DISCUSSION

This chapter deals with analyzing the present study findings in the context of established earlier findings of other similar studies. The present research was conducted to examine the effect of CBT on anxiety, depression, adherence and quality of life of people undergoing haemodialysis. An extensive review was carried out by the researcher to identify the relevant existing knowledge related to the present area of research and also to produce a justification for the present study. From the studies reviewed the researcher identified that most of the studies carried out in India were non experimental studies. Though the effect of CBT is being studied widely, most of the studies were conducted in psychiatric conditions and other medical conditions and there were only a few studies which were done among the people undergoing haemodialysis. The major contribution of the present study is the development of comprehensive CBT module itself. The choice of RCT design also adds to the credibility of the present study findings.

The discussion on the findings of the present study with reference to the findings of the other similar studies is organized under the following headings:

A. Research methodology
B. Structure and implementation of CBT
C. Demographic characteristics of the sample
D. Clinical characteristics of the sample
E. Outcome variables among people undergoing dialysis
F. Effect of CBT on anxiety and depression
G. Effect of CBT on adherence
H. Effect of CBT on quality of life
I. Opinion of people undergoing haemodialysis about CBT
A. Research methodology

The sample for the study was drawn from the Dialysis Unit of Kasturba Medical College, a tertiary care hospital of Udupi district in South Karnataka. The sample attending other hospitals were found different in their background variables such as income, education, food pattern and language and more over in the beginning period of the study many dialysis centers in and around Udupi had fewer dialysis machines and less number of dialysis staff. Hence the study was carried out in single center. Though Cukor, Sivadas and Nozaki, Oka and Chaboyer also had conducted single center studies on the effectiveness of CBT, many other researches in this area went for multicenter studies. The sample availability and recruitment process may be much easier in multicenter studies provided there are many researchers to carry out CBT simultaneously at different centers. Single center study in this context had the advantage of maintaining better control over the homogeneity of setting, sample, and the intervention, being carried out by single therapist for delivering CBT.

Researcher adopted an evaluative approach with RCT design for the present study. The previous researchers who had used RCT were Sharp, Wild, Gumley and Deighan at Glasgow in Scotland and Duarte, Miyazaki, Blay and Sesso in Brazil. Cukor, et al carried out a randomized crossover trial(with only control group brought into experimental group after three months of waiting period) on effect of individual CBT on depression among haemodialysis patients in New York in 2013 while most other earlier researchers have adopted quasi experimental designs or pre-test post-test designs for testing the effect of CBT among people undergoing haemodialysis (Nozaki, Oka and Chaboyer in Japan, Marvi, Bayazi, Rahmani and Deloei, in
Mashhad,⁸⁰ and Weiner, Kutner, Bowles and Johnstone in Louisiana).⁷⁹ Sivadas at Kottayam in Kerala had used only one group pre-test post-test design for studying the effect of CBT on depression among 30 people undergoing haemodialysis.⁸³

RCT promises better internal and external research validity when compared to the other designs. Cross over design also could be used to elicit a better control over the extraneous variables and compliance from the study participants but in such study only control group can be switched over to experimental because CBT might bring a long lasting effect in the experimental group as the targeted effect is brought by modifying the negative cognitions, thereby changing the mind. Hence the status of experimental group cannot be reversed to control group (after the wash out period) like in a drug trial or any other interventions that is intended to bring physical changes. So the researcher had chosen RCT which has standard controls like randomization, control group and blinding.

Single blinding was applied to the present study as the participants were kept away from knowing the difference between the two interventions given to both the groups. Only Duarte, Miyazaki, Blay and Sesso instituted single blinding by blinding the assessor, a trained psychologist who was unaware of the allocation administered and rated the self-reported rating scales from the participants.⁷⁸ Rest of the RCTs carried out open trials with precaution in the rating procedures²³,⁸² Blinding the participants were possible at the present context because most of them were from rural or semi-urban areas of Karnataka and not used to the various forms of psychotherapy and not technically as active in the internet usage as the patients from metropolitan cities or western countries. Two patients who were already exposed to
some form of psychological or psychiatric treatment were excluded from the study at
the screening level itself.

The present study screened 150 participants, out of which 80 people
undergoing haemodialysis met the sampling criteria. The participants included were
between 20 and 65 years of age, on maintenance dialysis for a minimum period of one
year, able to read and write Kannada or English, scored minimum seven (below seven
is considered normal) in any of the areas of anxiety or depression on the HADS and
consented to participate in the study. Seventy people were excluded from the study
who were aged more than 65 years of age (n=13), aged less than 20 years (n=2),
iliterate (n=9), less than one year of maintenance dialysis (n=3), waiting for
transplant (n=1), required full support for ambulation (n=4), scored less than seven on
HADS (n=19), currently on treatment of psychiatric disorder (n=1), had delirium
(n=2), needle phobia (n=1), visual impairment (n=4), current hospitalization (n=1)
and unwilling to participate in the study (n=9). No one was receiving psychotherapy
from other sources and none of them had any idea about CBT before entry to the
study. Out of the 80 remaining eligible sample, 40 each were randomly allocated to
experimental and control group using computer generated random order and
concealment block randomization procedure. In the experimental group there were
seven drop outs due to unwillingness to complete CHEQ (n=2), non-attendance to all
the sessions (n=2) and unwillingness to complete home works (n=3). In the control
group there were six drop outs due to unwillingness to complete CHEQ (n=5) and
death because of cardiac arrest within three months of study (n=1). Thus the samples
analyzed were 67 (33 in experimental group and 34 in control group).
The current research limited the age group initially, in par with the occurrence of CKD (20 to 60 years) and extended the age limit to 65 after the pilot study because many samples were in the upper age limit. Researcher excluded the people beyond 65 years, considering the physical and cognitive decline that might affect the quality of life. This is similar to the age group studied by Tsay.\textsuperscript{77} In contrast, Duarte, Miyazaki, Blay and Sesso included a large age group of sample (18 to 80 years) compared to the present study. They also reported similar difficulties in sample compliance as mean participation in CBT sessions was 78.5\% and two participants did not comply with sessions and withdrew consent. Compliance to homework also was 87.8\%. Control group’s mean participation to the weekly session was only 85\%.\textsuperscript{78}

Cukor, et al included 90 consenting haemodialysis patients out of 120 approached. After the screening for inclusion, 65 participants were selected in the trial, with 59 completing all assessments in the treatment first group (n=33) and the wait-list control group (n=26). Only one participant dropped out of the trial whereas two others exceeded the study time frame due to frequent hospitalizations and a third received a kidney transplant. Two patients switched dialysis centres during the study period.\textsuperscript{82}

Present study recruited sample based on a score of more than seven on either anxiety or depression areas of HADS. Computer generated concealment stratified block randomization procedure was instituted for allocating the sample into two groups. The stratification based on any of the outcome variables such as anxiety, depression, adherence or quality of life was not feasible as they varied largely across the sample. The stratification based on duration of haemodialysis (Strata A: one to
two years and Strata B: more than two years) was tried during pilot study, but found not feasible due to the prolonged data collection period. Stratification was applied in only one previous study by Duarte, Miyazaki, Blay and Sesso who did concealment stratified block randomization based on severity of depression.\textsuperscript{78} This could be possible when there is only one primary outcome variable. Rest of the studies in this area had gone for simple randomization procedure. Sharp, Wild, Gumley recruited sample based on their history of problematic fluid adherence, an average daily interdialytic weight gain (> 2.5 Kg). Fifty-six participants receiving haemodialysis randomly assigned to an immediate treatment group (n = 29) or deferred treatment group (n = 27).\textsuperscript{23} Marvi, Bayazi, Rahmani and Deloei randomly allocated 40 sample into experimental and control group of 20 each\textsuperscript{80} whereas Nozaki, Oka and Chaboyer assigned 11 participants to CBT and 11 to control group.\textsuperscript{87}

The present study instituted overall three measures; at baseline, post intervention at three months and follow up at six months. This is concurrent with the measurement placements of Cukor et al.\textsuperscript{82} Duarte, Miyazaki, Blay and Sesso had taken the follow up at nine months\textsuperscript{78} while Sagawa, Oka and Chaboyer at shorter intervals: at baseline, six weeks and ten weeks.\textsuperscript{85}

Researcher with the suggestion of Guide had chosen Hospital Anxiety and Depression Scale (HADS) for eliciting anxiety and depression in the current study, considering its specified application in somatic illness (as it excludes the overlap of physical attributes of depression that might be already existing in chronic physical conditions). HADS was used in similar studies to assess anxiety and depression of people undergoing haemodialysis\textsuperscript{23,81,89} whereas Beck Depression Inventory
(BDI)$^{80,82,83}$ and Depression Anxiety Stress Scale (DASS-21)$^{65}$ were used by other researchers.

Present study instituted objective measures (average IDWG, systolic blood pressure, diastolic blood pressure and haemoglobin) as well as subjective measures through self-reported rating scale Haemodialysis Adherence Scale which has subscales on dialysis, diet, fluid and drug adherence. IDWG was considered as an objective measure that reflects the accurate fluid adherence practices of people undergoing haemodialysis and the same was monitored by majority of the researchers who studied fluid adherence.$^{23,75,76,86}$ Sagawa, Oka and Chaboye assessed the average achievement of the fluid intake and change in fluid intake behaviours,$^{85}$ and in another study Nozaki, Oka and Chaboyer monitored the daily weight gain and salt intake.$^{87}$ Blood pressure was monitored by researchers who studied fluid adherence of people undergoing both haemodialysis$^{76}$ and peritoneal dialysis.$^{89}$

Quality of life was assessed by CHOICE Health Experience Questionnaire (CHEQ) in this study. Many of the earlier researches have used general scales like SF-36,$^{23,35,70,89}$ and Quality of Life Inventory$^{70}$ or shorter specific scales such as Kidney Disease and Quality of Life (KDQOL)$^{71,78,82}$ Researcher found that CHEQ is comprehensive and superior to SF-36 as this was developed by adding CRF related areas to SF-36, after large scale item pooling from dialysis patients as well as nephrologists by CHOICE study. The areas included in CHEQ in addition to SF-36 were freedom, cognitive function, diet, recreation, travel, work, finance, symptoms, sleep, sex, dialysis access and body image. Though it is comprehensive, many of the participants were found to be reluctant to complete the CHEQ as it was lengthy.
Hence researcher allowed one week time to fill it as it was done by the original authors of CHEQ\textsuperscript{103} but the researcher found that many of the participants were taking more time and needed reminders to complete the same.

B. Structure and implementation of CBT

In the present study, the experimental group was exposed to ten sessions of individual CBT for duration of 50 to 60 minutes each. The sessions were 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 followed by booster session at fourth month. The control group received 10 sessions of individual counselling at weekly intervals (with duration of 30 to 40 minutes), by applying therapeutic communication, active listening and clarification of doubts (particularly on diet, dialysis and drugs) by the Investigator, apart from the maintenance dialysis and standard care provided by the dialysis staff and nephrologists. The comparison of CBT across various studies as given in table 21 shows that the CBT adopted for the current study was comprehensive and appropriate to achieve the objectives.

Sharp, Wild, Gumley and Deighan administered the intervention in group (three to eight people) for hour long sessions once weekly for four weeks.\textsuperscript{23} Duarte, Miyazaki, Blay and Sesso conducted 12 sessions of cognitive behavioural group therapy at weekly intervals, led over three months while a control group of 44 patients received the usual treatment offered in the dialysis unit.\textsuperscript{78} Cukor reported treating people with major depression individually with a 15 week CBT.\textsuperscript{81} Marvi, Bayazi,
Rahmani and Deloei, gave 12 sessions of group cognitive behavioural training for the experimental group. The sessions were conducted twice a week and each session continued for about one hour.\textsuperscript{80} Sivadas applied CBT that had six sessions for six weeks.\textsuperscript{83} Anson, Byrd and Koch implemented CBT that involved 11 sessions of individual psychotherapy.\textsuperscript{88} Chen et al delivered one hour weekly treatment sessions for four weeks.\textsuperscript{105}

Cognitive techniques used in the present research were 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. Matteson and Russell had found that most of the effective interventions for improving adherence had consistently used cognitive techniques.\textsuperscript{84} Maintenance of thought record was one among the effective cognitive methods, used by researchers earlier.\textsuperscript{23} In the systematic review on psycho-educational intervention studies Welch and Hawkins identified self-monitoring to be a promising strategy to be considered to reduce IDWG.\textsuperscript{75} Self-monitoring was also been found consistently used by researchers in order to bring desired adherence related outcomes.\textsuperscript{23,84,86,87}

Present study considered self-monitoring as cognitive technique because it was used in the context for empowering them to be self-responsible with the dialysis, fluid, diet and drug adherence in the form of daily record of the same in CBT diary. On the contrary, Hegel, Ayllon, Thiel and Oulton categorized self-monitoring as a behavioural technique and hence stated that behavioural intervention was superior to the cognitive intervention in producing maintenance of reduced weight gain.\textsuperscript{86}
### Table 21: Comparison of structure and components of CBT for people undergoing haemodialysis across various studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Target variables</th>
<th>Format</th>
<th>Control group</th>
<th>Number of sessions</th>
<th>Components/techniques used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present study</td>
<td>Anxiety, Depression, Dialysis adherence, Fluid adherence, Diet adherence, Drug adherence, Quality of life</td>
<td>Individual sessions (n=34)</td>
<td>Non-directive counselling (n=33)</td>
<td>10 sessions</td>
<td>Socratic questioning, dysfunctional thought recording, verbal reattribution, questioning the evidence, cost benefit analysis, guided discovery, making action plan, self-monitoring, raising self-worth, relapse prevention</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(9 weekly sessions and one booster session at fourth month)</td>
<td></td>
</tr>
<tr>
<td>Sharp, Wild, Gumley and Deighan</td>
<td>Self-management of fluid consumption</td>
<td>Group sessions (n=29)</td>
<td>Usual treatment (n=27)</td>
<td>11 sessions</td>
<td>Maintenance of thought record, self-monitoring skills</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluid restriction, importance of effective social support</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Controlling environment, goal setting, self-regulation, muscular relaxation</td>
</tr>
<tr>
<td>Authors</td>
<td>Diagnosis</td>
<td>Protocol 1</td>
<td>Protocol 2</td>
<td>Discussion</td>
<td>Coping strategies to deal with CKD</td>
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<tr>
<td>Duarte, Miyazaki, Blay and Sesso&lt;sup&gt;78&lt;/sup&gt;</td>
<td>Depression, Quality of life</td>
<td>Group sessions (n=41)</td>
<td>Usual treatment (n=44)</td>
<td>12 weekly sessions&lt;br&gt;Discussion on connection among thoughts, mood and behaviour</td>
<td>Coping strategies to deal with CKD</td>
</tr>
<tr>
<td>Marvi, Bayazi, Rahmani and Deloei&lt;sup&gt;80&lt;/sup&gt;</td>
<td>Depression</td>
<td>Group sessions (n=20)</td>
<td>Usual treatment (n=20)</td>
<td>12 sessions twice a week&lt;br&gt;Discussion on negative thoughts, homeworks</td>
<td>Discussion on applicable methods of treatment</td>
</tr>
<tr>
<td>Cukor&lt;sup&gt;81&lt;/sup&gt;</td>
<td>Major depression</td>
<td>Individual sessions (n=16)</td>
<td>-</td>
<td>15 weekly sessions&lt;br&gt;Challenging distorted thoughts</td>
<td>-</td>
</tr>
<tr>
<td>Cukor et al&lt;sup&gt;82&lt;/sup&gt;</td>
<td>Depression, Quality of life, fluid compliance</td>
<td>Individual sessions (n=33)</td>
<td>Usual treatment (n=26)</td>
<td>12 weekly sessions&lt;br&gt;Dysfunctional thoughts, relapse prevention</td>
<td>Depression, compliance, Support network</td>
</tr>
<tr>
<td>Sivadas&lt;sup&gt;83&lt;/sup&gt;</td>
<td>Depression</td>
<td>Group sessions (n=30)</td>
<td>-</td>
<td>6 weekly sessions&lt;br&gt;Positive imagination, cognitive restructuring</td>
<td>-</td>
</tr>
<tr>
<td>Study</td>
<td>Intervention Description</td>
<td>Group Sessions</td>
<td>Fluid Compliance</td>
<td>Self-monitoring</td>
<td>Self-contract, self-monitoring</td>
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<tr>
<td>Sagawa, Oka and Chaboyer</td>
<td>Group sessions (n=10) - Self contract, self-monitoring</td>
<td>Not specified</td>
<td>Fluid compliance</td>
<td>Not specified</td>
<td>Self-contract, self-monitoring</td>
</tr>
<tr>
<td>Hegel, Ayllon, Thiel and Oulton</td>
<td>Counseling intervention designed to modify health beliefs - shaping, self-monitoring</td>
<td>(n=8)</td>
<td>Fluid compliance</td>
<td>-</td>
<td>Counseling intervention</td>
</tr>
<tr>
<td>Nozaki, Oka and Chaboyer</td>
<td>Standard patient education programme SPE (n=11) - Self-monitoring</td>
<td>(n=11)</td>
<td>Fluid compliance</td>
<td>Not specified</td>
<td>Self-monitoring</td>
</tr>
<tr>
<td>Anson, Byrd and Koch</td>
<td>Single patient - 11 sessions - Thought stopping, increasing effort, engaging in competing events, breaking repetitive routines</td>
<td>-</td>
<td>Fluid compliance</td>
<td>11 sessions</td>
<td>Thought stopping, increasing effort, engaging in competing events, breaking repetitive routines</td>
</tr>
</tbody>
</table>

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Chapter V

Discussion
Challenging the distorted thoughts or discussing about such thoughts as part of cognitive techniques in CBT were attempted by some researchers. Sivadas applied positive imagination and cognitive restructuring in her therapy whereas Anson, Byrd and Koch instituted thought stopping.

The didactic or educational techniques used in the present study encompassed teaching the people undergoing haemodialysis on the importance of dialysis, fluid, diet and drug adherence. Researcher explained the functions of kidney and correlated it with dialysis process and stressed in which all ways additional help can be provided by the person to the compromised kidney. Researcher developed fluid and dietary adherence guidelines and incorporated it in the power point and the diary for the people undergoing haemodialysis. The action of drugs and the ways to remember the timing also were discussed. Other areas included were importance of exercise and activity, seeking social support, sleep hygiene, symptom management, coping with illness and fistula care. The inclusion of fluid compliance education was in par with the previous researches. Seeking social support was addressed by earlier researchers. Some of the previous studies had the elements of coping strategies to deal with the illness.

Behavioural techniques included in the present study were 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. These techniques are concordant with the study by Sharp, Wild, Gumley and Deighan who used self-monitoring skills, including controlling their environment, goal setting, and self-regulation. The use of verbal praise as reinforcement in the present study is in par with the reports of Sagawa, Oka and
Chaboyer. They used verbal praise and encouragement, such as “you did a good job”, “great!” and “congratulations!” on achievement of desired fluid goals. Nozaki, Oka and Chaboyer used shaping, assertion training and response prevention.

The relaxation training in the study were autogenic relaxation and guided imagery whereas muscular relaxation technique was used in previous studies. The choice of autogenic relaxation was made in the present study considering the possibility of its extended use even during dialysis. Muscular relaxation requires the person to tighten the various muscles groups of the body that might cause alteration in the blood flow, especially in the fistula site while on dialysis.

From the above descriptions of various CBT interventions it is evident that researches ranged widely in terms of the number of sessions (four to 15 sessions) and duration of the therapy (four weeks to three months). The number and duration may vary depending upon the outcome variables; many have targeted any one or two domains whereas three major domains such as psychological balancing (anxiety and depression), overall haemodialysis adherence and quality of life were the focus of the current study. The cognitive model of the present study is based on the belief that change in cognition brings changes in the mind thereby to the behaviour as all these three areas are inevitably linked to each other.

We can further see the difference in the formatting of the sessions (either group or individual) of previous studies. Most of the researchers who have done large scale studies have followed group CBT except Cukor et al. The researcher during the pilot study experienced that all were not arriving at the given time because they
travel from long distances and even after arriving at the dialysis unit, most of them used to go for billing and refreshments. The starting of dialysis also varied based on the availability of machine and staff. Hence the time for CBT was set based on the convenience of each individual. Thus the researcher had chosen individual CBT sessions and the sessions were conducted in the class room of the dialysis unit.

C. Demographic characteristics of the sample

The present study showed that majority of the sample, 66.67% and 64.71% (p=0.535) were in 43 to 65 years of age, males 69.7% and 70.59% (p=0.936) and Hindus 78.79% and 76.47% (p=0.969) in the experimental and control group respectively. The majority of the participants in the present study were males which is in concordance with other studies\textsuperscript{23,80,85} while some studies have shown almost equal proportion of gender,\textsuperscript{78,81,87} unlike the participants in the study by Cukor et al, who were majority females (71.2%).\textsuperscript{82} This represents the gender disparity in the occurrence of CKD across different countries. In contrast with the present study, where all the sample were originally from South Karnataka, the western studies had sample from various ethnicity and culture.\textsuperscript{78,82} The heterogeneity would affect the adherence behaviours, food habits and thus overall quality of life. Moreover it would be difficult to establish the dietary guidelines for a multicultural group.

Maximum participants of the present study in the experimental group had education up to pre-degree (36.37%) whereas many of them (35.29%) in the control group had a better education; up to diploma or graduation (p=0.301). Majority of the people undergoing haemodialysis were married, 78.79% and 79.41% (p=0.809) and living with four to six family members, 75.76% and 79.41% (p=0.391) in the
experimental and control group respectively. Most of the participants of earlier studies also were married and living with family. Maximum participants of the study by Duarte, Miyazaki, Blay and Sesso were with the education level of primary school [25 (61.0%) and 31 (70.4%)]. The sample in the study of Sharp, Wild, Gumley and Deighan did not have formal education in experimental (58.6%) and control group (55.6%) whereas the present study excluded illiterates or people do not have formal education, considering their level of understanding of CBT conceptualization, bibliotherapy and homeworks.

Most of the participants of present study were residing in village 81.82% and 73.53% (p=0.56), 39.4% travelling six to ten kilometers in experimental group and 38.24% travelling 11 to 50 kilometers from home to hospital in control group (p=0.354). Majority in the experimental (66.67%) and control (82.36%) use bus as their mode of transport to hospital (p=0.416). The connectivity and transportation difficulties still affect the common man’s accessibility to health care in rural India.

Majority of the people undergoing haemodialysis in the current study were unable to attend a paying job 78.79% and 67.65% in the experimental and control group respectively. Sharp, Wild, Gumley and Deighan reported that most of them were retired in intervention group (55.2%) whereas unemployed in control group (33.3%). Sagawa, Oka and Chaboyer most of them were employed (40.9%) and housewives (27.27%). The difference in the employment rates of people undergoing haemodialysis in India and outside are wide, this again show the culture bound dependency, mal adaptation with chronic illness and depression.
Nearly half of the participants in both the groups in the current study (51.52% and 50%, p=0.678) had a family income of rupees only 5001 to 10,000. Maximum in both the groups were non-professionals in the past (36.37% and 29.41%, p=0.66). Majority of the sample 78.79% and 79.41% (p=1) received one or the other financial assistance towards the treatment expenditure. The economic issues are found to be a major concern among the people undergoing haemodialysis in India\textsuperscript{9,20} whereas dialysis population in the developed countries have better medical expense coverage by the Government that relieves a whole lot of financial burden from them.

D. Clinical characteristics of the sample

Nearly half the sample in experimental and control groups of the present study have stated that their CKD diagnosis was sudden [57.58% and 55.88% (p=0.332) in the experimental and control groups respectively]. Duration of disease ranged from one to three years in most of the person in experimental (57.58%) and control (76.47%) group (p=0.538). This is in striking contrast with people having longer years (more than four up to eleven years) of history of dialysis for most of the people in other countries.\textsuperscript{23,74,82,84,87} This highlights the possibility of higher mortality rates of Indian CKD affected population within short span of few years after the initiation of hemodialysis.

In India, the diagnosis of a chronic illness itself is considered as a threat for life. Patients withdraw from the job, social and otherwise pleasurable activities; soon they slip into depression leaving them in a state of being unable to cope up with the demands of illness. In atypical village set up of India, neighbors and immediate society become curious about this sudden resignation and start behaving inquisitively.\textsuperscript{9} The person who is already feeling low becomes all the more sensitive
to such enquiries and shuts down all the contacts which further deteriorates the health seeking behaviours and that affects the health negatively, accelerating mortality.

In the present study, almost half in experimental (54.55%) and control (55.89%) group were managing the haemodialysis without bystander (p=0.585) whereas the rest had the help of spouse or other significant people. Majority of them were not using any support for ambulation, [84.85% and 88.25% in experimental and control group respectively (p=0.734)], when the rest required partial support and the people who needed full support were excluded from the study as it affects their quality of life.

The self-reported reason for CKD by overall participants of the present study were hypertension (62.69%), diabetes mellitus (11.94%), complication of treatment for other illness (7.45%), hypertension and diabetes mellitus (5.97%), over the counter drugs (4.48%), heredity (4.48%) and nephritis (2.99%). Vast majority of the overall sample had comorbid diseases like hypertension (98.51%), diabetes mellitus (31.34%), hyperparathyroidism (8.96%), ischemic heart disease (7.46%), retinopathy (13.43%) and fracture (5.97%). This finding is in contrast with the report of Duarte, Miyazaki, Blay and Sesso in which Diabetes was the most common comorbidity 12(29.3%) and 17 (38.6%) followed by hypertension 14 (34.1%) and 12 (27.3%). In India, hypertension is putting the person at risk for CKD more than diabetes mellitus. This finding is in par with the study by Cukor et al, who reported hypertension as the most common comorbidity, 73.4 and 63.7% followed by diabetes, 24.4% and 35.8% in experimental and control group respectively.82

Mottari, Ebrahimi, Sharifi and Rouzbeh also have also reported higher prevalence of hypertension; 24 percent and 30.4 percent followed by diabetes 21.7
percent and 16 percent in experimental and control group respectively\textsuperscript{106} whereas Nozaki, Oka and Chaboyer reported primary diseases of chronic glomerulonephritis and diabetes among their sample.\textsuperscript{87} This gives us a clear picture of region wise difference in the distribution of non-communicable diseases. This could be due to the wide differences in the food practices and culture across these regions which in turn are associated with the risk for developing CKD.

**E. Outcome variables among people undergoing dialysis**

The present study sample had mean scores of anxiety $10.71 \pm 2.01$, $11 \pm 2.37$ (p=0.41) and depression $11.85 \pm 2.15$, $11.21 \pm 2.53$ (p=0.48) in experimental and control group respectively. There is a high prevalence of psychiatric disorders among the people undergoing haemodialysis due to the chronicity and burden of CKD. Cukor et al identified 48.5 percent of sample having major depression based on DSM-IV. In addition, 68.2 percent they had at least one primary mental health diagnosis, and 50 percent of the sample had at least one personality disorder.\textsuperscript{82} The reported HADS measured mean scores of anxiety $(7.41 \pm 3.28)$ and depression $(6.66 \pm 3.28)$ are much lower in people undergoing haemodialysis\textsuperscript{23} as well as in peritoneal dialysis [anxiety $(6.52 \pm 4.95)$ and depression $(5.41 \pm 3.84)$] in other countries.\textsuperscript{89} This again reaffirms that the psychological impact of illness is worse among Indian population.

Present study represented overall adherence of the people undergoing haemodialysis in terms of inter dialytic weight gain (IDWG) $4.47 \pm 0.92$, $4.39 \pm 0.78$ (p=0.25), systolic blood pressure $167.33 \pm 19.68$, $163.59 \pm 18.53$ (p=0.84), diastolic blood pressure $98.24 \pm 9.52$, $95.35 \pm 8.29$ (p=0.70), Haemoglobin $7.55 \pm 1.18$, $7.62 \pm 1.09$ (p=0.58), dialysis adherence $13.30 \pm 1.02$, $13.38 \pm 0.95$ (p=0.79), fluid adherence
34.27± 2.88, 33.85± 2.46 (p=0.58), diet adherence 138.45± 5.85, 136.18± 4.69 (p=0.71) and drug adherence 22.39± 4.09, 22.71± 3.47 (p=0.11) in experimental and control group respectively.

In contrast to these findings, the mean IDWG (in Kg.) reported in other countries were much better such as 3.42±0.88 in experimental and 3.72±0.98 in control group,23 2.2 ± 0.8108 and 2.8 ± 1.2109 in cross sectional studies conducted at Madrid, in Spain and Brooklyn in New York respectively. Blood pressure also seems to be lower in the previous studies conducted elsewhere. The mean systolic and diastolic blood pressures quoted by Kauric-Klein at Michigan were 155±10.5 and 88.4±9.9 mm of Hg respectively.110 The cross sectional study conducted among the haemodialysis patients reported the mean systolic blood pressure (in mm. of Hg.) of 136.4± 14.2 and diastolic blood pressure 72.9± 8.8.108 Similarly, the findings of a RCT among peritoneal dialysis patients stated mean systolic blood pressure (in mm. of Hg.) as 153.01± 23.89 and 153.43± 30.6, diastolic blood pressure 90.38± 10.09 and 91.86± 7.2 in experimental and control group respectively.89 Many of the previous studies have reported the combined mean systolic and diastolic blood pressure that hinders comparison.

In the present study, mean haemoglobin was clinically subnormal and lower than the earlier reported 10.98± 2.13 g/dL in people undergoing haemodialysis72 and 10.8± 2.1 and 10.2± 1.9 g/dL in experimental and control group respectively among the people undergoing peritoneal dialysis.105

The interdialytic weight gain is considered to be clear indicator of dialysis and fluid adherence, IDWG and blood pressure are linked with fluid and drug adherence.
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whereas blood pressure and haemoglobin are associated with diet and drug adherence. All these indices show a poor adherence among the current sample compared to the existing reports. Increased IDWG in the present study may be due to the variation in the pattern of dialysis, all were undergoing only two sessions of haemodialysis per week whereas in most of the other countries majority of the individuals were attending three sessions of dialysis per week. There is difference in the duration of dialysis as well, in Kasturba Hospital each session of haemodialysis lasts for five hours whereas most other settings it is only for four hours. Frequent dialysis is better for the patient point of view (removes the extra fluid from the body and relieves symptoms) when compared to the long dialysis. But it is extremely difficult for the Indian population to afford frequent dialyses due to financial difficulties. The long hours too would have caused lot of shortening (stopping the dialysis before the scheduled time) and skipping behaviours, leading low dialysis adherence. Another significant factor that pulled down the overall adherence among the present study sample might be the high anxiety and depression itself.

The variations and regional differences in the dietary pattern [high intake of sodium and potassium containing foods such as coconut, jaggery, high potassium containing vegetables that are commonly available, ragi (finger millet), oil etc.] might have a definitive link to the increased blood pressure and decreased dietary adherence. The low awareness on overall disease management, economic constraints, geographic and cultural influences also would have contributed significantly to the accentuation of the situation. Culturally and economically, there is a wide difference in the illness approach among Indian population. The other contributory factors could be the poor perceived social support and neurotic personality traits of people undergoing
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haemodialysis. The initial exploration of their cognitive domain reflected negative dimensions such as lack of acceptance of the illness, hopelessness, helplessness and worthlessness\(^9\) which could give rise to maladaptive illness and non-adherence behaviours. The psychological approach to analyze and improve the haemodialysis adherence is altogether a new concept in the country.

The pre-test mean, SD and p values of overall quality of life of participants of present study in the experimental and control groups were, 226.3± 26.86, 224.68± 30.27 respectively (p=0.79). The obtained scores of various dimensions of quality of life in the two were physical component score (PCS) 53.76± 7.93, 54.35± 8.14 (p=0.87), mental component score (MCS) 56.45± 8.26, 56.76± 8.62 (p=0.39) and chronic renal failure 116.09± 16.04, 113.56± 17.87 (p=0.86). As CHEQ was not used in the reported studies in which the mean quality of life scores were obtained through SF 36 and KDQOL. Sharp, Wild, Gumley and Deighan reported Physical function 53.79 ± 35.75, 41.67 ± 33.11, Role physical 48.28 ± 33.10, 37.27 ± 29.59, Bodily pain 54.02 ± 27.49, 50.21 ± 32.96, General health 37.41 ± 21.00, 34.30 ± 17.06, Mental health 65.52 ± 18.58, 60.56 ± 21.63, Role–emotional 66.09 ± 29.31, 46.30 ± 29.44, Social function 60.34 ± 26.31, 52.31 ± 28.17 and Vitality 36.85 ± 21.67, 41.44 ± 23.52 in the experimental and control group respectively.\(^{23}\) Cukor et al reported of the overall quality of life as measured by KDQOL as 101.6± 26.0 99.5 ± 29.5 104.8± 24.1 with t=0.65 and p=>0.05.\(^{82}\)

Though there are many descriptive studies on quality of life; the comparative analysis of the scores are not possible due to the difference in the usage of scales.
F. Effect of CBT on anxiety and depression

Present study categorized the people undergoing haemodialysis into three groups based on the scores on the Hospital Anxiety Depression Scale (HADS): normal (score ranging from 0-7), borderline abnormal (8-10) and abnormal (11-21) across experimental and control groups over time. There was a considerable amount of reduction in the abnormal level of anxiety in the experimental group in the post intervention period; from 19 (51.58%) at baseline to 2 (6.06%) at third month and 0% at sixth month compared to the control group; from 21 (61.76%) at baseline to 18 (52.94%) at third month and sixth month. Repeated measures ANOVA showed significant reduction of mean anxiety scores in the experimental group (10.7 to 7.18 at 3 months and 7.09 at 6 months) when compared with the control group (from 11 to 10.68 at 3 months and 11.29 at 6 months) (F=76.739, p=0.001). This was indicative of the effect of CBT in contributing to clinically and statistically significant outcome in anxiety reduction.

This result supports the finding of randomized controlled trial conducted by Hare, Clark-Carter, Forshaw that the CBT brought significant differences in HADS anxiety (t14 = 2.32; p = 0.034) (t14 = 2.73; p = 0.016) among the people undergoing peritoneal dialysis.89 Matusiewicz, Green and Kozowska reported participants in the experimental group after listening to a CD with a psychological intervention had a lower level of anxiety t(30) = 2.99; p < 0.05, a weaker intensity of cognitive appraisal of the treatment situation as a threat t(30)=3.48; p < 0.05, a weaker intensity of cognitive appraisal of the situation as a harm/loss t(30)=2.75; p < 0.05 and a stronger
intensity of cognitive appraisal of the situation as a challenge $t(30) = 3.49; p < 0.05$ when compared with the control group.\textsuperscript{64}

In the current study, there was a considerable amount of reduction in the abnormal level of depression in the experimental group in the post intervention period; 19 (51.58\%) at baseline to 1 (3.03\%) at third month and 0\% at sixth month compared to the control group; from 16 (41.06\%) at baseline to 9 (26.47\%) at third month and 10 (29.41\%) at sixth month. There was also reduction in the mean depression scores in the experimental group (from 11.85 to 6.82 at three month and 6.73 at six month) when compared with the control group (from 11.21 to 9.21 at three month and 9.74 at six month follow up), $F=57.326$, at 0.001 level of significance. CBT was found very effective in bringing down the depression scores of exposed group.

These results are in tune with the evidences put forth by previous researchers. The results obtained after the implementation of CBT at Kerala, the neighboring state by Sivadas showed that 73.3\% had moderate depression and 26.7\% had mild depression before CBT whereas 76.9\% had mild depression and 23.1\% had moderate depression after CBT. Paired t test showed there was a statistically significant difference between the pre-test and post-test mean depression scores ($p<0.001$).\textsuperscript{83}

The current finding concur with Duarte, Miyazaki, Blay and Sesso who reported significant reduction of BDI cognitive and somatic subscales and overall BDI mean scores at three and nine month assessments ($p<0.001$) after CBT whereas the control group had substantially lower changes. Mini International Neuropsychiatric Interview (MINI) also found to be lower in the CBT group at three
month (p<0.001) and nine month assessments (p=0.031). In the risk of suicide module, there was significant improvement in the intervention group after three and nine months (p=0.019 and p=0.002) whereas no difference was observed in the control group. Marvi, Bayazi, Rahmani and Deloei, brought out the results that the experimental group had significant reduction in their depression scores in the post test, t=8.678 (p<0.001).

In line with the present findings, Weiner, Kutner, Bowles and Johnstone reported that the participants of CBT after attending a class on stress management (through communication and problem solving) showed significant improvement in depression scores ((56% only had depressed mood at follow-up against the initial 65%) (p <0.05], compared to the control group. Cukor also found that the average BDI-II scores declined from 28.9 to 18.5 at the end of CBT and to 18.8 at a three month follow-up, indicating both a significant and sustained reduction in depression of haemodialysis patients. Cukor, et al reported that the treatment-first group achieved significantly larger reductions in BDI II (p=0.03) and Hamilton Depression Rating Scale (clinician-reported, p<0.001) scores after CBT. The comparison of studies show that CBT is effective intervention to bring down the anxiety and depression among the target population in a desirable way thus the objective to check the effectiveness of CBT in this direction was achieved.

G. Effect of CBT on Adherence

The objective measures of adherence in the present study were IDWG, systolic blood pressure, diastolic blood pressure and haemoglobin. The findings revealed that the average reduction of IDWG (in Kg) in experimental group (4.47 to 3.18 at three
month and 3.24 at six month) was higher than in the control group (from 4.39 to 4.3 at three month and 4.69 at six month) with F= 60.417 and p=0.001. The blood pressure also was monitored to assess the overall adherence and an average reduction of systolic blood pressure (in mm. of Hg.) in the experimental group (from 167.33 to 144.85 at three month and to 145.15 at six months) was observed which was significantly better than the control group (from 163.59 to 162.65 at three month and further to 165.59 at six month) F=76.662, at p=0.001. Average reduction of diastolic blood pressure (in mm. of Hg.) in the experimental group (98.24 to 87.27 at three month and further to 88.18 at six month) was significantly better than the control group (95.35 to 94.12 at three month and further to 95.88 in six month follow up), F=29.013, at p=0.001. Mean haemoglobin (g/dL) in the experimental group (7.55 to 8.08 at three month and further to 8.3 at six month) was again significantly better than the control group (7.62 to 7.52 at three month and six month) F=44.697 at p=0.001.

The subjective measures of adherence in the present study were dialysis adherence, fluid adherence, diet adherence and drug adherence. It was found that the average increase of dialysis adherence in the experimental group (13.3 to 14.24 at three month and at six month follow up) was better than the control group (13.38 to 13.41 at three month and slight decline to 13.32 at six month) F=33.607 at p=0.001. Fluid adherence in the experimental group (34.27 to 47.97 at three month and further to 50.61 at six month) was better than the control group (33.85 to 35.06 at three and six months F=252.506 at p=0.001.

Diet adherence in the experimental group (138.45 to 198.82 at three month and further to 199.64 at six month) was better than the control group (136.18, 137.53 and 138.35 at baseline, three and six months respectively) F=1.464 at the level of
p=0.001. These results indicate that although many subjects in the control group clarified their doubts pertaining to the correct diet, none of them were keen to bring a change in the existing dietary pattern. This further affirms that knowledge is not the only factor that affects the adherence behaviours. The mean increase in the subjective rating of drug adherence in the experimental group (22.39 to 32.36 at three month and further to 33.12 at six month) also was better than the control group (22.71, 24.91 and 25.09 at baseline, three and six months respectively) F=183.628 at the level of p=0.001.

Present finding support the results put forth by Sharp, Wild, Gumley and Deighan, that there was a significant main effect for mean IDWG \([F(1.76, 96.80) = 9.10; p< 0.001]\) and a significant difference between baseline and follow-up IWG values \((t55 = 3.85; p< 0.001)\) in the long-term assessment, reflecting improved adherence over time after attending the CBT.\(^{23}\) In line with the above findings, Cukor, et al reported that the treatment-first group experienced greater improvements in interdialytic weight gain \((p =0.002)\) than the wait-list group.\(^{53}\) Nozaki, Oka and Chaboyer also found reduction in the daily weight gain rates compared with the baseline period in both the CBT \((p<0.01)\) and structured patient education (SPE) \((p<0.05)\) groups with longer maintenance of the improvements in CBT. Daily salt intake also have been decreased in both the CBT and SPE groups which persisted for 12 weeks.\(^{87}\) Sagawa, Oka and Chaboyer reported a high achievement rate of the fluid consumption goal in the intervention phase on 65 percent of the assessments (that is 11.7 out of 18 pre haemodialysis assessments) with a range from 22 % to 94 % (4/18 to 17/18). Six out of the 10 participants achieved those goals at 2/3\(^{rd}\) of the time with only one individual achieving them less than 1/3\(^{rd}\) of the time. Fifty percent of
participants achieved their objectives at least $\frac{3}{4}$ of the time without individualized reinforcement.\(^85\)

Anson, Byrd and Koch reported of a person with difficult fluid adherence was able to decrease his fluid intake from 90 to 150 ounces of fluid to less than 60 ounces per day by after CBT. Declines in relapse frequency and in the total amount of liquid consumption were noted throughout the course of therapy. Findings also indicated that the patient successfully restricted his fluid consumption at or below recommended levels 83% of days long-term after the therapy.\(^88\) Hare, Clark-Carter, Forshaw observed significant difference in oedematous status among the people undergoing peritoneal dialysis in the longitudinal phase after CBT, at six week follow-up; which is indicative of improved fluid adherence.\(^89\)

On par with the above findings, Moattari, Ebrahimi, Sharifi and Rouzbeh identified significant difference in systolic blood pressure (<0.001), diastolic blood pressure (<0.003), interdialytic weight gain (<0.039), hemoglobin(<0.003) and haematocrit (<0.004) levels, in the experimental group after an empowerment programme with similar cognitive and behavioural components.\(^72\) Barnett, Li Yoong, Pinikahana and Si-Yen identified that the pre-dialysis mean blood pressure did not improve following a patient education programme, although the maximum recording for pre-dialysis systolic pressure dropped from 220 mmHg to 161 mm of Hg.\(^76\) The present evidences support their finding that an education alone may not bring change in adherence indices of people undergoing haemodialysis. Yurtkurana, Alpa, Yurtkuranb and Dilekb identified that yoga-based exercise program had a positive effect on improving the erythrocyte and haematocrit counts for 11 and 13 percent
respectively after 12 weeks of intervention. Thus CBT has been found consistently effective in improving the adherence of people undergoing haemodialysis across the studies worldwide which adds credibility to the objective as well as finding of the present study.

H. Effect of CBT on Quality of life

The average increase of overall quality of life in the experimental group (from 226.3 to 283.09 at three month and further 290.30 at six month) was greater than the control group (224.68, 224.03 and 219.85 at baseline, three and six months respectively) F=308.234 at p=0.001. The average increase of Physical Component Score in the experimental group (from 53.76 to 71.45 at three month and further to 76.42 at six month) was greater than the control group (54.35, 5.94 and 52.62 to baseline, three and six months respectively) F=243.796 at p=0.001 in the current study. Average increase of Mental Component Score in the experimental group (from 56.45 to 75.45 at three month and further to 76.09 at six month) was also greater than that of the control group (56.76, 57.76 and 65.68 at baseline, three and six months respectively) F=173.322, at p=0.001. Similarly, average increase of CRF related quality of life in the experimental group (from 116.09 to 136.18 at three month and further to 137.79 at six month) was also greater than that of the control group (113.56, 112.32 and 110.56 at baseline, three and six months respectively) F=163.1, at the level of p=0.001.

The present evidence concurs with the findings of Sharp, Wild, Gumley and Deighan, who after adjustment for appropriate baseline covariates, through analysis of covariance found significant differences on the SF-36 subscales; Mental Health
(F1,53 = 12.93; p= 0.01), Role Emotional (F1,53 = 18.78; p= 0.01) and Attribution(F1,53 = 8.01; p= 0.01). Duarte, Miyazaki, Blay and Sesso had also reported significant improvements in the average scores of MINI and in quality-of-life dimensions after CBT in the experimental group compared with the control.  

On par with the above findings, Weiner, Kutner, Bowles and Johnstone found that participants rated their general health status (p < 0.05) and social functioning (p < 0.05) significantly better after participating in the intervention. Cukor, et al also reported that the treatment-first group experienced greater improvements in quality of life (p =0.04) than the wait-list group.

Hare, Clark-Carter, Forshaw in their randomized controlled trial found that the CBT brought increased SF-36 subscale for Social Function (t14 = 2.73; p = 0.016). They also reported positive and significant differences in the desired direction for measures of psychological well-being, quality of life and health beliefs among the people undergoing peritoneal dialysis, who attended CBT.

Chen et al found that the CBT group in the people undergoing peritoneal dialysis had median percentage of change in positive direction in the Global Pittsburgh Sleep Quality Index scores (p=0.03) and Global fatigue severity scale scores (p=0.04). Serum Interleukin (IL-1) decreased in the intervention group whereas it increased in the control group. Moattari, Ebrahimi, Sharifi and Rouzbeh, after the empowerment programme with cognitive and behavioural components identified significant difference in the quality of life (<0.001) and all dimensions included within quality of life of experimental group.

Thus the study succeeded in attaining the objective of assessing the effectiveness of CBT in improving the quality of life of people undergoing
haemodialysis; and it is evident from the results as well as findings of related studies that CBT is an effective intervention for the same.

**Opinion of people undergoing Haemodialysis about CBT**

Majority of the participants of experimental group in the present study expressed that CBT helped them to get control over their negative thoughts (87.88%), on water intake (90.91%), on planning the diet (75.76%), in managing activities (60.61%), to regulate dialysis and drug intake (63.64%), to relax and sleep better (69.7%) and to come in terms with the disease as a whole (87.88%). All of them (100%) expressed that they felt better after attending the CBT sessions. Majority of them stated that the sessions were comprehensible (96.97%) and feasible to attend (84.85%). Maximum participants had rated the components of the CBT as very useful; i.e dietary guidelines (90.91%), diet and fluid adherence tips (84.85%) and stories (96.97%), whereas most of them (72.73%) felt that the home works were equally useful.

These findings support the evidences put forth by Sharp, Wild, Gumley and Deighan that there were significant positive changes in all the three items pertaining to health beliefs in their questionnaire [“To what extent do you believe that excessive fluid consumption is hazardous to your health?”(p=0.001), “To what extent is it important for you to avoid excessive drinking?”(p=0.001) and “To what extent do you believe that restricting fluid intake will help you in preserving good health?”(p=0.01)] at all the time points after the intervention. There was also a significant change in the attributions (”What percentage of the time do you feel that your adherence is due to your own efforts?”) at p=0.05 level in the post intervention assessment.23
Anson, Byrd and Koch stated that person undergoing CBT could readily engage in assessment, intervention and evaluation with the therapist during sessions and expressed pride in his improvement. Sagawa, Oka and Chaboyer recorded incidental comments made by participants such as “my body weight gain decreased markedly only when I tried to drink less water in the morning,” “my feet feel better,” and “I’m happy because I don’t have a blood pressure fall.” Most of comments were related to a variety of factors including fluid intake.

Weiner, Kutner, Bowles and Johnstone reported that the participants who gave more positive program evaluation after the group CBT showed higher quality of life and lower perceived burden of kidney disease (p = 0.05). Patient satisfaction and adaptation are important criteria to determine the user friendliness and worth of any intervention. The opinions of participants in the present study as well as other related studies are indicative of the user friendliness and positive impact that the CBT brought to its recipients.

Summary

This chapter dealt with the discussion on the findings of the present study with reference to the findings of other studies conducted across the world. It appears that CBT is a powerful mode of intervention that can relieve the co-occurring anxiety and depression among the people undergoing haemodialysis thus enhance treatment adherence thereby improving their quality of life.