CHAPTER III

MATERIAL AND METHODS

The present research was conducted on kidney transplant recipients. This chapter describes the methods and procedures utilized for the study.

Research Approach: A quantitative approach was considered to be apt and adopted.

Research Design: It was a prospective and randomized controlled trial with Pretest- post test control group design.

	Groups	Assessment at baseline	Nurse led Intervention Formal Health teaching, Relaxation therapy, counselling, Telephonic Reinforcement	Post Test 1 6 months post transplant	Post Test 2 9 months post transplant
Randomization	Experimental	O1	X	O2	O3
	Control	O1	-	O2	O3

O1 - Assessment at baseline

X - Nurse led intervention to experimental group

O2 - Assessment at six months post transplant

O3- Assessment at nine months post transplant

Variables: The variables for the present study were as following-

Independent Variable:

1. Nurse led intervention

Dependent Variable- In the present study dependent variables were:

1. Self-care Behaviour
2. Psychological Symptoms
3. Quality of Life

Setting: The present study was conducted in Transplant Clinic, RAK OPD Block, AIIMS, New Delhi. AIIMS is an autonomous tertiary care hospital, having exhaustive facilities for education, research & patient care. It has a main hospital complex and super speciality complex compromising of 2700 beds with OPD and OT. The hospital receives almost 1000 patients everyday from all over the country and is located in New Delhi. AIIMS has a specialized department of Nephrology. Kidney Transplant Unit is a six bedded unit, AIIMS Hospital. The patient after kidney transplantation is admitted for approximately two weeks post kidney transplantation. After discharge the recipient is followed up biweekly for three months in dedicated Transplant Clinic. Subsequently the recipient is followed up weekly for next three months. 10- 12 kidney transplantations are done per month in the hospital.

Population:

The population of the study consisted of kidney transplant recipients.

Sample:

The sample in the present study was kidney transplant recipients attending transplant clinic at AIIMS, New Delhi during the data collection 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 Jana et al[47], reported that quality of life of recipients of renal transplant was approximately 13.92(4.35). Assuming that the study subjects did not suffer from anxiety or depression and study subjects will be randomly assigned into two groups, we anticipated that our intervention will be 20% more effective in terms of QOL score. This assumption is build on inclusion & exclusion criteria. So for 90% power at 5% level of significance, we required to study approx. 52 study subjects in each arm. Considering an attrition rate of approx. 10%, we required 58~60 study subjects in each arm, so total sample size required was 120.

Considering the study "The Effect of Teach-Back Training on Self Management in Kidney Transplant Recipients" conducted by Mollazadeh F et. al(2018)[123] the self-management by the subjects was 82.45(10.49). So, for 90% power at 5% level of significance, approximately 22 subjects were required in each arm after considering an attrition rate of 10%.

The formula used for the calculation was as follow:

$$n = 2\, Sp^2 [Z_{1-\alpha/2} + Z_{1-\beta}]^2 / \mu_d^2$$

$$Sp^2 = S_1^2 + S_2^2 / 2$$

Where,

S_1^2 : Standard deviation in the first group

S_2^2 : Standard deviation in the second group

μ_d^2 : Mean difference between the samples

α : Significance level

$1-\beta$: Power

Sampling technique:

Convenience sampling technique was adopted for the study

Process of Randomization

Patients were randomized in a 1:1 ratio by computer-generated random numbers table utilizing block randomization with varied block sizes. Each block consisted of 6-10 number of patients. So, approximately 19 blocks were formed. Allocation concealment of the subjects to groups was done using sequentially numbered opaque sealed envelopes (SNOSE) prepared by the Biostatistics department. The researcher opened the envelopes after taking consent from the participants and allocated them to

experimental and control group. Blinding was not done due to the nature of the intervention. The table of Random numbers has been annexed. (Please refer Annexure No. A-1)

Sampling Criteria:

Sample was determined as per inclusion & exclusion criteria for the study.

Inclusion Criteria:

1) Patients who were willing to participate
2) Patients aged between 18-65 years
3) Patients who could understand Hindi or English
4) Patients who had just completed 3 months post transplantation.

Exclusion Criteria: The kidney transplant recipients were excluded if they-

1. Had psychopathology or serious cognitive impairment

Tools for data collection

Description of the tools: The tools used in the present study were:

1. Sociodemographic and clinical profile sheet
2. Self care practice scale
3. Morisky, Green and Levine Adherence Scale
4. Depression Anxiety and Stress Scale (DASS -21)

5. WHOQOL-BREF- Quality of life scale

Description of tool 1: Sociodemographic & clinical profile sheet (Annexure A-2)

Part a: Socio-demographic profile

It was a structured tool containing 10 items for assessing sociodemographic profile of participants. It included age, gender, educational status, marital state, employment, residential area, type of family, income of family, source of reimbursement and type of donor.

Part b: Clinical profile sheet

It was a structured tool comprising 7 items for assessing clinical status of the patient. It included history of medical condition, presence of any comorbidities, alcohol intake, smoking, tobacco intake, complications post transplant and serum creatinine.

Content Validity: The validity of the Sociodemographic and clinical profile sheet was established by five nursing specialists and two medical experts. (CVI-0.95)

Description of tool 2: Self care practice scale (Annexure A-3)

Development of tool: Self care practice scale was developed by researcher under the supervision of guide and co-guides. The items had been framed after extensive review of literature. The scoring of the items was done based on the expected level of self care of the recipients after kidney transplantation.

It was used to evaluate self care practices of kidney transplant recipients. It consisted of 30 items in total. The scale has 5 items regarding nutrition and diet, 4 items regarding medication management, 4 items regarding lifestyle modification, 5 items regarding self monitoring, 5 items regarding avoidance of infection, 3 items regarding follow up and 4 items regarding psychological care of kidney transplant recipients. Each item had scoring of 0 to 4 (0-never, 1-rarely, 2-sometimes, 3-often and 4-always). The aggregate score ranged from 0 to 120. Higher the score better was the self care practice.

Content Validity: The validity of Sociodemographic and clinical profile sheet was established by five nursing specialists and two medical experts. (CVI-0.94).

Description of tool 3: Morisky, Green & Levine Adherence Scale (MGLS) (Annexure A-4)

MGL adherence scale is a standard tool to determine adherence to medication therapy with reliability index of Cronbach's alpha of 0.61.[124] The tool is a self reported questionnaire comprising of four statements. Each statement has a response choice of Yes or No. Yes being rated as 1 and No being rated as 0. The total score of the tool range is from 0 to 4. The high adherence to medication is denoted by 0, medium adherence by 1-2 & low adherence by 3-4 scoring. The tool was used after obtaining permission for the same. Please refer to Annexure No. A-5.

Content Validity: The validity of MGL Scale was established by five nursing specialists and two medical experts. (CVI-0.95).

Description of tool 4: Depression Anxiety & Stress Scale (DASS -21) (Annexure A-6)

DASS is a standardized tool to assess depression, stress and anxiety.[125] Each subscale contains seven statements related to the feeling of the individual over the previous week. Each statement has four responses that ranged from 0 to 3. The scale is a Likert type scale and its scoring ranged amidst 0 to 21. The scoring denotes severity of the symptom of depression, anxiety and stress. The tool has been validated and tested in Indian setting with in English and Hindi with high internal consistency for both the versions Cronbach's alpha scores > 0.7.[126] Hindi version of the tool was used for the participants. The tool is available in the public domain.[127]

Content Validity: The validity of DASS -21 was established by five nursing specialists and two medical experts. (CVI-0.97).

Description of tool 5: WHOQOL-BREF (Annexure A-7)

WHOQOL-BREF is a standardized tool with self response 26 items questionnaire. It assesses the four domains of quality of life- physical health, psychological, social and environment. The tool is a valid and reliable tool and it thoroughly agrees with WHOQOL-100, approximately by 0.89. The scale is positively directed where high scores display a superior quality of life.[128] The item on tool is evaluated on a Likert scale varying from score 1 as the worst and score 5 as the best. The tool has been validated in Indian population for chronic diseases. Hindi version of the tool was also

used for the participants. Permission to use the tool was obtained. Please refer to Annexure No.A-8

Content Validity: The validity of WHOQOL-BREF was established by five nursing specialists and two medical experts. (CVI-0.98).

The list of experts for validation of tools id annexed as Annexure A-9.

Reliability of tools:

The reliability of tools was checked by administering tools to 20 subjects. The method used was test retest and internal consistency. The calculated reliability for self care practice scale (r= 0.96, α =0.87), MGL adherence scale (r= 0.74, α =0.77), Depression Anxiety and Stress Scale (r= 0.86, α =0.84), WHOQOL-BREF scale (r= 0.85, α =0.84). The reliability for Morisky Green Levine Adherence scale was also assessed with Cohen's kappa (κ)=0.72

Tool translation:

Socio-demographic and clinical profile sheet, self care practice scale and Morisky Green Levin Medication Adherence Scale (M.G.L.S) were transcribed to Hindi language with the help of specialists from Hindi section, AIIMS. Back translation was done to English language by the language experts to make certain that original meaning was retained after translation. Necessary corrections were made in the Hindi version of all the tools.

Pretesting of tools:

The tools were tried out on ten kidney transplant recipients attending kidney transplant clinic and were found to be appropriate for the population under study. The participants took 45 minutes to fill the tools.

Development of Nurse led intervention

Nurse led intervention on Self care management program for kidney transplant recipients was developed by referring to related literature, research studies and discussion with experts.

Content Validity: The validity of nurse led intervention was established by two nephrologists, two dieticians, two physiotherapists, two psychologists and two nursing experts. (Annexure A-9) Suggestions were incorporated and modifications were made in the program. It comprised of formal health education, relaxation therapy, counselling and telephonic reinforcement. The nurse led intervention was again given for content validation to the experts. (CVI- 0.96).

Components of Nurse led intervention

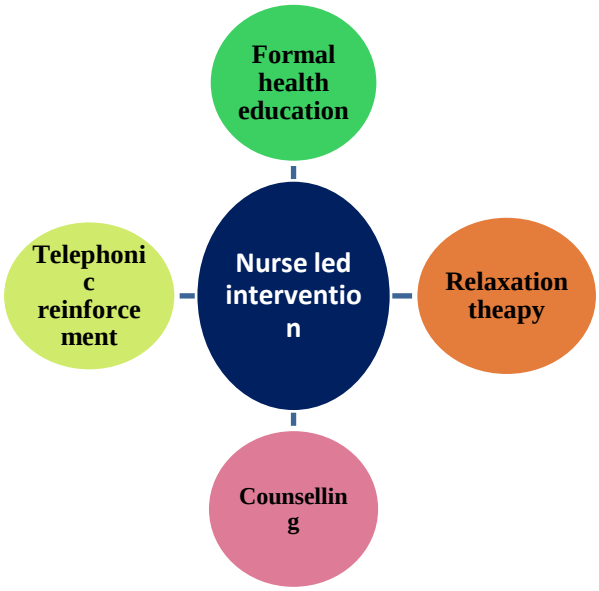

Figure 2: Components of nurse led intervention

1. **Formal health teaching**: It was provided to the participant and immediate care provider in the form of discussion and an information booklet on self care management after kidney transplantation was given. The information booklet was developed after substantial review of literature and validated for content from nephrologists, dieticians, physiotherapists, psychologists and nursing experts. The booklet included information on functions of kidneys, kidney transplantation- its meaning and benefits, immunosuppressive medications and self care management after kidney transplantation which discussed about medications, nutrition and diet, avoidance of infection, lifestyle modification, psychological care, follow up and complications after kidney transplantation. The booklet was made available in English and Hindi language as per the understanding of the participant. Please refer to Annexure No.A-10.

2. **Relaxation therapy**: Deep breathing exercise was practiced in relaxation therapy. The participant was asked to sit comfortably in the chair and perform deep breathing. The participant was instructed to place one hand on the chest and the other hand on the abdomen. The participant has to then breathe in from the nose and breathe out through pursed lips. Deep breathing helps to decrease stress in the body. The act of deep breathing helps the brain to relax and calm and ultimately relaxing the body.
3. **Counselling**: Individual face to face interaction was done with the participant to discuss their problems and help to find a solution to the problem. Any issues relating to adherence to therapy were also discussed.
4. **Telephonic reinforcement**: It was done once a week for two months and the script included the components of self care management on nutrition and diet, medication adherence, lifestyle modification, infection prevention, activity/ exercise, smoking and alcohol abstinence and regular follow up. In addition clarification of any doubts and reinforcement regarding the intervention was done.

Ethical Consideration:

1. Ethical permission to conduct the study was obtained from the ethical committee SRHU and AIIMS, New Delhi. (Please refer Annexure No. A-11 and A-12)

2. The participant information sheet was provided to all the participants and complete explanation about the study was done. The participants who

expressed their willingness to participate in the study were provided with consent form for sign. (Please refer Annexure No. A-13 and A-14) Confidentiality of information provided and anonymity of the subjects was maintained**.**

3. The study was registered with CTRI.Registration No. CTRI/2018/12/016630.

Pilot Study

Pilot study was done in September and October 2019 in the Transplant Clinic, RAK OPD Block, AIIMS, New Delhi. Pilot study was conducted among 12 kidney transplant recipients (6 in each group) who fitted the inclusion criteria. Sample was randomized into experimental and control group by computer generated Randomization table. Subjects were randomly assigned using sequentially numbered, opaque sealed envelopes (SNOSE). The data was analysed based on objectives. The study was perceived to be feasible**.**

Duration of Data collection:

The data collection was done from November 2019 to July 2020

Data collection technique

Data was collected by Self report method from participants who could read and write and from participants who could not read and write researcher read out the questions to them and asked them to give their response by putting tick mark in the questionnaire.

Data Collection Procedure/ Study protocol:

Sequentially, Numbered, Opaque, Sealed, Envelopes were prepared from the computer generated randomization table by the statistician. Permuted block randomization was used to avoid any bias. Interventions with many components pose a less risk of contamination.[129] Therefore, multidimensional intervention with health teaching, counselling, relaxation therapy and telephonic reinforcement was used in the study. It also included the behaviour change component through repeated education and reinforcement by three sessions and persuasion in the form of reminder during telephonic reinforcement and these components could not be transferred easily from one participant to another.

The patients visiting transplant outpatient clinic who were able to meet the inclusion criteria were included in study. Participant information sheet was provided to the subjects who fulfilled the eligibility criteria. The investigator described the objective and the procedure of data collection to the participants and their family member. It was explained to them that they will be placed in either experimental or control group according to the computer generated randomization table. They were ensured that their participation was voluntary and the information provided would be kept confidential. They were given the liberty to leave the study if they wished at any point of time. Participant informed consent form was provided and signed by them to show their willingness to participate in the study.

The investigator handed out the socio-demographic and clinical profile sheet, self care practice checklist, MGL Adherence scale, DASS-21, WHO-QOL Bref scale to collect the baseline data. All the participants could read and understand Hindi or

English language and filled the questionnaire by themselves by following the instruction on the questionnaire. The investigator assisted the participants by explaining the question to those who wanted some clarification in any item of the questionnaire. The participants were then randomized to experimental and control group by opening the Sequentially-numbered, opaque, sealed envelopes.

The participants in the experimental group were given the Nurse led intervention on Self care management programme in addition to standard care.

- Three sessions of individualized nurse led intervention including formal health teaching, relaxation therapy and counselling were done.
- Session 1: It was done on the day of randomization and it included formal health teaching on functions of kidneys, kidney transplantation, immunosuppressive medications- importance of adherence, action of drugs and their possible side effects. Self care management after kidney transplantation was also discussed which included information about medications, nutrition and diet, avoidance of infection, lifestyle modification, psychological care, follow up and complications after kidney transplantation. It took about 15 minutes as the participant was aware of the concepts. The sessions were given in the transplant clinic on Thursday.
- Session 2: It was done on Day 15 post randomization and included formal health teaching on functions of kidneys, kidney transplantation, immunosuppressive medications- importance of adherence, action of drugs and their possible side effects. Self care management after kidney transplantation was also discussed and reinforced. It took about 15 minutes as

the participant was aware of the concepts. The sessions were given in the transplant clinic on Thursday.

- ❖ Session 3: It was done on Day 15 post randomization and included formal health teaching on functions of kidneys, kidney transplantation, immunosuppressive medications- importance of adherence, action of drugs and their possible side effects. Self care management after kidney transplantation was also discussed and reinforced. It took about 15 minutes as the participant was aware of the concepts. The sessions were given in the transplant clinic on Thursday.

- ➢ The information booklet was prepared in Hindi and English with pictures and was provided to the participant in their choice of language for reference. The participants who were illiterate, all the content of information booklet was explained by the researcher and the booklet was given to the care provider accompanying the subject for reference.
- ➢ The investigator then demonstrated deep breathing exercise to the participant and return demonstration was also taken. The participant were instructed to practice deep breathing exercise for two times every day for 10 minutes at home. The investigator clarified any doubts related to the exercise to the participant.
- ➢ Counseling was done by the investigator related to importance of adherence to the therapy. The participant was also free to discuss any of their concerns or problems and they were helped to find solution to the problem. The counseling was done for 10-15 minutes.

Each session including formal health teaching, relaxation therapy and counselling took 40-45 minutes to complete.

- Telephonic reinforcement was done once a week for two months on of self care management regarding nutrition and diet, medication adherence, lifestyle modification, infection prevention, activity/ exercise, smoking and alcohol abstinence and regular follow up. In addition to this clarification of any doubts sought by the participant was done. It took about 10-15 minutes for each participant.

The participant was asked to maintain a diary for medications, diet, monitoring of blood pressure, blood sugar, fluid intake and weight. This was done to assess the adherence to the nurse led intervention. Self reporting was also used to check adherence to the intervention. It was found that there was 95% adherence to the nurse led intervention as checked by the diary.

Standard care was given to the control group. It included consultation with the nephrologist and routine laboratory investigations.

Assessment after the intervention was done for Self care behaviour (self care practice checklist, MGL Adherence scale), Psychological symptoms (DASS-21) & Quality of life (WHO-QOL Bref) at six and nine months post transplant for both the groups.

Summary

This chapter describes the research approach and design, variables, population, sample and sampling techniques, ethical clearance, pilot study, the procedure for data collection.

Data collection procedure/ Study protocol

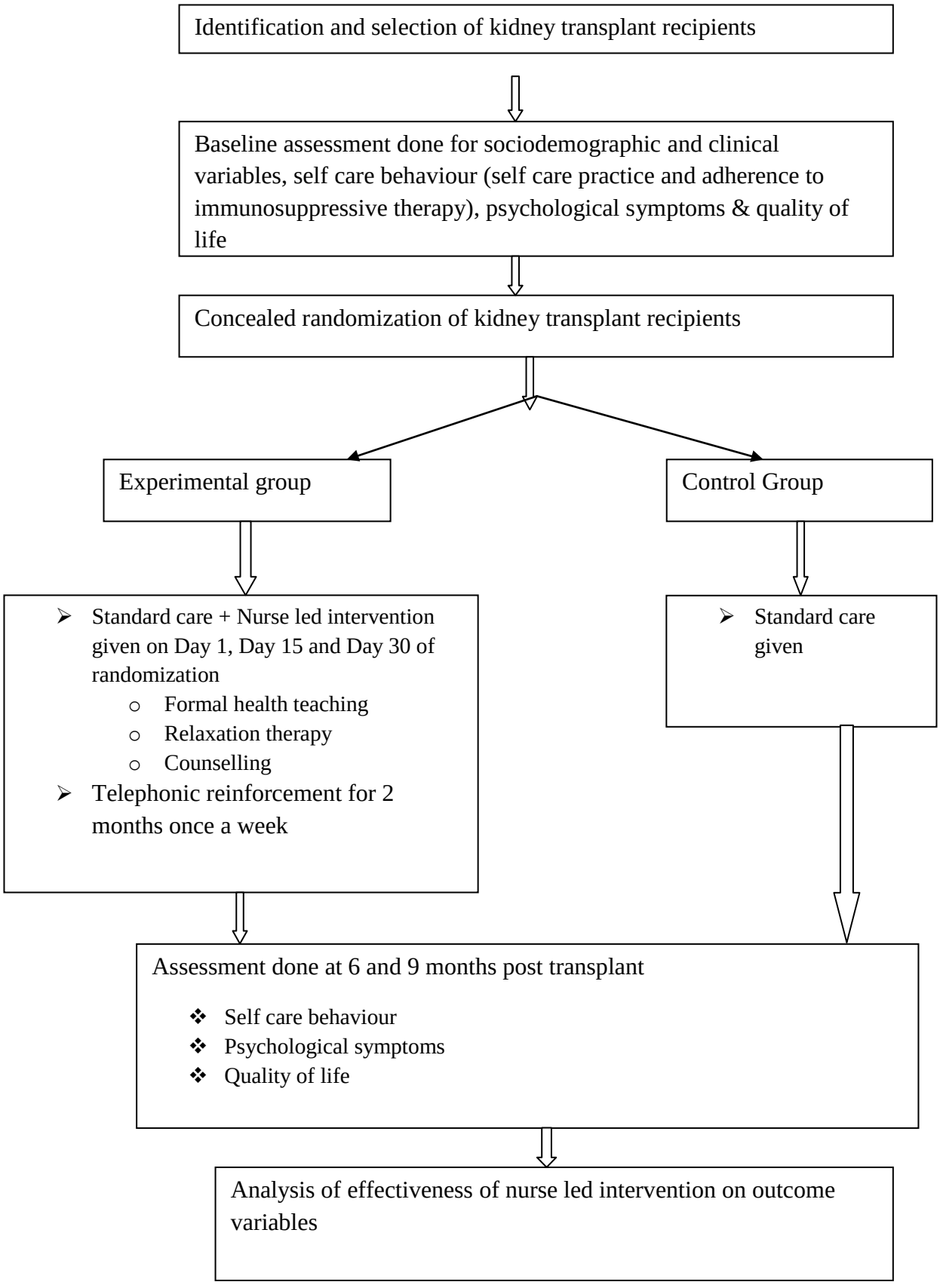

Figure 3: Study protocol

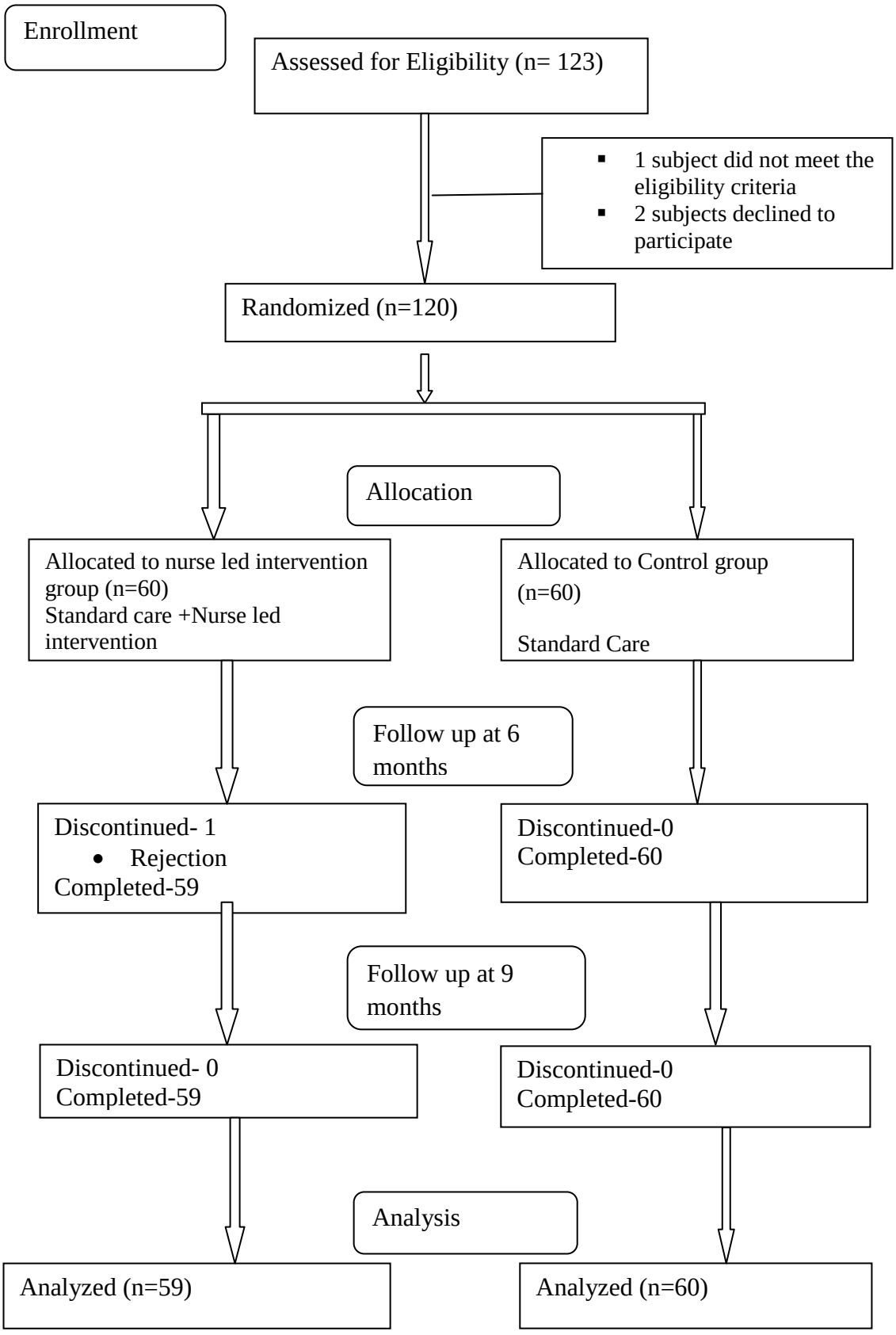

Figure 4 CONSORT Flow Diagram