INTRODUCTION

Illness is a term that has got a derogatory meaning in the current fast moving society, because during the period of illness the normal functioning of the individual is deviated to some extent. Any chronic illness puts a person at a more demanding situation as the suffering is guaranteed for prolonged period. Some way or the other chronic illness endangers the wellbeing of the person by representing its proximity to death. Similarly a plethora of florid psychopathology follow the individual who is diagnosed to have Chronic kidney disease (CKD).

CKD refers to the progressive failure of the renal cells to function normally, jeopardizing the clearance of metabolic waste products, balancing of blood pressure and maintenance of blood production and bones. The disorder was earlier known as end stage renal disease (ESRD) or chronic failure (CRF).

CKD is becoming a major public health problem worldwide. As per WHO Global burden of disease project, diseases of the kidney and urinary tract contribute to the global burden with approximately 850,000 deaths every year, and 115,010,107 disability adjusted life years. CKD is the 12th leading cause of death and 17th cause of disability.1

More than 20 million (more than 10% of people) aged 20 years or older in the United States have CKD and it is more common among women than men. More than 35% of people aged 20 years or older with diabetes and more than 20% of people aged 20 years or older with hypertension have CKD. Inadequately managed diabetes and hypertension increase the risk of progression of end stage renal disease to kidney
failure. Repeated episodes of acute kidney injury from a variety of causes (e.g., infections, drugs or toxins harmful to the kidney) can also contribute to progression of CKD to kidney failure, especially in the elderly. Though this disease is more common among women; men with CKD are 50% more likely than women to progress to kidney failure.²

A study on nationally-representative population in UK, revealed a prevalence of CKD stage three to five was six percent (five percent in males, seven percent in females). It varied with age, ranging from one percent of male and two percent of female aged between 16 to 54 years to 31 percent of male and 36 percent of female aged 75 years and above. There was an inverse socio-economic gradient. Prevalence of albuminuria was nine percent, higher in males (ten percent vs. eight percent) and with a strong inverse socio-economic gradient in males. The overall prevalence of CKD stages one to five was 14 percent in males and 13 percent in females. Only 1.5 percent of males and 1.3 percent of females reported being told by a doctor that they had kidney failure.³

The data for the first report of the Renal Registry of India was collected through a cross-sectional study from twelve different public and private renal care settings. Of the 52,273 adult patients, 35.5%, 27.9%, 25.6% and 11% patients came from South, North, West and East zones respectively. The mean age of the sample was 50.1 ± 14.6 years, with male/female ratio of 70:30. Patients from north zone were younger and those from the east zone older. The most common cause was Diabetic nephropathy (31%), followed by CRF of undetermined etiology (16%), chronic glomerulonephritis (14%) and hypertensive nephrosclerosis (13%). Stage V was
presented by 48% and they were younger than those in Stages III and IV. Diabetic nephropathy patients were older, more likely to present in earlier stages of CKD and had a higher frequency of males; whereas those with CRF of unexplained etiology were younger, had more females and more frequently presented in Stage V. Patients in lower income groups had more advanced CRF at presentation. Patients attending to public hospitals were poorer, younger and more frequently had end stage renal disease of unknown etiology.  

Agarwal, Dash, Irshad et al conducted a population screening in New Delhi including 4712 subjects in a blood biochemistry test. The mean age of the sample was 42.38±12.54 years and 56.16 percent were males. Thirty-seven were found to have CRF (prevalence rate of 0.78%). Another prospective study was conducted by the same researchers involving 4145 patients from 48 hospitals distributed all over India. The results showed 0.8 percent of CRF prevalence in India. When the two study results were combined, diabetes has emerged as the most frequent cause (30–40%) followed by hypertension (14–22%) for developing renal failure. The two studies, which are different in some ways, explain the wide range in incidence, suggesting regional influences.  

CKD is a global threat to health in general and for developing countries in particular, because therapy is expensive and life-long. In India 90 percent patients cannot afford the cost. Care for kidney disease is available only at the higher-level hospitals. There is no formal referral system; patients can go to any hospital, including to referral hospitals anywhere in the country. A shortage in the number of publicly funded specialized hospitals forces patients to seek care in expensive private
hospitals. A vast majority do not have access to health insurance, and hence have to fund treatment from their resources.\textsuperscript{8}

The situations of Udupi and nearby districts in Karnataka are not different. Though there are a few Government hospitals offering the haemodialysis with a subsidised cost, the patients are not satisfied with care due to compromised treatment conditions such as lack of nephrologists, dialysis nurses and technicians, reduced duration of dialysis and non-availability of consultation and emergency care.

Most of the patients undergoing maintenance haemodialysis are taxed with the huge treatment expenses: as of now, the cost of single dialysis in a private hospital ranges from ₹1,000 to ₹2,000 and hence a person requires ₹9,000 to ₹18000 for one month’s dialysis alone, whereas they are in need of additional medications and injections. Majority of the patients cannot afford the cost of Injection Erythropoietin (₹1,450 per single dose, for one month ₹26,100), which they have to take in order to maintain normal haemoglobin level in the blood but they cannot comply with it until it becomes a priority. Other medications cost minimum ₹3,000 for a month and the travel and other expenses vary depends on the mode of travel, distance and the need for an accompanying person. Many cannot access public transportation because of the fatigue or strict dialysis schedule. Further they are affected with sense of deep pain, guilt and loss of hope, physical limitations, lack of support, feelings towards the machine and dialysis, and uncertainty and fear of tomorrow.\textsuperscript{9} All these add to their misery and the patients tend to think that they are a burden to their family. These multiple factors endanger their psychological balance and coping mechanisms resulting in anxiety and depression.
Anxiety disorders and depression are common co-morbid conditions with any chronic medical illness. Anxiety and depression are important targets of psychological assessment in patients with an end-stage renal disease because it predicts their morbidity, mortality and poor quality of life.\textsuperscript{10,11} The tendency to focus on the patient as the reason for problems with adherence is continued, ignoring other factors that might have influence such as the patient-health care provider relationship and the health care system that surrounds the patient.\textsuperscript{12} It is indeed difficult for the CKD patients to adhere to the strict regimen of fluid, diet, medications and many hours of dialysis.\textsuperscript{13}

Dade-Montez et al identified that in the period of up to four years from the occurrence of depression symptoms, 18 percent of patients resigned from dialysis. Therefore, depression symptoms are a significant early indication of bad prognosis as to survival of patients treated with dialysis.\textsuperscript{14,15,16} Excessive non adherence is associated with higher morbidity and mortality.\textsuperscript{17} Early recognition of and therapeutic efforts directed toward the treatment of depression might modify outcome in CKD patients.\textsuperscript{14,18,19}

According to the WHO meeting report, the consequences of poor adherence to long-term therapies include poor health outcomes and increased health care costs. Non adherence severely compromises treatment’s effectiveness making it a critical issue in population health from both quality of life and health economic perspectives.\textsuperscript{20} A solid research foundation is essential for evidence based practice and the available data are not sufficient to develop clinical practice guidelines to promote fluid adherence among people undergoing haemodialysis. Living with the fluid
restrictions imposed by CKD is a major ongoing challenge. Researchers must be challenged to find effective and feasible interventions to assist patients to cope with and adhere to this restrictions and to reduce the negative effects of fluid restriction, non-adherence on the outcomes of individuals on chronic dialysis.\textsuperscript{17} Interventions utilizing a cognitive or cognitive/behavioral component showed significant results in improving compliance to diet, fluid, drug and dialysis.\textsuperscript{14,21,22}

Cognitive behavior therapy (CBT) aims to help patients identify the dysfunctional cognitions, test them against reality and alter them, thereby improving their emotional well-being, coping behavior and physical health. A CBT approach may be particularly beneficial to patients who, on the basis of experiencing multiple failures in attempting to manage fluid-intake restrictions, have little or no belief in their ability to cope adequately with the demands of the treatment regime. Such individuals may have developed strong negative beliefs regarding their fluid management. Negative thoughts such as “My fluid restrictions are beyond my control” can result in negative feelings like sadness, anger, hopelessness and maladaptive health behaviors like overdrinking thereby reinforcement of these problematic beliefs. Assisting people to develop more realistic, self-helping beliefs by using CBT could enable them to cope more effectively with fluid restrictions inherent in the haemodialysis treatment regime.\textsuperscript{23}

Nurses are in an excellent position to target the behavioral dimension by assessing adherence as an important clinical parameter and by implementing adherence-enhancing interventions that have the ultimate goal of improving clinical outcomes.\textsuperscript{14} Research supports the idea that a nephrology nurse spending time with
the patient on a regular basis, in order to understand the factors that hinder the individual patient from adhering to the treatment regimen. The nurse who knows the patient well is empowered to develop individualized interventions aimed at reducing barriers that interfere with the patient's ability to adhere to the prescribed treatment regimen. Hence it is important for nurses to practice interventions to help patients overcome the barriers that keep them from adhering to the prescribed treatment.\textsuperscript{13} The nurse can develop a strong relationship of support with the patient, identify barriers, and offer strategies to help patients improve adherence.\textsuperscript{12}

As psychiatric nursing specialist, researcher has learned Cognitive behavior therapy during the academic preparation, attended workshops on CBT and also underwent a one week Training programme for acquiring the hands on experience and clinical skills in CBT. Apart from this, researcher had the opportunity teach the same for Psychiatric Mental Health Nursing master students for many years. The expert guidance from the guide who is practicing psychotherapy oriented model of care and supervision from an experienced clinical psychologist also were motivating factors for the researcher. The researcher has a keen interest in counselling the needy and actively involved in the counselling of students facing personal, academic or family related problems and also the patients and family members in the clinical set up. The experience of the researcher reaffirms that deeply set hopelessness and anxiety of people undergoing haemodialysis are partly reality oriented and can be alleviated with cognitive and behavioural approaches than counseling alone.

The need was felt by the researcher to develop a comprehensive intervention that can help haemodialysis patient to adopt self-responsible strategies of thought
tracking, fluid control, diet control, dialysis and medication adherence, initiating with more activities and exercises, relaxation, symptom management, better sleep and thereby reduced anxiety, depression, improved quality of life.

There is a dearth of methodologically sound studies conducted in India on developing and testing an effective strategy to tackle the problems faced by the people undergoing haemodialysis. It was also the keen interest of researcher to develop an appropriate intervention to help them cope with this chronic illness in a better way. Based on the expertise, literature search and experts' suggestions, researcher decided to apply Cognitive Behaviour Therapy (CBT), a scientific intervention which is safe and cost effective in CKD patients who are undergoing Haemodialysis.

**Research Statement**

A randomized controlled trial on effectiveness of cognitive behavioural therapy (CBT) on anxiety, depression, adherence and quality of life among people undergoing haemodialysis in a selected tertiary care hospital of South Karnataka.

**Purpose of the Study**

The study findings will help establish the application of Cognitive Behavioural Therapy in CKD in order to prevent or reduce anxiety, depression and improve adherence which will enhance their quality of life and thereby contribute to a better therapeutic outcome.
Objectives of the study were to:

1. develop and validate CBT module for people undergoing haemodialysis.

2. find the effect of CBT in terms of significant difference in the mean scores of
   2.1. anxiety and depression among people undergoing haemodialysis in the experimental group and control group as measured by the Hospital Anxiety and Depression Scale (HADS).
   2.2. adherence on dialysis, fluid, diet and drug regimen among people undergoing haemodialysis in the experimental group and control group as measured by Heamodialysis Adherence Scale.
   2.3. quality of life among people undergoing haemodialysis in the experimental group and control group as measured by CHOICE Health Experience Questionnaire (CHEQ).

Hypotheses

1. There will be significant difference in the mean post test scores of anxiety and depression among people undergoing haemodialysis in the experimental and control group.

2. There will be significant difference in the mean post test scores of adherence among people undergoing haemodialysis in the experimental group and control group.

3. There will be significant difference in the mean post test scores of quality of life among people undergoing haemodialysis in the experimental group and control group.
Assumptions

1. Man is a bio-psycho-social being.
2. Quality of life is multidimensional and empirically measurable.
3. The peak incidence of CKD is between 20 and 64 years of age.
4. Psychiatric morbidity lowers the therapeutic outcome of medical conditions.
5. Improved adherence brings down the mortality in chronic illness.
6. Depression prone people possess negative self-beliefs.
7. Alterations in the content of underlying cognitive structures can bring change in affective state and behavioural pattern.
8. Every person is basically self-directed and dynamic.

Variables

Independent variables: Cognitive behavior therapy and Non-directive counselling

Dependent variables: Anxiety, depression, adherence and quality of life

Demographic variables: Age, gender, education, past occupation, current occupation, marital status, number of family members, family monthly income in Rupees, area of living.

Disease specific variables: Distance from home to hospital, means of transportation to hospital, presence of attender, support for ambulation, period after starting dialysis, duration of illness, co-morbidity.
Definition of terms

People undergoing haemodialysis: In this study, People undergoing haemodialysis refers the person diagnosed as having Chronic Kidney Disease (CKD), by a nephrologist and undergoing maintenance haemodialysis as a modality of management.

Chronic Kidney Disease (CKD): In this study, CKD patient refers to a person who is diagnosed as having progressive reduction of functioning renal tissue.

Cognitive Behavioural Therapy (CBT): Cognitive behavior therapy is an active, directive, time limited, structured approach designed to treat variety of disorders based on the theoretical rationale that affect and behavior is largely determined by the way people structure the world.24

In this study CBT is referred as the structured psychological intervention that include ten weekly sessions of individual therapy, with a duration of 50 to 60 minutes each on case conceptualization, modification of dysfunctional thoughts, education on dialysis and fluid adherence, education on diet and drug adherence, activity and sleep scheduling, reinforcement of strengths and coping with physical symptoms, relaxation training and fistula care, relapse prevention and booster session by applying cognitive, didactic and behavioural techniques.

The cognitive techniques in the present CBT include Socratic questioning, dysfunctional thought recording, verbal reattribution, questioning the evidence, cost benefit analysis, guided discovery, making action plan, raising self-worth(by maintaining gratitude diary) and self-monitoring.
Didactic techniques in the current CBT encompass education on dialysis adherence, fluid adherence, diet adherence, drug adherence, importance of exercise and activity, seeking social support, sleep hygiene, symptom management, coping with illness and fistula care.

Behavioural techniques in the present CBT consist of goal setting, activity scheduling, pleasure and mastery rating of activity, graded task, activity generation (increasing the activity), positive reinforcement, bibliotherapy, relaxation training and relapse prevention.

**Anxiety:** A diffuse, unpleasant, vague sense of apprehension, often accompanied by autonomic symptoms such as headache, perspiration, palpitations, tightness in the chest, mild stomach discomfort, and restlessness, indicated by an inability to sit or stand still for long.\(^25\)

In this study, anxiety refers to wounded, frightened, worried, restless or panic feelings with inability to sit at ease or feel relaxed, as measured by a score of seven or above in the domain of anxiety in Hospital Anxiety and depression Scale (HADS).

**Depression:** An alteration in the mood that is expressed by feelings of sadness, despair and pessimism.\(^26\)

In this study depression refers to inability to enjoy, laugh, remain cheerful and feeling slowed down in activities or lost interest in appearance, as measured by a score of seven or above in the domain of depression in HADS.

**Quality of life:** WHO defines Quality of life as an individual's perception of their position in life in the context of the culture and value systems in which they live and
in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment.27

In this study, quality of life refers to perceptions of CKD patients on their overall physical, mental and dialysis specific health perception of the patient as measured by CHOICE Health Experience Questionnaire (CHEQ).

**Adherence:** “the extent to which a person’s behavior in taking medication, following a diet, and-or executing lifestyle changes, corresponds with agreed-upon recommendations from a health care provider.”28 Successful haemodialysis depends on four factors: fluid restriction, dietary guidelines, medication prescriptions and attendance at haemodialysis sessions.29

In this study, adherence refers to person’s adherence to prescribed dialysis, fluid, diet and drug regimen that comprises of correct frequency and duration of dialysis, less intake of water (urine output + 500 ml.), low potassium, phosphorous and sodium diet and regular consumption of prescribed medications; as measured by Interdialytic weight gain, dialysis record, self-reported Haemodialysis Adherence Scale and Diary.

**Interdialytic weight gain (IDWG):** The gain in body weight of CKD patient in Kilograms in between any two given dialyses that is measured by a calibrated electronic weighing machine at the dialysis unit. The average of two consecutive inter dialytic weight gains are calculated in this study for more accuracy as the patients are
getting every third and second day dialysis respectively as there are no appointments given for maintenance dialysis on Sunday (fixed for dialysis unit cleaning for half a day and rest of the time is allotted for patients on non-appointment basis).

**Medical co-morbidity**: In this study, medical co-morbidity refers to the presence of any other diagnosed medical conditions such as; Diabetes mellitus, Hypertension and Ischemic heart disease.

**Non-directive counselling**: Ten weekly sessions of individual counselling (with duration of 30 to 40 minutes), by applying therapeutic communication, active listening and clarification of doubts (particularly on kidney disease, dialysis, diet and drugs) by the investigator, apart from the maintenance dialysis and standard care provided by the dialysis staff and nephrologists.

**Conceptual Framework**

A conceptual model provides for logical thinking, systematic observation and interpretation of observed data. They also give direction for relevant questions on phenomena and point out solution to practical problems. The conceptual framework for the study was developed by the researcher triangulating two models relevant to the present study, Cognitive model by Padesky and Mooney, 1990 and Model of Dynamic Integration by Dungan, 1997. The schematic representation of the conceptual framework is given in figure 1.
Chapter I

Introduction

Fig. 1 Conceptual framework on cognitive behaviour therapy for people undergoing haemodialysis based on cognitive model (Padesky and Mooney, 1990) and Dynamic Integration Model (Dungan, 1997)
The Cognitive model was developed by Padeskey and Mooney for presenting conceptual formulation for the clients during the cognitive therapy so that they get to know the connection of their own biology, thoughts, mood, behavior and environment. Changes in any one of the area can affect all rest of the areas and over time the effects can build up causing serious impact in the person’s living.

The Dungan’s model of Dynamic Integration presents human being as having three synergistic systems of body, mind and spirit, having dynamic integration of life events leading to ongoing development. It was used effectively in a study on nursing interaction enhancing the adherence of people undergoing haemodialysis. The key elements of the model are the axes, human dimensions, therapeutic relationship, environment, health assessment, modalities of care and the dynamic integration toward optimum functioning.

The Axes: The three axes that must be considered in the nursing situations are client, developmental level and wellness /illness scale.

Client: The client axis in the original model acknowledges the focus of nursing intervention, which may be either individual/family or larger groups developing concurrently within the environment. In the present study, client axis refers to the CKD patient undergoing dialysis. Dungan views human being as having the dimensions of body, mind and spirit that are continuous, open and indivisible. The present study equates the human dimensions with the concepts of Cognitive model by Padesky and Mooney, hence focus the link among the biology, thoughts, mood and behavior of the client which have reciprocal effects to the environment.

Biology refers to the physical and physiological aspects of client in which major factors are CKD, physical dependency to dialysis, associated illness like
hypertension, diabetes, anemia, fatigue, sleep problems etc. Thoughts refer to the ideas of helplessness, hopelessness and worthlessness which are reflected through the client’s statement such as “nothing can be done to improve my condition”, “this is the worst disease among all”. These sorts of thoughts lead to feelings (mood) of anxiety and depression later behavior such as withdrawal from earlier pleasurable activities and therapeutic non-compliance.

Environment: In Dynamic Integration model, environment is seen as the total milieu in which the people live, grow, develop and experience their being whereas in Cognitive model as person’s background such as family, job, culture and weather. In the present study, the environment is considered as the total living situations of the client that include therapeutic, family and social milieu. Therapeutic milieu of client considers the confidence in the care and treatment by the health team members and the warmth and quality of the therapeutic relationship with the therapist. Family milieu indicates the emotional and financial support provided by family members and motivation to main therapeutic compliance. Social milieu includes the perceived social support from significant others and participation in social activities.

Developmental level: The level of development sets the norm for nursing judgment and directs the choice of nursing intervention. This body of knowledge is characteristically categorized into three philosophical approaches: mechanic, organismic, and dialectal. The mechanistic school of thought sees people as passively reacting to stimuli in the environment. Organismic model views development as an innately determined, continuous, quantitative process that expresses potential from within. Dialectical model provide for incorporation of concepts from both the previous and views that growth and maturation are determined by interaction between
the organismic potential and mechanistic forces. In the present study, the developmental axis is considered at the level of dialectical model where the patient is provided with cognitive behavioural therapy but the processing of the relevant information and utilization of the same are done by the patient himself which will lead to the personal growth of the individual.

**Wellness/illness scale:** Nursing is committed to facilitate development through use of nursing process at any point of the wellness/illness scale. Any nursing interaction may offer opportunity for development of a potential for greater functional integrity across all three dimensions. In this study wellness/illness scale axis means the levels of anxiety, depression, symptoms related to poor therapeutic compliance and changes in the level of quality of life experienced by dialysis patients at all domains.

**Health assessment:** It includes the assessment of physiologic functioning, nutrition, drug, sleep, activity, sexuality, mental, physiologic and psychological status as well as spiritual responses. In this study the health assessment includes all the above aspects except spiritual responses such as assessment of anxiety, depression, therapeutic compliance and quality of life with the help of direct observation of the dialysis patient, lab investigations, diary, structured questionnaires and standardized scales.

**Cognitive behaviour therapy:** According to Dungan’s model, nursing modalities of care is the nurse’s infinite choices of interventions based on the client situation, to promote integration and healing such as direct care, teaching/learning, counselling, alternative healing, social support and augmented social support. In this study, modalities of care selected were: teaching/learning, counseling, alternative
healing in the form of Cognitive behavior therapy by instituting a set of cognitive techniques such as Socratic questioning, dysfunctional thought recording, verbal reattribution, questioning the evidence, cost-benefit analysis, generating alternative thoughts, guided discovery, didactic technique, diary writing, home works and behavioural techniques such as activity scheduling, positive reinforcement, self-monitoring, bibliotherapy and relaxation training to integrate the illness experience of the patient to all dimensions to promote growth.

**Therapeutic relationship:** It is the healing relationship of professional nurse that is achieved through use of presence, caring, unconditional positive regard, active listening and consensual validation. In this study, therapeutic relationship is the professional relationship with CKD patient undergoing dialysis, attained through open communication, genuine concern, unconditional positive regard, active listening and consensual validation while administering Cognitive behavior therapy.

**Dynamic Integration:** Integration of life events into the total functioning of all human dimensions is an essential process to grow and develop in a healthy way. Integration yields confidence in one’s ability to cope and contribute to the concept of ‘competent self’. Here the dynamic integration of the client is achieved through the integration of negative event that is CKD and its’ management into the totality of life so that patient can accept the reality of illness in order to live a better life.

**Outcome assessment:** The present study incorporates outcome assessment as a new component apart from the concepts of both the models since evaluation is a part of any structured therapeutic intervention. Here the outcome assessment is done though checking reduction in anxiety and depression, improvement in adherence and quality of life at three months and six months after completion of CBT.
Chapter I

Introduction

Delimitation of the study

Study was delimitated to the CKD patients undergoing dialysis in one tertiary care hospital of Udupi District.

Summary

This chapter clarified the background and need for the study and also dealt with research statement, purpose, objectives, hypotheses, assumptions, variables, definitions of terms, conceptual framework and delimitation of the study.

Outline of the Report

Further report of the study follows in five chapters

Chapter II: Review of literature- presents an overview of the related research and non-research literature.

Chapter III: Methodology- deals with the methodology and plan of analysis.

Chapter IV: Analysis and interpretation of data: presents analysis and interpretation of data

Chapter V: Discussion- compares the present study findings with other research findings.

Chapter VI: Summary- contains a brief summary of the study, conclusions based on the study findings, implications for nursing, limitations and recommendations for further study.

The report also consists of abstract, references and appendices.