time annually, 100,000 suffer from stroke for the second time and nearly 160,000 people die from stroke [2]. No comprehensive and national study performed regarding the prevalence and incidence of stroke in Iran and based on provincial and regional studies, the annual incidence rate was estimated between 113-149 per 100,000 people of 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 of care in the hospital and at home [4]. On the other hand, the ineffectiveness of these individuals and the resulting psychological problem are presented as the other problems [5]. Patients are exposed to several complications following a stroke, including not balance in a specific

condition and other 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 progresses gradually and slowly, and it usually takes time to stabilize the patient's condition [6]. Pharmaceutical treatment is used to recover the stroke and multiple complications, while the main treatment is continuous and long-term rehabilitation [7]. When the acute phase of the disease is abolished, the patient's care notices the early onset of rehabilitation activities for all the defects [4, 8]. Since stroke has unexpected and destructive effects on the patients' lives, leading to changes in their lifestyle and ultimately their life quality [7].

Patients suffering from the stroke are restricted in their routine life and basic daily activities, and rehabilitation plays a key role in improving the status of these patients [9]. The results of Clarke et al. study indicate that by training a care program, the functional status of patients with stroke can be improved [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 stroke [11]. The rehabilitation process in stroke may take several years [12]. Studies indicated that rehabilitation programs encounter severe constraints due to factors such as high rehabilitation costs and movement constraints in patients, as well as the difficulty in travel and dispersal of rehabilitation centers [9]. Therefore, the use and development of a home-based care program as an effective way is essential to provide this service [4].

Recent changes in health care systems in the world require caring the patients with long-term and complex care needs at home provided by family members [4, 13]. Family-based care is an innovative approach to planning, providing and evaluating the health care performed to health promotion, and since it unifies the patients, health care providers and families in all aspects of care, it is imperative [14]. Considering the long-term complications in these patients, the family is the most effective social institution that can provide physical and emotional support 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 the greatest role in the rehabilitation of the stroke patient. Hence, given the importance of the subject and its helpful consequences in planning the care and rehabilitation of 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

This is a randomized clinical trial that was conducted from Nov 2015 until March 2016 in two groups of intervention and control and registered with code IRCT2015070214333n38 in the Iranian clinical trial site.

In this study, all patients with hemiplegic stroke who were admitted to the neurology unit of Farabi Hospital in Kermanshah agreed in participating in the study were eligible to include in the work. Referring to the neurology unit of the center, the researchers selected subjects from eligible samples and as available and divided them randomly through the flip coin method in two intervention and control groups.

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 provided in the following, and it was calculated considering confidence interval of 95% ($\alpha-1$) and probability of 90% ($\beta-1$) using the results of various studies [15], and the minimum sample size required for each intervention and control group was 9. However, in terms of percentage as a drop, as well as increasing the test power, the researchers considered the minimum sample size of 20 for each group and a total of 40 people.

Questions for the caregiver include: Living with a hemiplegia patient with stroke, lack of mental disorders, ability to do care services, non-use of drugs and psychotropic, having at least a third-grade high school certificate and receiving previous training in this field. Exclusion criteria include the decision to discontinue the collaboration at any moment, early discharge, or the death of the patient.

Data Collection

Sampling was performed among patients with hemiplegic stroke admitted to the neurology unit of Farabi hospital in Kermanshah city. After obtaining written consent from the patients and their carers, the patients were randomly assigned to the two intervention and control groups according to the flip coin method. Through questionnaires, the demographic information of both groups was gathered including age, sex, marital status, educational level, occupation, family relationships, economic status of the patient's family, place of residence in the hospital, furthermore, the health status of both groups was assessed through completing the SQ2/0 questionnaires. In the intervention group, based on the educational needs of hemiplegic patients and based on the valid sources (1, 8, 16-18), the training program of these patients was designed with family-based attitude by the researcher and the research team's collaborators, and to obtain the validity the valuable comments of 3 neurologists, 4 faculty members, and 3 neurologist nurses were used. The training included information on the disease, symptoms, complications, influencing factors, nutrition, position change, and preventing the formation of ulcer, control of bowel and bladder function and mobility in the form of a care program that lasted four consecutive days, each day for 50 to 60 min. The plan was provided for the patient's carer during the hospitalization period. In some cases, training sessions incremented from 6 to 8 sessions. After training the care program, the carers were asked to perform the care activities in the hospital according to the program, and their actions were controlled by the researcher using the checklist (this checklist also validated using the mentioned experts' comments). The carers were trained comprehensively and evaluated by a person. After assuring the carers' empowerment (more than 95%), they were asked to provide a care program for the patient for a month at home, and the training pamphlets and contact numbers were provided for the caretakers for being responded within the 24 hours a day. During this one-month, the caregivers and patients were contacted once 4 or 5 days during and the continuity of care was

ensured. One month after the intervention, the control and intervention groups were coordinated with the research unit to refer to the patient training unit in the hospital to re-complete the health status questionnaire. For the people unable to attend, a researcher assistant was referred to the patients' home for completing the questionnaire. All of questionnaires were collected by a researcher assistant that he was not the research team.

Data collection tools

The data were collected using a demographic data collection form for the patient and the caregiver and the health status questionnaire.

Health Questionnaire, SQ2/ 0, of the patients consisted of 37 health status questions (19) in three aspects: physical, mental, and social, including subscales of General Health (2 questions), Physical Functioning (10 questions), Role Limitations Attributed to: Physical Health (4 questions) , Role Limitations Attributed to: Emotional Problems (3 questions), Bodily Pain (2 questions), Energy / Fatigue (4 questions), Mental Health (5 questions), Social Function (2 questions) and Health Perception (5 questions). Some questions were responded with "yes" and "no" and the rest with 3 or 5 options Likert 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 reviewed in the study of Kafami et al.[17] Using the 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 with the objectives of the study was provided to 5 neurologists and 3 faculty members, who all confirmed it. Moreover, for reconfirmation of the reliability of the tool, using the 20 similar samples before initiating the study, the alpha Cronbach coefficient was re-calculated as 0.885.

Data analysis

SPSS V.21 was used to analyze the data. The Kolmogorov Smirnov test was used to determine the 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 two control and intervention groups. From the beginning to the end of the study, 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 in this study was 1.66 ± 37.28 years with a minimum of 16 and a maximum

of 57 years. Other demographic information of samples and their carers were presented in Tables 1 and 2.

The results showed that the average score of health status before the intervention was within a range and there was no significant difference between the two groups, however, a significant difference was found in the mean scores after the intervention in both groups, and the mean scores in the intervention group was significantly higher than the control group.

There was no significant difference in the health status subscales in all aspects before the intervention in both groups, however, a significant difference was found after the intervention, in all aspects of the two groups, and there was no significant difference only in the aspects of Role Limitations Attributed to: Emotional Problems and Social Function Difference.

There was no significant difference in the mean scores in the control group in all aspects before and after the intervention, and only significant differences were observed in the Physical Functioning aspect. In the intervention group, there was a significant difference in all aspects after the intervention, and this difference was not significant in the aspects of Social Function and Energy / Fatigue.

Discussion

In this study, 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 intervention based on the care of patients with post-stroke hemiplegia by trained family members can improve the health status in most aspects. The results of the study showed that care training can be effective and can improve the health status of the patients. The results of Cordun and Marinescu studies showed that early rehabilitation intervention 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 also indicate the improved health status of stroke patients in relation to carers training [5, 18]. The study of Chuluunbaatar et al. showed that patients with stroke were dependent on others in their daily activities and were at a poor health level in terms of other aspects of health, which is consistent with the current study [19]. In the study of Chaiyawat and Kulkantrakorn, the majority of elderly people with stroke had significant defects in both physical and social functions [11]. In the study of Kafami et al., the health status of the patients in the intervention group in all of the sub-health scales, except the pain and social function scales, was statistically significant compared to the control group and self-management training improved the health status of the subjects in the intervention group [17]. Therefore, it can be said that social function is affected by numerous factors including family relationships, culture, attitude and economic status of individuals, and its change requires more activity and time.

In this study, the results showed that the subscales of Social Function and Role Limitations of Attributed to: Emotional Problems were not significantly increased, which could be due to the family's attitude towards the community and the refusal of the family to identify the caregiver's problems for relatives and communities, since the family social interactions are reduced during this period, practically. The results of

Clark et al. study indicated that after the intervention, the health status of patients in the control group increased compared to baseline, however, this level was not sufficient to make a significant difference [9]. In the Dunbar et al. study, on the effect of self-care training in patients with heart failure with diabetes, after intervention, physical activity and life quality of the patients in the intervention group were better than the control group and they achieved improve function than the control group [20], which is consistent with results of the present study.

The results of the study indicated that in the control group some subscales of health status were also increased significantly, in addition, in other subscales the mean scores increased. The results of the Forster et al. study showed that after one year of follow-up, there was no evidence of a decrease in the level of dependence in patients or a reduction in the care burden in the caregiver, and the care and health costs, as well as social costs in the intervention group, were similar to the control group, which are inconsistent with this study [21]. The differences in the implementation and measurement methods may lead to the mentioned results.

In the Hebel et al. study, the patients' functional status in the intervention group was better in the first three months after the implementation of the training program and 3-month follow up and 12 months after the study, however, in the second assessment, one year later, the functional status of both groups increased, not in a level that can make a significant difference [22]. Perhaps, it is as a result of the increased caregivers' information in the control group over time, and well following the training principles by the patients and caregivers in the first months.

In this study, as a result of the fact that stroke patients are not able to self-care by yourself, this training was carried out for their carers. In this research, a health status questionnaire, extensively used in health studies was utilized, and its reliability and validity were confirmed in Iran in various studies. The inclusion criterion of the study was for patients' carers were the literacy, which makes it difficult to generalize the outcomes for everyone. In addition, in the study due to limited time and the limited number of samples (most carers were not willing to participate in the study), the sampling took more 3 months and the assessment was inevitably performed one month after the start of care by the carers after the intervention.

Conclusion

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

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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Tables

Table 1. Demographic characters of subjects' base experimental and control group

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

Table 2. demographic characters of caregivers participants in study

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

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

Aspects	Time	Control. G	Experimental. G	
		Mean ± SD	Mean ± SD	
General health	Pre	2.95±0.95	3.2±0.77	Z*=-1.005
	Post	3.7±0.8	4.95±0.69	P=0.315
		T*=-0.919 P=0.364	Z**=-4.29 P=0.0001	Z*=-4.28 P=0.001
Physical Functioning	Pre	10.45±0.83	10.4±0.598	Z*=-0.181
	Post	14.1±1.16	15.7±1.25	P=0.857
		Z**=-0.181 P=0.0001	Z**=3.93 P=0.0001	T*=-10.88 P=0.001
Role Limitations Attributed to: Physical Health	Pre	4±0.00	3.65±0.49	Z=-1.91 P=0.06
	Post	4.05±0.22	4.65±0.83	Z=-2.93 P=0.003
		Z**=-1 P=0.317	Z**=-2.74 P=0.006	
Role Limitations Attributed to: Emotional Problems	Pre	3.85±0.037	4.00±0.00	Z=-1.78 P=0.075
	Post	3.7±0.57	3.95±0.23	Z=-1.88 P=0.06
		Z=-1 P=0.317	Z=-2.95 P=0.003	
Social function	Pre	5.5±0.61	5.6±0.598	Z=-0.58 P=0.562
	Post	5.75±0.44	5.95±0.689	Z=-0.96 P=0.335
		Z=-1.67 P=0.096	T=1.68 P=0.11	
Bodily Pain	Pre	4.75±0.64	5.05±0.69	T=-1.39 P=0.16
	Post	5.35±0.685	6.9±0.79	Z=-4.61 P=0.001
		T=-1.43 P=0.161	Z=-3.55 P=0.0001	
Mental Health	Pre	16.95±1.19	16.65±1.089	T=0.77 P=0.45
	Post	16.7±1.17	19.1±1.25	T=-5.75 P=0.001
		T=0.831 P=0.41	T=-6.25 P=0.001	
Health Perception	Pre	9.55±1.36	9.75±1.27	T=0.95 P=0.145
	Post	10.25±0.91	12.5±0.88	T=-9.83
		T=-0.492 P=0.625	T=-7.9 P=0.001	P=0.0001
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=-2.62 P=0.009
		Z=-1.18 P=0.236	Z=0.25 P=0.769	
Health Statue	Pre	67.75±3.013	67.9±2.73	T=0.055
	Post	73.15±2.77	84.1±2.29	P=0.956
		T=-6.5 P=0.001	T=-25.029 P=0.001	T=-13.6 P=0.001

Supplementary Files

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