**RESEARCH METHODOLOGY**

This chapter deals with the research methodology that includes the research approach, research design, description of the setting, population, sample and sampling, development and description of the tools used for data collection, content validity and reliability of the tools, pilot study, procedure for data collection and plan for data analysis.

**Research approach**

The aim of the present research was to find the effect of CBT to reduce anxiety, depression and improve quality of life and adherence among people undergoing haemodialysis. Hence an evaluative approach was considered the best. An evaluative research is an applied form of research that involves assessing how well a specific programme, method, procedure or product is tested to assess its applicability, quality, feasibility and desirability in terms of some meaningful criterion measure.  

**Research design**

The research design guides the researcher in planning and implementing the study in a way that is most likely to achieve the intended goal. RCTs are studies that measure an intervention’s effect by randomly assigning individuals (or groups of individuals) to an intervention group or a control group. Well-designed RCTs are considered the gold standard for measuring an intervention’s impact across many diverse fields of human inquiry, such as education, welfare and employment, medicine and psychology. The schematic presentation of the study design is developed according to the CONSORT statement 2010 and presented in figure 2.
Target population
People undergoing Haemodialysis

Study population (Screened for eligibility)
People undergoing Haemodialysis based on Sampling criteria (n = 150)
- Excluded (n = 70)
  - Not meeting inclusion criteria (n = 60)
  - Declined to participate (n = 10)

Block randomization
Number of Blocks = 8, Block Size = 10

Single blinding

Allocation to experimental group
(n = 40)
- Received Cognitive Behaviour Therapy
- Discontinued (n = 7)
  - Followed up (n = 33)
  - Analyzed (n = 33)

Allocation to control group
(n = 40)
- Received Non-directive Counselling
- Discontinued (n = 5)
  - Lost follow-up (n = 1)
  - Followed up (n = 34)
  - Analyzed (n = 34)

Fig. 2: Schematic representation of the RCT design on effect of CBT among people undergoing haemodialysis using CONSORT guidelines 2010
The present study design has all the properties of RCT such as randomization, control and manipulation and it follows the guidelines of Consolidated Standards of Reporting Clinical Trials (CONSORT)\(^9\) and is registered in the Clinical Trial Registry of India (CTRI) under Indian Council of Medical Research with the number REF/2013/08/005579.

The sample (people undergoing haemodialysis) were selected from the same setting and randomly allocated into experimental and control group using computer generated block randomization and the experimental group received CBT) whereas the subjects in the control group received non-directive counseling while both the groups were receiving routine care. The routine care includes maintenance haemodialysis, pharmacological management by nephrologists and occasional reminders on fluid restriction by nephrologists and dialysis unit staff (nurses and dialysis technicians). The observations were phased into three times; pre-assessment, after the therapy at three months and after six months.

**Setting of the study**

The present study was conducted in the Dialysis unit of Kasturba Hospital at Manipal. Kasturba Hospital is tertiary care multispecialty center which is attached to Kasturba Medical College. The hospital renders outpatient, inpatient, emergency and diagnostic services in almost all medical, allied health and indigenous fields. The bed strength of the hospital is 2032 with 80% patient occupancy rate and adequate staffing. The Dialysis unit has the facility for 15 dialyses at a time and there are four shifts in the morning (7.30am to 12.30pm), afternoon (1.30pm to 6.30pm) night (7.30pm to 12.30 am) and late night (1.30 am to 6.30 am). The dialysis center
functions round the clock except for Sunday half day (meant for sterilization of the unit). The staffs in the dialysis unit include nurses, dialysis technicians and visiting nephrologists.

**Population**

The study population consisted of the CKD patients undergoing maintenance dialysis at outpatient basis in the Kasturba hospital. The haemodialysis is given for five hours, though most of the patients are prescribed three dialyses per week, majority of them undergo only two dialyses per week.

**Sampling technique**

The entire population that is all the people undergoing haemodialysis was screened at first for eligibility criteria and as the second step Hospital Anxiety Depression Scale (HADS) was administered to the sample which met the criteria and those who were willing to participate in the study. The eligible sample was decided based on the cut off scores of the HADS; that is seven or above in the anxiety or depression subscales. As the third step the final sample were randomly allocated into experimental and control groups by using computer generated random order and block randomization procedure.

**Randomization**

Randomization is a process in which patients are allocated to control and intervention group by giving each participant equal chance of being assigned to a either intervention or control group. The balance between the numbers of subjects in each group is guaranteed during the course of randomization by adopting block randomization. The random blocks were generated through computer, for 80 sample
with the help of biostatistician. Eight blocks were prepared each containing 10 numbers (1 meant for control whereas 2 for experimental group). Though stratification of the sample based on the duration of dialysis was planned initially, it was found not feasible during the pilot study, because of the prolonged data collection period.

The eight blocks were individually put in sealed, sequentially numbered small opaque envelopes and altogether they were put another big envelope and centrally placed with the safe custody of dialysis unit in-charge. As and when the people undergoing haemodialysis finish the screening and provision of consent, they were given the sequentially numbered and sealed opaque envelope, with the instruction to open the envelope, read the number and then to strike the read number with a pen. The patient was given the code number based on the randomization. When all the ten numbers in the first envelope were allocated, second envelope was given for the next patient.

Blinding

Blinding (masking) indicates that knowledge of the intervention assignments is hidden from participants, trial investigators or assessors. The terminology single blind usually means that one of the three categories of individuals (normally participant rather than investigator) remains unaware of intervention assignments throughout the trial.

The present study is considered single blinded as the investigator only knew about who got which intervention whereas the study participants were not aware about the exact difference between the two psychological interventions; CBT and Non-directive counselling. The identity of the CBT group was kept masked from the
dialysis staff as well as the nephrologists because the IDWG and blood pressure were measured by the dialysis staff and both the two groups of professionals were seeing them while they were on dialysis. Haemoglobin was measured by the clinical laboratory and recorded by the dialysis staff from the online lab reports the patient record. The rest of the outcome measures were self-rated through questionnaires hence the measurement bias are minimized. Whenever the investigator approached the people during dialysis, a pattern of taking rounds (attending to both the group participants at equal duration) was adopted, to avoid the bias.

**Sample size**

The sample size of the study was calculated considering therapeutic adherence (compliance to the prescribed haemodialysis, fluid, diet and drugs) as the primary outcome measure. The following formula was used for calculating the sample size.\(^{94}\)

\[
\eta = \frac{(Z_{\alpha} \sqrt{2PQ} + Z_{\beta} \sqrt{P_{1}Q_{1} + P_{2}Q_{2}})^{2}}{(P_{1} - P_{2})^2}
\]

The level of significance, \(Z_{\alpha}\) was kept as 1.282 and power of the study \(Z_{\beta}\) at 80% (0.84). It was assumed that, the general adherence among people undergoing haemodialysis is 50% and expecting an improvement to 75% after CBT, therefore \(P_{1}\) and \(P_{2}\) are considered 0.5 and 0.75 respectively. \(P = \frac{P_{1} + P_{2}}{2}\), \(Q_{1} = 1 - P_{1}\), \(Q_{2} = 1 - P_{2}\), \(Q = 1 - P\). In order to detect 0.25 difference in the adherence after the intervention, the sample calculated as needed was 32.87, that is 33 in each group. Considering 20 percent attrition rate, the sample size assumed as needed was 39.44, thus it was decided to take a sample of 40 in each group.
Sampling criteria

The following criteria were set for the selection of the sample.

Inclusion Criteria:

1. Those who are between 20 and 65 years of age.
2. Those who are on maintenance dialysis for a minimum period of one year.
3. Those who can read and write Kannada or English.
4. Those who score above seven in any of the areas of anxiety or depression on the Hospital Anxiety and Depression Scale.
5. Those who are willing to participate in the study.

Exclusion Criteria:

1. Those who require full support for ambulation.
2. Those who are waiting for transplant.
3. Those who are currently on treatment for any of the psychiatric illness.
4. Those who have psychosis, phobia, delirium or dementia.
5. Those who have significant vision or hearing impairments.
6. Those who are currently hospitalized.
7. Those who are receiving any form of psychotherapy from other sources.

Data collection tools

The following tools were used for the present study

Tool 1: Background Proforma (Developed by the researcher and validated by the experts)
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Research Methodology

Tool 2: Hospital Anxiety and Depression Scale (HADS)

Tool 3: Haemodialysis Adherence Scale (Developed by the researcher)

Tool 4: CHOICE Health Experience Questionnaire (CHEQ)

Tool 5: Opinionnaire on Acceptability of CBT

Tool 1: Background Proforma

This was developed by the researcher to collect the background information of the subjects. It had 17 items such as age, gender, education, past occupation, current occupation if any, marital status, number of family members, family monthly income, area of living, distance from home to hospital, means of transportation to hospital, bystander if any, support for ambulation, period after starting dialysis, duration of kidney disease, type of onset of kidney disease and presence of other illness. The items did not have any scoring as they were meant to collect the factual information from the sample. (Appendix- 9)

Screening for psychiatric illness: Person’s answers to the items of Background Proforma were counterchecked with the bystander or dialysis staff to ensure their memory function. History of onset of illness along with any diagnosis or treatment of psychiatric illness was also taken. Further orientation was tested by asking them three questions, the date, place and approximate time of the day. If the answers were found to be faulty, patients were excluded from the study.

Content validity

To ensure the content validity, the Background Proforma, along with research statement, objectives and validation form were given to seven experts from the field of nephrology, dialysis technology and medical surgical nursing. The experts were
requested to give their valuable opinion and suggestions based on the relevance, accuracy and appropriateness. The initial tool contained 14 items and all the items had 100 percent agreement and two experts suggested to include ‘Distance from home to dialysis center’, ‘means of transportation to hospital’ and ‘support for ambulation’ which were added to the Background Proforma.

Pretesting

Pretesting was done by administering the tools to five subjects in the form of structured interview. No modifications were done in tools as there was no difficulty for the subjects to answer any of the items.

Tool 2: Hospital Anxiety and Depression Scale (HADS)

The Hospital Anxiety and Depression Scale (HADS) was developed by Zigmond and Snaith in the year 1983. This scale which was specifically developed for use with physically ill patients. The term ‘hospital’ in its title suggests that it is only valid in such a setting but many studies conducted throughout the world have confirmed that it is valid when used in community settings and primary care medical practice. HADS has been used extensively, and researchers identified 747 papers that referred to HADS in indexed journals by May 2000. (Appendix-10)

The HADS was chosen leaving behind other similar scales assessing anxiety and depression because of its high sensitivity and positive predictive value to detect the actual anxiety and depression without contaminating them with the symptoms of somatic illness such as dizziness, headaches, insomnia, anergia and fatigue. This scale gives clinically meaningful results as a psychological screening tool, in clinical group comparisons and in correlational studies with several aspects of disease and
quality of life. It is sensitive to changes both during the course of diseases and in response to psychotherapeutic and psychopharmacological intervention. The scale has 14 items, seven each on anxiety and depression. Each item has been given the responses on a four point response scale.

**Scoring:** The score of each of the items in the scale are from 0 to 3, so the possible scores range from 0 to 21 for anxiety (HADS-A) and 0 to 21 for depression (HADS-D). The six items in the scale (2, 4, 7, 9, 12 and 14) are given the score of 0, 1, 2 and 3 from left to right and the reverse score is applicable for the rest of the items. The interpretation of the total score is as given: a score of 0 to 7 for either subscale is regarded as being in the normal range, a score of 8 to 10 indicative of border line abnormality and 11 or higher indicating abnormal level of anxiety or depression.

**Validity and Reliability of original HADS**

The concurrent validity of HADS was established in relation to other commonly used rating scales of anxiety and depression was based on correlation coefficients. Most factor analyses demonstrated a two factor solution in good accordance with the HADS subscales for HADS-A and Depression HADS-D, respectively. The correlations between the two subscales varied from 0.40 to 0.74 (mean 0.56). Cronbach’s alpha for HADS-A varied from 0.68 to 0.93 (mean 0.83) and for HADS-D from 0.67 to 0.90 (mean 0.82). The sensitivity and specificity for both HADS-A and HADS-D of approximately 0.80 were very similar to the sensitivity and specificity obtained by the General Health Questionnaire (GHQ).100
Pretesting and Reliability of Kannada Version

Pretesting of the Kannada version of HADS was done among five people undergoing haemodialysis, followed by the reliability checking among 20 patients from Kasturba Hospital, Dr. Ambedkar Circle, Mangalore. The Cronbach’s alpha value obtained for the scale is 0.73 and hence it is considered reliable to be used in the study.

Tool 3: Haemodialysis Adherence Scale

The gold standard to assess the adherence of haemodialysis patients has not been established. Compliance parameters should be easily measured and verified, reproducible, clearly interpretable, and accurate. They should have meaning for the patient, clear pathophysiological significance unrelated to other factors and be related to important outcomes. Subjective and objective measures and laboratory adherence indices are poorly correlated. Different factors have been associated with differential compliance in different patient populations, depending on the measures assessed. Adherence to dialysis prescription, shortening and skipping behaviours of haemodialysis treatments have been identified recently. New data confirm that many compliance measures, including both laboratory and behavioral compliance indices, are associated with patient outcomes.102

Haemodialysis Adherence Scale was developed by the researcher after an extensive review, personal discussion with experienced nephrologists, dialysis technicians, dieticians, dialysis patients and their care givers, as there were no standardized scales available. The scale has five sections such as A: Adherence
indicators, B: Dialysis Adherence Subscale, C: Fluid Adherence Subscale, D: Diet Adherence Subscale and E: Drug Adherence Subscale. (Appendix-11)

The Section A: Adherence Indicators has a total of 14 items, in which first four are interdialytic weight gain, blood pressure, heamoglobin and number of dialysis per month. The data pertaining to these items are obtained from the clinical record maintained in the dialysis unit by the Dialysis Unit staff. Interdialytic weight gain is measured by using a calibrated electronic weighing machine planted in the entrance of the Unit and recorded by the dialysis staff initiating the dialysis for the patient, prior to each of the dialysis. The weighing machine is calibrated by the Biomedical engineers from G Lit Company and Kasturba Hospital once in every four months (thrice in a year). The researcher has computed the average of two consecutive Interdialytic weights of the patient, as the gap between two dialyses in a given week is varied between two and three days. (Ex. Patients’ appointments are fixed to Monday and Thursday, Tuesday and Friday, Wednesday and Saturday). The Sphygmomanometers in the dialysis unit are calibrated by sending them to the Bio-medical department once in every year as per the standard.

The rest of the ten items in this section are on the various signs and symptoms related to the non-adherence, such as breathlessness, swelling of the limbs, fatigue, headache, skin itching, abnormal sensations, confusion, bone and joint pain, palpitation and sleeplessness.

Scoring: The first four items do not have any scoring and treated as direct variables and the rest of the ten items (signs and symptoms) are rated as ‘always’, ‘sometimes’, ‘never’ each carries 1, 2 and 3 respectively.
Section B, Dialysis Adherence Subscale has five items on skipping, shortening, delaying dialysis, clarifying doubts and on taking extra dialysis. All these behaviours are considered as negative except clarifying doubt with doctor or dialysis unit staff.

Scoring: The items are again rated as ‘always’, ‘sometimes’, ‘never’ each carries a score of 1, 2 and 3 respectively except for the positive item on clarifying doubts has a direct score as 3, 2 and 1. The patients who do not want to do anything to improve their situation may not seek any information.

Section C, Fluid Adherence Subscale has a total of 15 items and the first item on fluid intake; the responses are ‘output+500 ml.’, ‘output + 501 ml to 750 ml.’ and ‘Output+ >750 ml.’ Next three items are on fluid control behaviours itself such as drinking more than advised level, control thirst thinking of the negative impact, and include intake of tea, curries and fruits along with the total fluid allowance. The responses given are ‘always’, ‘sometimes’ and ‘never’.

The remaining 11 items in the Fluid Adherence Subscale are on various drinks and juices commonly used by South Indians. Four out of 11 (tea with milk, herbal tea, Greek yogurt, juice cube) are consumable whereas the left seven are non-accepted drinks (orange juice, tender coconut water, milk >100ml, coffee, curd/butter milk, cola/soda and beer/alcohol) in CKD as they contain more amounts of potassium, phosphorus or sodium. The responses for these items are based on the frequency of consumption such as ‘daily’, ‘weekly once’, ‘once in 15 days’, ‘once in a month’ and ‘never’.

Scoring: First item in this section, gets a score of 1, 2 and 3 respectively for the responses given above as it is considered ideal to drink within 500 ml more than the
urine output, considering the fluid loss through body warming, breath and perspiration. Second item is negative in effect so scored as 1, 2 and 3 for the responses ‘always’, ‘sometimes’ and ‘never’ respectively and reverse for next two items as they are considered good fluid adherence behaviours.

Among the next 11 items, the four positive items are scored as 5, 4, 3, 2 and 1 for the responses ‘daily’, ‘weekly once’, ‘once in 15 days’, ‘once in a month’ and ‘never’ respectively whereas, the seven negative items are scored reverse.

Section D, Diet Adherence Subscale has a total of 54 items on variety of food types such as cereals, pulses, vegetables, fish, meat, fruits, nuts, snacks, sweets, pickles, oils and also on the method of cooking. The first 10 items are on pulses and vegetables; among that eight are consumable and two are non-consumable (item number: 1 and 2). The responses given are based on the frequency of intake: ‘daily’, ‘weekly once’, ‘once in 15 days’, ‘once in a month’ and ‘never’.

Next nine items are on leaching different vegetables. Leaching is supposed to be practiced before consuming vegetables such as potatoes, yam, bitter gourd, brinjal, pumpkin, radish, drumsticks and amaranth with high potassium content, as the potassium dissolves in water. The responses stated corresponding these items are ‘yes, always’, ‘only sometimes’, ‘no, never’ and ‘not applicable’.

Further in the Diet Subscale, there are 24 items on fresh and dried fruits, sweets, pickles, coconut and spices among these eight are consumable (item number: 22, 23, 26, 27, 28, 29, 33 and 41) and the rest majority are non-consumable as these items contain greater amounts of potassium which could be harmful to the heart.
function as the kidneys are unable do the vital function of potassium regulation. The responses for the items are again based on frequency and time of intake like: ‘daily’, ‘weekly once’, ‘once in 15 days’, ‘once in a month’ and ‘not applicable/never/during dialysis’. The next segment of this subscale contains nine items on non-vegetarian food items with three consumable, high biological value protein sources (item number: 44, 45 and 48). These items are given a similar response category like the previous group.

The last part of Diet Adherence Subscale has four items on general dietary adherence behaviours such as protein, minerals, spice and salt intake. Two of the items are worded positively (item number: 51 and 52). The patients are recommended to take 20 to 30 grams of high biological value protein in order to prevent weight loss and restrict the rest of the three, in order to maintain potassium, phosphorus and sodium balance. The responses of all the four items are ‘yes, always’, ‘sometimes’ and ‘no, never’.

**Scoring:** Among the first ten food items, two non-consumable are scored 1,2,3, 4 and 5 respectively for ‘daily’, ‘weekly once’, ‘once in 15 days’, ‘once in a month’ and ‘never’ and eight consumable food items are scored reverse.

Next nine items are scored 3, 2, 1 and 3 for the responses ‘yes, always’, ‘only sometimes’, ‘no, never’ and ‘not applicable’ as leaching is considered desirable for all the listed vegetables in this segment. ‘Not applicable’ also gets high rating if they are not including the food item in their diet.
Next 31 items (item number 20 to 50) in the Diet Adherence Subscale have the same list of responses such as ‘daily’, ‘weekly once’, ‘once in 15 days’, ‘once in a month’ and ‘not applicable/never/during dialysis’. The non-consumable food items are scored 1, 2, 3, 4 and 5 whereas the consumable items 5, 4, 3, 2 and 1 respectively.

In last part of this subscale, the positively worded items (51 and 52) are scored as 3, 2 and 1 for ‘yes, always’, ‘sometimes’ and ‘no, never’ respectively and the rest two negatively worded items are scored in reverse order.

**Section E, Drug Adherence Subscale** has a total of 11 items and the first six items are on positive adherence behaviours such as buying the prescribed medicines and taking on correct timings. These are with three responses such as ‘yes, always’, ‘sometimes’ and ‘no, never’.

Seventh item in this subscale is on the frequency of skipping each drug due to forgetfulness i.e. how many times in a week (1 to 7 times) they forget in the ‘morning’, ‘afternoon’ and ‘night’. Eighth item is on the way in which they maintain their hemoglobin level such as: ‘nothing at all’, ‘blood transfusion’, ‘blood transfusion along with dietary management’, ‘Injection Erythropoietin/ Iron along with blood transfusion’ and ‘Injection Erythropoietin/ Iron along with dietary management’. Ninth and 10th items are on the frequency of the intake of Injection Erythropoietin and Iron and Vitamin Injection and the last item is on whether they carry their medicines while going out of home for a day or more.

**Scoring:** The first six items are on positive drug adherence behaviours, hence scored 3, 2 and 1 for the responses ‘yes, always’, ‘sometimes’ and ‘no, never’ respectively.
Seventh item on forgetting to take the medicine is scored independently for morning, afternoon and night as: ‘Never forgot’=5, ‘forgotten twice in a week’=4, ‘forgotten 3 to 4 times’=3, ‘forgotten 5 to 6 times’=2 and ‘forgotten more than 6 times’=1. Eighth item is scored 1 to 7 and 9th and 10th items 4 to 1 from left to right. Eleventh item has a score of 3, 2 and 1 for the responses ‘always’, ‘sometimes’ and ‘never’ respectively.

**Content validity**

To ensure the content validity, the Haemodialysis Adherence Scale, along with research statement, objectives, blue print and validation form were given to nine experts from the field of nephrology, dietetics, dialysis technology and medical surgical nursing. (Appendix-7) The experts were requested to give their valuable opinion and suggestions based on the relevance, accuracy and appropriateness. The content validity index was then computed for the scale, which is an indicator of the degree to which an instrument is content valid based on an average ratings of a panel of experts. Fourteen items in the Section A had validity index of 1 and remaining three items (creatinine, potassium and phosphorus) had index of 0.77. The reason stated were: they are not been tested frequently by the nephrologists in the study setting to avoid taxing the patients with more expenses and the patients too are careful to avoid blood loss caused by frequent laboratory investigations. The three items were finally removed only after the pilot study, when the researcher could not get the approval from all the patients.

The Section C had 48 items out of which 45 had the validity index of 1 and the rest had 0.77 and hence they were removed. The items discarded were kidney beans, soya chunks and goat liver (not commonly consumed by south Indians in this region and confusing results regarding its inclusion in kidney diet). As per the suggestion of
the expert dieticians, a segment with nine items on leaching was included into this section, thus the final Diet Adherence Subscale has 54 items.

The responses on frequency of intake of various fluid and food items in both Sections B and C were made explicit by modifying the them from ‘always’, ‘sometimes’ and ‘never’ to ‘daily’, ‘weekly once’, ‘once in 15 days’, ‘once in a month’ and ‘never’ based on the suggestion of the experts. All the 11 items in Section E got a validity index of 1; hence all the items were retained.

Pretesting

Pretesting was done by administering the scale to five subjects. No modifications were done in tools as there was no difficulty for the subjects to answer these items.

Reliability

The reliability of the Haemodialysis Adherence Scale was determined by administering it to 10 people undergoing haemodialysis by inter rater reliability. Test re-test reliability was also done among 10 sample with a gap of one week. The Karl Pearson correlation coefficient was computed and the r value obtained were 0.9 and 0.89 for inter rater and test re-test methods respectively which indicated a good reliability for the tool.

Tool 4: CHOICE Health Experience Questionnaire (CHEQ)

The CHOICE Health Experience Questionnaire (CHEQ) is a comprehensive tool that assesses the quality of life of the people undergoing dialysis. This questionnaire was developed in the year 1999 by the CHOICE team of researchers. CHOICE stands for ‘Choices for Healthy Outcomes in Caring for ESRD’, which was an all-inclusive study of the relationship between patient and provider choices, patient
outcomes and health care costs for patients with ESRD who were undergoing dialysis. CHOICE is one of several Patient Outcomes Research Team (PORT) studies funded by the United States Agency for Health Care Policy and Research and the first one to focus on CKD.103

The CHEQ involves the generic Medical Outcomes Study Short Form-36 (SF-36) and disease-specific questions focused on aspects of quality of life potentially related to dialysis. The CHEQ include general health related domains of quality of life given in the SF-36 (physical function, role-physical, bodily pain, general health, vitality, social function, role-emotional, mental health) as well as specific dialysis related quality of life (freedom, cognitive functioning, diet, recreation, travel, work, finance, symptoms, sleep, sex, dialysis access and body image).104

Content validity and reliability of the original CHEQ

The original instrument went through a rigorous development process which included a structured literature review of 47 articles describing 53 different instruments, content analysis of five focus groups with dialysis patients, nephrologists and other providers, a survey of 110 dialysis providers about features of different modalities that affect patient quality of life and a semi-structured survey of 25 patients with CKD on the effects of dialysis on functioning and health related quality of life. One thirty six people undergoing dialysis rated each item for frequency and bother to help prioritize domains and items identified by these methods. A panel of nephrologists provided advice about the salience of items to modality or dose. Items and scales were selected with a preference for existing measures tested in patients with ESRD and were tested for reliability and validity. These items showed adequate internal consistency, Cronbach's alpha >0.70, except for time (α = 0.57) and quality of
life ($\alpha = 0.68$), as well as convergent and discriminant construct validity in a sample of 928 patients. The items on time was deleted from the original scale.\textsuperscript{102,103}

Permission to use the CHEQ and content validation

The researcher obtained the permission to use the instrument from the principal investigator of CHOICE study Neil R Powe and the original instrument from the project director Nancy Fink. The CHEQ was given to seven experts including two nephrologists, two professors of medical surgical nursing, one psychiatrist, one professor of psychiatric nursing and one professor of sociology for their opinion on the use of CHEQ in Indian context. All of the experts opined that it is wholesome but lengthy. Three of them suggested that two items (‘How do you feel about your life now’ and ‘On an average day how many good waking hours do you have, when do you think about the past four weeks?’) are vague to be precisely answered by Indians. Investigator felt that the two items among the three of sex domain (Inability to relax and enjoy sex and Difficulty in sexually aroused) may not suitable to be asked to unmarried, worried chronically ill people as per Indian culture. Hence all the four items were removed after communicating with the principal investigator. Thus the final CHEQ has 76 items in it. (Appendix-12)

**Scoring:** The first four general health related domains of quality of life (physical function, role-physical, bodily pain, general health) are put together to form Physical Component Summary (PCS) and the rest of the domains (vitality, social function, role-emotional, mental health) to Mental Component Summary (MCS). All the items are given on 2 to 6 point response scales that are rated on a continuous scale of 1 to 6, depending on the number of responses of each of the item, thus the total
scores ranged from 76 to 367. The total scores Domain scores are scaled in a positive direction, that is higher the scores, higher the quality of life of the individual.

**Translation, pretesting and reliability of CHEQ**

Researcher took the permission to translate the CHEQ and then it was translated into Kannada and back translated to English with the help of language experts. The Kannada tool was pretested among five people undergoing haemodialysis and reliability was tested among 20 patients of Kasturba Hospital, Dr. Ambedkar Circle, Mangalore. The obtained Cronbach’s alpha was 0.79 and it shows that the tool is reliable.

**Tool 5: Opinionnaire on Acceptability of CBT**

This tool was prepared in order to assess the acceptability of CBT among the people undergoing haemodialysis. A total of 14 items under the areas of outcomes of CBT (eight items), CBT sessions (two items) and diary contents (four items), were incorporated in the tool. The responses were given as ‘Strongly agree’ and ‘Agree’. There were no score assigned to the responses as they were opinions.

**Validation, pretesting and reliability of Opinionnaire on Acceptability of CBT**

The Opinionnaire was given to five validators and all the items had 100% agreement and some experts suggested to include space for open ended response at the end of the tool. The tool was pre-tested and found feasible. Co-efficient of stability by establishing test re-test reliability was done using Karl Pearson correlation coefficient for the tool (r=0.9) after the pilot study of CBT and the tool was found feasible and reliable to use. (Appendix-13)
Chapter III

Research Methodology

Training in CBT

The researcher explored widely in most of the South Indian States and Universities for a short term course in CBT in the year 2009, though a few workshops were conducted by NIMHANS Bangalore, those were focusing on specific psychiatric conditions. Some of the other institutions and distance education programmes offered courses on Guidance, Counseling and Psychotherapy without in depth training on CBT. The administrators of Mental Health Centre at Thiruvananthapuram in Kerala sanctioned permission for the training through the facilitation by the Nursing Superintendent. The researcher underwent one week training in CBT under the expert supervision of Dr. Ajith PR, Clinical Psychologist from 7-12-2009 to 12-12-2009.

The training included active discussions, daily assignments, presentations, research critique, clinical demonstration, return demonstration and CBT module preparation. The initial discussion was led by the trainer to assess the existing knowledge of the researcher on CBT followed by the discussion on various models of CBT, presentation on the concepts, principles and techniques by the researcher (to a group of MSc Clinical Psychology students) followed by demonstration of various techniques by the expert. The researcher was given with a couple of published and unpublished doctoral dissertation carried out on effect of CBT for review. Then researcher was allowed to attend to the CBT sessions carried out by the expert both in outpatient and inpatient set ups.

The researcher was assigned with clients having general and health related anxiety and depression (as it was most suited to the research requirement) for return
demonstration under the expert’s supervision. The home work was focused to module preparation by the end of 5\textsuperscript{th} day of the training. It was presented to the group and necessary modifications and suggestions were given by the expert along with many practical guidelines on the therapy conduction. The researcher found the training very useful and the trainer and the learning companions too felt happy about the active learning that had taken place in a week’s time. The Superintendent of the Mental Health Centre certified that the researcher can carry out CBT independently. (Appendix-6)

**Development of CBT Module for People undergoing Haemodialysis**

The first draft of the module was prepared based on the clinical experience, CBT training and referring related literature and it had 14 sessions. This included general guidelines, title of each session, specific objectives of session, steps or process involved in each session, therapist’s, person’s activity and references. It was modified after reviewing further literature and discussion with the guide and other experts from the field. One of the experienced Professors in Clinical Psychology from NIMHANS strongly opined to reduce the number of session to less than 10 in order to make it feasible and cost effective for further use.

The researcher in her constant interaction with similar clients and dialysis staff understood it is highly important to give them the relevant adherence education utilizing the didactic model of CBT because though many were aware what is right for them, they are not practicing it, thus landing up seeking emergency dialysis and hospitalization frequently due to the complications of non-adherence. Along with the dialysis staff, the chief nephrologist also had given valid inputs with regard to the
areas that have to be addressed. Thus the second draft of the module has evolved to be
concise (nine sessions, including one booster session) and wholesome (incorporating
health related areas of people undergoing haemodialysis).

Validation of CBT Module for People undergoing Haemodialysis

Module, manual and diary were sent along with the title of the study, objectives, instruments and criteria check list for validation to eleven National and International experts: seven Doctors/Professors of Clinical Psychology, one CBT nurse from Ireland, one professor of psychiatry, one professor of psychiatric nursing and one professor of Obstetrics and Gynecology Nursing from Chennai, who has tested the effect of positive therapy (CBT) among adolescents with dysmenorrhea for her doctoral thesis. Out of eleven experts, two could not respond as they had tight schedule. The following suggestions were obtained after the expert validation of the rest of the nine validators. (Appendix-7)

<table>
<thead>
<tr>
<th>Suggestions</th>
<th>Expert</th>
<th>Modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remove client expectancies as it same as mutual goal setting.</td>
<td>CBT Nurse, Ireland</td>
<td>Removed</td>
</tr>
<tr>
<td>Incorporate feedback as part of all the session.</td>
<td>CBT Nurse, Ireland</td>
<td>Incorporated in all sessions.</td>
</tr>
<tr>
<td>Specify the model used for the current CBT.</td>
<td>CBT Nurse, Ireland</td>
<td>Model of Padesky&amp;Mooney, 1990.</td>
</tr>
<tr>
<td>Discuss patient’s role in the Session I itself.</td>
<td>CBT Nurse, Ireland</td>
<td>Placed it in Session I.</td>
</tr>
<tr>
<td>Clarification on which thoughts are addressed in dysfunctional thought record (DTR).</td>
<td>CBT Nurse, Ireland</td>
<td>Based on each person case conceptualization.</td>
</tr>
<tr>
<td>Use more appropriate cognitive technique for modification of automatic thoughts.</td>
<td>CBT Nurse, Ireland</td>
<td>Verbal reattributon is added.</td>
</tr>
<tr>
<td>Specify the type of Relaxation</td>
<td>CBT Nurse, Ireland</td>
<td>Autogenic relaxation and Guided imagery</td>
</tr>
</tbody>
</table>
### Chapter III  
#### Research Methodology

<table>
<thead>
<tr>
<th>Task</th>
<th>Implemented By</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Place the session on activity scheduling before.</td>
<td>CBT Nurse, Ireland</td>
<td>Placed it as 5&lt;sup&gt;th&lt;/sup&gt; session instead of 6&lt;sup&gt;th&lt;/sup&gt;.</td>
</tr>
<tr>
<td>Incorporate activity diary as part of assessment of existing activity.</td>
<td>CBT Nurse, Ireland</td>
<td>Incorporated it in diary.</td>
</tr>
<tr>
<td>Specify the rating of activity on which aspect</td>
<td>CBT Nurse, Ireland</td>
<td>On pleasure and mastery.</td>
</tr>
<tr>
<td>Majority of the anxiety patients are not familiar with Homework</td>
<td>Professor of Clinical Psychology,</td>
<td>Suggestion by Professor of Clinical Psychology, KMC, Manipal to refer</td>
</tr>
<tr>
<td>(dairy writing). The CKD patients are all the more anxious and</td>
<td>Malaysia</td>
<td>Moorey &amp; Greer’s model of CBT in chronic illness (which doesn’t signify</td>
</tr>
<tr>
<td>worried over their illness, they may not write the diary.</td>
<td></td>
<td>diary use)</td>
</tr>
<tr>
<td>Incorporate coping as an area of assessment.</td>
<td>Doctor in Clinical Psychology,</td>
<td>Coping with the chronic illness as well as symptoms incorporated in the</td>
</tr>
<tr>
<td></td>
<td>KMCIC, Manipal</td>
<td>module, but avoided use of coping scale because CHEQ is already very</td>
</tr>
<tr>
<td></td>
<td></td>
<td>lengthy.</td>
</tr>
<tr>
<td>Patients’ own language to be used for CBT.</td>
<td>Doctor in Clinical Psychology,</td>
<td>Researcher attained fluency in Kannada, translated the Power point</td>
</tr>
<tr>
<td></td>
<td>KMC, Manipal</td>
<td>slides to Kannada</td>
</tr>
<tr>
<td>CBT module is okay.</td>
<td>5 Professors</td>
<td></td>
</tr>
<tr>
<td>The CKD patients undergoing haemodialysis cooperate with your study</td>
<td>CBT Nurse and Professor of Clinical</td>
<td>Researcher decided to spend some time with them to establish the</td>
</tr>
<tr>
<td>is really a challenge to face.</td>
<td>Psychology, Malaysia</td>
<td>rapport.</td>
</tr>
<tr>
<td>As it is a challenging job, reduce the sample size to 10.</td>
<td>3 Professors</td>
<td>Sample size calculation did not support this.</td>
</tr>
<tr>
<td>A multimodal approach will be more suitable for CKD patients than</td>
<td>Professor of Clinical</td>
<td>Didactic approach on disease specific areas and</td>
</tr>
<tr>
<td>CBT, as their anxiety</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
and depression are stemming from multiple factors.

| Psychology, NIMHANS | relaxation training within the CBT framework was already incorporated. |

All the necessary modifications were brought in to the module after the validation. One more session was added to the CBT later after the pilot study, on ‘Fistula care’ as per the request from the people undergoing haemodialysis, thus the final module has 10 Sessions namely: (1) Case conceptualisation, (2) Modification of dysfunctional thoughts, (3) Education on dialysis and fluid adherence, (4) Education on diet and drug adherence, (5) Activity and sleep scheduling, (6) Reinforcement of strengths and coping with physical symptoms, (7) Relaxation training, (8) Fistula care, (9) Relapse prevention and (10) Booster session. (Appendix- 14)

**Development of CBT Diary for People undergoing Haemodialysis**

The diary was prepared as a very simple, handy tool for the people undergoing haemodialysis to read, use and carry when they come for each of the appointments. The aim of the diary was to enhance the homework involved in each of the sessions and also to give the bibliotherapy material along with tips of adherence to review and remember. The title of the diary is ‘Cognitive Behavioural Diary for people Undergoing Haemodialysis’. The first draft of the diary contained nine sessions and motivational stories (carefully chosen from different web sources to inspire and induce behavioural change among the readers) in each of them and diary formats for filling in homework content.

The homework formats included Dysfunctional Thought Record (DTR) (to express the situation, automatic thought and corresponding feelings), fluid diary (to
monitor the fluid intake and output), dialysis diary (to know the skipping and shortening behaviours), diet diary (to know the food items they take each during each meals or tea time), drug diary (to write the name of the tablets they take), activity and sleep diary (to list the activities they engage in during the day and to know the hours of sleep and sleep quality), symptoms diary (to denote the physical problems such as body itching, fatigue, lack of sleep), self-monitoring diary (to monitor fluid, dialysis, diet and drug by the person) and validation of progress (assess the change in their thoughts, feelings and behavior at the end of the therapy).

Validation of CBT Diary for People undergoing Haemodialysis

The diary was send to the same set of experts who validated the CBT module for their suggestions modifications.

**Table 2: Validation report of CBT Diary for People undergoing Haemodialysis**

<table>
<thead>
<tr>
<th>Suggestions</th>
<th>Expert</th>
<th>Modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>The stories for Bibliotherapy are inspiring. Try to use locally motivated stories. In the state of illness how many of them will be willing to read all the stories?</td>
<td>Professor of Clinical Psychology, Malaysia</td>
<td>First story on recession, “Our life depends upon our thoughts” is removed as the concept may not be comprehensible to them. The dollar in the story “Value yourself” converted into rupees.</td>
</tr>
<tr>
<td>How the case conceptualization is going to be formulated?</td>
<td>CBT Nurse, Ireland</td>
<td>The interview findings with a few samples were applied to Padesky and Mooney’s model and given in the diary.</td>
</tr>
<tr>
<td>Incorporate activity diary as part of assessment of existing activity.</td>
<td>CBT Nurse, Ireland</td>
<td>Incorporated it in diary.</td>
</tr>
<tr>
<td>Include relaxation part of daily activity</td>
<td>CBT Nurse, Ireland</td>
<td>Included in the activity diary.</td>
</tr>
</tbody>
</table>
### Chapter III  
**Research Methodology**

<table>
<thead>
<tr>
<th>How the strengths are identified?</th>
<th>CBT Nurse, Ireland</th>
<th>Included gratitude diary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Include prologue and description before each area.</td>
<td>Professor of Psychiatric Nursing</td>
<td>Included cover page, prologue, instruction for the reader ahead of each of the diary contents and references</td>
</tr>
<tr>
<td>Categorize the food items*</td>
<td>Professor of Dietetics</td>
<td>Categorized food items into known food groups</td>
</tr>
</tbody>
</table>

*The diet part of the CBT diary was given further to three experts from the field of Dietetics separately.

The final CBT Diary includes a cover page with the title, a motivating prologue specifying the purpose of the therapy, description on each segment, case conceptualization, coping diary, gratitude diary, list of foods that can be taken, fluid, diet and drug adherence tips, a passage on illness experience and the list of references in addition to the pre validation content. (Appendix-17)

**Translation of CBT Diary for People undergoing Haemodialysis**

The CBT diary was given to language experts for translating to Kannada, the researcher took a series of translations from bilingual experts and was given to language experts for retranslation. In many of the retranslations, the originality and essence of the stories were missing and such sets were discarded. The translation process continued until the meaningful retranslation was obtained (done by a Psychiatrist) which was matching with the original version. The language validators felt that the latest version had good flow and continuity. It was given for editing and there were only a few spelling corrections and the editor too felt that the stories were well written.
Pretesting of CBT Diary for People undergoing Haemodialysis

The final Kannada version was given for to three people for reading. All of them felt that the stories are very interesting and there is a flow that motivates them to read it further. They opined that the language used is simple and comprehensible to common man and all the instructions are understandable.

Development CBT Manual for Therapist

The CBT manual was prepared as a handy reference material for the therapist while the therapy is being carried out. It is derived out of the CBT module with the elaboration of therapist’s activity and the didactic areas spelt out in the manual (Appendix-15).

Validation of CBT Manual for Therapist

The CBT manual was also given to the same experts for their validation. There was no suggestion for modification apart from those given for to the CBT module. All those modifications were replicated into the CBT manual as well.

Development and validation of the Relaxation Record for People undergoing Haemodialysis

Autogenic relaxation along with guided imagery was chosen as the mode of relaxation as per suggestion of Guide. Before any relaxation the body and mind need to be set free for the act and this can be achieved by the deep breathing. The deep breathing instruction was set by the professor of the department of Yoga whereas the
narration for the guided imagery was written by the researcher on by giving a beach situation. The script was sent to the same experts and obtained a validity index of only 0.77 for the guided imagery script as two experts felt that the beach may not be a relaxing situation for a common man in India, hence the script was rewritten based on garden and nature.

As a first step, the script was translated with help of language experts and retranslated back to English and obtained the same meaning as the original. Secondly ‘Prabhatha raga’ was selected to set as the background music for the recording by consulting two musicians. The relaxation was recorded first with a female voice and given to five experts in I pod for validation and got a validity index of 0.4, as two of them felt that the instructions are bit hasty and the pacing between the instructions are less. Thus the first recording was considered void and selected another female voice (with the psychiatric nursing background). The duration of the second record was 17 minutes. Further, it was given to the guide for approval, and then to the same experts and it obtained a validity index of 1 which was considered perfect. (Appendix-18)

The relaxation recording was pretested among five people and all of them felt that the narration is natural, soothing, comprehensible and truly relaxing, and at the end they felt that like slipping to a relaxing slumber. Therefore no modifications were brought to the recording.

**Preparation of visual aid for CBT sessions and its translation**

The sessions were transferred from module to the power point format, so that the intervention is made uniform to all individuals and pictures and correlations can
be visually presented to them. All the sessions are prepared and submitted to the guide for approval and then translated with the help of experts. (Appendix-16)

**Supervision of the CBT sessions by expert**

The CBT module along with the CBT diary and CBT manual were submitted to the Professor of Clinical Psychology, for seeking approval and expert supervision. The experiential information given by the expert was helpful to the researcher in the actual conduction of the CBT. The structure and pattern of the actual sessions were presented to the expert and sought the permission to carry on independently.

**Pilot study**

The pilot study was conducted among six people undergoing haemodialysis in Kasturba Hospital from January 2012 to August 2012. Informed consent was taken and three each were randomly allocated to experimental and control group. The baseline assessment was taken from the sample before the intervention. Individual CBT was given to each of the intervention sample once in a week, each session with duration of 50 to 60 minutes whereas 20 to 30 minutes of non-directive counseling is given to the control group. The only convenient time for CBT, agreed upon by the sample were prior to dialysis or during dialysis because all of them feel tired and drained towards the end of dialysis and will be in a hurry to get back home. The CBT sessions were taken in the conference room of dialysis unit and or at bedside, based on the appointment.

The immediate effect of the intervention was assessed one week after completion of CBT sessions and second and third follow ups were taken at third and
six months after completion of the study. The study was found feasible. A few changes were brought in the study based on the pilot study. The randomization procedure was changed from stratified block randomization to block randomization. Two strata were initially planned based on the duration of dialysis were, below and after two years of starting dialysis. The stratification based on the duration was found not feasible many of the people in the first strata may be shifted to second during the follow up period of six months. The duration of dialysis, less than one year was kept as an exclusion criterion, considering the initial adjustment with the haemodialysis. The clinical parameters creatinine, potassium and phosphorus were removed from the Haemodialysis Adherence Scale (as the people were not willing to do the frequent blood investigations), added one more session of fistula care as per the request of the one among the three sample from the experimental group.

**Procedure for data collection**

Administrative permission was taken from the medical superintendent (Appendix-1) and head of the Nephrology unit of Kasturba Hospital (Appendix-2) prior to the study. Ethics clearance obtained from the Ethics Committee of Kasturba Hospital. (Appendix-3)

The subjects were informed about the study and they were assured of the confidentiality of the information given (Appendix- 4). Informed consent (Appendix- 5) was taken from the sample after explaining the study details and right to withdraw from the study. The Kannada translation of the word ‘CBT’ in the consent form was simplified to ‘a psychological intervention’ as directed by the Ethics Committee.
The study was conducted from October 2012 to July 2013. The samples were selected based on the inclusion criteria and screened for memory deficit and disorientation. The eligible samples were further screened for border line or abnormal levels of anxiety or depression based on HADS. Those samples scored above 7 in any of the subscales of HADS were given the consent forms. The people agreed to take part in the study were given the centrally placed, sequentially numbered, sealed, opaque envelopes. Based on the number read out by them, they were randomly allocated into experimental and control groups.

All of them were interviewed on their adherence behaviours based on Haemodialysis Adherence Scale. As CHEQ is lengthy, it was sent with them in sealed envelope to answer personally at home and bring back in the next appointment (followed same strategy of data collection used by the original authors of CHEQ). The sessions were kept once in a week based on their dialysis schedule, and carried out in the conference room adjacent to the dialysis unit.

Conduction of CBT for the experimental group

Session I: Case conceptualization

The first session started with the introduction on importance of thoughts: ‘a man is the product of his thoughts’. Each person in the CBT group is informed about the score of HADS, therapeutic adherence levels and quality of life at the starting point. Therapist further explained the duration, structure and nature of therapy and need for their cooperation and types of homework involved to the person. They are given with the CBT diary with a description on how to use it.
The first cognitive technique applied was Socratic questioning (based on HADS response) which brought out many of their automatic thoughts, core beliefs and disease related worries such as ‘nobody can bear this much of trouble in life’, ‘this is the worst kind of illness’, ‘why I got this illness’, ‘the worst part of this illness is one can’t drink to quench their innate thirst’ and ‘I am a real burden to my family’, ‘I feel deep pain in my heart all the time’, ‘what if the fistula breaks’, ‘I can’t think of anything in the future’, ‘nothing can improve my situation’, ‘life is still after the diagnosis’, ‘everything is over after starting of this illness’, ‘there is no meaning in living like this’, ‘even an enemy should not get this disease’, ‘better to die, no use in living’.

Their body related perceptions were ‘I feel tired and weak all the time’, ‘I have itching all over my body’, ‘my hemoglobin is very low’, ‘I feel like tied down to this machine’, ‘lifelong dependence to this machine is horrible’, ‘I do not get any sleep’ and ‘breathlessness is the worst part’, ‘I feel bloated and heavy and will wait to have the dialysis at the earliest but we will get the slot only on the prior appointment basis’, ‘cannot eat anything on the previous day of dialysis due to heaviness and lack of taste’.

Their behaviours were expressed as ‘can’t control thirst and drinks two bottles of water soon after reaching home after the dialysis’, ‘can’t work due to the fear of fistula rupture’, ‘can’t go anywhere’ and ‘I don’t want to face anyone so not going for marriages or any functions’.

Their thoughts and feelings were clarified with them using reflection and restating and further presented to them in the form of cognitive model showing the
connection among biology, mood, behavior, thought and environment (based on Padesky & Mooney, 1990, used with permission). The connection was explained with the help of power point and further in their diary and encouraged them to identify or add their perceived physical problems, thoughts, feelings and behaviors along with the given model.

Further they were encouraged to set the goals mutually. The goals set were such as to bring down the HADS scores, to feel better, to reduce the interdialytic weight gain (IDWG), to reduce blood pressure, to reduce the frequency of episodes of breathlessness, to improve their adherence behaviours and to increase the level of activity and/or to improve sleep.

They were explained the way to prepare dysfunctional thought record (DTR) with an example of from their own situation, thoughts and feelings. Homework is given on DTR. Therapist summarized the points discussed on therapy nature, person’s roles, goals, conceptualization, DTR and homework and sought their feedback on clarity and understandability. They all agreed that they have understood the areas discussed.

**Session II: Modification of dysfunctional thoughts**

The second session started with the introduction ‘we can’t always choose our circumstances, but we can choose our attitude towards them’ and then with the review of IDWG, HADS scoring, previous session and week. The agenda were set as discussion of DTR, thought rating and modification of negative thoughts. The situations which gave rise to automatic thoughts and their subsequent feelings were
discussed at first. Most of them felt sad when they think of their illness and future, when they cannot drink the juice which they used to like a lot, when they think of their dependency on others and the machine, when they cannot do any work at home, when they face others and when they think their deteriorating financial sources. These thoughts and feelings were making them dull, putting in a restricted situation wherein they are not involving any activities around them. Each one of them was asked to rate their feelings such as heaviness on heart, deep rooted sadness, hopelessness, worthlessness or feelings of ending life or extreme anger that ‘why God has given the illness.’ They were asked to rate their feeling out of 0 to 100 percent in the DTR and majority of them rated it from 80 to 100 percent and a few as 70 percent.

As the next step verbal reattribution technique was used to modify the negative thoughts. The therapist raised appropriate questions to redirect their internal and enduring automatic thoughts to more external and transient ones which can alleviate their deep rooted worries to a great extent. For example the middle aged man (Mr. A) who was with the extreme anger that “why I got this deadly disease in spite of being so much faithful to God? I did not want to cause any trouble to anyone; did not want any riches but wanted to lead a peaceful life now I have every trouble in life without any peace of mind!” (Angry and sad expression)

Therapist: “How many people must be there in India?”

Mr. A: “Millions and millions!”

Therapist: “How many in Karnataka?”

Mr. A: “Lakhs and lakhs of people.”
Therapist: “How many people may be there in Udupi district?”

Mr. A: “May be one lakh!”

Therapist: “How many people among that must have kidney disease?”

Mr. A: “Yah… around one thousand!”

Therapist: “You are absolutely right! What about different kinds of cancer?”

Mr. A: “May be another one thousand.”

Therapist: “How about HIV AIDS, tuberculosis and skin diseases?”

Mr. A: “Definitely another thousand!”

Therapist: “How many people may have mental disorder or memory loss?”

Mr. A: “May be more than five hundred.”

Therapist: “How many people meet with accidents or sudden illness?”

Mr. A: “Another five hundred.”

Therapist: “What about people with diabetes, hypertension and asthma among adult population?”

Mr. A: “Diabetes and blood pressure, who doesn’t have those nowadays? If you ask me exactly…then may be around three to four thousand!” (Relaxed facial expression)

Therapist: “Now do you still feel that this is happening only in your life?”

Mr. A: “No, now I think that only a few will not have any physical or mental illness.”

Therapist: “What if they have financial or relational issues in life?” (Mr. A has a caring wife who accompanies him in each of the visit.)

Mr. A: “It is possible, I know!”
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Therapist: “The simple principle to be peaceful in life is to take things as it comes to you.”

Mr. A: “May be I will try for that.”

Similarly each person’s automatic thoughts were dealt one by one. In another instance a middle aged lady’s (Mrs. B) concern was “suffering like this at my age is like hell, I would become happy if I can die at this very same moment.” Therapist took age as the key focus for verbal reattribution in her case by bringing into her awareness about the suffering of children to adults much younger than her age.

Mrs. B also had another belief as “no man can control thirst” like many other people undergoing CBT. This was dealt with small experiment like not to touch their water bottle for the five hours during dialysis of the same day and thus making them to realize that it is possible and later mutually setting realistic goals on reducing water intake whereas such negative thoughts that they had earlier were preventing them from making an attempt ever before.

Mr. C (a 45 years old man from a low middle class family) has stopped going to work due to illness and later developed the thought that “fistula will break if I do anything.” This belief restricted him from doing the routine works outside and inside home and he turned to be totally dependent on wife, leading to lowered self-esteem. Such beliefs were validated to check the basis of dysfunctional thoughts by questioning the evidence.

Therapist: “How many people whom you know have kidney disease?”

Mr. C: “I must have seen about a hundred of them from this hospital and Udupi hospital.”
Therapist: “How many of them undergo haemodialysis?”

Mr. C: “Nearly all of them.”

Therapist: “How many among them have fistula?”

Mr. C: “All of them have.”

Therapist: “How many people’s fistulas have ruptured due to heavy work?”

Mr. C: “Only one.”

Therapist: “Do you think an accident at a rate of one out of hundred can come to you?”

Mr. C: “I don’t think so.”

Therapist: “What was the age of the person whose fistula damaged and do you know when it has happened?”

Mr. C: “He was around 65 years and I think it happened when he was climbing coconut tree.”

Therapist: “Does your daily routine involve such heavy work?”

Mr. C: “No, I don’t have to do anything of that sort, but now I think I can manage washing my cloths and other simple works.”

Majority of them were not able to put aside their worrying thoughts related to the finance, physical condition and future. Therapist used cost-benefit analysis of the worrying thoughts as an effective reattribution strategy. At the end of this exercise many of them realized that the worries will impede their sleep, reduce their activity, and increase their blood pressure and the dependence on drugs which in turn jeopardize the kidney function. Once the automatic thoughts are dealt, all of them
were encouraged to generate alternative thoughts using guided discovery or by making action plans based on their unique background. Each one of them was asked to rate the new feelings out of 100 and it has come down to the range between 10 to 20 percent for everyone in the intervention group. Therapist encouraged comparison of the earlier and the current rating which acted as a reinforcement to attend the therapy.

The homework of the second session included DTR, bibliotherapy on “Attitude makes a real difference”, maintaining dialysis and fluid diary. Therapist summarized the session and asked for their feedback.

Session III: Education on dialysis and fluid adherence

The third session began with review of IDWG, HADS, previous session, dysfunctional thought record and sharing of their week’s experiences. Everyone has read the story “Attitude makes a real difference” and were able to reflect on the meaning of it and correlate in own life with statements such as “it is better to give a try than worrying about the present situation.” The agenda of the session was set as education on dialysis and fluid adherence. The bystander also was encouraged to attend this session along with the person.

As part of dialysis adherence education, therapist explained the functions of kidney and why they require the haemodialysis and how they can comply better with it. Most of them considered dialysis as a punishment which were represented as statements like “It is horrible to be tied to a machine for five long hours”, “time just stay still”, “nothing can be done, can’t move or sleep” and “why can’t they reduce the
time to three or maximum four hours?” Many of them adopted shortening and skipping behaviours as result of their concept development.

Further they were encouraged how the compromised kidney function can be supported with their fluid adherence behaviours. It was described that how the intake of large quantity of fluids connected with their symptoms of swelling, feeling of heaviness, ascites, breathlessness, lack of sleep and appetite. The fluid adherence tips to reduce thirst and reduce quantity of fluid intake were presented to them with adequate explanation quoting examples and clarification of doubts. At the end of this session they were given the homework to continue with the DTR, bibliotherapy on “Value yourself”, dialysis, fluid, diet and drug diary. Therapist summarized the entire session and sought feedback from the participants.

Session IV: Education on diet and drug adherence

The fourth session started with the review of interdialytic weight gain, dialysis and fluid adherence, HADS, previous session, DTR and week and continued with reflection of the story “Value yourself” and they related the meaning to their life as “yes, our life is worthwhile”. The agenda of the IV session were to reinforce dialysis and fluid adherence and to educate diet and drug adherence.

Most of them started their fluid adherence practice and were keen to show their changed small bottles (from 1L size to 250 ml) and glasses (from 200ml size to 50ml). The reduction in the IDWG and related complications (reduced swelling, ascites, feeling of heaviness, breathlessness, and need for emergency dialysis) were acting as a reinforcer and they started feeling better as they could do something to
improve their situation. The therapist acknowledged their improvement by giving a hand shake by stating “congratulations for your positive attempt” or “congratulations for achieving your target”. The reduction in their IDWG was acknowledged by nephrologists also, this boosted their motivation.

Next therapist explained the dietary requirements and the importance of intake of high biological value protein, low sodium, potassium and phosphorus by describing each ones action on a kidney in compromised state. The connection between dietary non-adherence and symptoms like fatigue, weight loss, lethargy (due to decreased intake of high biological value protein and decreased haemoglobin), lack of appetite (due to increased levels of urea and creatinine in the blood) itching, bone and joint pain, brittle bones (due to increased levels of phosphorus), palpitation, chest pain, heart attack (due to increased levels of potassium), increased thirst, giddiness and increased blood pressure (due to increased levels of sodium).

Further they were given the diet adherence tips along with food items that need to be taken and avoided. Majority of the sample and their bystanders were very attentive and inquisitive on the diet adherence information. A few people reacted like “is there something that we can eat finally?” Such situations of resistance were effectively dealt with bringing the imagery of a symptom free state into their mind and at times by the timely motivation and involvement of their bystanders. Similarly, drug adherence tips also were explained to them.

The homework set for the sessions were described to them: to read the story with the title “Determination”, maintain diary on their pattern of diet, drug, activity and sleep. The session was summarized and important points were reaffirmed and
their doubts on renal diet were clarified. Most of the participants expressed that that the information was very useful to them during the feedback. All of them were taking the phosphorus binder before the food and they agreed to take it along the food for its effective action.

**Session V: Activity and sleep scheduling**

Fifth session started with the review of IDWG, adherence, HADS, previous session, week and month, followed by the reflection of the story “Determination”. Everyone related the meaning of the story to their own life as ‘determination is the key to succeed in life.’ The agenda of the session were to reinforce adherence and to improve activity and sleep. Each of them was asked to give the experience of progress with their adherence behavior. Apart from the verbal reinforcement by the therapist, the reduced IDWG and symptom reduction were used as the reinforcers to motivate them to continue with their adaptive behaviours. They were encouraged to discuss perceived barriers to adherence behaviours if any.

The people were asked to rate each of their current activity out of 1 to 10, in terms of pleasure and mastery. They were encouraged to involve in possible activities by giving examples of graded task. Therapist correlated the DTR finding (maximum negative thoughts happened when they were idle) to motivate them to engage in pleasurable activities. The positive effects of exercise and activity were discussed with them. Therapist further demonstrated simple stretching of limbs and joints rotation exercises to them. They were encouraged to start those slowly and gradually build up the speed and also cautioned to stop at once if they feel tired or giddy.
Their queries on how much they can do were dealt with discussion of real case examples of active people with long term haemodialysis. Mutual planning and activity rescheduling has followed based on individual choices and background. Many of them have made up their mind for visiting friends, going for shopping, driving car on their own, going for morning walk, restarting gardening, stitching, teaching music, joining back duty, reading book etc. which they had not attempted after the onset of illness. All of them were taught stretching and rotation exercises for all the limbs and joints.

Therapist further discussed various ways to improve sleep duration and quality, engaging in activities also was mentioned as a way to improve the sleep. Most of them expressed their difficulty in getting good sleep and adaptable ways of sleep improvement were planned mutually. Thereafter they were given with homework on bibliotherapy (“Importance of life”, “Illness experience” and “Be happy”), to maintain diary of activity, sleep and gratitude. At the end of the session, therapist summarized the activity plan and the tips to improve sleep.

Session VI: Reinforcement of strengths and coping with physical symptoms

As an introduction to this session, therapist brought in the example of ‘eagle in a storm’ to explain how they need to raise above the challenging situation of illness. Then continued with the review of IDWG, HADS, previous session, adherence, activity of the past week, followed by the reflection on “Importance of life”, “Illness experience” and “Be happy”. Arthur Ashe’s life story gave them the message that they should cherish the things that they have than worrying for the things they do not have. The passage on “Illness experience” was given as a suggestion from the
researcher to the participants to take illness as a different kind of experience and encouraging them to face it with their will power.

The agenda for the session were on reinforcing strengths and progress in activity and symptom focused intervention. To the therapist’s surprise many of them shared a very positive attempt in their activity schedule. Mrs. D, 64 year old widow who lived alone had lost interest even in her usual routine duties for four years (after onset of illness). She reported of improved enthusiasm to take care of her health and to do the daily chores after attending the sessions. She shared the event of cooking a special lunch at the week end and inviting her daughter and family with extreme satisfaction. Two middle aged men shared their experience of driving car to long distances (they had become totally dependent on others for coming for dialysis due to fear of driving), another two people shared their experience of driving two wheeler, many of them started watering plants or gardening. Many others shared the experience of trying new dish, starting morning walk, shopping, meeting friends etc. Verbal praise (“excellent” or “you could do it”) with a hand shake was given as positive reinforcement along with their perception of positive effects of the activity and satisfaction.

As next step of the session, gratitude diary was discussed and reinforced the important things in their life as strengths. This exercise gave each of them the opportunity to remember the ignored positive aspects of their life, thus reducing the preoccupation with the worrying thoughts of illness. Next therapist dealt with their physical symptoms one by one such as fatigue, itching, allergies, pimples, muscle and joint pain and skin dryness. The possible reasons for the problems and alternatives
were discussed and mutual goals were set to overcome the same. In some instances collaborative efforts were sought from the dialysis staff to rule out the cause. The care and prevention of diabetes and hypertension also were discussed with them.

Further in the session they were asked to rate the usual coping behaviours in a scale of 0 to 10 and the adaptive or positive coping behaviours were considered as those with a score of above five. Many of them expressed doing something new, going out for a walk, gardening, listening to music etc. as relaxing to them. Positive reinforcement of such adaptive coping behaviours was given. Therapist encouraged some of them to generate more adaptive coping strategies such as sharing the problems with a trusted friend, looking for a job, seeking financial support for fistula surgery from voluntary organization etc. based on various client situations.

To support their adaptive coping with the illness, they were given with the homework bibliotherapy on “Change the way you look at CRF, see the difference”. Long term adherence is only possible when they become self-sufficient in managing their own adherence behavior. With this intention they were encouraged to self-monitor their overall adherence. The points discussed under adaptive coping and symptom management were summarized and they were encouraged to give feedback of session. The session was concluded as “it is not the burdens of life that weigh us down, but how we handle them!”

Session VII: Relaxation training

The session started with the introduction “accept the positives in life and adjust with the negatives” and then with the review of HADS, adherence, activity,
management of physical symptoms and coping with the illness. The reflection on the biblio material “Change the way you look at CRF, see the difference” brought similar meaning from participants such as “I must control the illness than the illness controlling me”.

The main agenda of the session was relaxation practice. The person was given a calm environment, relaxed posture and made to listen to the record of deep breathing, autogenic relaxation followed by guided imagery through a headphone. All of them in the CBT group were given the audio record by copying to their mobile phones, pen drive or compact disc based on their convenience and choice.

The homeworks of the session were on bibliotherapy “Life lessons from baby giraffe” and practice of relaxation every day by incorporating it in the activity schedule. At the end of the session, therapist summarized the outlook on illness and relaxation technique. Each of the participants was asked to share how he or she felt after relaxation. Everyone expressed that it was a relaxing experience and those with sleep disturbance were encouraged to listen to the record prior to the bedtime.

**Session VIII: Fistula care**

The eighth session started with review of HADS, adherence, practice of relaxation and activity log, previous session, week and month. The bibliotherapy on “Life lessons from baby giraffe” was reflected as “the negative experiences in our life may have a positive meaning.”

Mrs. E, a 38 years old school teacher, living with husband (the couple do not had no offspring) who stopped going for job since one year as she felt her health is
deteriorating day by day. The latest symptoms she was suffering were chronic back pain and insomnia. She felt tired throughout the day because of the feelings of unrest and could not concentrate in daily life activities. She had tough time sleeping in the supine position during dialysis for five hours at a stretch due to back pain. Past few months she was on sedative hypnotics and she and her husband both were greatly concerned about on the escalating doses of sedatives and anti-hypertensives. Therapist observed Mrs. E with a relaxed supine position, closed eyes and peaceful face for the consecutive dialyses after the relaxation training. During the session Mrs. E clarified it as she is practicing relaxation twice daily at morning and night and also during the dialysis (using mobile earphones) and there is reduction in her back pain and improvement in the sleep. Further Mrs. E and therapist worked out a plan to taper down the sedatives and to convey this to the nephrologist. The comparative analysis of her blood pressure also showed reduction and this was shared with her to boost her motivation to continue the efforts. Similar experiences were shared by few other persons as well. They were supported for establishing a positive difference in their lifestyle.

The agenda of the session was fistula care and therapist discussed what is fistula, how to prevent infection and clotting of fistula and how to make sure of its proper functioning. Many of them had doubts on fistula care and how much weight they can carry etc. which were clarified. Therapist demonstrated the arm stretching exercise and graded weight lifting exercises (flexion and extension of elbow joints carrying two 500ml. water bottles in each hand and asked them to re-demonstrate) to improve the muscle strength and support the fistula and also to improve the fistula health. They were suggested to increase the weight gradually.
The fistula health was assessed and a few of them who required new fistula were encouraged to plan for the surgery. For example: Mr. F, 24 years old man from a low middle class family, covered his bulged fistula of the hand by wearing full sleeve shirt and while on dialysis with bed sheet to hide it from others. Though the nephrologist has suggested for the new fistula long back, he has adopted an avoidance coping towards the problem by neglecting the need for surgery (due to the poor finance) but retracting from all the works at the same time (due to fear of fistula rupture). A plan was made to write application to an NGO for the financial support towards the new fistula surgery and to take appointment with the vascular surgeon at Mangalore for the same.

At the end of the session, homeworks given to each of them on self-monitoring of adherence and Bibliotherapy on “The importance of setting goals”. The session was summarized and their feedbacks were discussed.

**Session IX: Relapse prevention**

The session began with review of HADS, adherence, practice of relaxation and activity log, previous session, week and month. Reflecting on “The importance of setting goals” gave responses from some of the participants such as “anything is possible if we make up our mind”.

The therapist next went on with the agenda of validating progress of thoughts, feelings and behaviours. Majority of them validated their progress as ‘my thinking pattern has totally changed’, ‘I learned to look at the positive side of things’, ‘got control on my fluid intake’ ‘I am no more worried’, ‘started healthy diet practices’
and ‘I sleep well now’. They were given positive reinforcement through verbal praise and motivated them to continue their efforts. The homeworks were given on relaxation practice, self-monitoring of adherence and bibliotherapy on “If I think, I can.”

Therapist summarized all the nine sessions, clarified their doubts and asked their opinion on how the therapy went on. They all felt that it was feasible for them to attend all the sessions as well as all the matters discussed were very useful and much needed for them. The booster session was scheduled for fourth month. They were given with HADS, Therapeutic Adherence Scale and Choice Health Experience Questionnaire for the post-test along with the CBT Opinionnaire (Appendix- ).

Session X: Booster session at fourth month

The booster session at fourth month began with the review of HADS, practice of relaxation, activity and adherence. Each one of them shared the changes in their lifestyle and related positive feelings and impact. The reflection of the bibliotherapy material “If I think, I can!” got the desired meaning from them such as “I myself is my change agent” or “we can achieve any difficult goal, if we decide”.

Therapist validated and reinforced the unique changes each one had achieved by their own will power and efforts. All of them reported of achieving the therapy goals and also their personal targets. Majority of their starting IDWG ranging from five to six liters have come down to the range of one to two liters. Many others got relief from breathlessness episodes and related emergency dialyses. As an example of meeting personal targets, Mrs. E resumed her job and started to give music classes for
children at home like many others. The nephrologists and dialysis unit staff felt that there are less complications and OPD visits after starting the intervention.

Therapist conveyed the therapeutic closure and termination of CBT as mentioned in the informed consent. The persons who underwent the CBT were encouraged to summarize the skills learned and validate the behavior changes. They were motivated to maintain activities including relaxation practice in the daily life. Therapist encouraged them to continue the practice of self-monitoring of adherence to the future for further progress.

The session was brought to the end by summarizing the whole CBT and then the post-test was taken. The people were informed about the follow up at sixth month.

**Non-directive counselling for the control group**

The people in the control group were given non-directive counselling where the therapist gave weekly counselling on their general issues or concerns for duration of 30 to 40 minutes for ten consecutive weeks applying therapeutic communication, active listening and clarification of doubts. This was given apart from the standard care they receive from the dialysis staff (dialysis technicians, renal nurses and nephrologists). The meetings were without any specific agenda but initiated by open ended question such as “How was your week?” Many of them shared their current experiences with illness and on some occasions they spoke about the onset, diagnosis and treatment related experiences of the illness. Some of them expressed their sadness of having got this illness; active listening and empathetic attitude were used as the
strategies in such instances. Many of them had doubts on diet and drugs which were clarified readily to them with adequate explanation. The post-test and follow-up also were taken from the control group at the same intervals as in that of experimental group.

**Plan for data analysis**

Based on the objectives of the study and the hypotheses to be tested descriptive and inferential statistics will be used for the statistical analysis of the data. Descriptive statistics such as frequency, percentage, mean and standard deviation will be used. Inferential statistics like Chi square or Fisher’s Exact test and t test will be used to compare the distribution of demographic, clinical and outcome variables between the experimental and control group. Inferential statistics used to test the hypotheses would be Repeated Measures ANOVA.

**Summary**

This chapter described the research approach and design, setting, population, sample and sampling technique. The study adopted an evaluative approach with a randomized controlled trial design. Subjects were allocated into experimental and control groups using block randomization. The chapter also gives the description on tool development and selection, development and validation of CBT module, manual and diary, pilot study, procedure for data collection and the conduct of CBT sessions.