Effect of Applying Continuous Care Model on Quality of Life Among Kidney Transplant Patients
A Randomized Clinical Trial

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Introduction. The aim of this study was to compare the effect of continuous care model with routine care on the quality of life among patients who receive a kidney transplant.

Materials and Methods. In a randomized clinical trial, 90 kidney transplant patients were selected from 4 hospitals in Tehran, Iran, and were randomly assigned to 2 group. In the experimental group, continuous care model was applied for 3 months and the control group received routine care. The scale scores of the Kidney Transplant Questionnaire concerning quality of life were monthly compared between the two groups.

Results. Of 90 patients, 4 in the experimental and 8 in the control group were excluded from the study. Final analysis was performed on 41 in the experimental and 37 in the control groups. No significant difference was found between the two groups in terms of demographic variables. Although the quality of life scores increased in both groups, the mean scores of the experimental group were significantly higher than those in the control group at 1, 2, and 3 months.

Conclusions. Continuous care model may improve the kidney transplant patients' quality of life.

INTRODUCTION

End-stage renal disease (ESRD) represents a clinical condition in which there has been an irreversible loss of endogenous kidney function, and patient will permanently be in need of kidney replacement therapies, such as dialysis and kidney transplant, in order to prevent life-threatening uremia.[1,2] A successful transplantation liberates the patients from annoying, time consuming, and often painful sessions of dialysis.[3] Although kidney transplantation has a lot of advantages, patients face numerous difficulties after the operation, including the necessity of using immunosuppressive drugs, constant fear of rejection of the transplanted kidney, feeling guilty about the kidney donor, worrying about the uncertain future, and need for follow-up.[4-8] Several studies have demonstrated that even if the quality of life (QOL) improves in transplanted patients, they still have many stressful factors and have a lot to worry about after the operation.[7]

In 1940, the World Health Organization defined health as a state of complete physical, mental, and social wellbeing and not only lack of disease or disability. Since then, QOL has been a matter of importance in clinical research studies.[9] Replacement therapies aim at not only extending the life span and preserving the health status, but also maintaining and improving the QOL of these patients. Quality of life is a predictive factor for death in ESRD patients and is the most important

scale for determining the outcome in these patients.[10] Assessing the QOL can help patients with chronic diseases in terms of diagnosis, prognosis, and evaluation of received medical care and treatment methods.[11] Considering the increased life span and longevity and improved function of the transplanted kidney in transplanted patients, it is really important to diagnose and manage medical complications in kidney recipients.[12] On the other hand, daily advancements in the field of medicine necessitate the need for finding the best method for improving the QOL of these patients.[13]

One way to QOL improvement is the use of nursing models and theories. Nurses use models to organize their caring activity. The *continuous care model*, proposed by Ahmadi in 2001, as a native nursing care model, is used to establish and maintain a dynamic, interactive, and mutual relationship between the nurse, the patient, and the patient's family, so that the QOL of the patients may be improved.[13,14] The aim of this study was to assess implementation of the continuous care model on the QOL among kidney transplant recipients.

MATERIALS AND METHODS

In this randomized clinical trial, 90 patients with kidney transplantation who met inclusion criteria were selected from 2009 to 2010. The study protocol was approved by the ethics committee of the Baqiyatallah Medical Sciences University's Research Deputy. Patients with 18 years of age and above, no history of any QOL-affecting disease or condition, and Persian as the first language who were admitted the first time for transplant in 4 selected transplant centers (Baqiyatallah, Labbafinejad, Hasheminejad, and Modarres Hospitals) in Tehran were included. Patients who had failed transplantation or rehospitalization or did not wish to continue the study were excluded.

Sample size was calculated using the Altman normogram. Each participant was randomly assigned to one of the two groups. In the treatment group, continuous care model was applied for 3 months and the control group received routine care including patient education about medications, nutrition, alarming symptoms, laboratory tests, and time of next nephrology visit. The scores of the kidney transplant questionnaire (KTQ-25) concerning QOL were monthly compared between the two groups.[15]

Data were collected, including age, sex, marital status, occupational status, level of education, place of residence, duration of ESRD, medical history, types and duration of previous replacement therapy. The KTQ-25 is designed for assessment of the QOL in kidney transplant patients. This questionnaire was first designed by Laupacis and colleagues[15] in 1993. It contains 25 questions in 5 dimensions of physical symptoms, fatigue, appearance, fear, and emotional insecurity. Its reliability indicator has been reported to be 0.8 to 0.93 by the Cronbach alpha reliability coefficient in different studies. In Iran, this questionnaire was translated and cross-culturally adapted by Tayyebi and colleagues, and its Cronbach alpha coefficient has been reported to be 0.93.[16] Any subject in each group completed KTQ-25 on the first days of transplantation and monthly for the next 3 months. After taking an informed consent a detailed medical history was taken and patients' physical, mental, and social status was assessed in 15 to 20 minutes. A cell phone number was provided, so that they could reach the research team whenever they had a question. No special intervention was performed in the control group, but in the treatment group, continuous care model was applied for 3 months.

The 4 phases of continuous care model diagram are shown in Figure 1. The first phase in the continuous care model was familiarization and sensitization of patients towards the disease to recognize the problem, and to create motivation and a sense of need and necessity of follow-up. After the first session, the researcher familiarized the patients and their family with this method in 30 minutes, encouraged them, clarified their expectations, and gave them some advice on the importance of continuation of the program. The sensitization process aims to involve patients and their family in the implementation of continuous care model and we could not achieve the goal of this study without successful passing the first phase. Implementation of this phase was through lectures, question and answer sessions, consultation, and providing an educational booklet containing simple, and explaining easily understandable facts about the process of kidney transplantation, its related complications, and self-care programs such as regular exercising, prevention of infection, complying with specific drug regimens and nutritional diets, and the need for regular life
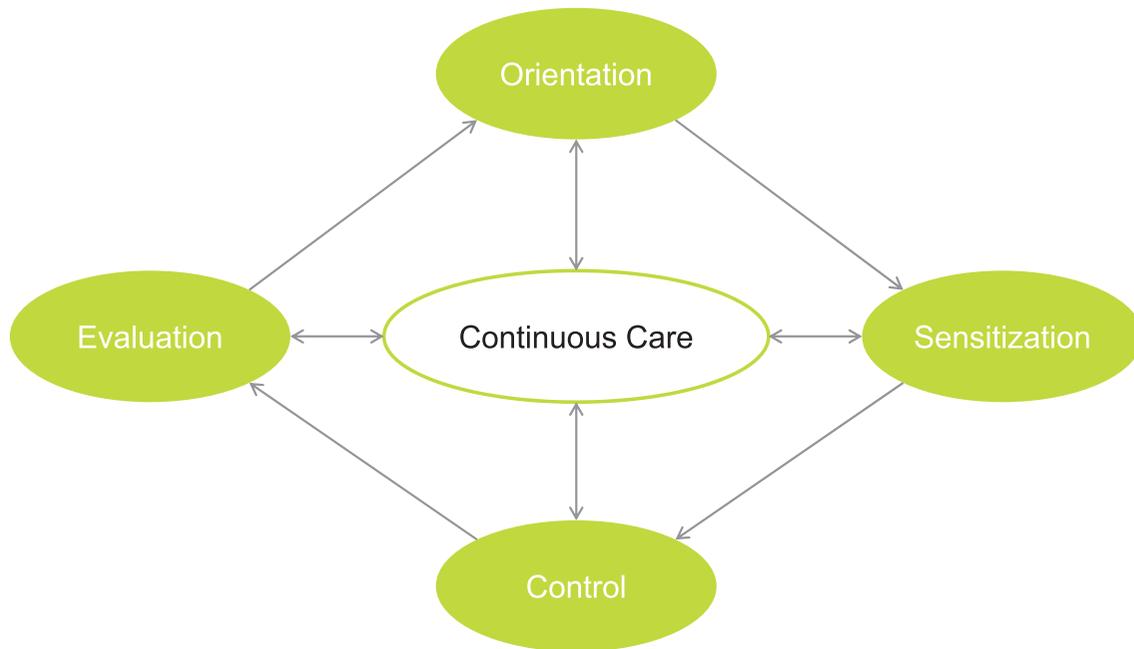
Figure 1. Stages of continuous care model (adopted with permission).

time follow-ups. Also, considering the importance of nutritional diet in these patients, a nutritionist gave each patient a specifically designed dietary regimen and the patients were encouraged to follow it. This phase took about 2 to 3 hours.

To achieve the objectives of continuous care model, compliance with the model and continuous follow-up play an important role and that is why it has been named "continuous" care model. Therefore, during the 3-month period of the study, the researcher made repeated phone calls and regular visits to evaluate the process and quality of care, check on the last week's problems and tend to new ones, evaluate control indexes, etc. Evaluation was the 4th and final step in this model. At the end of each month, QOL questionnaire would be filled out by the patients and compared by those of controls.

Data were analyzed using the SPSS software (Statistical Package for the Social Sciences, version 16.0, SPSS Inc, Chicago, Ill, USA). Descriptive analysis tests for demographic variable, independent *t* test, and the Mann-Whitney U test were used for comparison of the mean scores of QOL sections between the two groups. The Repeated measure analysis of variance was used for determination of changes in QOL in each group during the follow-up period. Statistical significance was set at a *P* value less than .05.

RESULTS

Of a total of 90 participants, 4 in the experimental group were excluded from the study (2 were unwilling and 2 had to be hospitalized) and 8 of the controls were excluded (2 unwilling and 6 hospitalized). Final analysis was performed on 41 participants in the experimental group and 37 in the control group (Figure 2). The main reason of hospital stay was increased creatinine level and infection with cytomegalovirus in both groups. The exclusion due to rehospitalization in the control group was 3 times more than that in the experimental group. Also, most exclusions were because of rehospitalization which occurred in the 1st month following transplantation (6 patients) in the control group.

The majority of the studied patients was men (73.1%) and married (69.2%). The mean age was 37.5 ± 12.9 years old (range, 21 to 65 years old). No significant difference was detected between the two groups when evaluating the frequency distribution of demographic variables.

The QOL scores improved in both groups. Analysis of the variance showed significant differences between the two groups ($P < .001$). At the end of the first month, the total score and the scores for all sections of QOL were higher in the experimental group (Table 1). After 2 months, the mean QOL section scores was higher in the
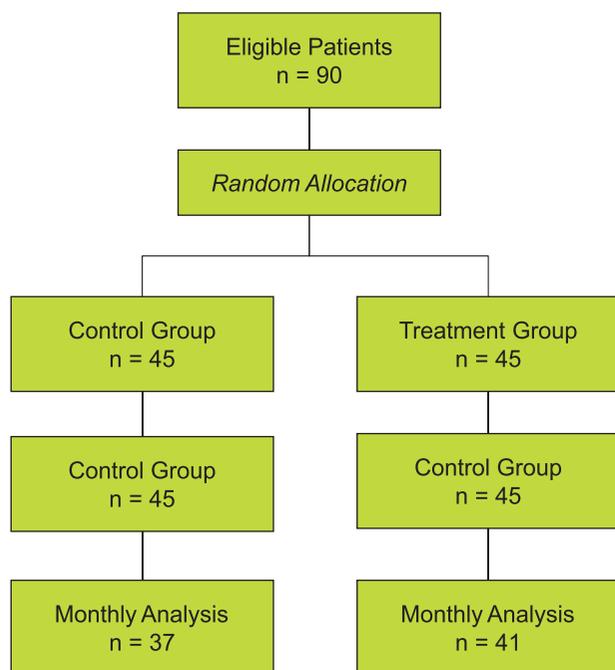
Figure 2. Flow diagram of patient recruitment

Table 1. Mean Scores of Quality of Life Sections After 1 Month in the Treatment and Control Groups

Section	Treatment Group	Control Group	P
Physical symptoms	90.1 ± 5.4	55.1 ± 4.3	.001
Fatigue	21.1 ± 5.9	21.1 ± 4.7	< .001
Fear	28.1 ± 5.3	27.1 ± 4.5	.007
Appearance	28.1 ± 5.7	18.1 ± 4.5	.45
Emotional insecurity	90.1 ± 5.9	37.1 ± 5.1	.002
Total score	94.0 ± 5.6	40.1 ± 4.8	< .001

experimental group compared to the controls and this difference was significant, except for the physical symptoms and appearance sections (Table 2). The scores for all sections of QOL were significantly higher in the experimental group compared to the control group 3 months after the intervention (Table 3).

Table 2. Mean Scores of Quality of Life Sections After 2 Months in the Treatment and Control Groups

Section	Treatment Group	Control Group	P
Physical symptoms	24.1 ± 5.5	14.1 ± 5.0	.09
Fatigue	93.0 ± 6.1	30.1 ± 5.0	< .001
Fear	44.1 ± 5.7	14.1 ± 5.1	.02
Appearance	60.1 ± 6.1	10.1 ± 5.7	.07
Emotional insecurity	92.0 ± 6.1	94.0 ± 5.5	.002
Total score	98.0 ± 5.9	86.0 ± 5.3	.004

Table 3. Mean Scores of Quality of Life Sections After 3 Months in the Treatment and Control Groups

Section	Treatment Group	Control Group	P
Physical symptoms	35.0 ± 6.0	32.1 ± 5.2	.009
Fatigue	73.0 ± 6.3	99.0 ± 5.6	.001
Fear	19.1 ± 6.0	28.1 ± 5.4	.01
Appearance	41.6 ± 6.2	17.1 ± 5.7	.04
Emotional insecurity	77.0 ± 6.4	83.0 ± 5.8	.002
Total score	87.0 ± 6.2	88.0 ± 5.5	.002

DISCUSSION

In this study, no significant difference was detected in the QOL scores between men and women, which were in accordance with Taghizadeh and colleagues' and Vosoughi and coworkers' study results.[17,18] However, in a study by Tayebi and colleagues, QOL score was significantly higher among men which were in contrast with our finding.[19] Several studies have demonstrated that QOL decreases with aging most probably because of the process of aging and increased complications of disease.[18] However, we did not find any correlation between the QOL and patient's age, that it may be related to our patient age that was younger than the mean age in other studies (mean age was 37.5 ± 12.9 years old). We did not find any correlation between the QOL and the time since kidney failure, either, which was in agreement with some other studies.[17,18]

Kidney transplant patients are under a different type of replacement therapy (hemodialysis, peritoneal dialysis, or control by strict dietary regimen) before the transplant. After the operation, the patient is in a critical condition and has to deal with complications and they also experience stress and anxiety due to the fear of graft rejection. Therefore, assessing the QOL in such conditions has no use and we could not assess the QOL of patients before this intervention in order to use as a reference (also because the questionnaire used in this study was specified for assessing the QOL of transplant patients). That is why we used the mean scores and also the trend of changes in order to compare the two groups.

Our results demonstrated that the QOL in both groups increased significantly after the transplantation. The total score and also individual scores for most of the studied sections were higher in the experimental group in all the three stages of

the study. Trend of changes in all three phases of the study was an ascending trend in the experimental group, but in the control group, most of the changes occurred in the second phase of the study and after that its pace slowed down and even in some cases slightly decreased (appearance section).

The two groups of experimental and control were matched in most of the key demographic variables like age, sex, occupational status, and income. The mean score of QOL in the experimental group had the greatest difference with that of the control group in the first month after the transplant. This shows that the two groups were probably in the same level of QOL before the intervention and by applying the continuous care model in the experimental group, the QOL in this group improved significantly compared to the controls, and this trend continued for the second and third months. An acceptable rise was also noticed in the QOL of the control group, which was expected after the transplant. Another issue that indicates the effect of intervention, especially in the first month, is the number and duration of hospital stay which were about 6 times greater than in the control group.

CONCLUSIONS

This study showed the positive effect of applying continuous care model on the QOL of patients. This positive effect was also mentioned by Rahimi and colleagues, in their study on hemodialysis patients,[11] Ghavami and colleagues, in a study on diabetic patients,[20] and other studies on elderly patients,[21] coronary bypass patients,[22] and patients with chronic bronchitis.[13] However, our study results might be slightly different from those of others which may be due to the special characteristics of kidney transplant patients, because unlike other chronic diseases, we expect the kidney transplantation to improve the QOL of patients in time (especially in the first year),[23] which is expected and understandable considering its imposed high costs. This was also confirmed in this study.

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CONFLICT OF INTEREST

None declared.

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