

**“EFFECTIVENESS OF NURSE LED INTERVENTION
ON SELF CARE BEHAVIOUR, PSYCHOLOGICAL
SYMPTOMS AND QUALITY OF LIFE AMONG
KIDNEY TRANSPLANT RECIPIENTS IN A
SELECTED TERTIARY CARE HOSPITAL OF NEW
DELHI”**



SYNOPSIS SUBMITTED

by

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Research Statement

A study on effectiveness of nurse led intervention on self care behaviour, psychological symptoms and quality of life among kidney transplant recipients in a selected tertiary care hospital of New Delhi.

Introduction

Chronic kidney disease (CKD) has become a fast expanding global state problem related to health in all the nations. Currently, the CKD's global prevalence is estimated to be ranging from 8 to 16% which is expected to increase in the future.¹ In India, recent studies have shown a variable prevalence ranging from 4% to 17.2% with wide regional differences.³ High incidences of mortality and morbidity are have been identified with CKD and approximately 735,000 deaths annually. Thus, CKD is the 12th most prevalent cause of death and the 17th biggest cause of disability. End-stage renal disease (ESRD) represents the terminal stage of CKD.⁴

There are different modalities for renal replacement therapy like peritoneal dialysis and hemodialysis; however the preferential choice of treatment for ESRD is kidney transplantation as it results in lengthened survival of the recipient and remarkable quality of life.⁵

After USA, India has the 2nd largest living kidney transplantation programme in numbers. It has evolved in the last 45 years. As per the estimation every year 3500 patients undergo kidney transplantation, 3000 new patients are being put on continuous ambulatory peritoneal dialysis and > 15,000 patients begin maintenance hemodialysis.⁸

Lifestyle modification plays an important role for the success of organ transplantation. The recommended lifestyle measures for kidney transplant recipients are adequate diet, exercise, visit to clinic, monitoring of clinical parameters and laboratory investigations as per schedule, protection from infections and abstinence from addictions.¹⁰

Complying with immunosuppressive drugs is critical for patients with kidney transplant as nonadherence can result in loss of the allograft and loss of life at the worst. Approximately 20% late acute rejection and 36% graft losses occur because of nonadherence to immunosuppressive therapy after kidney transplantation. Due to severe consequences of non adherence and dire shortage of donor organs, it is essential to improve adherence of patient to immunosuppressive therapy.¹⁶

The patients may face a number of challenges after transplantation which might lead to stress in the patients despite advances in transplant technology. The various factors that can affect quality of life are uncertainty about future health, cost and finances, follow up and side effects of medical treatment.¹⁸

There can be various complications of medications after kidney transplantation that can affect the different aspects of quality of life in patients with kidney transplant life and hence reduce their quality of life. One of the most significant indicator for defining health outcomes in a kidney transplant recipient is quality of life. Evaluating the quality of life in patients with incurable diseases can significantly contribute in the provision of care and effective methods can be implemented to help those patients.²²

The two most common psychological disorders that can affect the disease process and survival of graft in kidney transplant recipients are anxiety and depression. Noncompliance with treatment, inadequate personal care, adjusted quality of life and difficulty in assimilation of the newly acquired graft into sense of self are a result of anxiety and depression.²³

A meta analysis done by Di Matteo²⁴ reported that patients with depression were three fold more prone to be nonadherent to treatment regimen than patients who did not have depression. Psychological stress like anxiety and anger may result in nonadherence to treatment in adolescent kidney transplant recipients was indicated by Penkower et al.²⁵

Need for the study

Renal transplant patients' knowledge, infection control and self-care practices are deficient. The implementation of the educational program is effective in achieving significant improvements in their knowledge, reported practice of infection control, and total practice of self-care skills. Therefore educational programme with follow up is required. A predominant issue for patients in post transplant phase is deficit knowledge about immunosuppressive therapy. So effective educational strategy need to be investigated as an approach to improve the knowledge and preparation for the challenges that happen in post transplant period.²⁷

Although there is no guaranteed method leading to therapeutic adherence, the identification of the factors influencing it allows designing nursing interventions aimed ultimately at promoting the adherence to immunosuppressive therapy. Thus, through the combination of educational and behavioural interventions, nurses should promote adherence and self-care, which will translate into health gains.¹⁶

Compliance with lifestyle recommendations after renal transplantation in the Indian sociocultural setting remains suboptimal. The outcome of intervention strategies mainly ongoing education need to be implemented to improve compliance.²⁸

Kidney transplant recipients need to be made aware of depression and should be educated for its early identification and treatment. Screening can early detect depression and will help to provide prompt social and psychological support for kidney transplant recipients.

Interventional studies with longitudinal assessment could provide better understanding of depression and its management.³¹

However, to the best of researcher's knowledge there is no study conducted on effectiveness of self care management programme including education and behaviour therapy for kidney transplant recipients in India, though a sound knowledge of management of self in patients with kidney transplant is vital to enhance quality of life and adherence to immunosuppressive therapy. So, this study is undertaken to evaluate the effectiveness of nurse led self care management programme on self care behaviour, physical and psychological symptoms and quality of life among recipients of kidney transplant.

Review of Literature

Shimaa H et al (2017)¹⁰ studied the lifestyle modification among kidney transplant recipients. It was found that majority of recipients were overweight, had fried food, drank more than two and a half litres of water everyday. The results indicated statistical significant association between age of patients, marital status and occupation of patients of kidney transplant and their adherence score to prescribed immunosuppressive therapy. They recommended regular assessment for lifestyle and adherence to immunosuppressive therapy is required. There is a need to develop and implement educational programme for these patients regarding lifestyle modification after kidney transplantation.

Ricardo P et al (2016)¹⁸ did an integrative literature review related to adherence to immunosuppressive therapy in recipients of kidney transplantation. The study findings indicated that adherence to immunosuppressive therapy is influenced by various socioeconomic and cultural factors. These factors include age, gender and occupation of the recipient. The other patient related factors are forgetfulness and daily routine. Condition related factors that affect adherence are time since transplant and depression. Nursing

interventions (educational and behavioural) are important keeping in view of the above stated factors to promote adherence to immunosuppressive therapy and thereby improve kidney transplant recipient's health.

Jana A. K et al (2014)²⁰ addressed the psychological factors ie. anxiety and depression for determining the outcome of kidney transplant recipients. They cross-sectionally studied the renal function of these patients with level of depression, anxiety, compliance with drugs and their general quality of life. The findings revealed a significant poor quality of life in patients who suffer with depression in all domains as compared to the patients without depression. The episodes of complications or rejections and hospitalization were more in the group of renal transplant patients who had anxiety than their non anxious counterparts. The study suggested for longer period of observation for psychiatric comorbidities.

Ndermera H. (2017)²¹ qualitatively explored the various motivators and barriers to self management in kidney transplant patients in South Africa. The barriers identified include kidney transplant recipients' physiological, psychological and socioeconomic status. The study resulted in gaps in the management of kidney transplant recipients. They informed that strategies are needed to build up self management and modification in behaviour among recipients of kidney transplantation.

Kuwaiti S et al (2015)²⁶ A RCT was conducted to study the outcome of self management programme for patients with kidney transplant in Iran. The chronic disease self management programme was the intervention for the experimental group whereas the control group attended training session on diet. After the intervention, there was a positive effect of the programme on quality of life in recipients of patients with transplant.

Bethany J. et al. (2017)²⁹ conducted a randomized controlled trial of Teen Adherence in Kidney Transplant Effectiveness of Intervention Trial (TAKE-IT) in kidney transplant

recipients. The intervention was a multicomponent intervention for promotion of adherence to medication. Adherence to medication was recorded electronically. Study subjects in the experiment group had consequently higher odds of taking medication or taking medication at or near the time than the control group. The multicomponent TAKE-IT intervention significantly improved medication adherence. They concluded that graft outcomes can be improved with better adherence to therapy.

Lin X. et al (2016)³⁰ explored the symptoms of depression and their associated factors among renal transplant recipients in China. More than 50% of renal transplant patients presented with symptoms of depression. The factors identified with manifestations of depression were status of employment, economic burden in the family, area of inhabitation and social support of the patient.

Aim of the study

To evaluate the effectiveness of nurse led self intervention on self care behaviour, psychological symptoms and QOL among kidney transplant recipients in a selected tertiary care hospital of New Delhi.

Research Question

- Is nurse led intervention effective in improving self care behaviour, psychological symptoms and QOL of kidney transplant recipients?

Objectives of the study

1. To assess self care behaviour, psychological symptoms and quality of life in recipients with kidney transplant.
2. To determine the effectiveness of nurse led intervention by comparing self care behaviour, psychological symptoms and quality of life among kidney transplant recipients in experimental and control group.
3. To find the correlation between self care practice and psychological symptoms of kidney transplant recipients.
4. To find correlation between self care practice and quality of life in kidney transplant recipients.
5. To find correlation between psychological symptoms and quality of life in kidney transplant recipients.

Hypothesis

H₁ There will be significant improvement in self care practice of kidney transplant recipients after the implementation of nurse led intervention as assessed by Self care practice scale at $p < 0.05$.

H₂ There will be significant improvement in adherence to immunosuppressive therapy of kidney transplant recipients after the implementation of nurse led intervention as assessed by MGL adherence scale at $p < 0.05$.

H₃ There will be significant decrease in psychological symptoms of kidney transplant recipients after the implementation of nurse led intervention as assessed by DASS 42 at $p < 0.05$.

H₄ There will be significant improvement in quality of life of kidney transplant recipients after the implementation of nurse led intervention as assessed by WHOQOL- BREF at $p < 0.05$.

Operational Definitions

1. **Effectiveness:** Effectiveness refers to increase in self care behaviour scores and quality of life scores and decrease in psychological symptom scores after implementation of nurse led intervention in kidney transplant recipients.
2. **Self care behaviour:** Self care behaviour refers to self care practices, and adherence to immunosuppressive therapy by kidney transplant recipients as measured by self care practice scale and MGL adherence scale.
3. **Psychological symptoms:** Psychological symptoms refer to anxiety, stress and depression experienced by kidney transplant recipients as measured by Depression anxiety stress scale (DASS-42).
4. **Quality of life:** It refers to kidney transplant recipient's physical health, psychological health, personal beliefs, relationship with others in society and relationship to the environment as measured by WHOQOL-BREF.
5. **Nurse led intervention:** Refers to self care management programme prepared by investigator for empowering patients with kidney transplant for self management after transplantation at home. It includes formal health teaching on medication adherence, nutrition and diet, infection prevention, activity/exercise, smoking and alcohol abstinence, regular follow up and relaxation.

Assumptions

1. Subjects will be true representative of the population.
2. Subjects will adhere to the nurse led self care management programme.

Delimitation

The study is delimited to kidney transplant recipients only who will visit Transplant clinic at AIIMS New Delhi, and who have completed 3 months after kidney transplantation.

Research Methodology

Research Approach: Quantitative Research Approach

Research Design: Randomized controlled study – time series design.

Variables:

Independent Variable: Nurse Led Intervention.

Dependent Variables:

1. Self care behaviour
2. Psychological symptoms
3. Quality of life

Setting: The present study will be conducted in Transplant Clinic, RAK OPD Block, AIIMS, New Delhi.

Population: The population of the present study will be Kidney transplant recipients.

Sample: The sample in the present study will be Kidney transplant recipients attending transplant clinic at AIIMS, New Delhi during the study period fulfilling the inclusion criteria.

Sample size: Considering the study “Depression and anxiety as potential correlates of post-transplantation renal function and quality of life” done by A.K. Jana et al(2014), reported that quality of life in renal transplant recipients was approximately 13.92(4.35). Assuming that the study subjects do not suffer from anxiety or depression and the study subjects are randomly

assigned into two groups, we are anticipating that our intervention is 20% more effective in terms of Quality of life score. So for 90% power at 5% level of significance, we require to study approx. 52 study subjects in each arm. Considering an attrition rate of approx. 10%, we require 58~60 study subjects in each arm, so total sample size required is 120.

Inclusion Criteria:

- 1) Patients who are willing to participate
- 2) Patients aged between 18-65 yrs
- 3) Patients who can understand Hindi or English
- 4) Patients who have just completed 3 months post transplantation.

Exclusion Criteria:

- 1) Patients undergoing multiple organ transplantation
- 2) Patients having psychopathology or serious cognitive impairment

Tools for data collection

Tool 1: Sociodemographic and clinical profile sheet. It consists of demographic and clinical variables of study subjects.

Tool 2: Self care practice scale. It will be used to assess self care practices of kidney transplant recipients.

Tool 3: Morisky, Green and Levine Adherence Scale (MGLS). The scale has 4 items to be answered in Yes or No. A score of 0 indicates high adherence, 1 or 2 indicates medium adherence and 3 or 4 indicates low adherence.

Tool 4: Depression Anxiety and Stress Scale (DASS -42). The DASS is a standard clinical assessment scale that measures the three related states of depression, anxiety and stress. It will be used to assess the psychological symptoms in kidney transplant recipients.

Tool 5: WHOQOL-BREF- It is a 26 item assessment scale consisting of four domains- physical health, psychological, social relationships and environment. Cronbach alpha (internal consistency) is 0.84

Plan for data collection

1. Ethical clearance will be obtained from ethical committee from SRHU and AIIMS.
2. Study subjects will be identified from Transplant clinic who meet the inclusion criteria.
3. Explanation about the study will be given to participants.
4. Informed written consent will be taken.
5. Sociodemographic data and clinical data will be collected.
6. The patients will be assigned randomly to the intervention and control group.
Intervention group will receive nurse led intervention & control group will receive usual care.
7. The observations will be made at the baseline ie. at 3 months after transplantation, 6 months and 9 months after the transplantation.

Procedure for data collection

- **Phase I:** Developing the nurse led intervention for recipients with kidney transplant.
- **Phase II:** Implementing and evaluating the effectiveness of nurse led intervention for recipients with kidney transplant.

Intervention

Study subjects in the experimental group will receive three (3) sessions of Formal health teaching regarding self care management followed by relaxation.

Session 1: It includes formal health teaching on medication adherence, nutrition and diet, infection prevention, activity/ exercise, smoking and alcohol abstinence, regular follow up and relaxation. (at 3 months post transplantation)

Session 2: Reinforcement of health teaching followed by relaxation. ($3^{1/2}$ month post transplantation)

Session 3: Reinforcement of health teaching followed by relaxation. (4 month post transplantation)

Data Collection

Pre-test at 3 months after the transplantation (Assessment of Self care behaviour, psychological symptoms and quality of life)



Nurse led self care management programme (Three sessions at a gap of 15 days each)

Session 1 at 3 months post transplantation

Session 2 at $3^{1/2}$ months post transplantation

Session 3 at 4 months post transplantation



Telephonic reinforcement for 2 months once a week regarding self care management in experimental group.



Post-test at 6 months after the transplantation (Assessment of Self care behaviour, psychological symptoms and quality of life)



Post-test at 9 months after the transplantation (Assessment of Self care behaviour, psychological symptoms and quality of life)

Plan for data analysis

Appropriate descriptive and inferential statistics will be used as applicable to the study.

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