

Original Article

Can addressing family education improve adherence of therapeutic regimen in hemodialysis patients? A randomized controlled clinical trial

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ABSTRACT

Background & Aim: Today, one of the leading causes of pathogenicity and mortality in patients undergoing hemodialysis is their failure to follow the treatment plan. The present research was conducted to compare effects of patient-centered education with family-centered education on adherence with the treatment program.

Methods & Materials: This clinical trial was performed between May and October 2012 in hemodialysis ward of Imam Khomeini and Amir-Alam hospital in Tehran, Iran. Research samples were 60 patients aged 18-65 years old, randomly assigned into two groups: Training the patients (30 patients) and training the patients and one of close family member (30 people). Using a researcher made questionnaire, patients' adherence (diet, pharmaceutical regimen, and physical activity) was examined by the self-reporting method in three stages (before intervention, 2 and 4 weeks after intervention). Data were analyzed using independent t-test, Chi-square, and Fisher tests using SPSS software version 16.

Results: Prior to intervention, there was no significant difference between the two groups in terms of adherence to diet program ($P = 0.200$, mean difference 25.8 ± 25.7), to pharmaceutical regimen ($P = 0.600$, mean difference 1.96 ± 0.61), and physical activity ($P = 0.700$, mean difference 1.33 ± 0.66). After 2 weeks family-centered education group had significantly more adherence to the diet program ($P = 0.001$, mean difference 43.1 ± 11.1), pharmaceutical regimen ($P = 0.040$, mean difference 2.72 ± 0.5) and physical activity ($P = 0.035$, mean difference 2.41 ± 0.89), and total adherence score ($P = 0.030$) in comparison with patient-centered education group. After 4 weeks, just the adherence to pharmaceutical regimen showed a significant difference between groups ($P < 0.001$).

Conclusion: The results of this study showed that the family-centered education is more effective than patient-centered education on patients' adherence to the therapeutic program particularly pharmaceutical regimen, which suggests, by having family-centered education in hemodialysis patients, the outcome could be improved.

Introduction

Advancement of science and technology has helped patients, with a critical situation, leave

the acute phase of the disease behind and enter the chronic phase of the disease (1, 2). One of these diseases, which cause the patient considerable stress, is an end stage renal disease (ESRD). The overall incidence of ESRD is 260 cases per one million people of populations per year and approximately increases 6% each year (3, 4).

Despite advances in nursing care before, during, and after hemodialysis, there is a high mor-

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tality rate among the patients and lead to poor quality of life (5). Failure to follow the treatment plan causes an increase in hemodialysis complications, and, as a result, the reduction of dialysis quality. Patients' failure in this matter is one of the most important problems of health teams. Maintaining patient's adherence is one of the most difficult parts of treatment course (6). Adherence to the recommended lifestyle changes, such as adherence to the pharmaceutical regime, diet, and liquids restriction occurs outside the health care system and in the home (2). It is necessary to educate patients with chronic disease like chronic renal failure in order to improve their quality of life in long-term (3). One of the main aspects of the education is to improve patients' adherence to the treatment plan (7).

Although few studies have investigated the effect of patient-centered and family-centered education on the outcome of patients with chronic disease, it is not clear which educational approach is more beneficial; therefore this study was carried out to compare family-centered and patient-centered education on adherence to the therapeutic regimen (diet, drugs, and physical activity).

Methods

This study is a randomized clinical trial, which has been conducted in patients undergoing hemodialysis in Imam Khomeini and Amir-Alam Hospitals, affiliated with Tehran University of Medical Sciences, between May and October 2012. 60 patients aged 18-65 selected by Convenience method and randomly were assigned to two groups: Patient-centered (N = 30) and family-centered (N = 30). The characteristic of personnel, hemodialysis method, and patients in both hospitals were the same. The sample size was estimated by the following formula based on mean and standard deviation values reported in Karimi et al. study (8) in the level of confidence of 95% and the statistical power of 80%. Accordingly required sample for each group was estimated 25, with considering 20% loss, 30 people were recruited for each group.

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 (S_1^2 + S_2^2)}{(\mu_1 - \mu_2)}$$

Inclusion criteria included patients 18-65 years old undergoing hemodialysis 3 times a week and for 3-4 h each time, not be in uremic phase (patient's consciousness was not affected by increase in blood urea), and companioning with patients' primary caregiver (one of the close family member who spent the most time with patient). In addition, participants should be able to complete questionnaires by self. Furthermore, if the patients were candidates for a kidney transplant during the study or for any reason; their pharmaceutical and diet programs were changed by the physician, were excluded from the study. The study was reviewed and approved by TUMS Ethics Committee and registered in the Iranian clinical trial registry (IRCT201204161599N17).

Informed consent was taken from the eligible participants, and then they were randomly allocated to two groups (patient-centered and family-centered education). To prevent contamination, the patients in patient-centered education group underwent hemodialysis and educated in even days and patients of the family-centered education group in odd days.

In this study, the data collection tools included: (1) Personal and disease information questionnaire, (2) adherence with the treatment regime questionnaire. Adherence with the treatment regimen questionnaire was consisted of three sections below:

A. The first section, included questions about the patient's diet, was composed of 22 questions based on likert three points scoring from 0 to 2 (completely = 2, partially = 1, not at all = 0). The potential score range for this section was between 0 and 44

B. The second section included eight questions about adherence to the pharmaceutical regimen based on likert five points scoring from 0 to 4. Obtainable scores of this section may range from 0 to 32

C. The third section included six questions about their physical activity program, and their answers were scored on the 0-4 scoring system, the possible score of this section was 0-24.

Questionnaires were developed by researchers in this study through comprehensive literature review. In order to assess content validity

they were presented to 10 academic members of Tehran University of Medical Sciences and their comments were applied to the questionnaire. To determine the reliability, the test-retest method was used. The questionnaires were given to eligible individuals and the scores were calculated, the same process was done after 2 weeks. By using Pearson correlation coefficient, the reliability of 0.92 was achieved.

Both groups received education at the bedside. In a patient-oriented group, the educational content was only offered to patients individually and in the family-centered group, in addition to the patient, one of the close family members was attended in an educational session.

Educational intervention included four sessions, which lasted 30-45 min. In the first session, renal disease, the causes of renal failure, the hemodialysis machine working mechanism, the numbers of hemodialysis sessions, etc. were explained. In the second session, the nutrition (the proper diet regimen, the importance of adherence to the diet regimen, the allowed amount of food intake, dietary restrictions, etc.) was discussed.

In the third session, the physical activity (importance of regular exercise, its allowed level, and so on) was educated. Finally, in the fourth session, pharmaceutical program (drugs usage, their side effects, prescribing reason) was taught. At the end of each session, the related educational pamphlet was distributed among the participants. To answer the questions a phone number was given to the participants to contact if necessary, and their questions would be answered.

To assess the effectiveness and retention of intervention the questionnaires were completed in both groups before, 2 and 4 weeks. Data were analyzed using independent t test, Chi-square, and Fisher tests using SPSS software version 16. $P < 0.050$ was considered significant.

Results

The mean age of the patients in the patient-centered group was 47.41 ± 10.31 and in the family-centered group was 48.16 ± 9.21 . Other demographic characteristics are shown in table 1.

Table 1. Demographic characteristic of patients undergoing hemodialysis in patient-centered and family-centered groups referred to Imam Khomeini and Amir-Alam hospital hemodialysis Tehran, 2012

| Group | Characteristics | Patient-centered N (%) | Family-centered N (%) | Result |
|--------------------|------------------------|------------------------|-----------------------|--|
| Sex | Male | 11 (36/7) | 15 (50) | $\chi^2 = 1.08$ df = 1 P = 0.290 |
| | Female | 19 (63/3) | 15 (50) | |
| Job | Unemployed | 4 (13/4) | 3 (10) | Fisher exact test P = 0.070 |
| | Housewife | 16 (53/3) | 16 (53/4) | |
| | Worker | 1 (3/3) | 1 (3/3) | |
| | Employee | 5 (16/7) | 1 (3/3) | |
| | Retired | 2 (6/7) | 9 (30) | |
| | Self-employed | 2 (6/7) | 0 | |
| Income | Sufficient | 2 (6/7) | 5 (16/7) | Fisher exact test P = 0.160 |
| | Partially Sufficient | 18 (60) | 21 (70) | |
| | Insufficient | 10 (33/3) | 4 (13/3) | |
| Location | Rural | 20 (66/7) | 19 (63/3) | $\chi^2 = 1.08$ P = 0.780 |
| | Urban | 10 (33/3) | 11 (36/7) | |
| Level of education | Illiterate | 20 (66/7) | 19 (63/3) | Fisher exact test P = 0.800 |
| | Under diploma | 12 (40) | 14 (46/7) | |
| | Diploma | 9 (30) | 9 (30) | |
| | University degrees | 1 (3/3) | 2 (6/7) | |
| Marital Status | Married | 7 (23/3) | 26 (86/6) | Fisher exact test P = 0.070 |
| | Single | 7 (23/3) | 2 (6/7) | |
| | Widow/widower | 11 (36/7) | 2 (6/7) | |
| | Divorced | 5 (16/7) | 0 | |
| Insurance Status | Insurance | 21 (70) | 24 (80) | Fisher exact test P = 0.340 |
| | Forum hemodialysis | 1 (3/3) | 3 (10) | |
| | Welfare | 3 (10) | 1 (3/3) | |
| | Without social support | 5 (16/70) | 2 (6/7) | |
| Living status | Alone | 15 (50) | 0 | Fisher exact test P = 0.080 |
| | Wife and children | 8 (26/4) | 26 (86/6) | |
| | Parents | 6 (20/3) | 2 (6/7) | |
| | Private nurse | 1 (3/3) | 2 (6/7) | |

Table 2. Mean and SD adherence of therapeutic regime (dietary, pharmaceutical, physical activity) in both patient-centered and family-centered at different times

| Therapeutic program | Group adherence | Before intervention | | *P value | 2 weeks after intervention | | *P value | 4 weeks after intervention | | *P value |
|---------------------|-----------------|---------------------|-----------------|----------|----------------------------|-----------------|----------|----------------------------|------------------|----------|
| | | Patient-centered | Family-centered | | Patient-centered | Family-centered | | Family-centered | Patient-centered | |
| Dietary | Mean \pm SD | 26.9 \pm 7.2 | 25.8 \pm 25.7 | 0.200 | 35.4 \pm 11.8 | 43.1 \pm 11.1 | 0.001 | 44.3 \pm 12.5 | 47.94 \pm 9.8 | 0.100 |
| Pharmaceutical | Mean \pm SD | 1.86 \pm 0.50 | 1.96 \pm 0.61 | 0.600 | 2.72 \pm 0.52 | 2.72 \pm 0.50 | 0.040 | 2.22 \pm 0.42 | 2.86 \pm 0.54 | 0.001 |
| Physical activity | Mean \pm SD | 1.26 \pm 0.44 | 1.33 \pm 0.66 | 0.700 | 2 \pm 0.69 | 2.41 \pm 0.89 | 0.035 | 2 \pm 0.69 | 2.2 \pm 0.85 | 0.300 |
| Total adherence | Mean \pm SD | 1.23 \pm 0.43 | 1.16 \pm 0.37 | 0.600 | 2 \pm 0.69 | 2.41 \pm 0.89 | 0.030 | 1.86 \pm 0.69 | 2.2 \pm 0.85 | 0.130 |

*P < 0.05; SD: Standard deviation

The causes of dialysis in 43.3% of patients in both groups were diabetes, and 46.7% of patients in the patient-centered group and 43.3% of family-centered group have been dialyzed for 1-5 years.

According to table 2 in terms of adherence to the therapeutic program (diet, pharmaceutical, and physical activity), there were no significant differences between two groups before the intervention (baseline). Meanwhile in the 2nd week after the intervention, adherence to the diet program, pharmaceutical regimen, and physical activity in the family-centered group was significantly more than the patient-centered group. It should be noted to evaluate the retention of education in the 4th week after the intervention, therapeutic adherence were assessed again. The results showed that only the pharmaceutical regimen in the family-centered group was significantly more than the patient-centered group ($P = 0.001$) and there were no significant differences between two groups in term of adherence to the physical activity ($P = 0.300$) and diet program ($P = 0.100$).

Discussion

In the present study, the effects of educational intervention with family-centered and patient-centered approaches on patient's adherence with the Therapeutic program were investigated. The study results in the 2nd week after intervention suggest that although both educational approaches have a positive effect on patients' adherence but the family-centered group adherence was more significant. In addition, it should be noted that family-centered education (patient with a family active member) was more effective in comparison with patient-centered education on improving patient adherence with the

therapeutic program in three aspects of diet, pharmaceutical, and the physical activity.

In Yu et al. study (2008), performed under the title of the influence of family-centered interventions on quality of life of hemodialyzed patients, before the intervention, no significant differences was observed between albumin levels and quality of life in both groups ($P > 0.050$), but after the intervention, patients of family-centered group had a higher albumin levels and a better quality of life in relation to patient-centered group ($P < 0.050$) (9). Zarkhah et al. (2007) in a study entitled evaluating the effect of family-centered intervention on patient's nutritional patterns after heart stroke, concluded that before the intervention, the two groups had no significant statistical differences in terms of adherence with dietary patterns, but after the intervention the family-centered training caused the dietary pattern of family-centered group to be corrected ($P = 0.032$) (10). In the systematic review that was performed by Schmid et al. (2009) under the title of adherence to oral medications in patients undergoing chronic hemodialysis, more than half of the studies (67%) concluded that the lack of adherence to oral medications exists in these patients, and although this is life-threatening, but unfortunately, little attention is given to it, and these patients need to be trained in different ways such as to involve the families in this issue in order to increase patient adherence with the treatment plan (11), and the results of the present study indicate the effectiveness of the family participation on patients adherence with pharmaceutical regimen. Gance-Cleveland in his study (2007) entitled the motivation-centered interventions to increase adherence to medication in the patient's family, revealed that the family-centered educational programs in

pharmaceutical regimen area improves patient and family interaction. He emphasized the necessity of simplicity and understandability of medical educations, therefore in this study, in addition to the educational pamphlet provided to patients and their families, oral educational sessions were held for patients and their families and it was showed that the use of this technique in the success of such programs, which have educational goals, was functional (12).

Nonoyama et al. (2010), under the title of the effect of exercise program on physical ability and quality of life of elderly patients undergoing hemodialysis, concluded that exercise during dialysis and in home leads to an increase in physical ability and quality of life of the patients (13). In that research, using simple and understandable education for the patients, the researchers encouraged them to perform the exercise program. As it have shown in this study; by educational education and emphasize on the importance of exercise to the patients and their families, there would be more enthusiastic participation in exercise programs.

Furthermore, Pedram Razi et al. study results (2014), in a study entitled the effect of family-centered empowerment model on the knowledge and metabolic control in patients with Type II diabetes, suggests a positive effect of education, based on family-centered empowerment model, compared with common education (14). Sanaie et al. (2014), in a study entitled the effect of family-centered empowerment model on the degree of family cooperation in adherence with the treatment regimen in patients undergoing coronary artery bypass surgery, concluded that family-centered empowerment model, causes an increase in family cooperation in the patient's adherence with the treatment regimen in three dimensions of the diet regimen, physical activity, and pharmaceutical regimen (15).

As the results shown in our study, although intervention in family-centered education group had more positive effect on therapeutic adherence after 2 weeks; no significant difference was observed in adherence except in the area of the pharmaceutical regimen, after 4 weeks. This fact can be justified in this manner that even though, education has been effective on the improve-

ment of adherence with the therapeutic plan, for retention of its effect, it requires further actions and interventions such as cognitive-behavioral interventions, identifying barriers of learning, correction and modification in the lifestyle. As Xiu-Feng et al. study (2006), entitled the effect of long-term training of the family on quality of life of patients undergoing hemodialysis, showed that by creating the training sessions in the years and continuous training of the family, quality of life of the patients will be significantly increased 1-year after beginning the continuous training: $P = 0.010$ and 5 years after beginning the continuous education (16), also Mosavifar et al. (2011), in a study entitled evaluating the effects of the two follow-up methods (mobile and phone) on adherence to the treatment plan in diabetic patients showed that the telephone follow-up and follow-up through short messaging system leads to the promotion of the diabetic patients' adherence to the treatment plan (dietary, pharmaceutical, and movement) (17).

Therefore, it is recommended that the effect of long-term interventions and educational follow-ups on long-term adherence to the therapeutic program to be investigated in future longitudinal studies.

Among the limitations of this study was collecting the information by the self-reporting method. Due to the nature of self-reporting, there was a possibility of inaccuracies in recording the reported data.

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