CHAPTER 3

METHODOLOGY

Research methodology prescribes the method for systematically conducting a scientific study. This chapter discusses the specific methodology adopted for this study.

3.1 Research design

The design of the present study was experimental. Since there is paucity of controlled experimental studies in the area of efficacy of non-pharmacological management strategies for behavioural problems, this design was selected. This study was done on two groups of subjects randomly allotted to control group and experimental group. While the experimental group received the intervention according to specially devised management programme the control group received only routine care.

3.2 Population of the study

Persons diagnosed with Alzheimer’s dementia (Alzheimer’s disease) constituted the population of the study. Present study was conducted in Trissur region in Kerala. Patients who were identified as part of case identification studies conducted by 10/66 dementia research group were selected for the study. Also patients attending special clinics of 10/66 dementia research group in Trissur were selected. Patients identified and selected hailed from four districts in this region, Trissur, Ernakulam, Palakkadu and Malappuram. The 10/66 dementia research group is an international network of researchers interested in dementia. The focus of
this group is developing countries like India. Even the name of the research group is derived from the fact that 66% of persons affected with dementia are living in developed countries, but only 10% of total research in dementia is undertaken in these countries. Hence this group with research interest in developing countries was named as 10/66 dementia research group. Under the auspices of 10/66 dementia research group various research activities are undertaken. There are dementia clinics run on weekly/monthly basis and also community/home based services provided to demented persons.

3.3 Sample

Convenience sampling technique was used for selection of subjects for this study. Persons diagnosed with Alzheimer’s dementia was initially selected from either the clinics conducted by 10/66 dementia research group or from the cases identified by the research group in community survey. Each of this case was diagnosed by a senior consultant Psychiatrist based on DSM IV criteria (Diagnostic and Statistical Manual IVth revision, American Psychiatric Association, 1994).

After the primary selection of Alzheimer’s dementia cases, preliminary assessment was done using Neuropsychiatric Inventory to measure behavioural problems. Only those who have one or more behavioural problem with minimum score of above ten were included in the further stages of study.

Once selected the samples were randomly allotted to experimental and control group by allotting all the odd numbers to experimental group and even numbers to control group. The first sample was selected by drawing lot.
Sample selection was done according to the inclusion criteria specified below.

3.4 Inclusion criteria

1. Persons diagnosed as suffering from Alzheimer’s dementia by a consultant Psychiatrist based on DSM – IV criteria.
2. Patients and family caregiver who are willing to participate in the study.
3. Persons with Alzheimer’s dementia of mild/moderate stage and those who are above the age of 60 years.
4. Alzheimer’s dementia cases with minimum behavioural problem score of 10 as measured in Neuropsychiatric Inventory (NPI)

3.5 Exclusion criteria

1. Persons who had any other major psychiatric disorders prior to the diagnosis of Alzheimer’s dementia.
2. Those cases of Alzheimer’s dementia who are suspected to suffer from any other separate psychiatric disease simultaneously.
3. Persons who are debilitated due to any major physical illness.
4. Persons with diagnosis of Alzheimer’s dementia who are taking any psychopharmacological agents.

3.6 Tools for data collection

The tools for data collection included the following:

1. Neuropsychiatric Inventory (Cummings et al., 1994).
2. Clinical Dementia Rating Scale (Morris, 1993).
3. Socio Demographic data sheet (developed by author).

3.6.1. Neuropsychiatric Inventory (NPI)

Neuropsychiatric Inventory is a tool for assessment of behavioural problems or Psychopathology of dementia. This tool was developed by Cummings et al. (1994). The validity of the tool is determined both in content validity and concurrent validity and was rated as highly valid. The content validity employing Delphi technique demonstrated that NPI captures effectively the wide range of abnormal behaviours. Concurrent validity studies showed that NPI quantitates the symptoms of behavioural disturbance in dementia very well when compared with other standardized instruments. An item analysis also showed that there is internal consistency and behavioural domains assessed are largely independent of each other. Between rater reliability and high text reliability of this instrument also is high. Neuropsychiatric Inventory has many advantages over other existing tools in this area. Since NPI is scored on the basis of information provided by caregiver it avoids problem inherent in observer based strategies. NPI also avoids overlapping chance of dementia and depression by technically separating somatic area questions. The NPI also has the advantage of distinguishing between severity and frequency, a feature potentially useful in assessing behaviour and interventions. Another advantage of selecting NPI is that it explores a wide range of behavioral problems when compared with other scales that can be used in such investigations. (Cumming et al., 1994).

The NPI original version was used in this study. Original version is intended for use with patients living in household setting were family caregiver is asked questions for completing NPI by the trained rater. Other versions include NPI.NH (Nursing Home) which is used in nursing
home setting where the patient is institutionalized. The NPI Q (NPI Questionnaire) version is for brief assessment of symptomatology in clinical settings by clinicians.

NPI used in this study is intended to obtain information on behavioural problems in patients with Alzheimer’s disease and other dementias and also of related disorders. In this version, information is obtained by interview from a caregiver familiar with patient’s behaviour. A screening question assays each sub area of the Neuropsychiatric Inventory like delusions, hallucinations, agitation, apathy, anxiety depression, euphoria, irritability, disinhibition and aberrant motor behaviour. Another two questions inquire about alterations in appetite and night time behaviour disturbances. If the answer to the each screening question is no then no further question in that area is asked. If the answer to the screening question is yes or if there are any uncertainties in caregiver response and information known by rater, the category is marked as yes and is explored in more depth with the sub questions. If the sub questions confirm the screening question, the severity and frequency of the behaviour are determined according to the criteria provided.

The screening in NPI is based on presence and absence of a particular behavioural problem in the screening question followed by frequency and severity. In each domain there is total score obtained by multiplying frequency with severity. Also the distress caused by each behavioural problem is scored on a five point scale as reported by the caregiver.

The NPI is allowed for free use in research/study purposes. Prior permission to use the tool is required only in cases where it is used for commercial purposes only.
3.6.2. Clinical Dementia Rating Scale (CDR)

The Clinical Dementia Rating Scale or CDR was developed by the memory and ageing project at Washington University School of Medicine in 1979 for the evaluation of staging severity of dementia. It was developed primarily for persons with dementia of the Alzheimer type and it can also be used for other dementias. The CDR is a five point scale in which CDR = Zero connotes no cognitive impairment and the remaining four points are for various stages of dementia.

- CDR - 0.5 = Very mild dementia
- CDR - 1 = Mild dementia
- CDR - 2 = Moderate dementia
- CDR - 3 = Severe dementia.

In assigning a global score of dementia as mild, moderate or severe six domains are used to construct the overall score, each of which is scored individually. The six domains are Memory, Orientation, Judgement and Problem solving, Community affairs, Home and Hobbies and Personal care. In rating each of these domains the assessment should be on patient’s cognitive ability to function in these areas. If a limitation in performing activities at home is owing to physical difficulties this should not affect the CDR score.

The structured interview in scoring CDR collects information in a standard way from both the collateral source and the subject in areas related to memory, orientation and so forth. After the information is collected the individual box score can be rated and from the individual box scores for each of the six domains the global CDR is derived in accordance with CDR scoring rules.
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The CDR by classifying dementia as mild, moderate or severe stages assess the influence of cognitive loss on the ability to conduct everyday activities and represent ultimate test of efficacy for management strategies in dementia. The CDR has been standardized for multicentred use and inter rater reliability has been established. Criterion validity for both global CDR and scores on individual domains has been demonstrated, and has been validated neuropathologically using imaging techniques. Hence CDR has become widely accepted in clinical setting and in research trials as a reliable and valid global assessment measure for dementia of Alzheimer’s type (Morris, 1993; Meuser, 2001).

3.6.3 Sociodemographic data sheet

Socio demographic data sheet consisted of personal details like Name, Age, Sex, Education, Marital status etc. In this socio demographic sheet details like home address, contact phone number, details of location of housing like landmarks were also collected to maintain contact with patient and to make home visit as necessary.

3.7 Data collection

Data collection process included selecting an Alzheimer’s Disease patient who is willing to participate in the study and is otherwise eligible with presence of minimum score of behavioural problems as specified in the inclusion criteria. All the Alzheimer’s dementia cases reported in 10/66 dementia group either in the clinic or in the community were seen by the investigator. After establishing initial rapport and after obtaining written informed consent the person was screened for behavioural problems using Neuropsychiatric Inventory. If the person has all
eligibility fixed as per inclusion criteria he/she will be allotted to control group and experimental group as the case may be. This allotment was done randomly. The initial assessment of the person includes collection of Sociodemographic details, assessment using Neuropsychiatric Inventory and Clinical Dementia Rating scale.

After identifying the behavioural problems intervention was given for those in experimental group as per management programme while the those in the control group received routine care and guidance only.

The management programme formulated for intervention included aspects like carer education, environmental modification, carer counselling, behavioural intervention and working with carer to devise individualized and realistic plans for management. Intervention was carried out by the investigator with participation of family care giver and other family members in the home set up. For each patient individualized intervention was given according to individual needs and actual situation at home which was within the general frame work of management programme devised.

A hand book for intervention in dementia (Appendix 1) was prepared by investigator as a ready reference regarding the above mentioned management programme. This hand book was prepared after extensive review of literature and was reviewed and modified by incorporating suggestions given by many experts in the field. It explains all major areas of dementia care especially management of all common behavioural problems with examples. A Malayalam version was prepared (Appendix 11) for the use of family care givers. Malayalam version was given to each care giver in the actual study for easy reference. In cases where the primary care giver was not literate, another family member’s help was ensured in addition to
help from investigator.

Also the carer was given the contact telephone number of investigator for seeking clarifications or advices. Follow up through telephone and or home visit was given within 2-4 weeks after the initial intervention.

After a period of three months both experimental and control group was again assessed using Neuropsychiatric Inventory. In the experimental group intervention is reinforced and appropriate modification and alterations were made in this session which involves active participation of care giver. On many occasions modifications were made as per suggestions from care givers side also.

Again the third assessment using Neuropsychiatric Inventory was carried out at about six months after the initial assessment both in control and experimental group.

Though for a single case, data collection process took only 6 months it was difficult to get enough cases. In addition many patients had changed residence, died during the study period or became too ill physically either due to dementia or other physical illness. Also in many cases there was a change of intial care giver and also change of residence and care giver during the study period. All these cases were dropped during the course of study. Due to this type of, exclusion during the study the study period was extended over 7 years.

Data collection was mostly carried out in the home setting during home visit by the investigator. In cases when the initial data was collected in the clinic also, the investigators made a home visit within two to three weeks. This home visit was helpful to devise and modify management
programme in accordance with each patient’s home environment. Since the intervention part in experimental group is time consuming home visits was preferred by investigator and caregiver.

### 3.8 Plan for analysis of data

The data collected were tabulated and analysed using descriptive and inferential statistics. The analysis pertaining to sociodemographic and clinical variables were given in the frequency distribution tables, graphs, and wherever necessary in the form of mean and standard deviations.

The significance of difference in scores of behavioural problems after the intervention were tested by paired students ‘t’ test. Also the difference in distress caused by behavioural problems as a result of intervention in experimental group when compared to control group was tested by paired student’s ‘t’ test. The significance of difference in scores of behavioural problems and distress at three different stages of study (on entry, after three months and six months of intervention) were tested by using Analysis of Variance (ANOVA).

The correlation between behaviour problems and distress were tested by determining correlation coefficient.