

## Self-Support Group for chronic renal failure patients and caregivers on their quality of life: A Study Protocol

### Abstract:

**Background:** Chronic renal failure (CRF) or Chronic kidney disease (CKD) is an irreversible progressive loss of kidney functions in which, kidney fails to sustain the metabolic waste, fluid and electrolyte balance in the body. The prevalence of chronic renal failure is 15% to 17 % in adult population in many developing countries.

**Objective:** To find out the effectiveness of Self Support Group (SSG) for Chronic Renal Failure patients (CRF) and caregivers on their quality of life (QOL)

**Methodology:** It is a single arm trial, interventional hospital based study. The patients of chronic renal failure of age group 18 to 50 years and caregivers age group above 18 years. Selection of patients and caregivers as per inclusion criteria, detail explanation about nature and purpose of the study and the written and informed consent, from the subject will be taken before data collection by the investigator after that the formation of groups for chronic renal failure patients and caregivers. Empowerments of the group with knowledge of chronic renal failure and its management, than evaluation quality of life (QOL) for patient and their caregivers with use of QOL scale. The assessments of quality of life for four times, it include day one to three months, six months and nine months respectively. The setting of the study is selected hospitals of Vidarbha Region. The Ethical approval obtained from Institution Ethical Committee, DMIMS (DMIMS (DU)/IEC/2017-18/6979).

### Expected Results:

- Formation of Self Support Group for CRF patients and their caregivers in Hospital Setting
- Improvement in knowledge regarding CRF of patients and their caregivers
- Improvement in QOL for both CRF patients and caregivers

**Conclusion:** Conclusion will be drawn from the statistical analysis after completion of data collection.

**Keywords:** chronic renal failure, caregiver and quality of life, self-support group

### Introduction:

CRF is now identified as a major worldwide health related problem<sup>1</sup>. The Global Burden of Disease (GBD) studied in 2015 ranked chronic kidney disease 17<sup>th</sup> among the causes of deaths<sup>2</sup>. Chronic kidney disease is recently among the top five causes of death. In India, Global Burden of Disease 2015 ranks chronic kidney disease as the 8<sup>th</sup> leading cause of death<sup>3</sup>.

Due to non registry of chronic renal failure, the exact disease burden of chronic kidney disease/end stage renal disease is difficult to identify accurately in the Indian population. A population-based study from North India, multistage cluster sampling technique were used, in which serum creatinine and samples of urine were examined for all subjects, the stage 3 chronic kidney disease prevalence was found in 0.79% samples out of 4,972 examined<sup>4</sup>.

Kidney failure is characterized by loss of the renal functions and results in the accumulation of metabolic waste products in blood. This results the imbalance of fluids and electrolytes in the body, which leads to serious medical problems. An irreversible loss of kidney function for prolonged period of many years is called CRF or chronic kidney disease. Clinical manifestations are usually mild and unable to identify and it progresses without notice for a long period. In many patients the clinical manifestations are observe when it is too late, and in most of the cases, very less management can be done to control the progression of the condition<sup>5</sup>.

In the general people, improvement in the physical capacity and control of progress of chronic diseases such as chronic renal failure it depends upon the physical activity or exercises done by the people. It was found that improvement in the physical condition of hemodialysis clients helps to improve their physical capacity levels. Physical health is an important nursing management for patients with hemodialysis in improving their physical performances or activities<sup>5</sup>.

Clients with chronic renal failure (CRF) must take care of their disease condition to a lifelong to reduce disease progression effectively with regular follow-up with lifestyle modifications (e.g., dietary pattern, fluid intake, physical activities, habits and activity of daily living). Managing the level of daily activities is very complex and they require support from family, caregivers and peers. However, not all clients are needed the similar type or level of assistance<sup>6</sup>.

Self-care is very essential to prevent the progress of renal failure or kidney diseases. However, patients with chronic kidney disease might have less or early clinical manifestations so that they might consider self-care is not required for them. Therefore, the collaborative management and motivation for self-care in patients with renal failure is necessary<sup>7</sup>.

Related to chronic renal failure or conditions, peer support and similar social interventions has become strongly linked with an attempt to increase patients' ability to self care their disease. These interventions will drive to improve health outcomes among CKD patients. Peer support with these aims has been enthusiastically embraced in many of the countries health policy<sup>8</sup>.

An increasing number of patients with chronic renal failure or CKD depend on non-professional care providers, such as family members, friends and informal caregivers, to manage their disease progression all over the course of chronic kidney disease. The informal caregivers such as family members, friends and relatives can also experience pressure, hopelessness, loneliness and they may also have poor QOL. But, the needs of these caregivers are often neglected and not emphasized<sup>9</sup>.

Caregivers (family members or unpaid care providers) avoid informing their problems to others because they think no one will understand their problems. They think embarrassed of their feelings of tiredness, irritation, frustration, fear and anxiety of being recognized by others as insufficient or bad partners. Remain in control and handling the conditions within the family is important to caregivers. Many times chronic renal failure patients feel alone and

they acknowledge that gaining courage and motivation from people other than the family members is also necessary. They communicate a need for closeness to others to counteract the feelings of uncertainty<sup>10</sup>.

WHO has stated that empowerment as a “prerequisite for health” and “a proactive partnership and patient self-care strategy” to progress physical health related outcomes and QOL among the chronically ill patients the empowerment is an intervention oriented idea with the main aim on elimination of disease related problems, and on transformation of relationship between community people and organizations or institutions<sup>11</sup>.

Dialysis (Haemodialysis and Peritoneal) is a lifesaving management that can provide significant benefits for most of the patients; it is also having serious complications if the chronic renal failure patients and caregivers don't follow the guidelines, instructions and not understanding the ideas of its safety and security. Safety and security is the concern of being prevented and protected against physical health, social problems, spiritual concern, financial burden, occupational, psychological crises, educational or other types of consequences of disappointment, harm or any other situation which could be measured undesirable. Providing safety to the patient in the dialysis unit is a matter of more apprehension for patients and health care professionals such as nurses and technicians<sup>12</sup>.

Nitrogenous waste product such as serum urea, the end product of protein metabolism, level increases as the kidneys fail. Retention of serum urea can cause nausea, vomiting, anorexia and pancreatitis as complications<sup>13</sup>.

#### **Rationale of study:**

Chronic Renal Failure or Chronic Kidney Diseases or End Stage Renal Diseases is a chronic condition. In this condition patients physical, mental and psycho-social life effects some or other way. The client requires continued pharmacological and non-pharmacological management. Other than treatment they are in need of self-care and support from the family, friends, caregivers and others. Therefore the investigator wants to develop a group of people, which include chronic renal failure patients and caregivers, in which they can discuss their problems; share their feelings and some extent they can solve their problems with the help of their own group i.e. Self Support Group (SSG).

#### **Methodology:**

##### **Study Procedure:**

- First meeting: investigator will introduce herself with purpose of meeting.
- Written consent (if willing) and filling form of demographic data by patient/investigator.
- Planning for formation of group as per patients and their caregiver's convenience.
- The investigator will do the assessment of self administered Quality of life rating scale by the patients and caregivers.
- Formation of group with minimum numbers of 10 patients and 10 caregivers.
- Than empowerment of the group in the form of giving information about CRF and its management and assessment of Quality of Life for CRF patients and caregivers.
- the first group name will be Group P1 of 10 patients and Group C1 of 10 caregivers.
- Assessment of QOL at the interval of Three, Six and Nine Months for Patient and Caregiver.

- Same process will be continued till fulfilment of the criteria of sample size.
- That groups namely: P2 and C2, P3 and C3, P4 and C4, P5 and C5, P6 and C6, P7 and C7, P8 and C8, P9 and C9, P10 and C10, P11 and C11, P12 and C12, P13 and C13.

**Inclusion Criteria:**

- Willing to participate in present study.
- CRF Patients with domestic or committed caregivers.
- Both male and female patients and caregivers are included.
- Diagnosed case of CRF for >6 months and <6 years.
- Age from 18 years to 50 years.
- Ambulatory patients only.
- Both IPD and OPD patients are included.

**Exclusion criteria:**

- Chronic Renal Failure with tuberculosis, HIV/AIDS, Chronic Heart Diseases, Chronic Liver Diseases, Temporary Hemodialysis, Malignancies.
- Impaired cognition, unable to follow the instructions of investigator at the time of data collection.

**Withdrawal Criteria** - Participants who fulfil the following criteria will be withdrawn from the study:

1. Want to withdraw from the present study.
2. Not fulfilling study schedule.
3. Impaired memory due to chronic condition.

**Sample size calculation:**

Sample size calculation based on prevalence:

$$N = \frac{Z^2 * p(1-p)}{d^2}$$

Where

- Z=Statistic for the level of significance 5% = 1.96
- P=Prevalence of chronic renal failure from previous studies<sup>14</sup> =17.2% =0.172
- d= Error of margin =7% =0.07

$$N = \frac{1.96^2 \times 0.172 (1-0.172)}{0.07^2} = 111.52$$

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Samples =130 patients and 130 caregivers

**Interventions:**

1. Section I: Demographic data of CRF Patients and their caregivers.
2. Section II: Teaching and provision of learning resource material on knowledge regarding CRF and its Management.
3. Section III: Quality of Life Rating Scale for CRF Patients and their caregivers.

**Outcome measures:**

1. Primary outcome: To develop the Self Support Group of CRF patients and for their caregivers in hospital setting.
2. Secondary outcome: to assess the quality of life of CRF patients and their caregivers

**Data management and monitoring:** The demographic data for patient: Name, Age, Sex, Address, Educational status, Occupation, Income (monthly), Marital status, Patient's relation with Caregiver, Co-morbidity (if present), Year/s of diagnosis of CRF, Type of dialysis, Mobile number. The demographic data for caregiver: Name, Age, Sex, Address, Marital, Status, Occupation, Education, Income (monthly), Taking care of patient since last how many years, Relation with patients will be recorded when they are enrolled. The baseline assessment of quality of life and the quality of life after completion of the interventions i.e. at the end of every three months, six months and nine months, will be obtain. Investigator will record adverse events and withdrawals for any reason.

**Statistical analysis** - Descriptive (mean, mean percentage, standard deviation) Inferential, Comparative statistics (student's' test) and **co-relational statistics is planned for data analysis.**

**Ethics and dissemination-** Present study was approved by the IEC (Institutional Ethics Committee) of DMIMS (DMIMS (DU)/IEC/2017-18/6979). All participants will be asked to read and sign the informed consent. The study results will be disseminate to study participants and published in peer-reviewed publications.

#### **Expected Outcomes/Results:**

- Formation of Self Support Group for CRF patients and their caregivers in Hospital Setting
- Improvement in knowledge regarding CRF of patients and their caregivers
- Improvement in Quality of Life for both CRF patients and caregivers

#### **Discussion:**

Present study finding will be supported by a cross sectional study conducted by Havas K, Douglas C, and Bonner A. (2017). They have provided the information about chronic kidney disease and medications as well as everyday need based patient education. A result reveals different levels of interventions such as engagement in daily activities, enthusiasm and motivation to gain more knowledge about chronic kidney disease self-management highlight the need for a client-centred approach to self-management support <sup>6</sup>.

A randomized controlled trial (2017) conducted by Joboshi H, Oka M were supporting to present study, the total number of samples were 65, randomly divided in to two groups, n=33 i.e. experimental group and n=32 i.e. non-experimental group. The experimental group was introduced encourage autonomous self-enrichment program and follow the intervention for twelve weeks. The control group was introducing by standard education provided by staff nurses. Out of 33 participants of experiment group 1 patient died after four weeks, other continued the program of Encourage Autonomous Self-Enrichment for 12 weeks. Results reveal that statistically improvement in the perceived self-efficacy (  $p = 0.035$ , effect size  $r = 0.27$ ) and self-management behaviours (  $p = 0.026$ , effect size  $r = 0.29$ )<sup>7</sup>.

A qualitative research study conducted by Hughes J, Wood E, and Smith G. (2009), total number of 20 patients with purposive sampling were received the peer group support. The maximum participants were responded positively with peer support and its benefits. The peer support appreciated by participants because it had provided the practical information about kidney disease, which help them to take decision about kidney disease treatment. Peer support useful for the chronic ill patients to become familiar to chronic illness treatment and it also increases patients' sense of empowerment<sup>8</sup>.

Present study is supported by Mollaoğlu M, Deveci G. (2017) cross section study was done on 104 dialysis patients. The demographic data and kidney disease QOL scale were used for the data collection. Results shown, physical health -12 components and mental health -12 components, quality of life were mostly affected. The quality of life related to physical health was low in women (low education) as compare to man. Patients living with caregivers and undergoing dialysis for long period were also having low quality of life. Quality of life related to mental health related is low in people living alone<sup>15</sup>. A number of related studies were reviewed. Balwani et. al. reported on rapidly progressive renal failure in a lupus patient<sup>16</sup>. Dande et. al. reported on oral manifestations in diabetic and nondiabetic chronic renal failure patients<sup>17</sup>. Relevant studies on quality of life and supportive therapy were reviewed<sup>18-20</sup>. Related issues were addressed in studies of Sharma et. al.<sup>21-23</sup> and Zodpey et. al.<sup>24-28</sup>.

**Conclusion:** Conclusion will be drawn from the statistical analysis after completion of data collection.

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