■ **Original Article**

Evaluating the Effect of Family-Centered Intervention Program on Care Burden and Self-Efficacy of Hemodialysis Patient Caregivers Based on Social Cognitive Theory: A Randomized Clinical Trial Study

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Background: Caregivers of hemodialysis patients spend a large amount of time providing care to these patients while tolerating fatigue and stress. This study evaluated a family-centered empowerment program on the care burden and self-efficacy of hemodialysis patient caregivers based on social cognitive theory.

Methods: In this randomized clinical trial, 70 family caregivers of hemodialysis patients in Isfahan, Iran, were selected and randomly allocated to intervention and control groups, in 2015–2016. Two questionnaires were used to collect the family caregivers' characteristics, care burden, and self-efficacy, and patients' negative and positive outcomes expectancies. Data were analyzed using SPSS before, immediately after, and 2 months after the intervention.

Results: There was no significant difference in the mean scores of care burden, positive outcomes expectancies, negative outcomes expectancies, and self-efficacy between the two groups before the intervention. However, there were significant differences in the post-test and follow-up data analyses (P<0.05).

Conclusion: Given the degenerative nature of chronic kidney disease, it can be considered as a source of long-term and chronic stress for caregivers. Therefore, by implementing an empowerment program, caregiving behaviors can be improved, positive outcomes expectancies can be increased, and negative outcomes expectancies can be reduced.

Keywords: Family-Centered Nursing; Illness Burdens; Family Caregivers; Hemodialysis Patient

INTRODUCTION

The number of people with kidney failure worldwide is rising substantially, with more than 1 million people losing their lives to chronic kidney failure annually.[1,2] The incidence rate of chronic kidney failure is increasing not only in western societies, but also in the developing countries,[3] such that more than 1,500,000 people live on hemodialysis, dialysis, and kidney transplant today, which is predicted to double in the next decade.[4-6] A comparison of available statistics of recent years reveals that Iran is also facing an increased prevalence of kidney disease patients. Kazemi et al.[7] in 2011 reported that around 11,000 patients were undergoing dialysis in Iran.

Patients suffering from chronic kidney failure depend on family members for routine tasks. Studies show that the availability of the patient's spouse or other family members improves his/her quality of life.[8,9] Nowadays, most care for patients with chronic diseases, such as hemodialysis, is delivered by family members. It is estimated that more than 90% of care for chronic patients in the United States is delivered by their families.[5] Unfortunately, accurate statistics regarding the number of family members caring for patients with chronic diseases, including hemodialysis, are unavailable in Iran, which could be due to insufficient attention towards the families' role in caring for patients and documenting their conditions in the national health system.[4,5] Compared to the caregivers of other chronic diseases, caregivers of patients with hemodialysis face various difficulties and problems, including frequent hospitalization and multiple drug administration to the patients.[10] It should be mentioned that living with kidney failure is stressful and limiting for both the patient and the caregiver.[11,12] Since the family members usually perform difficult caregiving tasks without any prior instructions, readiness, or preparation, they face many difficulties and challenges in caring for the patient.[12,13] The pressure of delivering nursing care to the patient and the signs of depression are among the most common negative impacts.[14] The mere provision of care could threaten the caregivers' well-being, which in turn could hinder the caregiving process. For the caregivers to continue their role, their distress and needs must be addressed.[12,15] The care provided by caregivers under heavy pressure would also be insufficient. The amount of care needed, the time allocated to the patient per day or week, potential personality disorders in the patients, and the instability of their conditions, and worsening of their condition overnight could be used to predict the amount of physical and mental pressure on the caregiver. In the case of a domestic conflict or dispute, especially between primary and secondary caregivers, less care is provided to the patient.[16-18] One of the most important behavioral theories providing a good understanding of the patients' behavior outcomes is the social cognitive theory. The theoretical framework of this theory is based on the assumption that the actualization of the desired behavior results from the integration of cognitive, psychological, and social factors.[10] Considering the above-mentioned,[15] the social cognitive theory can also be used in family-centered intervention programs for hemodialysis patient caregivers. Family-centered care in Iran is the best way to identify the needs and physical and psychological problems of families. In this caretaking model, caregivers and other members of the treatment team provides care programs for all family members as caregivers, so that the family involvement in planning, decision-making, and provision of special care can transform a patient-centered care program into a patient-and-family-centered care program.

Therefore, given the increasing number of hemodialysis patients in Iran, its consequences on the country's health system and the patients' families, the importance and complexity of the subject of home caregiving, multiplicity of tasks that caregivers are expected to do for these patients for disease management, and the paucity of research on care-
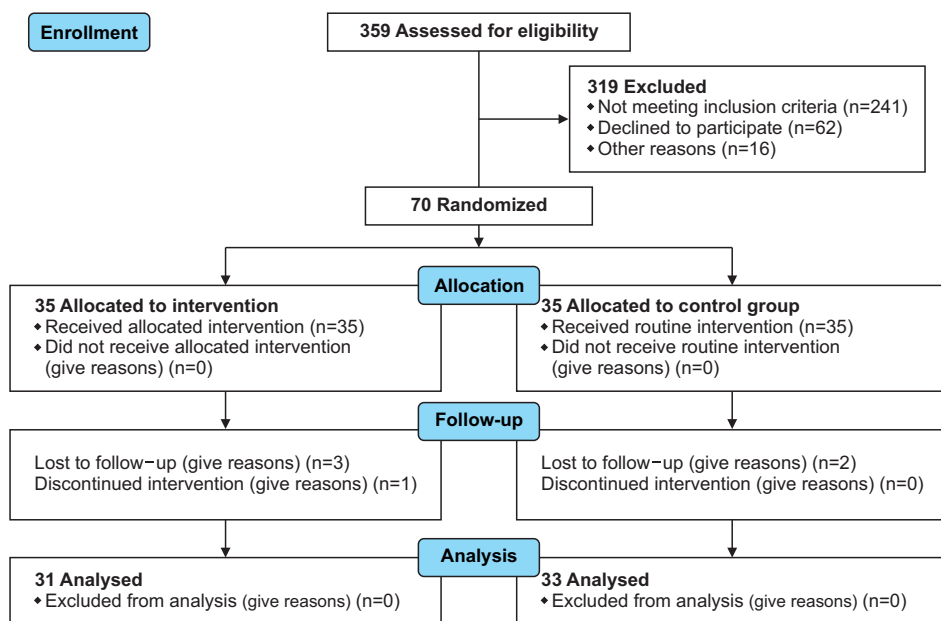

Figure 1. The CONSORT flow diagram for frequency and procedure of inclusion and exclusion of family caregivers to the interventional stage in intervention and control groups.

givers' needs, the researchers decided to evaluate a family-centered empowerment intervention program on care burden and self-efficacy of hemodialysis patient caregivers based on social cognitive theory.

METHODS

This randomized clinical trial study was conducted in Iran in 2015–2016. All research projects involving human participants must be submitted for review and approval before their conduction. To this end, the Iranian Nursing Society Review Board approved the study protocol (AHD-038-IRB-41056). The study population consisted of informal caregivers (family members, including parents, spouse, and children), or the first-degree relatives of hemodialysis patients in Al-Zahra Hospital in Isfahan, who were considered as the patient's primary caregiver and had to perform many (supportive, emotional, economic) tasks for the patient. The family members participating in this study were randomly allocated to either the group attending the empowerment intervention program meetings based on the social cognitive theory (intervention group) or the group receiving standard treatment (control group). The study design of this double-blind (participants and analyzers) clinical trial was parallel (Figure 1).

The inclusion criteria were: being a family caregiver according to the patient's statements; the family or the caregiver himself/herself; being the patient's primary caregiver and being assumed to do a wide range of tasks for him/her; aged above 18 years; being able to communicate and observe the rules of the training sessions; lack of history of participation in similar family training sessions (research projects). The exclusion criteria were: being the patient's primary caregiver but unwilling to attend all the training sessions and having a medical record including physical, mental, and psychological illnesses. Of all the people referred to the Al-Zahra (peace be upon him) Teaching Hospital, 70 people (divided into two groups of 35 each; namely, control and intervention) were enrolled in the study through convenience sampling.

After selecting the eligible samples, they were invited in-person and by telephone to attend a briefing session at Al-Zahra Hospital. They were explained the goals of this phase of the study, the process of allocation to intervention and control groups, the likely benefits of intervention for both groups, and the manner of completing the questionnaires. The pre-test was administered to the caregivers using quantitative tools after obtaining their written informed consent to participate in the study. The data collection tool was a two-section questionnaire. The first section included the patient's personal, family, and medical characteristics, and demographic characteristics of the primary caregiver, including age, gender, education level, occupation, monthly income, medical history, patient care-related experience, and relationship to the patient. The second section comprised 7, 5, 3, and 7 questions on care burden, negative outcomes expectancies, positive outcomes expectancies, and self-efficacy, respectively. Each question was rated on a 7-point Likert scale ranging from *absolutely disagree* to *absolutely agree*. The items of the care behaviors questionnaire were rated on a 4-point Likert scale. The total scores attained by caregivers on the questionnaire of the pressure and burden of care were presented as estimates, with scores ranging from 7 to 49. Scores less than 14 indicate a low level of care burden, scores between 15–36 indicate a moderate level of care burden, and scores between 37 and 49 indicate a high care burden. The scores on the negative outcomes expectancies questionnaire ranged from 5 to 35, and the scores on positive outcomes expectancies questionnaire ranged from 3 to 21. The range of self-efficacy questionnaire scores was 7 to 49. The content validity of all the questionnaires has been approved by an expert panel and a cross-sectional study. Cronbach's α was used to investigate the reliability of the tools used. The alpha coefficients for care burden, self-efficacy, negative outcomes expectancies, and positive outcomes expectancies were 0.89, 0.85, 0.87, and 0.78, respectively.

After randomly allocating the participants to the control and intervention groups (according to random numbers generated by random allocation software), the intervention group was invited to participate in the intervention program at Al-Zahra Hospital: 2 rooms were assigned, one each as education, and the other Patient-family health room. After dividing the treatment group into two groups of 15 to 20 each, a schedule was coordinated with the caregivers based on a prearranged timetable at their convenience regarding the time of implementation and the venue capacity. A written description of the goals, content, and implementation timing was given to them. This program was conducted for each group as a 2-hour session per week for 4 weeks with the assistance of the research team, including a nephrologist, a psychiatric nurse, and a hemodialysis nurse.

A brief description of empowerment intervention program meetings based on social cognitive theory in this study is as follows:

1. First Session

In the first session, the researcher first introduced himself to the caregivers, welcomed all the potential participants, explained the objectives, and provided a summary of the workshop. The purpose of the first session was to familiarize with each other and break the ice; the participants were asked to introduce themselves and briefly express their expectations and needs.

2. Second Session

The second session aimed to reduce the care burden of the patients. The meeting aimed to solve the caregivers' problems and help them familiarize with and understand the issues.

3. Third Session

The meeting was conducted as a focus group discussion to collect information and implement self-efficacy improvement strategies for caregivers. The purpose of increasing self-efficacy in this session was to develop and strengthen self-esteem, a sense of competence, self-awareness skills such as knowledge about rights and values, attitudes and strengths, creativity and reinforcement of goal-setting skills, development of self-assessment skills, and self-confidence.

4. Fourth Session

A comprehensive explanation of the psychological and spiritual benefits of care was included in the discussions about the strategies in this session. The purpose of the meeting was to increase the caregivers' positive expectancies and reduce their negative expectancies from patient care. During the meeting, caregivers were asked to think about the psychological and spiritual benefits of taking care of the patient and complete the relevant practice sheets and assignments. CDs and booklets were provided to the caregivers after the session.

The control group also received routine training pamphlets and brochures during the study. The researcher's contact number was also given to the participants so that they could provide further advice, if necessary.

Following the ethical considerations of research, after implementing the family-centered intervention program in the intervention group, which included two general sessions, an educational booklet, and a CD, it was also implemented for the caregivers in the control group. Data analysis included independent t-test, chi-square test, repeated-measures analysis of variance (ANOVA), two-way ANOVA, and paired t-test. The significance level was considered to be <0.05.

RESULTS

The control and intervention groups were demographically evaluated at baseline (Table 1). The majority of caregivers in the intervention group (35.7%) and the control group (35.6%) were aged between 32–39 years. There was no significant difference in age between the two

groups based on independent t-test (P=0.641). The majority of caregivers in the intervention and control group were female (76.2%, 84.4%), married (73.2%, 79.9%), had primary education (41%, 39.3%), and caregiving experience of 1–3 years (52.4%, 53.3%). The duration of caregiving in the majority of the caregivers was 7–10 and 3–6 hours in the intervention (50%) and control group (46.7%), respectively.

The results of the present study showed that there was no significant difference in the mean score of care burden between the two groups before the intervention. However, this difference was significant in post-test and follow-up data analysis based on two-way ANOVA (P≤0.05). An independent t-test was performed to evaluate the effect of training on care burden post-intervention. The test revealed a significant difference in the mean score between the pre-intervention and post-intervention in the intervention group (t=68.46, P<0.001), whereas the difference was insignificant in the control group (t=21.1, P=0.34). The repeated-measures ANOVA results in the intervention group showed a significant difference in the trend of changes in the mean score among the three measurements, whereas it was insignificant in the control group. The overall effect size of training in the three measurements of the intervention group was 0.27, while the effect of training was 0.021 in the second measurement (post-intervention) compared to the control group (Table 2).

The findings revealed no significant difference in the mean score of negative outcomes expectancies between the two groups before the intervention. However, this difference was significant in the post-test (P≤0.05). An independent t-test was used to evaluate the effect of training on decreasing negative outcomes expectancies in post-intervention data analysis. A significant difference in the mean score was found between the pre-intervention and post-intervention in the interven-

Table 1. Demographic variables

Characteristic	Category	Group Treatment group (N=31)	Group Control group (N= 33)	P-value
Sex	Men	15.6	23.8	0.16
	Women	84.4	76.2	
Age (y)	20–29	5.1	7.2	0.51
	30–39	35.7	35.6	
	40–49	14.7	16.9	
	50–59	2.2	21.6	
	≥60	24.3	18.7	
Education	Elementary	39.3	41	0.27
	Guide	16.7	22.2	
	High school	19.3	15.7	
	Academic	34.7	21.1	
Duration of family caregivers' patients' diseases (y)	<1	3.3	6.6	0.64
	1–3	52.4	53.7	
	4–5	25.7	27.8	
	≥6	18.6	12.9	
Marital status	Married	79.9	73.2	0.21
	Single	20.1	26.8	
Duration of care (h)	<3	2.4	2.2	0.59
	3–6	38.1	47	
	7–10	50	46.7	
	≥10	9.5	6.3	

Values are presented as %.

Table 2. Mean scores of within and between groups of the care burden in treatment and control groups in three stages of measurement

Group	Time		
	Pre-treatment	Post-treatment	2 mo after treatment
Treatment group (N=31)	37.22±4.30	32.96±4.92	34.16±5.46
Control group (N=33)	37.81±3.21	38.63±4.61	38.91±4.86
Independent t-test	t=0.25 P=0.61	t=6.46 P=0.003	t=4.53 P=0.037

Values are presented as mean±standard deviation, unless otherwise stated. The range of care burden scores is between 7 and 49.

Table 3. Mean scores of intra- and inter-group of negative outcome expectations in intervention and control groups in three stages of measurement

Group	Time		
	Pre-treatment	Post-treatment	2 mo after treatment
Treatment group (N=31)	22.02±6.01	17.13±5.70	18.91±5.12
Control group (N=33)	21.28±6.09	21.24±5.94	20.94±5.44
Independent t-test	t=0.52 P=0.61	t=7.88 P=0.007	t=0.52 P=0.61

Values are presented as mean±standard deviation, unless otherwise stated. The range of negative expectation scores is between 5 and 35.

tion group (t=7.29, P<0.001), whereas the difference in the control group (t=1.60, P=0.42) was insignificant. The repeated-measures ANOVA results in the intervention group showed a significant difference in the trend of changes in the mean score among the three measurements. However, it was not significant in the control group. The overall effect size of the training in the three measurements of the intervention group was 0.01, and the effect of training was 0.29 in the second measurement compared to the control group (Table 3).

No significant difference in the mean score of positive outcomes expectancies was found between the two groups before the intervention. This difference was significant in the post-test and follow-up based on the two-way ANOVA results (P≤0.05). The results revealed a significant difference in the mean score of positive outcomes expectancies between pre-intervention and post-intervention in the intervention group (t=5.42, P<0.001), whereas the corresponding difference in the control group was not significant (t=1.01, P=0.33). The repeated-measures ANOVA results in the intervention group showed a significant difference in the trend of change in the mean scores among the three measurements. However, this difference was insignificant in the control group. The overall effect size of the training in the three measurements of the intervention group was 0.38, and the effect of training was obtained 0.22 in the second measurement compared to the control group. The results indicated that the time factor was effective in decreasing the score of positive outcomes expectancies in the intervention group, but this effect was low so that there was no significant dif-

ference in the mean score of positive outcomes expectancies between the two groups at 2-month follow-up (Table 4).

The results of our study also revealed no significant difference in the mean score of self-efficacy between the two groups before the intervention. This difference was significant in the post-test and follow-up based on the two-way ANOVA results (P<0.05). Post-intervention data analysis was performed to evaluate the effect of training on the increase in self-efficacy, which showed a significant difference in mean score before and after the intervention in the intervention group (t=5.04, P<0.001), whereas the corresponding difference in the control group was not significant (t=0.69, P=0.49). As compared to the control group, the repeated-measures ANOVA results in the intervention group showed a significant difference in the trend of change in the mean score among the three measurements. The overall effect of training in the three measurements of the intervention group was 0.26, and the effect of training in the second measurement was 0.05 (Table 5).

DISCUSSION

The findings of this study showed that the mean score of care burden in the intervention group decreased both immediately and 2 months after the implementation of the empowerment program compared to pre-intervention, whereas the care burden in the control group intensified, but *not* significantly.

Table 4. Mean scores of intra- and inter-group of positive outcome expectations in intervention and control groups at three stages of measurement

Group	Time			Repeated-measure by analysis of variance		
	Pre-treatment	Post-treatment	2 mo after treatment	Time	Group	Group×time
Treatment group (N=31)	12.81±3.51	16.51±3.72	16.01±3.55	F(2,60)=18.61 P<0.001 ES=0.38	F(1,62)=8.15 P=0.006 ES=0.12	F(2,62)=17.93 P<0.001 ES=0.22
Control group (N=33)	12.39±4.38	12.45±3.95	12.55±4.31	F(2,64)=0.7 P=0.53 ES=0.021		
Independent t-test	t=0.17 P=0.68	t=6.09 P<0.001	t=4.16 P=0.001			

Values are presented as mean±standard deviation, unless otherwise stated. The range of positive outcome expectations scores is between 3 and 21.
ES, effect size.

Table 5. Mean scores of inter- and intra-group of self-efficacy in intervention and control groups in three stages of measurement

Group	Time			Repeated-measure by analysis of variance		
	Pre-treatment	Post-treatment	2 mo after treatment	Time	Group	Group×time
Treatment group (N=31)	27.35±7.35	33.06±5.73	26.21±6.42	F(2,60)=19.61 P<0.001 ES=0.38	F(1,62)=15.17 P<0.001 ES=0.197	F(2,62)=15.44 P<0.001 ES=0.20
Control group (N= 33)	26.01±6.28	26.21±6.42	26.78±6.35	F(2,64)=1.57 P=0.22 ES=0.05		
Independent t-test	t=0.68 df=68	t=6.49 P<0.001	t=5.12 P<0.001			

Values are presented as mean±standard deviation, unless otherwise stated. The range of self-efficacy scores is between 7 and 49.
df, degrees of freedom; ES, effect size.

Care burden refers to issues that are extremely challenging to the patients and their families. They usually report numerous health issues. Since the care burden is not a disease but a latent problem, both the patient and the caregiver suffer from it. They strongly need to be understood and supported.[19] In another study in a similar setting, Magliano et al.[20] in 2006 examined the effectiveness of a family intervention to reduce the care burden in the family caregivers of schizophrenic patients. After a 6-month intervention, consistent with our findings, a significant improvement in mental status and social functioning of the patients and a reduction in care burden in the caregivers were reported.

The findings of this study on the negative outcomes expectancies of caregivers showed that the mean scores in the intervention group decreased immediately after the intervention. However, the difference was not significant 2 months later. As for the positive outcomes expectancies, the current study showed that the mean score in the intervention group significantly increased immediately and 2 months after the intervention.

The study of Bullen et al.[21] in 2014 also revealed that merely participating in an intervention program would not help overcome perceived barriers and reduce negative cognitive-behavioral processes toward caregiving but would increase perceived benefits, which is consistent with the results of the present study.

Moreover, the findings of this study on self-efficacy of caregivers showed that the mean self-efficacy score in the intervention group increased immediately and 2 months after the intervention compared to pre-intervention, but it was unchanged in the control group.

Nogales-Gonzalez et al.[22] in 2015 conducted a similar study in which they observed that caregivers with high self-efficacy are protected against the risks of negative outcomes expectancies of care while focusing on their abilities to overcome weaknesses and failures. Additionally, the roles and responsibilities related to care, along with other roles in life, may be a challenge facing personal growth. Harmell et al.[23] in 2011 observed positive self-efficacy effects on physiological indices of body and health behaviors in caregivers of Alzheimer's patients. According to the available evidence, educators can play a significant role in improving the self-efficacy of caregivers of the elderly with Alzheimer's. Furthermore, Huang et al.[24] in 2013 reported that a home-based caregiver training program increased the self-efficacy of caregivers in managing patient behavioral problems. These results are consistent with the results of our study.

Recent meta-analyses of interventions for caregivers show inconsistent results, requiring further attention. Interventions with multiple components compared to individual interventions, such as the use of support groups along with training, have been reported to increase self-efficacy and reduce care burden among caregivers.[14,25]

Sorensen et al.[26] in 2002 similarly found that individual intervention for each caregiver was more effective in increasing their welfare and self-efficacy than group intervention. However, group interventions have been reported to be more effective in addressing the symptoms of the patients. They reported that the impact of interventions designed for caregivers lasted for about 7 months; few studies have been conducted with long-term follow-ups. In a study, counseling caused an increase in the quality of life and reduced the care burden among caregivers of stroke survivors.[26,27] The findings of our study also showed that a group empowerment intervention program effectively reduced care burden and increased self-efficacy in caregivers.

The limitations of this study include the short duration of the intervention and the difficulties of caregivers' follow-up, which prevented us from following up on the caregivers for a longer period. It is, therefore, suggested that subsequent studies should include long-term interventions with an increased number of follow-ups.

In conclusion, the results of the present study showed that caring for a hemodialysis patient can induce stressful situations for caregivers, and empowering caregivers through the implementation of interventions to learn the methods of patient care management will improve their well-being. Therefore, the care burden of caregivers can be reduced, and their self-efficacy can be improved by implementing empowerment programs.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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