Chapter VI  Summary, Findings, Conclusion, Implications, Limitations & Recommendations

SUMMARY, MAJOR FINDINGS, CONCLUSION, IMPLICATIONS, LIMITATIONS AND RECOMMENDATIONS

Summary

Objectives of the study were to:

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

Following null hypotheses were formulated for the study and tested at 0.05 level of significance

H01. There will be no significant difference in the mean pre and post test scores of anxiety and depression among people undergoing haemodialysis in the experimental and control group.
H02. There will be no significant difference in the mean pre and post test scores of adherence among people undergoing haemodialysis in the experimental group and control group.

H03. There will be no significant difference in the mean pre and post test scores of quality of life among people undergoing haemodialysis in the experimental group and control group.

The assumptions underlying the study were:

1. Man is a bio-psycho-social being.
2. Quality of life is multidimensional and empirically measurable.
3. The peak incidence of CKD is between 20 and 64 years of age.\(^2\)
4. Psychiatric morbidity lowers the therapeutic outcome of medical conditions.
5. Improved adherence brings down the mortality in chronic illness.
6. Depression prone people possess negative self-beliefs.
7. Alterations in the content of underlying cognitive structures can bring change in affective state and behavioural pattern.\(^{24}\)
8. Every person is basically self-directed and dynamic.

The conceptual framework was developed by the researcher by combining Cognitive model and Model of Dynamic Integration which are relevant to the present study. The Cognitive model was developed by Padeskey and Mooney in the year 1990 for presenting conceptual formulation for the clients during the cognitive therapy so that they get to know the connection among own biology, thoughts, mood, behavior and environment.\(^{31}\) The Dungan’s model of Dynamic Integration (developed in 1997), presents human being as having three synergistic systems of body, mind and spirit, having dynamic integration of life events leading to ongoing development. It was
used effectively in a study on nursing interaction enhancing the adherence of people undergoing haemodialysis.\(^3\) Thus the current conceptual framework explains the concepts such as the axes, client, environment, developmental level, wellness/illness scale, health assessment, cognitive behaviour therapy, therapeutic relationship, dynamic integration and outcome assessment and their relationship.

**The terms defined in the study were:** People undergoing haemodialysis, chronic kidney disease, cognitive behavioural therapy, anxiety, depression, quality of life, adherence, interdialytic weight gain, medical co-morbidity and non-directive counselling.

Extensive review of the literature was performed from various sources and content was organized in relation to study variables under the headings of impact of haemodialysis, physical impact of haemodialysis, psychological impact of haemodialysis, treatment adherence and outcome, interventions for the people undergoing haemodialysis, psychosocial interventions to reduce anxiety and depression, psycho social interventions to improve quality of life, psycho social interventions to improve adherence, cognitive behaviour therapy to reduce anxiety, depression and to improve quality of life and cognitive behaviour therapy to improve adherence.

Research approach used was experimental with RCT design. Purpose of the study was to establish the application of Cognitive Behavioural Therapy in CKD in order to prevent or reduce anxiety, depression and improve adherence which will enhance their quality of life and thereby contribute to a better therapeutic outcome.
The study population consisted of people undergoing haemodialysis in the Kasturba Hospital, Manipal. The sample was recruited to the study based on the cut off scores above seven in the any of the areas of anxiety or depression in the HADS. A total of 150 were screened for the study and out of 80 eligible, 40 each were randomly allocated to experimental and control group using computer generated block randomization procedure. The sample completed the study were 67; 33 and 34 in the experimental and control group respectively.

**The following tools were used for the present study**

Background Proforma, Hospital Anxiety and Depression Scale (HADS), Haemodialysis Adherence Scale and CHOICE Health Experience Questionnaire (CHEQ) and Opinionnaire on Acceptability of CBT. The Background Proforma, Haemodialysis Adherence Scale and Opinionnaire on Acceptability of CBT were tools developed by the researcher and validated by the experts from various fields. The HADS and CHEQ are standardized scales that have established their use in the similar population elsewhere. The reliability in terms of internal consistency of Kannada versions of HADS and CHEQ was established through Cronbach’s alpha and the obtained values were 0.73 and 0.79 respectively. Test re-test reliability was computed for Haemodialysis Adherence Scale and Opinionnaire on Acceptability of CBT using Karl Pearson correlation coefficient ($r = 0.9$).

The pilot study was conducted among six people undergoing haemodialysis in Kasturba Hospital from January 2012 to August 2012. The main study was conducted from October 2012 to July 2013. Based on the objectives of the study and the hypotheses to be tested, descriptive and inferential statistics were used for the analysis of the data. Frequency and percentage were used to analyze the sample characteristics. Other descriptive statistics used were mean and standard
deviation. The inferential statistics Chi square or Fissures Exact test and t test were used to check the difference between experimental and control group. The inferential statistics used to test the hypotheses was repeated measure ANOVA. All the calculations were done using the statistical software, SPSS version 16.

**Findings of the study**

**Demographic characteristics of experimental and control group**

- 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.
- Among the 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 unable to attend a paying job (78.79% and 67.65%) whereas most of them in both the groups were non-professionals in the past (36.37% and 29.41%, p=0.66).
- 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=0.39) in the experimental and control group respectively.
- Nearly half of the participants in both the groups (51.52% and 50%, p=0.678) had a family income of rupees 5001 to 10,000.
- Most of the people undergoing haemodialysis 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%) used public conveyance as their mode of transport to hospital (p=0.416).

Clinical characteristics of experimental and control group

• Nearly half of the sample in experimental and control groups have stated that their CKD diagnosis revelation was sudden [57.58% and 55.88% (p=0.332)].
• Duration of disease ranged from one to three years to most of the person in experimental (57.58%) and control (76.47%) group (p=0.538).
• Almost half in experimental (54.55%) and control (55.89%) group were managing the haemodialysis without bystander (p=0.585) whereas others had the help of spouse or other significant people.
• Majority of them were not using any support for ambulation (84.85% and 88.25%, p=0.734) in experimental and control group respectively, whereas the rest required partial support and the people who needed full support were excluded from the study.
• Majority of the sample (78.79% and 79.41%, p=1) received one or the other financial assistance towards the treatment expenditure.
• The self-reported reason for CKD by overall participants 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 conditions like hypertension (98.51%), Diabetes mellitus (31.34%), Hyperparathyroidism (8.96%), Ischemic heart disease (7.46%), Retinopathy (13.43%) and Fracture (5.97%).
Anxiety, depression, adherence and quality of life among the sample

- The sample had comparable mean scores of anxiety [10.71 ± 2.01, 11 ± 2.38 (p=0.41)] and depression [11.85 ± 2.15, 11.21 ± 2.53 (p=0.482)] in experimental and control group respectively.

- The overall adherence was represented in terms of inter dialytic weight gain (IDWG) [4.47 ± 0.92, 4.39 ± 0.78 (p=0.25)], systolic BP [167.33 ± 19.68, 163.59 ± 18.53 (p=0.84)], diastolic BP [98.24 ± 9.52, 95.35 ± 8.29 (p=0.70)], Haemoglobin [7.55 ± 1.18, 7.62 ± 1.09 (p=0.58)], dialysis adherence [13.30 ± 1.02, 13.38 ± 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.

- The overall as well as domain wise quality of life scores are equally distributed in the experimental and control groups. The mean, SD and p values of overall quality of life were [226.3 ± 26.86, 224.68 ± 30.27 (p=0.79)], dimensions of quality of life 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)].

Effect of CBT on Anxiety and depression

- There was a considerable amount of reduction in the abnormal level of anxiety scores 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 whereas in the control group reduction was just nominal; from 21 (61.76%) at baseline to 18 (52.94%) at third month and sixth month.
• There was a significant reduction of mean anxiety scores in the experimental group (from 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).

• There was a considerable amount of reduction in the abnormal level of depression score in the experimental group in the post intervention period (from 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 a reduction of 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.

**Effect of CBT on Adherence**

• The average reduction of IDWG (in Kg) in experimental group (from 4.47 to 3.18 at three month and to 3.24 at six month) was higher than the control group (from 4.39 to 4.3 at three month and to 4.69 at six month) F= 60.417 at p=0.001.

• The 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 higher 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.

• The average reduction of diastolic blood pressure (in mm. of Hg.) in the experimental group (from 98.24 to 87.27 at three month and further to 88.18 at
six month) was higher than in the control group (from 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.

- The mean increase of haemoglobin (in g/dL) in the experimental group (from 7.55 to 8.08 at three month and further to 8.3 at six month) was higher than the control group (from 7.62 to 7.52 at three month and six months) F=44.697 at p=0.001.

- The improvement of mean dialysis adherence scores in the experimental group (from 13.3 to 14.24 at three month and six month follow up) was higher than to the control group (from 13.38 to 13.41 at three month and slight decline to 13.32 at six month) F=33.607 at p=0.001.

- The increase in the mean subjective assessment of fluid adherence in the experimental group (from 34.27 to 47.97 at three month and further to 50.61 at six month) was higher than in the control group (from 33.85 to 35.06 at three and six months) F=252.506 at p=0.001.

- Diet adherence mean scores in the experimental group (from 138.45 to 198.82 at three month and further to 199.64 at six month) was greater than in the control group (136.18, 137.53 and 138.35 at baseline, three and six months respectively) F=1.464E3 at the level of p=0.001.

- Mean increase in subjective rating of drug adherence in the experimental group (from 22.39 to 32.36 at three month and further to 33.12 at six month) was higher than in 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.

**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 $p=0.001$.

- Average increase of Physical Component in the experimental group (from 53.76 to 71.45 at three month and further to 76.42 at six month) was greater than in the control group (54.35, 5.94 and 52.62 at baseline, three and six months respectively) $F=243.796$ at the level of $p=0.001$.

- The increment of mean 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 greater than in the control group (56.76, 5.76 and 65.68 at baseline, three and six months respectively) $F=173.322$, at the level of $p=0.001$.

- 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 greater than in the control group (113.56, 112.32 and 110.56 at baseline, three and six months respectively) $F=163.1$, at $p=0.001$.

**Opinion of people undergoing Haemodialysis on CBT**

- Majority of the participants of experimental group expressed that CBT helped them to get control over their negative thoughts (87.88%), decide on water intake (90.91%), plan diet (75.76%), manage activities (60.61%), regulate dialysis and drug intake (63.64%), relax and sleep better (69.7%) and 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 the people in the experimental group 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 useful.

**Conclusions**

- The people undergoing haemodialysis suffer considerable amount of anxiety and depression.
- Inter dialytic weight gain (IDWG) and blood pressure, among the people undergoing haemodialysis is much higher than the expected clinical norms. This could be attributed to poor fluid and dialysis adherence.
- Haemoglobin of the sample is lower than the normal clinical level, which might be due to the inadequate diet as well as drug (erythropoietin) adherence, which could be linked to financial constraints.
- CBT is effective in reducing the anxiety and depression among people undergoing haemodialysis.
- CBT is effective in improving the adherence to dialysis, fluid, diet and drug among people undergoing haemodialysis.
- CBT is effective in enhancing the quality of life among people undergoing haemodialysis.
- CBT helps the people undergoing haemodialysis to get control over their negative thoughts, decide on water intake, plan diet, manage activities, regulate dialysis and drug intake, relax and sleep better and come to terms with the disease as a whole.
- It is feasible to conduct CBT for the people undergoing haemodialysis and they feel better after attending the same.
Implications

The findings of the study have important implications for the current and future professionals in dialysis practice, education, administration and research.

Dialysis practice

Dialysis unit is a specialized area of work; hence the health care team members should be equipped with knowledge, skill and attitude to enable the mental health, adherence and well-being of the people undergoing haemodialysis. Researcher found that people undergoing haemodialysis are deeply engrossed with their meaning, experiences and perceptions of illness and not amenable to change with a casual teaching prior to the CBT. The adaptive behavioural change requires planned, theoretically oriented therapy. CBT aims to help patients identify dysfunctional cognitions, test them against reality and alter them, thereby improving their emotional well-being, coping behaviour and physical health. People can be assisted to develop more realistic, self-helping beliefs by using CBT that could enable them to cope more effectively with diet and fluid restrictions inherent in the haemodialysis treatment regimen.

Through the present study, researcher has developed and tested CBT for people undergoing haemodialysis. CBT materials developed and validated for the study include CBT manual and CBT module for the therapist, CBT diary and relaxation audio CD for people undergoing haemodialysis. The CBT has incorporated sessions on modification of negative cognition, plan for improved adherence to diet, fluid, dialysis and drugs, relaxation, exercise and improvement of sleep. CBT diary encompasses bibliotherapy materials, dietary and fluid adherence guidelines and self-
monitoring tools for enhancing adherence and quality of life. The CBT diary is available in English and Kannada, which can be translated to other languages and can be effectively utilized on a regular basis in various dialysis settings for the betterment of the people undergoing haemodialysis.

Ongoing psychometric assessment and screening for anxiety and depression should be made part of routine assessment for this population as we have evidences suggesting that the psychiatric comorbidities worsen their adherence and accelerate mortality. The haemodialysis adherence tool prepared for the study too can be made as handy tool to assess their adherence indices as well as behaviours so that the people undergoing the haemodialysis develop more insight into their own adherence practices. Further the individualized assessment of their family and social background will give a holistic view of the person that gives us better opportunity to intervene their situation empathetically.

The exercise, relaxation, adherence and motivational audio or video CDs can be played when they are on dialysis so the monotonous and lengthy hours attached to the machine can be transformed to a fruitful experience for the person. The goals for achieving the therapeutic outcome should be mutually set by the person and the health team member and it is a better option to include the family member also so that the dietary behavior can be supported well. The family members also require education for such psychological interventions. Dialysis, fluid, diet and drug adherence protocols and pamphlets can be made freely available in the dialysis units and OPD.
Education

A qualitative study conducted among the dialysis staff revealed that almost all of them underwent initial dilemma of how to respond to the psychological issues of their clients.\(^{107}\) The curriculum of various health professionals should address the psycho-social domains of the people undergoing dialysis. The curriculum must incorporate evidence based modalities to tackle their own stress as well as empower them to enable the needy population to manage their illness better. Continuing nursing, medical and technical education programmes on holistic aspects of patient care should be conducted at regular basis to meet such professional demands. Conferences and short courses also can be conducted for the professionals.

A study conducted in US at two Wisconsin hospital dialysis units on the experience of nurses while working with a specific migrant population called Hmong group, revealed that nurses felt a lack of training in the new culture though they adopted different methods to learn it themselves. Communication and patients’ health and treatment beliefs were identified as cultural challenges by the nurses.\(^{111}\) In the multi-cultural environment of Manipal, it is common that the health care professionals from various States work in the dialysis unit. On the other hand we are preparing professionals who are going to be placed globally in the near future. Hence it is important to design a culture sensitive curriculum. It is also practical to give adaptation course for the professionals that include influence of culture, religion and dietary practices in coping with the illness and also in the health outcomes of patients.

Administration

Dialysis staff spent maximum time with the patients. If they are trained in dealing with the psychological and adherence related issues right in the beginning, their patients will be benefited. The adaptation courses can be made a part of
recruitment and orientation process in the hospitals. Regular continuing education programs and attendance credits can be brought as part of audit, accreditation, professional licensure and affiliation to assure quality of patient care. Aptitude testing will help to recruit right students to professional degrees and also the right professional for the job in specialized areas. Stress management sessions need to be organized for dialysis staff. More offs and better payment for dialysis staff also will increase staff motivation and involvement in quality patient care.

Psychiatric professionals need to be appointed in the dialysis units who can assess and effectively deal with the psychological demands of the patients and family thereby yielding therapeutic benefits. Interdisciplinary model of care including nephrologists, dialysis nurses, dialysis technicians, psychiatric nurses, clinical psychologists, psychiatrist, psychiatric social workers and dieticians can assure holistic and supportive care to the people undergoing haemodialysis.

Government and other non-governmental social support organizations need to look into the struggle of dialysis patients and their families to sustain their lives. Private and public sector health care delivery systems should make dialysis acceptable and affordable to the common man. Large community based awareness programmes would help the people to build knowledge on CKD, which would bring twofold positive outcomes first by preventing the occurrences of CKD and second by developing positive attitude towards the people suffering with CKD.

Research

Research is an important tool for the continual development of a relevant body of knowledge. The present research was conducted based on the findings of qualitative study on the lived experiences of people undergoing haemodialysis. Similarly present study can become the base for larger studies conducted with
multicenter and multidisciplinary involvement so that wider generalizations and conclusions can be drawn out of it.

The data collection instruments and CBT materials can be translated and tested for its application in different populations. Researcher observed that dialysis unit becomes the regular meeting place for same group of people, eventually giving rise to a family kind of environment. Hence the impact of group dynamics and social support on illness adaptation and adherence can be studied. Active self-help groups, social networks and employment services as part of rehabilitation can be initiated and monitored for satisfying outcomes primarily to the patients and then to family and health care members.

Cost effectiveness of different models of dialysis care can be analyzed. This can include primary care (one health team member is assigned with specified group of patients), case management (total care by one expert nurse) and interdisciplinary model. Patient satisfaction surveys need to made part of the regular activity of dialysis units.

**Limitations**

Following limitations of the present study are identified by the researcher.

- The research had self-report measurements where researcher had to assume that the respondents were truthful.
- Many of the people undergoing haemodialysis were reluctant to fill the lengthy CHEQ on time, hence extra time had to be allotted to them.
- The drug adherence was measured based on self-report and the drug diary and pill count was not considered due lack of feasibility.
Recommendations

In the light of the present study findings, the researcher makes following recommendations for future research.

- A larger RCT can be done using a multidisciplinary, multi-center approach.
- Similar study can be replicated by adding other relevant laboratory parameters.
- The effectiveness of group CBT among the similar sample can be studied.
- Influence of perceived social support and personality traits on anxiety, depression and adherence of people undergoing haemodialysis can be analyzed.
- Appropriate dietary guidelines can be developed based on laboratory parameters.
- The exercise, relaxation, adherence and motivational videos can be prepared and incorporated into the CBT.
- Self-help groups, social networks and employment services can be initiated for the people undergoing haemodialysis and their impact on quality of life can be measured and followed up.
- Effect of CBT in terms of cost, prevention or reduction of complications and longevity can be studied.
- A similar RCT can be done with longer follow-up.

Summary of the chapter

This chapter dealt with summary of the present study, conclusions drawn from the findings, implications in nursing: practice, education, and research, limitations and recommendation for future research based on the present study findings.