CHAPTER 3

RESEARCH DESIGN

This study was a randomised control and intervention study done on 500 patients at Kovai Diabetes Speciality Centre and Hospital, Coimbatore, India. After procuring the approval by the Ethics Committee of M.S. Chellamuthu Trust and Research Foundations, Madurai, Tamil Nadu, India. Patients of various socio demographic characteristics were randomized as per the inclusion criteria. The study was based on complete patient data including the data collection form used for the study. The prospective study among diabetic cohort, both men and women living in and around the district of Coimbatore, Tamilnadu, India belonging to varying socio economic status was done over a period of 18 months.

Totally 500 patients were being enrolled and selected for the study. A sum of 250 from each age group were being selected and equally poised in their respective groups. The remaining 250 patients were considered as control. “Grouping of patients were intended for better data management rather than gaining there comparative data”. Patients satisfying the study criteria were enrolled after their informed consent; cognitive impairment examination was conducted in the subjects. A patient was considered a drop out provided the patient completely failed to attend any of the examinations.
3.1 STUDY POPULATION AND DATA COLLECTION

The study was based on complete patient data including the data collection form used for the study.

The prospective study was done among diabetic cohort, both men and women living in and around the district of Coimbatore, Tamilnadu, India belonging to varying socio economic status over a period of 18 months.

Figure 3.1 Flow chart for the patient inclusion during the baseline and follow up period of six months
3.2 METHODS

- Data collection forms were designed with respect to age, sex, education and income status.
- 500 patients of varying age groups (below 30, 30 to 60, above 60) were being recruited for the study.
- Study was conducted for the cognitive function through Mini Mental Test Score Examination.
- Study was conducted for the extent of adherence to treatment recommendations.
- Interpretation of the test results of patients under varying demographic data was done to conclude the effects of adherence, drugs, age, sex, education and income status.

3.3 INCLUSION CRITERIA

- Patients willing to participate in the study.
- Patients suffering from diabetes mellitus.
- Normal subjects willing to participate in the study.

3.4 EXCLUSION CRITERIA

Patients below 20 years and above 90 years.

Patients not willing to participate in the study.

Mentally challenged patients.
3.5 SOURCES OF DATA

The various resources used for the collection of data include the following:

- Interview with the patients.
- Mini Mental State Examination (MMSE) form (Appendix 4 and Appendix 5).
- Inpatients data collection form (Appendix 3).
- Patient case history.
- Patient treatment schedule charts.

3.6 ETHICAL CLEARANCE

The study was approved by the Ethics Committee of M.S. Chellamuthu Trust and Research Foundations, Madurai, Tamil Nadu, India. Patients were informed that the information they provided was confidential and would be presented only as group information without any identifying characteristics. Written informed consent was provided by all patient participants prior to entry into the study (shown in Appendix 2). The approval from the concerned ethics committee has been provided in the Appendix 1.

3.7 DATA AND SAFETY MONITORING

This research involves no more than minimal risk to participants. There is no participant name on the study forms and all forms will be stored in a locked file cabinet in the investigator’s office.
3.7.1 Human Subjects Instructions

The population for this study includes 500 participants of varying demographic population. The population is comprised of men and women in and around Coimbatore. It was assured that anyone not willing to participate in the study would not be enrolled in the study.

3.7.2 Recruitment Plan

All patients fulfilling the inclusion criteria and who are willing to participate in the study were being invited to participate in the study. It was estimated that completion of the survey, MMSE exam and demographic form will take approximately 15 minutes and was done as expected.

3.7.3 Potential Risks

This research presents no more than minimal risk to its participants.

3.7.4 Risk Reduction

All surveys will be completed anonymously and are returned in unmarked envelopes. Because the nature of the survey questions is not sensitive and no identifying information is collected, this poses almost no risk to participants. All data will be maintained by the Scholar. All data was completely anonymous, as there was no link between names and responses. Surveys will be stored by the scholar. Computer data files will be stored on a secure computer.
3.7.5 **Confidentiality**

All data will be maintained by the scholar and is accessible to the concern guides only. Survey data will not include personal data of the patients.

3.7.6 **Risk / Benefit**

The minimal risk to participants is reasonable in relation to the benefit of increased knowledge. The results of this study are important in understanding cognition with regard to diabetes in help framing a better diabetes management.

3.8 **RESEARCH PROCEDURE**

Patients satisfying the study criteria were enrolled after their informed consent.

Cognitive impairment examination was conducted in the subjects.

A patient was considered a drop out provided the patient completely fails to attend any of the examinations.

3.9 **MEASURES OF COGNITIVE PERFORMANCE**

Cognitive functioning in the cohort was measured using the MMSE scale (Mini Mental State Examination). The scale was administered on every subject and data recorded from baseline to the second follow up. The data were statistically analysed for the influence of gender, age and social habits on cognitive functioning in diabetic cohort (shown in Appendix 6). A pilot study was done prior to the study, pilot study was performed to standardise the scale as per the study environment.
A statistical power analysis was performed before the study start. It was calculated that 500 patients would be enough to detect significant differences in cognitive functioning (>5 points/dimension) in the optimal study, with a power of 80%. In order to compensate for a potential loss of 10% of patients during the course of the study, we intended to include 600 patients at the start of the study.

Statistical analysis was done using SPSS V10 on windows xp platform. Means of continuous measures across categorical variables were tested using t-Test and analysis of variance (ANOVA).