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General health of kidney donors: Implementation of Continuous Care Model

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Abstract

Introduction: Due to the increasing number of live kidney transplant donors, there is a demand for more comprehensive care programs to promote health and reduce complications of surgery and organ harvesting. The aim of this study was to investigate the impact of the continuous care model on the general health of kidney donors.

Methods: In the quasi-randomized controlled trial study, 55 kidney donors participated from three kidney transplant centers in Isfahan, Tehran, and Shiraz in 2019-2020. Samples were selected by the convenience sampling methods and then randomly divided into experimental (n=25) or control (n=30) groups. The data collection tool included a demographic information questionnaire and Goldberg general health questionnaire. The continuous care model was implemented for the experimental group and the control group received routine interventions. Data analysis was undertaken by Man-Whitney as well as Wilcoxon rank sum tests to compare mean difference between scores before and after the interventions. Significance level was defined 05/0 in this research. Statistical calculations were performed by SPSS (Version 22).

Results: According to the outcomes of the study, from 55 participants, 20 were women (36.34%) and 35 men (63.66%).Majority of the participants aged 29-38 , and financial problems were the leading reason of donation in most cases(8/81).the mean of the general health score had no significant difference before intervention in the two groups of experimental and control (45.16 vs 45.73, P=0.898). Yet, Mann-Whitney test showed a significant increase in the general health of the experimental group than the control group (19.40 vs 42.97, P < .001).

Conclusions: Continuous care model has the potential as a management strategy for increasing the general health of kidney donors. Therefore, it is recommended to use this care model for donors who are often unable to spend additional costs to improve the quality of their health.

Keywords: continuous care model, general health, kidney transplantation

Introduction

Since the beginning of 20th century, death toll attributed to infectious diseases has declined due to improvement of healthcare and immunization; nevertheless, these advancements lead to the fact that former fatal diseases transform to chronic ones. Chronic kidney disease (CKD) is a general term used for a variety of disorders that affect the

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structure and function of the kidneys. The incidence of this disease is, in most countries, more than 200 patients per million people per year (1). The Global Burden of Diseases 2020 study estimated that more than 700 million people have CKD worldwide. The global prevalence of CKD worldwide and in Iran is 9.1% and 15%, respectively (2). Kidney transplantation in patients leads to a better quality of life, improved physical strength, lower cost, and longer life. Possible defects in the corpse's kidney and the long waiting time for the transplant have increased the number of transplants from the living donor compared to the dead ones. (3).According to statistics only in 2008, there were more than 24000 chronic kidney patients in Iran and the number is rising. (4).The first kidney transplant in the Middle East was performed in 1967 in Iran. Lack of enough of kidneys is an international issue and demand for it, is dramatically rising worldwide. (5).

One of the most important aspects of kidney donation is possibility of complications development in donors (3). These include surgery complications of kidney resection, the risks of anesthesia such as atelectasis, pneumonia and infection also feeling restricted, fatigue, weakness, high blood pressure, job loss and depression that all of them affect the general health and quality of life of the kidney donor (6).

Today, one of the significant strategies in the field of health and in the current methods of care in hospitals and clinics is the concept of patient empowerment (7). Empowerment program is a collaborative approach in patient care and education (8). In other words, patient empowerment is a process that allows the patient to acquire the necessary knowledge and skills about his or her illness and to make informed decisions about care (9). One way to empower patients is to use a continuous care model (10). The aim of model is effective communication between patient and nurse in order to recognize existing needs and problems. The model of continuous care in Iran was designed and evaluated by Ahmadi for chronic coronary heart disease in 2001 (11). The fundamental implications of this model include the followings: recognizing the nature of the disease in addition to potential and actual problems related to the disease, having a role of diligent self-control in health behaviors and a positive attitude to health, family participation in solving existing problems, lifestyle modification as well as increasing self-confidence , knowing the care team and the process of asking them for help (12) This model includes 4 stages of familiarization, sensitization, control and evaluation (13).In the last three decades, examining the impact of psychological factors on chronic patients has been increasingly taken into consideration(14). Zolfaghari et al. (2015) showed that continuous telephone care in patients undergoing heart surgery has a significant impact on their general health (15). Harrison et al. (2018) also reported that there was a significant relation between the hospital-to-home transfer model, concentration on transferring the patient to home, and the ongoing patient-nurse relationship, with continuous care in donors (16). Lindsay et al. (2003) also showed the positive effect of rehabilitation and educational intervention on general health and social and physical limitations in patients undergoing coronary artery bypass graft surgery (17). Due to the increasing number of kidney transplants in different countries, it is very important to monitor the status of donors before and after transplantation and Incidence of possible complications (3). There have been few studies on follow-up results in live donors. In Iran, there are few evidences of continuous follow-up of kidney donors' status, while in Brazil, Germany and the United States, each donor after surgery will be followed every three months to one year, every six months to five years

and afterwards depending on the patient's condition, there would be a regular medical or psychological schedule (14). However, studies undertaken on the physical health and long-term effects of kidney donors have shown contradictory results. In many studies, follow-up is not long enough to properly evaluate the long-term impacts of donation (18). Not only does this follow-up care reduce the cost of treatment for the patient, but it also reduces the economic costs of the community and plays a crucial role in decreasing their problems (19). Despite the high number of kidney transplants from living donors in Iran, unfortunately, comprehensive studies on health promotion of kidney donors were not found in Iran. Therefore, this study was designed and performed with the aim to apply the continuous care model effectively on kidney donors (who are respectively distinguished from ordinary patients), in order to provide progress on their general health and every aspect of life.

Materials and Methods

The current research is a clinical trial study with a pretest-posttest design and a control group.

The study population includes donors in three kidney transplant centers of Iran in Isfahan (Khorshid and Al-Zahra Hospitals), Tehran Goldberg demographic data and General healthcare questionnaires were used to collect data. Goldberg questionnaire includes screening based on self-report, which is implemented in clinical collections with the aim of tracing individuals with psychological or physical disorders. This questionnaire has 28 questions from which the first 7 evaluate physical symptoms ,next 7 anxiety and sleeping disorders ,third 7 social function disorders and the last series , depression disorders as well as suicide tendencies . Scoring is based on Likerty method in which the choices are scored as (3-2-1-0).Lower score signifies more general health (20).According to (Labbafinejad and Hasheminejad Hospitals) and Shiraz (Bouali Hospital. The inclusion criteria were literacy, no mental illnesses and desire to participate in the study. The exclusion criteria include lack of participation and unavailability. Sample size was calculated 25 people in each group for conducting two-way test at a significance level of 5% ($\alpha = 0.05$), with test power of 80% ($\beta = 0.2$) and for detecting a difference of at least 80% of the standard deviation ($0= \eta /\sigma 8$).

. Due to the probable attrition of samples or abandoning the study, regarding 10 percent of surplus sample in each group, 30 people were selected in control and 25 in intervention group. It would be considerable that during Covid-19 pandemics, the decline in transplant surgeries led to the selection of minority of samples in this study.

The first stage of sampling was done by convenient methods. Therefore each patient who had the inclusion criteria and approved participation, entered the research. The random sampling based on the last digit of the national code was used to allocate donors in the each group. Samples were included with national code with odd number in the intervention group and with even numbers in the control group.

the conducted research ,reliability and validity of this study were reported as satisfactory in England and other countries. Goldberg and Williams (1988) presented the results of more than 70 relevant studies. Further, they reported 83/0 average reliability and 87/0 average validity. In 1380, Taghavi reported the reliability of the questionnaire applying three methods of remeasurment, descriptive and Cronbach's alpha with 70/0,93/0,90/0 in Iran. The steps of the research study can be seen in Figure 1.

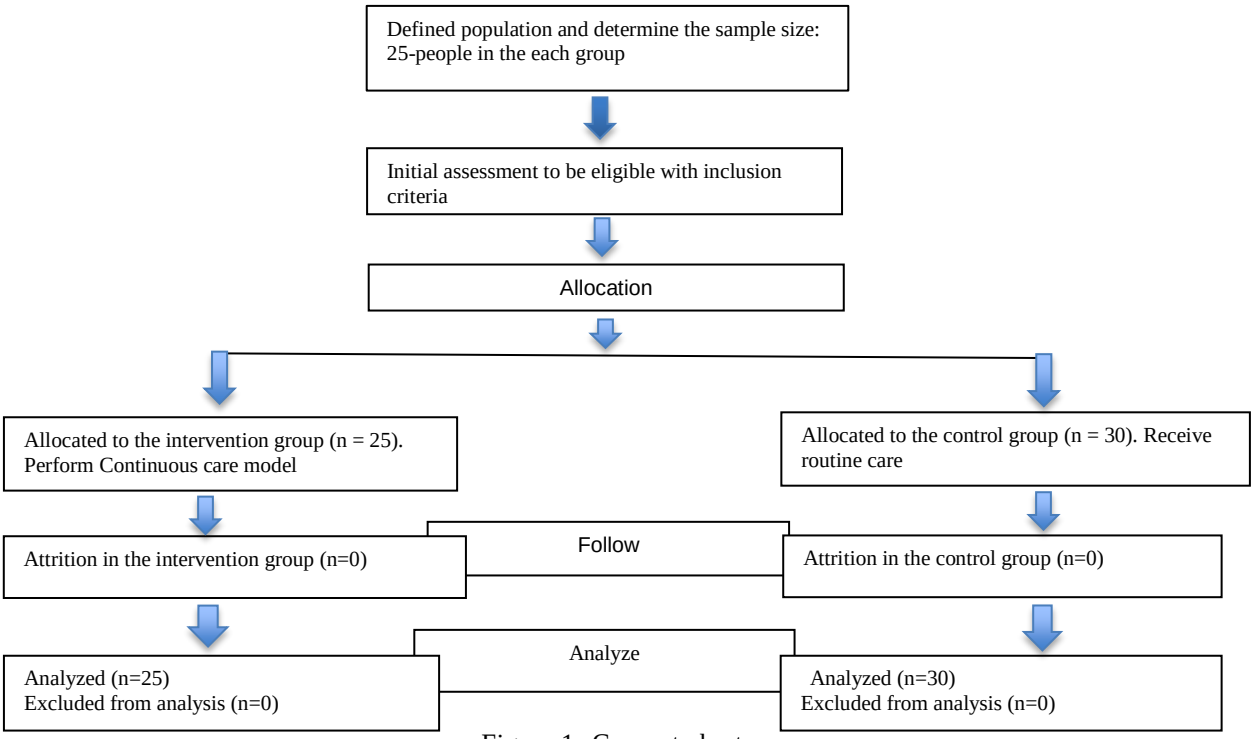

Figure 1- Concert chart

To conduct the present study, researchers started sampling after winning approval and cooperation of the participants based on entry criteria. Prior to conducting the research, participants would be informed of the objectives and methods of filling out the questionnaires .They would also be reassured that collaboration is absolutely voluntary. Questionnaires of demographic features and general health were filled in by all participants. Regarding the follow-up care model, the researcher would have direct and indirect supervision between himself (the nurse) and the donor in intervention group.

The intervention was presented in four stages of familiarization, sensitization, control and evaluation and lasted for 3 months. The study started with the presence of researchers in the patient's bedside with introduction and explanations about the study. The first meeting was face-to-face but due to corona pandemics and donor conditions, the communication continued through calls and social network. In average, continuous care was conducted in 1 attending and 17 non- attending sessions. (Table 1) Moreover, in centers (as in Shiraz and Tehran) where the direct presence of researcher was not provided for the primary session, the task was undertaken by nurse colleagues.

Table 1: stages of implementing the continuous care model

Number of stages	interventions	Time of stages

stage1	- Introduction - Provide the necessary susceptibility to the disease - Recognize the problem correctly - Creating a sense of need and necessity of the follow-up process in clients - Clarify mutual expectations and provide recommendations on the need for continuity and as much as possible not disconnect the relationship of medical care until the end of the prescribed time in the hospital and at home - Explain how to make a phone call and provide a phone number	First meeting 30-40 minutes
stage 2	-Explain and justify the importance of self-care - Important points of self-care within the understanding of the donor and family - The importance of recognizing the symptoms of kidney failure and the complications of kidney donation and how to control them - Adherence and control of diet - How to enforce the relevant restrictions - The importance of fluid intake and weight control - The importance of doing proper physical activity - The importance of controlling blood pressure and blood sugar - The importance of maintaining and adjusting weight -The need to reduce stress and mental pressures -The importance of regular check-ups and following the instructions given -The need to quit bad habits such as smoking - The importance of psychological counseling if necessary	5 sessions and each session: average 30 minutes
stage 3	- Phone calls according to care needs - Pay attention to new care issues and problems - Continue the follow-up process and review the care process and its quality - Check for new problems or not problems	11 sessions and each session: average 30 minutes
stage 4	-Assessment - Though this step was the final step but in all stages it was considered from the beginning.	One sessions: 30-40 minutes

No intervention was performed in the control group. After 3 months, again the general health questionnaire was completed by the intervention and control group. The questionnaires were sent via email and WhatsApp. In some cases, this stage was done by reading the questionnaire by the researcher over the phone and checking the donor answers.

Demographic information and 28-item Goldberg's General Health Questionnaire (GHQ-28) were used to collect data. The Goldberg Questionnaire is a self-report screening used in clinical settings to track people with a mental or physical disorder. This tool has 28 questions and includes subscales of somatic symptoms, anxiety and insomnia, social dysfunction and severe depression. The scoring method is the Likert of 0-3 point. The

maximum score is 84 and the minimum is zero, and lower scores indicate better general health (19). The validity and reliability of this test has been reported to be very good in the UK and other countries. Goldberg and Williams (1988) presented the results of more than 70 studies in this regard and reported an average validity of 0.83 and an average reliability of 0.87 (20). In Iran, Taghavi reported the reliability of the questionnaire using three methods of re-measurement, descriptive and Cronbach's alpha: 0.93 70 0.70 and 0.90, respectively (21).

Data analysis was performed in two ways: descriptive and inferential. Standard deviation , frequency distribution table as well as statistical charts were used in descriptive level as average index and at the inferential level non-parametric Mann-Whitney and Wilcoxon tests were applied to compare the average difference prior to and after the intervention. Significance level in this study was determined to be 0.05. Statistical calculations were performed using SPSS statistical software (version 21).

The objectives of the study were explained to all participants. Consent forms were completed by the donors. The rights to withdraw from the study at any stage, non-disclosure of information and the confidentiality of all data were observed by participation. This study has been approved by the Ethics Committee in Biomedical Research of Islamic Azad University - Isfahan branch (Khorasgan) with IR.IAU.KHUISF.REC.1399.053 code. After conducting the study, the phone numbers and e-mail addresses were given to the participants in the control group so that if they had any questions about self-care, they could ask the researchers for guidance. Also, by forming a group in WhatsApp, some important care for they were explained. This study was registered in the IRCT.ir at registry number of IRCT20200818048449N1 dated 10/10/2020.

Results:

The results of Shapiro-Wilk test showed that the data does not have a normal distribution ($p<.001$), so non parametric test was used. The results showed that the mean and standard deviation of donors' age in the intervention and control groups were 27.61 ±8.51 years and 32, 54 ±5.48 years, respectively. The results of Fisher Exact test showed that there was no significant difference between the two groups in terms of mean age ($p = 0.280$). Education level of the most of the participants was high school (50.90%) and most of them had low incomes (74.15%). Also, the majority of samples did not have relevant history of disease and drug use. Financial incentives were the most important reason for donating (81.8%). The results showed that there was no significant difference between the demographic and clinical characteristics of the participants in the two groups (Table 2).

Table 2: Demographic and Clinical Characteristics of donors

Characteristics	intervention N= 25	control N= 30	Total	P
Age	27.61 (±8.51)	32,54(±5.48)	30.21(±7.57)	.280[a]
Male Sex	15(60%)	20(66.66%)	35(63.63%)	.408[b]

Education	High school	17(68%)	11(36.66%)	28(50.9%)	
	Diploma	4(16%)	15(50%)	19(34.5%)	.056 [a]
	post graduate	4(16%)	4(13.33%)	8(14.5%)	
Marital status	Single	8(32%)	14(46.7%)	22(40%)	.350[b]
	Married	9(36%)	11(36.7%)	20(36.4%)	
	Widow	8(32%)	5(16.7%)	13(23.6%)	
Job	Unemployed	12(48%)	15(50%)	27(49.1%)	
	Not governmental	11(44%)	14(46.7%)	25(45.5)	.740[b]
	Governmental	2(8%)	1(3.3%)	3(5.5%)	
Income	No income	10(40%)	7(23.3%)	17(30.9%)	.387[b]
	Weak	10(40%)	14(46.7%)	24(43.6%)	
	medium	5(20%)	9(30%)	14(25.5%)	
	Top	0(0.0%)	0(0.0%)	0(0.0%)	
Post medical history	Yes	4(16%)	6(20%)	10(18.2%)	
	No	21(84%)	24(80%)	45(81.8%)	.702[b]
abuse drug	Yes	3(12%)	8(26.7%)	11(20%)	
	No	22(88%)	22(73.3%)	44(80%)	.176[b]
Reason for organ donation	Financial	20(80%)	26(86.3%)	45(81.8%)	0.950[b]
	Humanitarian	3(12%)	3(10.0%)	6(10.9%)	
	Family	2(8%)	2(6.7%)	4(7.3%)	

[a] Based on Mann Whitney test [a] Based on Fisher Exact test

The mean and standard deviation score of general health in kidney donors before the intervention was 45.59 ± 16.06 and was moderately low. The results of Mann-Whitney test showed that the mean score of general health before the intervention in the two groups was not statistically significant (p = 0.888) however ,after the intervention this mean in the intervention group (19.40 ± 12.64) was significantly lower than the control group (42.97 ±18.02), moreover general health was better in the intervention group (p <0.001). Also, the results of Wilcoxon test showed a significant difference in the mean score of general health before and after the intervention (differences = -25.76) with an increase in general health of the intervention group (p <0.001). In the subscales of somatic symptoms, anxiety and insomnia, social dysfunction and severe depression had no significant difference in the mean general health score before the intervention in the two groups (p = 0.700, p = 0.347, p = 0.744 and p = 0.220, respectively), but after the intervention, this difference was significant as the quality of health in these subscales was higher in the intervention group (p <0.001). The results of Wilcoxon test also showed that the mean of general health score in all of the subscales of general health in the intervention group before

and after continuous care decreased significantly ,as a result the quality of general health in this subscale was increased (p <0.001) (Table 3).

Table 3: The mean score of general health and subscales before and after intervention in the two groups

	Control (30 people)	Intervention (25 people)	**P-Value©**
	Mean(Standard deviation)	Mean(Standard deviation)	
General health before intervention	45.73(±16.61)	45.16(±16.39)	0.898
General health after the intervention	42.97(±18.02)	19.40(±12.64)	0.001
General health differences (pre-intervention-post-intervention)	-2.77(±2.46)	-25.76(±13.53)	0.001
P-Value®	0.001	0.001	
Somatic symptoms before intervention	13(±4.54)	12.48(±5.43)	0.700
Somatic symptoms after the intervention	12.60(±5.00)	5.68(±3.70)	0.001
Somatic symptoms difference (pre-intervention-post-intervention)	-0.400(±1.13)	-6.80(±4.18)	0.001
P-Value®	0.060	0.001	
Anxiety and insomnia before intervention	12.67(±3.95)	11.52(±5.02)	0.347
Anxiety and insomnia disturbance after intervention	11.83(±4.71)	5.32(±3.39)	0.001
Difference between anxiety and insomnia (pre-intervention-post-intervention)	-.0833(±1.60)	-6.20(±3.92)	0.001
P-Value®	0.001	0.001	
Social dysfunction before intervention	11.57(±5.18)	11.12(±4.84)	0.744
Social dysfunction after intervention	10.57(±4.99)	5.24(±3.52)	0.01
Difference in social dysfunction(pre-intervention-post-intervention)	-1.00(±1.20)	-5.88(±4.25)	0.001
P-Value®	0.001	0.001	
Severe depression before intervention	8.50(±4.82)	10.04(±4.28)	0.220
Severe depression after intervention	7.97(±4.97)	3.16(±3.25)	0.001
Severe depression (pre-intervention-post-intervention)	-0.53(±1.19)	-6.88(±4.73)	0.001
P-Value®	0.018	0.001	

P-Value®: Intragroup comparisons using Wilcoxon intervention

P-Value©: Intergroup comparisons using the Mann-Whitney intervention

P-value<0.05

The difference was significant in the mean score of general health in all subscales except physical health before and after the intervention in the control group and showed the effect of time on

increasing the quality of general health of donors (P <0.05). However, these differences were higher in the intervention group prior to and preceding continuous care (Table 3).

Discussion:

In this study, the results showed that the general health of kidney donors after surgery and implementation of the continuous care model improved in all of subscales. These dimensions included somatic symptoms, anxiety and insomnia, social dysfunction and severe depression. In examining the impact of continuous care model in patients with type 2 diabetes using a health-based educational program, the researchers concluded that the continuous care model is a management strategy to improve physical condition in patients (22). Tabrizi et al. findings showed significant difference in mean scores before and after continuous interventions in breast cancer patients and this model of care can be considered as an alternative to improving a healthy lifestyle of cancer patients (23). In our study, individual and environmental factors affecting the promotion of health were considered. Subsequently, appropriate educational content and strategies were prepared, including teaching a healthy diet, having physical activity and exercise, paying attention to warning signs of renal failure or symptoms of a surgical wound infection and side effects of smoking. These programs had positive impact on donors' awareness and attitudes. They increased the support of families as well as motivating and encouraging the patients.

Reduction of anxiety and sleep disorders in donors after continuous care were other result of this study. Gholamzadeh et al. (2018) in studying the effect of continuous care model on depression, anxiety and stress in the elderly concluded that not only the implementation of continuous care model does reduce mental problems, but it also improves and strengthens the mental state of the elderly (24). Another study showed that using continuous care improves the sleep quality of people with post-traumatic stress (6).

The positive effects of the continuous care model on sleep quality, pain, fatigue and nausea in breast cancer patients was confirmed by some researchers (25). Otaghi et.al (2016) examined the impact of continuous care model on sleeping quality of hemodialysis patients and approved the positive effects (26). Sleep hygiene education has an important and decisive impact on fatigue and sleep quality of patients. In addition, holding training courses in this field can be useful for patients (27). In the present study, all the factors affecting the control of problems (physical activity, diet, medication, lifestyle change, postoperative care, stress control, wound care, vital signs control...) caused by surgery were considered .

Continuous family involvement and their training were as basic principles in the continuous care process. On the other hand, the assurance to the donors and their families that there is a nurse who constantly answers their questions or problems and will provide the necessary advice and guidance if required, could be effective in reducing anxiety in addition to eliminating sleep disorders.

In this study, researchers covered ongoing education on the causes of anxiety and sleep disorders and approaches to improve them. Appropriate performance of these trainings regarding the provision of suitable environment could apparently decrease insomnia and anxiety

caused by post-surgery issues in patients. The results also showed that the rate of social dysfunction of donors after continuous care was significantly reduced. In one study, progress in social communication among patients with coronary artery bypass surgery was testified after using continuous care model based on home or nurses' managements. Ali Akbari et al. (1398) reported that education could enhance psychological -social health approach followed by improvement in social health (29).

In the present study, every impressive factor on controlling the issues caused by surgery must be taken into consideration (these factors include physical activity, food or medical diet ,lifestyle change ,post-surgery care ,stress control , wound care ,vital signs checking …).Furthermore, sensitization and family engagement are taken into account as a basic principle. Therefore, it seems as if controlling these issues after the surgery could be notably impressive on social efficiency of the donors.

The significant reduction was shown in the mean score of depression after implementation of continuous care model in this study. Robinson et al.(2020) concluded that primary care and health services have positive impact on behavioral depression.(30) In another study , continuous and integrated care as collaborative led to enhancement of individual care and reduction of depression in patients (31).

In a study by Zolfaghary et al. results of continuous cares by calling the patients signified a reduction in rehospitalization and depression. (15)In a research to investigate collaborative care for declining depression in people of villages in America, continuous care reduced the symptoms in depressed patients. (32) In relation to the issue of suicide, Stephanie et al. (2020) concluded that short-term interventions in acute depression had an effect on preventing suicide or reducing subsequent efforts (33).

In another study, constant care and contact by calling is being recommended after the surgery to decrease probable short-term depression. (15) Ongoing regular proceeding after being discharged from the hospital could significantly reduce the number of check-ins and outbreak of depression or suicide. During the pursuance, donor's potential and actual problems are identified and an opportunity to apply the correct method would be provided for their management.

There were several limitations in this research which include the followings : less attending visits for long-term supervisions due to Covid -19 pandemics ,lack of blinding in the research process for completing the questionnaire, lack of sufficient samples in the allocation of intervention and control groups as a result of significant reduction in the rate of transplant surgery. On the other hand it was difficult to win donor's trust because majority participated in donation due to financial incentive. Therefore, in this study, only one of the researchers was able to establish a close therapeutic relationship with them.

Conclusion:

According to the results, the implementation of a continuous care model for kidney donor could have a significant impact on increasing their general health by increasing physical health, reducing depression, social dysfunction as well as anxiety and sleep disorders. It is important that financial incentive in most donors was the reason for donating. Therefore, the pattern of continuous care would be beneficial at a lower cost, increase the general health of the donors and reduce the potential complications of kidney surgery in people who are not able to spend enough money to receive health services compared to other patients. It is suggested to examine other aspects of the life of kidney donors to solve their problems with a larger statistical sample and longer follow-up. Also, in all of the stages of

these interventions winning donors trust and willingness was tried, so that they could express all their problems and ask treatment and care team for help.

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Conflict of interest:

There was no conflict of interest for the authors in this study.

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